IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM OF LAW

Defendants Secretary Weida and the Florida Agency for Health Care Administration (individually, "AHCA," and collectively with Secretary Weida, the "State") move for summary judgment under Federal Rule of Civil Procedure 56 and Local Rule 56.1 on all four counts in Plaintiffs' complaint. *See* Doc.1.

For the reasons stated in the memorandum that follows, the State asks this Court to grant its motion. An index to the exhibits that the State references in its motion are included on pages 37 to 39.

Dated: April 7, 2023

Respectfully submitted by:

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CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
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INTRODUCTION

"[B]ased on current medical opinion," Florida's "determination" that certain treatments for gender dysphoria are "experimental is reasonable." *Rush v. Parham*, 625 F.2d 1150, 1157 n.13 (5th Cir. 1980). Since the preliminary-injunction hearing in this case, Norway has joined the growing list of countries that have found the support for "hormonal and surgical" treatments to be "insufficient," and their "long-term effects" to be "little known." Exhibit 1 (Norway Healthcare Investigation Board report). If Florida is wrong, then so too are Norway, Finland, Sweden, the United Kingdom, France, Australia, and New Zealand.

The expert reports appended to this summary judgment further support the State's position that the use of puberty blockers, cross-sex hormones, and surgeries for the treatment of gender dysphoria is experimental. Among others:

- **Dr. Stephen Levine**, a psychiatrist from Case Western Reserve University and an early proponent of gender-affirming care, provides a comprehensive discussion of the literature and the need for caution in administering the excluded treatments. Exhibit 12.
- **Dr. Paul Hruz**, a researcher and clinician at Washington University School of Medicine, does the same from the perspective of an endocrinologist. Exhibit 13.
- **Dr. Sophie Scott**, a neuroscientist from the United Kingdom, explains that the effects of certain chemicals on the human brain simply aren't well known; the first step in the road to surgical transition (the use of puberty blockers) is experimental. Exhibit 18.
- And, of course, the State's rulemaking process included a report from **Dr. Brignardello-Petersen**, a researcher who specializes in conducting systematic reviews of academic literature. Having never published on the issue of gender dysphoria, she took a fresh look

> and found the literature supporting the excluded treatments to be based on low-quality evidence. Doc.49-1 at 59.

By contrast, Plaintiffs and their experts cite WPATH's standards of care and the Endocrine Society's guidelines as the measuring stick for current medical opinion. Though WPATH and the Endocrine Society have resisted the State's discovery efforts to seek information concerning the guidelines and standards, their guidelines and standards acknowledge the problems with the excluded treatments: limited empirical data, lack of long-term studies, likelihood of adverse health effects, and reliance on low-quality evidence. Plaintiffs' experts use sleight of hand to address these problems: Dr. Antommaria, for example, suggests that low-quality evidence means something other than what it says. Plaintiffs' experts also attempt to make WPATH (whose members worked on the Endocrine Society guidelines) into the preeminent medical organization on the issue. WPATH acknowledges, however, that it's an advocacy organization where non-medical experts can work on the standards.

Under the circumstances, there isn't enough to create a genuine issue of material fact concerning the controlling question in this case: the reasonableness of the State's determination. At best, Plaintiffs' experts present their preferred approach to treating gender dysphoria, which includes the use of experimental treatments. Yet that doesn't establish that the State's reticence is unreasonable.

It follows that Plaintiffs can't succeed on their *Rush*-related Medicaid claims (Count III and IV). Section 1983 also doesn't create a mechanism to enforce Medicaid

claims. Nor can Plaintiffs succeed under the Equal Protection Clause (Count I) or the Affordable Care Act's anti-discrimination provision (Count II). That's because the State's health, safety, and welfare enactments are entitled to a "strong presumption of validity." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2282 (2022). Plaintiffs can't overcome the presumption by stacking low-quality scientific evidence on itself. To allow them to do so would confuse impassioned advocacy with dispassionate science and replace State-prescribed caution with private preference.

STATEMENT OF THE CASE & FACTS

Rush explains that it's "a simple matter of logic that the district court's determination should be based on current medical knowledge, regardless of the prevailing knowledge at the time [that the State issued its GAPMS Report or Rule 59G-1.050(7)]." 625 F.2d at 1157 n.13. Still, for the sake of completeness, it's important to trace (1) the steps leading up to the State's decision to exclude reimbursement for certain treatments for one psychiatric condition, (2) the litigation that has ensued, and (3) the state of current medical opinion.

I. The Federal Government's Stance

The State's assessment of the excluded treatments for gender dysphoria was a response to the federal government's actions. On March 2, 2022, the U.S. Department for Health and Human Services issued a notice and guidance on care. Exhibit 2 (HHS notice and guidance). HHS stated that it "stands with transgender and gender nonconforming youth and their families—and the significant majority of expert medical

associations—in unequivocally stating that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health." *Id.* HHS followed the notice and guidance with a department-issued factsheet that touted the benefits of hormone therapy and surgeries as effective treatments for minors with gender dysphoria. Exhibit 3 (HHS fact sheet). Little scientific support was included. The Department of Justice then threatened states that limited access to such treatments. Exhibit 4 (DOJ letter).

The federal government's 2022 position was an apparent departure from its prior position. In 2016, the Centers for Medicare and Medicaid Services declined to make a determination "on gender reassignment surgery for Medicaid beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population." Exhibit 5 at 1 (CMS memo). It reached that decision "[b]ased on an extensive assessment of the clinical evidence," concluding "there is not enough high-quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." *Id.* at 48. That 2016 determination memorandum has never been superseded by another.

In 2020, HHS declined to "take a definitive view on any of the medical questions raised" "about treatments for gender dysphoria" due to the "lack of high-quality scientific evidence supporting" treatments for gender dysphoria like "sex-reassignment surgeries" and to the reliance on "*advocacy group* (WPATH) rather than on independent

scientific fact-finding." Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37,160, 37,186-87 (Jun. 19, 2020) (emphasis added). And, as recently as May of 2022, the National Institutes of Health's acting director told the U.S. Senate that the long-term effects of puberty blockers for gender transition are unclear, and that the institutes have only funded *observational* studies in the area. *See* A Review of the President's FY 2023 Funding Request and Budget Justification for the National Institutes of Health, Sen. Comm. on Appropriations (May 17, 2022), https://bit.ly/3QTkaJD (1:12:49–1:14:55).

II. The State's Need to Assess the Science

Against this backdrop, the State decided to assess for itself whether the federal government's new position, which contradicts the still-operative 2016 CMS determination, was "actually[,] sufficiently supported" by quality science. Exhibit 6 (91:20–92:4) (Brackett February 8 deposition). The Florida Department of Health and AHCA were tasked with conducting an independent, evidence-based review of the treatments for gender dysphoria. *Id.* (90:5-11–91:1) (AHCA was tasked to "take a" "detailed look at the available medical evidence, or at least the peer-reviewed literature, and to see what it says.").

The Florida DOH acted first. On April 20, 2022, it released a factsheet in response to HHS's factsheet. Notably, the Florida DOH concluded that minors "should not be prescribed puberty blockers or hormone therapy" and that "reassignment surgery should not be a treatment option for children or adolescents."

Exhibit 7 (FDOH fact sheet). The Florida DOH based this conclusion on the "low-quality evidence" supporting gender-affirming care and the international consensus on this issue. *Id.*; *see also* Exhibit 6 (91:2-11).

Referencing the Florida DOH factsheet, AHCA's then-Secretary Marstiller directed Deputy Secretary Wallace to begin the GAPMS process to assess whether the State should reimburse under Medicaid certain treatments for gender dysphoria. *See* Exhibit 8. No one "instruct[ed] AHCA to ensure that Florida Medicaid would not cover treatment for gender dysphoria." Exhibit 6 (90:12-16). This was to be an independent review, and it was to be a GAPMS review, which "provides the best opportunity to go through" medical "literature on a large scale and to make a conclusion" on whether a treatment is clinically unproven or experimental. *Id.* (93:3-12); *see also* Fla. R. Admin. 59G-1.035 (GAPMS Rule adopted in 2015); Fla. Stat. § 409.905(9) (barring payment for services that are "clinically unproven" or "experimental").

Ann Dalton, the AHCA Bureau Chief of Medicaid Policy, recommended that Matt Brackett draft the GAPMS Report. Exhibit 9 (84:2-4, 85:22-15, 86:8-25) (Dalton deposition). She also recommended that two other employees, Devona Pickle, an AHCA program director, and Nai Chen, a pharmacist, assist Mr. Brackett. *Id.* (84:2-4, 86:8-25); Exhibit 6 (96:11-15).

According to Ms. Dalton, Mr. Brackett would be a good drafter, because he "worked with the bureau a long time and previously had the position" "primarily responsible for GAPMS." Exhibit 9 (84:11-23). She called his GAPMS-related

knowledge "extensive." *Id.* (86:15-25). Ms. Dalton also stated that Ms. Pickle had "been with the bureau and agency a very long time," *id.* (84:12-23), and that she previously worked "very closely" with Mr. Brackett and Ms. Pickle, *id.* (86:15-25). Ms. Dalton admitted that she hadn't worked with Mr. Chen as much as other members of the team, but she knew all three to have been part of the Canadian Prescription Drug Importation Program, a multifaceted and important policy initiative. *Id.* (25:6–26:2, 27:18–28:6, 83:19–85:15); *see also* Exhibit 10 (program press release). While the three were busy with this drug-importation program in 2021, by 2022, they had more "bandwidth" to devote to another important policy like the gender dysphoria GAPMS. Exhibit 9 (84:11–85:6).

III. Drafting the GAPMS Report

Ms. Dalton's staffing recommendations were approved, and work began on the GAPMS Report on April 20, 2022. *Id.* (157:22-24). Mr. Brackett drafted the GAPMS Report, with Ms. Pickle and Mr. Chen providing secondary assistance. *Id.* (96:11-15).

"When" Mr. Brackett "started working on [the GAPMS Report]," he "did not know where the evidence would take" him. *Id.* (115:13-17). He read and assessed all eighty-eight articles ultimately cited in the GAPMS Report. *Id.* (158:8-13). "[T]he more and more" he "read the articles that focused on the mental health benefits, the methods and so forth" of hormone therapies and surgeries, "the more" he "realized that all those articles left way too many unanswered questions." *Id.* (115:18–116:3).

Among the questions was a lack of available material on the "long-term" consequences of the excluded treatments. *Id.* (117:1-20). Another was the reliance on

"anonymous surveys" and "whether or not these responses [on the surveys] are credible," especially without "longitudinal history of the[] individuals." *Id.* Even if studies weren't anonymous, Mr. Brackett noted that they often had "sample sizes" that "were very, very small" or made observations over only a "one- or two-year period[]." *Id.* There were still more questions about the "potential causes and associations with gender dysphoria" like "autism, trauma, neglect, abuse, abandonment," and other comorbidities. *Id.*

Mr. Brackett also read materials from organizations, such as WPATH and various medical organizations. *Id.* (117:21–120:7). He gave this material due weight: "their conclusions required thoughtful analysis and probing of the evidence" because AHCA "take[s] the recommendations of clinical organizations very seriously." *Id.* (118:12-19). "[B]ut," Mr. Brackett added, "we also do reserve the right to question those recommendations and we did review those and we did analyze them." *Id.* After reviewing the organizations' recommendations, Mr. Brackett concluded that "very weak evidence" backed their support for gender-affirming care. *Id.* (118:20–120:7).

In addition, AHCA hired Dr. Grossman and Dr. Van Mol to assist Mr. Brackett. Outside consultants aren't usually hired for GAPMS reports, but AHCA hires them for other tasks. *Id.* (104:6-10, 137:10-17) (providing examples). The doctors didn't write or draft any section of the GAPMS Report; that task was Mr. Brackett's alone. *Id.* (98:10-21). They provided Mr. Brackett verbal feedback and research leads as he worked through the materials recommended by organizations such as WPATH. *Id.* (98:3-21,

104:6-20, 109:3-23, 145:17–146:5). Mr. Brackett spoke with the doctors approximately four or five times for a handful of hours. *Id.* (158:17–159:5).

At the same time Mr. Brackett was drafting the GAPMS Report, AHCA asked medical professionals to provide additional perspective, such as a review of the evidence supporting the excluded treatments. *Id.* (131:1–132:19). The experts were Dr. Romina Brignardello-Petersen, Dr. James Cantor, Dr. Quentin Van Meter, Dr. Patrick Lappert, and Dr. G. Kevin Donovan. *See* Doc.49-1 at 5-245.

AHCA didn't make substantive edits to the experts' reports; at most, style and grammar edits were made. Exhibit 6 (145:4-16). There was a possibility that the experts "disagreed with one another" or disagreed with the GAPMS Report, especially if Mr. Brackett had reached "a different conclusion." *Id.* (165:8-21).

This was especially true of Dr. Brignardello-Petersen's work. She's a Canadian researcher with a Ph.D. in clinical epidemiology and health care research, who conducted a systematic review of relevant medical studies through April 2022. Doc.49-1 at 59. That review could have cut against Mr. Brackett's review of the literature. But after reviewing "the best available evidence regarding the effects of" gender-dysphoria treatments, she "found low and very low certainty evidence suggesting improvements in gender dysphoria, depression, anxiety, and quality of life." Doc.49-1 at 62.

With a near-final draft ready in mid-May, AHCA finalized the GAPMS Report on June 2, 2022. Exhibit 6 (84:19-21, 146:20-25). Expert reports from Dr. Brignardello-Petersen and others were attached. Doc.49-1 at 5-245.

IV. Adopting Rule 59G-1.050(7) for the Exclusions

Florida's Administrative Procedures Act requires that "each agency statement of general applicability that implements, interprets, or prescribes law or policy" be "adopted pursuant to the requirements of s. 120.54." Fla. Stat. § 120.52(16), (20). AHCA thus initiated the rulemaking process to exclude puberty blockers, cross-sex hormones, and gender-reassignment surgeries as treatments for gender dysphoria. *See* Exhibit 6 (164:23–165:7).

AHCA issued a notice of proposed rulemaking on June 2. *Id.* (165:22–166:4). Rulemaking can "move very quickly," and because the GAPMS Report was completed (and DOJ had threatened litigation), the process moved along. *Id.* (170:4–171:5).

AHCA solicited public comments as part of the process. It received around 600 comments, and the agency read every one. *Id.* (189:12-16). Many attacked the agency rather than its position, *id.* (192:14-21), but the agency thoroughly considered comments from medical organizations and clinicians who took issue with the substance of the agency's position, *id.* (192:22–193:12). Cases and studies identified in the comments were also reviewed. *Id.* (194:1-16). In particular, the agency searched for new evidence that could "mortal[ly] wound" the GAPMS Report, and therefore the proposed rule, and looked for "contradictory evidence" or "modern, high-quality evidence" that supported the use of the excluded treatments. *Id.* (197:20–198:17). As Mr. Brackett put it, "we want[ed] to make sure that we had not left any stones unturned." *Id.*

AHCA also held a public rulemaking hearing on July 8, 2022. There the agency heard impassioned public testimony from all sides of the issue, Doc.49-2 at 82 ¶¶ 24-25, and AHCA employees Jason Weida, Shena Grantham, and Mr. Brackett, served as panelists. Exhibit 6 (176:13-25). Dr. Van Mol, Dr. Grossman, and Dr. Van Meter also served as panelists for good measure, *id.* (128:18-25), because at this point, the State's position on the excluded treatments expressly conflicted with the federal government's position. The State finalized Rule 59G-1.050(7), and it became effective August 21.

Of course, as with all rules, case-by-case variances and waivers are available. *See* Fla. Stat. § 120.542; Fla. Admin. Rules 28-104.001 – 28-104.006. "Variances and waivers *shall* be granted when the person subject to [a] rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person" and when "substantial hardship" or violation of "principles of fairness" are shown. Fla. Stat. § 120.542(2) (emphasis added). "The agency's decision to grant or deny the petition shall be supported by competent substantial evidence," and that decision is subject to a de novo hearing before an administrative law judge, who is then responsible for the fact-finding in the matter. *Id.* § 120.542(8) (referencing hearings under §§ 120.569 and 120.57). To date, AHCA has yet to receive a request for a variance or waiver from its generally applicable rule excluding certain treatments for gender dysphoria; no one has yet said that the excluded treatments are *not* experimental as to a particular set of circumstances unique to the requestor.

V. The Litigation Begins (and Continues in Other Courts)

Plaintiffs filed their complaint on September 7, 2022. Doc.1. They moved for a preliminary injunction on September 12, 2022. Doc.11. This Court held a hearing on the motion on October 12, 2022, Doc.61, and then denied the motion. Doc.64.

In the order denying the preliminary injunction motion, based on *Rush*, this Court stated that the "controlling" "question" in this case is "whether, based on current medical knowledge, the state's determination that [the excluded] treatments are experimental is reasonable." Doc.64 at 4. In its colloquy with counsel during the preliminary injunction hearing, and again consistent with *Rush*, this Court said that the *Rush*-related review is "not an administrative review of what the State knew at the time" about current medical opinion. Exhibit 11 (hearing transcript).

To assess the current state of medical opinion, on November 8, 2022, the State served subpoenas for depositions and documents on WPATH, the Endocrine Society, and the American Academy of Pediatrics. *E.g.*, *In re Subpoenas Served on Am. Acad. of Pediatrics, et al.*, No. 23-MC-00004 (D.D.C. 2023) (herein "D.C.Doc.") D.C.Doc.1-4. Days later, the State served document subpoenas on fifteen medical organizations that track WPATH and Endocrine Society's perspective. D.C.Doc.1-19.

The eighteen organizations moved the D.C. District Court to quash the subpoenas on First Amendment grounds. D.C.Doc.1. On January 26, 2023, the district court agreed that the State should be entitled to assess whether these organizations represent the so-called medical consensus. Among other things, the court required the

production of documents "sufficient to show how" each organization established its position on treatments for gender dysphoria. D.C.Doc.18. The court held the deposition requests in abeyance.

On February 9, 2023, the eighteen organizations produced a total of 387 documents. Six produced less than five documents each. None adequately responded to the question of *how* they established their guidelines or policy positions.

This response prompted another hearing. After the February 27, 2023 hearing, the court held that the *how* included "the process" used to adopt any "guidelines or policy positions" and "the substantive materials and opinions" "considered." D.C.Doc.26. The latter category covered documents "sufficient to show" "why a particular study was relied upon or rejected," and "whether any dissenting views" were "acknowledged," "considered," and "why such views were rejected." *Id.* The court also ordered WPATH, the Endocrine Society, and the American Academy of Pediatrics to sit for limited depositions. *Id.*

The D.C. Circuit stayed the district court's order on the evening of March 8, 2023. *See In re Subpoenas Served on Am. Acad. of Pediatrics, et al.*, No. 23-7025 (D.C. Cir. Mar. 8, 2023). It did so without explanation and hours before the depositions were to begin. The medical organizations' appeal remains pending. And this discovery dispute serves as the basis of the separate motion in limine filed before this Court.

VI. The Experimental Nature of the Excluded Treatments

The continued reluctance of the organizations to share how they crafted their

preferred treatment protocols is significant, especially when Plaintiffs and their experts rely extensively on the WPATH standards of care and the Endocrine Society's guidelines. That said, the experimental nature of the excluded treatments is clear from the material that's available. Before discussing the material, however, a brief discussion of gender dysphoria is provided.

A. Gender dysphoria and the State's Choices

Gender dysphoria is the distressing incongruence between an individual's *biological sex* and *gender identity*. Exhibit 12 ¶ 28 (Levine report); Exhibit 13 ¶ 54 (Hruz report). Biological sex is "determined at conception" at the chromosomal level, and it "structures [an] individual's biological reproductive capabilities." Exhibit 12 ¶¶ 20-21; *see also* Exhibit 13 ¶¶ 13-18. While sex is biologically based, gender "is a human phenomenon." Exhibit 12 ¶ 22 (quoting Endocrine Society). Gender is the traits society associates with biological males and biological females. *Id.* ¶¶ 19-27 (quoting Endocrine Society); Exhibit 13 ¶ 19. Gender identity is an individual's subjective sense of his or her gender. Exhibit 12 ¶¶ 24-27; Exhibit 13 ¶ 20. Unlike sex, gender identity is mutable. *See* Exhibit 13 ¶ 58; Exhibit 14 at 43 (WPATH standards of care) ("[P]eople may spend some time in a gender identity or presentation before they discover it does not feel comfortable and later adapt it or shift to an earlier identity or representation.").

Gender dysphoria is a psychiatric diagnosis. Exhibit 12 ¶ 36. There are no laboratory tests, imaging, or biopsies that can help establish a diagnosis. Exhibit 13 ¶¶ 57-58; *see also* Exhibit 15 ¶ 24 (Laidlaw redacted report).

For those with gender dysphoria, however, behavioral health services can help. *See, e.g.*, Exhibit 12 ¶¶ 42-49; Exhibit 16 ¶ 136 (Kaliebe report). Florida continues reimbursing for these services. Doc.49-2 at 84 ¶ 28 (providing list). But, unlike behavioral services, surgeries, puberty blockers, and cross-sex hormones alter primary and secondary sex characteristics. They come with risks and their efficacy is suspect.

Drs. Hruz, Laidlaw, and Van Meter all discuss the concerns associated with puberty blockers and cross-sex hormones. Exhibit 13 ¶¶ 67-87; Exhibit 15 ¶¶ 66-40, ¶¶ 149-58; Exhibit 17 ¶ 20 (Van Meter rebuttal report). Dr. Hruz explains that puberty blockers suppress natural puberty. Exhibit 13 ¶¶ 67-68. But he cautions that after "an extended period of pubertal suppression," you can't "turn back the clock" and "reverse changes in the normal coordinated pattern of adolescent psychological development and puberty." *Id.* ¶ 75. Evidence to the contrary is "very weak." *Id.* ¶ 78. Puberty blockers and cross-sex hormones also come with a laundry list of potential health consequences, including issues with bone density, fertility, cancer, and brain maturation. *Id.* ¶¶67-87.

Dr. Scott provides a neuroscientist's perspective on puberty blockers, which are the first step on the road to physical transition. She explains that the current science doesn't support puberty-blocking treatments for minors and that such science is needed, given the "considerable changes" that are happening to brain development during and after puberty. Exhibit 18 ¶¶ 12-13 (Scott report). She states that "more research" is needed to justify this treatment. *Id.* ¶ 16. Current studies suggest that

puberty blockers could lead to negative (and perhaps "irreversible") effects: lower IQ scores, lower heart rates, greater emotional reactivity, higher anxiety, greater avoidance behavior, and more risk-taking behavior. *Id.* ¶ 15.

Dr. Lappert, a plastic surgeon, worries that surgical treatments to cut healthy tissue are firmly in the realm of cosmetic surgeries. Exhibit 19 ¶¶ 47-50 (Lappert report). These treatments introduce the prospect of complications and pose ethical concerns because, unlike other cosmetic procedures, the goal is to induce "functional loss" of the breasts and genitalia. *Id.* ¶¶ 47-50.

There are also mental-health consequences to hormone therapies and surgeries. Dr. Levine, a psychiatrist, comments that "[g]ender transition routinely leads to isolation from at least a significant portion of one's family in adulthood" and can impact future romantic relationships. Exhibit 12 ¶¶ 198-99. That can negatively affect mental health. Dr. Levine also responds to claims of *positive* mental health outcomes and *lower* suicidality after hormone therapies: many of those claims are simply backed by low-quality evidence. *Id.* ¶¶ 134-73. And Dr. Levine notes that those with gender dysphoria likely have mental health comorbidities—anxiety disorders, ADHD, autism spectrum disorder, OCD, for example. *Id.* ¶¶ 43, 134. As such, it remains unclear whether hormone therapies and surgeries will resolve underlying mental-health concerns.

B. Plaintiffs' Reliance on WPATH and the Endocrine Society

1. In disagreeing with the State, Plaintiffs and their experts rely almost exclusively on WPATH's standards of care, Exhibit 14, and the Endocrine Society's clinical

practice guideline, Exhibit 20 (Endocrine Society guidelines). Dr. Olson-Kennedy claims that the WPATH standards of care are "the best available science and expert professional consensus" on treatments for gender dysphoria. Exhibit 21 ¶¶ 10-11, 47 (Olson-Kennedy report). Dr. Shumer states that as "a board-certified pediatric endocrinologist, [he] follow[s] the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care when treating [his] patients." Exhibit 22 ¶¶ 38, 48-56 (Shumer report). Plaintiffs' other experts also rely on WPATH and the Endocrine Society. *E.g.*, Exhibit 23 ¶¶ 9, 31 (Baker report); Exhibit 24 ¶¶ 17-23 (Antommaria report); Exhibit 25 ¶¶ 27, 34 (Karasic report); Exhibit 26 ¶¶ 8, 24, 26, 50-51 (Schechter report). That's not surprising because most of the Plaintiffs' experts are members of or are linked to WPATH. Exhibit 26 ¶ 7 (co-lead author of standards-of-care chapter); Exhibit 25 ¶¶ 8-9 (lead author of standards-of-care chapter and former board member); Exhibit 21 ¶ 11 (member); Exhibit 27 ¶ 13 (Edmiston rebuttal report) (contributing author of standards-of-care chapter and former member); Exhibit 28 ¶ 11 (Janssen rebuttal report) ("member of revision committees" for standards-of-care chapters).

The feedback loop between medical professionals and these two organizations is problematic. That's especially so when other organizations (like the American Medical Association) simply adopt WPATH and the Endocrine Society's perspective as their own, *e.g.*, Exhibit 22 ¶ 55, and when those organizations refuse to reveal the bases of their standards in response to discovery requests.

2. Specifically, WPATH acknowledges that it's an *advocacy* organization focused on transgender health care. Exhibit 14 at 7. Its method of revising the standards of care exacerbates the potential for bias. *First*, both medical professionals *and* non-medical professionals are responsible for revisions. *Id.* at 250; Exhibit 29 (WPATH standards-of-care-revision team criteria). *Second*, for medical professionals to contribute, they must be "[l]ongstanding WPATH Full Member[s] in good standing," "[w]ell recognized advocate[s] for WPATH and the [standards of care]," and "[w]ell known expert[s] in transgender health." Exhibit 29.

In other words, the "best available science and expert professional consensus" on medical treatments for gender dysphoria, Exhibit 21 ¶ 10, comes from a self-selecting group of members of one organization, who are noted advocates for the organization, who all strive to preserve the conclusions reached in previous standards of care, and who may not be medical professionals. Exhibit 14 at 7; Exhibit 29. Dr. Levine calls this an "echo-chamber" that can't "claim[] to speak for the medical profession." Exhibit 12 ¶¶ 53, 71. And Dr. Levine is no transgender-skeptic. He's a medical professional who has "recommended or supported social transition, cross-sex hormones, and surgery for particular patients" with gender dysphoria and was himself a former high-ranking member of WPATH's predecessor organization, the Harry Benjamin International Gender Dysphoria Association. *Id.* ¶¶ 5, 6, 66.

Federal courts also recognize that WPATH's standards don't reflect the medical consensus on the issue. *See, e.g.*, *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019) (The

"WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate over sex reassignment surgery"); *Kosilek v. Spencer*, 774 F.3d 63, 88 (1st Cir. 2014) (en banc) ("Prudent medical professionals" "reasonably differ in their opinions regarding [WPATH's] requirements.").

WPATH is clearly critical of Florida's decision to exclude reimbursement for certain gender dysphoria treatments. It has also been critical of the federal government and other countries like Japan and the United Kingdom. And WPATH took issue with the *New York Times*'s coverage of the treatments for gender dysphoria. *See* Exhibit 31 (WPATH press release); Exhibit 32 (same); Exhibit 33 (WPATH letter to Japanese officials); Exhibit 34 (WPATH press release); Exhibit 35 (same).

3. Bias and advocacy aside, WPATH's standards must concede that the excluded treatments don't rest on a solid scientific foundation *and* that the treatments pose the potential for negative and irreversible consequences. For instance, Chapter 5's Assessment for Adults states:

- The "empirical evidence base for the assessment of" transgender and gender diverse adults "is limited." Exhibit 14 at 34-35.
- "Each gender-affirming surgical intervention has specific risks and potentially unfavorable consequences," including "loss of fertility." *Id.* at 40, 43.
- "Gender-affirming hormone treatments have been shown to impact reproductive functions and fertility, although the consequences are heterogenous for people of all birth-assigned sexes." *Id.* at 41.

4. Like WPATH's standards of care, the Endocrine Society can't speak for the medical community either. In 2017, an Endocrine-Society-appointed panel created its clinical practice guidelines for treating gender dysphoria. Exhibit 20. The guidelines were co-sponsored by WPATH. *Id.* at 1. The panelists responsible for the guidelines had ties to WPATH. Exhibit 13 ¶ 95.

The guidelines themselves used the Grading of Recommendations Assessment, Development and Evaluation or GRADE approach—the same methodology utilized by Dr. Brignardello-Petersen. Exhibit 30 at 12-13 (GRADE handbook); 49-1 at 60. GRADE rates the evidence quality for a treatment recommendation: evidence is either high, moderate, low, or very-low quality. Exhibit 30 at 12-13; Exhibit 24 ¶ 19. With higher-quality evidence comes more confidence that treatments will produce the intended result. Exhibit 30 at 13. With low-quality evidence, or even very-low-quality evidence, such confidence is either "limited" or "little." *Id.* Evidence can be of lower quality based on an underlying study's risk of bias, limitations in study design, inconsistency of results, or imprecision and indirectness of evidence. *Id.*

Plaintiffs' expert, Dr. Antommaria, concedes that of the twenty-eight recommendations in the Endocrine Society's guideline, three are backed by moderate-quality evidence, fourteen are backed by low-quality evidence, five are backed by very-low-quality evidence, and six are backed by no evidence at all. Exhibit 24 ¶ 23; Exhibit 20 at 2-8; Exhibit 30 at 40. Notably:

- Low-quality evidence backs the following: "[w]e suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty." Exhibit 20 at 3.
- Very-low-quality evidence backs the recommendation that "there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years," "*even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years*." *Id.* (emphasis added).
- And the recommendation that "clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment" is backed by no evidence at all. *Id.* at 4 (ungraded good practice statement).

These recommendations thus support the State's conclusion concerning the quality of the evidence supporting the excluded treatments.

Dr. Antommaria responds that treatment recommendations, especially for children, are "infrequently based" on high-quality evidence. Exhibit 24 ¶ 23. Among other things, he cites obesity recommendations for children. *Id.* But recommendations for obesity and other ailments are qualitatively different from those for gender dysphoria; the latter includes treatments with permanent, potentially negative consequences while the former advises that kids eat better and exercise.

C. Policy Choices Concerning Acceptable Risk

To be sure, there's agreement among the experts that the excluded treatments can have permanent, potentially negative, health consequences. Dr. Olson-Kennedy admits, for example, that "deepening of the voice" and "breast tissue development" are "irreversible" consequences of hormone therapy. Exhibit 21 ¶ 32**.** Dr. Shumer mentions potential fertility issues with hormone therapy. Exhibit 22 ¶ 81. Dr. Edmiston

agrees with Dr. Scott that "[t]here is not a large literature on the effects of GnRHa treatment on the brain in humans," and that "[t]here is a small body of literature on the effects of gender-affirming hormone care on the brain in transgender adolescents." Exhibit 27 ¶¶ 29, 31. And some of WPATH's concessions are noted above.

What's left then is a dispute about the magnitude of potential harm and tolerable risk limits. On these policy issues, the State of Florida remains firmly tethered to the international consensus.

Finland's National Science Review concluded that "[i]n light of available evidence, gender reassignment of minors is an experimental practice." Exhibit 13 ¶ 124. Finland reached this conclusion after noting that "there are no medical treatments (for transitioning) that can be considered evidence-based" and that the "reliability of the existing studies with no control groups is highly uncertain," especially considering the potential "risks" of such treatments, such as bone-growth and neurological issues. *Id.*

Sweden reached a similar conclusion. Its board of health said that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatment[s]" in minors, and that such treatments should be provided only in rare cases and ideally as part of experimental trials. *Id.* ¶ 125.

The United Kingdom went further still. Its National Institute of Health and Care Excellence reviewed studies that support hormone therapy for gender-dysphoric minors. *Id.* ¶ 126. The institute concluded that "all small, uncontrolled observational studies" for puberty blockers "are of very low certainty using modified GRADE" and

they "reported physical and mental health comorbidities and concomitant treatments very poorly." *Id.* As for cross-sex hormones, the institute stated that evidence of their effectiveness was also of a "very low" quality. *Id.* The United Kingdom's Cass Report, which reviewed gender-identity services in the country, stated that there's a "lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response." *Id.*

Others agree. France's Académie Nationale de Médecine says that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [gender-dysphoric minors] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." Doc.53 at 11. The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of quality evidence on the outcomes of those presenting with gender dysphoria." Doc.53 at 11. And, as noted above, Norway has also found the support for the excluded treatments to be "insufficient," and their "long-term effects" to be "little known." Exhibit 1.

Under the circumstances, the State's choices are reasonable.

LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Disputes are "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty*

Lobby, Inc., 477 U.S. 242, 248 (1986). Facts are "material" if they "might affect the outcome of the suit under the governing law." *Id.*

ARGUMENT

The State is entitled to summary judgment under *Rush* and, separately, Plaintiffs cannot use § 1983 as the vehicle for their Medicaid claims. The State is also entitled to summary judgment on the constitutional and Affordable Care Act claims.

I. The State's Decision Is Reasonable Under *Rush v. Parham*

A. Plaintiffs assert that the State violated two of Medicaid's reimbursement requirements: the early and periodic screening, diagnostic, and treatment service (EPSDT) requirement, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43)(C), 1396d(a)(4)(B), and 1396d(r)(5), and the comparability requirement. 42 U.S.C. § 1396a(a)(10)(B)(i); *see* Doc.1, Counts III & IV**.** But the State need not reimburse payments for experimental treatments. *Rush*, 625 F.2d at 1150. Whether the State's determination concerning the excluded treatments is "reasonable" is governed by "current medical opinion, regardless of the prevailing knowledge at the time" the State adopted the exclusions. *Id.* at 1157 n.13. *Rush*'s standard is thus closer to a rational-basis standard than a mean-ends tailoring standard, which makes sense, because courts aren't medical policymakers.

The State meets *Rush*'s deferential standard. As detailed above, the weight of the scientific literature does not support the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria. Caution is instead the watchword. There's no certainty that the excluded treatments are reversible. *E.g.*, Exhibit 13 ¶¶67-87; Exhibit

19 ¶ 49. The chances are great that those prescribed the treatments suffer from other comorbidities. Exhibit 12 ¶¶ 43, 134. For most, behavioral therapies will help them through this psychiatric condition. *Id.* ¶¶ 42-49; Exhibit 16 ¶ 136. For the exceptional few who can establish that their circumstances warrant it, variances and waivers are available under § 120.542. This approach aligns with the growing global consensus.

And it aligns with CMS's guidance that States "are not required to provide any items or services" the State determines "are not safe and effective or which are considered experimental." *See* CMS, U.S. Dep't of Health & Human Servs., State Medicaid Manual, ch.5, § 5122, //www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.

True, Plaintiffs' experts provide an alternative approach to treatment. At best, however, it's just that: an alternative perspective that can't supersede the State's decision to take a more cautious approach. *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905). At worst, it's the product of an untested and flawed approach sanctioned only by WPATH and the Endocrine Society. Either way, this alternative approach falls short of creating a genuine issue of material fact under *Rush*. The State's conclusion concerning the excluded treatments is reasonable.

B. Nor can Plaintiffs establish comparability. Medicaid requires that services "made available" to an eligible person "shall not be less in amount, duration, or scope" than services "made available to any other" eligible person." 42 U.S.C. § 1396a(a)(10)(B)(i). Thus, there must be some "equivalence between" "Florida-

Medicaid-eligible service[s] and" the excluded treatments for gender dysphoria. Doc.64 at 4-5. For example, a mastectomy is an effective and appropriate treatment for breast cancer, where diseased breast tissue is removed from the body. Exhibit 19 ¶¶ 49, 52, 54. The efficacy of mastectomies for breast cancer treatment says nothing about their efficacy for gender-dysphoria treatment. More broadly, accepting a false equivalency between a treatment approved for a specific malady and gender dysphoria is inappropriate. Plaintiffs' expert reports contain little to no information on this front. Plaintiffs can't show an equivalence.

II. There's No Medicaid Cause of Action Under 42 U.S.C. § 1983

A. Nor can Plaintiffs enforce their Medicaid-related EPSDT or comparability claims through § 1983. *See* Doc.1 at ¶¶ 277, 280. Section 1983 allows for vindication of federally protected *rights* guaranteed by the *requirements* of federal law. *See Collins v. City of Harker Heights*, 503 U.S. 115, 119 (1992).

Broadly speaking, Medicaid dangles a carrot in front of the States. States that meet the criteria in 42 U.S.C. § 1396a receive federal funds. If State plans fall short of Medicaid's requirements after accepting funds, then the HHS Secretary "in his discretion" can "limit payments" to unaffected categories of a Medicaid plan until he is "satisfied" that the State has come back into compliance. 42 U.S.C. § 1396c. While HHS is partially funding a non-compliant Medicaid plan, the affected State can decide whether to accept partial reductions or change its policy. *NFIB v. Sebelius*, 132 S. Ct. 2566, 2607 (2012); *see also id.* at 2642 n.27 (Ginsburg, J., concurring in part, concurring

in judgment in part, and dissenting in part). Notably, HHS has taken no action to defund the State's Medicaid program based on the conduct at issue here.

Neither the Supreme Court nor the Eleventh Circuit has specifically addressed whether the EPSDT or comparability provisions create federally enforceable rights. Though other courts have allowed the use of § 1983 to enforce these provisions, they did so based on the erroneous assumption that "obligations on participating states" are enough. *Smith v. Benson*, 703 F. Supp. 2d 1262, 1273 (S.D. Fla. 2010) (quoting *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 605 (5th Cir. 2004)); *see also Cruz v. Zucker*, 116 F. Supp. 3d 334, 345 (S.D.N.Y. 2015). They aren't. Only an "unambiguously conferred right," not an obligation, can "support a cause of action brought under § 1983." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002).[1]

In sum, Counts III and IV present no rights to enforce under federal law. Because § 1983 "does not provide a remedy for abuses that do not violate federal law," *Collins*, 503 U.S. at 119, Plaintiffs can't use it as a vehicle to pursue their Medicaid claims.

B. Relatedly, equity doesn't permit Plaintiffs' Medicaid claims. To be sure, courts of equity have "long" granted injunctions to prevent "illegal executive action." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015). But that power is "subject to express and implied statutory limitations." *Id.* A "[c]ourt[] of equity can no

[1] The question of whether statutes like Medicaid can ever give rise to privately enforceable rights under § 1983 is currently before the U.S. Supreme Court in *Health and Hospital Corporation of Marion County v. Talevski*, No.21-806, which was argued November 8, 2022.

more disregard statutory and constitutional requirements and provisions than can courts of law." *I.N.S. v. Pangilinan*, 486 U.S. 875, 883 (1988) (quotation omitted).

In *Armstrong*, the Supreme Court concluded that in enacting another section of the Medicaid Act—§ 1396a(30)(A)—Congress had impliedly foreclosed equitable remedies for two reasons. *First*, "the sole remedy Congress provided for a State's failure to comply with Medicaid's requirements—for the State's 'breach' of the Spending Clause contract—is the withholding of Medicaid funds by the Secretary of Health and Human Services." *Armstrong*, 575 U.S. at 328. *Second*, the clause at issue, which "mandate[d] that state plans provide for payments that are 'consistent with efficiency, economy, and quality of care,' all the while 'safeguard[ing] against unnecessary utilization of' "care and services[,]' was "judicially unadministrable" because it was "broad[]" and lacked "specific[s]." *Id.* As the Court explained, that vague duty evinced Congressional intent for an "exclusive" agency remedy that could bring to bear administrative "expertise" and "uniformity." *Id.*

That rationale fits Plaintiffs' theory hand in glove. For one, no one doubts that the Medicaid Act provisions Plaintiffs hope to enforce are only textually enforceable by the Secretary. 42 U.S.C. § 1396c. And Plaintiffs' chosen statutes are just as broad and non-specific as the one in *Armstrong*; they tell States, for example, in Plaintiffs' own words, to provide "all services necessary to 'correct or ameliorate' a physical or mental health condition," Doc.1 ¶ 276, without defining necessity.

III. The State's Decision Is Constitutional Under the Equal Protection Clause

A. Plaintiffs' equal-protection claim fails as well. The State's health, safety, and welfare actions are subject to a "strong presumption of validity." *Dobbs*, 142 S. Ct. at 2284 (cleaned up). They "must be sustained if there is a rational basis on which" the State "could have thought that it would serve legitimate state interests." *Id.*

Rule 59G-1.050(7) is a health, safety, and welfare regulation that makes a distinction based on a medical diagnosis: the excluded treatments are generally unavailable to those with gender dysphoria but are available to those with other diagnoses (like breast cancer or precocious puberty). The distinction furthers the State's interest in protecting its citizens from unnecessary and experimental treatments that are grounded in low-quality evidence and that threaten to cause permanent harm like sterilization and infertility. Rational-basis review is easily met. *Dobbs*, 142 S. Ct. at 2268; *Otto v. City of Boca Raton*, 981 F.3d 854, 868 (11th Cir. 2020); *Jacobson*, 197 U.S. at 25.

B. Plaintiffs ask for some heightened level of scrutiny to apply because, in their estimation, Rule 59G-1.050(7) makes facially discriminatory distinctions based on sex or transgender status. The problems with this argument are threefold.

First, the en banc Eleventh Circuit in *Adams v. School Board of St. Johns County* foreclosures the sex-based discrimination argument. In that case, the court held that a school board's sex-based bathroom-assignment policy doesn't violate the Equal Protection Clause. 57 F.4th 791, 796 (11th Cir. 2022) (en banc). The court elaborated

that sex-based discrimination is discrimination based on biological sex. *Id.* at 807-08. After all, the Equal Protection Clause protects immutable characteristics, like biological sex. *Id.* (citing *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973)). Exhibit 12 ¶¶ 19-27; Exhibit 13 ¶ 19. That stands in strong contrast to gender identity, which is mutable and isn't afforded heightened constitutional protection. 57 F.4th at 807-08.

The *Adams* school-board policy made a distinction on the basis of biological sex: mainly, biologically male students use one bathroom, biologically female students use another bathroom, or a sex-neutral bathroom is available. *Id.* at 802. "This is a sex-based classification," the Eleventh Circuit held. *Id.* at 801.

That's different from Rule 59G-1.050(7). The rule doesn't make a distinction based on biological sex. The State's rule makes a distinction based on a medical diagnosis—gender dysphoria—which applies to biological males and biological females. *See Lange v. Houston County*, 608 F. Supp. 3d 1340, 1354 (M.D. Ga. 2022); *see also Geduldig v. Aiello*, 417 U.S. 484, 497 n.20 (1974).

Regardless of biological sex, the State will not reimburse gender-affirming care: puberty blockers, hormones or hormone antagonists, sex reassignment surgeries, or any procedures that alter primary or secondary sexual characteristics. Therefore, rational basis—and not heighted scrutiny—applies, and rational basis is still satisfied.

Second, the *Adams* court explained what constitutes unconstitutional discrimination based on transgender status. Notably, the court didn't hold that transgender status is a quasi-suspect class. It said that "we have grave 'doubt' that

transgender persons constitute a quasi-suspect class" and that "the Supreme Court has rarely deemed a group a quasi-suspect class." 57 F.4th at 803 n.5 (citing *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 442-46 (1985)). Transgender individuals thus aren't entitled to heightened constitutional review per se. *Id.*

Whether to apply heightened review then turns on a *Geduldig v. Aiello* "identity" analysis. In *Adams*, the Eleventh Circuit asked if there was either an "identity" or "lack of identity" between the school-board bathroom policy and transgender status; an "identity" between the two would demonstrate unconstitutional discrimination, but a "lack of identity" would demonstrate a lack of unconstitutional discrimination. *Id.* at 809 (quoting 417 U.S. at 497).

In conducting the analysis, the *Adams* court observed what "group" was affected by the bathroom policy and what "group" wasn't affected. The court found that the affected group consisted of transgender students who wanted to use a bathroom that didn't align with their biological sex. The unaffected group consisted of non-transgender students and transgender students who wanted to use bathrooms that aligned with their biological sex. *Id.* at 809. Because transgender students were in both groups, there was a "lack of identity" between the policy and transgender status. Thus, the policy didn't discriminate based on transgender status. *Id.*

So too here. Rule 59G-1.050(7) creates two groups. The group affected by the rule is comprised of transgender individuals who suffer from gender dysphoria. The group unaffected by the rule is comprised of non-transgender individuals and

transgender individuals *who don't* suffer from gender dysphoria. Under *Adams* and *Geduldig*, there's a "lack of identity" between the rule and transgender status.

Third, Plaintiffs can't prove that the State engaged in purposeful discrimination that violates the Equal Protection Clause. "[A] disparate impact alone does not violate the Constitution. Instead, a disparate impact on a group offends the Constitution when an otherwise neutral policy is motivated by 'purposeful discrimination.'" *Id.* at 810 (citing *Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979)). In their facial challenge, Plaintiffs can't prove that the State promulgated its rule "because of" and not "in spite of" its allegedly adverse effect on transgender individuals. *Feeney*, 442 U.S. at 274.

In sum, rational basis applies. That test is met.

III. The State's Decision Complies with the Affordable Care Act

Finally, the State's actions comply with the ACA. Under Section 1557 of the ACA, "an individual shall not, on the ground prohibited under" "title IX of the Education Amendments of 1972," "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity." 42 U.S.C. § 18116. Title IX prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681.

As in the constitutional context, the en banc Eleventh Circuit recently held that, as a statutory matter, "sex" in Title IX means biological sex. 57 F.4th at 812-14 (disavowing reliance on *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)). For the reasons

discussed above, the State didn't discriminate on the basis of sex. The State thus complied with the ACA.

CONCLUSION

The State asks this Court to grant its motion for summary judgment.

Dated: April 7, 2023

Respectfully submitted by:

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CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F) and 56.1(E), I certify that this motion contains 7,951 words.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

INDEX TO EXHIBITS

The State provides this index to assist this Court with identifying and finding exhibits in their summary-judgment motion.

Exhibit Number	Exhibit Description[2]
Exhibit 1	Norway Healthcare Investigation Board Report
Exhibit 2	U.S. Health and Human Services Notice and Guidance on Care
Exhibit 3	U.S. Health and Human Services Fact Sheet on Gender-Affirming Care
Exhibit 4	U.S. Department of Justice Letter to State Attorneys General
Exhibit 5	Centers for Medicare and Medicaid Services Decision Memo for Gender Dysphoria and Gender Reassignment Surgery
Exhibit 6	Deposition of Matt Brackett (February 8, 2022) (Combined Volumes)

[2] An unredacted version of Exhibit 15 will be submitted to the court clerk; Plaintiffs are already in position of the unredacted version. And though Exhibit 36 is marked confidential, the parties conferred and agreed that it should not be marked confidential.

Exhibit 7	Florida Department of Health Fact Sheet on Treatments for Gender Dysphoria
Exhibit 8	Letter from then-Secretary Marstiller to Deputy Secretary Wallace
Exhibit 9	Deposition of Ann Dalton
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Ukom

Menu

Patient safety for children and young people with gender incongruence

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Scroll through the report

People with gender incongruence and gender dysphoria have different wishes and needs for health services. Many people live well with their gender incongruence and manage it without health care, and others want and need health care. (See glossary in chapter 13 for word explanations)

When Ukom enters the topic of gender incongruence, we look at how patient safety is safeguarded in help and treatment services for gender incongruence and gender dysphoria. Our aim with the survey is to ensure safe help and treatment for children and young people with gender incongruence.

There is an ongoing public debate about treatment options for gender incongruence. This is demanding, and many refuse to participate in the debate. It can be challenging and difficult to participate because disagreements are large both between groups and within groups. We see that choice of words and understanding of the complexity is important. The situation of insecurity and disagreement affects the development of healthcare services.

In our report, we have tried to highlight different perspectives. At the same time, it is important for us to be clear about our findings. That is, what challenges patient safety. Many have worked and are working to confirm and build a good health service for people with gender incongruity and gender dysphoria, both nationally and internationally. Ukom's report builds on this work. We point out that this field now needs a boost to improve patient safety, especially for the health care that is to be provided to children and young people in Norway.

Summary

Ukom has carried out a survey of the treatment offered to children and young people with gender incongruence. The background was notifications directly to Ukom from relatives who question several matters related to patient safety. Several actors, both from the authority side, healthcare personnel and patient and relative organisations, are questioning the soundness and organization of the treatment offer.

The report deals with children and young people in general. There has been a large increase in inquiries to the health service from people with gender incongruity in recent years. In particular, the number of children and young people in their teens who apply to, or are referred for assessment and treatment in the specialist health service, has increased significantly. The biggest increase is among adolescents and young adults who are registered as girls at birth, but identify as boys. Our attention has therefore been particularly directed at teenagers and young people with gender incongruence and gender dysphoria who seek health care.

Children and young people are not fully developed physically, mentally, sexually or socially. This requires special vigilance with regard to patient safety. Our findings and recommendations will also be relevant for the offer for adults.

In the report, we have divided our findings into six main areas:

Insufficient knowledge

The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is deficient and the long-term effects are little known. This is particularly true for the teenage population where the stability of their gender incongruence is also not known. There is a lack of research-based knowledge about the treatment of patients with non-binary gender incongruence. In order to safeguard patient safety, Ukom considers it necessary that the knowledge base on gender incongruity and gender dysphoria be strengthened, and that the health service offer be arranged in line with the knowledge base.

General management - a guideline with a different background

The Norwegian Directorate of Health's national professional guidelines for gender incongruity lay down guidelines for the health service offer. It concentrates on organisation, equality and rights. This may have been important at the time the guideline was drawn up, because it was necessary to confirm the health service offer to people who experience gender incongruity. At the same time, we consider that deviating from the requirement for the development of knowledge-based guidelines has created room for uncertainty and diverging expectations. Health personnel have been given great opportunities for interpretation within a relatively narrow subject area that lacks a systematic summary of knowledge in Norway. The guideline gives rights without clarifying questions related to prioritization and soundness. This is demanding for the health personnel who manage the services on a daily basis.

Requirements for soundness - particularly related to children and young people

The national professional guideline for gender incongruence is not normative. It does not set specific requirements for investigation or requirements for a medical indication for starting treatment. The mention of children's competence to consent and parents' right to information leaves room for interpretation. The guideline does not establish a sufficient standard for the health service offer, and we believe that for some patients it may pose a patient safety risk. This may go beyond the soundness requirement, which has broad roots in health legislation, and may also be demanding for the supervisory authorities.

Right to healthcare – a gap in expectations

Our investigation suggests that there is a gap between what the guideline outlines and what is possible, given today's available offer and knowledge base. The national professional guideline creates expectations in patients that the health service can only fulfill to a small extent. This applies, among other things, to the right to specialist healthcare services. It is difficult for the service to meet expectations without the knowledge base being well documented, and without a good overview of any negative and harmful aspects of the various treatments. If there is a requirement to use principles for experimental treatment, it will provide a framework that ensures information, thorough follow-up and contributes to more knowledge.

The help and treatment offer - variation in practice and expertise

There is great variation in what offers and what expertise is offered in different parts of the country. There is a risk of both under-, over- and incorrect treatment of children and young people with gender incongruence and gender dysphoria. In addition, we see that there are challenges in establishing a decentralized offer in a narrow and complex specialist field. In order to strengthen the offer, Ukom believes that it is important to strengthen the health service offer in the primary healthcare

service, to build increased interdisciplinary expertise in the specialist healthcare service at regional level and to ensure that the national treatment service has sufficient capacity to meet today's demands.

Speech climate and interaction

We see that in the field of gender incongruence, a demanding climate of expression has developed. The speech climate in the public space affects the information available for children and young people with gender incongruence and gender dysphoria and their families. There is a significant impact on children and young people, also related to treatment and health services. We hear about fear and dread of making mistakes from all quarters. Different opinions about what is the right treatment can create a difficult cross-pressure. Different emphasis and mention of what is necessary at group level can confuse and destroy the patient-therapist relationship and a personalized approach for the person concerned. There is a need to establish a constructive community for everyone who is engaged in good health care for people with gender incongruity.

Ukom recommends

We are concerned that children and young people with gender incongruence have a safe and sound healthcare service. We therefore come up with recommendations that can contribute to this group receiving a better and safer health service offer in the long term. Our recommendations relate to revision of the guidelines, safe frameworks for treatment offered to children and young people and measures to strengthen the knowledge base. The recommendations will also contribute to the systematic collection of data and promote follow-up research. It is important that children and young people with gender incongruence and gender dysphoria, including non-binary ones, are properly looked after while the development of the healthcare service is ongoing.

Ukom recommends:

1. that the Ministry of Health and Care commissions the Directorate of Health to revise the national professional guideline, Gender congruence. The revision must, among other things, be based on a systematic summary of knowledge. We point to several elements that should be included in the audit.
2. that puberty delaying treatment (puberty blockers) and hormonal and surgical gender confirmation treatment for children and young people are defined as experimental treatment. This is particularly important for teenagers with gender dysphoria.
3. that the Ministry of Health and Care is considering whether a national medical quality register should be established for the treatment of children and young people with gender incongruity and gender dysphoria. Necessary measures must be implemented so that such a national quality register can be established, operated and financed in order to contribute to an overview, better quality and reduce unjustified variation in patient treatment.

Continue reading: **Background**

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March 2, 2022

On October 1, 2022, the District Court for the Northern District of Texas issued a judgment vacating the March 2, 2022 document. HHS is evaluating its next steps in light of that judgment but is complying with it.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy

The Department of Health & Human Services (HHS) stands with transgender and gender nonconforming youth and their families—and the significant majority of expert medical associations—in unequivocally stating that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health. Attempts to restrict, challenge, or falsely characterize this potentially lifesaving care as abuse is dangerous. Such attempts block parents from making critical health care decisions for their children, create a chilling effect on health care providers who are necessary to provide care for these youth, and ultimately negatively impact the health and well-being of transgender and gender nonconforming youth. The HHS Office for Civil Rights (OCR) will continue working to ensure that transgender and gender nonconforming youth are able to access health care free from the burden of discrimination. HHS understands that many families and health care providers are facing fear and concerns about attempts to portray gender affirming care as abuse. To help these families and providers navigate those concerns, HHS is providing additional information on federal civil rights protections and federal health privacy laws that apply to gender affirming care.

As a law enforcement agency, OCR is investigating and, where appropriate, enforcing Section 1557 of the Affordable Care Act[1] cases involving discrimination on the basis of sexual orientation and gender identity in accordance with all applicable law. This means that if people believe they have been discriminated against in a health program or activity that receives financial assistance from HHS, they can file a complaint.

Federal Civil Rights Laws:

Parents or caregivers who believe their child has been denied health care, including gender affirming care, on the basis of that child's gender identity, may file a complaint with OCR.

Health care providers who believe that they are or have been unlawfully restricted from providing health care to a patient on the basis of that patient's gender identity may file a complaint with OCR.

OCR enforces federal civil rights laws that prohibit discriminatory restrictions on access to health care. Among these laws is Section 1557, which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs or activities. OCR

[1] 42 U.S.C. 18116; *see also* 45 C.F.R. part 92.

also enforces Section 504 of the Rehabilitation Act,[2] which prohibits discrimination on the basis of disability in any program or activity receiving federal financial assistance.

Section 1557 protects the right of individuals to access the health programs and activities of recipients of federal financial assistance without facing discrimination on the basis of sex, which includes discrimination on the basis of gender identity. Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557. For example, if a parent and their child visit a doctor for a consultation regarding or to receive gender affirming care, and the doctor or other staff at the facility reports the parent to state authorities for seeking such care, that reporting may constitute violation of Section 1557 if the doctor or facility receives federal financial assistance. Restricting a health care provider's ability to provide or prescribe such care may also violate Section 1557.

Section 504 protects qualified individuals with disabilities from discrimination in programs and activities receiving federal financial assistance. Title II of the Americans with Disabilities Act[3] (ADA) protects qualified individuals with disabilities from discrimination in state and local government programs. Gender dysphoria may, in some cases, qualify as a disability under these laws. Restrictions that prevent otherwise qualified individuals from receiving medically necessary care on the basis of their gender dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may, therefore, also violate Section 504 and Title II of the ADA.

If you believe that you or another party has been discriminated against on the basis of gender identity or disability in seeking to access gender affirming health care, visit the OCR complaint portal to file a complaint online. To read more about Section 1557 and other laws that OCR enforces, please visit our website at https:www.hhs.gov/ocr.

Federal Health Care Privacy Laws - Health Insurance Portability and Accountability Act of 1996 (HIPAA):

HIPAA, the cornerstone patient privacy law, limits the circumstances under which health care providers and other entities may disclose protected health information, such as gender affirming physical or mental health care administered by a licensed provider.

Providers who may be concerned about their obligations to disclose information concerning gender affirming care should seek additional legal guidance regarding their legal responsibilities and other laws.

[2] 29 U.S.C. 794; *see also* 45 C.F.R. part 84.
[3] 42 U.S.C. 12132.

OCR enforces the HIPAA Privacy, Security and Breach Notification Rules,[4] which establish requirements with respect to the use, disclosure, and protection of protected health information (PHI) by covered entities and business associates;[5] provide health information privacy and security protections; and establish rights for individuals with respect to their PHI.[6]

OCR reminds covered entities (health plans, health care providers, health care clearinghouses) and business associates that the HIPAA Privacy Rule permits, **but does not require,** covered entities and business associates to disclose PHI about an individual, without the individual's authorization,[7] when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[8] This "required by law" exception to the authorization requirement is limited to "a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law."[9] Where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law.[10] Disclosures of PHI that do not meet the "required by law definition" or exceed what is required by such law do not qualify as permissible disclosures under this exception.

HIPAA prohibits disclosure of gender affirming care that is PHI without an individuals' consent[11] except in limited circumstances.

If you believe that your (or someone else's) health privacy rights have been violated, visit the OCR complaint portal to file a complaint online.

DISCLAIMER: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or the Departments' policies.

To obtain this information in an alternate format, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing OCRMail@hhs.gov. Language assistance services for OCR matters are available and provided free of charge.

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[4] 45 C.F.R. Parts 160 and 164, Subparts A, C, D, and E.
[5] *See* 45 C.F.R. 160.103 ("covered entity" and 'business associate" definitions).
[6] *See* 45 C.F.R. 160.103 ("protected health information" and "individually identifiable health information" definitions).
[7] *See* 45 C.F.R. 164.508(c) (HIPAA authorization required elements).
[8] 45 C.F.R. 164.512(a)(1).
[9] 45 C.F.R. 164.103 ("required by law" definition). Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
[10] 45 C.F.R. 164.512(a)(1).
[11] For purposes of this guidance, "consent" refers to a valid HIPAA authorization. *See 45 C.F.R. 164.508.*

OASH | Office of Population Affairs

Gender-Affirming Care and Young People

What is gender-affirming care?

Gender-affirming care is a supportive form of healthcare. It consists of an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people.

For transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the healthcare system.

Why does it matter?

Research demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents.[1] Because gender-affirming care encompasses many facets of healthcare needs and support, it has been shown to increase positive outcomes for transgender and nonbinary children and adolescents. Gender-affirming care is patient-centered and treats individuals holistically, aligning their outward, physical traits with their gender identity.

Gender diverse adolescents, in particular, face significant health disparities compared to their cisgender peers. Transgender and gender nonbinary adolescents are at increased risk for mental health issues, substance use, and suicide.[2],[3] The Trevor Project's 2021 *National Survey on LGBTQ Youth Mental Health* found that 52 percent of LGBTQ youth seriously considered attempting suicide in the past year.[4]

A safe and affirming healthcare environment is critical in fostering better outcomes for transgender, nonbinary, and other gender expansive children and adolescents. Medical and psychosocial gender affirming healthcare practices have been demonstrated to yield lower rates of adverse mental health outcomes, build self-esteem, and improve overall quality of life for transgender and gender diverse youth.[5,6] Familial and peer support is also crucial in fostering similarly positive outcomes for these populations. Presence of affirming support networks is critical for facilitating and arranging gender affirming care for children and adolescents. Lack of such support can result in rejection, depression and suicide, homelessness, and other negative outcomes.[7,8,9]

Common Terms:
(in alphabetical order)

Cisgender: Describes a person whose gender identity aligns with their sex assigned at birth.

Gender diverse or expansive: An umbrella term for a person with a gender identity and/or expression broader than the male or female binary. Gender minority is also used interchangeably with this term.

Gender dysphoria: Clinically significant distress that a person may feel when sex or gender assigned at birth is not the same as their identity.

Gender identity: One's internal sense of self as man, woman, both or neither.

Nonbinary: Describes a person who does not identify with the man or woman gender binary.

Transgender: Describes a person whose gender identity and or expression is different from their sex assigned at birth, and societal and cultural expectations around sex.

Additional Information

- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline
- Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents | American Academy of Pediatrics
- Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People | World Professional Association for Transgender Health

HHS Office of Population Affairs
Web: opa.hhs.gov | Email: opa@hhs.gov
Twitter: @HHSPopAffairs | YouTube: HHSOfficeofPopulationAffairs

Gender-Affirming Care and Young People

Affirming Care	What is it?	When is it used?	Reversible or not
Social Affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities	At any age or stage	Reversible
Puberty Blockers	Using certain types of hormones to pause pubertal development	During puberty	Reversible
Hormone Therapy	Testosterone hormones for those who were assigned female at birth Estrogen hormones for those who were assigned male at birth	Early adolescence onward	Partially reversible
Gender-Affirming Surgeries	"Top" surgery – to create male-typical chest shape or enhance breasts "Bottom" surgery – surgery on genitals or reproductive organs Facial feminization or other procedures	Typically used in adulthood or case-by-case in adolescence	Not reversible

Resources

- Discrimination on the Basis of Sex | HHS Office of Civil Rights
- Lesbian, Gay, Bisexual, and Transgender Health | Healthy People 2030
- Lesbian, Gay, Bisexual, and Transgender Health: Health Services | Centers for Disease Control and Prevention
- National Institutes of Health Sexual & Gender Minority Research Office
- Family Support: Resources for Families of Transgender & Gender Diverse Children | Movement Advancement Project
- Five Things to Know About Gender-Affirming Health Care | ACLU
- Gender-Affirming Care is Trauma-Informed Care | The National Child Traumatic Stress Network
- Gender-Affirming Care Saves Lives | Columbia University
- Gender Identity | The Trevor Project
- Genderspectrum.org
- Glossary of Terms | Human Rights Campaign
- Health Care for Transgender and Gender Diverse Individuals | ACOG
- Transgender and Gender Diverse Children and Adolescents | Endocrine Society

[1] Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2021). Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. *Journal of Adolescent Health*, 70(4). https://doi.org/https://doi.org/10.1016/j.jadohealth.2021.10.036

[2] Rimes, K., Goodship N., Ussher, G., Baker, D. and West, E. (2019). Non-binary and binary transgender youth: Comparison of mental health, self-harm, suicidality, substance use and victimization experiences. *International Journal of Transgenderism*, 20 (2-3); 230-240.

[3] Price-Feeney, M., Green, A. E., & Dorison, S. (2020). Understanding the mental health of transgender and nonbinary youth. *Journal of Adolescent Health, 66*(6), 684–690. https://doi.org/10.1016/j.jadohealth.2019.11.314

[4] Trevor Project. (2021). *National Survey on LGBTQ Youth Mental Health 2021*. Trevor Project. https://www.thetrevorproject.org/survey-2021/.

[5] Wagner J, Sackett-Taylor AC, Hodax JK, Forcier M, Rafferty J. (2019). Psychosocial Overview of Gender-Affirmative Care. *Journal of pediatric and adolescent gynecology,* (6):567-573. doi: 10.1016/j.jpag.2019.05.004. Epub 2019 May 17. PMID: 31103711.

[6] Hughto JMW, Gunn HA, Rood BA, Pantalone DW. (2020). Social and Medical Gender Affirmation Experiences Are Inversely Associated with Mental Health Problems in a U.S. Non-Probability Sample of Transgender Adults. *Archives of sexual behavior*, 49(7):2635-2647. doi: 10.1007/s10508-020-01655-5. Epub 2020 Mar 25. PMID: 32215775; PMCID: PMC7494544.

[7] Brown, C., Porta, C. M., Eisenberg, M. E., McMorris, B. J., & Sieving, R. E. (2020). Family relationships and the health and well-being of transgender and gender-diverse youth: A critical review. *LGBT Health*, *7*, 407-419. https://doi.org/10.1089/lgbt.2019.0200

[8] Seibel BL, de Brito Silva B, Fontanari AMV, Catelan RF, Bercht AM, Stucky JL, DeSousa DA, Cerqueira-Santos E, Nardi HC, Koller SH, Costa AB. (2018). The Impact of the Parental Support on Risk Factors in the Process of Gender Affirmation of Transgender and Gender Diverse People. *Front Psychol*, 27;9:399. doi: 10.3389/fpsyg.2018.00399. Erratum in: Front Psychol. 2018 Oct 12;9:1969. PMID: 29651262; PMCID: PMC5885980.

[9] Sievert ED, Schweizer K, Barkmann C, Fahrenkrug S, Becker-Hebly I. (2021). Not social transition status, but peer relations and family functioning predict psychological functioning in a German clinical sample of children with Gender Dysphoria. *Clin Child Psychol Psychiatry*, 26(1):79-95. doi: 10.1177/1359104520964530. Epub 2020 Oct 20. PMID: 33081539.

U.S. Department of Justice

Civil Rights Division

Assistant Attorney General
950 Pennsylvania Ave, NW - RFK
Washington, DC 20530

March 31, 2022

Dear State Attorneys General:

The U.S. Department of Justice (the Department) is committed to ensuring that transgender youth, like all youth, are treated fairly and with dignity in accordance with federal law. This includes ensuring that such youth are not subjected to unlawful discrimination based on their gender identity, including when seeking gender-affirming care. We write to remind you of several important federal constitutional and statutory obligations that flow from these fundamental principles.

People who are transgender are frequently vulnerable to discrimination in many aspects of their lives, and are often victims of targeted threats, legal restrictions, and anti-transgender violence.[1] The Department and the federal government more generally have a strong interest in protecting the constitutional rights of individuals who are lesbian, gay, bisexual, transgender, queer, intersex, nonbinary, or otherwise gender-nonconforming,[2] and in ensuring compliance with federal civil rights statutes. The Department is also charged with the coordination and enforcement of federal laws that protect individuals from discrimination in a wide range of federally-funded programs and activities.[3]

Intentionally erecting discriminatory barriers to prevent individuals from receiving gender-affirming care implicates a number of federal legal guarantees. State laws and policies that prevent parents or guardians from following the advice of a healthcare professional regarding what may be medically necessary or otherwise appropriate care for transgender minors may infringe on rights protected by both the Equal Protection and the Due Process Clauses of the Fourteenth Amendment. The Equal Protection Clause requires heightened scrutiny of laws that discriminate on the basis of sex[4] and prohibits such discrimination absent an "exceedingly

[1] *See, e.g.*, Michelle M. Johns et al., Ctrs. for Disease Control and Prevention, *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017*, Morbidity and Mortality Weekly Report 68: 67-71 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6803a3.htm?s_cid=mm6803a3_w (finding that transgender youth reported higher levels of violence victimization compared to their cisgender peers).

[2] *See, e.g.*, Exec. Order No. 13,988, § 1, 86 Fed. Reg. 7023 (Jan. 20, 2021); Pamela S. Karlan, Principal Deputy Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Application of Bostock v. Clayton County to Title IX of the Education Amendments of 1972* (Mar. 26, 2021), https://www.justice.gov/crt/page/file/1383026/download.

[3] Exec. Order No. 12,250, § 1-201, 45 Fed. Reg. 72,995 (Nov. 2, 1980).

[4] *See*, *e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 610-13 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *reh'g en banc denied*, 976 F.3d 399 (4th Cir. 2020), *cert. denied*, 2021 WL 2637992 (June 28, 2021); *Whitaker* v.

persuasive" justification.[5] Because a government cannot discriminate against a person for being transgender "without discriminating against that individual based on sex,"[6] state laws or policies that discriminate against transgender people must be "substantially related to a sufficiently important governmental interest."[7]

A law or policy need not specifically single out persons who are transgender to be subject to heightened scrutiny. When a state or recipient of federal funds criminalizes or even restricts a type of medical care predominantly sought by transgender persons, an intent to disfavor that class can "readily be presumed."[8] For instance, a ban on gender-affirming procedures, therapy, or medication may be a form of discrimination against transgender persons, which is impermissible unless it is "substantially related" to a sufficiently important governmental interest.[9] This burden of justification is "demanding."[10] Such a law or policy will not withstand heightened scrutiny when "the alleged objective" differs from the "actual purpose" underlying the classification.[11] In addition, the Due Process Clause protects the right of parents "to seek and follow medical advice" to safeguard the health of their children.[12] A state or local government must meet the heavy burden of justifying interference with that right since it is well established within the medical community that gender-affirming care for transgender youth is not only appropriate but often necessary for their physical and mental health.[13]

In addition to these constitutional guarantees, many federal statutes require recipients of federal financial assistance to comply with nondiscrimination requirements as a condition of receiving those funds. Relevant statutes include:

- **Section 1557 of the Affordable Care Act**[14] protects the civil rights of people—including transgender youth—seeking nondiscriminatory access to healthcare in a range of health

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Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1051 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018); *see also* Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Brandt v. Rutledge*, No. 21-2875 (8th Cir. Jan. 21, 2022); En Banc Brief for the United States as Amicus Curiae Supporting Plaintiff-Appellee, *Adams v. School Board of St. John's County*, No. 18-13592 (11th Cir. Nov. 26, 2021); Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellees, *Corbitt v. Taylor*, No. 21-10486 (11th Cir. Aug. 2, 2021).

[5] *United States v. Virginia*, 518 U.S. 515, 531 (1996) ("Parties who seek to defend gender-based government action must demonstrate an 'exceedingly persuasive justification' for that action.") (quoting *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982)).

[6] *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020).

[7] *Grimm*, 972 F.3d at 608 (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 441 (1985) (internal quotations omitted)).

[8] *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed.").

[9] *Virginia*, 518 U.S. at 533.

[10] *Id.*

[11] *Miss. Univ.*, 458 U.S. at 730.

[12] *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

[13] *See, e.g.*, *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 891, 893 (E.D. Ark. 2021).

[14] 42 U.S.C. § 18116.

programs and activities.[15] Categorically refusing to provide treatment to a person based on their gender identity, for example, may constitute prohibited discrimination under Section 1557. As the U.S. Department of Health and Human Services has stated, restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care providers solely on the basis of their sex assigned at birth or their gender identity may also violate Section 1557.[16]

- **Title IX of the Education Amendments of 1972**[17] prohibits sex discrimination, including sex-based harassment, by recipients of federal financial assistance that operate education programs and activities.[18] Policies and practices that deny, limit, or interfere with access to the recipient's education program or activity because students are transgender minors receiving gender-affirming care may constitute discrimination on the basis of sex in violation of Title IX.

- The **Omnibus Crime Control and Safe Streets Act of 1968**[19] prohibits sex discrimination in certain law enforcement programs and activities receiving federal financial assistance.[20] If a law enforcement agency takes a transgender minor who is receiving gender-affirming care into custody or arrests the child's parents on suspicion of child abuse because the parents permitted such medical care, that agency may be violating the statute's nondiscrimination provision.

- **Section 504 of the Rehabilitation Act of 1973**[21] protects people with disabilities, which can include individuals who experience gender dysphoria.[22] Restrictions that prevent, limit, or interfere with otherwise qualified individuals' access to care due to their gender

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[15] *See, e.g.*, Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, reprinted at 86 Fed. Reg. 27,984 (May 25, 2021).
[16] U.S. Dep't Health & Hum. Servs., *Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy* (Mar. 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf.
[17] 20 U.S.C. § 1681, *et seq*.
[18] *See* Karlan, *supra* note 2; *see also Doe v. Snyder*, --- F.4th ---, 2022 WL 711420, at *9 (9th Cir. Mar. 10, 2022); *Grimm*, 972 F.3d at 619.
[19] 34 U.S.C. § 10101, *et seq*.
[20] *See* 34 U.S.C. § 10228(c)(1); *see also* Kristen Clarke, Assistant Attorney General, Civ. Rts. Div., U.S. Dep't of Justice, Memorandum, *Interpretation of Bostock v. Clayton County regarding the nondiscrimination provisions of the Safe Streets Act, the Juvenile Justice and Delinquency Prevention Act, the Victims of Crime Act, and the Violence Against Women Act* (Mar. 10, 2022), https://www.justice.gov/crt/page/file/1481776/download.
[21] 29 U.S.C. § 794. Additionally, Title II of the Americans with Disabilities Act extends disability civil rights protections with respect to all programs, services and activities of state and local governments, regardless of the receipt of federal financial assistance. *See* 42 U.S.C. § 12132.
[22] *See, e.g.*, *Doe v. Penn. Dep't of Corrections*, No. 1:20-cv-00023-SPB-RAL, 2021 WL 1583556, at *12 (W.D. Pa. Feb. 19, 2021), report and recommendation adopted in relevant part, 2021 WL 1115373 (W.D. Pa. March 24, 2021); *Lange v. Houston Cnty.*, 499 F. Supp. 3d 1258, 1270 (M.D. Ga. 2020); *Doe v. Mass. Dep't of Correction*, No. 1:17-cv-12255-RGS, 2018 WL 2994403 at *6 (D. Mass. June 14, 2018); *Blatt v. Cabela's Retail, Inc.*, No. 5:14-CV-04822, 2017 WL 2178123 (E.D. Pa. May 18, 2017).

dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may violate Section 504.

All persons should be free to access the services, programs, and activities supported by federal financial assistance without fear that they might face unlawful discrimination for doing so. Courts have held that many nondiscrimination statutes contain an implied cause of action for retaliation based on the general prohibition against intentional discrimination, and agencies have made this clear in regulations.[23] Thus, any retaliatory conduct may give rise to an independent legal claim under the protections described above.

* * *

Thank you for your continued commitment to improving the well-being of children and their families. The Department is always available to help ensure that state and local governments, many of which are recipients of federal financial assistance, meet their obligations under federal law. Please feel free to contact the Department's Civil Rights Division for assistance if you have further questions.

Sincerely,

Kristen Clarke
Assistant Attorney General
Civil Rights Division
U.S. Department of Justice

[23] *See, e.g.*, *Jackson v. Birmingham Bd. of Ed.*, 544 U.S. 167, 173 (2005) ("Retaliation against a person because that person has complained of sex discrimination is another form of intentional sex discrimination…"). Examples of agency regulations that prohibit retaliation include 24 C.F.R. § 1.7(e) (Dep't of Housing and Urban Development); 34 C.F.R. § 100.7(e) (Dep't of Education); 38 C.F.R. § 18.7(e) (Dep't of Veterans Affairs); and 45 C.F.R. § 80.7(e) (Dep't of Health and Human Services). Other relevant regulations can be found in the Civil Rights Division's Title VI Legal Manual. Civ. Rts. Div., U.S. Dep't of Justice, *Title VI Legal Manual*, Section VIII, https://www.justice.gov/crt/book/file/1364106/download.

NCA - Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) - Decision Memo

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

Decision Memo

To: Administrative File: CAG #00446N

From: Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group

Joseph Chin, MD, MS
Deputy Director, Coverage and Analysis Group

James Rollins, MD, PhD
Director, Division of Items and Devices

Elizabeth Koller, MD
Lead Medical Officer

Linda Gousis, JD
Lead Analyst

Katherine Szarama, PhD
Analyst

Subject: Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria

Date: August 30, 2016

I. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination related to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

II. Background

Below is a list of acronyms used throughout this document.

AHRQ - Agency for Healthcare Research and Quality
AIDS - Acquired Immune Deficiency Syndrome
ANOVA - Analysis of Variance

APA - American Psychiatric Association
APGAR - Adaptability, Partnership Growth, Affection, and Resolve test
BIQ - Body Image Questionnaire
BSRI - Bem Sex Role Inventory
CCEI - Crown Crips Experimental Index
CDC – Centers for Disease Control
CHIS - California Health Interview Survey
CI - Confidence Interval
CMS - Centers for Medicare & Medicaid Services
DAB - Departmental Appeals Board
DSM - Diagnostic and Statistical Manual of Mental Disorders
EMBASE - Exerpta Medica dataBASE
FBeK - Fragebogen zur Beurteilung des eigenen Korpers
FDA - Food and Drug Administration
FPI-R - Freiburg Personality Inventory
FSFI - Female Sexual Function Index
GAF - Global Assessment of Functioning
GID - Gender Identity Disorder
GIS - Gender Identity Trait Scale
GRS - Gender Reassignment Surgery
GSI - Global Severity Indices
HADS - Hospital Anxiety Depression Scale
HHS - U.S. Department of Health and Human Services
HIV - Human Immunodeficiency Virus
IIP - Inventory of Interpersonal Problems
IOM - Institute of Medicine
KHQ - King's Health Questionnaire
LGB - Lesbian, Gay, and Bisexual
LGBT - Lesbian, Gay, Bisexual, and Transgender
MAC - Medicare Administrative Contractor
MMPI - Minnesota Multiphasic Personality Inventory
NCA - National Coverage Analysis
NCD - National Coverage Determination
NICE - National Institute for Health Care Excellence
NIH - National Institutes of Health
NZHTA - New Zealand Health Technology Assessment
PIT - Psychological Integration of Trans-sexuals
QOL - Quality of Life
S.D. - Standard Deviation
SADS - Social Anxiety Depression Scale
SCL-90R - Symptom Check List 90-Revised
SDPE - Scale for Depersonalization Experiences
SES - Self Esteem Scale
SF - Short Form
SMR - Standardized Mortality Ratio SOC – Standards of Care
STAI-X1 - Spielberger State and Trait Anxiety Questionnaire
STAI-X2 - Spielberger State and Trait Anxiety Questionnaire
TSCS - Tennessee Self-Concept Scale
U.S. - United States
VAS - Visual Analog Scale
WHOQOL-BREF - World Health Organization Quality of Life - Abbreviated version of the WHOQOL-100
WPATH - World Professional Association for Transgender Health

A. Diagnostic Criteria

The criteria for gender dysphoria or spectrum of related conditions as defined by the American Psychiatric Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders (DSM) has changed over time (See Appendix A).

Gender dysphoria (previously known as gender identity disorder) is a classification used to describe persons who experience significant discontent with their biological sex and/or gender assigned at birth. Although there are other therapeutic options for gender dysphoria, consistent with the NCA request, this decision only focuses on gender reassignment surgery.

B. Prevalence of Transgender Individuals

For estimates of transgender individuals in the U.S., we looked at several studies.

The Massachusetts Behavior Risk Factor Surveillance Survey (via telephone) (2007 and 2009) identified 0.5% individuals as transgender (Conron et al., 2012).

Derivative data obtained from the 2004 California Lesbian Gay Bisexual and Transgender (LGBT) Tobacco Survey (via telephone) and the 2009 California Health Interview Survey (CHIS) (via telephone) suggested the LGB population constitutes 3.2% of the California population and that transgender subjects constitute approximately 2% of the California LGBT population and 0.06% of the overall California population (Bye et al., 2005; CHIS 2009; Gates, 2011).

Most recently, the Williams Institute published a report that utilized data from the Centers for Disease Control's (CDC) Behavioral Risk Factor Surveillance System (BRFSS). Overall, they found that 0.6% or 1.4 million U.S. adults identify as transgender. The report further estimated 0.7% of adults between the ages of 18-25 identify as transgender, 0.6% of adults between the ages of 25-65 identify as transgender, and 0.5% of adults age 65 or older identify as transgender (Flores et al., 2016).

In a recent review of Medicare claims data, CMS estimated that in calendar year 2013 there were at least 4,098 transgender beneficiaries (less than 1% of the Medicare population) who utilized services paid for by Medicare, of which 90% had confirmatory diagnosis, billing codes, or evidence of a hormone therapy prescription. The Medicare transgender population is racially and ethnically diverse (e.g., 74% White, 15% African American) and spans the entire country. Nearly 80% of transgender beneficiaries are under age 65, including approximately 23% ages 45-54. (CMS Office of Minority Health 2015).

For international comparison purposes, recent estimates of transgender populations in other countries are similar to those in the United States. New Zealand researchers, using passport data, reported a prevalence of 0.0275% for male-to-female adults and 0.0044% female-to-male adults (6:1 ratio) (Veale, 2008). Researchers from a centers of transgender treatment and reassignment surgery in Belgium conducted a survey of regional plastic surgeons and reported a prevalence of 0.008% male-to-female and 0.003% female-to-male (ratio 2.7:1) surgically reassigned transsexuals in Belgium (De Cuypere et al., 2007). Swedish researchers, using national mandatory reporting data on those requesting reassignment surgery, reported secular changes over time in that the number of completed reassignment surgeries per application increased markedly in the 1990s; the male-to- female/female-to-male sex ratio changed from 1:1 to 2:1; the age of male-to-female and female-to-male applicants was initially similar, but increased by eight years for male-to-female applicants; and the proportion of foreign born applicants increased (Olsson and Moller 2003).

III. History of Medicare Coverage

Date	Action
August 1, 1989	CMS published the initial NCD, titled "140.3, Transsexual Surgery" in the Federal Register. (54 Fed. Reg. 34,555, 34,572)
May 30, 2014	The HHS Departmental Appeals Board (DAB) determined that the NCD denying coverage for all transsexual surgery was not valid. As a result, MACs determined coverage on a case-by-case basis.

CMS does not currently have a NCD on gender reassignment surgery.

A. Current Request

On December 3, 2015, CMS accepted a formal complete request from a beneficiary to initiate a NCA for gender reassignment surgery.

CMS opened this National Coverage Analysis (NCA) to thoroughly review the evidence to determine whether or not gender reassignment surgery may be covered nationally under the Medicare program.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories as outlined in the Act. For gender reassignment surgery, the following are statutes are applicable to coverage:

Under §1812 (Scope of Part A) Under §1832 (Scope of Part B)
Under §1861(s) (Definition of Medical and Other Health Services)
Under §1861(s)(1) (Physicians' Services)

This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

Timeline of Medicare Coverage Policy Actions for Gender Reassignment Surgery

Date	Action
December 3, 2015	CMS accepts an external request to open a NCD. A tracking sheet was posted on the web site and the initial 30 day public comment period commenced.
January 2, 2016	Initial comment period closed. CMS received 103 comments.
June 2, 2016	Proposed Decision Memorandum posted on the web site and the final 30 day public comment period commenced.
July 2, 2016	Final comment period closed. CMS received 45 comments.

V. FDA Status

Surgical procedures per se are not subject to the Food and Drug Administration's (FDA) approval.

Inflatable penile prosthetic devices, rigid penile implants, testicular prosthetic implants, and breast implants have been approved and/or cleared by the FDA.

VI. General Methodological Principles

In general, when making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. (§ 1862 (a)(1)(A)). The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical question relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve health outcomes for patients.

A detailed account of the methodological principles of study design the agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, blinding of readers of the index test, and reference test results.

VII. Evidence

A. Introduction

Below is a summary of the evidence we considered during our review, primarily articles about clinical trials published in peer- reviewed medical journals. We also considered articles cited by the requestor, articles identified in public comments, as well as those found by a CMS literature review. Citations are detailed below.

B. Literature Search Methods

CMS staff extensively searched for primary studies for gender dysphoria. The emphasis focused less on specific surgical techniques and more on functional outcomes unless specific techniques altered those types of outcomes.

The reviewed evidence included articles obtained by searching literature databases and technology review databases from PubMed (1965 to current date), EMBASE, the Agency for Healthcare Research and Quality (AHRQ), the Blue Cross/Blue Shield Technology Evaluation Center, the Cochrane Collection, the Institute of Medicine, and the National Institute for Health and Care Excellence (NICE) as well as the source material for commentary, guidelines, and formal evidence-based documents published by professional societies. Systematic reviews were used to help locate some of the more obscure publications and abstracts.

Keywords used in the search included: Trans-sexual, transgender, gender identity disorder (syndrome), gender dysphoria and/or hormone therapy, gender surgery, genital surgery, gender reassignment (surgery), sex reassignment (surgery) and/or quality of life, satisfaction-regret, psychological function (diagnosis of mood disorders, psychopathology, personality disorders), suicide (attempts), mortality, and adverse events-reoperations. After the identification of germane publications, CMS also conducted searches on the specific psychometric instruments used by investigators.

Psychometric instruments are scientific tools used to measure individuals' mental capabilities and behavioral style. They are usually in the form of questionnaires that numerically capture responses. These tools are used to create a psychological profile that can address questions about a person's knowledge, abilities, attitudes and personality traits. In the evaluation of patients with gender dysphoria, it is important that both validity and reliability be assured in the construction of the tool (validity refers to how well the tool actually measures what it was designed to measure, or how well it reflects the reality it claims to represent, while reliability refers to how accurately results of the tool would be replicated in a second identical piece of research). Reliability and validity are important because when evaluating patients with gender dysphoria most of the variables of interest (e.g., satisfaction, anxiety, depression) are latent in nature (not directly observed but are rather inferred) and difficult to quantify objectively.

Studies with robust study designs and larger, defined patient populations assessed with objective endpoints or validated test instruments were given greater weight than small, pilot studies. Reduced consideration was given to studies that were underpowered for the assessment of differences or changes known to be clinically important. Studies with fewer than 30 patients were reviewed and delineated, but excluded from the major analytic framework. Oral presentations, unpublished white papers, and case reports were excluded. Publications in languages other than English were excluded. The CMS initial internal search for the proposed decision memorandum was limited to articles published prior to March 21, 2016. The CMS internal search for the final decision memorandum continued through articles published prior to July 22, 2016.

Included studies were limited to those with adult subjects. Review and discussion of the management of children and adolescents with the additional considerations of induced pubertal delay are outside the scope of this NCD. In cases where the same population was studied for multiple reasons or where the patient population was expanded over time, the latest and/or most germane sections of the publications were analyzed. The excluded duplicative publications are delineated.

CMS also searched Clinicaltrials.gov to identify relevant clinical trials. CMS looked at trial status including early termination, completed, ongoing with sponsor update, and ongoing with estimated date of completion. Publications on completed trials were sought. For this final decision, CMS also reviewed all evidence submitted via public comment.

C. Discussion of Evidence

The development of an assessment in support of Medicare coverage determinations is based on the same general question for almost all national coverage analyses (NCAs): "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this specific NCA, CMS is interested in answering the following question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

The evidence reviewed is directed towards answering this question.

1. Internal Technology Assessment

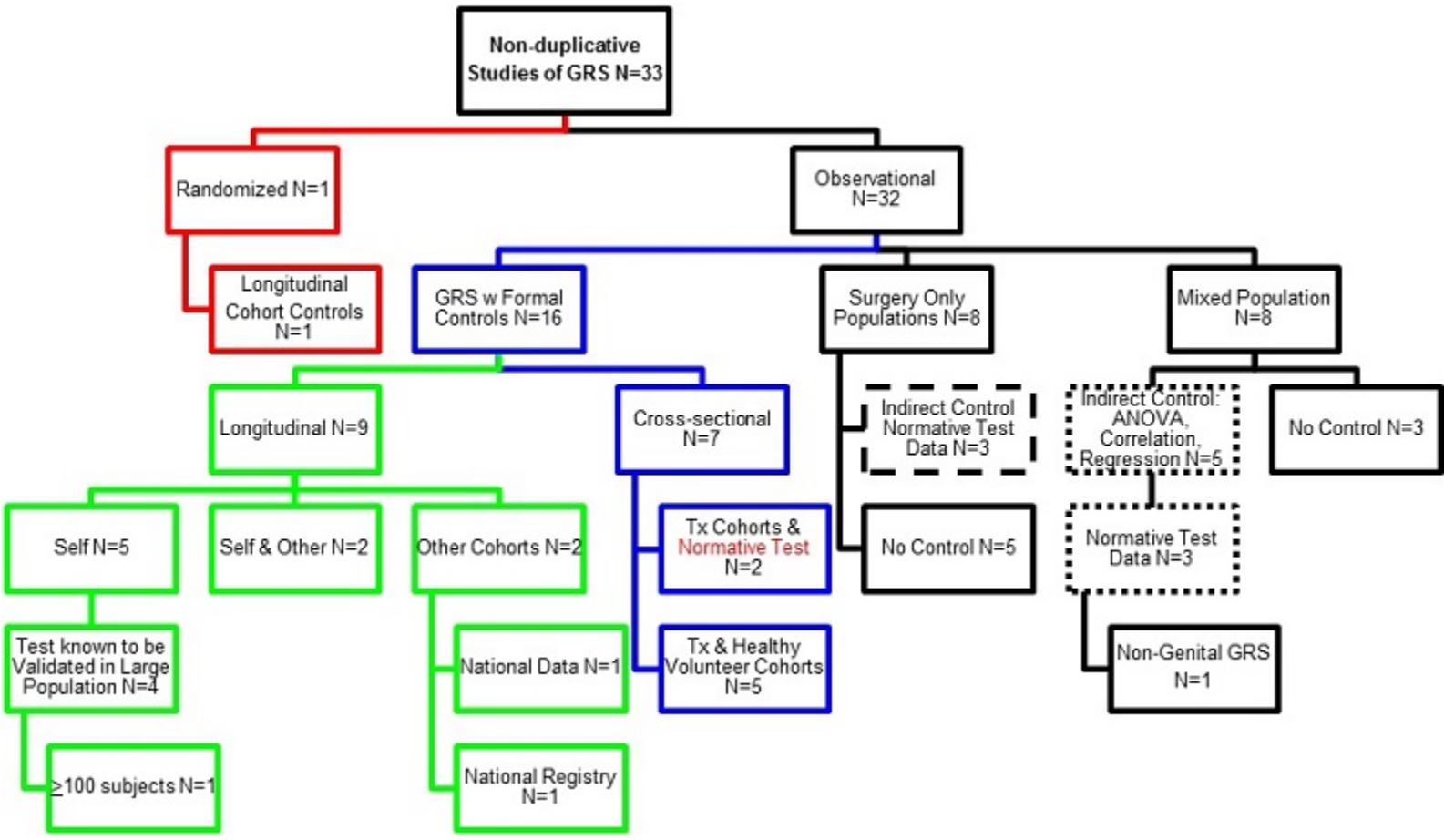
CMS conducted an extensive literature search on gender reassignment related surgical procedures and on facets of gender dysphoria that provide context for this analysis. The latter includes medical and environmental conditions.

CMS identified numerous publications related to gender reassignment surgery. A large number of these were case reports, case series with or without descriptive statistics, or studies with population sizes too small to conduct standard parametric statistical analyses. Others addressed issues of surgical technique.

CMS identified and described 36 publications on gender reassignment surgery that included health outcomes. Because the various investigators at a site sometimes conducted serial studies on ever-enlarging cohort populations, studied sub-populations, studied different outcomes, or used different tools to study the same outcomes, not all study populations were unique. To reduce bias from over-lapping populations, only the latest or most germane publication(s) were described. Subsumed publications were delineated.

Of these 36 publications, two publications used different assessment tools on the same population, and, so for the purposes of evaluation, were classified as one study (Udeze et al., 2008; Megeri and Khoosal, 2007). A total of 33 studies were reviewed (See Figure 1). Appendices C, D, and F include more detail of each study. The publications covered a time span from 1979 to 2015. Over half of the studies were published after 2005.

Figure 1. Studies of Gender Reassignment Surgery (GRS)



ANOVA=Analysis of Variance Normative=Psychometric Tests with known normative for large populations

Figure 1 Legend: The studies in Figure 1 are categorized into three groups. The first group, depicted by the colored

boxes (red, blue, and green), had explicit controls. There was a single randomized study. The remainder in the first group were observational studies. These were subdivided into longitudinal studies and cross-sectional studies. The second group, depicted by black boxes (starting with the surgery only population box) consisted of surgical series. The third group, depicted by black boxes (starting with mixed population), was composed of patients whose treatment could involve a variety of therapeutic interventions, but who were not stratified by that treatment.

When looking at the totality of studies, the 33 studies could be characterized by the following research design groups:

a. Observational, mixed population of surgical and non-surgical patients without stratification

Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2011 Apr;164(4):635-42. Epub 2011 Jan 25.

Asscheman et al. conducted a retrospective, non-blinded, observational study of mortality using a longitudinal design to assess a mixed population treated with hormones, as well as, reassignment surgery in comparison to a population-based cohort. The study was not designed to assess the specific impact of gender reassignment surgery on clinical outcomes.

The investigators assessed mortality in patients who (a) were from a single-center, unspecified, Dutch university specialty clinic, (b) had initiated cross-sex hormone treatment prior to July 1, 1997, and (c) had been followed (with or without continued hormone treatment) by the clinic for at least one year or had expired during the first year of treatment. The National Civil Record Registry (Gemeentelijke Basis Administratie) was used to identify/confirm deaths of clinic patients. Information on the types or hormones used was extracted from clinic records, and information on the causation of death was extracted from medical records or obtained from family physicians. Mortality data for the general population were obtained through the Central Bureau of Statistics of the Netherlands (Centraal Bureau voor Statistiek). Mortality data from Acquired Immune Deficiency Syndrome (AIDS) and substance abuse were extracted from selected Statistics Netherlands reports. The gender of the general Dutch population comparator group was the natal sex of the respective gender dysphoric patient groups.

A total of 1,331 patients who met the hormone treatment requirements were identified (365 female-to-male [27.4%]; 966 male- to-female [72.6%]; ratio 1:2.6). Of these, 1,177 (88.4%) underwent reassignment surgery (343 [94.0% of female-to-male entrants]; 834 [86.3% of male-to-female entrants]; ratio difference 1:2.4 with a p-value $p<0.0001$). Later calculations did not distinguish between those with hormone therapy alone versus those with hormone therapy plus reassignment surgery. The mean age at the time of hormone initiation in female-to-male and male-to-female patients was 26.1±7.6 (range 16–56) years and 31.4±11.4 (range 16–76) years respectively, although the male-to-female subjects were relatively older ($p<0.001$). The mean duration of hormone therapy in female-to-male and male-to-female patients was 18.8±6.3 and 19.4±7.7 years respectively.

There were a total of 134 deaths in the clinic population using hormone therapy with or without surgical reassignment. Of these patients, 12 (3.3%) of the 365 female-to-male patients and 122 (12.6%) of the 966 male-to-female patients died. All-cause mortality for this mixed population was 51% higher and statistically significant (Standardized Mortality Ratio [SMR] 95% confidence interval [CI]) 1.47-1.55) for males-to-females when compared to males in the general Dutch population. The increase in all-cause mortality (12%) for females-to-males when compared to females in the general Dutch population was not statistically significant (95% CI 0.87-1.42).

Ischemic heart disease was a major disparate contributor to excess mortality in male-to-female patients but only in older patients (n=18, SMR 1.64 [95% CI 1.43-1.87]), mean age [range]: 59.7 [42-79] years. Current use of a

particular type of estrogen, ethinyl estradiol, was found to contribute to death from myocardial infarction or stroke (Adjusted Hazard Ratio 3.12 [95% CI 1.28-7.63], p=0.01). There was a small, but statistically significant increase in lung cancer that was thought to possibly be related to higher rates of smoking in this cohort.

Other contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide (n=17, SMR 5.70 [95% CI 4.93-6.54]), AIDS (n=16, SMR 30.20 [95% CI 26.0-34.7]), and illicit drug use (n=5, SMR 13.20 [95% CI 9.70-17.6]). An additional major contributor was "unknown cause" (n=21, SMR 4.00 [95% CI 3.52-4.51]). Of the 17 male-to-female hormone treated patients who committed suicide, 13 (76.5%) had received prior psychiatric treatment and six (35.3%) had not undergone reassignment surgery because of concerns about mental health stability.

Overall mortality, and specifically breast cancer and cardiovascular disease, were not increased in the hormone-treated female-to-male patients. Asscheman et al. reported an elevated SMR for illicit drug use (n=1, SMR 25 [6.00-32.5]). This was the cause of one of the 12 deaths in the cohort.

This study subsumes earlier publications on mortality (Asscheman et al. 1989 [n=425]; Van Kesteren et al. 1997 [n=816]).

Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Cruz Almaraz M, Halperin I, Salamero M. Hormone-treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology. 2012 May;37(5):662-70. Epub 2011 Sep 19.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a cross-sectional design and non-specific psychiatric distress tools in Spain. The investigators assessed anxiety and depression in patients with gender dysphoria who attended a single-center specialty clinic with comprehensive endocrine, psychological, psychiatric, and surgical care. The clinic employed World Professional Association for Transgender Health (WPATH) guidelines. Patients were required to have met diagnostic criteria during evaluations by 2 experts. Investigators used the Hospital Anxiety and Depression Scale (HADS) and the Social Anxiety and Distress Scale (SADS) instruments. The SADS total score ranges from 0 to 28, with higher scores indicative of more anxiety. English language normative values are 9.1±8.0. HAD-anxiety and HAD-depression total score ranges from 0 to 21, with higher scores indicative of more pathology. Scores less than 8 are normal. ANOVA was used to explore effects of hormone and surgical treatment.

Of the 200 consecutively selected patients recruited, 187 (93.5% of recruited) were included in the final study population. Of the final study population, 74 (39.6%) were female-to-male patients; 113 (60.4%) were male-to-female patients (ratio 1:1.5); and 120 (64.2%) were using hormones. Of those using hormones, 36 (30.0%) were female-to-male; 84 (70.0%) were male-to-female (ratio 1:2.3). The mean age was 29.87±9.15 years (range 15-61). The current age of patients using hormones was 33.6±9.1 years (n=120) and older than the age of patients without hormone treatment (25.9±7.5) (p=0.001). The age at hormone initiation, however, was 24.6±8.1 years.

Of those who had undergone reassignment surgery, 29 (36.7%) were female-to-male; 50 (63.3%) were male-to-female (ratio 1:1.7). The number of patients not on hormones and who had undergone at least one gender-related surgical procedure (genital or non-genital) was small (n=2). The number of female-to-male patients on hormones who had undergone such surgery (mastectomy, hysterectomy, and/or phalloplasty) was 28 (77.8%). The number of male-to-female patients on hormones who had undergone such surgery (mammoplasty, facial feminization, buttock feminization, vaginoplasty, orchiectomy, and/or vocal feminization (thyroid chondroplasty) was 49 (58.3%).

Analysis of the data revealed that although the mean scores HAD-Anxiety, HAD-Depression, and SADS were statistically lower (better) in those on hormone therapy than in those not on hormone therapy, the mean scores for

HAD-Depression and SADS were in the normal range for gender dysphoric patients not using hormones. The HAD-Anxiety score was 9 in transsexuals without hormone treatment and 6.4 in transsexuals with hormone treatment. The mean scores for HAD-Anxiety, HAD- Depression, and SADS were in the normal range for gender dysphoric patients using hormones. ANOVA revealed that results did not differ by whether the patient had undergone a gender related surgical procedure or not.

Gómez-Gil E, Zubiaurre-Elorza L, de Antonio I, Guillamon A, Salamero M. Determinants of quality of life in Spanish transsexuals attending a gender unit before genital sex reassignment surgery. Qual Life Res. 2014 Mar;23(2):669-76. Epub 2013 Aug 13.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a non-specific quality of life tool. There were no formal controls for this mixed population ± non-genital reassignment surgery undergoing various stages of treatment.

The investigators assessed quality of life in the context of culture in patients with gender dysphoria who were from a single-center (Barcelona, Spain), specialty and gender identity clinic. The clinic used WPATH guidelines. Patients were required to have met diagnostic criteria during evaluations by both a psychologist and psychiatrist. Patients could have undergone non-genital surgeries, but not genital reassignment surgeries (e.g., orchiectomy, vaginoplasty, or phalloplasty). The Spanish version of the World Health Organization Quality of Life-Abbreviated version of the WHOQOL-100 (WHOQOL- BREF) was used to evaluate quality of life, which has 4 domains (environmental, physical, psychological, and social) and 2 general questions. Family dynamics were assessed with the Spanish version of the Family Adaptability, Partnership Growth, Affection, and Resolve (APGAR) test. Regression analysis was used to explore effects of surgical treatment.

All consecutive patients presenting at the clinic (277) were recruited and, 260 (93.9%) agreed to participate. Of this number, 59 of these were excluded for incomplete questionnaires, 8 were excluded for prior genital reassignment surgery, and 193 were included in the study (the mean age of this group was 31.2±9.9 years (range 16-67). Of these, 74 (38.3%) were female-to-male patients; 119 (61.7%) were male-to-female patients (ratio1:1.6). Of these, 120 (62.2%) were on hormone therapy; 29 (39.2%) of female-to-male patients had undergone at least 1 non-genital, surgical procedure (hysterectomy n=19 (25.7%); mastectomy n=29 (39.2%)); 51 (42.9%) of male-to-female patients had undergone at least one non-genital surgical procedure with mammoplasty augmentation being the most common procedure, n=47 (39.5%), followed by facial feminization, n=11 (9.2%), buttocks feminization, n=9 (7.6%), and vocal feminization (thyroid chondroplasty), n=2 (1.7%).

WHOQOL-BREF domain scores for gender dysphoric patients with and without non-genital surgery were: "Environmental" 58.81±14.89 (range 12.50-96.88), "Physical" 63.51±17.79 (range 14.29-100), "Psychological" 56.09+16.27 (range 16.67- 56.09), "Social" 60.35±21.88 (range 8.33-100), and "Global QOL and Health" 55.44+27.18 (range 0-100 with higher score representing better QOL). The mean APGAR family score was 7.23±2.86 (range 0-10 with a score of 7 or greater indicative of family functionality).

Regression analysis, which was used to assess the relative importance of various factors to WHOQOL-BREF domains and general questions, revealed that family support was an important element for all four domains and the general health and quality- of-life questions. Hormone therapy was an important element for the general questions and for all of the domains except "Environmental." Having undergone non-genital reassignment surgery, age, educational levels, and partnership status, did not impact domain and general question results related to quality of life.

Hepp U, Kraemer B, Schnyder U, Miller N, Delsignore A. Psychiatric comorbidity in gender identity disorder. J Psychosom Res. 2005 Mar;58(3):259-61.

Hepp et al. conducted a single-site (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design. There was some acquisition of retrospective data. The investigators assessed current and lifetime psychiatry co-morbidity using structured interviews for diagnosis of Axis 1 disorders (clinical syndromes) and Axis 2 disorders (developmental or personality disorders) and HADS for dimensional evaluation of anxiety and depression. Statistical description of the cohort and intra-group comparisons was performed. Continuous variables were compared using t-tests and ANOVA.

A total of 31 patients with gender dysphoria participated in the study: 11 (35.5%) female-to-male; 20 (64.5%) male-to-female (ratio 1:1.8). The overall mean age was 32.2±10.3 years. Of the participants, seven had undergone reassignment surgery, 10 pre- surgical patients had been prescribed hormone therapy, and 14 pre-surgical patients had not been prescribed hormone therapy. Forty five and one half percent of female-to-male and 20% of male-to-female patients did not carry a lifetime diagnosis of an Axis 1 condition. Sixty three and six tenths percent of female-to-male and 60% of male-to-female patients did not carry a current diagnosis of an Axis 1 condition. Lifetime diagnosis of substance abuse and mood disorder were more common in male-to-female patients (50% and 55% respectively) than female-to-male patients (36.4% and 27.3% respectively). Current diagnosis of substance abuse and mood disorder were present in male-to-female patients (15% and 20% respectively) and absent in female-to-male patients. One or more personality disorders were identified 41.9%, but whether this was a current or lifetime condition was not specified. Of the patients, five (16.1%) had a Cluster A personality disorder (paranoid-schizoid), seven (22.6%) had a Cluster B personality disorder (borderline, anti-social, histrionic, narcissistic), six (19.4%) had a Cluster C personality disorder (avoidant, dependent, obsessive-compulsive), and two (6.5%) were not otherwise classified.

HADS scores were missing for at least one person. The HADS test revealed non-pathologic results for depression (female-to-male: 6.64±5.03; male-to-female: 6.58±4.21) and borderline results for anxiety (female-to-male: 7.09±5.11; male-to-female: 7.74±6.13, where a result of 7-10 = possible disorder). There were no differences by natal gender. The investigators reported a trend for less anxiety and depression as measured by HADS in the patients who had undergone surgery.

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

Johansson et al. conducted a two center (Lund and Umeå, Sweden) non-blinded, observational study using a semi-cross-sectional design (albeit over an extended time interval) using a self-designed tool and Axis V assessment. The study was prospective except for the acquisition of baseline Axis V data. There were no formal controls in this mixed population with and without surgery.

The investigators assessed satisfaction with the reassignment process, employment, partnership, sexual function, mental health, and global satisfaction in gender-reassigned persons from two disparate geographic regions. Surgical candidates were required to have met National Board of Health and Welfare criteria including initial and periodic psychiatric assessment, ≥1 year of real-life experience in preferred gender, and ≥1 year of subsequent hormone treatment. In addition, participants were required to have been approved for reassignment five or more years prior and/or to have completed surgical reassignment (e.g., sterilization, genital surgery) two or more years prior. The investigators employed semi-structured interviews covering a self-designed list of 55 pre-formulated questions with a three or five point ordinal scale. Clinician assessment of Global Assessment of Functioning (GAF; Axis V) was also conducted and compared to initial finding during the study. Changes or differences considered to be biologically significant were not pre- specified except for GAF, which pre-specified a difference to mean change ≥5 points. Statistical corrections for multiple comparisons were not included. There was no stratification by treatment.

Of the pool of 60 eligible patients, 42 (70.0% of eligible) (17 [40.5 %] female-to-male; 25 [59.5%] male-to-female;

ratio 1:1.5) were available for follow-up. Of these, 32 (53.3% of eligible) (14 [43.8%] female-to-male; 18 [56.2%] male-to-female [ratio 1:1.3]) had completed genital gender reassignment surgery (not including one post mastectomy), five were still in the process of completing surgery, and five (one female-to-male; four male- to-female; ratio 1:4) had discontinued the surgical process prior to castration and genital surgery.

The age (ranges) of the patients at entry into the program, reassignment surgery, and follow-up were 27.8 (18-46), 31.4 (22- 49), and 38.9 (28-53) years in the female-to-male group respectively and 37.3 (21-60), 38.2 (22-57), and 46.0 (25.0-69.0) years in the male- to-female group respectively. The differences in age by cohort group were statistically significant. Of participants, 88.2% of all enrolled female-to-male versus 44.0% of all enrolled female-to-male patients had cross-gender identification in childhood (versus during or after puberty) ($p<0.01$).

Although 95.2% of all enrolled patients self-reported improvement in GAF, in contrast, clinicians determined GAF improved in 61.9% of patients. Clinicians observed improvement in 47% of female-to-male patients and 72% of male-to- female patients. A ≥5 point improvement in the GAF score was present in 18 (42.9%). Of note, three of the five patients who were in the process of reassignment and five of the five who had discontinued the process were rated by clinicians as having improved.

Of all enrolled 95.2% (with and without surgery) reported satisfaction with the reassignment process. Of these 42 patients, 33 (79%) identified themselves by their preferred gender and nine (21%) identified themselves as transgender. None of these nine (eight male-to-female) had completed reassignment surgery because of ambivalence secondary to lack of acceptance by others and dissatisfaction with their appearance. Of the patients who underwent genital surgery (n=32) and mastectomy only (n=one), 22 (66.7%) were satisfied while four (three female-to-male) were dissatisfied with the surgical treatment.

Regarding relationships after surgery, 16 (38.1%) (41.2% of female- to-male; 36.0% of male-to-female patients) were reported to have a partner. Yet more than that number commented on partner relationships: (a) 62.2 % of the 37 who answered (50.0% of female- to- male; 69.6% of male-to-female patients) reported improved partner relationships (five [11.9%] declined to answer.); (b) 70.0% of the 40 who answered (75.0% of female-to-male; 66.7% of male-to-female patients) reported an improved sex life. Investigators observed that reported post-operative satisfaction with sex life was statistically more likely in those with early rather than late cross-gender identification. In addition 55.4% self-reported improved general health; 16.1% reported impaired general health; 11.9% were currently being treated with anti-depressants or tranquilizers.

This study subsumes earlier work by Bodlund et al. (1994, 1996). The nationwide mortality studies by Dhejne et al. (2011) may include all or part of this patient population.

Leinung M, Urizar M, Patel N, Sood S. Endocrine treatment of transsexual persons: extensive personal experience. Endocr Pract. 2013 Jul-Aug;19(4):644-50. (United States study)

Leinung et al. conducted a single-center (Albany, New York) a partially prospective, non-blinded, observational study using a cross-sectional design and descriptive statistics. There were no formal controls. The investigators assessed employment, substance abuse, psychiatric disease, mood disorders, Human Immunodeficiency Virus (HIV) status in patients who had met WPATH guidelines for therapy, and who had initiated cross-sex hormone treatment.

A total of 242 patients treated for gender identity disorder in the clinic from 1992 through 2009 inclusive were identified. The number of those presenting for therapy almost tripled over time. Of these patients, 50 (20.7%) were female-to-male; 192 (79.3%) male-to-female (ratio 1:3.8).

The age of female-to-male and male-to-female patients with gender dysphoria at the time of clinic presentation was 29.0 and 38.0 years respectively.

The female-to-male and male-to-female patients with gender dysphoria at the time of hormone initiation were young: 27.5 and 35.5 years old respectively ($p<0.5$). Of the male-to-female cohort, 19 (7.8%) had received hormone therapy in the absence of physician supervision; Of the patient population, 91 (37.6%) had undergone gender-reassignment surgery (32 female-to-male [64.0% of all female-to- male; 35.2% of all surgical patients]; 59 male-to-female [30.7% of all male-to-female; 64.8% of all surgical patients]; ratio 1:1.8).

Psychiatric disease was more common in those who initiated hormone therapy at an older age (>32 years) 63.9% versus 48.9% at a younger age and by natal gender (48.0% of female-to-male; 58.3% male-to-female). Mood disorders were more common in those who initiated hormone therapy at an older age (>32 years) 52.1% versus 36.0% at a younger age and this finding did not differ by natal gender (40.0% of female-to-male; 44.8% male-to-female). The presence of mood disorders increased the time to reassignment surgery in male-to-female patients.

Motmans J , Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. J Sex Med. 2012 Mar;9(3):743-50. Epub 2011 Dec 21.

Motmans et al., conducted a prospective, non-blinded, observational study using a cross-sectional design and a non-specific quality of life tool. No concurrent controls were used in this study. Quality of life in this Dutch-speaking population was assessed using the Dutch version of a SF-36 (normative data was used). Participants included subjects who were living in accordance with the preferred gender and who were from a single Belgian university specialty clinic at Ghent. The Dutch version of the SF-36 questionnaire along with its normative data were used. Variables explored included employment, pension status, ability to work, being involved in a relationship. Also explored, was surgical reassignment surgery and the types of surgical interventions. Intragroup comparisons by transgender category were conducted, and the relationships between variables were assessed by analysis of variance (ANOVA) and correlations.

The age of the entire cohort (n=140) was 39.89±10.21 years (female-to-male: 37.03±8.51; male-to-female: 42.26±10.39). Results of the analysis revealed that not all female-to-male patients underwent surgical reassignment surgery and, of those who did, not all underwent complete surgical reassignment. The numbers of female-to-male surgical interventions were: mastectomy 55, hysterectomy 55, metaoidplasty eight (with five of these later having phalloplasty), phalloplasty 40, and implantation of a prosthetic erectile device 20. The frequencies of various male-to-female surgical interventions were: vaginoplasty 48, breast augmentation 39, thyroid cartilage reduction 17, facial feminization 14, and hair transplantation three.

The final number of subjects with SF-36 scores was 103 (49 [47.6%] female-to-male; 54 [52.4%] male-to-female; ratio 1:1.1). For this measure, the scores for the vitality and mental health domains for the final female-to-male cohort (n= 49 and not limited to those having undergone some element of reassignment surgery) were statistically lower: 60.61±18.16 versus 71.9±18.31 and 71.51±16.40 versus 79.3±16.4 respectively. Scores were not different from the normative data for Dutch women: vitality: 64.3±19.7 or mental health 73.7±18.2. None of the domains of the SF-36 for the final male-to-female cohort (n=54 and not limited to those having undergone some element of reassignment surgery) were statistically different from the normative data for Dutch women.

Analysis of variance indicated that quality of life as measured by the SF-36 did not differ by whether female-to-male patients had undergone genital surgery (metaoidoplasty or phalloplasty) or not. Also, ANOVA indicated that quality of life as measured by the SF-36 did not differ by whether male-to-female patients had undergone either breast augmentation or genital surgery (vaginoplasty) or not.

Whether there is overlap with the Ghent populations studied by Heylens et al. or Weyers et al. is unknown.

Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 2006 Nov;15(9):1447-57. Epub 2006 Jun 7. (United States study)

Newfield et al. conducted a prospective, observational internet self-report survey of unknown blinding status using a cross- sectional design and a non-specific quality of life tool in a mixed population with and without hormone therapy and/or reassignment surgery. There were no formal controls.

The investigators recruited natal female participants identifying as male using email, internet bulletin boards, and flyers/postcards distributed in the San Francisco Bay Area. Reduction of duplicate entries by the same participant was limited to the use of a unique user name and password.

The investigators employed the Short-Form 36 (SF-36) Version 2 using U.S. normative data. They reported using both male and female normative data for the comparator SF-36 cohort. Data for the eight domains were expressed as normative scoring. The Bonferroni correction was used to adjust for the risk of a Type 1 error with analyses using multiple comparisons.

A total of 379 U.S. respondents classified themselves as males-or-females to males with or without therapeutic intervention. The mean age of the respondents who classified themselves as male or female-to-male was 32.6±10.8 years. Of these 89% were Caucasian, 3.6% Latino, 1.8% African American, 1.8% Asian, and 3.8% other. Of these, 254 (67.0%) reported prior or current testosterone use while 242 (63.8%) reported current testosterone use. In addition, 136 (36.7%) reported having had "top" surgery and 11 (2.9%) reported having "bottom" surgery.

Complete SF-36 data were available for 376 U.S. respondents. For the complete, non-stratified U.S. cohort the Physical Summary Score (53.45±9.42) was statistically higher (better) than the natal gender unspecified SF-36 normative score (50±10) (p=<0.001), but was within one standard deviation of the normative mean. The Mental Summary Score (39.63±12.2) was statistically lower (worse) than the natal gender unspecified SF-36 normative score (50±10) (p<0.001), but was well within two standard deviations of the normative mean. Subcomponents of this score: Mental Health (42.12±10.2), Role Emotional (42.42±11.6), Social Functioning (43.14±10.9), and Vitality (46.22±9.9) were statistically lower (worse) than the SF-36 normative sub-scores, but well within one standard deviation of the normative sub- score means. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

Additional intragroup analyses were conducted, although the data were not stratified by type of therapeutic intervention (hormonal, as well as, surgical). Outcomes of hormone therapy were considered separately and dichotomously from reassignment surgery. The Mental Summary Score was statistically higher (better) in those who had "Ever Received Testosterone" (41.22±11.9) than those with "No Testosterone Usage" (36.08±12.6) (p=0.001). The Mental Summary Scores showed a trend towards statistical difference between those who "Ever Received Top Surgery" (41.21±11.6) and those without "Top Surgery" (38.01±12.5) (p=0.067). These differences were well within one standard deviation of the normative mean. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

b. Observational, surgical series, without concurrent controls

Blanchard R, Steiner BW, Clemmensen LH. Gender dysphoria, gender reorientation, and the clinical management of transsexualism. J Consult Clin Psychol. 1985 Jun; 53(3):295-304.

Blanchard et al. conducted a single-center (Ontario, Canada), prospective, non-blinded, cross-sectional study using a self-designed questionnaire and a non- specific psychological symptom assessment with normative data. The investigators assessed social adjustment and psychopathology in patients with gender dysphoria and who were at least one year post gender reassignment surgery. Reassignment surgery was defined as either vaginoplasty or mastectomy/construction of male chest contour with or without nipple transplants, but did not preclude additional procedures. Partner preference was determined using Blanchard's Modified Androphilia-Gynephilia Index, and the nature and extent of any psychopathology was determined with the Symptom Check List 90-Revised (SCL-90R). Differences in test scores considered to be biologically significant were not pre-specified in the methods.

Of the 294 patients (111 natal females and 183 natal males, ratio: 1:1.65) initially evaluated, 263 were diagnosed with gender dysphoria. Of these 79 patients participated in the study (38 female-to-male; 32 male-to-female with male partner preference; 9 male-to-female with female partner preference). The respective mean ages for these 3 groups were 32.6, 33.2, and 47.7 years with the last group being older statistically (p=0.01).

Additional surgical procedures in female-to-male patients included: oophorectomy/hysterectomy (92.1%) and phalloplasty (7.9%). Additional surgical procedures in male-to-female patients with male partner preference included facial hair electrolysis 62.5% and breast implantation (53.1%). Additional procedures in male-to-female patients with female partner preference included facial hair electrolysis (100%) and breast implantation (33.3%). The time between reassignment surgery and questionnaire completion did not differ by group.

Psychopathology as measured by the Global Severity Index of the SCL-90R was absent in all three patient groups. Interpretation did not differ by the sex of the normative cohort.

Of participants, 63.2% of female-to-male patients cohabitated with partners of their natal gender; 46.9% of male-to-female patients with male partner preference cohabitated with partners of their natal gender; and no male-to-female patients with female partner preference cohabitated with partners of their natal gender.

Of participants, 93.7% reported that they would definitely undergo reassignment surgery again. The remaining 6.3% (one female-to-male; one male-to-female with male partner preference; three male-to-female with female partner preference) indicated that they probably would undertake the surgery again. Post hoc analysis suggested that the more ambivalent responders had more recently undergone surgery. Of responders, 98.7% indicated that they preferred life in the reassigned gender. The one ambivalent subject was a skilled and well compensated tradesperson who was unable to return to work in her male dominated occupation.

Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.

Eldh et al. conducted a non-blinded, observational study using a prospective cross-sectional design with an investigator designed questionnaire and retrospective acquisition of pre-operative data. The investigators assessed economic circumstances, family status, satisfaction with surgical results, and sexual function in patients who had undergone gender reassignment surgery.

Of the 175 patients who underwent reassignment surgery in Sweden, 90 responded. Of this number, 50 were female-to-male and 40 were male-to-female (ratio: 1:0.8). Patients reportedly were generally satisfied with the appearance of the reconstructed genitalia (no numbers provided). Of the patients who had undergone surgery prior to 1986, seven (14%) were dissatisfied with shape or size of the neo-phallus; eight (16%) declined comment. There were 14 (35%), with 12 having surgery prior to 1986 and two between 1986 and 1995 inclusive, were moderately satisfied because of insufficient vaginal volume; 8 (20%) declined comment. A neo-clitoris was not constructed until the later surgical cohort. Three of 33 reported no sensation or no sexual sensation. Eight had difficulties

comprehending the question and did not respond.

A total of nine (18%) patients had doubts about their sexual orientation; 13 (26%) declined to answer the question. The study found that two female-to- male patients and two male-to-female patients regretted their reassignment surgery and continued to live as the natal gender, and two patients attempted suicide.

Hess J, Rossi Neto R, Panic L, Rübben H, Senf W. Satisfaction with male-to-female gender reassignment surgery. Dtsch Arztebl Int. 2014 Nov 21;111(47):795-801.

Hess at al. conducted a prospective, blinded, observational study using a cross-sectional design and a self-designed anonymous questionnaire. The investigators assessed post-operative satisfaction in male-to-female patients with gender dysphoria who were followed in a urology specialty clinic (Essen, Germany). Patients had met the ICD-10 diagnostic criteria, undergone gender reassignment surgeries including penile inversion vaginoplasty, and a Likert-style questionnaire with 11 elements. Descriptive statistics were provided.

There were 254 consecutive eligible patients who had undergone surgery between 2004 and 2010 identified and sent surveys, of whom 119 (46.9%) responded anonymously. Of the participants, 13 (10.9%) reported dissatisfaction with outward appearance and 16 (13.4%) did not respond; three (2.5%) reported dissatisfaction with surgical aesthetics and 25 (21.0%) did not respond; eight (6.7%) reported dissatisfaction with functional outcomes of the surgery and 26 (21.8%) did not respond; 16 (13.4%) reported they could not achieve orgasm and 28 (23.5%) did not respond; four (3.4%) reported feeling completely male/more male than female and 28 (23.5%) did not respond; six (5.0%) reported not feeling accepted as a woman, two (1.7%) did not understand the question, and 17 (14.3%) did not respond; and 16 (13.4%) reported that life was harder and 24 (20.2%) did not respond.

Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. Arch Sex Behav. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)

Lawrence conducted a prospective, blinded observational study using a cross-sectional design and a partially self-designed quality of life tool using yes/no questions or Likert scales. The investigator assessed sexual function, urinary function, and other pre/post-operative complications in patients who underwent male-to-female gender reassignment surgery. Questions addressed core reassignment surgery (neo-vagina and sensate neo-clitoris) and related reassignment surgery (labiaplasty, urethral meatus revision, vaginal deepening/widening, and other procedures), use of electrolysis, and use of hormones.

Questionnaires were designed to be completed anonymously and mailed to 727 eligible patients. Of those eligible, 232 (32%) returned valid questionnaires. The age at the time reassignment surgery was 44±9 (range 18-70) years and mean duration after surgery was 3±1 (range 1-7) years.

Happiness with sexual function and the reassignment surgery was reported to be lower when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life was impaired when pain in the vagina or genitals was present.

Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past; whereas, more satisfaction with vaginal depth and width was present in more recent surgical treatment.

Salvador J, Massuda R, Andreazza T, Koff WJ, Silveira E, Kreische F, de Souza L, de Oliveira MH, Rosito T, Fernandes BS, Lobato MI. Minimum 2-year follow up of sex reassignment surgery in Brazilian male-to-female transsexuals. Psychiatry Clin Neurosci. 2012 Jun; 66(4):371-2. PMID: 22624747.

Salvador et al. conducted a single center (Port Alegre, Brazil) prospective, non-blinded, observational study using a cross-sectional design (albeit over an extended time interval) and a self-designed quality of life tool. The investigators assessed regret, sexual function, partnerships, and family relationships in patients who had undergone gender reassignment surgery at least 24 months prior.

Out of the 243 enrolled in the clinic over a 10 year interval, 82 underwent sex reassignment surgery. There were 69 participants with a minimum 2-year follow up, of whom 52 patients agreed to participate in the study. The age at follow-up was 36.3±8.9 (range 15-58) years with the time to follow-up being 3.8±1.7 (2-7) years. A total of 46 participants reported pleasurable neo-vaginal sex and post-surgical improvement in the quality of their sexual experience. The quality of sexual intercourse was rated as satisfactory to excellent, average, unsatisfactory, or not applicable in the absence of sexual contact by 84.6%, 9.6%, 1.9%, and 3.8% respectively. Of the participants, 78.8% reported greater ease in initiating and maintaining relationships; 65.4% reported having a partner; 67.3% reported increased frequency of intercourse; 36.8% reported improved familial relationships. No patient reported regret over reassignment surgery. The authors did not provide information about incomplete questionnaires.

Tsoi WF. Follow-up study of transsexuals after sex-reassignment surgery. Singapore Med J. 1993 Dec; 34(6):515-7.

Tsoi conducted a single-center (Singapore) prospective, non-blinded, observational study using a cross-sectional design and a self-designed quality of life tool. The investigator assessed overall life satisfaction, employment, partner status, and sexual function in gender-reassigned persons who had undergone gender reassignment surgery between 1972 and 1988 inclusive and who were approximately 2 to 5 years post-surgery. Acceptance criteria for surgery included good physical health, good mental health, absence of heterosexual tendencies, willingness to undergo hormonal therapy for ≥6 months, and willingness to function in the life of the desired gender for ≥6 months. Tsoi also undertook retrospective identification of variables that could predict outcomes.

The size of the pool of available patients was not identified. Of the 81 participants, 36 (44.4%) were female-to-male and 45 (55.6%) were male-to-female (ratio 1:1.25).

The mean ages at the time of the initial visit and operation were: female-to-male 25.4±4.4 (range 14-36) and 27.4 ±4.0; (range 14-36); male-to-female 22.9±4.6 (range 14-36) and 24.7±4.3 (14-36) years respectively. Of all participants, 14.8% were under age 20 at the time of the initial visit. All were at least 20 at the time of gender reassignment surgery. The reported age of onset was 8.6 years for female-to-male patients and 8.7 years for male-to-female patients.

All participants reported dressing without difficulty in the reassigned gender; 95% of patients reported good or satisfactory adjustment in employment and income status; 72% reported good or satisfactory adjustment in relationships with partners. Although the quality of life tool was self-designed, 81% reported good or satisfactory adjustment to their new gender, and 63% reported good or acceptable satisfaction with sexual activity. Of the female-to-male patients, 39% reported good or acceptable satisfaction with sex organ function in comparison to 91% of male-to-female patients ($p<0.001$). (The author reported that a fully functioning neo-phallus could not be constructed at the time.) The age of non-intercourse sexual activity was the only predictor of an improved outcome.

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. J Sex Med. 2009 Mar;6(3):752-60. Epub 2008 Nov 17.

Weyers at al. (2009) conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments including a non-specific quality of life tool and a semi-specific quality of life tool (using normative data) along with two self-designed tools.

The investigators assessed general quality of life, sexual function, and body image from the prior four weeks in Dutch-speaking male-to-female patients with gender dysphoria who attended a single-center (Ghent, Belgium), specialized, comprehensive care university clinic. Investigators used the Dutch version of the SF-36 and results were compared to normative data from Dutch women and U.S. women. The 19 items of the Dutch version of the Female Sexual Function Index (FSFI) were used to measure sexual desire, function, and satisfaction. A self-designed seven question visual analog scale (VAS) was used to measure satisfaction with gender related body traits and appearance perception by self and others. A self-designed survey measured a broad variety of questions regarding personal medical history, familial medical history, relationships, importance of sex, sexual orientation, gynecologic care, level of regret, and other health concerns. For this study, hormone levels were also obtained.

The study consisted of 50 (71.5% of the eligible recruits) participants. Analysis of the data revealed that the patient's average age was 43.1 ±10.4 years, and all of the patients had vaginoplasty. This same population also had undergone additional feminization surgical procedures (breast augmentation 96.0%, facial feminization 36.0%, vocal cord surgery 40.0%, and cricoid cartilage reduction 30.0%). A total of two (4.0%) participants reported "sometimes" regretting reassignment surgery and 23 (46.0%) were not in a relationship. For the cohort, estradiol, testosterone, and sex hormone binding globulin levels were in the expected range for the reassigned gender. The SF-36 survey revealed that the subscale scores of the participants did not differ substantively from those of Dutch and U.S. women. VAS scores of body image were highest for self-image, appearance to others, breasts, and vulva/vagina (approximately 7 to 8 of 10). Scores were lowest for body hair, facial hair, and voice characteristics (approximately 6 to 7 of 10).

The total FSFI score was 16.95±10.04 out of a maximal 36. The FSFI scores averaged 2.8 (6 point maximum): satisfaction 3.46±1.57, desire 3.12+1.47, arousal 2.95±2.17, lubrication 2.39±2.29, orgasm 2.82±2.29, and pain 2.21±2.46. Though these numbers were reported in the study, data on test population controls were not provided.

A post hoc exploration of the data suggested the following: perceived improvement in general health status was greater in the subset that had undergone reassignment surgery within the last year; sexual orientation impacted the likelihood of being in a relationship; SF-36 scores for vitality, social functioning, and mental health were nominally better for those in relationships, but that overall SF-36 scores did not differ by relationship status; sexual orientation and being in a relationship impacted FSFI scores; and reported sexual function was higher in those with higher satisfaction with regards to their appearance.

Wierckx K, Van Caenegem E, Elaut E, Dedecker D, Van de Peer F, Toye K, Weyers S, Hoebeke P, Monstrey S, De Cuypere G, T'Sjoen G. Quality of life and sexual health after sex reassignment surgery in transsexual men. J Sex Med. 2011 Dec;8 (12):3379-88. Epub 2011 Jun 23.

Wierckx at al. conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments (a non-specific quality of life tool with reported normative data along with three self-designed tools). The investigators assessed general quality of life, sexual relationships, and surgical complications in Dutch-speaking female-to-male patients with gender dysphoria who attended a single-center, specialized, comprehensive care, university clinic (Ghent, Belgium). Investigators used the Dutch version of the SF-36 with 36 questions, eight subscales, and two domains evaluating physical and mental health. Results were compared to normative data from Dutch women and Dutch men. Self -designed questionnaires to evaluate aspects of medical history, sexual functioning (there were separate versions for those with and without partners), and surgical results were also used. The Likert-style format was used for many of the questions.

A total of 79 female-to-male patients with gender dysphoria had undergone reassignment surgery were recruited; ultimately, 47 (59.5%) chose to participate. Three additional patients were recruited by other patients. One of the 50 participants was later excluded for undergoing reassignment surgery within the one year window. The age of patients was: 30±8.2 years (range 16 to 49) at the time of reassignment surgery and 37.1 ±8.2 years (range 22 to 54) at the time of follow-up. The time since hysterectomy, oopherectomy, and mastectomy was 8 years (range 2 to 22). The patient population had undergone additional surgical procedures: metaidoiplasty (n=9; 18.4%), phalloplasty (n=8 after metaidoiplasty, 38 directly; 93.9% total), and implantation of erectile prosthetic device (n=32; 65.3%). All had started hormonal therapy at least two years prior to surgery and continued to use androgens.

The SF-36 survey was completed by 47 (95.9%) participants. The "Vitality" and the "Mental Health" scales were lower than the Dutch male population: 62.1±20.7 versus 71.9±18.3 and 72.6±19.2 versus 79.3±16.4 respectively. These subscale scores were equivalent to the mean scores of the Dutch women.

None of the participants were dissatisfied with their hysterectomy-oopherectomy procedures; 4.1% were dissatisfied with their mastectomies because of extensive scarring; and 2.2% were dissatisfied with their phalloplasties. Of the participants, 17.9% were dissatisfied with the implantation of an erectile prosthetic device; 25 (51.0%) reported at least one post-operative complication associated with phalloplasty (e.g., infection, urethrostenosis, or fistula formation); 16 (50.0% of the 32 with an erectile prosthetic device) reported at least one post-operative complication associated with implantation of an erectile prosthetic (e.g., infection, leakage, incorrect positioning, or lack of function).

A total of 18 (36.7%) participants were not in a relationship; 12.2% reported the inability to achieve orgasm with self-stimulation less than half the time; 12.2% did not respond to the question. Of those participants with partners, 28.5% reported the inability to achieve orgasm with intercourse less than half the time and 9.7% did not respond to this question. Also, 61.3% of those with partners reported (a) no sexual activities (19.4%) or (b) activities once or twice monthly (41.9%), and there were 12.9% who declined to answer.

c. Observational, surgical patients, cross-sectional, with controls

Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010 Sep;19(7):1019-24.

Ainsworth and Spiegel conducted a prospective, observational study using a cross-sectional design and a partially self-designed survey tool. The blind status is unknown. Treatment types served as the basis for controls.

The investigators, head and neck surgeons who provided facial feminization services, assessed perception of appearance and quality of life in male-to-female subjects with self-reported gender dysphoria. Patients could have received no therapeutic intervention, hormone therapy, reassignment surgery, and/or facial feminization surgery and an unrestricted length of transition. (Transition refers to the time when a transgender person begins to live as the gender with which they identify rather than the gender assigned at birth.) Criteria for the various types of interventions were not available because of the survey design of the study. Patients were recruited via website or at a 2007 health conference. Pre-specified controls to eliminate duplicate responders were not provided. The investigators employed a self-designed Likert-style facial feminization outcomes evaluation questionnaire and a "San Francisco 36" health questionnaire. No citations were provided for the latter. It appears to be the Short-form (SF) 36-version 2. Changes or differences considered to be biologically significant were not pre-specified. Power corrections for multiple comparisons were not provided.

The investigators reported that there were 247 participants. (The numbers of incomplete questionnaires was not reported.) Of the 247 participants, 25 (10.1%) received only primary sex trait reassignment surgery, 28 (11.3%)

received facial surgery without primary sex trait reassignment surgery, 47 (19.0%) received both facial and primary sex trait reassignment surgery, and 147 (59.5%) received neither facial nor reassignment surgery.

The mean age for each of these cohorts was: 50 years (no standard deviation [S.D.]) only reassignment surgery, 51 years (no S.D.) only facial surgery, 49 years (no S.D.) both types of surgery, and 46 years (no S.D.) (neither surgery). Of the surgical cohorts: 100% of those who had undergone primary sex trait reassignment surgery alone used hormone therapy, 86% of those who had undergone facial feminization used hormone therapy, and 98% of those who had undergone both primary sex trait reassignment surgery and facial feminization used hormone therapy. In contrast to the surgical cohorts, 66% of the "no surgery" cohort used hormonal therapy, and a large proportion (27%) had been in transition for less than one year.

The investigators reported higher scores on the facial outcomes evaluation in those who had undergone facial feminization. Scores of the surgical cohorts for the presumptive SF-36 comprehensive mental health domain did not differ from the general U.S. female population. Scores of the "no surgery" cohort for the comprehensive mental health domain were statistically lower than those of the general U.S. female population, but within one standard deviation of the normative mean. Mean scores of all the gender dysphoric cohorts for the comprehensive physical domain were statistically higher than those of the general female U.S. population, but were well within one standard deviation of the normative mean. Analyses of inter-cohort differences for the SF-36 results were not conducted. Although the investigators commented on the potential disproportionate impact of hormone therapy on outcomes and differences in the time in "transition", they did not conduct any statistical analyses to correct for putative confounding variables.

Kraemer B, Delsignore A, Schnyder U, Hepp U. Body image and transsexualism. Psychopathology. 2008;41(2):96-100. Epub 2007 Nov 23.

Kraemer et al. conducted a single center (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design comparing pre-and post- surgical cohorts. Patients were required to meet DSM III or DSM IV criteria as applicable to the time of entry into the clinic. Post-surgical patients were from a long-term study group (Hepp et al., 2002). Pre-surgical patients were recent consecutive referrals. The assessment tool was the Fragebogen zur Beurteilung des eigenen Korpers (FBeK) which contained three domains.

There were 23 pre-operative patients: 7 (30.4%) female-to-male and 16 (69.6%) male-to-female (ratio 1:2.3). There were 22 post-operative patients: 8 (36.4 %) female-to-male and 14 (63.6%) male-to-female (ratio 1:1.8). The mean ages of the cohorts were as follows: pre-operative 33.0±11.3 years; post-operative 38.2±9.0 years. The mean duration after reassignment surgery was 51±25 months (range 5-96).

The pre-operative groups had statistically higher insecurity scores compared to normative data for the natal sex: female-to-male 9.0±3.8 versus 5.1±3.7; male-to-female 8.1±4.5 versus 4.7±3.1 as well as statistically lower self-confidence in one's attractiveness: female-to-male 3.1±2.9 versus 8.9±3.1; male-to-female 7.0±2.9 vs 9.5±2.6.

Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of transsexualism. Br J Psychiatry. 1988 Apr;152: 550-3.

Mate-Kole at al. conducted a single site (London, United Kingdom) prospective non-blinded, observational study using a cross-sectional design and two psychological tests (one with some normative data). Concurrent controls were used in this study design. The investigators assessed neuroticism and sex role in natal males with gender dysphoria. Patients at various stages of management, (i.e., under evaluation, using cross-sex hormones, or post reassignment surgery [6 months to 2 years]) were matched by age of cross-dressing onset, childhood neuroticism, personal psychiatric history, and family psychiatric history. Both a psychologist and psychiatrist conducted assessments. The

instruments used were the Crown Crisp Experiential Index (CCEI) for psychoneurotic symptoms and the Bem Sex Role Inventory. ANOVA was used to identify differences between the three treatment cohorts.

For each cohort, investigators recruited 50 male-to-female patients from Charing Cross Hospital. The mean ages of the three cohorts were as follows: 34 years for patients undergoing evaluation; 35 years for wait-listed patients; and 37 years for post-operative patients. For the cohorts, 22% of those under evaluation, 24% of those on hormone treatment only, and 30% of those post-surgery had prior psychiatric histories, and 24%, 24%, while 14% in each cohort, respectively, had a history of attempted suicide. More than 30% of patients in each cohort had a first degree relative with a history of psychiatric disease.

The scores for the individual CCEI domains for depression and somatic anxiety were statistically higher (worse) for patients under evaluation than those on hormone treatment alone. The scores for all of the individual CCEI domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were statistically lower in the post-operative cohort than in the other two cohorts.

The Bem Sex Role Inventory masculinity score for the combined cohorts was lower than for North American norms for either men or women. The Bem Sex Role Inventory femininity score for the combined cohorts was higher than for North American norms for either men or women. Those who were undergoing evaluation had the most divergent scores from North American norms and from the other treatment cohorts. Absolute differences were small. All scores of gender dysphoric patients averaged between 3.95 and 5.33 on a 7 point scale while the normative scores averaged between 4.59 and 5.12.

Wolfradt U, Neumann K. Depersonalization, self-esteem and body image in male-to-female transsexuals compared to male and female controls. Arch Sex Behav. 2001 Jun;30(3):301-10.

Wolfradt and Neumann conducted a controlled, prospective, non-blinded, observational study using a cross-sectional design. The investigators assessed aspects of personality in male-to-female patients who had undergone vocal cord surgery for voice feminization and in healthy non-transgender volunteers from the region. The patients had undergone gender reassignment surgery 1 to 5 years prior to voice surgery. The volunteers were matched by age and occupation.

The primary hypothesis was that depersonalization, with the sense of being detached from one’s body or mental processes, would be more common in male-to- female patients with gender dysphoria. German versions of the Scale for Depersonalization Experiences (SDPE), the Body Image Questionnaire (BIQ), a Gender Identity Trait Scale (GIS), and the Self-Esteem Scale (SES) were used in addition to a question regarding global satisfaction. Three of the assessments used a 5 point scale (BIQ, GIS, and SDPE) for questions. One used a 4 point scale (SES). Another used a 7 point scale (global satisfaction). The study consisted of 30 male-to-female patients, 30 healthy female volunteers, and 30 healthy male volunteers. The mean age of study participants was 43 years (range 29- 67).

Results of the study revealed that there were no differences between the three groups for the mean scores of measures assessing depersonalization, global satisfaction, the integration of masculine traits, and body-image-rejected (subset). Also, the sense of femininity was equivalent for male-to-female patients and female controls and higher than that in male controls. The levels of self-esteem and body image-dynamic (subset) were equivalent for male-to-female patients and male controls and higher than that in female controls, and none of the numeric differences between means exceeded 0.61 units.

Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller M, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. Fertil Steril. 2009 Nov;92(5):1685-1689.e3. Epub 2008 Nov 6.

Kuhn et al. conducted a prospective, non-blinded, observational study using a cross-sectional design and semi-matched control cohort. The investigators assessed global satisfaction in patients who were from gynecology and endocrinology clinic (Bern, Switzerland), and who had undergone some aspect of gender reassignment surgery in the distant past, but were still receiving cross-sex hormones from the clinic. The quality of life assessment tools included a VAS and the King's Health Questionnaire (KHQ), which consists of eight domains with scores between zero and five or one and five, with lower scores indicating higher preference. The KHQ and the numerical change/difference required for clinical significance (≥5 points in a given domain, with higher scores being more pathologic) were included in the publication. Twenty healthy female controls from the medical staff who had previously undergone an abdominal or pelvic surgery were partially matched by age and body mass index (BMI), but not sex. No corroborative gynecologic or urologic evaluations were undertaken.

Of the 55 participants, three (5.4%) were female-to-male and 52 (94.5%) were male-to-female (ratio 1:17.3). Reassignment surgery had been conducted 8 to 23 years earlier (median 15 years). The median age of the patients at the time of this study was 51 years (range 39-62 years). The patients had undergone a median of nine surgical procedures in comparison to the two undergone by controls. Reassignment patients were less likely to be married (23.6% versus 65%; p=0.002); partnership status was unknown in five patients. The scores of VAS global satisfaction (maximal score eight) were lower for surgically reassigned patients (4.49±0.1 SEM) than controls (7.35±0.26 SEM) (p<0.0001).

The abstract stated that quality of life was lower in reassignment patients 15 years after surgery relative to controls. One table in the study, Table 2, delineated statistically and biologically significant differences for four of the eight KHQ domains between the patients and controls: physical limitation: 37.6±2.3 versus 20.9±1.9 (p<0.0001), personal limitation: 20.9±1.9 versus 11.6±0.4 (p<0.001), role limitation: 27.8+2.4 versus 34.6+1.7 (p=0.046), and general health: 31.7±2.2 versus 41.0±2.3 (p<0.02). There is a related paper by Kuhn et al. 2006.

Haraldsen IR, Dahl AA. Symptom profiles of gender dysphoric patients of transsexual type compared to patients with personality disorders and healthy adults. Acta Psychiatr Scand. 2000 Oct;102(4):276-81.

Haraldsen and Dahl conducted a single-center (Oslo, Norway) partially prospective, non-blinded, observational study using a cross-sectional design and a non-specific psychometric test. There was a control group, but it was not concurrent.

In the germane sub-study, the investigator assessed psychopathology in patients with gender dysphoria. Patients, who were independently evaluated by two senior psychiatrists, were required to meet DSM III-R or DSM IV diagnostic criteria and the Swedish criteria for reassignment surgery. The Norwegian version of the SCL-90 was used. The testing was conducted from 1987 to 1989 for those who had undergone reassignment surgery between 1963 and 1987 and from 1996 to 1998 for pre- surgical patients who had applied for reassignment surgery between 1996 and 1998. In addition, Axis I, Axis II, and Axis V (Global Functioning) was assessed.

Of 65 post–surgical and 34 pre-surgical patients, 59 post-surgical and 27 pre-surgical patients ultimately entered the study. The combined cohorts consisted of 35 (40.7%) female-to-male patients and 51 (59.3%) male-to-female patients (ratio 1:1.5). The ages were female-to-male 34±9.5 years and female-to-male 33.3±10.0 years. The other control group consisted of patients with personality disorder. Of these, 101 (27 men (33.9±7.3 years) and 74 women (31.6±8.2) were tested during a treatment program. One year later, 98% were evaluated. A total of 28 (32.5%) of the pre- and post- reassignment surgery patients had an Axis I diagnosis compared to 100 (99.0%) of those with personality disorders. Depression and anxiety were the most common diagnoses in both groups, but were approximately three to four times more common in the personality disorder cohort. Seventeen (19.8%) of the pre- and post-reassignment surgery patients had an Axis II diagnosis whereas the mean number of personality disorders in the personality disorder cohort was 1.7±1. The Global Assessment of Function was higher (better) in the gender

dysphoric groups (78.0±8.9) than in the personality disorder cohort (53.0±9.0).

Global Severity Indices (GSI) were highest for those with personality disorder regardless of gender and exceeded the cut-point score of 1.0. The GSI scores for females-to-males and males-to-females were 0.67±57 and 0.56±0.45. Although they were nominally higher than the healthy normative controls (males: 0.32±0.36 and females 0.41±0.43), they were well within the non- pathologic range. The same was true for the subscales.

SCL-90 GSI scores did not differ substantively between pre- and post-surgical patients, nor did the SCI subscale scores differ substantively between pre- and post-surgical patients. Any small non-significant differences tracked with the age and sex differences.

Beatrice J. A psychological comparison of heterosexuals, transvestites, preoperative transsexuals, and postoperative transsexuals. J Nerv Ment Dis. 1985 Jun;173(6):358-65. (United States study)

Beatrice conducted a prospective, non-blinded, observational study using a cross-sectional design and control cohorts in the U.S. The investigator assessed psychological adjustment and functioning (self-acceptance) in male-to-female patients with gender dysphoria (with and without GRS), transvestites from two university specialty clinics, and self-identified heterosexual males recruited from the same two universities. The criteria to qualify for the study included being known to the clinic for at least one year, cross-dressing for at least one year without arrest, attendance at 10 or more therapy sessions, emotionally self-supporting, and financially capable of payment for reassignment surgery, and all of these criteria were met by the pre-operative cohort as well as the post-operative cohort. The cohorts were matched to the post-operative cohort (age, educational level, income, ethnicity, and prior heterosexual object choice). The post-operative cohort was selected not on the basis of population representation, but on the basis of demographic feasibility for a small study. The instruments used were the Minnesota Multiphasic Personality Inventory (MMPI) and the Tennessee Self-Concept Scale (TSCS). Changes or differences considered to be biologically significant were not pre-specified.

Of the initial 54 recruits, ten subjects were left in each of the cohorts because of exclusions identified due to demographic factors. The mean age of each cohort were as follows: pre-operative gender dysphoric patients 32.5 (range 27-42) years, postoperative patients 35.1 (30-43) years old, transvestite 32.5 (29-37) years old, and heterosexual male 32.9 (28-38) years old. All were Caucasian. The mean age for cross-dressing in pre-operative patients (6.4 years) and post-operative patients (5.8 years) was significantly lower than for transvestites (11.8 years).

The scores for self-acceptance did not differ by diagnostic category or surgical status as measured by the TSCS instrument. As measured by the T-scored MMPI instrument (50±10), levels of paranoia and schizophrenia were higher for post-operative (GRS) patients (63.0 and 68.8) than transvestites (55.6 and 59.6) and heterosexual males (56.2 and 51.6). Levels of schizophrenia were higher for pre-operative patients (65.1) than heterosexual males (51.6). There were no differences between patients with gender dysphoria. Scores for the Masculine-Feminine domain were equivalent in those with transvestitism and gender dysphoria with or without surgery, but higher than in heterosexual males. The analysis revealed that despite the high level of socio-economic functioning in these highly selected subjects, the MMPI profiles based on the categories with the highest scores were notable for antisocial personality, emotionally unstable personality, and possible manic psychosis in the pre-operative GRS patients and for paranoid personality, paranoid schizophrenia, and schizoid personality in the post-operative GRS patients. By contrast, the same MMPI profiling in heterosexual males and transvestites was notable for the absence of psychological dysfunction.

d. Observational, surgical patients, longitudinal, with controls

Dhejne C, Lichtenstein P, Boman M, Johansson A, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011;6(2):e16885. Epub 2011 Feb 22.

Dhejne et al. conducted a retrospective, non-blinded, observational study of nation-wide mortality using a longitudinal and a population-based matched cohort. The investigators assessed conditions such as, but not limited to, mortality, suicide attempts, psychiatric hospitalization, and substance abuse in gender-reassigned persons and randomly selected unexposed controls matched by birth year and natal sex (1:10) as well as by birth year and the reassigned gender (1:10). Data were extracted from national databases including the Total Population Register (Statistics Sweden), the Medical Birth Register, the Cause of Death Register (Statistics Sweden), the Hospital Discharge Register (National Board of Health and Welfare), the Crime Register (National Council of Crime), and those from the Register of Education for highest educational level. The criteria required to obtain the initial certificate for reassignment surgery and change in legal status from the National Board of Health and Welfare were the 2002 WPATH criteria and included evaluation and treatment by one of six specialized teams, name change, a new national identity number indicative of gender, continued use of hormones, and sterilization/castration. Descriptive statistics with hazard ratios were provided.

Investigators identified 804 patients with gender identity disorder (or some other disorder) in Sweden during the period from 1973 to 2003 inclusive. Of these patients, 324 (40.3%) underwent gender-reassignment surgery (133 female-to-male [41.0%]; 191 male-to-female [59.0%]; ratio 1:1.4). The average follow-up time for all-cause mortality was 11.4 years (median 9.1). The average follow-up time for psychiatric hospitalization was 10.4 years (median 8.1).

The mean ages in female-to-male and male-to-female reassigned patients were: 33.3±8.7 (range 20–62) and 36.3± 10.1 (range 21–69) years, respectively. Immigrant status was two times higher in reassigned patients (n=70, 21.6%) than in either type of control (birth [natal] sex matched n=294 [9.1%] or reassigned gender matched n=264 [8.1%]). Educational attainment (10 or more years) was somewhat lower for reassigned patients (n=151 [57.8%]) than in either type of control (birth sex matched n=1,725 [61.5%] or reassigned gender matched n=1804 [64.3%]) (cohort data were incomplete). The biggest discordance in educational attainment was for female-to-male reassigned patients regardless of the control used. Prior psychiatric morbidity (which did not include hospitalization for gender dysphoria) was more than four times higher in reassigned patients (n=58, 17.9%) than in either type of control (birth sex matched n=123 [3.8%] or reassigned gender matched n=114 [3.5%]).

All-cause mortality was higher for patients who underwent gender reassignment surgery (n=27 [8.3%]) than in controls (hazard ratio 2.8 [CI 1.8-4.3]) even after adjustment for covariants (prior psychiatric morbidity and immigration status). Divergence in the survival curves began at 10 years. Survival rates at 20 year follow-up (as derived from figure 1) were: female control 97%, male controls 94%, female-to-male patients 88%, and male-to-female patients 82%. The major contributor to this mortality difference was completed suicide (n=10 [3.1%]; adjusted hazard ratio 19.1 [CI 5.8-62.9]). Mortality due to cardiovascular disease was modestly higher for reassigned patients (n=9 [2.8%]) than in controls (hazard ratio 2.5 [CI 1.2-5.3]).

Suicide attempts were more common in patients who underwent gender reassignment surgery (n= 29 [9.0%] than in controls (adjusted hazard ratio 4.9 [CI 2.9–8.5]). Male-to-female patients were at higher adjusted risk for attempted suicide than either control whereas female-to-male patients were at higher adjusted risk compared to only male controls and maintained the female pattern of higher attempted suicide risk. Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common in reassigned persons n= 64 [20.0%] than in controls (hazard ratio 2.8 [CI 2.0–3.9]) even after adjusting for prior psychiatric morbidity. Hospitalization for substance abuse was not greater than either type of control.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and much of the Dhejne et al. (2014) population.

Dhejne C, Öberg K, Arver S, Landén M. An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014 Nov;43(8):1535-45. Epub 2014 May 29 and Landén M, Wålinder J, Hambert G, Lundström B. Factors predictive of regret in sex reassignment. Acta Psychiatr Scand. 1998 Apr;97(4):284 (Dhejne et al., 2014; Landén et al., 1998) Sweden-All

Dhejne et al. conducted a non-blinded, observational study that was longitudinal for the capture of patients with "regret" in a national database. This same group (Landén et al., 1998) conducted a similar study along with retrospective acquisition of clinical data to explore the differences between the cohorts with and without regret. There were no external controls; only intra- group comparisons for this surgical series.

The investigators assessed the frequency of regret for gender reassignment surgery. Data were extracted from registries at the National Board of Health and Welfare to which patients seeking reassignment surgery or reversal of reassignment surgery make a formal application and which has maintained such records since a 1972 law regulating surgical and legal sex reassignment. The investigators reviewed application files from 1960 through 2010. The specific criteria to qualify for gender surgery were not delineated. Patients typically underwent diagnostic evaluation for at least one year. Diagnostic evaluation was typically followed by the initiation of gender confirmation treatment including hormonal therapy and real-life experience. After two years of evaluation and treatment, patients could make applications to the national board. Until recently sterilization or castration were the required minimal surgical procedures (Dhejne et al., 2011). Secular changes in this program included consolidation of care to limited sites, changes in accepted diagnostic criteria, and provision of non-genital surgery, e.g., mastectomy during the real- life experience phase, and family support.

There were 767 applicants for legal and surgical reassignment (289 [37.7%] female-to-male and 478 [62.3%] male-to-female; ratio 1:1.6). The number of applicants doubled each ten year interval starting in 1981.

Of the applicants, 88.8% or 681 (252 [37.0%] female-to-male and 429 [63.0%] male-to-female; ratio 1:1.7] had undergone surgery and changed legal status by June 30, 2011. This number included eight (four [50.0%] female-to-male and four [50.0%] male to female; ratio 1:1) people who underwent surgery prior to the 1972 law. This number appears to include 41 (two [4.9%] female-to-male and 39 [95.1%] male-to-female; ratio 1:19.5) people who underwent surgery abroad at their own expense (usually in Thailand or the U.S.). This cohort (6% of 681) includes one person who was denied reassignment surgery by Sweden.

Twenty-five (3.3%) of the applications were denied with the two most common reasons being an incomplete application or not meeting the diagnostic criteria. An additional 61(8.0%) withdrew their application, were wait-listed for surgery, postponed surgery (perhaps in hopes of the later revocation of the sterilization requirement), or were granted partial treatment.

The formal application for reversal of the legal gender status, the "regret rate", was 2.2%. No one who underwent sex- reassignment surgery outside of Sweden (36 of these 41 had surgery after 1991) has requested reversal. The authors noted, however, that this preliminary number may be low because the median time interval to reversal request was eight years-only three of which had elapsed by publication submission- and because it was the largest serial cohort. This number did not include other possible expressions of regret including suicide (Dhejne et al., 2011).

Dhejne et al. in 2014 reported that the female-to-male (n=5): male-to-female (n=10) ratio among those who made formal applications for reversal was 1:2. The investigators also reported that the female-to-male applicants for reversal were younger at the time of initial surgical application (median age 22 years) than the complete female-to-

male cohort at the time of surgical application (median age 27 years). By contrast the male-to-female applicants for reversal were older at the time of initial surgical application (median age 35 years) than the complete male-to-female cohort at the time of initial surgical application (median age 32 years). Other clinical data to explore the differences between the cohorts with and without regret were not presented in this update publication.

In their earlier publication, in addition to determining a regret rate (3.8%), Landén et al. extracted data from medical records and government verdicts. Pearson Chi-square testing with Yates' correction for small sample sizes was used to identify candidate variables predictive of regret. They observed that: (a) 25.0% of the cohort with regrets and 11.4% of the cohort without regrets were unemployed, (b) 16.7% of the cohort with regrets and 15.4% of the cohort without regrets were on "sick benefit", (c) 15.4% of the cohort with regrets and 13.9% of the cohort without regrets had problems with substance abuse, (d) 69.2% of the cohort with regrets and 34.6% of the cohort without regrets had undergone psychiatric treatment, (e) 15.4% of the cohort with regrets and 8.8% of the cohort without regrets had a mood disorder, and (f) 15.4% of the cohort with regrets and 1.5% of the cohort without regrets had a psychotic disorder.

The putative prognostic factors that were statistically different between the cohorts with and without regret included prior psychiatric treatment, a history of psychotic disorder, atypical features of gender identity, and poor family support. Factors that trended towards statistical difference included having an unstable personality, sexual orientation and transvestitism. Univariate regression analyses further clarified the most important variables. These variables were tested with logistic regression. Initial modeling included the variable "history of psychotic disorder". Although this variable was predictive, it was excluded from future analyses because it was already a contraindication to reassignment surgery. Additional multivariate regression analyses identified poor family support as the most predictive variable and atypical features of gender identity as the second most important variable. Presence of both variables had a more than additive effect.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and most of the Dhejne (2014) population. There is a related paper by Landén et al. 1998b that included the criteria to qualify for surgical intervention at that time.

Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. J Sex Med. 2014 Jan;11(1):119-26. Epub 2013 Oct 28.

Heylens et al. conducted a prospective, non-blinded observational study using a longitudinal design in which patients served as their own controls. They used a non-specific psychiatric test with normative data along with two self-designed questionnaires. The investigators assessed psychosocial adjustment and psychopathology in patients with gender identity disorders. Patients were to be sequentially evaluated prior to institution of hormonal therapy, then 3 to 6 months after the start of cross-sex hormone treatment, and then again one to 12 months after reassignment surgery. The Dutch version of the SCL-90R with eight subscales (agoraphobia, anxiety, depression, hostility, interpersonal sensitivity, paranoid ideation/psychoticism, and sleeping problems) and a global score (psycho-neuroticism) was used serially. A seven parameter questionnaire was used serially to assess changes in social function. Another cross-sectional survey assessed emotional state. The cohorts at each time point consisted of patients who were in the treatment cohort at the time and who had submitted survey responses.

Ninety of the patients who applied for reassignment surgery between June 2005 and March 2009 were recruited. Fifty seven entered the study. Forty-six (51.1% of the recruited population) underwent reassignment surgery. Baseline questionnaire information was missing for 3 patients. Baseline SCL-90 scores were missing for 1 patient but included SCL-90 scores from some of the 11 recruits who had not yet undergone reassignment surgery. Time point 2 (after hormone therapy) SCL-90 information was missing for 10, but included SCL-90 scores from some of the 11

recruits who had not yet undergone reassignment surgery. At time point 3, 42 (91.3% of those who underwent reassignment surgery) patients completed some part of the SCL-90 survey and the psychosocial questionnaires. Some questionnaires were incomplete. The investigators reported response rates of 73.7% for the psychosocial questionnaires and 82.5% for the SCL-90.

Of those who responded at follow-up after surgery, 88.1% reported having good friends; 52.4% reported the absence of a relationship; 47.6% had no sexual contacts; 42.9% lived alone; 40.5% were unemployed, retired, students, or otherwise not working; 2.4% reported alcohol abuse; and 9.3% had attempted suicide. The frequency of these parameters reportedly did not change statistically during the study interval, but there was no adjustment for the inclusion of patients who did not undergo surgery.

In a cross-sectional, self-report mood survey, of the 42 study entrants who completed the entire treatment regimen including reassignment surgery and the final assessment (refers to the initial 57) reported improved body-related experience (97.6%), happiness (92.9%), mood (95.2%), and self-confidence (78.6%) and reduced anxiety (81.0%). Of participants, 16.7% reported thoughts of suicide. Patients also reported on the intervention phase that they believed was most helpful: hormone initiation (57.9%), reassignment surgery (31.6%), and diagnostic-psychotherapy phase (10.5%).

The global “psycho-neuroticism” SCL-90R score, along with scores of 7 of the 8 subscales, at baseline were statistically more pathologic than the general population. After hormone therapy, the score for global “psycho-neuroticism” normalized and remained normal after reassignment surgery. More specifically the range for the global score is 90 to 450 with higher scores being more pathologic. The score for the general population was 118.3±32.4. The respective scores for the various gender dysphoric cohorts were 157.7±49.8 at initial presentation, 119.7±32.1 after hormone therapy, and 127.9±37.2 after surgery. The scores for the general population and the scores after either hormone treatment or surgical treatment did not differ.

Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex Behav. 1987 Dec;16 (6):511-22.

Kockott and Fahrner conducted a single center (Munich, Germany) prospective, observational study using a longitudinal design. Treatment cohorts were used as controls, and patients served as their own controls. The investigators assessed psychosocial adjustment in patients with gender identity issues. Patients were to have met DSM III criteria. Trans-sexuality, transvestitism, and homosexuality were differentiated. The criteria required for patients to receive hormone therapy and/or reassignment surgery were not delineated. After receiving hormone therapy, patients were later classified by surgical reassignment status (pre-operative and post-operative) and desire for surgery (unchanged desire, hesitant, and no longer desired).

The first investigative tool was a semi-structured in-person interview consisting of 125 questions. The second investigative tool was a scale that organized the clinical material into nine domains which were then scored on a scale. The Psychological Integration of Trans-sexuals (PIT) instrument developed according to the scale used by Hunt and Hampson (1980) for assessment of 17 post-operative patients. There were 15 interviews and two separate interviewers. There were 80 patients identified, but 58 (72.5%) patients (26 pre-operative; 32 post-operative) were ultimately included in the analysis. The duration of follow-up was longer for post-operative patients (6.5 years) than for pre-operative patients (4.6 years) (including time for one patient subsequently excluded). The mean age of the post-operative patients was 35.5±13.1 years, and the age of the patients who maintained a continued desire for surgery was 31.7±10.2 years. The age of the patients who hesitated about surgery was somewhat older, 40.3±9.4 years. The age of the patients who were no longer interested in surgery was 31.8±6.5 years. All were employed or in school at baseline. Patients with hesitation were financially better-off, had longer-standing relationships even if unhappy, and had a statistical tendency to place less value on sex than those with an unchanged wish for surgery.

Post-operative patients more frequently reported contentment with the desired gender and the success of adaption to the gender role than the pre-operative patients with a persistent desire for surgery. Post-operative patients more frequently reported sexual satisfaction than pre-operative patients with a continuing desire for surgery. Post-operative patients also more frequently reported financial sufficiency and employment than pre-operative patients with a persistent desire for surgery. Suicide attempts were stated to be statistically less frequent in the post-surgical cohort.

Psychosocial adjustment scores were in the low end of the range with "distinct difficulties" (19-27) at the initial evaluation for the post-operative patients (19.7), the pre-operative patients with a persistent wish for surgery (20.2), and the hesitant patients (19.7). At initial evaluation, psychosocial adjustment scores for patients no longer wanting surgery were at the high end of the range with "few difficulties" (10-18). At the final evaluation, Psychosocial adjustment scores were at the high end of the range "few difficulties" (10-18) for the post-operative patients (13.2) and the patients no longer wanting surgery (16.5). Psychosocial adjustment scores at the final evaluation were in the borderline range between "few difficulties" (10-18) and "distinct difficulties" (19-27) for both the pre-operative patients with a persistent desire for surgery (18.7), and the hesitant patients (19.1).

The changes in the initial score and the final follow-up score within each group were tracked and reported to be statistically significant for the post-operative group, but not for the other groups. Statistical differences between groups were not presented. Moreover, the post-operative patients had an additional test immediately prior to surgery. The first baseline score (19.7) would have characterized the patients as having "distinct difficulties" in psychosocial adjustment while the second baseline score (16.7) would have categorized the patients as having "few difficulties" in psychosocial adjustment despite the absence of any intervention except the prospect of having imminent reassignment surgery. No statistics reporting on the change between scores of the initial test and the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the final follow-up were provided.

Meyer JK, Reter DJ. Sex reassignment. Follow-up. Arch Gen Psychiatry. 1979 Aug;36(9):1010-5. (United States study)

Meyer and Reter conducted a single-center (Baltimore, Maryland, U.S.) prospective, non-blinded, observational study using a longitudinal design and retrospective baseline data. Interview data were scored with a self-designed tool. There were treatment control cohorts, and patients served as their own controls. The investigators assessed patients with gender dysphoria. The 1971 criteria for surgery required documented cross-sex hormone use as well as living and working in the desired gender for at least one year in patients subsequently applying for surgery. Clinical data including initial interviews were used for baseline data. In follow-up, the investigators used extensive two to four hour interviews to collect information on (a) objective criteria of adaptation, (b) familial relationships and coping with life milestones, and (c) sexual activities and fantasies. The objective criteria, which were the subject of the publication, included employment status (Hollingshead job level), cohabitation patterns, and need for psychiatric intervention. The investigators designed a scoring mechanism for these criteria and used it to determine a global adjustment score. The score value or the change score that was considered to be biologically significant was not pre-specified in the methods.

The clinic opened with 100 patients, but when the follow-up was completed, 52 patients were interviewed and 50 gave consent for publication. Of these, 15 (four female-to-male, 11 male-to-female; ratio 1:2.8) were part of the initial operative cohort, 14 (one female-to-male; 13 male-to-female; ratio 1:13) later underwent reassignment surgery at the institution or elsewhere, and 21 (five female-to-male; 16 male-to-female; ratio 1:3.2) did not undergo surgery. The mean ages of these cohorts were 30.1, 30.9, and 26.7 years respectively. The mean follow-up time was 62 months (range 19-142) for those who underwent surgery and 25 months (range 15-48) for those who did not. Socioeconomic status was lowest in those who subsequently underwent reassignment surgery.

Of patients initially receiving surgery, 33% had some type of psychiatric contact prior to the initial clinic evaluation and 8% had psychiatric contact during the follow-up. Of the patients who had not under gone surgery or who had done so later, 72% had some type of psychiatric contact prior to the initial clinic evaluation and 28% had psychiatric contact during follow-up. There was a single female-to-male patient with multiple surgical complications who sought partial reassignment surgery reversal.

The adjustment scores improved over time with borderline statistical significance for the initial operative group and with statistical significance for the never operated group. The absolute score value at follow-up was the same for both groups (1.07+1.53 and 1.10+1.97 respectively). By contrast, the adjustment scores did not improve for those who were not in the cohort initially approved for surgery, but who subsequently underwent surgery later. This was particularly true if the surgery was performed elsewhere. The absolute score value at follow-up was 0.21+1.89.

Related papers include Meyer et al. (1971), Meyer et al. (1974a-d), and Derogatis et al. (1978) along with commentary response by Fleming et al. (1980).

Rakic Z, Starcevic V, Maric J, Kelin K. The outcome of sex reassignment surgery in Belgrade: 32 patients of both sexes. Arch Sex Behav. 1996 Oct;25(5):515-25.

Rakic et al. single-center (Belgrade, Yugoslavia) conducted a prospective, non-blinded, observational study using a cross-sectional design and an investigator- designed quality of life tool that asked longitudinal (pre- and post-treatment) questions. Patients served as their own controls. The authors state that the study was not designed to assess the predictors of poor outcomes.

The investigators assessed global satisfaction, body image, relationships, employment status, and sexual function in patients with gender dysphoria who underwent reassignment surgery between 1989 and 1993 and were at least six months post-operative. The criteria to qualify for gender surgery were delineated (1985 standards from the Harry Benjamin International Gender Dysphoria Association) and included cross-gender behavior for at least one year and sexual orientation to non-natal sex. The questionnaire consisted of 10 questions using yes/no answers or Likert-type scales. Findings were descriptive without statistical analysis. As such, changes or differences considered to be biologically significant were not pre-specified, and there were no adjustments for multiple comparisons.

Of the 38 patients who had undergone reassignment surgery, 34 were eligible for the study and 32 participated in the study (two were lost to follow-up and four were in the peri-operative period) - 10 (31.2%) female-to-male and 22 (68.8%) male-to-female (ratio 1:2.2). The duration of follow-up was 21.8 ±13.4 months (range 6 months to 4 years). The age was female-to-male 27.8±5.2 (range 23-37) and male-to-female 26.4±7.8 (range 19-47).

Using an investigator-designed quality of life tool, all patients reported satisfaction with having undergone the surgery. Of the total participants, four (12.5%) (all male-to-female) and eight (25%) (87.5% male-to-female) reported complete dissatisfaction or partial satisfaction with their appearance. Regarding relationships, 80% of female-to-male and 100% of male-to-female patients were dissatisfied with their relationships with others prior to surgery; whereas, no female-to-male patients and 18.1% of male-to-female patients were dissatisfied with relationships after surgery. Regarding sexual partners, 60% of female-to-male and 72.7% of male-to-female patients reported not having a sexual partner prior to surgery; whereas, 20% of female-to-male patients and 27.3% of male-to-female patients did not have a sexual partner after surgery. Of those with partners at each time interval, 100% of female-to-male and 50% of male-to-female patients reported not experiencing orgasm prior to surgery; whereas, 75% of female-to-male and 37.5% of male-to-female patients reported not experiencing orgasm after surgery.

Ruppin U, Pfäfflin F. Long-term follow-up of adults with gender identity disorder. Arch Sex Behav. 2015 Jul;44(5):1321-9. Epub 2015 Feb 18.

Ruppin and Pfafflin conducted a single-center (Ulm, Germany) partially prospective, non-blinded, observational study using a longitudinal design and non-specific psychometric tests and a self-designed interview tool and questionnaire. Patients served as their own controls.

The investigators assessed psychological symptoms, interpersonal difficulties, gender role stereotypes, personality characteristics, societal function, sexual function, and satisfaction with new gender role in patients with gender dysphoria. Patients were required to have met the ICD-10 criteria for trans-sexualism, been seen by the clinic by prior to 2001, and completed an official change in gender including name change prior to 2001. Assessment tools included German versions of standardized surveys with normative data: the SCL 90R, the Inventory of Interpersonal Problems (IIP), Bem Sex Role Inventory (BSRI), and the Freiburg Personality Inventory (FPI-R), along with semi-structured interviews with self-designed questionnaires. The prospective survey results were compared to retrospective survey results. Changes or inter-group differences considered to be biologically significant were not pre-specified. Diagnostic cut points were not provided. Statistical corrections for multiple comparisons were not included.

Overall, 140 patients received recruitment letters and then 71 (50.7%) agreed to participate. Of these participants, 36 (50.7%) were female-to-male; 35 (49.3%) were male-to-female (ratio 1:0.97). The ages of the patients were: 41.2±5.78 years (female-to-male) and 52.9±10.82 years (male-to-female). The intervals for follow-up were 14.1±1.97 years and 13.7±2.17 years, respectively.

All female-to-male patients had undergone mastectomy; 91.7% had undergone oopherectomy and/or hysterectomy; 61.1% had undergone radial forearm flap phalloplasty or metaoidioplasty. Of male-to-female patients, 94.3% had undergone vaginoplasty and perhaps an additional procedure (breast augmentation, larynx surgery, or vocal cord surgery). Two male-to-female patients had not undergone any reassignment surgery, but were still included in the analyses.

A total of 68 patients ranked their well-being as 4.35±0.86 out of five (three patients did not respond to this question). Of respondents, 40% reported not being in a steady relationship. Regular sexual relationships were reported by 57.1% of 35 female- to-male respondents and 39.4% of 33 male-to-female respondents (three patients did not respond to this question). A total of 11 patients reported receiving out-patient psychotherapy; 69 did not express a desire for gender role reversal (two did not respond to this question). The response rate was less than 100% for most of the self-designed survey questions.

Changes from the initial visit to the follow-up visit were assessed for the SCL-90R in 62 of 71 patients. The effect size was statistically significant and large only for the “Interpersonal Sensitivity” scale (one of 10 parameters). The absolute magnitude of mean change was small: from 0.70±0.67 to 0.26±0.34 (scale range 0-4). The duration of follow-up did not correlate with the magnitude of change on the various scales. Differences in baseline SCL-90R scores of 62 participants were compared with the score of 63 of the 69 eligible recruits who declined to enter the study and were notable for higher “Depression” scores for the latter.

Changes from the initial visit to the follow-up visit were assessed for the IIP in 55 of 71 patients. The effect size was statistically significant and large only for the “Overly Accommodating” scale (one of eight parameters). The absolute magnitude of mean change was small: from 11.64±5.99 to 7.04±4.73 (scale range 0-32). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the FPI-R in 58 of 71 patients. The effect size was statistically significant and large only for the “Life Satisfaction” scale (one of 12 parameters). The absolute magnitude of mean change was substantive: from 4.43±2.99 to 8.31±2.63 (scale range 0-12). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the BSRI in 16 of 36 female to male patients and 19 of 35 male to female patients. The "Social Desirability" score increased for the female-to-male respondents. At endpoint, both categories of respondents reported androgynous self-images.

This current report is an update of prior publications by Pfafflin including work with Junge which was published in a variety of formats and initially in German.

Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.

Smith et al. conducted a single-center (Amsterdam, Netherlands) prospective, non-blinded, observational study using a longitudinal design and psychological function tools. Patients served as their own control prior to and after reassignment surgery. The investigators assessed gender dysphoria, body dissatisfaction, physical appearance, psychopathology, personality traits, and post-operative function in patients with gender dysphoria. Patients underwent some aspect of reassignment surgery. The test instruments included the Utrecht Gender Dysphoria Scale (12 items), the Body Image Scale adapted for a Dutch population (30 items), Appraisal of Appearance Inventory (3 observers, 14 items), the Dutch Short MMPI (83 items), the Dutch version of the Symptom Checklist (SCL)(90 items), and clinic-developed or modified questionnaires. Pre-treatment data was obtained shortly after the initial interview. Post- surgery data were acquired at least one year post reassignment surgery.

Three hundred twenty five consecutive adolescents and adults were screened for the study. One-hundred three (29 [28.2%] female-to-male patients and 74 [71.8%] male-to-female patients [ratio 1:2.6]) never started hormone therapy; 222 (76 [34.2%] female-to-male patients and 146 [65.8%] male-to-female patients [ratio 1:1.9]) initiated hormone therapy. Of the patients who started hormone therapy, 34 (5 [14.7%] female-to-male patients and 29 [85.3%] male-to-female patients [ratio 1:5.8]) discontinued hormone therapy.

Subsequently, the study analysis was limited to adults. One hundred sixty-two (58 [35.8%] female-to-male and 104 [64.2%] male-to-female [ratio 1:1.8]) were eligible and provided pre-surgical test data, and 126 (77.8% of eligible adults) (49 [38.9%] female-to-male and 77 [61.1%] male-to-female [ratio 1:1.6]) provided post-surgical data. For those patients who completed reassignment, the mean age at the time of surgical request was 30.9 years (range 17.7-68.1) and 35.2 years (range 21.3-71.9) years at the time of follow-up. The intervals between hormone treatment initiation and surgery and surgery and follow-up were 20.4 months (range 12 to 73) and 21.3 months (range 12 to 47) respectively.

Of the 126 adults who provided post-surgical data, 50 (40.0%) reported having a steady sexual partner, three (2.3%) were retired, and 58 (46.0%) were unemployed. Regarding regret, six patients expressed some regret regarding surgery, but did not want to resume their natal gender role, and one male-to-female had significant regret and would not make the same decision.

Post-surgery Utrecht dysphoria scores dropped substantially and approached reportedly normal values. The patients' appearance better matched their new gender. No one was dissatisfied with his/her overall appearance at follow-up. Satisfaction with primary sexual, secondary sexual, and non-sexual body traits improved over time. Male-to-female patients, however, were more dissatisfied with the appearance of primary sex traits than female-to-male patients. Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents (not including 11 non-respondents) reported incomplete satisfaction with their mastectomy procedure. For five of these patients, the incomplete satisfaction was because of scarring. Regarding vaginoplasty, 20 of 67 (29.8%) male-to-female respondents (not including 10 non-respondents) reported incomplete satisfaction with their vaginoplasty.

Most of the MMPI scales were already in the normal range at the time of initial testing and remained in the normal

range after surgery. SCL global scores for psycho- neuroticism were minimally elevated before surgery 143.0±40.7 (scoring range 90 to 450) and normalized after surgery 120.3±31.4. (An analysis using patient level data for only the completers was not conducted.)

Udeze B, Abdelmawla N, Khoosal D, Terry T. Psychological functions in male-to- female people before and after surgery. Sexual and Relationship Therapy. 2008 May; 23(2):141-5. (Not in PubMed) and Megeri D, Khoosal D. Anxiety and depression in males experiencing gender dysphoria. Sexual and Relationship Therapy. 2007 Feb; 22(1):77-81. (Not in PubMed)

Udeze et al. conducted a single-center (Leicester, United Kingdom) prospective, non-blinded, longitudinal study assessing a randomized subset of patients who had completed a non-specific psychological function tool prior to and after male-to-female reassignment surgery. Patients served as their own controls. The investigators used the WPATH criteria for patient selection. Psychiatric evaluations were routine. All patients selected for treatment were routinely asked to complete the self-administered SCL-90R voluntarily on admission to the program and post-operatively. A post-operative evaluations (psychiatric and SCL-90R assessment) were conducted within six months to minimize previously determined loss rates. The patient pool was domestic and international. There were 546 gender dysphoric patients from all over the United Kingdom and abroad, of whom 318 (58.2%) progressed to surgery. Of these, 127 were from the local Leicester area in the United Kingdom and 38 (29.9%) progressed to surgery. The mean age for the selected male-to-female patients at the time of study was 47.33±13.26 years (range 25 to 80) and reflected an average wait time for surgery of 14 months (range 2 months to 6 years). For this investigation, 40 male-to-female subjects were prospectively selected.

The raw SCL-90 global scores for psycho-neuroticism were unchanged over time: 48.33 prior to surgery and 49.15 after surgery. If the scale was consistent with T-scoring, the results were non-pathologic. No psychiatric disorders were otherwise identified prior to or after surgery.

Investigators from the same clinical group (Megeri, Khoosal, 2007) conducted additional testing to specifically address anxiety and depression with the Beck Depression Inventory, General Health Questionnaire (with 4 subscales), HADS, and Spielberger State and Trait Anxiety Questionnaire (STAI-X1 and STA-X2). The test population and study design appear to be the same. No absolute data were presented. Only changes in scores were presented. There were no statistically significant changes.

e. Randomized, surgical patients, longitudinal, with controls

Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.

Mate-Kole at al. conducted a prospective, non-blinded, controlled, randomized, longitudinal study using investigator-designed patient self-report questionnaires and non-specific psychological tests with some normative data. The investigators assessed neuroticism and sex role in natal males with gender dysphoria who had qualified for male-to-female reassignment surgery at a single-center specialty clinic (London, United Kingdom). Forty sequential patients were alternately assigned to early reassignment surgery or to standard wait times for reassignment surgery. Patients were evaluated after acceptance and 2 years later. The criteria used to qualify for gender surgery were the 1985 standards from the Harry Benjamin International Gender Dysphoria Association. These included a ≥2 year desire to change gender, a ≥1 year demonstrable ability to live and be self-supporting in the chosen gender, and psychiatric assessment for diagnosis and reassessment at six months for diagnostic confirmation and exclusion of psychosis.

Reassignment surgery was defined as orchidectomy, penectomy, and construction of a neo-vagina. The instruments used were the CCEI for psychoneurotic symptoms and the Bem Sex Role Inventory along with an incompletely

described investigator- designed survey with questions about social life and sexual activity.

The mean age and range of the entire cohort was 32.5 years (21-53). Members of the early surgery cohort had a history of attempted suicide (one patient), psychiatric treatment for non-gender issues (six patients), and first degree relatives with psychiatric histories (four patients). Members of the standard surgery cohort were similar, with a history of attempted suicide (two patients), psychiatric treatment for non-gender issues (five patients), and first degree relatives with psychiatric histories (six patients). The early surgery group had surgery approximately 1.75 years prior to the follow-up evaluation. In both groups, cross-dressing began at about age 6.

At baseline, the Bem Sex Role Inventory femininity scores were slightly higher than masculinity scores for both cohorts and were similar to Bem North American female normative scores. The scores did not change in either group over time.

At baseline, the scores for the CCEI individual domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were similar for the cohorts. The total CCEI scores for the two cohorts were consistent with moderate symptoms (Birchnell et al. 1988). Over the two year interval, total CCEI scores increased for standard wait group and approached the relatively severe symptom category. During the same interval, scores dropped into the asymptomatic rage for the post-operative patients.

The investigator-designed survey assessed changes in social and sexual activity of the prior two years, but the authors only compared patients in a given cohort to themselves. Though the researchers did not conduct statistical studies to compare the differences between the two cohorts, they did report increased participation in some, but not all, types of social activities such as sports (solo or group), dancing, dining out, visiting pubs, and visiting others. Sexual interest also increased. By contrast, pre-operative patients did not increase their participation in these activities.

2. External Technology Assessments

a. CMS did not request an external technology assessment (TA) on this issue.

b. There were no AHRQ reviews on this topic.

c. There are no Blue Cross/Blue Shield Health Technology Assessments written on this topic within the last three years.

d. There were two publications in the COCHRANE database, and both were tangentially related. Both noted that there are gaps in the clinical evidence base for gender reassignment surgery.
Twenty Years of Public Health Research: Inclusion of Lesbian, Gay, Bisexual, and Transgender Populations Boehmer U. Am J Public Health. 2002; 92: 1125–30.

"Findings supported that LGBT issues have been neglected by public health research and that research unrelated to sexually transmitted diseases is lacking."

A systematic review of lesbian, gay, bisexual and transgender health in the West Midlands region of the UK compared to published UK research. West Midlands Health Technology Assessment Collaboration. Health Technology Assessment Database. Meads, et al., 2009. No.3.

"Further research is needed but must use more sophisticated designs with comparison groups. This systematic review demonstrated that there are so many gaps in knowledge around LGBT health that a wide variety of studies are needed."

e. There were no National Institute for Health and Care Excellence (NICE) reviews/guidance documents on this

topic.

f. There was a technology assessment commissioned by the New Zealand Ministry of Health and conducted by New Zealand Health Technology Assessment (NZHTA) (Christchurch School of Medicine and the University of Otago).

Tech Brief Series: Transgender Re-assignment Surgery Day P. NZHTA Report. February 2002;1(1). http://nzhta.chmeds.ac.nz/publications/trans_gender.pdf

The research questions included the following:
1. Are there particular subgroups of people with transsexualism who have met eligibility criteria for gender reassignment surgery (GRS) where evidence of effectiveness of that surgery exists?

2. If there is evidence of effectiveness, what subgroups would benefit from GRS?"

The authors concluded that there was not enough evidence to answer either of the research questions.

3. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting

CMS did not convene a MEDCAC meeting.

4. Evidence-Based Guidelines

a. American College of Obstetricians and Gynecologists (ACOG)

Though ACOG did not have any evidence-based guidelines on this topic, they did have the following document:
Health Care for Transgender Individuals: Committee Opinion
Committee on Health Care for Underserved Women; The American College of Obstetricians and Gynecologists. Dec 2011, No. 512. Obstet Gyncol. 2011;118:1454-8.

"Questions [on patient visit records] should be framed in ways that do not make assumptions about gender identity, sexual orientation, or behavior. It is more appropriate for clinicians to ask their patients which terms they prefer. Language should be inclusive, allowing the patient to decide when and what to disclose. The adoption and posting of a nondiscrimination policy can also signal health care providers and patients alike that all persons will be treated with dignity and respect. Assurance of confidentiality can allow for a more open discussion, and confidentiality must be ensured if a patient is being referred to a different health care provider. Training staff to increase their knowledge and sensitivity toward transgender patients will also help facilitate a positive experience for the patient."

b. American Psychiatric Association

Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. Byne, W, Bradley SJ, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Richard R. Pleak RR, Tompkins DA. Arch Sex Behav. 2012; 41:759–96.

The American Psychiatric Association (APA) was unable to identify any Randomized Controlled Trials (RTCs) regarding mental health issues for transgender individuals.

"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an

improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

Relevant Descriptions of APA Evidence Coding System/Levels:

[B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial."

[G] Other. Opinion-like essays, case reports, and other reports not categorized above."

c. Endocrine Society

Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline.

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ 3rd, Spack NP, Tangpricha V, Montori VM; Endocrine Society. J Clin Endocrinol Metab. 2009; 94:3132-54.

This guideline primarily addressed hormone management and surveillance for complications of that management. A small section addressed surgery and found the quality of evidence to be low.

"This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

d. World Professional Association for Transgender Health (WPATH)

Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (Version 7). Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, Fraser L, Green J, Knudson G, Meyer WJ, Monstrey S, Adler RK, Brown GR, Devor AH, Ehrbar R, Ettner R, Eyler E, Garofalo R, Karasic DH, Lev AI, Mayer G, Meyer-Bahlburg H, Hall BP, Pfäfflin F, Rachlin K, Robinson B, Schechter LS, Tangpricha V, van Trotsenburg M, Vitale A, Winter S, Whittle S, Kevan R. Wylie KR, Zucker K.
www.wpath.org/_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf
Int J Transgend. 2011;13:165–232.

The WPATH is "an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health."

WPATH reported, "The standards of care are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b)."

The WPATH standards of care (SOC) "acknowledge the role of making informed choices and the value of harm-

reduction approaches."

The SOC noted, "For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience."

e. American Psychological Association

Suggested citation until formally published in the American Psychologist: American Psychological Association. (2015): *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People Adopted by the Council of Representatives, August 5 & 7, 2015. www.apa.org/practice/guidelines/transgender.pdf*

"The purpose of the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (hereafter Guidelines) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people."

"These Guidelines refer to psychological practice (e.g., clinical work, consultation, education, research, training) rather than treatment."

5. Other Reviews

a. Institute of Medicine (IOM)

The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Robert Graham (Chair); Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. (Study Sponsor: The National Institutes of Health). Issued March 31, 2011. http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and- Transgender-People.aspx

"To advance understanding of the health needs of all LGBT individuals, researchers need more data about the demographics of these populations, improved methods for collecting and analyzing data, and an increased participation of sexual and gender minorities in research. Building a more solid evidence base for LGBT health concerns will not only benefit LGBT individuals, but also add to the repository of health information we have that pertains to all people."

"Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population. Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and

implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

b. National Institutes of Health (NIH)

National Institutes of Health Lesbian, Gay, Bisexual, and Transgender (LGBT) Research Coordinating Committee. Consideration of the Institute of Medicine (IOM) report on the health of lesbian, gay, bisexual, and transgender (LGBT) individuals. Bethesda, MD: National Institutes of Health; 2013. http://report.nih.gov/UploadDocs/LGBT%20Health%20Report_FINAL_2013-01-03-508%20compliant.pdf

In response to the IOM report, the NIH LBGT research Coordinating Committee noted that most of the health research for this set of populations is "focused in the areas of Behavioral and Social Sciences, HIV (human immunodeficiency virus)/AIDS, Mental Health, and Substance Abuse. Relatively little research has been done in several key health areas for LGBT populations including the impact of smoking on health, depression, suicide, cancer, aging, obesity, and alcoholism."

6. Pending Clinical Trials

ClinicalTrials.gov
There is one currently listed and recently active trial directed at assessment of the clinical outcomes pertaining to individuals who have had gender reassignment surgery. The study appears to be a continuation of work conducted by investigators cited in the internal technology assessment.

NCT01072825 (Ghent, Belgium sponsor) European Network for the Investigation of Gender Incongruence (ENIGI) is assessing the physical and psychological effects of the hormonal treatment of transgender subjects in two years prior to reassignment surgery and subsequent to surgery. This observational cohort study started in 2010 and is still in progress.

7. Consultation with Outside Experts

Consistent with the authority at 1862(l)(4) of the Act, CMS consulted with outside experts on the topic of treatment for gender dysphoria and gender reassignment surgery.

Given that the majority of the clinical research was conducted outside of the United States, and some studies either took place in or a suggested continuity-of-care and coordination-of-care were beneficial to health outcomes, we conducted expert interviews with centers across the U.S. that provided some form of specialty-focused or coordinated care for transgender patients. These interviews informed our knowledge about the current healthcare options for transgender people, the qualifications of the professionals involved, and the uniqueness of treatment options. We are very grateful to the organizations that made time to discuss treatment for gender dysphoria with us.

From our discussions with the all of the experts we spoke with, we noted the following practices in some centers: (1) specialized training for all staff about transgender healthcare and transgender cultural issues; (2) use of an intake assessment by either a social worker or health care provider that addressed physical health, mental health, and other life factors such as housing, relationship, and employment status; (3) offering primary care services for transgender people in addition to services related to gender-affirming therapy/treatments; (4) navigators who connected patients with name-change information or other legal needs related to gender; (5) counseling for individuals, groups, and families; (6) an informed-consent model whereby individuals were often referred to as

"clients" instead of "patients," and (7) an awareness of depression among transgender people (often measured with tools such as the Adult Outcomes Questionnaire and the Patient Health Questionnaire).

8. Public Comments

We appreciate the thoughtful public comments we received on the proposed decision memorandum. In CMS' experience, public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link: https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=282&ExpandComments=n#Results

a. Initial Comment Period: December 3, 2015 – January 2, 2016

During the initial comment period, we received 103 comments. Of those, 78% supported coverage of gender reassignment surgery, 15% opposed, and 7% were neutral. The majority of comments supporting coverage were from individuals and advocacy groups.

b. Second Comment Period: June 2, 2016 – July 2, 2016

During the second 30-day public comment period, we received a total of 45 public comments, 7 of which were not posted on the web due to personal health information content. Overall, 82% supported coverage of gender reassignment surgery, 11% opposed, and 7% were neutral or silent in their comment whether they supported or opposed coverage. Half of the comments were submitted by individuals who expressed support for coverage of gender reassignment surgery (51%). We also received comments from physicians, providers, and other health professionals who specialize in healthcare for transgender individuals (17%). We received one comment from a municipality, the San Francisco Department of Public Health. Associations (American Medical Association, American College of Physicians, American Academy of Nursing, American Psychological Association, and LBGT PA Caucus) and advocates (Center for American Progress with many other signatories, Jamison Green & Associates) also submitted comments.

Below is a summary of the comments CMS received. In some instances, commenters identified typographical errors, context missed, and opportunities for CMS to clarify wording and classify articles for ease of reading in the memorandum. As noted earlier, when appropriate and to the extent possible, we updated the decision memorandum to reflect those corrections, improved the context, and clarified the language. In light of public comments, we re-evaluated the evidence and our summaries. We updated our summaries of the studies and clarified the language when appropriate.

1. Contractor Discretion and National Coverage Determination

Comment: Some commenters, including advocates, associations, and providers, supported CMS' decision for MAC contractor discretion/case-by-case determination for gender reassignment surgery. One stakeholder stated, "We agree with the conclusion that a NCD is not warranted at this time."

Response: We appreciate the support and understanding among stakeholders for our proposed decision to have the MACs determine coverage on a case-by-case basis. We have clarified in this final decision memorandum that

coverage is available for gender reassignment surgery when determined reasonable and necessary and not otherwise excluded by any other relevant statutory requirements by the MAC on a case-by-case basis. "The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule." (78 Fed. Reg. 48165 (August 7, 2013)).

Comment: Some commenters cautioned that CMS' choice to not issue a NCD at this time must not be interpreted as a national non-coverage determination or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals. Multiple commenters indicated their disappointment that CMS did not propose a National Coverage Determination (NCD) and, instead, chose to continue to have local MACs make the coverage decisions on a case-by-case basis. Commenters stated this could result in variability in coverage.

Response: We appreciate the comments. We are not issuing a NCD at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery. In the absence of a NCD, the MAC's use the same statutory authority as NCDs, section 1862(a)(1)(A) of the Social Security Act (the Act). Under section 1862(a)(1)(A) an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. While CMS did not have enough evidence to issue a NCD, we believe the MACs will be able to make appropriate coverage decisions on a case-by-case basis taking into account individual characteristics of the Medicare beneficiary.

Comment: Some commenters sought a NCD that would establish guidelines for coverage and include elements such as a prescribed set of surgeries and a shared decision making element.

Response: For the reasons stated above, we are not issuing a NCD at this time and, therefore, are not establishing specific gender reassignment surgery coverage guidelines for the Medicare program. We generally agree that shared decision-making is a fundamental approach to patient-centered health care decisions and strongly encourage providers to use these types of evidence based decision aids. We have not found a shared decision aid on GRS and encourage the development of this necessary element to conduct formal shared-decision making.

Comment: Some commenters expressed concern that there is a misunderstanding of transgender individuals as having a disorder or being abnormal. Some commenters indicated a history of bias and discrimination within society as a whole that has occurred when transgender individuals have sought health care services from the medical community. Some commenters are concerned that the decision not to make a NCD will subject individuals seeking these services to corporate bias by Medicare contractors.

Response: We acknowledge the public comments and that there has been a transformation in the treatment of individuals with gender dysphoria over time. In this NCA, we acknowledge that gender dysphoria is a recognized Diagnostic and Statistical Manual of Mental Disorders (DSM) condition. With respect to the concern about potential bias by Medicare contractors, we have no reason to expect that the judgments made on specific claims will be influenced by an overriding bias, hostility to patients with gender dysphoria, or discrimination. Moreover, the Medicare statue and our regulations provide a mechanism to appeal an adverse initial decision if a claim is denied and those rights may include the opportunity for judicial review. We believe the Medicare appeals process would provide an opportunity to correct any adverse decision that was perceived to have been influenced by bias.

Comment: Commenters mentioned the cost of gender reassignment surgery could influence MAC decision making.

Response: The decisions on whether to cover gender reassignment surgery in a particular case are made on the basis of the statutory language in section 1862 of the Social Security Act that establish exclusions from coverage and

would not depend on the cost of the procedure.

2. Coverage with Evidence Development and Research

Comment: In our proposed decision memorandum, we specifically invited comments on whether a study could be developed that would support coverage with evidence development (CED). One organization commented, "We strongly caution against instituting a CED protocol." Commenters were opposed to coverage limited in clinical trials, suggesting that such coverage would restrict access to care. Several commenters provided suggested topics for clinical research studies for the transgender population. For example, one commenter suggested a study of non-surgical treatment for transgender children prior to puberty.

Response: While we appreciate the comments supporting further research, in general, for gender reassignment surgery, we agree that CED is not the appropriate coverage pathway at this time. While CED is an important mechanism to support research and has the potential to be used to help address gaps in the current evidence, we are not aware of any available, appropriate studies, ongoing or in development, on gender reassignment surgery for individuals with gender dysphoria that could be used to support a CED decision.

3. Gender Reassignment Surgery as Treatment

Comment: One group of commenters requested that CMS consider that, "The established medical consensus is that GRS is a safe, effective, and medically necessary treatment for many individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment."

Response: We acknowledge that GRS may be a reasonable and necessary service for certain beneficiaries with gender dysphoria. The current scientific information is not complete for CMS to make a NCD that identifies the precise patient population for whom the service would be reasonable and necessary.

4. Physician Recommendations

Comment: Several commenters stated that gender reassignment surgery should be covered as long as it was determined to be necessary, or medically necessary by a beneficiary's physician.

Response: Physician recommendation is one of many potential factors that the local MAC may consider when determining whether the documentation is sufficient to pay a claim.

5. WPATH Standards of Care

Comment: Several commenters suggested that CMS should recommend the WPATH Standards of Care (WPATH) as the controlling guideline for gender reassignment surgery. They asserted it could satisfy Medicare's reasonable and necessary criteria for determining coverage on a case-by-case basis.

Response: Based on our review of the evidence and conversations with the experts and patient advocates, we are aware some providers consult the WPATH Standards of Care, while others have created their own criteria and requirements for surgery, which they think best suit the needs of their patients. As such, and given that WPATH acknowledges the guidelines should be flexible, we are not in the position to endorse exclusive use of WPATH for coverage. The MACs, Medicare Advantage plans, and Medicare providers can use clinical guidelines they determine useful to inform their determination of whether an item or service is reasonable and necessary. When making this

determination, local MACs may take into account physician's recommendations, the individual's clinical characteristics, and available clinical evidence relevant to that individual.

6. Scope of the NCA Request

Comment: One commenter stated that CMS did not address the full scope of the NCA request.

Response: The formal request for a NCD is publicly available on our tracking sheet. (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf) The letter did not explicitly seek a national coverage determination related to counseling or hormone therapies, but focused on surgical remedies. CMS is aware that beneficiaries with gender dysphoria use a variety of therapies.

Comment: Other commenters stated the scope of the proposed decision is unnecessarily broad because it discussed therapies other than surgery. They suggested this discussion could lead to the unintended consequence of restricting access to those services for transgender Medicare beneficiaries and other transgender individuals.

Response: As we noted in our proposed decision, our decision focused only on gender reassignment surgery. In the course of reviewing studies related to those surgeries, occasionally authors discussed other therapies that were mentioned in our summaries of the evidence. To the extent possible, we have modified our decision to eliminate the discussion of other therapies which were not fully evaluated in this NCA.

7. NCA Question

Comment: Some commenters expressed concern about the phrasing of the question in this NCA.

Response: The phrasing of the research question is consistent with most NCAs and we believe it is appropriate.

8. Evidence Summary and Analysis

Comment: Several commenters disagreed with our summary of the clinical evidence and analysis. A few commenters contended that the overall tone of the review was not neutral and seemed biased or flawed. One commenter noted that the Barrett publication was available on the Internet.

Response: We appreciate the comments that identified technical errors, and we made the necessary revisions to this document. However, we disagree with the contention that our evidence review was not neutral and seemed biased or flawed. We believe that the summary and analysis of the clinical evidence are objective. As with previous NCAs, our review of the evidence was rigorous and methodical. Additionally, we reviewed the Barrett publication, but it did not meet our inclusion criteria to be included in the Evidence section.

9. Evidence Review with Transgender Experts

Comment: Several commenters requested that CMS re-review the clinical evidence discussed in the proposed decision memorandum with outside experts in the field of transgender health and transition/gender reassignment-related surgeries. Several offered the expertise within their organization to assist in this effort.

Response: We appreciate these comments and the transgender health community's willingness to participate. For

this NCA we discussed gender reassignment surgery protocols with experts, primarily in coordinated care settings. Additionally, the public comment periods provide opportunities for expert stakeholder input. According to our process for all NCAs, we do not jointly review evidence with external stakeholders but have carefully reviewed the very detailed comments submitted by a number of outside experts in transgender health care.

10. Previous Non-Coverage NCD

Comment: One commenter noted that they thought research studies for gender reassignment surgery could not take place when the old NCD that prohibited coverage for gender reassignment surgery was in effect.

Response: CMS does not directly conduct clinical studies or pay for research grants. Some medical services are non-covered by Medicare; however, national non-coverage does not preclude research via a number of avenues and other funding entities such as the National Institutes of Health. In this instance, the previous NCD did not preclude interested parties from funding research for gender reassignment surgery that could have been generalizable to the Medicare population.

11. How the Medicare Population Differs from the General Population

Comment: One commenter questioned how the Medicare population differed from the general population, and why any differences would be important in our decision-making.

Response: The Medicare population is different from the general population in age (65 years and older) and/or disability as defined by the Social Security Administration. Due to the biology of aging, older adults may respond to health care treatments differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility. All of these factors can impact health outcomes. The disabled Medicare population, who are younger than age 65, is different from the general population and typical study populations due to the presence of the causes of disability such as psychiatric disorders, musculoskeletal health issues, and cardiovascular issues.

12. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

Comment: One commenter suggested CMS should have convened a MEDCAC for this topic.

Response: We appreciate the comment. Given the limited evidence, we did not believe a MEDCAC was warranted according to our guidance document entitled "Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee" (https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html).

13. §1557 of the Affordable Care Act (ACA)

Comment: Some commenters asserted that by not explicitly covering gender reassignment surgery at the national level, CMS was discriminating against transgender beneficiaries in conflict with Section 1557 of the Accountable Care Act (ACA).

Response: This decision does not affect the independent obligation of covered entities, including the Medicare program and MACs, to comply with Section 1557 in making individual coverage decisions. In accordance with Section 1557, MACs will apply neutral nondiscriminatory criteria when making case-by-case coverage determinations related

to gender reassignment surgery.

14. Medicaid

Comment: Some commenters observed that some states cover gender reassignment surgery through Medicaid or require commercial insurers operating in the state to cover the surgery.

Response: We appreciate the information about Medicaid and state requirements; however, State decisions are separate from Medicare coverage determinations. We make evidence-based determinations based on our statutory standards and processes.

15. Commercial Insurers

Comment: In several instances, commenters told us that the healthcare industry looks to CMS coverage determinations to guide commercial policy coverage.

Response: CMS makes evidence-based national coverage determinations based on our statutory standards and processes as defined in the Social Security Act, which may not be the same standards that are used in commercial insurance policies or by other health care programs. In addition as noted above, the Medicare population is different (e.g., Medicare covers 95% of adults 65 and older) than the typical population under commercial insurers. We do not issue coverage decisions to drive policy for other health organizations' coverage in one way or the other.

16. Healthcare for Transgender Individuals

Comment: Numerous professional associations wrote to CMS to explain their support for access to healthcare for transgender individuals.

Response: CMS recognizes that transgender beneficiaries have specific healthcare needs. Many health care treatments are available. We encourage all beneficiaries to utilize their Medicare benefits to help them achieve their best health.

17. Intended Use of the Decision Memorandum

Comment: Several commenters expressed concern that the analysis provided in the proposed and final decision memorandums may be used by individuals, entities, or payers for purposes unrelated to Medicare such as denial of coverage for transgender-related surgeries.

Response: The purpose of the decision memoranda is to memorialize CMS' analysis of the evidence, provide responses to the public comments received, and to make available the clinical evidence and other data used in making our decision consistent with our obligations under the § 1862 of the Act. The NCD process is open and transparent and our decisions are publicly available. Congress requires that we provide a clear statement of the basis for our determinations. The decision memoranda are an important part of the record of the NCD. Our focus is the Medicare population which, as noted above, is different than the general population in a number of ways. Other entities may conduct separate evidence reviews and analyses that are suited for their specific populations.

18. Cost Barriers to Care and Effects

Comment: A few commenters stated that without Medicare coverage, surgery is difficult to afford and there may be a risk of negative consequences for the individual. One commenter suggested that CMS should consider prior-authorization for these surgeries.

Response: CMS is aware that paying out-of-pocket for medical care is a strain on a beneficiary's finances. We are also aware of beneficiaries' hesitancy to undergo surgery prior to knowing whether or not Medicare will pay the claim. Gender reassignment surgeries are not the only procedures whereby payment is not determined until after the provider submits the claim to Medicare. Importantly, documentation for the claims need to be explicit about what procedures were performed and include the appropriate information in the documentation to justify using the code or codes for surgery. Of note, CMS has claims data that indicate Medicare has paid for gender reassignment surgeries in the recent past. Determining which services are designated for prior-authorization is outside of the scope of the NCA process.

19. Surgical Risks and Benefits

Comment: A number of commenters conveyed the benefits of gender reassignment surgery, while other commenters expressed concern that gender reassignment surgery was harmful.

Response: We appreciate these comments.

20. Expenditure of Federal Funds

Comment: Some commenters opposed spending Medicare program funds on gender reassignment surgery for a variety of reasons. For example, some commenters believe it is an "elective" procedure. Other commenters suggested that funds should first be spent on other priorities such as durable medical equipment (DME) or mobility items such as power chairs; increasing reimbursement to providers; or that spending should be limited to the proportion to the transgender adult population in the Medicare program.

Response: The purpose of this NCA is to determine whether or not CMS should issue a NCD to cover surgery for patients who have gender dysphoria. NCAs do not establish payment amounts or spending priorities and, therefore, these comments are outside the scope of this consideration.

VIII. CMS Analysis

National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(l)(6) of the Act. In general, in order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage.

Moreover, in most circumstances, the item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)). The Supreme Court has recognized that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." Heckler v. Ringer, 466 U.S. 602, 617 (1984). See also, 78 Fed. Reg. 48,164, 48,165 (August 7, 2013)

When making national coverage determinations, we consider whether the evidence is relevant to the Medicare

beneficiary population. In considering the generalizability of the results of the body of evidence to the Medicare population, we carefully consider the demographic characteristics and comorbidities of study participants as well as the provider training and experience. This section provides an analysis of the evidence, which included the published medical literature and guidelines pertaining to gender dysphoria, that we considered during our review to answer the question:

Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?

CMS carefully considered all the studies listed in this decision memorandum to determine whether they answered the question posed in this NCA. While there appears to be many publications regarding gender reassignment surgery, it became clear that many of the publications did not meet our inclusion/exclusion criteria as explained earlier in the decision memorandum.

Thirty-three papers were eligible based on our inclusion/exclusion criteria for the subsequent review (Figure 1). All studies reviewed had potential methodological flaws which we describe below.

A. Quality of the Studies Reviewed

Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up (Appendices C and F). The impact of a specific therapeutic intervention can be difficult to determine when there are multiple serial treatments such as psychotherapy, hormone treatment and surgery. To reduce confounding, outcome assessment just prior to and after surgery such as in a longitudinal study would be helpful. The objective endpoints included psychiatric treatment, attempted suicide, requests for surgical reversal, morbidity (direct and indirect adverse events), and mortality (Appendix F). CMS agrees with the utility of these objective endpoints. Quality of life, while important, is more difficult to measure objectively (Appendix E).

Of the 33 studies reviewed, published results were conflicting – some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population. The majority of studies were non-longitudinal, exploratory type studies (i.e., in a preliminary state of investigation or hypothesis generating), or did not include concurrent controls or testing prior to and after surgery. Several reported positive results but the potential issues noted above reduced strength and confidence. After careful assessment, we identified six studies that could provide useful information (Figure 1). Of these, the four best designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies did not demonstrate clinically significant changes or differences in psychometric test results after GRS. (Heylens et al., 2014; Ruppin, Pfafflin, 2015; Smith et al., 2005; Udeze et al., 2008) (Appendix C Panel A and Appendix G.)

Two studies (three articles) assessed functional endpoints (request for surgical reassignment reversal and morbidity/mortality) (Dhejne et al., 2011; Dhejne et al., 2014 along with Landén et al., 1998) (Figure 1 and Appendix C, Panel A and Appendix G). Although the data are observational, they are robust because the Swedish national database is comprehensive (including all patients for which the government had paid for surgical services) and is notable for uniform criteria to qualify for treatment and financial coverage by the government. Dhejne et al. (2014) and Landén et al. (1998) reported cumulative rates of requests for surgical reassignment reversal or change in legal status of 3.3% while Dhejne et al. (2014) reported 2.2%. The authors indicated that the later updated calculation had the potential to be an underestimate because the most recent surgical cohorts were larger in size and had shorter periods of follow-up.

Dhejne et al., (2011) tracked all patients who had undergone reassignment surgery (mean age 35.1 years) over a 30 year interval and compared them to 6,480 matched controls. The study identified increased mortality and psychiatric hospitalization compared to the matched controls. The mortality was primarily due to completed suicides (19.1-fold greater than in control Swedes), but death due to neoplasm and cardiovascular disease was increased 2 to 2.5 times as well. We note, mortality from this patient population did not become apparent until after 10 years. The risk for psychiatric hospitalization was 2.8 times greater than in controls even after adjustment for prior psychiatric disease (18%). The risk for attempted suicide was greater in male-to-female patients regardless of the gender of the control. Further, we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality. The study, however, was not constructed to assess the impact of gender reassignment surgery *per se.*

We believe at minimum study designs should have a pre-test/post-test longitudinal design accompanied by characterization of all patients lost to follow-up over the entire treatment series as well as those patients who did not complete questionnaires, and the use of psychometric quality-of-life tools which are well validated with linkage to "hard" (objective) patient outcomes in this particular patient population (Trentacosti 2007, PRO 2009) (Appendices C and D).

Patient Care

Clinical evidentiary questions regarding the care of patients with gender dysphoria remain. Many of the publications focused on aspects of surgical technique as opposed to long-term patient outcomes. The specific type(s) of gender/sex reassignment surgery (e.g., genital, non-genital) that could improve health outcomes in adults remain(s) uncertain because most studies included patients who had undertaken one or more of a spectrum of surgical procedures or did not define the specific types of surgical procedures under study. Furthermore, surgical techniques have changed significantly over the last 60 years and may not reflect current practice (Bjerrome Ahlin et al., 2014; Doornaert, 2011; Green, 1998; Pauly, 1968; Selvaggi et al., 2007; Selvaggi, Bellringer, 2011; Tugnet et al., 2007; Doornaert, 2011).

The WPATH care recommendations present a general framework and guidance on the care of the transgender individual. The standards of care are often cited by entities that perform gender reassignment surgery. WPATH notes, "More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria." Appendix D in the WPATH Standards of Care briefly describes their evidence base and acknowledges the historical problems with evidentiary standards, the preponderance of retrospective data, and the confounding impact of multiple interventions, specifically distinguishing the impact of hormone therapy from surgical intervention.

Additionally, CMS met with several stakeholders and conducted several interviews with centers that focus on healthcare for transgender individuals in the U.S. Primary care rather than gender reassignment surgery was often the main focus. Few of the U.S.-based reassignment surgeons we could identify work as part of an integrated practice, and few provide the most complex procedures.

Psychometric Tools

CMS reviewed psychometric endpoints because gender dysphoria (inclusive of prior nomenclature) describes an incongruence between the gender assigned at birth and the gender(s) with which the person identifies.

The psychometric tools used to assess outcomes have limitations. Most instruments that were specific for gender dysphoria were designed by the investigators themselves or by other investigators within the field using limited populations and lacked well documented test characterization. (Appendices E and F) By contrast, test instruments with validation in large populations were non-specific and lacked validation in the gender dysphoric patient populations. (Appendices E and F). In addition, the presentation of psychometric results must be accompanied by

enough information about the test itself to permit adequate interpretation of test results. The relevant diagnostic cut-points for scores and changes in scores that are clinically significant should also be scientifically delineated for interpretation.

Generalizability

It is difficult to generalize these study results to the current Medicare population. Many of the studies are old given they were conducted more than 10 years ago. Most of these studies were conducted outside of the U.S. in very different medical systems for treatment and follow-up. Many of the programs were single-site centers without replication elsewhere. The study populations were young and without significant physical or psychiatric co-morbidity (Appendix D). As noted earlier, psychiatric co-morbidity may portend poor outcomes (Asscheman et al., 2011; Landén et al., 1998).

Knowledge Gaps

This patient population faces complex and unique challenges. The medical science in this area is evolving. This review has identified gaps in the evidentiary base as well as recommendations for good study designs. The Institute of Medicine, the National Institutes of Health, and others also identified many of the gaps in the data. (Boehmer, 2002; HHS-HP, 2011; IOM, 2011; Kreukels-ENIGI, 2012; Lancet, 2011; Murad et al., 2010; NIH-LGBT, 2013) The current or completed studies listed in ClinicalTrials.gov are not structured to assess these gaps. These gaps have been delineated as they represent areas in which patient care can be optimized and are opportunities for much needed research.

B. Health Disparities

Four studies included information on racial or ethnic background. The participants in the three U.S. based studies were predominantly Caucasian (Beatrice, 1985; Meyer, Reter, 1979; Newfield et al., 2006). All of the participants in the single Asian study were Chinese (Tsoi, 1993). Additional research is needed in this area.

C. Summary

Based on an extensive assessment of the clinical evidence as described above, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.

The knowledge on gender reassignment surgery for individuals with gender dysphoria is evolving. Much of the available research has been conducted in highly vetted patients at select care programs integrating psychotherapy, endocrinology, and various surgical disciplines. Additional research of contemporary practice is needed. To assess long-term quality of life and other psychometric outcomes, it will be necessary to develop and validate standardized psychometric tools in patients with gender dysphoria. Further, patient preference is an important aspect of any treatment. As study designs are completed, it is important to include patient-centered outcomes.

Because CMS is mindful of the unique and complex needs of this patient population and because CMS seeks sound data to guide proper care of the Medicare subset of this patient population, CMS strongly encourages robust clinical studies with adequate patient protections that will fill the evidence gaps delineated in this decision memorandum. As the Institute of Medicine (IOM, 2011) importantly noted: "Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population.

Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

IX. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We have a received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination on whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery would be reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination relating to counseling, hormone therapy treatments, or any other potential treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

A. Appendix A

Diagnostic & Statistical Manual of Mental Disorders (DSM) Criteria for Disorders of Gender Identity since 1980

DSM Version	**Condition Name**	**Criteria**	**Criteria**	**Comments**
DSM III 1980 *Chapter: Psychosexual Disorders*	**Trans-sexualism** *302.5x [Gender Identity*	Required A (cross-gender identification) and B (aversion to	Sense of discomfort and inappropriateness about one's anatomic sex. Wish to be rid of one's own genitals and	Further characterization by sexual orientation Distinguished

	Disorder of Child-hood (302.6)]	one's natal gender) criteria Dx excluded by physical intersex condition Dx excluded by another mental disorder, e.g., schizophrenia	to live as a member of the other sex. The disturbance has been continuous (not limited to periods of stress) for at least 2 years.	from Atypical Gender Identity Disorder 302.85
DSM III-Revised **1987** *TS classified as an Axis II dx (personality disorders and mental retardation) in a different chapter. GID included under Disorders Usually First Evident in Infancy, Childhood, Adolescence*	**Trans-sexualism** *(TS) (302.50) [GID of C]*	Required A and B criteria	Persistent discomfort and sense of inappropriateness about one's assigned sex. Persistent preoccupation for at least 2 years with getting rid of one's 1^{o} and 2^{o} sex characteristics and acquiring the sex characteristics of the other sex. Has reached puberty	Further characterization by sexual orientation Distinguished from Gender Identity Disorder of Adolescence or Adulthood, Non-trans-sexual Type • e.g., cross-dressing not for the purposes of sexual excitement Gender Identity Disorder Not Otherwise Specified 302.6 • e.g., intersex conditions Gender Identity Disorder Not Otherwise Specified 302.85 • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
	GID of adulthood,			

	non-trans-sexual type, added			
DSM IV **1994** *Chapter: Sexual & Gender Identity Disorders*	**Gender Identity Disorder** in Adolescents and Adults (302.85) (Separate criteria & code for children, but same name)	Required A and B criteria Dx excluded by physical intersex condition	Cross-gender identification • e.g., Stated desire to be another sex • e.g., Desire to live or be treated as a member of the other sex • e.g., conviction that he/she has the typical feelings and reactions of the other sex • e.g., frequent passing as the other sex Persistent discomfort with his/her sex or sense of inappropriateness in the gender role of that sex. • e.g., belief the he/she was born the wrong sex • e.g., preoccupation with getting rid of 1^{o} and 2 ^{o} sex characteristics &/or acquiring sexual traits of the other sex • Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6 • e.g., intersex conditions • e.g., stress related cross-dressing • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM IV-Revised **2000** *Chapter: Sexual & Gender Identity Disorders*	**Gender Identity Disorder** (Term trans-sexual-ism eliminated)	Required A & B criteria Dx excluded by physical intersex condition	Cross-gender identification • e.g., stated desire to be the other sex • e.g., desire to live or be treated as the other sex • e.g., conviction that he/she has the typical feelings & reactions of the other sex	Outcome may depend on time of onset Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise

			• e.g., frequent passing as the other sex Persistent discomfort with his or her sex OR sense of inappropriateness in the gender role of that sex • e.g., belief the he/she was born the wrong sex • e.g., preoccupation with getting rid of 1^{o} and 2 ^{o} sex characteristics &/or acquiring sexual traits of the other sex Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Specified 302.6 • e.g., intersex conditions • e.g., stress related cross-dressing • e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
DSM V **2013** *Separate Chapter from Sexual Dysfunctions & Paraphilic Disorders*	**Gender Dysphoria** *(302.85)*	Gender nonconformity itself not considered to be a mental disorder The dysphoria associated with the gender incongruence is Eliminates A & B criteria Considers gender incongruence to be a spectrum Considers intersex/ "disorders of sex development" to be a	• Marked discordance between natal 1^{o} and 2^{o} sex characteristics* and experienced/expressed gender • Conviction that he/she has the typical feelings & reactions of the other sex (or some alternative gender) • Marked desire to be the other sex (or some alternative gender) • Marked desire to desire be treated as the other sex (or some alternative gender) • Marked desire to be rid of natal 1^{o} and 2^{o} sex characteristics** • Marked desire to acquire 1^{o} and 2^{o} sex characteristics of the other sex (or some alternative gender) Clinically significant	Includes diagnosis for post transition state to permit continued treatment access Includes disorders of sexual development such as congenital hyperplasia and androgen insensitivity syndromes

		subsidiary and not exclusionary to dx of GD	distress or impairment in social, occupational, or other important areas of functioning * or in young adolescents, the anticipated 2^{o} sex characteristics ** or in young adolescents, prevent the development of the anticipated 2^{o} sex characteristics ≥ 6 month marked discordance between natal gender & experienced/expressed gender as demonstrated by ≥ 6 criteria: • Strong desire to be of the other gender or an insistence that one is of another gender. • Strong preference for cross-gender roles in make-believe play. • Strong preference for the toys, games, or activities of the other gender. • Strong preference for playmates of the other gender. • In boys, strong preference for cross-dressing; in girls, strong preference for wearing masculine clothing • In boys, rejection of masculine toys, games, activities, avoidance of rough and tumble play; in girls, rejection of feminine toys, games, and activities.	
	Unspecified Gender Dysphoria		This category applies to presentations in which sx c/w gender	

	(302.6) (F64.9)		dysphoria that cause clinically significant distress or impairment, but do not meet the full criteria for gender dysphoria & the reason for not meeting the criteria is not provided.	
	Specified Gender Dysphoria 302.6 (F64.8)		If the reason that the presentation does not meet the full criteria is provided then this dx should be used	

C/W=consistent with Dx=diagnosis GD=gender dysphoria Sx=symptoms TS=transsexual 1^{o}=primary 2^{o}=secondary

B. Appendix B

1. General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant

outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e.g., using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and

consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of

the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix C

Patient Population: Enrolled & Treated with Sex Reassignment Surgery Loss of Patients & Missing Data

Panel A (Controlled Studies)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Dhejne 2011	Longitudinal Controlled	804 w GD	324	324 (100%)	-
Dhejne 2014 Landén	Longitudinal for test variable Controlled	767 applied for SRS 25 applications denied. 61 not granted full legal status 15 formal applications for surgical reversal	681	681 (100%)	NA: Clinical data extracted retrospectively in earlier paper
Heylens	Longitudinal Controlled	90 applicants for SRS 33 excluded 11 later excluded had not yet received SRS by study close.	57 (→46)	46 (80.7%) Only those w SRS evaluated	Psycho-social survey missing data for 3 at baseline & 4 after SRS. SCL90 not completed by 1 at baseline, 10 after hormone tx, & 4 after SRS →missing data for another 1.1% to 11.1%.
Kockott	Longitudinal Controlled	80 applicants for SRS 21 excluded	59	32 (54.2%) went to surgery	1 preoperative patient was later excluded b/c lived completely in aspired gender w/o SRS. Questions on financial sufficiency not answered by 1 surgical pt. Questions on sexual satisfaction & gender contentment not answered by 1 & 2 patients awaiting surgery respectively.
Mate-Kole 1990	Longitudinal Controlled	40 sequential patients of accepted patients. The number in the available patient pool was not specified.	40	20 (50%) went to surgery	-
Meyer	Longitudinal Controlled	Recruitment pool: 100 50 were excluded.	50	15 (30%) had undergone surgery 14 (28%) underwent surgery later	The assessments of all were complete

Rakic	Longitudinal Controlled	92 were evaluated 54 were excluded from surgery 2 post SRS were lost to follow-up 2 post SRS were excluded for being in the peri-operative period	32	32 (100%)	Questionnaire completed by all.
Ruppin	Longitudinal Controlled	The number in the available patient pool was not specified. 140 received recruitment letters. 69 were excluded	71	69 (97.2%)	The SCL-90, BSRI, FPI-R, & IPP tests were not completed by 9, 34, 13, &16 respectively. Questions about romantic relationships, sexual relationships, friendships, & family relationships were not answered by 1, 3, 2, & 23 respectively. Questions regarding gender security & regret & were not answered by 1& 2 respectively.
Smith	Longitudinal Controlled	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. 103 were excluded from additional tx	162	162 (100%)	36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete various post-SRS tests.
Udeze Megeri	Longitudinal Controlled	International patient w GD 546 & post SRS 318. 40 M to F subjects were prospectively selected.	40	40 (100%)	-
Ainsworth	Internet/convention Survey Cross-sectional Controlled	Number of incomplete questionnaires not reported	247	72 (29.1%) 75 (30.6%) facial 147 (59.5%) had received neither facial nor reassignment surgery	-
Beatrice	Cross-sectional Controlled	14 excluded for demographic matching reasons	40	10 (25%)	The assessments were completed by all
Haraldsen	Cross-sectional Controlled	Recruitment pool: 99	86	59 (68.6%)	-
Kraemer	Cross-sectional	The number in the	45	22 (48.9%)	-

	Controlled	available patient pool was not specified.			
Kuhn	Cross-sectional Controlled	The number in the available patient pool was not specified.	75	55 (73.3%)	-
Mate-Kole 1988	Cross-sectional Controlled	150 in 3 cohorts. Matched on select traits. The number in the available patient pool was not specified.	150	50 (66.7%)	-
Wolfradt	Cross-sectional Controlled	The number in the available patient pool was not specified.	90	30 (33.3%)	-

Panel B (Surgical Series: No Concurrent Controls)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Blanchard et al.	Cross-sectional Control: Normative test data	294 clinic patients w GD had completed study questionnaire 116 authorized for GRS. 103 completed GRS & 1 yr post-operative. 24 excluded	79	79(100%)	-
Weyers et al.	Cross-sectional Control: Normative test data	>300 M to F patients had undergone GRS 70 eligible patients recruited 20 excluded	50	50 (100%)	SF-26 not completed by 1
Wierckx et al.	Cross-sectional except for recall questions Control: Normative test data	79 F to M patients had undergone GRS & were recruited. 3 additional non-clinic patients were recruited by other patients. 32 excluded initially; 1 later.	49	49 (100%)	SF-36 test not completed by 2. Questions regarding sexual re-lationship, sex function, & surgical satisfaction were answered by as few as 27, 28, 32 respectively.
Eldh et al.	Cross-sectional except for 1 variable Control: Self for 1 variable-employ-ment	136 were identified. 46 excluded	90	90 (100%)	Questions regarding gender iden-tity, sex life, acceptance, & overall satisfaction were not answered by 13, 14, 14 & 16 respectively. Employment data missing for 11.
Hess et al.	Cross-sectional No control	254 consecutive eligible patients post GRS identified & sent surveys. 135 excluded.	119	119 (100%)	Questions regarding the esthetics, functional, and social outcomes of GRS were not answered by 16 to 28 patients.
Lawrence	Cross-sectional	727 eligible patients	232	232	-

	No control	were recruited. 495 were excluded		(100%)	
Salvador et al.	Cross-sectional No control	243 had enrolled in the clinic 82 completed GRS 69 eligible patients were identified. 17 excluded.	52	52 (100%)	-
Tsoi	Cross-sectional No control	The number in the available patient pool was not specified.	81	81 (100%)	-

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Gómez-Gil et al. 2012	Cross-sectional No direct control: Analysis of variance	200 consecutive patients were recruited. 13 declined participation or were excluded for incomplete questionnaires.	187	79 (42.2%)	See prior box.
Hepp et al.	Cross-sectional No direct control: Analysis of variance	The number in the available patient pool was not specified.	31	7 (22.6%)	HADS test not completed by 1
Motmans et al.	Cross-sectional No direct control: Analysis of variance & regression	255 with GD were identified. 77 were excluded.	148 (→140)	Not clearly stated. At least 103 underwent some form of GRS.	8 later excluded for incomplete SF-36 tests. 37 w recent GRS or hormone initiation were excluded from analysis of SF-36 results→103.
Newfield et al.	Internet survey Cross-sectional No direct control: Analysis of variance	Number of incomplete questionnaires not reported 446 respondents; 384 U.S respondents 62 non-U.S. respondents excluded from SF-36 test results 8 U.S. respondents excluded	376 (U.S.)	139 to 150 (37.0-39.9%) in U.S.	-
Gomez-Gil et al. 2014	Cross-sectional No direct control: Analysis w regression	The number in the available patient pool was not specified. 277 were recruited. 25 excluded	252(→193)	80 (41.4%) non-genital surgery	59 were excluded for incomplete questionnaires. See prior box.
Asscherman	Longitudinal No analysis by tx	The number in the available patient pool	1331	1177 (88.4%)	-

	status	was not specified.			
Johansson et al.	Cross-sectional except for 1 variable No analysis by tx status except for 1 question	60 eligible patients 18 excluded.	42	32 (76.2% of enrolled & 53.3% of eligible) (genital surgery)	-
Leinung et al.	Cross-sectional No analysis by tx status	242 total clinic patients	242	91 (37.6%)	Employment status data missing for 81 of all patients

*Data obtained via a survey on a website and distributed at a conference
B/C=because
BSRI=Bem Sex Role Inventory
F=Female
FP-R=Freiberg Personality Inventory
GD=Gender dysphoria
GID=Gender identity disorder
HADS=Hospital Anxiety & Depression Scale
IPP=Inventory of Interpersonal Problems
M=Male
NA=Not applicable
SCL-90=Symptom Checklist-90
SF-36=Short Form 36
GRS=Sex reassignment surgery
Tx=Treatment
W/o=without

Appendix D

Demographic Features of Study Populations

Panel A (Controlled Studies)

Author	**Age (years; mean, S.D., range)**	**Gender**	**Race**
Ainsworth	Only reassignment surgery:50 (no S.D.) Only facial surgery: 51 (no S.D.) Both types of surgery: 49 (no S.D.) Neither surgery: 46 (no S.D.)	247 M to F	-
Beatrice	Pre-SRS M to F: 32.5 (27-42), Post-SRS: 35.1 (30-43)	20 M to F plus 20 M controls	100% Caucasian
Dehjne 2011	Post-SRS: all 35.1±9.7 (20-69), F to M 33.3+8.7 (20–62), M to F 36.3+ 10.1(21–69)	133 (41.0%) F to M, 191 (59.0%) M to F; ratio 1:1.4	-
Dhejne 2014 Landén	F to M SRS cohort: median age 27 M to F SRS cohort: median age 32 F to M applicants for reversal: median age 22 M to F applicants for reversal: median age 35	767 applicants for legal/surgical reassignment 289 (37.7%) F to M, 478 (62.3%) M to F; ratio 1:1.6 681 post SRS & legal change 252 (37.0%) F to M, 429 (63.0%) M to F; ratio 1:1.7	-

		15 applicants for reversal 5 (33.3%) F to M, 10 (66.7%) M to F; ratio 1:2	
Haraldsen	Pre-SRS & Post-SRS: F to M 34±9.5, F to M 33.3±10.0 Post-SRS cohort reportedly older. No direct data provided.	Pre & Post SRS 35 (40.7%) F to M, 51 (59.3%) M to F; ratio 1:1.5	-
Heylens	-	11 (19.3% of 57) F to M, 46 (80.7%); ratio 1:4.2 (80.7% underwent surgery)	-
Kockott	Pre-SRS (continued wish for surgery): 31.7±10.2 Post-SRS: 35.5±13.1	Pre-SRS (continued wish for surgery) 3 (25%) F to M, 9 (75%) M to F; ratio 1:3 Post SRS: 14 (43.8%) F to M, 18 (56.2%) M to F; ratio 1:1.3	-
Kraemer	Pre-SRS: 33.0±11.3, Post-SRS: 38.2±9.0	Pre-SRS 7 F to M (30.4%), 16 M to F (69.6%); ratio 1:2.3 Post-SRS 8 F to M (36.4%), 14 M to F (63.6%); ratio 1:1.8	-
Kuhn	All post SRS: median (range): 51 (39-62) (long-term follow-up)	3 (5.4%) F to M, 52 (94.5%) M to F; ratio 1:17.3.	-
Mate-Kole 1988	Initial evaluation: 34, Pre-SRS: 35, Post-SRS: 37	150 M to F	-
Mate-Kole 1990	Early & Usual wait SRS: 32.5 years (21-53)	40 M to F	-
Meyer	Pre-SRS: 26.7 Delayed, but completed SRS: 30.9 Post-SRS: 30.1	Pre-SRS: 5 (23.8%) F to M, 16 (76.2%) M to F; ratio 1:3.2 Delayed, but completed SRS: 1 (7.1%) F to M, 13 (92.9%) M to F; ratio 1:13 Post-SRS: 4 (26.7%) F to M, 11 (73.3%) M to F; ratio 1:2.8	86% Caucasian
Rakic	All: 26.8±6.9 (median 25.5, range 19-47), F to M: 27.8±5.2 (median 27, range 23-37), M to F: 26.4±7.8 (median 24, range 19-47).	10 (31.2%) F to M, 22 (68.8%) M to F; ratio 1:2.2	-
Ruppin	All: 47.0±10.42 (but 2 w/o SRS) (13.8±2.8 yrs post legal name change) (long-term follow-up) F to M: 41.2±5.78, M to F 52.9±10.82	36 (50.7%) F to M, 35 (49.3%) M to F; ratio 1:0.97	-
Smith	Time of surgical request for post-SRS: 30.9 (range 17.7-68.1) Time of follow-up for post-SRS: 35.2 (range 21.3-71.9)	Pre-SRS: 162: 58 (35.8%) F to M, 104 [64.2%] M to F; ratio 1:1.8 Post-SRS: 126: 49 (38.9%) F to M, 77 (61.1%) M to F; ratio 1:1.6	-
Udeze Megeri	M to F: 47.33±13.26 (range 25-80).	40 M to F	-
Wolfradt	Patients & controls: 43 (range 29-67).	30 M to F plus 30 F controls plus 30 M controls.	-

*Data obtained via a survey on a website and distributed at a conference SD=Standard deviation

Panel B (Surgical Series: No Concurrent Controls)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Blanchard et al.	F to M: 32.6, M to F w M partner preference: 33.2, F to M w F partner preference: 47.7 years	Post-GRS: 47 (45.6%) F to M, 56 (54.4%) M to F; ratio 1:1.19. In study: 38 (48.1%) F to M, 32 (40.5%) M to F w M partner preference, 9 (11.4%) M to F w F partner preference; ratio 1:0.8: 0.2	-
Weyers et al.	Post-GRS M to F: 43.1 ±10.4 (long-term follow-up)	50 M to F	-
Wierckx et al.	Time of GRS: 30±8.2 years (range 16 to 49) Time of follow-up: 37.1 ±8.2.4 years (range 22 to 54)	49 M to F	-
Eldh et al.	-	50 (55.6%) F to M, 40 (44.4%) M to F; ratio 1:0.8 There is 1 inconsistency in the text suggesting that these should be reversed.	-
Hess et al.	-	119 M to F	-
Lawrence	Time of GRS: 44±9 (range 18-70)	232 M to F	-
Salvador et al.	Time of follow-up for post-GRS: 36.28±8.94 (range 18-58) (Duration of follow-up: 3.8±1.7 [2-7])	52 M to F	-
Tsoi	Time of initial visit: All: 24.0±4.5, F to M: 25.4±4.4 (14-36), M to F: 22.9±4.6 (14-36). Time of GRS: All: 25.9±4.14, F to M: 27.4±4.0 (20-36), M to F: 24.7+4.3 (20-36).	36 (44.4%) F to M, 45 (55.6%) M to F; ratio 1:1.25	0% 100% Asian

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Gómez-Gil et al. 2012	W & W/O GRS: All: 29.87±9.15 (range 15-61), W/O hormone tx: 25.9±7.5, W current hormone tx: 33.6±9.1. (At hormone initiation: 24.6±8.1).	W/O hormone tx: 38 (56.7%) F to M, 29 (43.3%) M to F; ratio 1:0.8. W hormone tx: 36 (30.0%) F to M, 84 (70.0%) M to F; ratio 1:2.3. Post-GRS: 29 (36.7%) F to M, 50 (63.3%) M to F; ratio 1:1.7.	-
Hepp et al.	W & W/O GRS: 32.2±10.3	W & W/O GRS: 11 (35.5%) F to M; 20 (64.5%) M to F; ratio 1:1.8.	-
Motmans et al.	W & W/O GRS: All (n=140) : 39.9±10.2, F to M: 37.0±8.5, M to F: 42.3±10.4	W & W/O GRS: N=140 63(45.0%) F to M, 77 (55.0%) M to F; ratio 1:1.2 N=103 49 (47.6%) F to M; 54 (52.4%) M toF; ratio 1:1.1	-
Newfield et al.	W & W/O GRS: U.S.+ non-U.S. : 32.8±11.2, U.S. 32.6±10.8	W & W/O GRS: U.S.+ non-U.S.: F to M, 438, U.S.: F to M: 376	89% of 336 respondents Caucasian
Gomez-Gil, et al. 2014	W & W/O Non-genital GRS: 31.2±9.9 (range 16-67).	W & W/O Non-genital GRS: 74 (38.3%) F to M, 119 (61.7%) M to	-

		F; ratio1:1.6.	
Asscherman	Time of hormone tx: F to M: 26.1±7.6 (16–56), M to F: 31.4±11.4 (16–76)	Met hormone tx requirements: 365 (27.4%) F to M, 966 (72.6%) M to F; ratio 1:2.6. Post-GRS: 343 (29.1%) F to M, 834 (70.9%) M to F; ratio 1:2.4.	-
Johanssen	Time of initial evaluation: F toM: 27.8 (18-46), M to F 37.3 (21-60). Time of GRS: F to M: 31.4 (22-49), M to F 38.2 (22-57). Time of follow-up for post-GRS: F to M: 38.9 (28-53), M to F 46.0 (25-69) (Long-term follow-up)	Approved for GRS: 21 (35%) F to M, 39 (65%) M to F; ratio 1:1.9) Post GRS: 14 (43.8%) F to M; 18 (56.2%) M to F; ratio 1:1.3)	-
Leinung et al.	Time of hormone initiation : F to M: 27.5, M to F 35.5	W & W/O GRS: 50 (20.7%) F to M, 192 M to F (79.3%); ratio 1:3.8. Post-GRS: 32 F to M (35.2%); 59 (64.8%) M to F; ratio 1:1.8.	-

Appendix E

Psychometric and Satisfaction Survey Instruments

Instrument Name and Developer	**Development and Validation Information**
APGAR Family Adaptability, Partner-ship Growth, Affection, and Resolve *Smilkstein*	Published in 1978 Initial data: 152 families in the U.S. A "friends" component was added in 1983. Utility has challenged by many including Gardner 2001
Beck Depression Inventory *Beck, Ward, Mendelson, Mock, & Erbaugh*	Published initially in 1961 with subsequent revisions It was initially evaluated in psychiatric patients in the U.S.A. Salkind (1969) evaluated its use in 80 general outpatients in the UK. Itis copyrighted and requires a fee for use
Bem Sex Role Inventory *Bem*	Published 1974 Initial data: 100 Stanford Undergraduates 1973 update: male 444; female 279 1978 update: 470; female 340
Body Image Questionnaire *Clement & Lowe*	Validity study published 1996 (German) Population: 405 psychosomatic patients, 141 medical students, 208 sports students
Body Image Scale *Lindgren & Pauly (Kuiper, Dutch adaptation 1991)*	1975 Initial data: 16 male and 16 female transsexual patients in Oregon
Crown Crisp Experiential Index (formerly Middlesex Hospital Questionnaire)	Developed circa 1966 Manual published 1970 Initial data: 52 nursing students while in class in the UK

Crown & Crisp	
(2nd) European Quality of Life Survey *Anderson, Mikuliç, Vermeylen, Lyly-Yrjanainen, & Zigante,*	Published in 2007 The pilot survey was tested in the UK and Holland with 200 interviews. The survey was revised especially for non-response questions. Another version was tested in 25 persons of each of the 31 countries to be surveyed. Sampling methods were devised. 35,634 Europeans were ultimately surveyed. Additional updates
Female Sexual Function Index *Rosen, Brown, Heiman, Leiblum, Meston, Shabsigh, Ferguson, D'Agostino Wiegel, Meston, & Rosen*	Published in 2000 Initial data: 131 normal controls & 128 age-matched subjects with female sexual arousal disorder from 5 U.S. research centers. Updated 2005: the addition of those with hypoactive sexual desire disorder, female sexual orgasm disorder, dyspareunia/vaginismus, & multiple sexual dysfunctions (n=568), plus more controls (n=261).
Fragebogen zur Beurteilung des eigenen Korpers *Strauss*	Published 1996 (German)
Freiberg Personality Inventory *Fahrenberg, Hampel, & Selg*	7th edition published 2001, 8th edition in 2009 (Not in PubMed) German equivalent of MMPI
"gender identity disorder in childhood" *Smith, van Goozen, Kuiper, & Cohen-Kettenis*	11 items derived from the Biographical Questionnaire for Trans-sexuals (Verschoor Poortinga 1988) (Modified by authors of the Smith study)
Gender Identity Trait Scale *Altstotter-Gleich*	Published 1989 (German)
General Health Questionnaire *Goldberg & Blackwell (initial study)* *Goldberg & Williams (manual)*	Initial publication 1970 Manual published ?1978, 1988 (Not in PubMed) Initial data: 553 consecutive adult patients in a single UK primary care practice were assessed. Sample of 200 underwent standardized psychiatric interview. Developed to screen for hidden psychological morbidity. Proprietary test. Now 4 versions.
Hospital Anxiety & Depression Scale *Zigmond & Snaith*	Published in 1983 Initial data: Patients between 16 & 65 in outpatient clinics in the UK >100 patients; 2 refusals. 1st 50 compared to 2nd 50.
Inventory of Interpersonal Problems *Horowitz*	Published 1988 Initial data: 103 patients about to undergo psychotherapy; some patients post psycho-therapy (Kaiser Permanente-San Francisco) Proprietary test
King's Health Questionnaire	1997 Initial data: 293 consecutive women referred for urinary

Kelleher, Cardozo, Khullar, & Salvatore	incontinence evaluation in London Comparison to SF-36
Minnesota Multi-phasic Personality Inventory *Hathaway & McKinley* *Butcher, Dahlstrom, Graham, & Tellegen*	Published in 1941 Updated in 1989 with new, larger, more diverse sample. MMPI-2: 1,138 men & 462 women from diverse communities & several geographic regions in the U.S.A. The test is copyrighted.
Modified Androphia-Gynephilia Index	Neither the underlying version or the Blanchard modified version could be located in PubMed (Designed by the author of the Blanchard et al. study)
"post-operative functioning 13 items" *Doorn, Kuiper, Verschoor, Cohen-Kettenis*	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
"post-operative functioning 21 items" *Doorn, Kuiper, Verschoor, Cohen-Kettenis*	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
Scale for Depersonalization Experiences *Wolfradt*	Unpublished manuscript 1998 (University of Halle) (Designed by 1 of the authors of the Wolfradt study)
"sex trait function" *Cohen-Kettenis & van Goozen*	Published 1997 Assessed in 22 adolescents (Designed by 1 of the authors of the Smith Study)
Self-Esteem Scale *Rosenberg*	Published 1965 (Not in PubMed) Initial data: 5,024 high-school juniors & seniors from 10 randomly selected New York schools
Short-Form 36 *RAND* *Ware & Sherbourne1992* *McHorney, Ware, & Raczek 1993*	Originally derived from the Rand Medical Outcomes Study (n=2471 in version 1; 6742 in version 2 1989). The earliest test version is free. Alternative scoring has been developed. There is a commercial version with a manual.
Social Anxiety & Distress Scale *Watson & Friend*	Initial publication in1969 Requires permission for use
Social Support Scale *Van Tilburg 1988*	Published 1988 (Dutch) (Not in PubMed)
Spielberger State & Trait Anxiety Questionnaire *Spielberger, Gorsuch, Lushene, Vagg, & Jacobs*	Current format published in 1983 Proprietary test
Symptom Checklist-90 *Derogatis, Lipman, Covi* *Derogatis & Cleary*	Published in 1973 & 1977 Reportedly with normative data for psychiatric patients (in- & out-patient) & normal subjects in the U.S. Has undergone a revision Requires qualification for use
Tennessee Self-Concept	In use prior to 1988 publication.

Scale *Fitts & Warren*	Initial data: 131 psychiatric day care patients. Updated manual published 1996. Update population >3000 with age stratification. No other innformation available. Requires qualification for use
Utrecht Gender Dysphoria Scale *Cohen-Kettenis & van Goozen*	Published in 1997 Initial population: 22 transgender adolescents who underwent reassignment surgery. (Designed by 1 of the authors of the Smith study)
WHO-Quality of Life (abbreviated version) *Harper for WHO group*	Field trial version released 1996 Tested in multiple countries. The Seattle site consisted of 192 of the 8294 subjects tested). Population not otherwise described. The minimal clinically important difference has not been determined. Permission required

Althof et al., 1983; Greenberg, Frank, 1965; Gurtman, 1996; Lang, Vernon, 1977; Paap et al., 2012; Salkind et al., 1969; Vacchiano, Strauss, 1968.

Appendix F

Endpoint Data Types and Sources

Panel A (Controlled Studies)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Substantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Dhejne 2011	Yes	-	-	-	-	Mortality (Suicide, Cardiovascular Disease [possible adverse events from Hormone Tx], Cancer), Psych hx & hospitalization, Suicide attempts
Dhejne Landén	Yes	-	-	-	Includes demographics*	Education, Employment, Formal application for reversal of status, Psych dx & tx, Substance abuse** More elements in earlier paper
Beatrice	-	MMPI form R, TSCS	-	-	Demographic	Education, Income, Relationships

Haraldsen	-	SCL-90/90R	-	-	Demographic	DSM Axis 1, II, V (GAF), Substance abuse
Heylens	-	SCL-90	-	Yes-2	Demographic	Employment, Relationships, Substance abuse, Suicide attempts
Ainsworth	-	Likely SF-36v2*	-	Yes-1	Demographic	-
Ruppin	-	SCL-90R	BSRI, FPI-R, IIP	Yes-2	Demographic	Adverse events from surgery, Employment, Psych tx, Relationships, Substance abuse
Smith	-	MMPI-short, SCL-90?R	BIS, UGDS, ? Cohen-Kettenis', Doorn's x2, (Gid-c, SSS)	Yes-1 or 2	Demographic	Adverse events from surgery, Employment, Relationships
Udeze Megeri	-	SCL-90R	BDI, GHQ, HADS,STAI-X1, STAI-X2	-	-	Psych eval & ICD-10 dx
Kuhn	-	-	KHQ	Yes-1	Demographic	Relationships
Mate-Kole 1990	-	-	BSRI, CCEI	Yes-1	Demographic	Employment (relative change), Psych hx, Suicide hx
Wolfradt	-	-	BIQ, GITS, SDE, SES	Yes-1	-	-
Kraemer	-	-	FBeK	-	Demographic	-
Mate-Kole 1988	-	-	BSRI, CCEI	-	Demographic	Employment, Psych hx, Suicide hx,
Kockott	-	-	-	Yes-1	Demographic	Employment, Income, Relationships, Suicide attempts
Meyer	-	-	-	Yes-1	Demographic	Education, Employment, Income, Psych tx, Phallus removal request
Rakic	-	-	-	Yes-1	Demographic	Employment, Relationships

Panel B (Surgical Series: No Concurrent Controls)

Author	**National Data**	**Instrument w Substantive Normative Data**	**Instrument w/o Sub-stantive &/or Accessible Normative Data**	**Investigator-designed**	**Other**	**Other**
Weyers	-	SF-36	FSFI	Yes-2	Demographic	Hormone levels, Adverse events from surgery, Relationships
Blanchard	-	SCL-90R	(AG)	Yes-1	Demographic	Education, Employment, Income,

						Relationships, Suicide (Incidental finding)
Wierckx	-	SF-36	-	Yes-3	Demographic	Hormone levels, Adverse events from surgery, Relationships
Eldh	-	-	-	Yes-1	-	Adverse events from surgery, Employment, Relationships, Suicide attempts
Hess	-	-	-	Yes-1	-	-
Lawrence	-	-	-	Yes-4	Demographic	Adverse events from surgery
Salvador	-	-	-	Yes-1	Demographic	Relationships
Tsoi	-	-	-	Yes-1	Demographic	Education, Employment, Relationships (relative change)

Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	**National Data**	**Instrument w Substantive Normative Data**	**Instrument w/o Sub-stantive &/or Accessible Normative Data**	**Investigator-designed**	**Other**	**Other**
Asscheman et al.	Yes	-	-	-	Demographic	Mortality (HIV, Possible adverse events from Hormone Tx, Substance abuse, Suicide)
Motmans et al.	-	SF36 EQOLS (2nd)	-	-	Demographic	Education, Employment, Income, Relationships
Newfield et al.	-	SF-36v2	-	-	Demographic	Income
Gómez-Gil et al. 2014	-	WHOQOL-BREF	APGAR	Yes-1	Demographic	Education, Employment, Relationships
Gómez-Gil et al. 2012	-	-	HADS, SADS	-	Demographic	Education, Employment, Living arrangements
Hepp et al.	-	-	HADS	-	Demographic	DSM Axis 1& II Psych dx
Johansson et al.	-	-	-	Yes-1	Demographic	Axis V change (Pt & Clinician) Employment (relative change) Relationship (relative change)

Leinung et al.	-	-	-	-	Demographic	Employment, Disability, DVT, HIV status, Psych dx

*Listed as San Francisco-36 in manuscript

** From medical charts & verdicts ?=Possibly self-designed

AG=Androphilia-Gynephilia Index (investigator designed 1985) (used more for classification)

APGAR=Family Adaptability, Partnership growth, Affection, and Resolve

BDI=Beck Depression Inventory

BIQ=Body Image Questionnaire

BIS=Body Image Scale

BSRI=Bem Sex Role Inventory

CCEI=Crown Crisp Experiential Index

Cohen-Kettenis'= Sex trait function (An author helped design)

Dorn's x2= Post-operative functioning 13 items (An author helped design)

Post-operative functioning 21 items (An author helped design)

EQOLS (2nd)=2nd European Quality of Life Survey

FBeK=Fragebogen zur Beurteilung des eigenen Korpers

FPI-R=A version of the Freiberg Personality Inventory

FSFI+Female Sexual Function Index

GHQ=General Health Questionnaire

Gid-c=Gender identity disorder in childhood (used more for predictors) (An author helped design)

GITS=Gender Identity Trait Scale

HADS=Hospital Anxiety Depression Scale

IIP=Inventory of Interpersonal Problems

KHQ=King's Health Questionnaire

MMPI=Minnesota Multi-phasic Personality Inventory

SADS=Social Anxiety & Distress Scale

SCL-90 (±R)=A version of the Symptom Checklist 90

SDE=Scale for Depersonalized Experiences (An author designed)

SES=Self-Esteem Scale

SF-36 (v2)=Short Form-36(version2)

SSS=Social Support Scale (used more for predictors)

STAI-X1, STAI-X2=Spielberger State and Trait Anxiety Questionnaire

TSCS=Tennessee Self-Concept Scale

UGDS=Utrecht Gender Dysphoria Scale (An author helped design)

WHOQOL-BREF=World Health Organization-Quality of Life (abbreviated version)

Appendix G.

Longitudinal Studies Which Used Patients as Their Own Controls and Which Used Psychometric Tests with Extensive Normative Data or Longitudinal Studies Which Used National Data Sets

Author		**Test**	**Patient and Data Loss**	**Results**
		Psychometric Test		
Heylens et al. Belgium 2014		SCL-90R	90 applicants for SRS were recruited. • 8 (8.9%) declined participation.	At t=0, the mean global "psychoneuroticism" SCL-90R score, along with scores of 7 of 8 subscales, were statistically

			• 12 (13.3%) excluded b/c GID-NOS dx. • 12 (13.3%) did not complete the treatment sequence b/c of psychiatric/physical co-morbidity, personal decision for no tx, or personal decision for only hormone tx. • 1 (1.1%) committed suicide during follow-up. 57 (63.3% of recruited) entered the study. • 1 (12.2% of initial recruits) had not yet received SRS by study close. →**46 (51.1% of recruited) underwent serial evaluation** • The test was not completed by 1 at t=0, 10 at t=1 (after hormone tx), & 4 at t=2 (after SRS) →**missing data for another 1.1% to 11.1%.**	more pathologic than the general population. After hormone tx, the mean score for global "psychoneuroticism" normalized & remained normal after reassignment surgery.
Ruppin,Pfafflin, Germany 2015		SCL-90R	The number in the available patient pool was not specified. 140 received recruitment letters. • 2 (1.4% of those with recruitment letters) had died. • 1 (0.7%) was institutionalized. • 5 (3.6%) were ill. • 8 (5.7%) did not have time. • 8 (5.7%) stated that GD was no longer an issue. • 8 (5.7%) provided no reason. • 28 (20.0%) declined further contact. • 9 (6.4%) were lost to follow-up. →**71 (50.7%) agreed**	At t=0, the "global severity index "SCL-90R score was 0.53±0.49. At post-SRS follow-up the score had decreased to 0.28±0.36. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 0-4. In the same way, all of the subscale scores were statistically different, but the effect size was reported as large only for "interpersonal sensitivity": 0.70±0.67 at t=0 and 0.26±0.34 post-SRS.

			to participate. • **2 (1.4%) had not undergone SRS** • The test was not completed by 9. →**missing data for another 6.4%.**	
Smith et al. Holland 2005		MMPI SCL-90	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. • 103 (31.7%) were not eligible to start hormone tx & real-life experience. • 34 (10.7%) discontinued hormone tx 162 (an unknown percentage of the initial recruitment) provided pre-SRS test data. • **36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete post-SRS testing.**	Most of the MMPI scales were already in the normal range at the time of initial testing. At t=0, the global "psychoneuroticism" SCL-90 score, which included the drop-outs, was 143.0±40.7. At post SRS-follow-up, the score had decreased to 120.3±31.4. The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 90 to 450, with higher scores consistent with more psychological instability.
Udeze, et al. 2008 Megeri, Khoosal 2007 UK		SCL-90R	The number in the available patient pool was not specified. 40 subjects were prospectively selected. • Post-operative testing was conducted within 6 months to minimize previously determined loss rates.	At t=0, the mean raw global score was 48.33. At post-SRS follow-up, the mean score was 49.15. There were no statistically significant changes in the global score or for any of the subscales.
	National Databases			
Dehjne Sweden 2011		Swedish National Records	804 with GID in Sweden 1973 to 2003 were identified. • 480 (59.7%) did not apply or were not approved for SRS 324 (40.3%) underwent SRS. • All were followed. 3240 controls of the natal sex and 3240 controls of the reassigned gender	All cause mortality was higher (n=27[8%]) than in controls (H.R 2.8 [1.8-4.3]) even after adjustment for covariants. Divergence in survival curves was observed after 10 years. The major contributor was completed suicide (n=10 [3%]; adjusted H.R. 19.1 [5.8-62.9]). Suicide attempts were more

		were randomly selected from national records	common (n= 29 [9%]) than in controls (adjusted H.R. 4.9 [2.9–8.5]). Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common n= 64 [20%] than in controls (H.R. 2.8 [2.0–3.9]) even after adjusting for prior psychiatric morbidity.
Dhejne et al. 2014 Landén et al. 1998 Sweden	Swedish National Registry	767 applied for SRS/legal status (1960-2010) • 25 (3.3%) applications denied. • 61 (8.0%) not granted full legal status 681 (88.7%) underwent SRS. • All were followed.	15 formal applications for reversal to natal/original gender (2.2% of the SRS population) were identified thus far (preliminary number). (Does not reflect other manifestations of regret such as suicide.)

GID-NOS=Gender Identity Disorder-Not Otherwise Specified HR=Hazard Ratio SRS=Sex reassignment surgery Tx=Treatment

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CASE NO. 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants
_____/

Volume 1, Pgs. 1 - 124

VIDEOTAPED DEPOSITION OF:	MATTHEW BRACKETT
AT THE INSTANCE OF:	THE PLAINTIFFS
DATE:	FEBRUARY 8, 2023
TIME:	COMMENCED: 10:00 A.M.
LOCATION:	AGENCY FOR HEALTH CARE ADMINISTRATION 2727 MAHAN DRIVE TALLAHASSEE, FLORIDA 32308
REPORTED BY:	DANA W. REEVES Court Reporter and Notary Public in and for State of Florida at Large

APPEARANCES:

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ALSO PRESENT:
RL Minnich, Videographer

INDEX TO WITNESS

INDEX TO EXHIBITS

*Uh-uh is a negative response
*Uh-huh is a positive response

D E P O S I T I O N

VIDEOGRAPHER: This is the video-recorded deposition of corporate representative for Agency for Healthcare Administration, in the matter of August Decker, et al. vs. Jason Weida, et al. Case No. 4:22-cv-00325, RH-MAF. This deposition is being held at 2727 Mahan Drive in Tallahassee, Florida. Today's date is February 8th, 2023 and the time is 10:08 a.m. The court reporter is Dana Reeves. My name is RL Minnich. I'm the videographer. Would counsel please introduce themselves and the court reporter please swear in the witness?

MS. DEBRIERE: Yes, Katy DeBriere and I represent the plaintiffs.

MS. CHRISS: Simone Chriss and I also represent the plaintiffs.

MS. DUNN: Chelsea Dunn. I also represent the plaintiffs.

MR. JAZIL: Mohammad Jazil for the defense.

MS. DEBRIERE: And we have a few people on the Zoom link from the plaintiff's side. That would be Catherine McKee and Omar Gonzalez-Pagan.

MR. PERKO: And Gary Perko on behalf of the defendants on the Zoom link.

MS. DEBRIERE: And Shani Rivaux has joined us from the plaintiff's side as well.

COURT REPORTER: All right, sir, if you would raise your right hand, please.

Whereupon,

MATTHEW BRACKETT

was called as a witness, having been first duly sworn to speak the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

THE WITNESS: I do.

COURT REPORTER: Thank you.

EXAMINATION

BY MS. DEBRIERE::

Q All right. So we're just going to mark exhibits as they're discussed, if that's okay with you, Matt.

A That's fine.

Q As we walk through those exhibits, I'm going to read off the Bates numbers on the bottom of each page. So those are just the -- that line of numbers I'm reading out loud as we discuss exhibits, and that should help you track what page I'm on as we're discussing them. So we're going to go ahead and mark the notice of deposition as Exhibit 1. I saw that you brought the copy with you, as well, Mr. Brackett.

(Whereupon, Exhibit No. 1 was marked for identification.)

MR. JAZIL: Is this the court reporter's copy?

MS. CHRISS: The witness' copy that can become the court reporter's copy.

BY MS. DEBRIERE::

Q Okay. So just some preliminary stuff before we go over this notice. I'm going to be using the acronym GAPMS quite a bit. That stands for Generally Accepted Professional Medical Standards, and is the acronym that refers to the process described at Florida Administrative Code Rule 59-G-1.035. When I refer to the GAPMS or GAPMS process, do you understand what I mean?

A Yes.

Q I will also use the term gender dysphoria, which is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics. Can we agree that when I say gender dysphoria, that's the definition I'm using?

A Yes.

Q I will also be using a phrase categorical exclusion of treatment for gender dysphoria, which

refers to the exclusion in Florida Administrative Code Rule 59-G-1.050(7). Do you understand that that phrase refers to all the services in that particular portion of the rule when I say categorical exclusion?

A I do.

Q And then I will also be using the term EPSDT services, which stands for Early Periodic -- Early and Periodic Screening Diagnostic and Treatment Services. When I say EPSDT, do you know what I mean?

A Yes.

Q Have you ever been deposed before?

A Yes, I have.

Q Okay. So if there's at any point that you don't understand my question, what I want you to do is I want you to stop and ask me to rephrase it. I don't want you to try to attempt to ask -- answer the question if you don't understand it. Okay?

A Okay.

Q I have a problem sometimes of speaking over someone else, I don't know if you have the same problem, but what we need to try to do is just give each other space to pause in between the questions so we're not speaking over each other. Okay?

A I'm fine with that.

Q Okay. Verbal answers. Sounds like, you know,

you speak very clearly, so we shouldn't have a problem, but obviously -- although we do have a videographer here, it's better to speak your answer out loud.

A I do understand. Articulating hand gestures, the court reporter cannot get those into the transcripts.

Q Exactly. All right, if you need to take a break for any reason, totally fine, just let me know. I do ask that you answer my question before we take a break.

A Okay.

Q And then are you on any medications or other substances that could impact your memory today?

A No.

Q And state your name for the record.

A So my full name is John Matthew Brackett.

Q Okay. And it's your understanding that you're representing the Florida Agency for Health Care Administration in a 30(b)(6) deposition?

A That's correct.

Q Okay. What topics, looking at the notice, which is Exhibit 1, notice of 30(b)(6) deposition, what topics were you designated for? Were they all of them here?

A Yes.

Q And you're prepared to testify on behalf of the Agency on each of these topics?

A Yes.

Q Have you seen the 30(b)(6) deposition topics?

A You mean as those listed in the -- yes, I have seen them.

Q And who provided them to you?

A Those were provided to me by our outside counsel.

Q Okay. And did you consent to acting as the agency representative?

A Yes, I did.

Q What did you do to -- excuse me. What did you do to prepare for today?

A Mostly just familiarize myself with areas and topics that are on the list that are not familiar to my current job role, and that's pretty much it. So pretty much standard operating procedures here at the Agency that are -- that might fall under different divisions or different teams, et cetera. And just kind of, like, reviewed some of our coverage policies, some of our rules and some of our own materials.

Q Okay. Who did you speak to?

A Principally, consulted with Andrew Sheeran and for any questions that involved managed care, I

consulted my supervisor Devona Pickle.

Q Did you gather information from anyone, anyone besides counsel?

A I gathered a little bit of information from Devona Pickle, since one of the questions directly involved her role in the process.

Q Okay. I saw that you brought a document with you today, it looks like maybe you reviewed that to prepare. What is that?

A So that is pertinent to the question. I can provide you the exact one. Yeah, I think -- yeah, question three. It was -- since that asked about the process of how we looked at other states' Medicaid programs, which that spreadsheet was -- Devona Pickle administered that role of the GAPMS process. And since that question was on there, I did ask her to provide me with what she used to -- and the research methods used to go through each state Medicaid program to find out what their coverage criteria is, or if they have a statement prohibiting coverage, or if they just don't have any statement whatsoever.

MS. DEBRIERE: Okay. And, Mo, do you know if that was produced to us in discovery?

MR. JAZIL: I don't believe it was. So we'll make copies and get it to you.

BY MS. DEBRIERE::

Q How long did it take you to prepare for the deposition today?

A Well, given that we received these questions about a week ago, I'd probably say I spent probably off and on -- I mean, in between other projects, probably I'd say three, maybe four working days.

Q Okay. A little bit about you. Describe your educational background.

A So I received a -- my -- started off, I got my AA at Tallahassee Community College. I received my Bachelor of Arts in history at Florida University, 2003. I graduated magna cum laude. Received my Master of Arts in History from Florida University in 2005. During my time in graduate school, I did spend a few extra years working on a PhD, which I decided not to finish, but during my grad school years, I presented research papers on numerous topics at numerous conferences. And I also published scholarly articles in the Florida Historical Quarterly and Southern Studies and Interdisciplinary Journal of the South.

Q The conferences, what were those about?

A The conferences ranged. They could -- they were, I think, either conference on Florida history, conferences on environmental history. I think there

were, like, graduate symposiums. So often they're also, like, regional conferences. The topics I represented on ranged from anything from environmental history to public health history.

Q And your PhD, what -- what were you attempting to get it in?

A So I was actually looking at getting my PhD in the history of medicine and public health. And actually, I was -- my dissertation topic was on tuberculosis, on how during the late 19th century, how kind of the infancy of public health agencies and how public health was actually becoming a common concept and how -- and, of course, with the emerging sciences -- well, pretty much with the discovery of microbiology and discovery of the tuberculosis bacteria, how all that was coming together to affect changes in the south in public health, and looking at also how, since tuberculosis was very common, on how that shapes southern identity.

Q Okay. And what's your current position at the Agency for Health Care Administration?

A So my current position is Program Consultant. I work on the Canadian Drug Importation Program primarily.

MS. DEBRIERE: And, Court Reporter, just to note, we're going to refer to the Agency for Health

Care Administration's throughout as either AHCA or the Agency.

BY MS. DEBRIERE::

Q Prior to your role with the Canadian Drug Importation Program -- did I get that right?

A Yeah, close enough.

Q What was your role at the Agency?

A My role at the Agency, I was the Program Administrator over the Specialized Services and Behavioral Health teams. Of course, we oversaw the development and, of course, updating of policies, such as durable medical equipment, community behavioral health, non-emergency transportation, school-based services, hospice. There's actually quite a lengthy list.

Q And how long did you do that for?

A I was in that position for three and a half years.

Q Okay. And prior to that, were you at the Agency?

A Yes, I was.

Q And what was your role then?

A I was a Government Analyst II. And during that time period, that was from January 2017 to November 2017, I was -- my role specifically tasked with

completing the Generally Accepted Professional Medical Standards reports.

Q And prior to that time, were you at the Agency?

A Yes.

Q And what did you do then?

A I would -- I worked in the Office of the Deputy Secretary for Health Quality Assurance.

Q So your time in the Bureau of Medicaid policy was from December 2017 to --

A January 2017 to November 2017. But my job -- but becoming a program administrator, I was still in the same bureau.

Q So GAPMS -- working on GAPMS was January 2017 to November 2017, and then you shifted to another role in Bureau and Medicaid Policy?

A Yes.

Q And that was in December of 2017 through --

A November 2017 through April of 2021.

Q And so since May of 2021 or April 2021 you've been with the Canadian Drug --

A April 2021.

Q Okay. Let's look at the Florida definition of medical necessity. And that is in the Florida Medicaid Definitions Policy, which I'm sure you're intimately

familiar, at Section 2.83, and it's incorporated by reference into rule by Florida Administrative Code Rule 59-G-1.010.

MR. JAZIL: Simone, would you happen to have an extra copy?

MS. CHRISS: Yes.

MR. JAZIL: I'd rather just not lean over his shoulder.

MS. DEBRIERE: You know what, Mo, you can use mine. I basically have it committed to memory.

MR. JAZIL: Thank you.

MS. DEBRIERE: So we'll go ahead and mark this policy as Exhibit 2.

(Whereupon, Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE::

Q And, Mr. Brackett, if you want to turn to it, it's 2.83.

A Okay.

Q What's the purpose of the Medical Necessity standard listed here?

A So is -- kind of clarify -- can you clarify what's meant by purpose?

Q What does AHCA use that medical necessity standard for?

A So these prongs for medical necessity, as defined, these are our guidelines for determining whether or not Florida Medicaid should cover a service.

Q Okay. Is it correct to say that the standard is used to determine whether Medicaid service should be prior authorized?

A I don't -- I don't -- I don't think so.

Q Okay. Tell me why.

A Because for medical necessity, being medically necessary, this is generally -- this is a criteria for whether or not Medicaid should cover a service. The prior authorization process is just mostly more clinical review to determine whether or not delivery of that service, coverage of that service corresponds to the definition of medical necessity.

Q Okay. So when you're doing a prior authorization review, you do determine whether or not the service corresponds to the definition of medical necessity?

A So since our subcontractors and our managed care plans do our prior authorizations, they do have to make sure that the -- that with the service they're prior authorizing would, if subjected to the medical necessity guidelines and definition, yeah, they have to make sure it corresponds.

Q Okay. And that's part of the prior authorization process?

A That's part of the prior authorization process, yes.

Q If a Medicaid service is found to be experimental by AHCA, would AHCA or its contractors, subcontractors like a managed care plan, still review whether the service meets any other portion of AHCA's medical necessity rule?

A No.

Q Okay. Why not?

A Because it does have to meet the five prongs of medical necessity, and one of those prongs is it has to be in alignment with GAPMS.

Q Okay. So if it's not in alignment with GAPMS, would you analyze it under any other portion of that definition?

A No, we wouldn't.

Q If a Medicaid service has not been determined experimental, using like GAPMS process, can a Medicaid managed care plan use the portion of the medical necessity standard that reads, be consistent with Generally Accepted Professional Medical Standards?

A Once the Agency deemed that it's not consistent, and often these requests usually come to us

from the plans, the plan is not going to cover it.

Q Okay. Is the plan able to make an independent determination of whether those services are experimental in nature, or must that come from -- decision come from AHCA?

A It does not necessarily have to come from AHCA. We do grant our managed care plans a great deal of flexibility when it comes down to the services they wish to cover, but sometimes when they get a service that they're not sure about, they do often -- sometimes will ask us to do a GAPMS review of it to determine whether or not that -- if they should cover it. So sometimes we're kind of more of a reference point, but the plans function pretty independently in these areas.

Q Okay. So the plan can make an independent determination as to whether or not a service is experimental or investigational?

A No. Whether or not to cover -- we don't allow them to do -- we don't allow them to do independent GAPMS reviews, if that's what you're asking.

Q What I'm asking is looking at the prong about whether this service is consistent with GAPMS, whether the plan can deny coverage of a service on that basis without AHCA's initial determination?

A No, they need to consult with us before

they -- they need to consult with us before they use experimental and investigational as a basis for denial, which they will -- we do get requests from the health plans.

Q Okay. All right. So moving on to what's Bates-stamped as defendant DEF_000126105. This is the GAPMS report on cross-sex hormone therapy, which is dated --

MS. CHRISS: May '22.

BY MS. DEBRIERE::

Q May 20th, 2022.

VIDEOGRAPHER: Counsel, can you put that mic on, please? They placed it right beside you.

MS. DEBRIERE: Yes. Yes.

VIDEOGRAPHER: The one to your right. Thank you.

MS. DEBRIERE: I should have worn my suit jacket tonight.

THE WITNESS: It might get hot here shortly, so I may be taking mine off.

MS. DEBRIERE: Should I mark this as 3?

MS. CHRISS: Yes, the one for him.

MS. DEBRIERE: I think we got it split up. I'm sorry. Mo, do you want to copy?

MR. JAZIL: Sure. Do you really have all these

committed to memory?

MS. DEBRIERE: Well, not this one, no, no, but somewhat.

MR. JAZIL: Here's the last one, Katy.

MS. DEBRIERE: Thanks.

MR. JAZIL: That's pretty impressive if you do.

MS. DEBRIERE: Well, not these, but definitely, you know, you practice Medicaid in Florida for seven years, you know what the medical necessity definition is.

(Whereupon, Exhibit No. 3 was marked for identification.)

MS. DEBRIERE: All right. Not a day past seven years, either.

BY MS. DEBRIERE::

Q Okay. So looking at -- do you have a copy, Mr. Brackett?

A Yes.

Q Okay. Looking at -- if you'll flip to what's marked as DEF_000126112, it's page eight.

A Okay.

Q Starting under coverage policy, there's some discussion about federal regulations, and then moving through to the Florida Medicaid section that ends on the top of page 10, if you could just review that for me.

A Okay.

Q So is this an accurate portrayal of the standard to determine Florida Medicaid coverage for prescription drugs?

A Yes, this is.

Q Do all prescription drugs require prior authorization to be reimbursed by Florida Medicaid?

A I can't speak fully to that one. I don't -- I don't believe so, but often our managed care plans, we grant them a lot more flexibility when it comes down to prior authorizations, so they may require prior authorization for every drug. But as far as, like, every single drug, as far as the fee for service system goes, I'm not a hundred percent certain, but I believe that we do not require prior authorization for every single drug.

Q Okay. Do you know if anybody at the Agency would have a hard answer to that question?

A One of our staff pharmacists probably would.

Q So can you briefly describe the process a Medicaid recipient undertakes in seeking prior authorization for a drug?

A Usually, that's taken by the provider usually, or in the case of pharmacy, I'm not sure who would submit the prior authorization. I don't think that

that's -- process is not initiated by the recipient themselves, it's usually initiated by the provider. Of course, it goes through, like, a one-two level review process. That first level is usually done by, like, a nurse or an RN. They just determine whether or not it's medically necessary. If it is, then that one level stops. If it's a denial, it has to go -- I think it goes to a second-level review.

Q Okay. And what is -- what is involved in that review? What is being reviewed?

A Well, I'm not intimately familiar with it because we used it a long, long time ago, prior to SM's. We did that stuff in-house. That was before my time with the Agency, but now that's outsourced to EQ Health Solutions in the fee-for-service system. But they do review the medical records, et cetera, and then, I think, any other materials that are submitted by the doctor, so --

Q Do they compare it to coverage policies or guidelines?

A Well, for children, I don't -- it wouldn't be necessary to because of EPSDT, but for adults, I don't know. That's information that we would have to ask our vendors. I assume they would, but that's an assumption.

Q Okay. Tell me a bit more about what you mean

by coverage guidelines when it needs to be reviewed for children because of EPSDT.

A Well, because of EPSDT, in which, since you're familiar with all this, of course, even regardless of what something says on the coverage policies -- because our coverage policies and our fee schedules are very prescriptive, they list out what services can be covered, what services can't be covered. Our fee schedules, of course, outline the amount of money that we pay for each service and our perimeter service gaps, most importantly, the service gaps. So for children, if it's deemed medically necessary, and usually it does have to go through the prior authorization process for an EPSDT consideration, if it's determined medically necessary, regardless of whether it's on a fee schedule or not, or in excess of our fee schedule, or if it's not listed in that coverage policies, because of EPSDT requirements from the feds, we do have to cover it.

Q Okay. Okay. And how do you define medical necessity for EPSDT?

A It's the same as listed in definitions policy.

Q Okay. What would be the process for obtaining Medicaid coverage for a drug where prior authorization is not required?

A Well, so the thing about Medicaid coverage for

drugs is that we do cover all drugs that are FDA approved. So if -- unless it has a prior authorization requirement and if that FDA approved covered drug can be covered by Medicaid.

Q Okay. What if it's not FDA approved?

A If it's not FDA approved or if it's -- so are we talking about, like, complete non-FDA approval or are we talking about like our off-label usage?

Q Actually, let's back up. So if it's FDA approved, does that mean it does not need to go through the prior authorization process for Medicaid to authorize it?

A If it's not FDA approved, we -- I mean, we're not going to cover it if it's not FDA approved.

Q Okay. If it is FDA approved, does the Medicaid recipients still have to undertake the prior authorization process to --

A If it's FDA approved, and it's a drug that we've required prior authorization, then, yes.

Q Okay. If it's a drug that does not require prior authorization, what does that process look like for coverage?

A I generally -- I think it just -- the pharmacy fills the prescription, they file a claim, agency pays the claim and the dispensing fee.

Q Okay. So there's no review in medical necessity under that --

A Providing the drug does not -- does not have prior authorization criteria, yes.

Q Okay. So if it's a drug that does not require authorization, AHCA does not determine if it's being prescribed for a medically necessary use; is that correct?

A Can you repeat that?

Q Yep. If a drug does not require prior authorization, AHCA does not -- AHCA or its contractors does not undertake a determination as to whether it's being prescribed for a medically necessary use?

MR. JAZIL: Object to form.

THE WITNESS: We covered -- we cover services that are medically necessary. So if it's -- that would be in violation of policy if drugs are being covered -- if drugs are being prescribed and covered, when for -- when medical records and the documentation -- when medical necessity is not being met, that is that -- no, we would not cover in those circumstances.

BY MS. DEBRIERE::

Q How would you make that determination that you would not cover if you're not doing a prior

authorization review?

A So generally when issues like that, when providers are billing Medicaid for services that are not medically necessary, that's usually when our Medicaid -- Medicaid program Integrity, they start getting involved in looking at -- looking at such claims.

Q How would that rise to the surface of triggering an investigation with Medicaid Integrity?

A Well, there are lots of tip-offs. I mean, we do have a -- we do have a fraud hotline. So somebody could report a provider for fraud. There -- it could be result from an on-site survey. Our Bureau of Recipient Provider Assistance does -- they often do Medicaid surveys on providers. It could also potentially result from a -- one of our health quality assurance surveys, if they're going in and looking at, like, their compliance with licensure rules. So it really depends on where the fraud's detected. So there are multiple avenues for reporting Medicaid fraud.

Q Does AHCA have a pharmacy coverage policy for every prescription drug?

A We do have our outpatient prescribed drugs services coverage policy. And that, of course, is for our covered outpatient drug benefit.

Q Does that policy list every potential

prescription drug prescribed under -- prescribed to a Florida Medicaid recipient?

A No. So -- because Florida Medicaid covers any drug that's FDA approved, when these medical necessity guidelines, that's kind of an encompassing umbrella. And then, of course, we do have the preferred drug list which is assembled by the Pharmaceutical and Therapeutics Committee. We always just call P&T, so -- but because the list is so vast we don't actually reproduce it in any kind of a form. So the prescribed drug services policy, the way it's worded is supposed to be all-encompassing, but there are exclusions in Section 5.2 of non-covered service -- of drugs that we won't cover under certain circumstances.

Q Okay. So it lists some drugs you won't cover, but it doesn't list all the drugs you will potentially cover?

A Right. But it's also -- but it's not -- it doesn't specifically state drugs, it's just -- it's more specific to conditions. Like we don't say we won't cover -- well, let me use it -- Viagra, but we say that we will not cover drugs for ED.

Q Okay. So there's some general descriptions of what you won't -- will and won't cover?

A Yes.

Q Is there a pharmacy -- is there an AHCA pharmacy coverage policy for estradiol? And I'm happy to spell it for you if you need it.

A Oh, are we talking about estradiol.

Q Estradiol. Thank you.

A No, we don't have specific coverage policies for specific drugs. And by estradiol, I mean, that's an -- that's a kind of name brand estrogen.

Q Okay. And how about for medroxyprogesterone acetate, or Provera?

A We don't have specific coverage policies for those.

Q Okay. How about micronized progesterone?

A Those would all be encompassed under the prescribed drug services policy.

Q Okay, but not specifically named?

A We don't specifically name drugs.

Q I'm just going to run down the list. Spiro -- and you're going to correct me when I say it wrong -- Spironolactone.

A Spironolactone. That one, I mean, once again, the previous answer applies. It's enveloped by our prescribed drug services coverage policy. We don't have, like, an individual policy addressing that specific drug.

Q Okay. Finasteride.

A I think that's close enough. Same as before it's covered -- it's enveloped by the prescribed drug services coverage policy. We do not have an individual coverage policy for that drug.

Q Dutasteride.

A We do not have an individual coverage policy for that drug, but it is covered. It is -- it is addressed through the prescribed drug services coverage policy.

Q Okay. Testosterone.

A The same as before, we don't have an individual coverage policy for it, but it is covered through the prescribed drug services coverage policy.

Q Testosterone enanthate.

A Same as before, as in, we don't have a specific coverage policy, but it is covered through the prescribed drug services coverage policy.

Q Okay. Two more. Testosterone undecanoate.

A We do not have an individual coverage policy for that, but it is enveloped by our prescribed drug services policy.

Q Gonadotropin-releasing hormone antagonists.

A Gonadotropin, yeah. So, yeah, we do not have an individual coverage policy for GnRH. And that, of

course, would be covered through the prescribed drug services coverage policy, is how it would be addressed.

Q Okay. You do not have a policy, a pharmacy policy for GnRH antagonists?

A Not promulgated into rule.

Q Okay. Do you have any coverage policies -- I didn't realize that when I asked whether there was a coverage policy that you interpreted that to mean that it had to be promulgated into rule. Do you have any coverage policies regarding these drugs that are not promulgated into rule?

A As far as the policy goes, we don't really have a policy so for it -- so much. There was a guideline produced, I think, in 2016 that was given to Magellan for guidance on the prior authorization process, but as far as a policy goes, no, we don't have -- we don't have a specific policy for these drugs.

Q Okay. So there was some guidance that AHCA provided to Magellan regarding GnRH antagonists.

MS. DEBRIERE: Simone, can I have that coverage guidance?

MS. CHRISS: This one?

MS. DEBRIERE: Yes, please. Thank you. We'll mark that as Exhibit 4. You definitely need a copy of this one.

(Whereupon, Exhibit No. 4 was marked for identification.)

THE WITNESS: I've seen it enough times.

BY MS. DEBRIERE::

Q Well, so is that what you're referring to when you said the guidance provided to Magellan?

A Yes.

Q That's all I needed to know. Okay. So I'm sure we'll come back to that. And so you referenced FDA approval in Medicaid coverage earlier. When making decisions about individual claims for coverage for Medicaid recipients, does AHCA or its contractor determine whether the use the drug is being prescribed for is FDA approved?

A Well, absolutely, yes. I mean -- I mean, if it doesn't have FDA approval, I mean, it's still -- I mean, it's either not FDA-approved, it's still going through clinical trials. It's not FDA-approved, then no, it's not eligible for coverage.

Q Okay. How does AHCA do that on an individualized basis?

A So for an individualized basis, generally this is a prior authorization process, the request is put in. The recipients, or health care plan enrollees, the specific condition is evaluated and determination of

medical necessity is made.

Q Okay. What if the drug does not require prior authorization, then how does AHCA determine whether the use it's being prescribed for is FDA-approved?

A That would normally have to involve a retrospective claims review.

Q Okay. So at the time it'd be covered, but then AHCA would go back and look to see if it should have been covered?

A That's correct.

Q And how do they do that?

A How do they do that?

Q Yeah.

A I don't know the specifics, generally either MPI or another bureau. Often people in the field will often look at review claims, and this has happen frequently, that if claims are found to be paid in error or paid for services that were not necessarily -- not medically necessary, but the Agency does have the ability and frequently does gather recoupments on providers.

Q Okay. MPI stands for --

A Medicaid Program Integrity.

Q So that's like a fraud investigation?

A Yes, there are two fraud investigation teams

of the state. For MPI, they're specifically here for Medicaid. Every Medicaid program in the country is required to have a program integrity team, but we also have Medicaid Fraud Control Unit over at the Attorney General's Office.

Q Okay. Just turning back quickly to Exhibit 4, why is this not considered a coverage policy?

A Because coverage policies are generally -- well, first of all, it's not promulgated in a rule. So all of our coverage policies go through the rulemaking process, which is, of course, allows for public input and everything like that. This is mostly more -- these are guidelines developed in-house and provided to our PBM subcontractor.

Q Okay. For use in determining whether or not to prescribe GN -- strike that.

Are there other coverage guidelines like this not promulgated into rule for other drugs?

A For other -- I am not aware of whether or not we have any other guidelines like this.

Q Okay. What about for cross-sex hormone therapy?

A There was -- to my knowledge, there was no guidance or for cross-sex hormones.

Q Okay. So going back to the MPI post-claim

reviews, how often does that happen? Can you quantify?

A I don't have enough numbers of how often it happens, because obviously we have thousands of Medicaid providers. Then we do hear about cases of recoupment, so I couldn't tell you what the percentage of providers that had to pay back to the Agency money, but I can tell -- I can definitely tell -- like, I know -- well, for instance, I know -- like, I think Miami-Dade or Broward County have -- like, their school district actually they had -- after they had received a Federal Audit from HHS, they ended up having to pay back, I think, a million or so dollars in funds because they were delivering services that weren't properly documented and weren't meeting that medical necessity criteria. So as far as the larger numbers go, I don't have those.

Q Is there somewhere publicly the public can access that information, or where we can access that information?

A So a public records request can always be put in. We don't have that information available on our website, but anyone can put in a public records request and find out, like, how often recoupments do occur.

Q Do you know what a drug compendium is?

A Yes. Yeah, I'm aware of three.

Q Which three are you aware of?

A Drug Index is one. There are two others whose names do not -- whose names I do not recall immediately offhand. I believe they are listed. And, of course, they do usually consist of, like, a very large amount of information on each specific drug, and it talks about, like, appropriate uses and so forth. So, for each of these compendia -- and I -- they are -- we do utilize them when evaluating whether or not we can use an FDA-approved drug for an off-label purpose.

Q Okay. Do you know if those three compendia are Drug Text Information System, United States Pharmacopoeia Drug Information and American Hospital Formulate -- Formulary Service Drug --

A That sounds correct.

Q And those are the three compendia listed in the Federal Medicaid Act?

A Yes.

Q Okay. So when I'm using compendium, or compendia for next set of questions, I'm referring only to those three listed in the Federal Medicaid Act.

A Okay, that's fine.

Q For drugs that do not require prior authorization, when making decisions about individual claims for coverage, does AHCA or its contractors

determine whether the use that drug is being prescribed for is supported by citation in one of the compendia?

A So is this for drugs that do not require prior authorization, or drugs that do require prior authorization?

Q Do not require.

A We really don't because we don't require prior authorization. We're not able to check.

Q So that means where AHCA does not require prior authorization for a Medicaid recipient to obtain coverage of a particular drug, it covers the drug without knowing in advance whether the use it's being prescribed for is supported by citation in one of the compendia?

A If we're not requiring prior authorization, there's no way for us to know in advance.

Q Okay. So I know you mentioned it earlier. I'm just going to reference it on my computer, and that is the prescription drug list. And the website link -- I'll turn it so both you and counsel can see it, without spilling my drinks. That URL is HTTPS://AHCA.myflorida -- Florida is spelled out -- .com//Medicaid/prescribed_drug/pharm -- P-H-A-R-M -- _thera -- T-H-E-R-A -- /PDF/PDL.pdf. So I'm showing you what is AHCA's preferred drug list. Do you recognize

it?

A Yes, I recognize that.

Q What is the PDL?

A So the preferred drug list -- so even though we have everything that's FDA-approved, our Pharmaceutical and Therapeutics Committee, they do place drugs on the preferred drug list. I don't know the -- necessarily all the details. I think often it has to do with the ability for the agency to obtain rebates and so forth, so -- but they do put this together. It is publicly available on our website. And, of course, it does -- it does, of course, have age -- it does have age, minimum age, maximum age, clinical care required.

I would like to clarify, though. I know for our -- in our Medicaid Management Information System, which we often dub as FMMIS, we do program for procedure codes and so forth, corresponding diagnosis codes. So if a claim does not correspond to a diagnosis code, and -- that claim can be denied automatically in the system.

Q Okay. Okay.

A Which, I'm sorry, I forgot --

Q No, no, no. It's helpful. I just want to make a note of it.

A And we do program our system with ICD-10

codes, so we do have a build in our system for claims to deny if they don't necessarily correspond to a specific diagnosis code.

Q And that's regardless of whether the drug requires prior authorization?

A If it's prior authorized, the prior -- there's a different process for entering claims into the system that are prior authorized. So I think if it was prior authorized, that would override the automatic denials, but I would have to confirm that, but I believe that's how the system does work.

Q So FMMIS can be programmed to deny a certain service if it's associated with a particular diagnostic code, and that's done automatically?

A That's automatic. Yeah. Claims can deny automatically in the system, so we do have a fail-safe there.

Q Okay. And that's even if the drug does not require prior authorization?

A That's correct.

Q Okay.

A So I know it's definitely the case for the procedure codes that I administered when I was over -- when I was over specialized services. I'm going to assume that we have the same in place for NDC's,

National Drug Codes.

Q Okay. Because the services you were previously working on were not prescription drugs, is that correct, they were other Medicaid services?

A No, they were a little of everything.

Q Do you have a diagnostic code for every drug in the system?

A I can't speak to that at the moment.

Q Okay. Is there some way we can find that information out?

A Yeah, we can -- we can find that out for you.

MS. DEBRIERE: Okay. Can we flag that as a question, follow-up question?

BY MS. DEBRIERE::

Q If a drug is on the PDL, does it mean it's on the fee schedule?

A So we don't -- so with drugs, and this is one of the things with having worked -- working on the Canadian Drug Importation Program is that drug pricing is not a transparent process, so we don't actually list rates, we just list what we cover, or we list what's on the PDL. We don't actually say what we'll reimburse.

Q Okay, but if it's listed on the PDL, even if the rate's not on the fee schedule, AHCA is going to cover it?

A Yeah.

Q Okay. Does the PDL apply to managed care plan coverage of prescription drugs?

A Yes, that's actually -- well, yes, actually. I think -- I think -- I believe it does. That we wouldn't -- I would need to verify, but as far as -- like, I know that's the way our pharmacy benefit works. So with pharmacy benefit managers, generally the law ensures subcontract, that's the pharmacy benefit managers, who handle both their prior authorization of drugs and also negotiating rebates with manufacturers to help, of course, lower expenses. And so -- but for Medicaid, the SMC health plans, they have PBM's that they're really only there for the prior authorization process of prescription drugs. So their PBM's do not negotiate rebates. All that's done on the Agency side. So the agencies have contracted PBM, which is another branch of Magellan. They're the ones that negotiate all the rebates.

Q Okay. Just for clarity of the record, PBM stands for --

A Pharmacy Benefit Manager.

Q Okay. And then SMC PBM's, they're using the PDL to determine whether or not to authorize coverage for a prescription drug?

A Well, since with Medicaid we'll cover anything that's FDA-approved, they're going to be reviewing primarily medical necessity.

Q Okay. Are they going to match up the request for drug coverage to the PDL?

A I don't know if they do that or not.

Q Okay. So you don't know if Medicaid managed care plans rely on the PDL to authorize coverage?

A I don't. I can't speak to that.

Q All right. Let's look at a few specific drugs. Say this one for me again.

A Estradiol.

Q Estradiol. Thank you. Okay. So the PDL indicates that AHCA covers estradiol in each of these formulations, there's many listed here, for at least one indication, but we don't know what the indication is, or at least the PDL doesn't indicate it, correct?

A That's correct.

Q Okay, but AHCA does not cover estradiol to treat gender dysphoria?

A That's correct.

Q For what uses or indications does AHCA authorize coverage for estradiol?

A So for -- well, when estradiol needs to be covered, generally, as I speak very generally, of

course, usually it's used for hormonal imbalances, but I mean, but still we go back -- we defer back to the medical necessity guidelines.

Q So what does the no -- let's look at the very first list -- listed formulation of estradiol, which is associated with Climara 0.025-milligrams-per-day patch. And looking over at the clinical PA required, it says no. What does that mean?

A That means if the provider wants to prescribe it, that, of course, they can prescribe it without having to have a clinical review process.

Q So that means no prior authorization is ever required?

A Not under fee-for-service. Managed care plans, however, they have the flexibility to make it go through prior authorization.

Q Okay. So in fee-for-service, estradiol will be covered without AHCA or its contractor first determining for what purpose it's being used?

A Right, not until the claim comes in.

Q Okay. So that would mean that Medicaid could cover this drug if it were prescribed for non-FDA-approved uses?

A That's, of course, where our claim system comes in. So our claim -- our claim system was

programmed -- and, of course, I'm speaking generally of our CPT codes, et cetera, that if it doesn't -- if the diagnosis code doesn't align with what's in the system, that can come back as a denial.

Q Okay. So for estradiol, let's use this as an example, but not a hypothetical, in real life.

A Okay.

Q If estradiol is prescribed for treatment of gender dysphoria, is FMMIS programmed to automatically deny that claim?

A I would have to confirm with our -- with our Medicaid fiscal agent operations to make sure -- to know whether or not that the system has been updated for -- to deny that.

Q Is it possible to program a system to do that?

A To program it to deny it?

Q Based on -- based on the diagnostic code --

A From my experience, it's pretty -- it's a pretty simple affair to update the system to -- when we -- because we are uploading new and deleting diagnosis codes or uploading new procedure codes, I mean, it's generally a pretty straightforward process.

Q Okay. Can you provide us a list of those diagnostic codes at some point?

A For estradiol?

Q I think -- well the diagnostic codes would be -- are you using CPT codes? What are you using?

A So we use ICD-10 for --

Q ICD. Okay.

A -- because it's going to be primarily -- those are going to be like your -- well, those are your service codes. Those aren't drug codes.

Q Okay. So you use -- for your diagnostic codes, it's associated with ICD-10?

A That's correct.

Q Okay. So, looking at testosterone, this indicates that -- we've got to get there first, don't we? So this indicates that AHCA covers testosterone, and each of these formulations listed on the PDL for at least one indication, although based on the PDL, we don't know which indications for which it covers; is that correct?

A Yeah. I mean, there's a very large number of FDA-approved clinical indications for testosterone.

Q Okay. Just for clarity, AHCA will never cover testosterone when used to treat gender dysphoria, is that correct?

A Yes.

Q And it looks like, at least some of these formulations, including, for example, Andrew Durham,

four milligrams, 24-hour patch, that there is a clinical prior authorization that's required. Is that correct?

A Yes. Yeah. Based on the PDL? Yes, there would be a PA required.

Q For what uses or indications does AHCA provide prior authorization or approve coverage?

A So that goes back to our definition of medical necessity.

Q Okay. Would it also be governed by AHCA's drug criteria? And I'll just -- I'll pull that up. So when I say AHCA's drug criteria, I'm referring to that criteria listed at https://AHCA -- A-H-C-A --.myflorida.com/Medicaid/prescribed_ drug/drug _criteria.shtml.

And so would the drug criteria -- I'm looking at the screen. It says testosterone criteria updated 6-16-2022. Would the indications for which testosterone will be prior authorized -- prior authorized, would it be contained in this criteria?

A It would be contained in that criteria. That's correct.

Q Okay. Is this list exhaustive of all prescription drugs that AHCA will cover?

A I think -- I mean, I haven't seen the entire list, so -- but, I mean, for any drugs that we deem that

criteria is necessary, I imagine that would be an exhaustive list.

Q Okay. This applies in fee-for-service, correct?

A Those would apply for fee-for-service, yes.

Q How about for managed care?

A Managed care plans would need to be able to -- they would -- they would need to mirror their criteria and align it with the agency's.

Q So it can't -- my understanding is the managed care plan criteria cannot be more restrictive than what AHCA --

A That's correct. So they can be less restrictive, they can't be more restrictive.

Q Okay. Would the drug criteria listed here at the link to testosterone provide all the instances in which testosterone would be covered after prior authorization review?

A On the criteria?

Q Uh-huh?

A After --

Q Yes.

A Well, I would -- I'd have to -- I haven't actually had a chance to physically look at the criteria, so -- but I would assume that what we have the

criteria is accurate, especially given that it was updated in June 2022.

Q Okay. Turning back to EPSDT briefly. If the drug was being prescribed to a child under age 21, when AHCA or its contractor was undertaking the prior authorization process, could AHCA or that contract -- would AHCA or that contractor deviate from this criteria if the drug was otherwise prescribed for a medically necessary use?

A I have trouble following that question.

MR. JAZIL: Object to form.

BY MS. DEBRIERE::

Q So where testosterone was prescribed to a child under 21.

A Okay.

Q And EPSDT applies, then could AHCA or its contractor in its prior authorization review deviate from the criteria listed here? If medically necessary.

A As long as it meets medical necessity criteria, whether or not there's criteria involved and it meets -- if it's for an off-label use and it meets our off-label criteria, I mean, under EPSDT, I mean, yes, Florida Medicaid can cover it, but -- I mean, that would, of course, require significantly in-depth review, et cetera, but, I mean, hypothetically speaking, yes.

Q And one of the requirements -- just to circle back -- one of the requirement under that medical necessity review is that the prescribed drug cannot be for an experimental or investigational use, correct?

A That's correct.

Q All right. Just turning quickly back to FMMIS programming of the ICD-10 codes, what ICD-10 codes are programmed into the system for estradiol?

A What ICD-10 codes?

Q Yes.

A We would have to check the system. I would -- because I know pharmacy codes are set up a little differently than our procedure codes. So I'm kind of using the procedure code as analogous to the drug codes, but we would need to speak with one of our pharmacists.

MS. DEBRIERE: Can we flag that as a follow-up question, too? I had one more. So if you -- can we take a break for two minutes? I just want to confer -- or we can do longer if you need a second to go to the bathroom.

THE WITNESS: If you need a break, you can go ahead and take the break. That's fine.

MS. DEBRIERE: Thank you. Okay.

VIDEOGRAPHER: This concludes video one. The time is 11:05 a.m.

(Brief recess.)

VIDEOGRAPHER: This is the beginning of video two. The time is 11:08 a.m.

BY MS. DEBRIERE::

Q All right. So turning back to the preferred drug list, AHCA's preferred drug list, and looking at the formulation of testosterone cypionate -- did I say that correctly?

A I really don't know.

Q The PDL indicates that AHCA covers testosterone cypionate for at least one indication, although it doesn't say what indication, correct?

A Not on the PDL, no.

Q Does it say it anywhere? Is there anywhere we can find that information?

A Unless there's that criteria, unless we have a criteria listed on the website, generally, no, that's like one of the things -- I mean, we do have our claim system set up, which -- but like all that information is -- I mean, I suppose it could be obtained through public records request. That's usually the process.

Q Okay. So AHCA will never cover testosterone cypionate, or any formulation of testosterone for treatment of gender dysphoria, is that correct?

A That's correct.

Q So looking at the formulation of testosterone cypionate of testosterone CYP 1000 milligrams per 10 milliliters, that indicates there's no clinical prior authorization required, correct?

A That's correct.

Q So that means that AHCA will cover the drug or reimburse for the drug without determining for what use it's being prescribed?

A Well, based on my understanding of how our system works, through my experience is that the claim would deny.

Q Because why?

A Because the diagnosis code that'd be associated with that drug would trigger the system to do a denial.

Q Okay. So you're looking not at the indication of the -- what indication the drug's being prescribed for, but instead you're looking at the diagnostic code?

A So -- that's correct. Part of the process requires the procedure code, diagnostic code and place of service. Of course, those are for our health services, but those three all have to be programmed into the system. So say you're delivering a -- doing a checkup in a other setting, or you're doing like a setting that's not approved by us, it's not in our

policy, that claim would deny.

Q Okay. What if it wasn't for the treatment of gender dysphoria? What if it was for a diagnostic code that was not programmed to automatically deny?

A If it was for -- so if it was for a diagnosis code that was not programmed to deny?

Q Right.

A If it's programmed in the system -- we don't -- so we program the codes that it will approve. So all the other codes, it's not loaded in the system would automatically deny. So each -- so there'll be a set of ICD-10 codes that are -- that would link up with a particular service. As long as the diagnostic code corresponds to that service, the claim will pay.

Q Okay. So with the formulation of testosterone cypionate that we've been discussing that no clinical prior authorization is required, if the diagnostic code is programmed into the system, then it's going to automatically approve without looking at the indication for which the drug is prescribed?

A Provide that the claim form is -- it's a clean claim and all the pertinent information corresponds with the physician requirements, they will pay.

Q What is involved in a clean claim?

A No errors.

Q Errors of what?
A Someone might type in the wrong code by accident. Maybe they -- human error.
Q Okay. But you're -- but in that clean claim, there's no requirement to submit the indication for which it's being prescribed or AHCA undertaking a review of that?
A I mean, we do do retrospective review of claims.
Q At the time the coverage is being requested.
A Okay. Can we go back a little bit?
Q Yeah, yeah. Yeah. So looking at this formulation of testosterone cypionate, where no clinical prior authorization is required, when the claim is submitted and -- when the claim is submitted, AHCA is not doing a review of whether the indication it's being prescribed for -- sorry. Scratch that.
Looking at testosterone cypionate, in the formulation that we've been discussing where no clinical prior authorization was required, when the claim is submitted, AHCA -- neither AHCA nor its contractors does a review to determine for what indication the drug is being prescribed for?
A Right, there'd be no manual clinical review process or prior authorization process, if that's what

you're asking.

Q And when you said AHCA will only cover drugs that are FDA-approved, does that mean that AHCA never covers off-label use of a drug?

A We do have a -- no, we definitely would never -- we have a procedure for covering FDA-approved drugs for non-approved clinical indications, AKA off-label use. We do have a procedure for that. So we wouldn't necessarily -- no, we would never say never. That's --

Q Okay. I thought you said earlier that AHCA will only cover FDA-approved drugs?

A Right. But, I mean, like, let's say there's a drug that -- okay. Let's say it's been manufactured by European pharmaceutical or, you know, it's a pharmaceutical and it hasn't gone through the FDA review process, brand new drug. It's not FDA-approved. It's really not even approved -- it's not even approved for sale on the market. We won't cover those.

Q Okay. Okay. But you will cover drugs that are FDA-approved for uses that in and of themselves are not FDA-approved, for off-label uses?

A Yes, we have a procedure for that.

Q Okay. Do you ever program into the system the use of a drug for a condition for which the drug is not

FDA-approved?

A I can't speak to a hundred percent for that, but it seems it'd be counter to the process we have in place for reviewing off-label use for drugs.

Q Okay. And what is that process?

A So, it's a three-prong process. Step one is that there has to be a trial period for FDA-approved drugs for that clinical indication to have tried to have been used. And, of course, if the FDA-approved drugs for that kind of indication are not successful, then the -- then it moves to the second prong, which, you know, that requires like phase-three clinical trials having had to be completed on that drug. Then the third step is that the peer-review literature and one of the three drug compendia that we mentioned earlier has to pass the list or support it.

Q So you're looking at when determining whether or not you'll authorize coverage for a prescribed drug, you're looking at more than just whether the indication for which it's being prescribed is listed in the compendia?

A Yes, it's a little bit more comprehensive, correct.

Q Yeah. And so first you look at the individual Medicaid recipient and you determine whether or not they

tried other drugs?

A That's correct, yeah.

Q Okay.

A It would be an individualized basis.

Q Okay. And then the second step was what?

A A phase-three -- the drug had to have completed phase three clinical trials.

Q And then the third step is you look to see if the indication that's being prescribed for is listed in the compendia plus --

A Plus support in the peer-reviewed literature.

Q Okay. Let's look back at Exhibit 3.

MS. DEBRIERE: Simone, do you have that handy? That's the cross-sex hormone therapy GAPMS.

MS. CHRISS: You should still have those two versions.

MS. DEBRIERE: I might have it. I have a notice of deposition and I have a cross-sex hormone therapy. Here it is.

BY MS. DEBRIERE::

Q Is there anywhere on this GAPMS that describes the process for the criteria used?

A It's on page nine, if you're referring to the off-label use.

Q Okay. And that starts with the criteria that

utilized under the Florida Medicaid program and authorization for drugs for off-label purposes are as follows?

A Uh-huh.

Q Okay. And that's what you just described to me?

A Yes.

Q Yeah. Okay. All right. Turning to past GAPMS regarding gender dysphoria.

A Okay.

Q We are aware, plaintiff's counsel is aware of three pre-2022, at least draft GAPMS reports regarding Medicaid coverage of the treatment for gender dysphoria. One we've already marked as Exhibit 3, and that is the May 20th, 2022 version of the GAPMS for cross-sex hormone therapy. We actually know of two other versions, one dated June 23rd, 2017 and one dated April 19th, 2022. So we're going to mark the June 23rd one as Exhibit 5?

MS. DUNN: Yes.

(Whereupon, Exhibit No. 5 was marked for identification.)

THE WITNESS: Yeah. I have to apologize for the auto-dating on those documents, so I can probably give you more accurate dates --

BY MS. DEBRIERE::

Q Yeah, let's get the documents in front of you, and then that's exactly what we were wondering about. It can get confusing.

A I can give you more --

Q That would be -- that's exactly what we're after. We appreciate that.

MR. JAZIL: They're identical except for the date, right?

MS. DEBRIERE: Yes. Yeah -- well, that's not true. Yeah --

THE WITNESS: Well, I have this one. I mean, it's fine. There's one -- there should be one for surgeries.

MS. DEBRIERE: No, no. We're just looking at the versions of cross-sex hormone therapy right now. We have three different versions, at least, that we've found so far.

MR. JAZIL: Thank you.

BY MS. DEBRIERE::

Q Okay. So let's first look at the one with the June 23rd date.

A Okay.

Q June 23rd, 2017. Who authored the version of this report?

A So listed in our assignment writing and tracking page in SharePoint, the author of this was Sarah Craig.

Q Okay. And do we have that routing form?

MR. JAZIL: You should.

THE WITNESS: They should have it. We -- I did produce it for everybody.

BY MS. DEBRIERE::

Q Okay. And then that was back in 2017 when she authored this?

A She authored it in 2016. This is actually -- so to provide a little context.

Q Please.

A So in 2016, this was before I came to the Bureau of Medicaid Policy, there wasn't -- there wasn't a GAPMS position. Because they were accumulating a lot of services, a lot of requests for coverage, they created two GAPMS positions in the fall of 2016. They were filled in January 2017. So GAPMS reports often went to subject matter experts. So that's -- so in 2016 when this one was completed, the person who completed it, their primary job was not GAPMS.

Q Okay. What was Sarah Craig a subject matter expert in?

A She was one of our pharmacists.

Q Okay. And right now, just for clarity of the record, we're looking at June 23rd, 2017. That's labeled Exhibit 6.

(Whereupon, Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE::

Q Who -- so saying that, let's move on to the April 19th, 2022, which is labeled as Exhibit 5, who authored this report -- or made the revisions, I should say, in the April 19th, 2022 version?

A The only person I'm aware of who worked on this one was Sarah Craig. Since this was done before my entrance into the Bureau, and she's the only author listed in our system.

Q And were any changes made on the April 19th, 2022?

A No. That may have been a day when it was pulled out to be printed.

Q Okay. Why would it have been pulled out to be printed?

A I think -- because there had been some questions about the history of whether the Agency had previously done any work on this subject.

Q Okay. And why did those questions arise?

A Those questions had arisen as part of the

request process for the GAPMS report we did, and that was approved on June 2nd.

Q And that's related to the treatment of gender dysphoria?

A That's correct.

Q Okay. Does Sarah Craig still work at the Agency?

A Sarah Craig, I think, left in 2020.

Q Okay. Do you know where she went?

A I do not.

Q Were there any changes -- looking back at Exhibit 3, which is dated May 20th, 2022, there are some revisions on this one.

A Okay.

Q For example, Beth Kidder is crossed out and Ashley Peterson's name is put in. And the subject line is crossed out and there's just some edits and comments. And it looks like some text was added, for example, on page three.

A I was not privy to any edits or changes being made after -- I was not privy to any changes being made to that document.

Q Okay. Well, just to be clear, you're here as the Agency representative and not in your individual capacity, so you should have some knowledge about any

revisions to these reports, based on your designation as the Agency representative. Can you not speak in that capacity to it?

A As far as the work goes during the time period that we were working on the June 2nd GAPMS?

Q Uh-huh.

A That -- the work for the determination of the transgender dysphoria in relation to consistency with GAPMS, that task was specifically designated to myself, and Nai Chen and Devona Pickle in supporting roles.

Q Okay. Right now, though, I'm just asking about revisions made to the May 20th, 2022 version. You do not know who made these revisions, is that correct?

A I do not know who made those revisions, because -- as the Agency witness. Nobody was requiring revisions to that document.

Q But there were revisions made based on what I'm looking at.

A Whoever did so was doing so on their own accord.

Q Okay. Who had access to this document?

A Well, given that any -- actually, anybody has access to that document because the documents -- it's available on our SharePoint site. It doesn't require a password. Anyone in the bureau, anyone who's

knowledgeable of our repository could go through and pull up that document.

Q Okay. Could it have been Ashley Peterson who made the revisions?

A It's possible. We would have to find out from our IT department.

Q Okay. I think we do need that information. And then who's GS? There's some comments on the side there on the front page, Exhibit 3. It says GS 1.

A Well, GS would be initials. Would usually like last name first, first name second. I might -- might occur to me later on. I can't --

Q Would it be Sheena Grantham?

A It's possible. I don't know.

Q Okay. Can you track who has access to this document?

A Yeah, our IT department can track whoever had made edits to that.

Q Okay. Okay. So we can find out the answer to that question?

A Yes.

MS. DEBRIERE: Let's flag that.

BY MS. DEBRIERE::

Q Was this report ever finalized?

A To my knowledge, and I did actually do some

history -- do historical digging on this one. Since our pharmacy manager at the time, and I do need to add it because I forgot to add, that I did consult Arlene Elliot, who was the pharmacy manager at the time that this report was initially prepared, I did confer with her to determine whether or not it was finalized. And what I mean by finalized, it went through the review process and was signed off by the deputy secretary. She let me know that it had not.

Q Okay. Do you know why or why not? Why was it never finalized?

A Well, generally, and this is often the case with GAPMS reports, is that because it's -- well, Medicaid is a -- it's very busy -- we're a very busy division. We have lots of requests, lots of asks, lots of projects, and often GAPMS reports, usually, for those of us who like to be very detailed and very analytical, we, you know, it's -- it's a craft. It's almost like each one is like a seminar paper or scholarly article. It takes time to read and review. And usually it's -- and sometimes often, because unless somebody's asking for it, or if it's deemed a low priority, often it just -- it just often waits. And that may have been why. That's speculation, though.

Q Okay.

A But it's not surprising that a GAPMS draft is out there and didn't complete the review process. Solely it's because there's just too many other projects going on.

Q And GAPMS is generally low priority?

A It depends.

Q What does it depend on?

A Depends on the situation, because often when the managed care plan requests for the GAPMS, that's usually -- those usually have to be addressed quickly.

Q Okay. Let's set expedited GAPMS aside. Just traditional GAPMS, are they generally low priority?

A A traditional GAPMS? Well, like I said -- like I said, it often depends on the context. It depends on the request. Sometimes it could be -- sometimes it's a stakeholder who made their voice known downtown. Sometimes -- I mean, it really depends on the context.

Q Okay. When you're referencing downtown, what do you mean by that?

A The Capitol.

Q Okay. So sometimes GAPMS will get bumped up if the Capitol is the person who's raising --

A It just depends on the situation/I just don't want to commit to an absolute answer saying that they're

all low priority, because not every single circumstance or every single GAPMS means that it will be.

Q Okay, but with the cross-sex hormone therapy GAPMS, you're guessing that one reason why it was never finalized is because it was low priority?

A That's a guess in relation to my experience when I had the role.

Q Okay. And what was your experience when you had the role?

A When I -- when I had the role, I had it for about 10 months, and I think I drafted ten reports and two of them made through the review process. Those two I reviewed in January. They weren't finalized and signed off on until July of that year. So often, it was more trying to -- you know, reminding supervisors at different levels to review them so they can move forward. And given how busy everything was, especially with legislative session going on or other special projects taking precedence, often if it could be done -- put on hold until the next day or later, it was.

Q Okay. And so for the two of the ten reports that were finalized, it took seven months for the reports to be finalized, reviewed and finalized?

A Yes.

Q Prior to its adoption, prior to AHCA's

adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid -- were there any instances where Florida Medicaid ever authorized coverage for cross-sex hormone therapy to treat gender dysphoria?

A Were there any circumstances? The Agency didn't have a policy or criteria regarding cross-sex hormones or, like, hormones for that clinical indication.

Q So that wasn't quite my question. My question is prior to the adoption of the categorical exclusion of treatment for gender dysphoria, were there any instances, so --

A Under -- so, well --

Q Did Florida Medicaid ever cover treatment of gender -- use of -- did Florida Medicaid ever authorize coverage for cross-sex hormone therapy to treat gender dysphoria?

A So by Florida Medicaid, are you referring to the Agency?

Q AHCA or any of its contractors, Medicaid managed care plans or EQ Health or --

A Under fee-for-service, that was -- no, it was not an approved clinical indication. Obviously, with managed care plans, since they have the flexibility to

cover services that, you know, that are not necessarily clarified in our coverage policies so -- I mean, it's possible that we could have done that, yes.

Q Okay. So, to be clear, in fee -- under fee-for-service, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, there was never an instance of Florida Medicaid covering cross-sex hormone therapies to treat gender dysphoria?

A Are you referring to the fee-for-service?

Q Fee-for-service only.

A We don't necessarily have that information available.

Q Why?

A Well, not offhand.

Q Why?

A Well, going -- because we want to go back several years. We're assessing an extensive data pull.

Q Or even just six months prior to August 21st, 2022.

A So I think we did do a data pull for the past year. And that data pull, of course, show the results of what services we were covering, had the number of recipients with the diagnosis for gender dysphoria, and those who received treatment. So I'll defer to that

data.

Q So we don't have that data in front of us. And, again, you were produced as the 30(b)(6) representative, so what did that data show?

A That data did show that some -- that there were a handful of recipients who were receiving the services.

Q In fee-for-service?

A I think fee-for-service. I think managed care.

Q Okay. So there were times, prior to the adoption of the categorical exclusion for the treatment of gender dysphoria, that Florida Medicaid covered cross-sex hormone therapy for treatment of gender dysphoria?

A Cumulatively for the whole program, yes, there were.

Q Okay. So another previous GAPMS regarding gender dysphoria is the GAPMS entitled puberty suppression therapy, and that begins at DEF_ 000288776. Although, for clarity of the record, I do want to say we received multiple versions of this document, as well.

MS. DEBRIERE: Do we have the final one, by any chance? I'm positive it was my mistake in terms of listing exhibits.

MS. DUNN: The one that was signed?

MS. DEBRIERE: Yeah.

MS. DUNN: That's a whole different -- it has a different name.

MS. DEBRIERE: I'm sorry, guys. That's my fault. My fault.

MR. JAZIL: Counsel, do you want him to clarify that date issue? I think he mentioned it as you were --

MS. DEBRIERE: Oh, yeah, I thought he did. I'm sorry if -- please, go ahead and clarify the date issue.

THE WITNESS: So both of these GAPMS were initiated in 2016.

BY MS. DEBRIERE::

Q Okay. When you say both of these GAPMS, you're referring to --

A Referring to the one on the cross-sex hormone therapy.

Q Okay.

A And the one on the puberty suppression.

Q Okay. Let's not talk about the puberty suppression one just yet, because I want to get the right exhibit into the record first.

A Okay, but as far as the date goes, these were

projects from 2016.

Q Okay. Okay.

MR. JAZIL: Counsel, if you'd like me to just make additional copies of that, I'm sure we can.

MS. DEBRIERE: So there are multiple versions that were provided to us of this document. We are looking for another version that has a signature on it, although I'm sure Mr. Brackett can speak to it being finalized. But just to make everyone's life easier in the long run, we are going to try to -- yeah, this is great. Okay.

Chelsea, should we mark it?

MS. DUNN: Yeah. Do you want that Exhibit 7?

MS. DEBRIERE: Are we on 7? Okay.

(Whereupon, Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE::

Q All right. We have only one copy of this, and it's DEF_000288776, entitled puberty suppression therapy, dated September 14th, 2016. And the reason we were -- and that's going to be marked as Exhibit 7. The reason we wanted that one is because if you turn to the back page, it's signed by Mr. Senior. So we assume then that's the final report?

A This would be the final report if he signed

it.

Q Okay. So it was adopted by the Agency?

A The recommendations in this GAPMS were -- yes, they would be adopted.

Q Who authored this report?

A So in the --in our system, our SharePoint system, that was the individual listed for this report was Monique Johnson.

Q Okay. And who was Ms. Johnson? What was her subject matter expertise?

A So she was a program administrator and she oversaw the primary care services team, which is primarily like surgeries, inpatient -- inpatient services, dental services. Like, I think like surgical procedures, things like that. Of course, child health checkup procedures. Generally be like primary care and preventive, anything that would fall into those categories.

Q Why would she then look at puberty suppression therapy?

A So this was, at the time before we had the defined GAPMS individuals, so I can only speculate as to why she was selected. It may have been she had bandwidth at the time to do it, but since there was no one who actually did GAPMS full time, I don't -- I can't

speak as to -- because I'm not that familiar with her background, I can't -- and, of course, this was 2016, but more or less, there may have been a number of reasons for why she was selected for this.

Q Okay. Why wouldn't it have gone to a pharmacist?

A We don't have the -- an answer for that.

Q Was Ms. Johnson a pharmacist or pharmacy tech or had any --

A I think she was an RN.

Q Okay.

MR. JAZIL: Counsel, just so the record's clear, this copy of Exhibit 7 has highlights on it. Did you --

MS. DEBRIERE: It would have not been -- it would have been highlighted by us. Is that right? Yeah. So my apologies.

MS. DUNN: It's the only copy we have, but we can potentially print a clean copy.

MS. DEBRIERE: And it's Bates-stamped.

MR. JAZIL: It's fine. I just want the record to be clear that it's highlighted and the highlights were added by counsel for plaintiffs, not the witness.

MS. DEBRIERE: Yes. Thank you for that, Mo.

BY MS. DEBRIERE::

Q Okay. So going back to Exhibit 4, pubertal suppression -- yep. This is the special services criteria. This was developed only six days after the puberty suppression therapy GAPMS report. Is that correct?

A You mean the criteria?

Q Yes. Yes. Exhibit 4.

A Based -- I'm going to defer to the dates on this, because it predates my time in the Bureau of Medicaid Policy. So if the dates say 30 days, then that would be --

Q The dates say six days.

A The dates say six days?

Q Yeah.

A I'll defer to that.

Q Okay. Are these two documents related?

A Can you provide some context on what related means?

Q Is one based off another?

A It seems -- it would appear that following the completion and approval of the GAPMS process, that this document was completed, routed and then approved, based on the time stamps.

Q Okay. So was the special services criteria at

Exhibit 3, was it drafted based on the information contained in the GAPMS report related to puberty suppression therapy?

MR. JAZIL: Exhibit 4?

MS. DEBRIERE: Did I say 3? I'm sorry. Exhibit 4. Thank you, Mo.

THE WITNESS: It looks like it's fairly consistent.

MS. DEBRIERE: Okay.

THE WITNESS: Based on the EPSDT consideration portion.

BY MS. DEBRIERE::

Q So based on your understanding of office operations, then it's likely that the special services criteria was drafted in response to the puberty suppression therapy GAPMS?

A Yes.

Q Okay. And this is the -- this policy, Exhibit 4, is the criteria that AHCA used prior to its adoption of the categorical exclusion of treatment for gender dysphoria to determine whether gonadotropin-releasing hormone analog would be prior authorized for pubertal suppression and treating gender dysphoria, correct?

A Yes, correct.

Q Okay. Between the time this policy was

adopted, which was October 6th, 2016, and the time AHCA adopted the categorical exclusion of treatment for gender dysphoria in August of 2022, if an individual's condition met the criteria laid out in this policy, then Florida Medicaid would cover the cost of the drug for pubertal suppression and the treatment of gender dysphoria, is that correct?

A Providing that the criteria, and prior to the challenge exclusion, yes.

Q Okay. Between October 6, 2016, and the time AHCA adopted its categorical exclusion of treatment for gender dysphoria, how many times did AHCA authorize the drug set forth in this policy for the treatment of gender dysphoria?

A We would have to defer at least -- at least prior to the challenge exclusion being implemented, we'd have to defer that data for that time period, but we'd have to go all the way back to 2016 as far as the data goes, at least in fee-for-service, to determine how many recipients actually received the -- actually received authorization for it.

Q Do you have any knowledge of any time period in which fee-for-service covered it, based on the criteria in this policy?

A So this -- so once this policy -- so once this

criteria was released to Magellan, Magellan was our PBM for fee-for-service. So they did the prior authorizations for fee-for-service. So Magellan would review each case individually.

Q Okay. Do you know how many times Magellan authorized it based on the criteria?

A I do not have those numbers.

Q Okay. Can we get those numbers?

A We can try to find them. We can try to get those numbers. It's a very long time period.

Q But it is your understanding that in certain instances, Magellan did authorize it?

A We would have to -- we would have to look at those numbers.

Q Okay. Because previously, when we were discussing cross-sex hormone therapy, you did know that in some instances fee-for-service had covered the drug to treat gender dysphoria, but you don't have that same information for pubertal suppression?

A That's speaking more about Medicaid, cumulatively as far as the differences between fee-for-service and managed care encounters, I would have to take a look at the data to get the exact numbers of what was in the fee-for-service system versus the encounters for the managed care were. But we would --

have we would have to go ahead and get this information from Magellan going back to find out exactly how many times that they get pre-authorization requests versus how many approval/how many denials.

Q Okay. Let's just look quickly at exhibit -- it's going to take me a second to find it.

MS. DEBRIERE: Simone, is the list of Medicaid recipients and discussion of their authorizations -- yeah. I don't know. Yeah, that's it. Not surgery, though. There should be a drug one. Maybe I'm wrong. They probably didn't include it.

BY MS. DEBRIERE::

Q Mr. Brackett, while we're looking for that, let's go back to the notice of deposition. In the deposition topics, we do list the number of Florida Medicaid recipients who -- participants who have sought any form of care for gender dysphoria from January 1st, 2015 until the enactment of the challenged exclusion. And so as we're sitting here today, you're telling me you can't answer whether -- or how many times AHCA or one of its contractors authorized coverage of pubertal suppression therapy for treatment of gender dysphoria, is that correct?

A That's correct, as of now, but we can get that

information.

Q And you will provide us that information?

A We will obtain that information.

Q Okay.

MS. DEBRIERE: So I think that given that there are a few places where we have follow-up questions I do, at this point, just want to say that once those questions are answered, we're going to reserve some time for this deposition so that we can do follow-up questions based on the information that's provided to us, because right now there's some holes that Mr. Brackett is not able to fill, and once that information is provided to us, of course, we will probably have follow-up questions. So we just need to reserve some time for --

MR. JAZIL: Okay. And just so the record's clear, I think I provided objections to the last set of depo topics. There may have been an objection to this particular topic, going back to 2015, but we'll work with you. If we can gather the information, we'll provide it.

MS. DEBRIERE: Okay.

BY MS. DEBRIERE::

Q So looking at the final GAPMS report related to treatment of gender dysphoria, it's entitled gender

confirmation surgery.

MS. DEBRIERE: Oh, gosh. Do we have it from the past deposition? I'm sorry. We had, like, over 50 exhibits and clearly it's completely my fault not putting them in the list. We can always pull back around to them and print it out at lunch, too. There it is. Okay. We're going to mark this one as Exhibit 8, and it's entitled GAPMS gender confirmation surgery, dated July 19th, 2017.

(Whereupon, Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE::

Q And this one does have markups on it that are not our markups, they're from the Agency. Who authored this report?

A So this report is authored by Rebecca Buceo.

Q Okay. When?

A This was authored in the summer of 2017.

Q How do you know who was authored by?

A I was in the bureau at the time and was present when the project was being assigned out.

Q Okay. Why weren't you assigned the project?

A I was actually being assigned -- I was working on another project related to designated state health programs and getting approval for those through the

Centers for Medicaid -- Medicare and Medicaid Services. So I was actually on a kind of a legislative priority project. And so I was not assigned to this one.

Q It's my understanding that there's only one hard copy of this report, is that correct?

A That's correct.

Q Okay. Whose office was it found in?

A So, I -- this report, I did -- it was in a binder with -- so this report was found in Rebecca Buceo's old office. So she had an office in the bureau. I know she maintained her GAPMS materials there.

Q Okay. And what else was in that binder?

A I think some of the research articles she used.

Q Is that it?

A That was it.

Q Okay. Is Rebecca Buceo still with AHCA?

A No, she's not.

Q When did she leave?

A I believe she left in 2019.

Q Okay. And what was her subject matter expertise?

A She had a behavioral health background. That was her -- that was her subject matter expertise.

Q Did she have any expertise in surgery?

A Not professionally, no.
Q What about not professionally?
A In other words, she's never worked as a surgeon or anything like that. But, I mean -- but I mean -- or in the formal education in that area.
Q Okay. But did she have any experience with surgery that would help her inform the drafting of this GAPMS?
A I couldn't speak to that.
Q Did AHCA ever rely on the conclusions in this report?
A So this report did not get past her immediate supervisor, so, no.
Q Okay. Prior to its adoption of the categorical exclusion of treatment for gender dysphoria, did Florida Medicaid ever cover gender confirmation surgery for the treatment of gender dysphoria?
A Under fee-for-service, to the best of my knowledge, we didn't. In managed care, there were a few instances where the managed care plan did approve the procedure.
MS. DEBRIERE: Okay. Can we look at those exhibits now? The -- I forget what they're called. They're a weird name. ATTB, ATTA. It's a weird name. It wouldn't come to me.

BY MS. DEBRIERE::

Q Okay. So I'm handing you -- these were natives, so they were not Bates-stamped, but I'm handing you documents produced to plaintiffs in discovery. They were also not labeled, and I just want to ask you some questions about what they mean. We'll mark that as exhibit -- actually, I'll take those copies. I'm sorry. Well mark this as Exhibit 9 and 10. And, I'm sorry, because they're natives, they don't have Bates stamps.

(Whereupon, Exhibit Nos. 9 - 10 were marked for identification.)

BY MS. DEBRIERE::

Q So looking at Exhibit 9 first, which is two pages total, front and back.

MS. DEBRIERE: Seems like they -- yeah, it printed out -- I see. Do I put it together? What do we do?

BY MS. DEBRIERE::

Q Let's look at under service type, outpatient surgery. Line item status is approve. Does that mean that Florida Medicaid approved outpatient surgery?

A Yes, that would mean it was approved.

Q Okay. And the product description was mastectomy with a primary diagnosis code of F649?

A Uh-huh.

Q So that means that the outpatient surgery was approved for a mastectomy for a diagnosis code of F649, is that correct?

A That's correct.

Q Okay. And F649, what is that diagnosis code?

A That's gender dysphoria.

Q Do you know if -- can you tell by this document whether -- it appears that it was approved by children's medical services under product roll-up.

A So based on these two -- so based on these two, I can't tell if the recipient is in managed care or if they're in fee-for-service. So in Exhibit 10 --

Q Yeah.

A -- this looks like this would be managed care.

Q Okay. And how do you know that?

A Because it has, like, the member effective category.

Q Okay. If the title of both of these documents had the term CMS on it, would that mean that it's managed care?

A Children's Medical Services is overseen by Sunshine Health. So, yes, it's managed care.

Q And looking at Exhibit 10, the Medicaid ID, does that correspond to individual Medicaid recipients?

A Each Medicaid recipient has a unique Medicaid

ID assigned to them. That's correct.

Q Okay. And these documents are indicating that there were authorizations of surgeries for primary diagnosis codes of F640 and F649, is that correct?

A Yeah, that's correct.

Q Okay. And F640 is a diagnostic code for what?

A So F64, generally, there is a decimal point after the 4. So it was F64. The way ICD-10 codes work, it's kind of like a taxonomy. So F64, categorically, is gender dysphoria. So F64.9 would be like a -- like a subcategory of that general diagnosis.

Q So these documents are showing that, at least in managed care, prior to the categorical exclusion -- prior to AHCA's adoption of the categorical exclusion for the treatment of gender dysphoria, there were times in which Florida Medicaid covered surgery to treat gender dysphoria; is that correct?

A That would be correct.

Q Okay. Let's turn to the June 2022 GAPMS. We have this exhibit. And Exhibit 11 will be the June 2nd, 2022 GAPMS related to the treatment of gender dysphoria.

(Whereupon, Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE::

Q I'm going to refer to this throughout as the

June 2022 GAPMS.

A That's fine.

Q When was the request to initiate this GAPMS made?

A So the formal request was made on April 20th. That was the date of the Secretary's letter.

Q Were there any informal requests prior to that time?

A There were some informal, I guess, indicators of, you know, trying -- when they were trying to determine whether or not we had bandwidth, you know, and so there was some informal indicators that this project would be coming down the pipeline because they were trying to figure out who to do it. So we were aware of the Secretary's letter it would be coming to us.

Q Okay. When you say they were trying to figure out. Who is they?

A Our Agency leadership.

Q And who is that comprised of?

A So that was primarily for the Bureau of Medicaid Policy, Ann Dalton was our bureau -- is still our bureau chief at the time.

Q So Ann Dalton had knowledge of the potential for this project coming down prior to April 20th, 2022; is that correct?

A Yes.

Q Okay. Who else in leadership was aware that this would be coming to AHCA prior to April 20th, 2022?

A At the time, Secretary Weida was serving as Assistant Deputy Secretary. He did have knowledge.

Q Okay. Anybody else?

A To my --to my knowledge, those two were the ones with the knowledge of this project.

Q Okay. When did you have knowledge of the project?

A Just probably a few days before we were given the letter.

Q Okay. So, like, April 17th?

A Something around there. Yeah, I don't remember the exact date.

Q Okay. Who did you gain the knowledge -- who did AHCA leadership gain the knowledge from?

A As far as the project goes, the decision to do a GAPMS to my -- so that was to do a GAPMS report, that was determined by our legal as the best route to evaluate the medical necessity for treatments for gender dysphoria. It was that -- it was subjected to the GAPMS process.

Q Okay. And which counsel was that?

A Andrew Sheeran, who's now our General Counsel.

Q Okay. And who contacted -- was Mr. Sheeran the first point of contact related to what eventually became the June 2022 GAPMS?

A No, I don't think he would have been the first point of contact.

Q Who would have been the first point of contact?

A Generally, our first point of contact would have been our General Counsel at the time.

Q And that was?

A Josephina Tamayo.

Q Okay. And who contacted Josephina Tamayo about this project?

A So this project, about the GAPMS in particular --

Q No.

A -- or about requesting a Medicaid review?

Q Requesting a Medicaid review.

A So that, of course, that did come down from the Governor's office.

Q Okay. Who in the Governor's office made the request?

A So that is -- so it was a multi-party meeting. So the three staffers from the Governor's office that were involved were, I think, Katie Strickland, Ryan

Newman and Maureen Farino.

Q Okay. What other agencies were involved?

A As far as the decision for Medicaid's review?

Q No, as far as that initial request coming from the Governor's office. You said there was a multi-party meeting.

A Well, between AHCA's staff and Governor's office staff.

Q I see. Okay. What other AHCA staff were present at that meeting besides Ms. Tamayo?

A I think at that meeting, I think Deputy Secretary Weida may have been present, I think the General Counsel, I think, Andrew Sheeran, may have been present as well.

Q Okay. Anybody else present at that meeting, besides those people that you just named?

A I can't name them with any specificity.

Q Okay. Were they from other agencies other than the Governor's office or AHCA?

A So in regards specifically to this project?

Q Are there other projects we should be aware of?

A Well, I -- there were, I think, some people present from the Department of Health.

Q Regarding what project?

A But that was regarding their review of treatments for gender dysphoria.

Q Based on actions related to the Board of Medicine or based on CMS guidance?

A What do you mean -- when you say CMS, are you referring to Children's Medical Services or --

Q No. Centers for Medicare. Great question.

A That guidance was actually not by CMS, it was from HHS.

Q Excuse me, HHS.

A It was in regard to that guidance.

Q Okay. So there was some presence of Department of Health there, as well, but not related to Medicaid?

A Right.

Q Okay. And what was the date of that initial meeting?

A I don't have -- know the date offhand. I think it was like early April.

Q Okay. And at that meeting, it had not yet been determined that AHCA would use the GAPMS process to evaluate whether treatment for gender dysphoria was experimental, is that correct?

A I think that -- yes, I believe that is correct, based on -- based on the information we've

gathered, is that the decision is to route it to the GAPMS process was done after that conversation.

Q Okay. So what was the Governor's office request for the meeting?

A The Governor's office request was to -- in response to the HHS documents, the Department of Justice documents, Department of Education documents regarding gender dysphoria, designing treatments for gender dysphoria, the evidence for gender dysphoria, it was that the Department of Health and AHCA both undertake reviews.

Q Did the Governor's office instruct AHCA to find -- did the Governor's office instruct AHCA to ensure that Florida Medicaid would not cover treatment for gender dysphoria?

A No.

Q Okay. Did the Governor's office make any specific requests about Florida Medicaid coverage as it related to the treatment of gender dysphoria?

A The Governor's office wanted the Agency to undertake the review.

Q But what type of review did it want the Agency to undertake?

A It wanted to take a look at -- a detailed look at the available medical evidence, or at least the

peer-reviewed literature, and to see what it says.

Q Okay. You referenced earlier the Florida Department of Health's investigation on the HHS fact sheet. What did that investigation find?

A So the Department of Health's fact sheet, of course, provide some cursory information, like go into some snapshots of some literature out there, you know, stating that the evidence for support -- that was supporting gender dysphoria treatment was too weak for this to be considered a standard treatment for that condition.

Q Okay. And so at the time of this initial meeting in early April, when there was a discussion of DOH's findings, at that point there was a conclusion that the information or evidence to support treatment of gender dysphoria was weak?

MR. JAZIL: Object to form.

MS. DEBRIERE: I can strike that.

BY MS. DEBRIERE::

Q Why did the Governor's office want AHCA to review Medicaid coverage for treatments of gender dysphoria?

A So in response to these documents, there were questions about whether or not the evidence supported what HHS, DOJ and DOE was -- at least the United States

DOJ, United States DOE, the claims they were making. They wanted to do a review to see whether or not this -- the evidence that's supporting was -- actually sufficiently supported those claims.

Q Did the Governor have a specific position on whether HHS' findings were accurate, prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: No.

BY MS. DEBRIERE::

Q Did DOH have a position on whether HHS' findings were accurate prior to AHCA's review?

MR. JAZIL: Object to form.

THE WITNESS: Can you rephrase that question?

BY MS. DEBRIERE::

Q Yeah. Did DOH -- at that initial meeting, what conclusions had DOH drawn about the HHS report?

A So DOH, they didn't -- they didn't release their opinions until April 20th, the day we got the letter.

Q Okay. But had they -- at that meeting, had they formulated those opinions?

A To my -- based on the information given to me, they had not yet formulated those.

Q So why did AHCA general counsel decide that

the best process to undertake the review was the GAPMS process?

A Because, well, I'm speaking based on our -- on how policy works is that, of course, the medical necessity definition does have a prong saying that the service has to be consistent with generally accepted professional medical standards. So the best way to do a review to either -- to determine whether or not something is consistent with GAPMS is to do that, undertake that review process, and that really provides the best opportunity to go through the literature on a large scale and to make a conclusion.

Q Okay. To your knowledge, had there ever been a time previous where a GAPMS was used to determine the experimental nature of services previously covered by Florida Medicaid?

A To my knowledge, there was not.

Q So this is the first time the GAPMS process was used to determine whether services that were already being covered by Florida Medicaid were experimental?

A To my knowledge, yes.

Q The folks at the initial early April meeting, did they reach out to HHS to get the info they relied on before conducting their own review?

A Are you talking about the Florida Department

of Health folks?

Q Or the Governor's office, anyone involved in that meeting.

A No, we -- with the releases, the document releases from those -- from those federal agencies was sufficient.

Q So AHCA did not reach out to HHS either?

A No, we had their documents. We didn't -- we didn't have any need to question them on them.

Q In the letter you're referring to from Secretary Marstiller dated April 20th, 2022, is that correct?

A Uh-huh.

Q That's the letter that directed Tom Wallace, the Director -- I'm sorry --

A State Medicaid Director, Deputy Secretary.

Q Thank you. That was the letter directing him to undertake GAPMS related to treatment of gender dysphoria, right?

A Yes.

Q Why did Secretary Marstiller's letter say that she was making the request in response to DOH guidance rather than a request from the Governor?

A Because the DOH guidance had just been published.

Q Okay. But she was asking Mr. Wallace to undertake that GAPMS process because it was a request from the Governor's office, correct?

A A request for the state agencies to look at the existing evidence and making recommendations, that initially came from the Governor's office. Since I wasn't physically -- since I personally was not present for those meetings, I can't exactly speak to the sequence, but DOH would undertake its review. And, of course, once they published their guidance, we undertook ours.

Q Okay. Just to be clear, there's a few times that you said to your knowledge, but, again, you're testifying as an Agency representative?

A Yes.

Q So this is to the knowledge of the Agency, correct?

A To the knowledge of the Agency, yes.

Q When did AHCA begin work on the 2022 GAPMS? What date?

A We started work on April 20th.

Q You didn't do anything prior to that?

A No. I mean, I may have done, like, an article search, just to see what was out there, but as far as any large-scale work goes, no, we didn't do -- we didn't

do anything like that.

Q Okay. And, again, just to be clear, no one at the Agency, because you're in the capacity as an Agency representative. So my question is not just about whether you started anything related to the 2022 GAPMS.

A The Agency did not -- did not start work until April 20th.

Q Who worked on the 2022 GAPMS at the Agency?

A You mean the June 2022 GAPMS?

Q Yes.

A So I was primarily the author. It was myself, Devona Pickle prepared the maps of the United State Medicaid programs. Nai Chen prepared the maps for the internet -- for the European countries to classify who covered what, but that was it. It was the three of us.

Q Okay. And I apologize. Can you just one more time run through what everybody's roles were? You were the primary author. Mr. Chen worked on the maps.

A Worked on the maps for Western Europe.

Q Okay. And what did Dede Pickle do?

A The maps for the State Medicaid programs.

Q Okay. And as primary author -- so you wrote everything else except for the maps in the state Medicaid coverage, then?

A That's correct.

Q Okay. And did you have any assistance?

A It's -- GAPMS are a solitary project, any extensive research project is, because once you immerse yourself in the literature, it's very difficult to have assistance because you're trying to get up to -- you have to transplant knowledge from yourself to them. It's actually just easier to do it, to kind of sail the waters on your own. And this is coming from speaking from experience on, like, a myriad of research projects, from scholarly articles, master's theses for, like, works -- other works for the Agency, previous GAPMS reports. Once you under -- once you reach a certain understanding of that knowledge, it comes a point where you -- it makes sense -- it's more efficient for you to do it in a solitary fashion.

Q Okay. So you were the only one involved in outlining and reviewing the literature that became the June 2022 GAPMS?

A Yes.

Q Okay. Was there anyone else at the Agency -- so you didn't work with Mr. Chen on the literature or --

A Nai, he did -- he occasionally he'd find an article and give it to me, but other than give me the occasional article, that was -- that was it. I went through, reviewed the article, like, broke it down. As

far as any content or analysis, he just gave me copies of articles.

Q Okay. Okay. And so no one else at the Agency -- did anybody else at the Agency take on that role to where they were sending you articles or anything related to that? I guess what I'm trying to determine is whether anyone else assisted you with drafting?

A Nobody assisted me with the drafting.

Q Inside or outside the Agency?

A We did have a few consultations with some of our contracted experts --

Q Were they a verbal consultations?

A They were verbal.

Q Only verbal?

A Yeah, but as far as drafting went, they weren't involved in that process.

Q Okay. So they didn't write any of the main report?

A They did not write any of the main report.

Q Or outline it or anything?

A No.

Q Okay. Looking at -- I have another exhibit, the Van Mol ATF. We're going to mark this as Exhibit -- Exhibit 12. What is wrong with me today? And it's entitled Agency for Health Care Administration

after-the-fact request form under 35k.

(Whereupon, Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE::

Q So, reason for occurrences, where I'm reading and second sentence to the last, due to the need to start work quickly, all of the purchase order elements were not available until May 6th. Why was there a need to start work quickly?

A Since this is -- since we did have a request, and since we were writing in response to the Department of Health, which had already had published their findings, the Agency, of course, we considered this a priority project, and this was mostly that's -- that's pretty much, it was a priority project.

Q I'm sorry. Why was it a priority project?

A It was priority project because in relation to -- in relation to the Department Health guidelines, which had been released, then, of course, because, you know, as the state of Florida wanted to respond to the HHS documents, which had also been released, because we didn't want a significant amount of time, like, five or six or seven months to elapse before the Agency had gotten its response out.

Q Okay. So you wanted to make sure that there

would be a quick response to the HHS guidance?

A Yes.

Q Okay. When I say a decision tree checklist for GAPMS, do you know what I mean?

A Are you referring to, like, to a checklist?

Q Yes.

A Yes, I do know what you're referring to.

Q Okay. Did AHCA do a decision tree checklist for this report?

A So that decision tree checklist, that was a -- is an internal process, and each person who does GAPMS often kind of brought their own unique perspective or unique approach to them, since these are research projects and there's not really a formula for it, but I believe -- I think Jeffrey English, I think, helped to develop a checklist, which I think he used when making evaluations. I kind of have my own mental checklist when I did them. And also, actually, I actually wanted to kind of help refine, to help cut down the number of GAPMS requests we had. As we started going through requests, we started realizing, well, some of these really aren't GAPMS, these are just coverage determinations.

Q What -- How did you know that?

A Generally -- okay, well, FDA approval for the

clinical indication.

Q Okay.

A If a national coverage determination's been released by Medicare, things like that.

Q Okay. What about if it was already listed on AHCA's fee schedule?

A Not necessarily.

Q Why?

A Because -- just because it's listed on AHCA's fee schedule, it does not necessarily mean that it's -- wouldn't be experimental or investigational for another clinical indication.

Q So based on the checklist, if it was listed on the fee schedule, that one isn't going to determine whether or not it should go through GAPMS?

A It shouldn't, no. And that was -- when I -- when I did GAPMS, that was not part of my criteria.

Q After the checklist was developed, how many GAPMS did you do?

A The checklist was developed well after I had left that role.

Q Okay. So -- but we know you did the June 2022 GAPMS, so at least one right?

A Uh-huh.

Q Okay. After the checklist was developed, for

any other time that AHCA undertook a GAPMS, was a checklist completed?

A I think there were some completed checklists that I was able to find in our PDM, but that was after the fact. When I embarked on this one, I was not aware a checklist even existed. Not that I didn't apply kind of a mental checklist when I was going through it to check to see if there were certain elements in there that would either come to the conclusion that this shouldn't be that way through GAPMS or not.

Q What was your mental checklist?

A FDA approval for a clinical indication, which would mean that there was already substantiating research for it, which had been done by federal agency, which would kind of render GAPMS point moot, or a national coverage determination by Medicare. And the national coverage determination is pretty much -- it's like a Medicare GAPMS, and it's -- there aren't that many NCD's out there because there's a risk involved in getting an NCD, but if -- but Medicare NCD's are backed by substantial amounts of research. So if there's an NCD out there supporting a treatment and mandating coverage for a specific service, and all the research they do behind it, it kind of also -- it renders doing the GAPMS moot.

Q Okay. Any other -- anything else on your checklist?

A No, those were the two items I usually look for.

Q So that's it. And then if they didn't pass those two tests, they went to a GAPMS?

A Went to a GAPMS.

Q Okay. So -- I'm sorry. I just need to find my place in the outline. When was the checklist developed? Remind me. 2017?

A No, the checklist would have been developing in 2019.

Q 2019. Okay. During the 2022 -- the start of the 22 -- 2022 GAPMS, you mentioned that you were having conversations with the Governor -- or there was an initial meeting with the Governor's office when the request was made and DOH was also present?

A Prior to the request being made.

Q After the request was made, was there any communication with the Governor's office?

A No.

Q After the request was made, was there any communication with the Department of Health?

A No.

Q What about HHS?

A No.
Q And what about Alliance Defending Freedom?
A No.
Q Liberty Counsel?
A No.
Q Okay. What consultants were used by AHCA in the development of the GAPMS.
A So during the development, we have a few verbal conversations with Doctors Miriam Grossman and Andre Van Mol.
Q Okay. And what did those conversations entail?
A Well, Dr. Van Mol, he just offered suggestions for articles and research for us to look at. He did provide us with a bibliography for our consideration, as far as -- mostly just leads on research to help save time in finding resources. And Dr. Grossman, of course, she provide us with some history of gender dysphoria treatments, and gave us more reviews of some scientific techniques.
Q How did you get connected with Dr. Van Mol?
A So Dr. Van Mol, like all of our experts, who also provide published reports, so the process for those was that we did get a name at the very outset of the process, which was Michelle Cretella. And by contacting

her, she led us to other providers -- or other practitioners who had expertise in the fields, and that's how AHCA made contact with these individuals.

Q So Michelle was the only person who connected AHCA to the consultants it relied on for the 20 -- June 2022 GAPMS?

A Yeah.

Q Okay. And who Michelle?

A Michelle -- Dr. Michelle Cretella?

Q Uh-huh.

A She's a physician. I think she has some affiliations with, like, a couple of -- I think American College of Pediatrics, I think. I'm not sure what her other affiliations are.

Q How did you find her?

A Well, her name was passed on to us from the Department of Health.

Q Okay. What's her relationship with to the Department of Health?

A I -- the Agency does not know what her relation to the Department of Health is.

Q Okay. So you just accepted this recommendation by the Department of Health as the person who would connect you to the consultants you would use to develop the 2022 GAPMS?

A Yes.
Q You didn't do any outside research on whether you should seek out other consultants?
A Well, we were vouching for our -- for the consultants. I mean and so we did want individuals who had expertise in their respective fields of medicine, and who also were going to take an evidence-based approach.
Q Okay. Who at Department of Health recommended Dr. Cretella?
A Don't -- we don't have the name of the individual.
Q Because it was sent in an anonymous email? Why don't you have the name?
A We can get that information for you.
Q So you don't have the name, but the Agency has the name, correct?
A The Agency might have a name. We need to confirm that.
Q And who at the Agency was this communication sent to? I mean, how was it communicated?
A To my knowledge, it was verbal. It was a verbal exchange.
Q Okay. So who at AHCA was part of that conversation?

A So I think when it came down to, you know, reaching out to experts and determining who the experts we should use were, I think Andrew Sheeran and Jason Weida were involved.

Q Okay. So it was either Andrew Sheeran or Jason Weida who received that information from the Department of Health related to Dr. Cretella?

A Yes.

Q Could it have been anybody else at the Agency?

A I don't think so. I mean --

Q It seems like you have a name in mind.

A Well, I mean, there were other senior leaders. The Secretary may have been given the name, or Chief of Staff may have been given the name, so, but --

Q Who was the chief of staff?

A Cody Farrell.

Q And who was the person who spoke with Dr. Cretella about her recommendations?

A I think -- I think Andrew Sheeran and Jason spoke about that -- spoke to them about the recommendations.

Q And she recommended everyone, is that correct?

A Well, she -- from what I gathered, there was, like, recommendations. She gave some names. And not everyone she recommended, of course, we decided to go

with. So there were some that we did turn down.
Q Who did you turn down?
A We can get that -- we can get that -- we can get those names for you.
Q With Dr. Cretella, was there any consideration given to the associations, the medical associations of which she was a member?
A No.
Q Okay. So you didn't look to see if she was associated with any particular medical association?
A No.
Q You just went off the recommendation of Department of Health?
A Yes.
Q Was Dr. Cretella paid for her assistance with -- to AHCA?
A No.
Q So DOH didn't pay her or anything?
A Well, I don't know at DOH, that's a question for the Department of Health. AHCA did not -- we did not establish a financial arrangement with her.
Q Okay. Are you -- are you personally aware of any financial arrangement between Dr. Cretella and Department of Health?
A No.

Q Okay. I'm sorry. Who did you turn down?
A We would have to get those for you.
Q Okay. And so Dr. Grossman and Dr. Van Mol just gave you some article leads, and that's all?
A Gave some article leads, some background information. Yeah, it was -- I mean, as far as providing us with content to include in the report, they did not.
Q Why not?
A Because it was an independent assessment by the Agency.
Q Okay. Did -- but they didn't write any of the reports that were in the attachments to the June 2022 GAPMS either?
A Right?
Q Why not?
A I think because we had experts. We already had a psych -- one psychologist who was writing one. We already had -- we, of course, we had physicians for, like, plastic surgery. We had a bioethicist, as well. Since those bases were covered, we felt they would best benefit us by helping provide guide -- guidance with research.
Q Were they ever given the option of writing a report for one of the attachments?

A No, we didn't ask them to write a report.
Q Okay. Did they ask if they could write a report?
A No, they did not.
Q How did you identify Dr. Romina Brignardello-Petersen?
A So through the contacts we were making, her name was passed on to us as someone at McMaster University who had some experience in doing evidence evaluation.
Q Did Dr. Cretella pass on that name?
A As far as the actual contact that gave us that name?
Q Uh-huh.
A Dr. Cretella was kind of the head of the tree of the contacts. We would have to go back and get that information on who gave us the exact name for Dr. Brignardello-Petersen.
Q Okay. But Dr. Cretella was the one who -- so what -- if Dr. Cretella didn't recommend Dr. Brignardello-Petersen, who would have?
A We would have to get that information for you.
Q Would it have been another physician?
A Yes, it likely -- yes, it would have probably been another physician.

Q What other physicians provided recommendations for consultants?

A We would have to get that information.

Q What all physicians did you talk to you prior to -- or in the process of drafting the --

A So in the process of drafting the report, we really -- we talked to Doctors Grossman, Van Mol. There were a couple conference calls with the experts who provided the reports, but those weren't about our report, that was just mostly more -- that was talking to them about them doing their reports.

Q Okay. So who recommended Dr. Cantor?

A We -- that may have been Dr. Cretella who had recommended him. We would need to confirm that.

Q Okay. So, again, just pointing to topic 24 in the notice of deposition, we asked for an Agency representative who was knowledgeable as to --

MS. DEBRIERE: No, no. I just don't know what -- I have no idea where it is.

BY MS. DEBRIERE::

Q So looking at topic 24, and we asked very specifically about the identification of Dr. Brignardello-Petersen, Dr. Cantor, Dr. Van Meter, Dr. Lappert, Dr. Donovan, in the inclusion of the written assessment. So I don't know what to say. I mean, it

seems like you're not able to answer the question.

MR. JAZIL: So, counsel, the topic says the process by which AHCA prepared the memo, and I read that to mean the process by which we identify these experts. And so he's detailed the process. It was an initial consultation with one physician, and then it was -- one person recommends another, recommends another. And I think he said that a lot of these were oral. To the extent that we have any written records of who specifically said, hire Dr. Romina Brignardello-Petersen, we'll supplement the production with that.

MS. DEBRIERE: Other than written records, Mo, can you get us -- can you just do an investigation of who spoke with these individuals and collected this?

MR. JAZIL: So who -- so I think he's answered that, it was General Counsel's Office, and it's now Secretary Weida, who spoke to these individuals. If the question is who specifically recommended each expert --

MS. DEBRIERE: Yes.

MR. JAZIL: -- I'll ask. And if there's a written record, it would have been turned over to you already. If there's an oral record, beyond

what he's talked about, well --

MS. DEBRIERE: If someone knows. Because if someone knows at the Agency --

MR. JAZIL: -- you know, Bob talked to Jill, Jill talked to Jane, Jane talked to Jason and said, hey, hire Brignardello-Petersen, I'll get that information for you.

MS. DEBRIERE: Thank you.

BY MS. DEBRIERE::

Q Whose decision was it to engage with Dr. Van Meter? I'm sorry. Who recommended Dr. Van Meter? I apologize.

A That's information we would have to --

Q So you don't know who recommended any of these individuals other than Dr. Cretella?

A Right.

Q Okay. When did AHCA first become aware of the HHS fact sheet on gender-affirming care in young people?

A We became aware of it, since we do follow HHS publications, much of our staff in Medicaid, so forth, they are actually on -- they receive automatic updates, so we became aware of them as they came out.

Q What was AHCA's independent reaction to the fact sheet?

A Well, as the Agency initially didn't -- didn't

have a reaction. There was -- we didn't -- we don't react publicly to HHS documents.

Q Okay. So did AHCA -- you stated in your declaration filed with the court on January 23rd -- are you aware of what I'm talking about? I can get you a copy, if not.

A I should be aware of it. I've reviewed it.

Q Okay. That litigation was highly likely because in drafting the GAPMS report, the GAPMS determination might conflict with federal standards. Do you remember saying that?

A Yeah. If I -- yeah, I mean, it's written and signed off on, then, yes.

Q Okay. With what federal standards, did you think it might conflict?

A Well, it might -- it would probably conflict with that guidance that was released from HHS.

Q Any other federal standards?

A No.

Q Why did you think it would conflict with the guidance from HHS?

A Because the guidance from HHS, the conclusions we made -- that we made following an independent assessment, conflicted with the HHS guidance. The HHS guidance did state that these were, like, medically

necessary treatments, that evidence supporting them, so that they would alleviate mental health systems symptoms, et cetera. Our concluded -- our conclusions and our assessment of literature deemed otherwise, so we knew that there would be a potential conflict.

Q At what point did you realize that there would be a potential conflict?

A When we -- during the drafting process. So we realized that the evidence was inadequate to support the claims that HHS was making, or that -- that's when we realized that there would be -- there would be a conflict.

Q Okay. Did you anticipate that the GAPMS report would conclude that the relevant services were experimental?

A When I started working on it, I did not know where the evidence would take me.

Q At what point did you realize that you were going to conclude that the services were experimental?

A As -- the more and more I read the articles that focused on the mental health benefits, the methods and so forth, the more I realized that all those articles left way too many unanswered questions. This -- there was also -- there wasn't any evidence available to answer those outstanding questions. I

realized that I couldn't -- that there was not going to be -- that the conclusion was going to be, no, it was not consistent.

Q Okay. So your analysis of those services. So I think one of your concerns related to the treatment of services for gender dysphoria that is now excluded under 59-G-1.050(7), was that the services were not supported by randomized controlled trials, is that correct?

A That was one element of many elements.

Q Okay. Does AHCA ever require that -- does every -- does AHCA require that every treatment or procedure it covers be supported by randomized controlled trials?

A So to contextualize that question, every medical service is unique. So we don't apply a uniform set of standards to every single medical service, because every single medical service is for a specific condition, every medical service carries its own pros and cons, risks versus benefits. So we don't necessarily -- we don't have a one-size-fits-all model for evaluating each and every medical service.

Q You mentioned unanswered questions as you were reviewing the literature for treatment of gender dysphoria, or the services you were analyzing. What were those?

A So those are iterated in the GAPMS report, but generally like -- well, number one, long-term. And other unanswered questions, like a lot of these studies were based on anonymous surveys. How are we supposed to know whether or not these responses are credible, if we don't have any longitudinal history of these individuals? I mean, one of the things that we came up with when we were doing the literature review is the etiology. There are lots of potential causes and associations with gender dysphoria, not -- not including but not limited to autism, trauma, neglect, abuse, abandonment, things like that. So because there was so many unanswered questions, I mean, how are we supposed to know whether or not a one-time survey is going to accurately capture all of that, especially if it's done -- being taken by anonymous people, or if the survey -- or for those that weren't anonymous, the sample sizes were very, very small. So and, of course, you're talking about one- or two-year periods. These -- the changes prompted by these treatments are permanent.

Q Did you adopt any of the conclusions about treatment for gender dysphoria relied upon by the American Academy of Child and Adolescent Psychiatry?

A The American College of -- can you repeat that?

Q American Academy of Child and Adolescent Psychiatry. I think it's AACAP.

A No, I don't recall we -- us using their recommendations.

Q What about the American Academy of Family Physicians?

A No, we didn't use theirs.

Q What about the American Academy of Pediatrics?

A We did do an evaluation of theirs.

Q Did you rely on them, their conclusions?

A So what do you mean by --

Q Did you -- did you lend credence to their conclusions?

A Yeah, yeah. It was -- their conclusions required thoughtful analysis and probing of the evidence. We do take the recommendations of clinical organizations very seriously, but we also do reserve the right to question those recommendations and we did review those and we did analyze them.

Q And after you reviewed and analyzed them, did you adopt them?

A No, we found that they were based on very weak evidence.

Q Okay. What about the American College of Obstetricians and Gynecologists?

A No. I mean -- I mean, there -- we didn't -- so, aside from AAP, we did notice, like most of the recommendations, guidelines, were very, very similar, very straightforward, and they usually are based on Endocrine Society and WPATH guidelines.

Q And did you adopt the recommendations from the Endocrine Society and the Pediatric Endocrine Society?

A No, we did not. We did review those in close detail, though, and analyze them.

Q What about -- I'm sorry. The other WPATH?

A Yes. So the World Professional Association for Transgender Health, we did closely review their guidelines. We did -- we did analyze them. And, of course, we do discuss them in lengthy detail in multiple areas of the GAPMS report.

Q And ultimately you disagreed with their standards?

A Ultimately, yes.

Q What about the American Psychiatric Association?

A I think we actually didn't make reference to them in the GAPMS report.

Q Did you adopt their conclusions related to the treatment of gender dysphoria?

A No, we did not.

Q What about the American Psychological Association?

A No, we did not.

Q American Medical Association?

A We did not.

Q When you say we, you mean --

A The Agency.

VIDEOGRAPHER: Excuse me, counsel. Sometime soon, I need to take a short --

MS. DEBRIERE: Oh, yes.

VIDEOGRAPHER: -- to start the next video. Do you want to take a break? We could take a -- do you want to take a 30-minute lunch break or --

THE WITNESS: I'm good with that, yeah.

VIDEOGRAPHER: Okay. This concludes video two. The time is 12:42 p.m.

(Whereupon, the deposition resumes in Volume 2.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that the above-named witness personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 21st day of February, 2023.

_____

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, DANA W. REEVES, Professional Court Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 5 through 120, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 21st day of February, 2023.

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

Gary V. Perko, Esq.
gperko@holtzmanvogel.com

February 21, 2023

RE: August Dekker, et al. vs. Jason Weida, et al.
February 8, 2023/Matthew Brackett/5696545

The above-referenced transcript is available for review. The witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason on the attached Errata Sheet. The witness should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties. It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard. If the witness fail(s) to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions
*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

August Dekker, et al. vs. Jason Weida, et al.

February 8, 2023/Matthew Brackett

E R R A T A S H E E T

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REASON_____

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Matthew Brackett DATE

p

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

CASE NO. 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,
Plaintiffs,
vs.
JASON WEIDA, et al.,
Defendants
_____/

Volume 2, Pgs. 125 - 261
VIDEOTAPED DEPOSITION OF: MATTHEW BRACKETT
AT THE INSTANCE OF: THE PLAINTIFFS
DATE: FEBRUARY 8, 2023
TIME: COMMENCED: 1:30 P.M.
LOCATION: AGENCY FOR HEALTH CARE ADMINISTRATION
2727 MAHAN DRIVE
TALLAHASSEE, FLORIDA 32308

REPORTED BY: DANA W. REEVES
Court Reporter and
Notary Public in and for
State of Florida at Large

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ALSO PRESENT:
RL Minnich, Videographer

INDEX TO WITNESS

INDEX TO EXHIBITS

*Uh-uh is a negative response
*Uh-huh is a positive response

D E P O S I T I O N

Whereupon,

MATTHEW BRACKETT

was called as a witness, having been previously duly sworn to speak the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

VIDEOGRAPHER: This is beginning of video three. The time is 1:30 p.m. We're on the record.

EXAMINATION

BY MS. DEBRIERE::

Q So prior to break, we were talking a little bit about Dr. Van Mol and Dr. Grossman's involvement in the 2022 GAPMS. How did AHCA identify them to participate in the July 8th rule hearing that was related to?

A So the -- are we talking about the rule hearing?

Q Yes, related to the June 2022 GAPMS.

A So since we had already been working with them in relation to the GAPMS project, because Dr. Grossman is a psychiatrist, and Dr. Van Mol is a family -- family practice practitioner, that's based on their backgrounds and their knowledge of the existing evidence, that was our basis for selecting them to be on the panel for the July 8th hearing.

Q And turning back to the individuals who wrote reports for the June 2022 GAPMS, who made the decision to contract with them to prepare those reports?

A So after establishing each one, we wanted to -- their backgrounds and their suitability to provide reports, that decision was made by, I think, now Secretary Weida.

Q And who was involved in determining whether they had the appropriate backgrounds to write the reports?

A So I think those individuals who were working with the experts, I think that was, of course, now Secretary Weida, I think at our time, General Counsel Josephina Tamayo.

Q Okay. Anybody else?

A I don't --

Q Were you involved?

A I was not.

Q Was Nai Chen involved?

A He was not.

Q Was Dede Pickle involved?

A She was not.

Q Okay. So now Secretary Weida and Josephina Tamayo were the two people who decided whether the consultants who read the reports were qualified to do

so?

MR. JAZIL: Object to form.

THE WITNESS: So are you asking that whether or not those two only assessed their credentials?

BY MS. DEBRIERE::

Q Yes.

A I mean, yeah. I mean, they assessed their credentials and looked at their background and experience and knowledge.

Q Were those the only two people that assessed their credentials before deciding whether to engage them?

A In regarding the Agency, I mean, the -- Andrew Sheeran may have been involved. So it's possible a couple others with the principal decision to rely on those experts was theirs.

Q Okay. And so just to be clear, you were not involved in that decision?

A I was not involved in that decision.

Q And Nai Chen was not involved in that decision?

A That's correct.

Q And Dede Pickle was not involved in that decision?

A Correct.

Q When making that decision, did AHCA investigate whether any of the consultants had a stance related to the treatment of gender dysphoria?

A We, of course, were looking for those that had -- were knowledgeable about the existing literature of gender dysphoria, and those who would, for the supplemental reports, would take an evidence-based approach.

Q Did it -- so those were the only two criteria that you used to determine which consultants you would engage with?

A Correct.

Q And so opposition to gender-affirming care was not a factor in who you chose?

A We were specifically looking -- I think we might be talking semantics on what we consider opposition, but we were looking for individuals who were going to make reports and recommendations based on the existing evidence.

Q Okay. Was whether the vendor had experienced treating -- I'm sorry. Was whether the consultant had experienced treating gender dysphoria a factor?

A Not so much a factor that would outweigh the knowledge of the existing literature and the evidence, since this was going to be a -- the GAPMS process really

takes into account peer-reviewed literature. It takes into account evidence-based clinical guidelines, et cetera, so those are our primary -- our primary factors in evaluating the experts and their ability to contribute to this report.

Q Would people who actually provide treatment in gender dysphoria be most familiar with peer-reviewed literature as it relates to their practice?

A Well, that is a complicated question. They don't necessarily have to be. It's possible to -- I mean, it is possible -- I mean, it is hypothetically speaking, someone could engage in treatment of these individuals and run and follow anecdotes.

Q So it's not important to AHCA that the consultants with whom you engaged had actual experience treating gender dysphoria?

A So based on how the GAPMS rule is written, the needs of the report, we really -- the primary ask was for individuals who were steeped in the evidence.

Q But didn't necessarily have actual real life experience treating gender dysphoria?

A Right, that wasn't a primary consideration.

Q Okay. For -- was AHCA aware that all the consultants with which you engaged took a stance to oppose mainstream medical organizations' stance on

gender-affirming care?

MR. JAZIL: Object to form.

THE WITNESS: So are you talking about in opposition or in contradiction?

BY MS. DEBRIERE::

Q Contradiction.

A We -- whether contradiction or alignment really was irrelevant, it really was taking a look and making evidence-based conclusions.

Q Speaking to Dr. Brignardello-Petersen -- I'm sorry. I'll start here actually. In deciding on whether to use these consultants, was any input provided from the Alliance Defending Freedom?

A No.

Q What about the Heritage Foundation?

A No.

Q Liberty Council?

A No.

Q Society for Evidence-Based Gender Medicine?

A We may have gotten Romina's name from that organization.

Q Okay. And what about the Family Christian Coalition?

A No.

Q Did you get anybody else's name from the

Society for Evidence-Based Gender Medicine?

A Because the -- because it was verbal conversations, so don't -- don't think so, but the kind of details -- because there's a lot of verbal conversations and no written record, so --

Q Maybe?

A It could be a maybe at best.

Q And did the Family Christian Coalition recommend any of -- or play any role in the recommendation of the consultants --

A No.

Q -- with AHCA engaged? What about the Florida Citizens Alliance?

A No.

Q The Florida Department of Health?

A Well, the Florida Department of Health passed along to the name of Dr. Michelle Cretella. So, yes.

Q What about the Governor's office?

A No.

Q The Surgeon General Ladapo?

A Well, he would be acting in his capacity as, of course, the agency head for the Department of Health. So the Department of Health, cumulatively, gave us that name.

Q Did he personally?

A There was a conversation, like, once with our general counsel Tamayo at the time with Dr. Ladapo, but we don't recall whether or not the name was given during that conversation.

Q I think you touched on this a bit earlier, so I apologize for circling back around, but did AHCA consider using any other consultants in the development of the June 2022 GAPMS?

A By any other --

Q Other than those that wrote the reports or Grossman or Dr. Van Mol?

A There were those who were contacted. Of course, there was -- it was all verbal conversations, but not necessarily -- not necessarily considered to write a report either.

Q And do you remember who you were -- who you contacted?

A Since it was all through verbal conversations, it was eight months ago, it wasn't through written correspondence, the -- we're not really aware of all those details.

Q And who was the one who did the contacting?

A The contacting was done, I think -- I think by Andrew Sheeran. He's now our General Counsel. I think Josephina Tamayo -- Tamayo. Sorry. I think she also

was involved in contacting them.

Q Okay. And those were all phone calls?

A These were verbal conversations, yes.

Q So no communication by email?

A No.

Q Did you use the folks who ended up not offering the reports -- aside from Dr. Van Mol and Dr. Grossman and the individuals who authored the reports, did you use the people that you contacted in any other capacity?

A No.

Q And what was the scope of the agreement between AHCA and each consultant?

A So each consultant, of course, they provide us their hourly rate. We wrote up purchase agreements that those amounts cannot exceed $35,000 because of the nature of the procurement.

Q Can you speak a little bit more to that? I'm not -- I'm unfamiliar with the way that -- the regulations that govern that.

A So if it were to exceed $35,000, it would have to be a competitive procurement, and that's why -- so the -- so we, of course, we enter in agreements with each of these experts. The amounts paid to them cannot exceed 35,000.

Q Okay. What was each vendor -- in procurement of consultants, was this the usual procedure? I'm sorry. In contracting.

A Yeah, this is the procedure that we can follow.

Q That you can follow, but is it the usual procedure?

A Well, I mean, what is defined by a usual procedure? I mean --

Q How many times in prior GAPMS have you contracted with a consultant to develop the GAPMS?

A Well, we haven't, but then there are instances -- I know with coverage determinations, et cetera, that sometimes we will actually send stuff for a physician review, like over at EQ Health Solutions. So it's not unusual for us to ask for medical experts or clinical expertise on a prospectus.

Q Had you ever previously contracted and paid the person for that clinical expertise?

A No, we had not.

Q What was the total budget allocated to the development of the GAPMS?

A You know, 35,000 times seven. That'd be 210 -- 245,000.

Q So each consultant is capped at --

A That was the cap of the budget.
Q And is that 34,999, or 35 straight?
A I'm leaning towards 34,999, so we can subtract $7 from that amount.
Q Okay. Has each consultant been paid in full for that work?
A Each consultant has been paid in full for the work they completed.
Q Okay. Some of those consultants now, though, are acting as experts in this case and being reimbursed for that, as well?
A Those would be under separate agreements.
Q Okay. In the example you just gave about using outside physician consultants for the other GAPMS, did AHCA pay those other consultants?
A For other GAPMS? Those consultants are usually salaried or have hourly rates from our subcontractors.
Q Okay. Okay. But you didn't enter into any kind of vendor agreement with them?
A No, they're already employed by one of our subcontractors.
Q Okay. Did all of the $35,000 paid to the vendor -- paid to the consultants come directly from AHCA?

A Yes.
Q Was AHCA reimbursed by anyone else for those consultant payments?
A No.
Q Other than through its subcontractors, has AHCA ever previously retained outside consultants to undertake a review of the evidence-based clinical practice guidelines for GAPMS?
A Well, previously, we did actually have -- of course, we discontinued it, but we did have PAYS, which was back -- and we had it throughout 2017 -- which was a course and evidence review guide program that I had to subscribed to. We did have that and often referenced that in the early days, but after the amount of time, and because it was an expensive subscription, we discontinue it.
Q So that was a subscription service. Do you -- can you recall any time that you engaged with an outside consultant, other than those employed by your subcontractors?
A No.
Q What about to undertake a review of professional literature?
A No.
Q To actively participate by making a

recommendation or assessment as to the experimental or investigational nature of the service?

A No.

Q Why didn't you use the subcontractors -- AHCA subcontractors, why didn't you rely on their expertise in developing the June 2022 GAPMS?

A Because of this GAPMS and because of the nature of the subject. We did anticipate litigation after -- once the report was done and once we were working on it. So because of that anticipation, we needed to have experts that were -- that did have a degree of expertise in this field. Our subcontractors, their practices are more like general practitioners, or may be specialized in other areas, and they wouldn't be able to adapt quickly enough to the learning curve to provide a valuable assessment.

Q So you were concerned about attacks litigation might have on the integrity of that report itself?

A Can you repeat that?

Q Well, you said that because you anticipated litigation, that's why you engaged with consultants who had expertise, in particular --

A The Agency needed as robust a report as possible. So because we needed such a robust report, and because of the HHS guidance, the Department of

Health, so the fact that there were published documents out there, the Agency did need to come up with a response that we needed to disseminate as robust as possible, and that's why we engaged with the outside experts.

Q Why is gender-affirming care different from any other Medicaid service?

A Well, I'm going to defer to GAPMS process and our GAPMS report. For -- for the response to that is that gender-affirming care, of course, we are looking at, like, a treatment model that has very weak and low-quality evidence supporting it. And because we did a review and assessment of the literature, because there are a lot of claims made, especially by HHS, in particular, about its efficacy, because of its nature, because of -- and because of the low-quality evidence, that's how we deemed it. I mean, it is a different sort of care than we can consider traditional.

Q The GAPMS process is used to determine whether a Medicaid service is experimental, right?

A Yes.

Q So then that question is presented in any Medicaid service you're evaluating under GAPMS?

A That's right.

Q So why is gender-affirming care different?

A I'm going to defer to the conclusions we drew in the GAPMS report.

Q Why did you anticipate litigation before you even reached a decision?

A Well, I think that's because, I mean, this is often a very touchy subject. It's something that's frequently seen in the mainstream media. And, of course -- of course, the documents from HHS. It is a high-profile issue. It's considered by many to be controversial. So that should -- that's kind of why we did anticipate potential litigation resulting from whatever determination we made.

Q Why didn't you need gender dysphoria experts from the prior gender dysphoria GAPMS?

A For the prior ones?

Q Uh-huh.

A So for the prior ones, I think at the time -- I mean, we have to take it in context at the time, and, of course, these were done piecemeal, these were all separate reports, not one large one. So in the course -- at the time because this wasn't viewed as far as a potential hot topic, there wasn't the HHS guidance at the time, that's -- I think the best explanation as far as to why we decided not to engage with consultants.

Q HHS releases guidance all the time, though,

about coverage?

A Uh-huh. That's correct. It does.

Q Did you anticipate litigation for the 2016 GAPMS memo on puberty suppression therapy?

A The staff of the Agency who were present for that determination are no longer with the Agency, so we, in our current capacity, can't speak to that.

Q Did you undertake any research to derive an answer for that question?

A No, we didn't.

Q Did you look at any past memos related to whether or not the GAPMS might have litigation initiated?

A It's always a concern with every coverage determination and every GAPMS we do because inevitably, if we do say no to a service, there's going to be disappointed party. So it is a consideration we always have in place that there might be litigation.

Q Well, then that brings me back to the question as to why gender-affirming -- why this GAPMS is different?

A Well, this brings us back to the present circumstances behind how much attention the subject's been drawing in the media. The -- and it goes back also to the HHS guidance, which was making claims based on

evidence that we determined was insufficient.

Q So I only listen to NPR, I'll be honest. I don't watch any news. What media? Where's this a hot topic in the media?

A Oh, I mean, let's see here. I mean, we can name a lot of sources. I also -- I do listen to NPR myself. So NPR actually does periodically have an article on it. Then, of course, let's see here, there's quite a few other sources of things listed here. CNN, MSNBC, ABC, NBC. Your major outlets. New York Times. The Guardian.

Q How long has the media coverage been going on for?

A So as far as media coverage goes, well, the media coverage, there's always been smatterings of it here and there, but I think when -- as far as it becoming a consistent theme probably the past year. But that's not me speaking on behalf of the Agency, that's me speaking from personal observation.

Q Okay. Fair enough. Did AHCA share any of the draft consultant reports with external entities?

A We did not.

Q The Governor's office?

A We did not.

Q Department of Health?

A We did not.
Q No one?
A No, they stayed internal.
Q Did AHCA provide any material to the consultants to review in drafting their reports?
A No, we did not.
Q Did AHCA edit the reports of the consultants?
A There was some copy editing for style and grammar. Other than that, no, we did not make edits to the content.
Q So no substantive edits?
A No substantive edits.
Q And that includes Lappert's report?
A That includes Dr. Lappert's report.
Q And Dr. Donovan's report?
A And that's for Dr. Donovan.
Q And did any of the consultants provide edits to the AHCA GAPMS report?
A So after we finished the draft, we did send drafts to Doctors Grossman and Dr. Van Wol and they provided some feedback, but none of the feedback met -- were made -- resulted in drastic changes. I think -- I think Dr. Van Mol suggested we -- there's one more article we could discuss, and we added some content in there regarding that. They did help us correct some

terminology errors. There are some -- so there are some technical edits that were made. But as far as anything substantive, my first draft, I mean, was largely intact by -- from the first draft process to when we had the final draft.

Q Okay. And you were the only person involved in making the first draft?

A I can articulate a little bit more on how that went. So while the experts -- while the experts were composing their reports, I was composing mine. And once we had their reports, then that was -- then we did add -- we added some snippets from their reports in our report to make it more, I guess you could say, cumulative.

Q Okay. So only after the consultants who wrote a report, those reports were done, then you pulled some of that information into your --

A Correct. So my section was complete when we started receiving their reports.

Q Okay. Okay. What was the date of your first draft?

A I think the date of my first draft -- let's see here -- want to say early to mid May.

Q Okay. So, like, second week of May-ish?

A Somewhere around there, yeah.

Q Going back to the edits that the consultants provided to your report, what terminology had to be corrected?

A What was it? I mean, it was some medical terminology. I don't remember the specifics. I mean, it was very, like, miniscule changes.

Q Where they red lines in, like, a Word document?

A No, the edits were given to me verbally and I made them -- sometimes I made them right there when we were talking to them.

Q Okay. You stated in your declaration filed with the court on January 25th, 2023, that the only sources you relied on for the June 2022 GAPMS, were those cited in the works cited section of the report; is that a correct statement?

A That's correct.

Q So that means that the only sources that you consulted or considered -- or cited in the June 2022 GAPMS report?

A During the -- yeah, during the writing of the GAPMS, those were the sources consulted.

Q Nothing else?

A During the drafting of the report, nothing else.

Q What about after?

A Afterwards, more out of intellectual curiosity, I did want to try to see what else was out there, but that was more for personal intellectual curiosity than it was for professional purposes.

Q Okay. What were those things that you reviewed?

A Articles by Jack Turban.

Q Can you spell his last name?

A T-U-R-B-A-N.

Q I'm not familiar.

A Well, it's -- he is cited in our report, but he also is -- he's frequently quoted a lot, so I was curious to see what other in print articles he had produced.

Q Quoted in what?

A He's often cited in, like, news stories, media.

MS. DEBRIERE: Simone just got a note that folks are having trouble hearing me.

BY MS. DEBRIERE::

Q All right. When you were considering whether the services listed at 59-G-1.050(7) were experimental, did you evaluate whether excluding those services would be budget neutral?

A No, we did not.

Q Did you consider whether private insurance covers the services excluded by 59-G-1.050(7)?

A For this one we didn't, but primarily when we do GAPMS, we really aren't interested in public and private insurers. We're primarily interested in state Medicaid programs and Medicare since, like, Florida Medicaid, they're public payers. So primarily, we really want to know what the public payers say. Usually, our lowest priority for GAPMS is to provide analyses of what private payers pay. And generally, often we need those to supplement if we're unable to get that many policies from Medicaid programs across the nation, but since it's -- for this GAPMS, we actually surveyed all 50 states, then we had adequate information from that. Most GAPMS reports, usually we get maybe 10 or 12 when it comes down to coverage policies, it's -- it's pretty much what we can find in a certain amount of time. But for this one, we've -- since Dede Pickle was working on it independent, she was able to survey all 50.

Q And why is it covered under private insurance informative of whether or not a service is experimental?

A Can you repeat that?

Q Uh-huh. Why don't you rely on -- why don't

you consider private insurance coverage to be something -- I'm having trouble formulating what should be a simple question.

Why don't you look at private insurance coverage when you're determining whether or not a service is experimental?

A Well, private insurance works differently. I mean, Florida Medicaid, like Medicare, is a taxpayer-funded health care system. Private insurers, since they're privately funded, there's a great deal more latitude, what they can cover and what they don't have to cover, and they're more subject to the competition of the market, as opposed to Medicaid programs. So we -- while we do -- some often will look, but often it's -- we often try to find what private payers pay for following what we get from Medicare and Medicaid. So, I mean, when it comes down to it, we can, but it's not an absolute requirement, and we really do want to find out what the Medicaid programs are paying for. That's our first and foremost criteria for looking at the coverage of -- other payers coverage.

Q So it's not apples to apples, because in Medicaid and Medicare, you've got state taxpayer dollars to consider, correct?

A That's correct.

Q Okay. But when you undertook the June 2022 GAPMS, you did not evaluate whether or not excluding those services would be budget neutral?

A No, we didn't for this one, but we -- but that's also not necessarily unique to this, as well.

Q So in other GAPMS, you've not evaluated the budget neutrality of the service, whether or not you're going to cover it?

A That's correct. In the GAPMS I did in 2017, for, I think, like the nitrous oxide of -- pretty much like an adjuvant to this, kind of jumped-up asthma test, we didn't do a cost budget analysis because, like, we weren't going to cover, it's not going to affect anything.

Q So then you did evaluate whether it was budget neutral. You won't be covering it, so, therefore, it was neutral?

A Well, we just -- we just don't -- we just don't do one, because, I mean, we're not covering it. So it comes down to if we were going to make a coverage determination, that's when you do a fiscal analysis. So a coverage determination is definitely turned into a fiscal -- it needs -- it needs a fiscal analysis, because we're -- need to find out whether or not we're going to be able to stay within our budget.

Q I see. I see. So in this instance, because we are talking about the only GAPMS that excluded a service previously covered, did you do anything to determine whether or not that would cost or save the state money?

A No.

Q I think you have -- you brought information with you today about this. How did you collect state Medicaid program coverage data?

A So on that spreadsheet, so Dede Pickle, she went across the -- yeah. So she --

MR. JAZIL: Do you want to mark it as an exhibit?

(Whereupon, Exhibit No. 13 was marked for identification.)

THE WITNESS: She surveyed 50 states and I think territories -- even up in the territories -- and was looking to see what their stances were on gender-affirming care, to see whether or not they had statements saying that they will cover it or policy saying that they wouldn't. And then there -- those that just didn't have a policy available, or had no policy in place.

BY MS. DEBRIERE::

Q So Dede Pickle was the one who put together

the spreadsheet?

A Yes.

Q Okay. And where did she look to find this information in each state?

A Well, she went to their state Medicaid web pages, looked at their -- like, their coverage guides or materials in each state Medicaid -- Medicaid programs. There can likely be idiosyncrasies. I mean, some have -- some are like ours, have a ton of coverage policies, others are like Texas, Texas has one gigantic coverage policy, which actually does -- despite the fact it's huge, it's actually kind of more efficient. It's -- you can get everything from there. But that's -- that's what they do in Texas. Everything's bigger in Texas. But she went and looked at all of the different state -- various state Medicaid programs and saw what their policies were and saw what was available. And, of course, put the findings in the GAPMS report.

Q Did she only do an online search?

A Yeah, it was only an online search.

Q Did she contact any of the Medicaid programs?

A No.

Q Did she look at any of the policy reporters?

A No, we -- no, we didn't use policy reporter for this GAPMS.

Q So just looking at the state's Medicaid Agency websites?

A For the Medicaid, yes. But, generally, without having worked in Medicaid, one of our research criteria for across all kinds of reports and projects is that we do want to see what other states do. And so that gives us a great deal of familiarity of how to navigate other states' programs. And one of our side projects is the statewide Medicaid managed care program. And, of course, we're always looking to see what other states are doing. So we get a great deal familiar with how to navigate the web pages of other states.

Q So at least half the states' Medicaid programs explicitly cover pubertal suppression treatment for gender dysphoria, is that correct?

A Based on -- based on the findings of the map. So what -- so I will defer to the findings on the map.

Q Only ten exclude?

A Defer to the findings as stated in the map.

Q Okay. How about we do this: Based on the findings in the map, only 10 states explicitly exclude pubertal suppression therapy. How did you take that into account when you reached the conclusions that you did about the services being experimental, that particular service being experimental?

A As far as that goes, it's informational, but there was -- there was a divide between states that do cover and states that don't. Primarily when making the determination we focus -- we really focused on the evidence and what the evidence said about treatments for gender dysphoria since the Medicaid program -- since there is -- seems like there's an absence of policies for a lot of states. There are some states that come out and say yes, and then there are some states that say no. There is a -- there's a divide and you can even potentially say like there could be a debate between amongst the 50 states plus territories of whether or not coverage is appropriate.

Q But you did say earlier on that you -- whether a service is covered under the other state Medicaid programs is usually a factor that you weigh heavily in determining whether a service is experimental.

MR. JAZIL: Object to form.

THE WITNESS: So when it comes down to it -- it's like, so often, it's not just other Medicaid programs, but also Medicaid programs are similar to Florida. There are some Medicaid programs -- I'll name two -- New York and California that are -- that cover things very, very liberally, as far as services. Like, these added everything in their

fee schedules, where Florida Medicaid -- and Florida Medicaid prides itself on being a very fiscally responsible Medicaid program. So often we try to see what states that are similar to our Medicaid program, what they do. But we also do see, we see overwhelming amounts of coverage from states like us and states across the union, then that does factor in our decision, but for in this circumstance, because there is a split, if we were going to have to more -- rely more so on the evidence, than the notion that all these states cover services, there -- it's not -- it's not unanimous at all.

BY MS. DEBRIERE::

Q Did you ever contact the states that explicitly exclude and ask them why they explicitly exclude?

A We did not.

Q Did you ever call those states that have no coverage statement one way or another and ask them?

A We didn't reach out to states. I mean, their policy's online. I mean, that -- I mean, their published policy is sufficient to give us the responses we need to look at -- to look at it. Even for other GAPMS, we don't contact other states.

Q Did you analyze how much Florida Medicaid spends on -- spent on treatment for gender dysphoria prior to the categorical exclusion?

A No, we did not.

Q Do you have any plans to reevaluate your findings in the GAPMS report based on the September 2022 release of the WPS standards of care version eight?

A So in the immediate term, well, we don't, so -- but, I mean, we can reopen the GAPMS later on, there is -- there is a process for that. But generally, I mean, these standards of care, I mean, based on the release of one set of new standards of care, I mean, for the time being we don't have any immediate plans, not based on the release of one new update.

Q Okay. How long did you personally work on that initial draft of the June 2022 GAPMS report?

A Oh, I was working on it pretty much until the day it came out.

Q And you started that second week in May?

A Well, no, that was after I had the very first initial draft done.

Q Okay. So tell me when you first started working on it.

A April 20th.

Q Okay. So from April 20th until when it came

out. Published on what -- well, we know that it was first reviewed by your higher-ups on June 1st. So April 20th to June 1st?

A Yeah, that's sufficient.

Q Okay. And you worked with Nai Chen and Dede Pickle.

A Uh-huh.

Q Did you read all of the articles in the work-cited section?

A I read every single document in that works cited section.

Q 88 articles?

A All of them.

Q Okay. Were you able to read everything, understand it, and draft a report in --

A Yes.

Q How often during that time period did you communicate with the consultants?

A Oh, I think between four and five times.

Q And four or five times over that entire time period?

A Yeah, during those time periods, yes, we have -- periodically have, like, a one-hour discussion with them.

Q So you talked to them about five hours total

over that time period?

A I think that's a valid estimate, yes.

Q Okay. Do you think it's more than that, like more like 10 hours?

A No.

Q Okay. Turning back really quickly to the amount of -- the cost of treatment for gender dysphoria. How much was spent on the coverage of gender dysphoria versus how much was spent -- strike that.

Do you know how much, prior to the adoption of the categorical exclusion, how much annually AHCA spent on the coverage of gender dysphoria?

A We did not.

Q Are you able to obtain that information?

A Our data analytics between managed care plans paid per claim, and anything in fee-for-service, our data bureau could probably muster that up.

Q Is there a way that we should ask for that information to make the question clearer?

A You'd want to -- you would -- to put in a request we would need diagnosis code, we'd need NDC, and we would need CPT codes.

Q And what's NDC?

A National Drug Code.

Q Okay. And then for surgery, what would you

need?

A You would need the corresponding CPT code.

Q Okay. So you need the diagnostic code, the NDC for drug coverage, and the CPT code?

A And the time -- the date ranges.

Q And the date ranges. Okay. And then you could tell us how much AHCA -- or the Florida Medicaid program paid in coverage of -- treatment for gender dysphoria over a given period of time. Okay. When you were communicating with the consultants about drafting the June 2022 GAPMS report, what kinds of questions did you ask?

A Generally, questions about -- mostly just questions about, like, articles, like studies, making sure we have our bases covered, things like that. We wanted to make sure we didn't miss anything, or there's anything glaring we -- because it isn't a piece of academic work it is, it is -- mainly it's like a thesis or a dissertation, because we make a case, we have to support that case. So we want to make sure we have our bases covered.

Q What were the consultants' positions on WPATH?

A Their positions were that -- I think they identified -- all they did was identified it as an advocacy group, like a combination of clinical

professionals, plus advocates, community activists can join it. So that -- it's kind of a hybrid organization, that they explained that to us. So that was pretty much all the information they gave.

Q And you felt like that was an adequate explanation of what WPATH was?

A Yes.

Q What about the Endocrine Society? What was their position on?

A Their position was the Endocrine Society. I mean, it is an established clinical organization. They felt like the other guidelines, they had released guidelines, but the Endocrine Society was transparent in releasing their guidelines. They did clarify that their recommendations were based on weak or very weak evidence. They also clarified that their guidelines were not a standard of care, that they were just guidelines.

Q And that's the Endocrine Society. Who does that -- or your consultancy, who did that?

A The Endocrine Society. So the Endocrine Society, in the text of their guidelines, they do identify each line of the treatment model, like the puberty suppression, the cross-sex hormones and surgeries. Primarily the hormones is the Endocrine

Society, but they are very clear that it's either low- or very-low-quality evidence that supports it, and they also do put that disclaimer on there, this is not a standard of care.

Q What was your -- what was the consultants' position on the American Psychiatric Association's recommendations for gender-affirming care?

A It didn't come up in the conversations.

Q Okay. How about the AAP?

A The AAP was that the evidence available to support the AAP's positions wasn't sufficient.

Q Okay. What about the AMA?

A We didn't talk about the AMA.

MS. DEBRIERE: Okay. So I would like to -- do you have the exhibit of the Medicaid policy routing and tracking form for the June 2002 GAPMS?

MR. JAZIL: Can you re-mark on this --

MS. DEBRIERE: Yes, please. I think -- I need a bigger one.

(Whereupon, Exhibit No. 14 was marked for identification.)

THE WITNESS: Yeah, that new formulation makes it taste just like the real thing.

VIDEOGRAPHER: It's pretty good.

MR. JAZIL: See, we're finding common ground.

THE WITNESS: Wasn't, like, Coca-Cola and all their peace commercials, they were holding hands around the world? That was from the '70s, I think.

BY MS. DEBRIERE::

Q Okay. So I'm handing you what's been marked as Plaintiff's Exhibit 14. It's the Medicaid policy Routing and Tracking Form for the June 2022 GAPMS. There's a start date column there. What's that mean?

A That's a start with the routing process. So generally, for this, usually -- usually they try to provide like a window. We always have, like, a window of review. So for this, we enter the dates in the system. The GAPMS is routed to first -- well, actually, since my supervisor Dede was out, I was her delegate, so I did sign on her behalf. Then it went to Ann Dalton who signed. And, of course, Secretary Weida, of course, signed in his role, and then went to Deputy Secretary Wallace.

Q Okay. So start date's when the document hits their desk?

A Yes.

Q Okay. And then end date's when they've reviewed it and passed it on?

A Yes.

Q Okay. Date received is going to measure the

date that it hit their desk, but they didn't necessarily pick it up and start reviewing it? I'm trying to understand what's the difference between --

A Date received should be when they got it.

Q Okay. And the start date's when they start reviewing it? What's the difference there?

A Start date, end date -- yeah, that should be.

Q And the approval column means that the GAPMS was approved by each person that checked the box and initial by it?

A That's correct.

Q Okay. So the June 2022 GAPMS report, which is 46-pages long and contains five separate reports from AHCA consultants, it was reviewed and approved by each person on this list in one day?

A Yes.

Q And all four people on this list reviewed and approved the June 2022 GAPMS report in the span of two days?

A Uh-huh, that's correct.

Q Oh, I see there MB for DVP.

A Yeah.

Q Why choose to adopt the 2022 GAPMS report into rule?

A Because -- so since we had determined it to be

experimental and investigational, so we decided that we didn't need to make the -- based on the evidence, based on what the GAPMS said, the categorical exclusion promulgating the rule is necessary.

Q Okay. So you adopted into rule because it was a categorical exclusion?

A It was going to be, yes.

Q When was that decision made?

A The decision that was made -- the decision to make -- to make a new categorical exclusion, of course, that was not going to be made until after we had completed the GAPMS report and signed off on, because obviously, had either the experts had they disagreed with one another, or if I'd come up with a different conclusion, can't make a categorical exclusion unless everyone was in sync. So it was one of those things where had -- had the expert opinions disagreed with each other, had I come up with a contradictory conclusion, there -- you had -- we had to wait until after the report was done before we'd sign whether or not to proceed with the categorical exclusion.

Q And when was the decision made to adopt it into rule? Was that at the same time that you decided to make it a categorical exclusion?

A That was made after we had had the report

signed and done.

Q Okay. Sorry. I need to be more specific. What date was that decision made?

A Well, I think it was probably made June 2nd.

Q Okay. And who made that decision?

A That would have probably have come down from Secretary Marstiller, that would have come down from now-Secretary Weida, and it would have come from our General Counsel, Josephina Tamayo?

Q Why would it have come from those people?

A So -- because, of course, with our General Counsel, with our Secretary, I mean, they do make the decisions for the Agency. It's not out of the -- I mean, it is typical in their role to make a decision to promulgate something into rule.

Q Would that generally, though, be handled by the Bureau of Medicaid policy?

A Sometimes. It depends on -- depends on the nature of the rule change. Depends on where -- where it's originating from.

Q How often has that decision come from the Medicaid Secretary?

A So let's -- so to talk about the rulemaking process a little bit.

Q Yeah.

A So rule -- proposes for rule changes come from all different directions and --

Q Let's back up. Instead of talking generally about rule changes, let's talk about changes to coverage policies.

A Those can be made by our Deputy Secretary. Those can come from the Secretary. I mean, anyone who --

Q How often does that happen?

A We can't speak to how often it happens. I mean, it does happen.

Q Had it happened more with the Bureau of Medicaid policy?

A You mean, those in Medicaid policy who initiated these changes?

Q More often than not?

A I actually would probably say not.

Q Oh, okay. I'm just -- I'm surprised because we learned from Ms. Dalton that the -- both the rulemaking process and the coverage policy units are housed within the Bureau of Medicaid policy.

A Well, that's correct, they are, but often they're responding to directives given to them from either senior leadership or legislative changes.

Q Okay.

A So, yeah, while they are the ones that implement and write and craft the new policies or update the policies, they're often not the ones that are piloting these new policies.

Q Or initiating the decision as to whether or not --

A Precisely.

Q -- or adopt them into rule?

A Correct.

Q So you said that it was the decision to adopt into rule was made on June 2nd, is that correct?

A That's correct.

Q Okay. And the notice of rule development, that was issued on June 3rd, correct?

A Yeah.

Q I swear.

A Yeah, I'm deferring to the record on that.

Q Sure.

A The rulemaking process is highly documents, so I'm going to be deferring to the documentation for the rulemaking process.

Q Okay. So it took less than 24 hours for AHCA to decide to adopt the conclusion in the 2022 GAPMS report into a rule? And even less than that, because you made it the same day that the report was released,

correct?

A Yes.

Q And at that time, you also knew which section of 59-G it was going to go into?

A Yes, we did.

Q And who had to sign off on that decision?

A So all of our -- so whenever we adopt a rule, it does go through a lengthy routing process. So it does start -- the process starts in the Bureau of Medicaid Policy, starts with the rules -- we have a rules unit. That gets signed off on, then it goes to the AHCA administrator authorities section, they have to sign off. Then after that it goes to the Bureau Chief of Medicaid Policy. Of course, likewise, they have to review and sign off. Then it goes to the Assistant Deputy Secretary of Policy and Quality. They have to sign. Then, of course, the Deputy Secretary for Medicaid has to sign. General Counsel's Office has to sign. And then the Secretary is privy to all the changes. And if Secretary decides like, wait, wait, we can't do this or, no, there's a problem, yeah, that sometimes can result in a frustrating headache, because it takes a lot of work to get something that far.

Q Well, so the decision to adopt a categorical exclusion to rule was made on June 2nd and the Notice of

Proposed Rule was made on June 3rd. So it was routed through that entire process in less than 24 hours?

A Are we talking about the GAPMS or the rule?

Q The rule?

A Yes. And that -- and that's not unusual sometimes for -- for the process to move very quickly.

Q Okay. Because you just made it sound like it was a very lengthy process.

A It is with the number of people, but it's -- the rule content is very -- it's a very small addition. It's not like a brand new coverage policy, because often -- it depends on the nature of the rules. Like one addition, that can move fast. Sometimes with -- like, for instance, in my experience as a program administrator, we completely overhauled the community behavioral health policies. That was five new coverage policies. So that, of course, is going to require a much lengthier review process rather than a quick amendment to a rule. So it really depends on the nature of the rule. If it's a very lengthy coverage policy, yeah, that can take some more time if it's -- but if it's like adding a few bullets or amending a line, that can -- that can move along much faster because the review time's just not -- a lengthy review process is not necessary.

Q Or deciding to eliminate three types of services that were previously covered by Florida Medicaid?

A Correct. And, of course, but -- and, of course, we have the GAPMS memo to substantiate that.

Q Okay. Okay. So speaking to the rule, it bans Medicaid coverage for -- puberty blockers or cross-sex hormone therapy and surgery if done so to treat gender dysphoria, correct?

A That's correct.

Q But not to treat other diagnoses?

A Not to treat other diagnoses. Only for the diagnosis of gender dysphoria.

Q Okay. Is this the only time that GAPMS has been used to categorically eliminate coverage of treatment for a particular diagnosis?

A For the one -- I think pretty much since the institution of the GAPMS process, I think this was a first.

Q Once the decision was made to adopt the conclusions of the 2022 GAPMS report into rule, who was in charge of that process?

A So our rule promulgation process, Cole Gerring, he oversees the rule promulgation process for our coverage policies and administrative rules for

Medicaid.

Q Does he head the Rules Unit under the Bureau of Medicaid policy?

A Yes, he does.

Q Who drafted the actual language for the rule?

A I believe -- I believe he drafted the language.

Q Did anybody revise it or have any input that --

A There was input. So I mean, there were some discussions. I remember we did have a meeting with everyone to -- between, I think, like, Sheena Grantham, myself, I think Dede Pickle, I think Secretary Weida, I think like Sheena Grantham from General Counsel's office, since rules are her area. I think there were there was a -- there was a discussion on making sure this was the finalized content we wanted.

Q And how long did that discussion take?

A About an hour.

Q Okay. And what kinds of topics were discussed during that?

A Just determining how granular we should get, mostly.

Q Okay. Okay. Was there any conversation about whether adopting this categorical exclusion might

violate comparability under the Federal Medicaid Act?

A No.

Q What about EPSDT?

A No, because since we already have the -- we've already had the GAPMS report to substantiate the overriding EPSDT guideline -- guidance and requirements.

Q Because Florida Medicaid does not have to cover a service under EPSDT if it's experimental?

A That's correct.

Q I had another question. Talking about how granular to get with the language, was there any conversation about what the Federal Medicaid Act requires in terms of prescription drug coverage?

A I don't think so. Not during that conversation.

Q Any other conversations had about that?

A As far as the federal requirements for prescription drug coverage? No, I don't think we had any conversations like that.

Q Okay. Any other conversations about comparability under the Federal Medicaid Act?

A No.

Q So comparability under the Federal Medicaid Act was not taken into consideration when adopting the categorical exclusion?

A No.

Q Who planned the public hearing regarding the proposed language in 59G-1.050(7)?

A So for the public hearing, since we did anticipate a larger than normal crowd, we -- so I think that was a joint effort between Cole Gerring I think, Chief -- now Chief of Staff Brock Juarez, then Chief of Staff Cody Farrell, and I think -- I think Secretary Weida also had a little bit of input when it came down to selecting the venue and making sure that we had adequate staff and then also arranging for security as well.

Q Why did you feel a need for security?

A Because of this -- the controversial nature of the change and how those with opinions on it -- those with feelings about it, I mean, they are deep-seated. I mean, there's -- so because of the sensitivities involved, we just felt that it would be best in the event -- and we did think it was unlikely, but in the event that someone might get upset or unruly, to have security.

Q Why did you pick the venue you picked?

A Size and location.

Q What factors did you take into consideration for size and location?

A That we would have adequate seating. That, of course -- of course, location where it was, being downtown, so --

Q Downtown being an easier location to get to?

A Yes.

Q Why did the location need to be easy to get to?

A Because, I mean, since -- I mean, you know, we do government in the Sunshine, we wanted the hearing to be accessible to as many people as possible, so we wanted to be able to fill as many seats as we could. The facilities here at AHCA weren't going to be sufficient for that. The Department of Transportation auditorium was a very, very good venue, not just -- not just to be able to provide those of us who were on the panel visibility to the audience, but also just because of the seating capacity. So it just was an ideal venue compared to what we had available at the Agency.

Q Where do you normally hold rule hearings?

A We usually hold them here.

Q Why were you concerned about adequacy of seating?

A Because we did expect a large turnout.

Q Why did you expect a large turnout?

A Because of the amount of coverage that the

GAPMS report had received, because of everything that we'd been seeing, as far as -- per previous news stories prior to the release, we just knew that this was a sensitive subject. A lot of people have a deep-seated conviction about it one way or the other, and we just anticipated a large turnout.

Q In the planning of the public hearing, did AHCA communicate with the Governor's office at all?

A No.

Q Did AHCA communicate with Department of Health at all?

A No.

Q Who participated in the public hearing from AHCA?

A So the participants from AHCA were myself, Sheena Grantham, whose General Counsel's office, Secretary Weida. Those are the -- those are the three of us who were on the panel for AHCA. And, of course, I think Cole Gerring handled the administrative procedures and then I think to help -- help with crowd control, we had, I think, Brock Juarez and some of the staff from communications also helped arrange in making sure that there's adequate seating, and just kind of serve -- just helping out in any way, or any capacity that was necessary, as needed.

Q Did anybody at AHCA help facilitate the attendance at the hearing?

A There -- I think there's a speaker sign-in sheet at the entrance. I think that -- like, I think one of the Agency staff under Brock at the time was -- was allowing people to sign in.

Q Were there any particular people that were encouraged to be at the hearing?

A No.

Q Are you aware of the Governor's office encouraging anybody to attend the hearing, anybody in particular?

A No. No.

Q Did anybody pay someone to attend the hearing?

A So for our -- for our experts, Dr. Grossman, Dr. Van Meter and Dr. Van Mol, they were compensated for their time spent at the hearing, or their time traveling -- for Dr. Van Mol and Dr. Van Meter, their time traveling and their travel expenses. So we did reimburse them, but that was it.

Q Did that include the same agreement with the $35,000 cap or was that a separate agreement?

A I don't think it was a separate agreement, because the three of them had not come anywhere close to exhausting their caps.

Q Did AHCA provide any materials to those consultants prior to the hearing to review for the hearing?

A On the day of the hearing we gave -- we gave them each bound copies of the report, but those materials were already available online, so -- but we just -- we just gave him paper copies or to reference but nothing -- no other additional materials.

Q You didn't provide them any other materials other than the GAPMS -- the June 2022 GAPMS?

A That's correct.

Q To review prior to the hearing?

A Correct.

Q Did you have any meetings with the consultants prior to the hearing to prepare for the hearing?

A We had a couple -- there were a couple Zoom calls.

Q How long did those last?

A About an hour?

Q What kind of things were discussed during those meetings?

A Mostly the format. You know, we were talking about, like, of course, Dr. Grossman, who was not going to be able to travel. So we were talking about technological arrangements. I think with Doctors Van

Meter and Van Mol, we were mostly talking about travel arrangements and, like, where they'd sit and so forth, so I mean --

Q Did you offer any questions that they might anticipate from the audience and how they should respond?

A To our experts? We didn't.

Q And why was it necessary to have the consultants there?

A So -- well, since -- because we were actually anticipating a crowd that was going to be largely opposed to the challenge exclusion, we wanted to be able to respond promptly and articulately to any comments that were provided.

Q If you wanted to respond promptly and articulately to any comments that were provided, what was the purpose of having a public hearing?

A So the public hearing is to, of course, gather feedback, but we also knew that we were likely going to have either some type maybe medical professionals or advocacy groups, or other advocates, and we did want to be able to provide them with a little bit of engagement to show that we do take their comments into consideration, that we do think about them, that we do engage with them.

Q Did the consultants respond to any comments by a supporter of the rule?

A I don't think they did, actually.

Q How about those that were opposed to the rule?

A There was really -- I think Dr. Van Meter responded once. I think Dr. Van Mol responded once. And Dr. Grossman didn't respond to anything.

Q And that was -- both of those responses were in response to individuals who were speaking in opposition to the rule?

A Yes.

Q Have you ever participated in another rule hearing where there is direct and prompt response to public comment?

A Yes. Yeah, we do. Yeah, I mean, I've participated in numerous rule hearings here at the Agency. We do respond to comments.

Q When you say we, do you mean the office staff?

A Office staff, yes.

Q What about consultants with which AHCA has contracted?

A We -- we generally don't -- we generally don't. It's a -- it was a unique experience for this case, but we generally don't have contracted consultants at our hearings.

Q And where did the slogan, Let Kids Be Kids come from?

A So that came from within, I think, our own Agency, our Communications Department or the Chief of Staff's office.

Q Was there any input in developing that from outside entities?

A No.

Q So AHCA is wholly responsible for that slogan?

A Yes.

Q Was AHCA responsible for the printing off of the stickers that had the slogan contained on it that were being passed out at the hearing?

A No.

Q Do you know who was responsible for that?

A We do not know where those came from.

Q Is it normal to have slogans of an Agency passed out at a rule hearing? Have you ever seen that before?

A I have not seen that before, so -- but we -- that was not something that the Agency had anticipated, and we certainly were not responsible for the passing out of stickers with a slogan on it.

Q Did outside counsel appear at the public hearing? Did AHCA outside counsel appear at the --

A Yes, they did.
Q Why?
A Because, of course, sensitive nature. I mean, there were -- there were attorneys also -- there was -- because there was counsel that -- you know, who are representing the plaintiffs who were also there. We do anticipate litigation, so it was -- we did see to it that we had outside counsel there to gather information and be able to observe the procedures.
Q So AHCA had -- at the point of the public hearing, AHCA had retained outside counsel to defend against any potential litigation that the rule invited?
A Yes.
Q What was outside counsel's role at the hearing?
A Outside counsel's role, I think -- I think just calling up the speakers as they came. I think they actually -- we had them helping out with the -- with the hearing process and procedures.
Q What kind of -- well, okay. Did AHCA give the consultants any instructions to prepare for the hearing?
A Basic ones. Most of -- I think, you know, like to when responding that, you know, we would prompt them to respond. Basic -- very basic instructions.
Q And so the instruction was that when AHCA

wanted someone to -- one of the consultants to respond, you would prompt them to?

A So, yes. And during the hearing, Secretary Weida would defer either to Dr. Van Meter or he would defer to Dr. Van Mol when he needed -- when a response was needed from one of them.

Q Okay. Just going back to the slogan really quick, who in AHCA came up with that Let Kids Be Kids slogan?

A I think -- I think it was a -- I think it was a team effort. I think, like, it was Cody Farrell and, I think, Brock Juarez. I think they worked on the Let Kids be Kids slogan.

Q Anybody else?

A No, it would have been primarily them.

Q Who directed them to develop the slogan, or was it their idea?

A So the orders would have been given verbally. We don't know, like, exactly how they were told to do that specific slogan.

Q When was the -- when was the slogan developed?

A It was developed, I think, in the days preceding the release of the report.

Q When was the final draft of your report done?

A So the final draft -- so the final draft as

far as -- so the very, very final draft, like the last finishing touches, as much as copy edits, was done that week of the 2nd, but as far as the substantive components of the report, that was done probably a few weeks prior to the release.

Q So when was the slogan developed?

A Slogan was developed -- I think they did -- were working on it, like, the week before the release.

Q Is it normal for AHCA to develop a slogan for the conclusions found in a GAPMS report?

A No, this is -- this was a first.

Q Why develop a slogan?

A Well, we do develop slogans for whenever we do have -- do releases, or whenever we have new programs. For instance, Canadian Prescription Drug Importation, we do have a slogan for that. We do have a web page dedicated to prescription drug transparency pricing. So we do have -- often to correspond with our press releases, we often will do a logo.

Q But you just said it's not normal for a slogan to be developed for GAPMS. So why do it in this instance?

A So because HHS had already -- had made announcements with the publication of their documents, Department of Health had done theirs, we, of course,

likewise, because we were publishing this document, was to, of course, create the website and to, of course, create some graphics along with that website.

Q So was the slogan meant to draw attention to a particular message that the Agency was trying to send?

A No, I mean, other than that, we did the report and we did was evidence-based and concluded these treatments were experimental and investigational.

Q For children and adults, right?

A For children and adults.

Q And why was it Let Kids be Kids?

A Because -- so for adults with -- when it comes to Medicaid, states -- because you don't have the EPSDT consideration, states can be much more -- have much more discretion in denying coverage. They have a lot more latitude to be able to deny coverage, so -- but for services that are intended for pediatrics, or are under EPSDT considerations, that's partially -- partially why not -- like one of the services that we evaluated was puberty suppression, adults aren't going to use that.

Q But the conclusion of the GAPMS report was that all treatment for gender dysphoria was experimental for kids and adults?

A That's correct.

Q The slogan's just targeted at kids?

A Yes, that's correct.
Q Why?
A So it comes back down to the EPSDT considerations. Because like -- well, for starters, I mean, when it comes to adult coverage, that's a totally different category. But for kids, especially with puberty suppression and especially with the cross-sex hormones, because of the experimental and investigational nature, that's probably why we -- why the Agency embarked on a, I guess, child-based kind of graphic for its web page.
Q What does it mean Let Kids be Kids?
A I think, well, as far as semantics go, I think that could mean something different to everybody.
Q What did AHCA by it?
A Let kids be free to explore their own identities and figure out who they are.
Q What are some examples of other slogans AHCA's used for its programs?
A Well, lower prescription drug costs.
Q That's a slogan that we can find?
A Yeah. I mean, that's one we've been using for a while. I was using as -- under my signature on my email, so things -- yeah, but, I mean, there are slogans. I think like prescription drug transparency.

I mean, that's part of, you know, the state's mission is when it's coming up with new programs -- and obviously it's not isolated to AHCA, I mean, every agency's going to have slogans and graphics for their new programs. I mean, if you look at the Department of Children and Families, they're promoting Hope Florida in a big capacity. So for a lot of these -- so for a lot of these programs that they want to have -- they want them to be now such high profile, of course there's going to be graphics and slogans.

Q Prescription Drug Transparency is not very catchy, I'll say. Why create a web page dedicated to supposedly fact-checking Health and Human Services? Is that normal?

A No, it's not, but following -- but the thing is following the review of the evidence and how our findings really did contradict what was in HHS documents, because we really wanted to demonstrate -- because we do understand, it's a GAPMS report, it's 46 pages. Not many people are going to take the time to read it. So we wanted to kind of put it -- we wanted to put the case in more simplistic layman's terms and make it accessible to the audience to show that, hey, yeah, this is a sensitive report. Yeah, if you got an hour and a half and you understand medical terminology and

literature, you might have fun reading it, but for quick information, we wanted to provide a resource, because HHS had made all these claims regarding gender dysphoria treatment, we want to make it accessible to everybody that they could look at it and five minutes later understand the gist of what we were saying in the GAPMS report.

Q Prior to the July 8th public hearing, did AHCA communicate with anyone from the Christian Family Coalition?

A No.

Q Anyone from Florida Citizens Alliance?

A No.

Q Including Pastor Rick Stevens?

A No.

Q Anyone from Warriors of Faith, the Florida Chapter?

A No.

Q Including Troy Peterson?

A No.

Q Anyone from Protect our Children Project?

A No.

Q That includes Pastor Ernie Rivera?

A That's correct.

Q Okay. Anyone from Florida Prayer Network?

A No.
Q And that includes Pam Olsen?
A Correct.
Q Anyone from Partners for Ethical Care?
A No.
Q What about Chloe Cole?
A No.
Q Sophia Galvin.
A No.
Q Anyone from the Rainbow Redemption Project?
A No.
Q How many comments did AHCA receive in response to the proposed changes to 59G-1.050?
A 600 or so.
Q Oh, that's all? Did AHCA read them all?
A We did.
Q Who at AHCA reviewed them?
A It was a combination. So, like, I think Cole Gerring, Nai Chen, myself, I remember we did sit down once and we started going through all the emails. Most of them were very brief, maybe like one or two lines, not substantive whatsoever. For the more substantive ones, those I did careful reviews of.
Q So it's three people. You, Nai Chen and Cole Gerring?

A Uh-huh.

Q Okay. And you split them up amongst each other?

A We read them together.

Q What process did you use to decide whether or not to incorporate the input into the final rule?

A We wanted to look at the -- we looked at the content of every -- of every single comment. A lot of the comments were just saying don't do this, or something -- or something very sensationalist. So a lot of the comments we really couldn't take into consideration because there wasn't -- there wasn't -- there was no substance behind them. So there were some comments that were -- we did receive some feedback from -- I think we got something -- we got -- we got a lengthy comment from American Academy of Pediatrics. We got a very lengthy one from Yale University. We got feedback from the Endocrine Society. I think one of UF's gender clinic physicians wrote us up, not a terribly long comment, but wrote us a comment. So we did want to take a look at the substantive onces. But we did them into -- we did take into consideration every comment submitted to us.

Q Did you receive any comments from the people who had Medicaid coverage for treatment of gender

dysphoria?

A During the comment review, there wasn't any -- we didn't -- we didn't notice any comments from those offhand, but, of course, that was over six months ago. So we -- because of the volume of comments, we did have to read them fairly quickly.

Q Had you received a comment from anyone who was receiving Medicaid coverage for treatment of gender dysphoria, how would you have factored that into your ultimate determination?

A Well, we would -- we would have looked at it. We would look at the content. We were wondering, like, what kind of services they were receiving and so forth, but it depends on what the comment was. If they provided a case for why they were getting it, you know, but we didn't -- we didn't receive anything like that.

Q For those people who lost Medicaid coverage for treatment of gender dysphoria, or were going -- stood to lose based on the categorical exclusion, during any of this process, was there any consideration given to the inability to access that care?

A There was. We did have questions. We wanted to make sure that if we were to discontinue individuals who were receiving, particularly cross-sex hormones, we wanted to -- we did have questions like, would there be

withdrawal? What would -- would they need some -- would they be weaned off the medication? How would -- how would the Agency take that into consideration? And we actually kind of realized that if, say, if they do need to discontinue testosterone because of the categorical exclusion and their doctor deems, well, they're going to need some small doses to wean themselves off, but we also realized that necessarily wouldn't be for gender dysphoria, that would be because of withdrawal symptoms, and that would be a different diagnosis.

Q Did you give that guidance to any treating professionals or Medicaid recipients?

A No, we didn't.

Q Okay. Why was it necessary to review the comments quickly?

A It wasn't necessary to; it was just -- I mean, most of the comments were because the nature, they were -- most of them were sensationalist, a lot of them just hurled insults at us, a lot of them ad hominem attacks, things like that. We just kind of went through a lot of them very fast.

Q So that wasn't quite my question. It sounds like you were able to review them quickly.

A I think I want to rephrase as we were able to. We weren't really in a hurry. Because, obviously, like,

we got a 47-page comment from Yale University. That was not a five-minute skim, obviously. So there were those we deemed to be substantive comments that warranted in-depth attention, and then there were those we deemed non-substantive comments and just read. They're like -- yeah, we received some ones that were using, I will say, the colorful metaphors. And then we don't -- I mean, obviously, not going to pay attention to those, so -- but the substantive ones that where they're putting together, like, an argument or making points, being something that we have to take back and think over, we did invest time in those, yes.

Q Were there any discussions about the comments between you and Cole and Mr. Chen?

A As far as the discussions go, no, most of discussions were like, okay, let's move on to that one, that one's just insulting us or that one's -- that one's expletive-laden, let's move on. So when we got the substantive ones, of course, those were -- those were handled differently.

Q How were they handled differently?

A So those, because they were going to take in-depth review is not something that's going to be a group activity. Of course, we printed those out and started reviewing with a fine-tooth comb.

Q Did AHCA review the underlying cases and studies cited in those substantive comments?

A Yeah.

Q Okay. How did they factor those in to the ultimate determination?

A So we did take a look. So we checked to see what studies that Yale University and the AAP brought into it. And we looked at two responses from the Yale University, not just the response that they made to us, because Yale University frequently cited their response to Texas and Arkansas, we pulled that up as well and did -- and analyzed that. So we looked to see what articles they were citing and we were -- so we checked to see whether our GAPMS report or any of the expert reports also did evaluations of those studies to see that -- make sure that we were in alignment.

Q Okay. Do you remember any particular underlying cases or studies?

A There's -- I think there's one by Jack Turban that they cited. I think there was one that we did cite in GAPMS review. We didn't discuss it at length, this was by Tordoff, et al. And we looked at that. And, of course, but we also captured those in Dr. Brignardello-Petersen's piece that they were evaluated as, like, being very low-quality or in a critical risk

of bias.

Q Okay. How did you determine whether -- okay. Turning to the implementation. Sorry.

A Okay.

Q Hold on. One second. Something breaking is coming in. Did you review any comments that reference court cases?

A We did see some comments that referenced, I think, like Bostock v. Clayton. I mean, there were some cases referenced in the comments, but, of course, I mean, we were primarily interested in -- we were looking for comments that were providing -- that were either providing examples of literature or anything that was going to contradict the GAPMS report. In other words, we were looking -- we were looking for anything that, I guess you could say, delivered, like, a mortal wound or something like that, something that would foreseeably cause us to have to go back and make revisions or cause us to have to retract the rule, or something that -- or a comment that we couldn't just dismiss or a comment that we couldn't explain. So those were what we were looking for.

Q What types of information provided by the public would have mortally wounded your conclusion?

A So a mortal wound would have come from a

quality study, or a number of quality studies.

Q And define a quality study.

A So something that -- well, a quality study, well, I mean, that -- that's a pretty broad definition of what you're asking for, and there are different ways a quality study can come about, but something that, of course, lengthy longitudinal histories on participants, either has adequate control groups. And this is not an all-inclusive list. These are just examples. Also follows participants for a lengthy period.

Q Well, what's the difference between that and a lengthy longitudinal study?

A Long -- when it comes to a longitudinal history, what we mean by longitudinal history, and this is often for behavioral health, is that longitudinal history is necessary to really ascertain the full impacts of somebody's mental health conditions. Because it's -- because mental health, it's not necessarily like an acute illness or a chronic condition diagnosis. So, like there's treatment histories, medications and -- like, in other words, and, of course, like activities of daily living, how that all is affected. So it's usually something that has to be obtained over a number of years.

So, mental health longitudinal histories, but

we also were finding in the studies that we evaluate for the GAPMS process that they lacked participants' longitudinal histories. If they even -- if they even did -- provided any histories or any -- identified the recipients or the participants at all. I mean, there were so many studies where they were -- I think there was one that we came across, and this was during the comment period, that was just a massive survey and they were trying to give gift cards to participants. And, of course, people were just completing it, but it was like a one-time snapshot, and it's subjective self-reports. So I mean, there are a myriad examples that we can say for high-quality evidence, and not to mention RCT's, as well. So --

Q What does that stand for?

A Randomized control trials. So there -- so, yeah, so that was what we were looking for, evidence that -- evidence that would hold up to questioning, and that's not what we were finding.

Q So in undertaking the review of the comments, the only thing you were looking for is anything that would, in your definition, cause a mortal wound to your conclusion in the GAPMS?

A That was among one of the things we were looking for.

Q What else were you looking for?

A I mean, we were looking -- we were looking for -- I mean, we, of course, we were looking to see if there's anything that would directly conflict with the GAPMS report. That was one thing, because the rule's foundation was the GAPMS report. So that's the big reason why we were looking for contradictory evidence or evidence that would be like, well, wait a second, we say it's all -- you know, because our primary argument is it's low-quality evidence and therefore experimental, experimental investigational. That basis doesn't sustain itself if all of a sudden there's modern, high-quality evidence out there. So we want to make sure that we had not left any stones unturned. But we were just -- you know, I mean, we -- this things we weren't -- that was the primary thing we were looking for.

Other things -- I mean, we also, I mean, anything that spoke to the legality of it, but I mean, of course, we wouldn't necessarily evaluate that. We'd turn that over to legal, but anything that was looking -- that was looking at the legality of what we were doing. So I mean -- so, I mean, there were different angles. I think when I was looking at it through my personal lens, that was what I was looking

for.

Q Are you aware that similar exclusions have been found unconstitutional in other federal districts?

A I am aware at the district level that there have been some -- some exclusions that have been tossed, yes.

Q All right. Turning to the implementation --

MR. JAZIL: We've been going for an hour and a half. Could we do a five-minute break?

MS. DEBRIERE: Sure.

VIDEOGRAPHER: This concludes video three. The time is 3:00 p.m.

(Brief recess.)

VIDEOGRAPHER: This is beginning of video four. The time is 3:08 p.m. we're on the record.

BY MS. DEBRIERE::

Q Just after that break, and I should have asked this earlier, just after that break, did you have any conversations with anyone during that break?

A During --

Q Just this recent break? Did you have conversations with anyone?

A I mean, talked about, like, personality types on 16 personalities, just had a conversation, but as far as the case goes, no.

Q Okay. What about at lunch?
A Just a quick touch-base with our attorneys.
Q Okay. How long did you talk?
A 15 minutes.
Q Okay. All right. Turning to implementation of the rule with managed care plans. Did Florida Medicaid managed care plans -- well, we've already answered that. What's the purpose of Inter-Qual?
A Inter-Qual?
Q Uh-huh.
A I don't have the answer to that.
Q Okay. Are you familiar with it at all?
A I'm not familiar with Inter-Qual.
Q Did AHCA develop, or help develop language for notices of adverse benefit determinations in order to incorporate the categorical exclusion of treatment for gender dysphoria?
A No.
Q AHCA didn't assist at all in developing the language for those denials for terminations?
A No, managed care plans were -- handled those themselves.
Q Okay. Did AHCA review any of the language that managed care plans submitted to AHCA for review?
A No.

Q Same question for notices of outcome relied on by EQ Health?

A No, AHCA wasn't directly involved in those.

Q Did they review the notices of outcome language?

A No.

Q Okay. What about Magellan?

A Magellan? No.

Q Did AHCA develop or help develop language for any other types of notices used to notify a Medicaid recipient of a denial or termination of treatment for gender dysphoria?

A No.

Q All right. Can I have the notice of adverse benefit determination, and that's Bates-stamped Defendant_ 000292335, I think. We'll check? Did I get it right? I don't think I did. I'll read the correct Bates-stamp on -- so this is going to be the Molina Health Care Notice of Adverse Benefit Determination. I'm not going to name the Medicaid recipient. And the date stamp appears to be cut off, but it is dated October 26th, 2022, and the initials for the recipient are AS.

(Whereupon, Exhibit No. 15 was marked for identification.)

MR. JAZIL: Counsel, can we agree that this should be confidential, attorney's eyes only?

MS. DEBRIERE: Absolutely.

MR. JAZIL: Do you mind if I write that on top of the --

MS. DEBRIERE: Not at all. Not at all. So the previous Bates stamp I gave was not correct, but the Bates stamp on this exhibit is cut off, so I can't provide the actual number, but I think I've sufficiently described it. And, of course, it will be Exhibit 15.

BY MS. DEBRIERE::

Q All right. This particular notice of adverse benefit determination is from Molina. In that second page there, it runs through AHCA's medical necessity definition, correct?

A Yes, that's consistent.

Q And that's consistent across notices of adverse benefit determinations?

A So each health plan is a little idiosyncratic in how they do NABD's. We'd have -- we'd have to verify with managed care plans. I mean, the contracts does provide specific requirements when it comes down NABD's and sending them.

MS. DEBRIERE: Mo, do you know if you guys have

produced an NABD template to us?

MR. JAZIL: We've never --

MS. DEBRIERE: I know they exist. They should be pretty easy to --

MR. JAZIL: I'll check. What's that stand for, again?

THE WITNESS: Notice of Adverse Benefit Determination. It's a long phrase for a denial.

BY MS. DEBRIERE::

Q Or termination or reduction?

A Or termination, or reduction.

Q Or partial reduction.

A It's --

Q Okay. So this particular notice of adverse benefit determination is to an actual Medicaid recipient, correct?

A Yes.

Q And it looks like it's been it's denying a request for coverage of testosterone cypionate.

A That's correct.

Q Okay. And what is the reason for the denial?

A The box for other authority non-covered benefits is checked off.

Q Why isn't the, request service is not a covered benefit, checked off?

A We would have to ask that question of the plans.

Q Okay. So you don't require some kind of uniform response to not -- that plans must provide when there's a non-covered benefit?

A We're not aware of one. There -- I don't think there's one mentioned in the contract.

Q Okay, but I guess my other question is, would it be equally sufficient, had they checked off, must meet accepted medical standards and not be experimental?

A They could have checked that box. They could have checked, the requested service is not a covered benefit. They could have checked other boxes, as well.

Q Okay, but it is accurate to say that it is not a covered benefit?

A Yeah, that is accurate.

Q Is any plan allowed to currently cover treatment for gender dysphoria of the services listed and 59G-1.050(7)?

A For any plan right now currently?

Q Yes.

A No. No plan can cover them.

Q Since the adoption of the categorical exclusion of treatment for gender dysphoria, how many notices of adverse benefit determination have been sent

to Medicaid beneficiaries that denied coverage for services on the basis of --

A So for MMA plans, so we did a little looking into this -- so for managed medical assistance, which most of these recipients, given their ages, are going to be on MMA, we do not actually require the MMA plans to submit reports regarding how many NABD's that they actually mail out to their enrollees. Long-term care, that process is different. We do require them for long-term care to mail those to report to the Agency how many NABD's they are sending out, but for MMA we currently don't have that as a requirement.

Q Okay. So is that -- does the same hold true for notice of appeal plan -- plan appeal resolutions?

A As far as that goes, I don't think -- I don't think we're collecting information from the plans on those.

Q Okay. So generally, not just as related to treatment of gender dysphoria?

A Generally.

Q What about notice of outcomes?

A Notice of outcomes, I don't think we're collecting them from those informations either.

Q Okay. Just generally, do any of those notices include reference to the variance in waiver process

described at Florida Statute 120.542?

A No. I mean, we definitely -- I mean, so looking at this, this is in compliance with what we do, we require them to have, which is an appeals process. So, no, we don't -- we do not require the plans to include the procedures for variances.

Q Okay. So those procedures are not listed in notices of denial?

A That would be correct.

Q Okay. How many grievances have been submitted to AHCA regarding a claim related to AHCA's adoption of the categorical exclusion of treatment for gender dysphoria?

A So that information, we do have a complaint hub for recipients and providers who'd like to submit complaints, be given the -- when the questions came in, we, of course, have to reach out because our complaint hub is actually down in Fort Myers, so it's not -- it's not here locally, so that's information we're still in the process of obtaining.

Q And once you obtain that, you'll provide it to us?

MR. JAZIL: Yes.

MS. DEBRIERE: Can you put that as a follow-up?

BY MS. DEBRIERE::

Q How many -- how many appeals of Notice of Adverse Benefit Determination denying care on the basis of the exclusion have there been?

A As far as appeals going up to the fair hearing level, I think that's zero.

Q Okay. What about -- yeah, so that would include both notice of plan appeal resolutions as well as notice of outcome?

A Yeah.

Q Okay. Prior to August 21st, 2022, did AHCA ever reverse a decision made by AHCA or by a plan to deny pubertal suppression therapy for the treatment of gender dysphoria?

A We did not.

Q You never reversed a decision to deny?

A To deny?

Q Yeah.

A No, we never did. Sorry. I misunderstood the question.

Q Okay. I just want to make sure you're understanding. So prior to the adoption of the categorical exclusion, did AHCA ever reverse a decision to deny puberty suppression therapy for the treatment of gender dysphoria?

A So if a plan reviewed for medical necessity

criteria decided, no, it didn't meet the criteria and issued denial, no, we never reversed it.

Q What about upon a fair hearing review?

A Are we talking about, like, since 2015?

Q Well, I'm asking ever, but if 2015 is a helpful marker.

A I don't have that information offhand.

Q Is that information you can obtain?

A I think we can.

Q Prior to August 21st, 2022, did AHCA ever reverse a decision to deny cross-sex hormone therapy for the treatment of gender dysphoria? And by reverse I include at the fair hearing level.

A That's information that we would have to obtain.

Q Same question for surgery in furtherance of the treatment for gender dysphoria.

A At the fair hearing level, we would have to obtain that.

Q So you will tell us the number of times, if ever, that AHCA reversed a decision at the fair hearing level to provide treatment in furtherance of -- services and treatment for gender dysphoria?

A We can confirm it. It's probably zero.

Q Okay.

A As far as overturning a decision that was already a denial, it's probably going to be zero, but we just want to confirm.

Q Okay. I'll tell you, we have different information.

A Okay.

Q How many AHCA fair hearings have been provided where the categorical exclusion of treatment for gender dysphoria was an issue?

A Well, can you repeat that?

Q How many AHCA fair hearings have occurred where the subject at issue was the categorical exclusion of treatment for gender dysphoria? So where the rule exclusion --

A We'll have to obtain those numbers.

Q Did any -- do final orders in general reference the variance and waiver process described at Florida Statute 120.542?

A You'll have to slow down and ask the question a little bit --

Q Sure. Sure. The final orders that are issued at the end of any AHCA Medicaid fair hearing, do those written final orders contain any reference to the variance and waiver process at Florida Statute 120.542?

A I don't think the final orders do. I don't

think they do.

Q Okay. Is there any way you can get confirmation of that answer?

A I mean, we could obviously pull up a copy of the final order and see if that information is included.

Q If we had a copy of an AHCA final order, would that be sufficient to determine, and it did not list it, would that --

A I'll defer to our attorneys, if that's sufficient.

MR. JAZIL: That'd be sufficient. If you have one, you can show it to him.

MS. DEBRIERE: Well, we can pull one up, can't we?

MS. CHRISS: Just one?

MS. DEBRIERE: Yeah. Yeah. Why not. Yeah, as long as their name's blocked out, which really shouldn't matter here because we're dealing with an AHCA employee.

THE WITNESS: Yeah. I mean, I'm cleared to review PHI and recipient information. It shouldn't be a problem.

MS. DEBRIERE: Do you want another one? I can send you another one. Bear with me one second.

I'm going to forward you this email. And

it's -- I can tell you what the name of the document is. It's the last document, 23. That should be the last one. Chelsea's copied on that one, too.

THE WITNESS: Okay.

MS. DEBRIERE: Okay. Okay. So feel free to just scroll through it and see if you see any reference -- oh I'm sorry, it isn't a touchscreen?

THE WITNESS: I don't know where the scroll bar.

MS. CHRISS: It's just -- just use two fingers and just go like that.

MS. DEBRIERE: Oh, it's a Mac.

MS. CHRISS: I'm sorry.

THE WITNESS: Okay. There it goes. Yeah. Ipads and iPhones I'm good with, Mac's I never got comfortable with.

MS. DEBRIERE: The next exhibit I'm going to do is emails related to the policy transmittal and the policy transmittal itself, if that helps.

MS. DUNN: Yep.

THE WITNESS: So are we talking about the -- that last paragraph on the final page that's, like, notice of judicial review?

BY MS. DEBRIERE::

Q Yes. So does that relate to the variance waiver process?

A I mean, it doesn't point out the variance processes as described in section -- or Chapter 120. I think that's more if they want to appeal to the next level -- next court level. I don't think that's in response to the variance process. That's a different process.

Q Okay. Thank you. So it does not mention the variance waiver process --

MR. JAZIL: Would it be possible just to read off the --

MS. DEBRIERE: Yes, absolutely. So it says at the bottom: Notice of a right to judicial review. A party who is adversely affected by this final order is entitled to judicial review, shall be instituted by filing the original notice of appeal with the Agency clerk of AHCA, and a copy along with the filing fee prescribed by law with the District Court of Appeal and appellate district where the Agency maintains its headquarters or where a party resides. Review proceedings shall be conducted in accordance with the Florida appellate rules. The Notice of Appeal must be filed within 30 days at the rendition of the order to be

reviewed.

THE WITNESS: Our various processes doesn't involve appellate courts, so it would not be an appellate case, so it's a different affair.

BY MS. DEBRIERE::

Q Thank you. Okay. Did AHCA work with Florida Medicaid managed care plans to implement the exclusion set forth in 59G-1.050(7) in any way?

A No. I mean, the publication's in the Florida Administrative Register, that was to provide ample notice -- public notice that the rule's changing, the managed care plans are responsible for keeping up with changes to manage -- to AHCA's coverage policies and administrative policies.

Q What about plan transmittal? Are you maybe forgetting those?

A We do not do a plan transmittal for this. Are you referring to a policy transmittal?

Q Yes.

A We did not send out a policy transmittal.

Q Okay. Okay. So we have what's marked as Exhibit 16 and Exhibit 17. Exhibit 16 is some emails from Dede Pickle to Jason Weida, cc'ing Ann Dalton. And those are dated August 22, 2022. I believe that's where they start. Also involved are you, Matt, and Ashley

Peterson. Also, I just want to note that Exhibit 17 is an SMMC policy transmittal dated August 22nd, 2022.

(Whereupon, Exhibit Nos. 16 - 17 were marked for identification.)

BY MS. DEBRIERE::

Q Getting back to the list of questions. So did AHCA not send the plan policy transmittal out, Exhibit 17?

A We did not send them out.

Q Why?

A Pretty much because all it's doing is reproducing what was already stated in the rule. The rules -- the rule -- the policy changes already in rule, that was announced through the FAR. Policy transmittal's a little superfluous at this point.

Q Why draft an entire plan transmittal and then not send it out?

A Which this happens frequently. Sometimes we will draft something and later decide not to -- not to use it, or not to utilize that content in favor of different strategy. So, in this case, since the rule -- since the rule change itself was pretty self-explanatory and pretty direct, just we later deemed wasn't necessary.

Q Who made the decision not to send out the

policy transmittal?

A I think that would have been -- that would have been Secretary Weida.

Q Only Secretary Weida? Is it Weida or Weida?

A Weida. I mean, as Assistant Deputy Secretary, he would be within his purview to decide whether or not to send something out -- or to send something out, but given that the rule itself was self-explanatory, and we just decided that a policy transmittal wasn't necessary.

Q All right. In the email exchanges -- I think it's on the second page -- oh, and Jason Weida, at this time that he made this decision, was not the Secretary -- AHCA's Secretary, correct? At the time this was sent, Mr. Weida was not the AHCA Secretary, correct?

A Right, he was Assistant Deputy Secretary for Policy and Quality.

Q On the last page, it looks like you were the person who drafted the first policy transmittal, is that correct?

A Yes. Yeah, I mean, Dede and I, it was a collaborative effort between the two of us. We were, of course, working on each other's language.

Q Why did you think Dede -- why did you and Dede think it was important to draft a policy transmittal?

A We were asked to.
Q By who?
A I think Ann Dalton asked Dede to work on it.
Q Okay. And later -- well, let's look to -- Ashley Peterson says on August 22, 2022 at 10:35 a.m.: I added one thing to help clarify that these drugs will still be provided, just not for gender dysphoria. Please let me know if you think this is unnecessary or adds confusion.

So at least Ashley thought there was some clarity that could be provided to plans on the implementation of the exclusion.

MR. JAZIL: Object to form.

THE WITNESS: Okay. There's several emails. Which one are you --

BY MS. DEBRIERE::

Q This one is from Ashley to Dede, copying you.
A August 22nd, 11:04 a.m. That's Dede --
Q 10:35 a.m.
A Okay.
Q It's DEF_0002587.
A Okay. I think it was just a minor, minor technical catch. I mean, when we worked on this, I mean, we were just fine tuning the drafts.
Q And further up Ann wants to include the 60-day

language in the alert, which has been later included. What is the 60-day language?

A That would be the bottom paragraph of the policy transmittal.

Q Okay. And that you're referring to starts with: To ensure the safe discontinuation of puberty blockers or hormone and hormone antagonists for the treatment of gender dysphoria?

A Uh-huh.

Q Then the managed care plan must notify its subcontractors, providers, enrollees receiving active treatment and changes in coverage, and they must honor any current prior authorization of prescribed outpatient drugs for the treatment of gender dysphoria through 60 days after the date of this policy transmittal. So that means that under the 60-day rule for continuity of care, the managed care plans were to continue coverage of the prescribed outpatient drugs for the treatment of gender dysphoria, correct?

A Only for those existing prior authorizations had already been approved.

Q Okay. So that meant that AHCA was -- or that Florida Medicaid was covering this drugs?

A Yeah, just for the sake of honoring existing PA's.

Q Was it not important that the plans know that they should maintain continuity of care?

A It's actually in the contract. I mean, when you refer to continuity of care, can you clarify what you mean by continuity of care?

Q In this instance, I'm talking about the continued coverage for 60 days of those prescribed outpatient drugs for the treatment of gender dysphoria.

A As far as the continuity of care went, I mean, there -- as far as medically necessary services, enrollees are always going to have access to those. So when it comes to the continuity of care, whether or --

Q They're not going to have access to services that have been previously covered, but now are excluded, correct?

A That'd be correct.

Q Okay. So the 60-day continuity of care ensures that after that categorical exclusion is adopted, those individuals continue to access that care for 60 days?

A This, of course, was a draft. It was never sent out.

Q At some point, AHCA thought that the 60-day period of continuity of care should apply in this situation, correct?

A Since this was a draft and it was not -- not officially sent out, this is not -- since it is draft language, it is not an official transmittal, we sent out to the health plan, so this does not formally represent the views of the Agency. This is a -- this is a draft that we created, deliberated upon and decided not to send out.

Q Who decided?

A That would, of course, been leadership. That would have been -- would have gone to Assistant Deputy Secretary Weida.

Q And he was the only one who was involved in that decision, correct?

A I mean, since he oversees the bureau policy, that's -- which means policy transmittal, yes, he had -- is within his -- is within his job description and his responsibilities and rights to veto sending out a policy transmittal.

Q Okay. Since the policy transmittal was not sent out, then is it AHCA's position that those who had a current prior authorization at the time that categorical exclusion was adopted, was not entitled to the 60-day continuity of care period -- were not entitled?

A So once the rule went into effect, that was,

of course, the notice of the plans that the coverage for these services has to stop.

Q Immediately?

A Well, I mean, that's based on what the rules say, yeah.

Q Okay. So they -- that means that the plans were not to implement this 60-day period of continuity of care as described in this transmittal?

A Right, we didn't provide notice of -- them of this.

Q Okay. And it was AHCA's position that Medicaid beneficiaries were not entitled to that?

A That's correct.

Q Okay. You previously noted how people on hormones may go through withdrawal, there was something as part of your 2022 GAPMS request. Why wasn't that important to communicate to the plans?

A Well, because withdrawal is not gender dysphoria. It's a different -- that's a different -- it'd be a different diagnosis altogether.

Q But in the decision to no longer cover drugs that may cause withdrawal, was it important to communicate to the plans or providers that they may need to help facilitate transition off those drugs that would no longer be covered?

A We were leaving that to the health plans to manage independently, as well as the providers of these services.

MS. DEBRIERE: Do we have a document titled Florida Medicaid health alert? You just -- under DEF_000258815. I feel like I've had the same Bates stamp number. So we're marking as Exhibit 18, the Florida Medicaid health care alert sign-off form.

(Whereupon, Exhibit No. 18 was marked for identification.)

THE WITNESS: I'm familiar with that. I drafted it.

BY MS. DEBRIERE::

Q That would definitely have been one of my questions.

A No, I'm listed on there as the analyst who drafted it.

Q And there's Dede and Ann.

A Yeah.

Q Okay. Did this healthcare alert go out to all providers?

A That provider alert did not go out.

Q And the provider alert on the back, it lists that same language to ensure the safe discontinuation of puberty blockers or hormones and hormone antagonists for

the treatment of gender dysphoria, or allow transition to payment to non-Medicaid funding sources. You incorporated the reference to the 60-day continuity of care period. You drafted that one. Did you include that 60-day language?

A Yeah. I -- yeah, I did include that.

Q Why did you think it was important to include?

A Because at the time we were -- we were creating a provider alert in sync with -- in sync with the policy transmittal, so we wanted to make sure that they used the same language and addressed the same things.

Q And why wasn't this sent out?

A Because -- because, well, we've deemed that the notice of the rule is sufficient, and that once the rule had said that AHCA will no longer cover these services, we could no longer cover those services. I mean, the rule was clear-cut. It's very -- I mean, language is pretty -- pretty straight to the point and direct.

Q Who made the decision not to send this out?

A That would have come from Assistant Deputy Secretary Weida at the time.

Q Did you agree with that decision?

A I thought it was sufficient. I actually

thought given that we put the rule out there, the rule is very straightforward, noticing, like, we had the providers, health plans, adequate notice was given.

Q Did Ms. Dalton agree with the decision not to send any of this out?

A I can't speak to Ms. Dalton. She and I didn't confer on our opinions of whether to -- we didn't confer on how we felt about it.

Q Was there any stated opposition to not sending these out?

A Not that I'm aware of, no.

Q So in managing withdraw, how would a plan or provider know how to navigate that if AHCA wasn't -- if AHCA notified them that they weren't going to cover the service that was needed to help titrate individuals off of their hormones or puberty suppression therapy?

A So it comes back down to practitioners delivering treatment to their -- to their patients. Once again, it comes down to how, like -- you know, when they know that they can't treat for gender dysphoria anymore, and they know that the individual might suffer -- might suffer withdrawal symptoms from testosterone. We, of course, did see some conflicting information on that one, whether they would experience symptoms or not, or estrogen, or if there were

withdrawal symptoms, you'd be treating the withdrawal. And, of course practitioners, we do trust the medical professionals to know what condition they're treating, when the -- because they do so every day when their course -- when they're, of course, diagnoses. And, of course, when the medical coders come in there to do the billing, it's --

Q If transition involved smaller dosages of hormones over time to treat gender dysphoria, how was the provider and the plan to know that they could continue to prescribe that?

A It would be coming through a different diagnosis code. And since we only said that for -- we only said in the rule only for the diagnosis of gender dysphoria. So if they're -- so if they're taking on some small doesn't testosterone because of withdrawal, that's a different -- that's a different diagnosis altogether.

Q How would they know what diagnosis code to use?

A So, practitioners and providers often don't -- aren't that familiar with the coding system. That's where their coders do to figure out. So their coders, of course, review the medical records and, of course, put in the CPT codes, they put in the ICD-10 codes, the

place of service. So usually the claims process is usually done either by often, like, a clearing house or individual coders that sometimes just rotate like a circuit through different physicians offices and so forth.

Q So when we're talking about the safe discontinuation of a medication, wouldn't the prudent thing to do would be to notify providers and plans of the options they had to ensure that individuals who could no longer access this treatment could at least come off of it as safely as possible?

A Given that physicians deal with that kind of situation, for other diagnoses and medical services, we just didn't feel it was necessary. That's one area we were going to, like, leave it. Practitioner discretion was how to withdraw their patients from testosterone or estrogen, if it was even necessary at all.

Q Did any managed care plan ask questions about how to implement the categorical exclusion of gender-affirming care?

A I don't think we received any questions for managed care plans.

Q What about from providers?

A I don't think we received any provider questions either.

Q Did any plan communicate that they will continue coverage in spite of the categorical exclusion?
A Definitely no.
Q Could a plan do that?
A Well, they hypothetically can --
Q Would Florida Medicaid allow them to do that?
A No, we would not.
Q I'm showing you what's marked as -- well, I will be in a second -- what is marked as DEF_ 000169125. It's the template member handbook -- actually, let's skip that one. I'm sorry. I'm sorry.
MS. DUNN: Oh, I'm sorry, we have numbers that aren't lining up with --
MS. DEBRIERE: Yeah, let's actually -- let's move to the emails from Susan Williams between her and Magellan. I'm not sure what the Bates stamp is. Okay. Thank you.
(Whereupon, Exhibit No. 19 was marked for identification.)
BY MS. DEBRIERE::
Q And that's marked as 19 and it's a series of emails between Susan Williams, Jessica Forbes at AHCA, Ashley Peterson, and the first date on the document is June 3rd, 2022. The subject is for treatment of gender dysphoria for children and adolescents.

A Well, this was -- well, we received this prior to the promulgation of the challenge exclusion.

Q You did. So, Stephanie McGriff over at Magellan says, Hi, Ashley and Susan, attached are the internal criteria not publicly posted. CCM that the implemented all meds with the gender code equals B, both in the subsequent updated denial letter that includes the non-discriminatory verbiage. What are the internal criteria she's referring to?

A So it looks like the email chain started on April 20th, following the release of the Department of Health's guidelines. So there were 14 impressions to AHCA at that time. We had just initiated the GAPMS process for these treatments.

Q Yeah. In fact -- so looking at the email from Alicia King Wilson dated April 20th -- so that would be the day that the Florida Department of Health released its guidance, right?

A Yes.

Q And Secretary Marstiller directed Tom Wallace just to start the GAPMS process.

A Yes.

Q It says: Leslie noted MMA does have an internal gender dysphoria criteria, which is attached. This internal document serves for a GnRH analog used to

delay puberty in adolescence with gender dysphoria, but it does not speak to use of hormone therapy. This document was provided by the Agency due to a fear of hearing requests received from Lupron for recipient with this diagnosis. All requests for use of the drug at that time to delay puberty were to be vetted by AHCA before a final determination is made. Can you explain that a little bit more? What does it mean that AHCA had to vet all determinations? What determinations was AHCA vetting?

A I don't -- I mean, it's tough to fully understand the context of this email. I mean, the context level is light throughout the chain, because I mean, Magellan does handle the prior authorization of clinical reviews for drugs in the fee-for-service system.

Q Okay, but it says that this document was provided the Agency due to a fair hearing request received from Lupron first, recipient with this diagnosis, all requests required vetting by AHCA before a final determination was made. So, I mean, I interpret that to mean that anytime Magellan received a request for Lupron to treat gender dysphoria, AHCA had to vet it before a decision as to coverage would be reached. Am I wrong?

A No, that's what it sounds like. The pharmacy -- the pharmacy processes may involve -- as far as like the pharmacist job descriptions go -- I mean, as far as like vetting, that's the kind of the questions like, are they -- because we don't do in-house prior authorizations or clinical determinations anymore. We haven't done those since SMC went into a fact.

Q Was a special exception made for the coverage of hormone therapy to treat gender -- I'm sorry -- for the treatment of puberty suppressant?

A No. No. Yeah.

Q So not to your knowledge --

A I'm just trying to figure out what they mean by vetting. Like, in other words, does this mean -- like, is Magellan sending the determination back to AHCA for yes or no approval?

Q Yeah.

A So they could be doing that.

Q But you don't know?

A Don't know.

Q Can we find that information out?

A We might be able to, because like -- because it's only a few emails, and we're trying to go over the process. I mean, it is possible that we could ask people who do oversee this area. I mean, they might

give us some information, but they may not be able to describe the exact context of the email because, I mean, sometimes things get lost in translation.

Q Does Susan Williams still work here?

A Yes, she does.

Q Does Ashley Peterson still work here?

A Ashley Peterson recently left us.

Q What's recent?

A Last week.

Q Find another opportunity?

A Yeah.

Q How about Kelly Reuben?

A Kelly Reuben's still here.

Q Jessica Forbes.

A Jessica Forbes is still with the Agency.

Q Shantice Green.

A No, she's not here anymore.

Q She find another opportunity?

A I believe so, yes.

Q All right. So, as a reminder, all gender codes were removed from programming as directed by the Agency in 2017. What does that mean?

A I'm not sure because I'm not sure what they mean by CCM. Generally, when we do -- when we make systems updates, it's either done through a file

maintenance or a customer service request to Gainwell Technologies oversees the FMMIS, so --

Q You were familiar with the programming of the ICD-10 codes, but you're not familiar with programming of the gender codes?

A Well, no, I'm familiar with the -- how diagnosis codes are programmed in the system, but this CCM acronym I'm not familiar with.

Q What is a gender code?

A You mean a gender code? Well, what they mean by gender codes, I'm assuming that means the ICD-10 Code F64. That's -- that's assuming that's what that means.

Q What's a B for both?

A Maybe that's written reference to male and female.

Q What is the significance of that? Why does it matter if it's -- what are the options? B for both and then, what, M for male, F for female?

A That could -- I mean, that's what I'm assuming based on -- based on this email chain. I mean, it's a little difficult because -- I mean, there's a lot of extrapolation and it's -- much of it's open to interpretation, so --

Q Sorry, I lost my place. Please prepare a CCM to remove gender code from all the NDC's. What are

NDC's? You said that?

A National drug codes. So that's almost like -- kind of like a procedure code, because each drug has a corresponding NDC. So the system doesn't recognize drug names or recognize national drug codes.

Q Okay. And that was actually -- that instruction was provided to someone -- Arlene Elliot sent that instruction to someone back in 2017, to remove the gender code. Do you have any idea why Magellan and AHCA were talking about this on June 3rd?

A No. We hadn't announced that we were going to do a categorical exclusion yet.

Q Okay. I think this is just a place where we're going to need to reserve some time for deposition after you're able to do some adequate research on what the information this email contains, and then we can do some follow-up questioning. Okay.

You mentioned earlier, were there any communications from the plans about the exclusion prior to its adoption?

A What do you mean? Do the plans have any -- do we discuss with the plans prior? No.

Q All right. Turning to waivers and variances under Chapter 120, are you familiar with that process?

A Oh, yes, I am.

Q Okay. I'm going to hand you a copy of the statute, Section 120.542. We'll mark that as Exhibit 20.

(Whereupon, Exhibit No. 20 was marked for identification.)

BY MS. DEBRIERE::

Q Are you familiar with the statute?

A Yes, I'm familiar with it.

Q Based on your understanding, what is the purpose?

A So the purpose of this is because, of course, agencies are granted rulemaking authority. And because agencies now -- and, of course, the rulemaking process, I mean, it's public, transparent, but there are times that there may be an exception that's required, so it's kind of like the check and balances that if a variance is required on a rule that -- like a party could apply to that agency that administers that rule for consideration of a variance.

Q Does the purpose of the underlying rule have to -- the spirit of it have to be met in granting the variance or waiver?

A What's meant by the spirit?

Q I'm trying to look for the specific language. So under subpart two, variance and waiver shall be

granted when the person subject to this rule demonstrates the purpose of the underlying statute -- I guess in this case it would be a rule -- or what statute will we be referencing?

A Well, in legal terminology, I mean, differences between rule and statute, I mean, statutes, of course, are approved by the legislature, goes to the Governor, and the rules are done under the authority of the statutes. So, I mean, like agencies are authorized to grant variances and waivers to requirements of the rules consistent with the section and with rules adopted under the authority of the section. So, I mean, they do call out rules, specific. Then, of course, this applies to all state agencies, so --

Q Who makes a determination at AHCA whether a petitioner has established a substantial hardship under the statute?

A Those come through our General Counsel's office. So if somebody wants to request a variance, they do so through our agency clerk.

Q And how is the determination itself made?

A So the agency clerk will reach out to individuals to, of course, who have pertinent knowledge about the -- about the circumstances of the request of the variance, will ask for input. And, of course, the

determination's made. It rides up to the Secretary. The Secretary has to do the final approval for a variance.

Q So same question as to determining whether principle -- principles of fairness are violated, who makes that determination?

A So when it comes to waivers and variances, that's same process. Goes to the agency clerk. Then, of course, does an investigation, consults with individuals who are knowledgeable about the pertinent subject, and then it goes up to the Secretary.

Q Has AHCA developed any criteria to guide its determination of whether to grant a variance or waiver from the categorical exclusion of gender-affirming care?

A No. No, we haven't. Variances are determined on a very individualized basis.

Q So, again, turning back to the -- ensuring the purpose of the underlying statute, 120.542 specifically states that variance and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means for the person. So that means the granting of the variance or waiver shows that the purpose of the underlying statute will be or has been achieved by granting it. What statute -- in reviewing

any request for a variance or waiver from 159G-1.050(7), how would you demonstrate that the purpose -- well, what statute will be at issue, first of all?

A Well, for the statute -- I mean, would be Chapter 409. Those are the Florida Medicaid -- that consists of the Florida Medicaid statute, so --

Q What specific -- what specific provision of 409 would you be looking at?

A I mean, we'd be looking at -- well, for the variance, we'd probably be looking at, like, I mean, somewhere under 409.9, probably under covered services or optional services.

Q Okay. So how -- if someone requested a waiver or variance from 59G-1.050(7), under what circumstances would AHCA authorize coverage of the services listed in that rule?

A Well, we can't speak to those because I don't think -- we haven't gotten a request for variances on this yet. So like it says, a highly individualized process. We will be looking at in-depth at the recipient, looking at all the records available, and, of course, discussing things with various experts and so forth. But each request is individualized. So because each request is individualized and focuses on the specific individual, we can't project on what grounds we

would grant a variance under.

Q Well, so the June -- the categorical exclusion of treatment for gender dysphoria was adopted because the certain -- AHCA found that those services were experimental, correct? And Florida Medicaid cannot cover services that are experimental?

A That's correct.

Q So in what situation could AHCA grant a waiver or variance covering services that AHCA has found to be experimental?

A Well, I mean, based on the rule we wouldn't. I mean, based on the rule, we would deny the variance, but because each variance, it's individualized requests, we would have to go through and evaluate each one individually.

Q Would the person have to establish that the service they're requesting is not experimental?

A We will not be placing the burden on the recipient.

Q Who would the burden be on?

A Well, that would be on -- it'd be an individualized process, evaluating all the -- all -- whatever medical records that we can get a hold of. That's -- that's process that we use in the past, but based on the rule, I mean, yeah, we say that these

would -- you have a categorical exclusion. While we -- while the variance process is available, but because we have a categorical exclusion, we do declare the services to be experimental, investigational due to very-low-quality evidence that -- yeah, I mean, we would deny variance, but because variance reviews are individualized, we don't want to speak in absolute terms on the variance process. But for -- because, I mean, there's all kinds of questions that could come up in the review of the medical records. Maybe it was a -- maybe it was a misdiagnosis. Maybe something else could come up. That's pretty much why. So --

Q Okay.

A Everything is different and --

Q If a person sought a waiver of the application of 59G-1.050(7) so they can receive Medicaid coverage for a mastectomy that is specifically to treat their gender dysphoria, under what circumstances would that waiver be granted?

A For -- under what circumstances?

Q Yeah.

A Well, I mean, we did declare this service to be experimental investigational.

Q So they could not get a waiver, correct? The waiver would be denied?

A Based on the very general, hypothetical situation that you provided, straight out just for gender dysphoria, they got denied by their insured so they request a variance.

Q Yeah.

A Based on our rule language, yeah, it'd be denial.

Q And someone is entitled to a fair hearing when Medicaid coverage is denied, correct?

A Yes, they are.

Q Given that the Agency has found the services in 1.057 -- 59G-1.050(7) to be experimental, and therefore never medically necessary, correct?

A Correct.

Q Could someone ever prevail at a fair hearing where they sought coverage of the services for gender dysphoria?

A Well, based on our rule, based on our findings, no.

Q Could someone use the variance or waiver process to get around the final decision issued after the fair hearing?

A Well, I mean, they can request a variance, but then they would go through the process, but based on our rule and our findings, no.

Q How often do Medicaid beneficiaries file variance requests?

A So in the research for this case, we found 10 requests, and that's since going back to about 2015, 2016.

Q Okay. So between 2015, 2016 to present, there has been 10 requests?

A That's correct.

Q Okay. These variances -- and I have copies of all of them, if you'd like to reference them. They request that a service that AHCA affirmatively covers. So there's -- there's a few types of variances we found in our review. There's situations in which AHCA affirmatively covers the service, but the individual wants an amount greater -- in a greater amount or duration.

A Yeah, I'm familiar with that one. It's -- there was a variance request -- and it was actually several various requests, because they were granted for six months at a time. We're talking about our recipient under our I-budget waiver. So, of course, our I-budget waiver -- and no, it isn't, it's codified in rule. So, of course, there was a service limit on these behavior assistance services at the time. They were requesting additional behavior assistance services. So while -- so

because we already covered the service, and they're just looking for additional services, you know, and that that's -- that's flexibility that we can grant because we haven't actually gone through -- the service they are requesting, we have not codified as a categorical exclusion, and we've not deemed that service be experimental investigational.

Q Okay. And that's true for all the services that are contained in the variances --

A Yeah, from what I could tell, they're pretty much all I-budget.

Q Okay. And they -- none of the services that they were requesting some kind of variance on had been categorically excluded, correct?

A Correct.

Q Okay. And none of them have been determined experimental?

A Right.

Q Okay. Do you know of every Medicaid recipient who made a request for a variance, if they were represented by counsel?

A No, we don't know if they were all represented by counsel or not.

Q Because I did notice that the recipients were all listed.

A Yeah, the recipients were listed. The information is referred to the agency clerk. Then the Agency does its internal processes.

Q Do you know what pro se means?

A No.

Q So, in any of the requests for variances to the Medicaid recipient, him or herself, do any of the direct request for the variance, or did they need assistance?

A Given the complexities of request and legalities of it, I would -- I think it's safe to say that they had some assistance, although it's not required.

Q Okay. Between April of 2022 and August 21st of 2022, did anyone at AHCA ever discuss the variance or waiver process for use in challenging a denial based on the categorical exclusion of treatment for gender dysphoria?

A No.

Q All right. Turning to our specific clients, at anytime prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for the treatment of gender dysphoria and that actually --

A You're talking about --

Q Everyone.
A You're talking about after the hard date when the ruling took effect?
Q Anytime prior to that, did Florida Medicaid cover any of the services listed at 59G-1.05 --
A Prior to the effective date, yes.
Q Okay. So they covered puberty blockers?
A Yes. Well, for that small handful of recipients we pulled the data on, yes.
Q They cover cross-sex hormone therapy for the treatment of gender dysphoria?
A Yeah. I mean, as far as data showed.
Q Did they cover surgery for the treatment of gender dysphoria?
A From our data revealed, yes.
Q At any time prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for August Dekker?
A We did go through our -- we did go through there the recipient's histories, yeah.
Q Did Florida Medicaid cover puberty blockers for August Dekker to treat gender dysphoria?
A For August Dekker?
Q Yes.
A Puberty blockers?

Q Yes.
A I don't believe so, no.
Q Did Florida Medicaid cover hormone therapy for August Dekker in treatment of gender dysphoria?
A For August Dekker, yes. I think -- I think his managed care plan, Humana was providing him those.
Q And he's still currently eligible for Florida Medicaid?
A Last time we checked he was still Medicaid eligible.
Q Okay. And he's still enrolled in Humana, or did he switch to another plan?
A Well, we haven't -- we haven't verified since -- we did have an enrollment period and recipients are eligible to switch plans during that enrollment period.
Q In the coverage of hormones for treatment of August Dekker's gender dysphoria, how long -- for how long did AHCA authorize that treatment? For how long did Florida Medicaid cover that treatment?
A I don't know the exact length. We would have to go back and take a look at the records we received from Humana on the case.
Q More than six months?
A I think it was more than six months.

Q More than a year?
A That's where it gets hazy.
Q Was coverage for hormones to treat gender dysphoria terminated for August Dekker after August 21st?
A According to rule, yes, it would be terminated.
Q Did Florida Medicaid cover surgery for August Dekker and treatment of gender dysphoria?
A Yes.
Q When?
A So that would have been prior to the -- that would have been prior to the challenge exclusion being implemented. Then to clarify, that was -- is -- the managed care plan was covering that outside our state plan benefits.
Q How do you know that?
A Because our state plan does not -- does not specify the service as being -- as being mandated for coverage. In other words, if Humana had denied the service, well, it would have just been a denial because it's not a -- Medicaid doesn't -- we don't have that in our state plan. Managed care plans have to cover all state plan services. Sex change operations are not a state plan covered service.

Q Surgery is a state plan covered service?

A Surgery, yes, but for -- but not for this -- necessarily this condition.

Q Does the state plan specify for what conditions services are provided?

A No, it doesn't break down the diagnosis codes, but this was one -- was the plan's discretion. The plan could have said yes. The plan could have said no. It was up to the plan.

Q Were federal Medicaid match dollars used to pay for August Dekker's surgery?

A So capitation rates that we pay to the plans are per-member per-month rate. That is a combination of federal matching dollars and state revenue.

Q Okay. At any time prior to August 21st, 2022, did Florida Medicaid cover any of the services listed at 59G-1.050(7) for Brit Rothstein?

A Based on the -- based on the records that we pulled, based on the recipient's individual histories that we were -- we were able to locate, looked like, yes, we did.

Q Okay. Did Florida Medicaid ever cover puberty blockers for Mr. Rothstein?

A So for Mr. Rothstein -- so for Mr. Rothstein -- I -- so. Sorry. I think he's one of the

adult plaintiffs?

Q Yes. Yes. And you said that he -- I'm sorry -- pulled in a lot of directions.

A We did cover services that we did determine to be experimental investigational prior to the challenge exclusion.

Q And no longer cover them, correct?

A Yes, because of the challenge exclusion.

Q Same question for KF.

A Since -- with KF, we did have a hard time since for the minors we didn't have, like, their full identification information. Trying to locate their records in the system, I think there were encounters, based on information we had, that did show they were receiving GnRH.

Q Okay. For the treatment of gender dysphoria?

A Yeah.

Q Okay. And that includes Susan Doe, as well?

A Based on what we could find, looked like they -- that there had been some coverage.

Q And they're -- KF is still currently eligible for Florida Medicaid, is that correct?

A We would have -- I think -- I think they would be, because we haven't been doing these determinations because of COVID. So, yes, they would still be

Medicaid-eligible. That would go for all the plaintiffs.

MS. DEBRIERE: Okay. Let's -- can we take a five-minute break?

MR. JAZIL: Sure.

VIDEOGRAPHER: Okay. This concludes video four. The time is 4:15 p.m.

(Brief recess.)

VIDEOGRAPHER: This is the beginning of video five. The time is 4:30 p.m. We're on the record.

BY MS. DEBRIERE::

Q All right. Turning back quickly to plaintiff August Dekker, did Humana violate Florida Medicaid policy by covering his surgery for treatment of gender dysphoria?

A No, they did not at the time.

Q Okay. And then I just want to talk about a few more exhibits. One labeled -- we've marked as Exhibit 21, and that is the GAPMS queue that was provided to us.

(Whereupon, Exhibit No. 21 was marked for identification.)

BY MS. DEBRIERE::

Q And it looks like the most recent date on that queue was maybe an update to one of the GAPMS in 2019.

That's as far as it goes. Are all -- are these the only GAPMS that are currently pending?

A So the requests came in to pull the most recent GAPMS queue.

Q Yeah.

A So at this -- when I went through our -- we have a GAPMS folder that's on our shared drive. I did look through to see what -- we have a folder for the GAPMS queues. I did pull the most recent one. This was the most recent one that had been updated that was in there --

Q I'm sorry. Go ahead.

A This does -- this does consist of a lot of GAPMS reports, which I do remember drafting some of those as well, but this was our most recent one.

Q And have there been GAPMS reports created after 2018?

A Yeah, I think there have been.

Q Why aren't they on this list?

A I'm not -- I'm not sure why they wouldn't be included on this list. This list should be updated on regular basis, so I'm not sure why they wouldn't be included on this, or on the list on the share drive, because the GAPMS queue is really is not so much for the GAPMS analyst, because GAPMS analysts generally have a

pretty good idea of what's outstanding, what's pending, and what's been turned in. It's more for leadership -- or their supervisor to pull and take a look at when necessary, so I'm not sure why this hasn't been listed to update in this current.

Q So whoever's working in GAPMS at the time has a good understanding of which GAPMS are pending.

A When I was -- when I had the role, I could tell you exactly where all my reports were, what their status was and where they stood in the queue. So, yeah, I kind of had all committed to memory.

Q Okay. Would that be true of anyone holding that GAPMS position?

A As far as pulling it from memory, I couldn't vouch for the other employees as to their memories, when it came down to their reports that are outstanding.

Q But they should have a good sense?

A They should have a good sense of what's pending and what's been turned in.

Q Can you provide us a list of what's pending that's not listed on this queue?

A So I think -- so I think the ones that are still pending aren't -- I think there were, like, reopened reports. I think we had gotten requests from the manufacturers of Atheno, was the asthma tests that I

discussed earlier. That was one I had to have finalized. We've gotten a request for them to -- for us to review it, provided that they don't send some more evidence and more studies that have been done after our original report. So I think that one was reopened. That one should still be pending. Then there was specially modified low-protein foods. That was another one that I had written up. We had gotten requests to reopen that one that, and to reevaluate that service. I think there was another one, which was the -- which was a bone growth stimulator called Exigent. I think that one is still outstanding and pending. Now, those are just some examples of ones I can think are still pending.

Q Were there any new requests made after December of 2018?

A Yeah. I mean, there have been some new requests for either, like, expedited GAPMS or full GAPMS. I mean, we do get the service requests in fairly frequently, so --

Q Because it would be odd if any new requests hadn't come in almost five years --

A Correct. Yeah.

Q Okay. But there's no way -- all right. And then I just want to put into the record, because we've

been referring to it quite a bit, we'll Mark it as Exhibit 22, and that is the document from Health and Human Services that we've referenced multiple times during the deposition. Is that the one you're referring to?

A That's correct. This is it.

(Whereupon, Exhibit No. 22 was marked for identification.)

BY MS. DEBRIERE::

Q Thank you. And then the guidance from the Florida Department of Health regarding treatment of gender dysphoria for children and adolescents dated April 20th, 2022. That's Exhibit 23. Is that the document that we've been referring to when we're talking about DOH guidance?

A Yes, it is.

(Whereupon, Exhibit No. 23 was marked for identification.)

MS. DEBRIERE: And then -- I think that's it for my questions. The only thing I wanted to put on the record, Mo, is we are at what time, Videographer?

VIDEOGRAPHER: Do you mean the whole run time or --

MS. DEBRIERE: Just the questioning time.

Yeah, the time that we've been live and active on the record.

VIDEOGRAPHER: Five hours, eight minutes plus five and a half minutes.

MS. DEBRIERE: Okay. So want to just say that we have an hour and 45 minutes of questioning --

MR. JAZIL: Sure.

MS. DEBRIERE: -- to reserve?

MR. JAZIL: And so the depo is open. I'd like to ask questions at the end. So I'll just reserve that until after our second session, is that okay, or would you like for me to --

MS. DEBRIERE: Can I confer with my team quickly? Okay.

VIDEOGRAPHER: We will remain on the record?

MS. DEBRIERE: We'll go off the record.

VIDEOGRAPHER: Okay. Off the record at 4:36 p.m.

(Discussion off the record.)

VIDEOGRAPHER: We're back on the record. The time is 4:37 p.m.

MS. DEBRIERE: And plaintiff's counsel is all finished with their questioning.

EXAMINATION

BY MR. JAZIL::

Q This is Mohammed Jazil for the defense. I'll try to be brief, recognizing we have time limitations here. Mr. Brackett, I'd like to have you look at Exhibit 3 again.

A Okay.

Q Exhibit 3 has a date on it, May 20th, 2022. I want the record to be clear, why is that date not accurate?

A This date isn't accurate because that date is -- automatically sets to the date you print it out.

Q And what sets that date?

A The template is automatically set to enter in this current date that you're viewing the document. So it automatically updates the second you open it.

Q And that's the template in the AHCA document?

A That is our template, yeah.

Q And when was this GAPMS report created?

A This GAPMS was originally created in 2016.

Q Thank you. You discussed with my friend the variance and waiver process. Do you recall that testimony?

A Yes.

Q You testified that the variance and waiver process is individualized. Do you recall that testimony?

A Yes, I do.
Q Once a variance and waiver request comes in, it goes to the clerk is what you testified to, if my understanding is correct?
A Yes.
Q And then the clerk routes it to whom?
A The clerk gathers information and it has to be routed up to the secretary.
Q Is it routed directly to the Secretary or is there any other office that it goes through first?
A I'd have to take a look at the variances again. It might be -- I think it probably have to route through General Counsel before it goes to the Secretary.
Q Okay. And is the General Counsel's office responsible for the formulating the Agency's position on legal issues?
A Yes.
Q Does that include the variance and waiver process?
A Yes.
MR. JAZIL: I have no further questions.

FURTHER EXAMINATION

BY MS. DEBRIERE::
Q Just one redirect. Very brief. On Exhibit 3, which is the GAPMS memo dated May 20th, 2022, that was

the date it was printed out. It also appears changes were made on that date, is that correct?

A Based on the comments in the edits, yeah, it looks like somebody had made changes to that document on that date.

Q But you don't know who that person is?

A SG, I'm -- I can't speak to who SG is.

Q But you will find that information out for us?

A We can -- we can figure out who, but we would -- probably want to verify with IT.

MS. DEBRIERE: Okay. That's all.

MR. JAZIL: So, counsel, while we're still on the record, he's still under oath, so I'm not going to obviously talk to him about any issues that might come up, but with your consent, I'd like to at least work with him to gather the additional information that's being sought. Is that appropriate?

MS. DEBRIERE: I mean, I would assume that would be your process.

MR. JAZIL: He is under oath, and so I'm obviously not going to try to, you know --

MS. DEBRIERE: I see. I see.

MR. JAZIL: -- work with him while -- work with him on his testimony, I say, as I try to gather

additional information, so I'll make that clear on the record.

VIDEOGRAPHER: Anyone else? Anybody by Zoom?

MS. DEBRIERE: No.

VIDEOGRAPHER: Okay. This concludes the February 8th, 2023 portion of the video-recorded deposition of Corporate Representative for Agency for Health Care Administration. The time is 4:40 p.m.

COURT REPORTER: Are you going to be ordering this?

MS. DEBRIERE: Yes.

COURT REPORTER: All right. And Mo has requested a rough draft. I told him I could get it to him tomorrow. Do you guys -- would you guys like one, as well?

MS. DEBRIERE: Yes, please.

(Whereupon, the deposition was concluded at 4:40 p.m., and the witness did not waive reading and signing.)

CERTIFICATE OF OATH

STATE OF FLORIDA)
COUNTY OF LEON)

I, the undersigned authority, certify that the above-named witness personally appeared before me and was duly sworn.

WITNESS my hand and official seal this 21st day of February, 2023.

_____.
DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, DANA W. REEVES, Professional Court Reporter, certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages, numbered 128 through 257, are a true and correct record of the aforesaid proceedings.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 21st day of February, 2023.

_____.

DANA W. REEVES
NOTARY PUBLIC
COMMISSION #GG970595
EXPIRES MARCH 22, 2024

Gary V. Perko, Esq.
gperko@holtzmanvogel.com

February 21, 2023

RE: August Dekker, et al. vs. Jason Weida, et al.
February 8, 2023/Matthew Brackett/5696545

The above-referenced transcript is available for review. The witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason on the attached Errata Sheet. The witness should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties. It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard. If the witness fail(s) to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions
*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

August Dekker, et al. vs. Jason Weida, et al.

February 8, 2023/Matthew Brackett

E R R A T A S H E E T

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REASON_____

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Matthew Brackett DATE

f

m

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

Veritext Legal Solutions complies with all federal and State regulations with respect to the provision of court reporting services, and maintains its neutrality and independence regardless of relationship or the financial outcome of any litigation. Veritext requires adherence to the foregoing professional and ethical standards from all of its subcontractors in their independent contractor agreements.

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Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

Treatment of Gender Dysphoria for Children and Adolescents

April 20, 2022

The Florida Department of Health wants to clarify evidence recently cited on a fact sheet released by the US Department of Health and Human Services and provide guidance on treating gender dysphoria for children and adolescents.

Systematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex. One review concludes that "hormonal treatments for transgender adolescents can achieve their intended physical effects, but **evidence regarding their psychosocial and cognitive impact is generally lacking**."

According to the Merck Manual, “gender dysphoria is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth.”

Due to the lack of conclusive evidence, and the potential for long-term, irreversible effects, the Department's guidelines are as follows:

- Social gender transition should not be a treatment option for children or adolescents.
- Anyone under 18 should not be prescribed puberty blockers or hormone therapy.
- Gender reassignment surgery should not be a treatment option for children or adolescents.
    - Based on the currently available evidence, "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an **unacceptably high risk of doing harm**."
- Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider.

These guidelines do not apply to procedures or treatments for children or adolescents born with a genetically or biochemically verifiable disorder of sex development (DSD). These disorders include, but are not limited to, 46, XX DSD; 46, XY DSD; sex chromosome DSDs; XX or XY sex reversal; and ovotesticular disorder.

The Department’s guidelines are consistent with the federal Centers for Medicare and Medicaid Services age requirement for surgical and non-surgical treatment. These guidelines are also in line with the guidance, reviews, and recommendations from Sweden, Finland, the United Kingdom, and France.

Parents are encouraged to reach out to their child’s health care provider for more information.

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

April 20, 2022

Tom Wallace
Deputy Secretary for Medicaid
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Dear Deputy Secretary Wallace:

On April 20, 2022, the Florida Department of Health released guidance on the treatment of gender dysphoria for children and adolescents.[1] The Florida Medicaid program does not have a policy on whether to cover such treatments for Medicaid recipients diagnosed with gender dysphoria. Please determine, under the process described in Florida Administrative Code Rule 59G-1035, whether such treatments are consistent with generally accepted professional medical standards and not experimental or investigational. Pursuant to Rule 59G-1035(5), I look forward to receiving your final determination.

Sincerely,

Simone Marstiller
Secretary

[1] *See* https://www.floridahealth.gov/newsroom/2022/04/20220420-gender-dysphoria-press-release.pr.html (last visited Apr. 20, 2022).

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

April 20, 2022

Tom Wallace
Deputy Secretary for Medicaid
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

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Sincerely,

Simone Marstiller
Secretary

[1] *See* https://www.floridahealth.gov/newsroom/2022/04/20220420-gender-dysphoria-press-release.pr.html (last visited Apr. 20, 2022).

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

TALLAHASSEE DIVISION

CASE NO.: 4:22-cv-00325-RH-MAF

AUGUST DEKKER, et al.,

Plaintiffs,

vs.

JASON WEIDA,

Defendant.

_____/

DEPOSITION OF: ANN DALTON

DATE: TUESDAY, JANUARY 24, 2023

TIME: 10:04 A.M. - 6:05 P.M.

PLACE: AGENCY FOR HEALTH CARE ADMINISTRATION
2727 MAHAN DRIVE
TALLAHASSEE, FLORIDA 32308

STENOGRAPHICALLY REPORTED BY: GREG T. SMITH

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I N D E X

INDEX OF EXHIBITS

S T I P U L A T I O N S

It is hereby stipulated and agreed by and between the counsel for the respective parties and the deponent that the reading and signing of the deposition transcript be reserved.

P R O C E E D I N G S

THE COURT REPORTER: Do you swear or affirm that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes.

ANN DALTON,

having first been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. DEBRIERE:

Q. Ms. Dalton, have you ever had your deposition taken before?

A. Yes.

Q. Okay. So I'm just going to walk through some preliminary issues and go over some basic instructions that you've probably heard a million times, and then I'll get started with the questioning.

A. Okay.

MS. DUNN: Sorry. Before we start, can we introduce everybody who is on the phone.

MS. DEBRIERE: Absolutely. Thank you, Chelsea.

Before we start, we want to introduces folks on the phone.

MS. DUNN: I think there's one person who is currently muted. Someone just joined.

Shani, are you there?

MS. RIVAUX: Good morning. This is Shani Rivaux.

MS. DEBRIERE: Anyone else, Chelsea?

MS. DUNN: There is one person. I just don't know who it is.

MS. DEBRIERE: Is anybody else there?

MS. DUNN: It's a 305 number. So it's Miami.

MS. CHRISS: That's Jennifer.

MS. DEBRIERE: Okay. Jennifer Altman is the other person.

MS. DUNN: If folks on the line could mute their phones just so we don't have any background noise, that would be helpful. Thanks.

MS. DEBRIERE: So we're just going to mark exhibits as they're discussed. I'll be showing you papers to read off, and we'll just mark them as we move through. As I mark those exhibits, I'm going to read something called a Bates number; that just helps us track what pages we're on when we discuss things. If there's a Bates number, it's probably going to start with "DEF," then underscore, then the Bates number.

I'd like to go ahead and mark the notice of deposition as Exhibit 1. There's no Bates number on

that one.

MS. DUNN: And Catherine McKee just joined the line as well.

MS. DEBRIERE: It's just the notice that brings you here today.

(Plaintiff's Exhibit No. 1 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm going to be using the acronym GAPMS quite a bit. Do you know what that stands for?

A. Yes.

MS. DEBRIERE: And, Court Reporter, it's G-A-P-M-S.

BY MS. DEBRIERE:

Q. And it stands for generally accepted professional medical standards; which is set forth in 59G-1.035. You probably don't have that memorized. That's okay.

I will use the term "gender dysphoria," which is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth and the associated gender role and/or primary and secondary sex characteristics. When I use that term, can we just agree that's the definition I'm using?

A. Okay.

Q. I'm also going to be using the phrase "categorical exclusion of gender affirming care." And that's just the exclusion set out in 59G-1.050, Subpart 7. That's why we're here for today, for that exclusion of gender affirming care. Do you understand what I mean when I say that?

MR. PERKO: I'm going to object to the form. You can answer.

THE WITNESS: Yes.

BY MS. DEBRIERE:

Q. Well, I do want to make sure you understand what I'm talking about. Would you like to see a copy of the rule before we can agree on use of that phrase? Because as I use it, I do want to make sure we're talking the same thing.

A. Yeah.

MS. DEBRIERE: So we'll mark this as Exhibit 2. It's a copy of 59G-1.050.

(Plaintiff's Exhibit No. 2 was marked for identification.)

BY MS. DEBRIERE:

Q. If you scroll down to Subpart 7 -- scroll down; you're not a computer. If you follow down to Subpart 7 --

MR. PERKO: It's on the back of the page.
BY MS. DEBRIERE:
Q. So when I'm using the phrase "categorical exclusion of gender affirming care," I'm referring to that Subpart 7. Can we agree that that's the phrase that encompasses that portion of the rule?
MR. PERKO: I'm going to object to form.
But you can answer.
MS. DEBRIERE: Well, I think we do need -- Gary, I understand where you're coming from. But I think we just need to figure out a way to shorthand --
MR. PERKO: That's fine.
MS. DEBRIERE: -- that reference.
MR. PERKO: I'm just objecting to the use of "gender affirming care."
MS. DEBRIERE: Okay. How about "treatment for just gender dysphoria"? Would you --
MR. PERKO: That's fine.
BY MS. DEBRIERE:
Q. So we're going to use "categorical exclusion of treatment for gender dysphoria." And when I use that phrase -- categorical exclusion of treatment for gender dysphoria -- I'm referring to that Subpart 7. Can we agree to that?

A. Okay.

Q. I'm also going to use the term "EPSDT services"; which is an acronym for early and periodic screening, diagnostic, and treatment services. When I say "EPSDT," do you know what I mean when I say that?

A. Yes.

Q. So my name is Katy DeBriere. And I represent the plaintiffs August Dekker, Brit Rothstein, and Susan Doe and K.F.

I know you've been deposed before. I'm just going to go over some very brief instructions, just as a refresher.

If I ask a question ask and you don't understand it, don't try to, you know, understand what I'm saying and try to answer the question. Instead, just stop me and tell me to rephrase so that you understand the question. That's no problem at all.

A. Yes.

Q. And speaking one at a time -- I have a horrible habit of speaking over people. But we need to try and do our best to speak one at a time, so the court reporter can get down everything we say. I don't think you're going to have that problem, but I will. So please just let me finish my question before you answer. And I will do my best to do the same when you're

providing an answer back to me; okay?

A. Yes.

Q. Verbal answers -- again, it's clear that you understand. But as we move through, the court reporter can't record things like "uh-huh," or "huh-uh." So if you could just use "yes," or "no," or words whenever you are responding to a question; okay?

A. Yes.

Q. If you need to take a break for any reason, please feel free to ask me. Stop me; tell me you need to take a break. That's not going to be a problem at all. The only thing I ask is that you finish answering your question before we do.

A. Yes.

Q. Okay. Are you on any medications or other substances that can impact your memory today?

A. No.

Q. Can you state your name.

A. Ann Dalton.

Q. And, Ms. Dalton, what did you do to prepare for today?

A. I met with my attorneys.

Q. Okay. And how long did you meet with them for?

A. 45 minutes.

Q. Okay. Did you review any documents?

A. No.

Q. Okay. Can you describe your educational background for me.

A. I have master's degree in music from Florida State University and a bachelor's degree in music from Northern Kentucky University.

Q. What's your current position at the Agency for Health Care Administration?

MS. DEBRIERE: And, Court Reporter, probably throughout the deposition we'll be using "AHCA"; which is the acronym -- AHCA. Or I might reference "the agency" at times. And when I reference "the agency," I mean the Agency for Health Care Administration.

BY MS. DEBRIERE:

Q. So what is your current position at AHCA?

A. I'm the bureau chief of the Bureau of Medicaid Policy.

Q. How long have you worked in that role?

A. Since -- officially, since August 2021.

Q. Okay. What did you do prior to that role?

A. I was an AHCA administrator in the Bureau of Medicaid Policy.

Q. What does that mean to be an AHCA administrator?

A. I was a manager of a team -- the Program Authority Section in the Bureau of Medicaid Policy.

Q. What kind of responsibilities does that entail?

A. The Program Authorities Section was responsible for submitting and maintaining the Medicaid waivers, the Medicaid state plan with the federal partners at CMS; the promulgation of administrative rules; and the PACE program.

Q. And how long were you in that role for?

A. Since August 2018.

Q. What did you do prior to that?

A. I was a program administrator over a section in the Bureau of Medicaid Policy.

Q. And what responsibilities does that entail?

A. That section was titled Program Policy. And it was responsible for the Children's Health Insurance Program or CHIP Program; the provider enrollment policy; the eligibility rule; and a few other rule areas that I can't remember.

Q. What do you mean by eligibility rule? What's that?

A. The -- I don't remember the exact rule number. But it is the rule that outlines the eligibility criteria for recipients in the Medicaid program.

Q. Okay. Is that related to what category of

Medicaid someone would fall under in order to be eligible for Medicaid?

A. I believe so.

Q. Okay. And how long were you in that position for?

A. From January 2018 to August of 2018.

Q. And what did you do prior to that?

A. I worked at the Department of Elder Affairs as a senior management analyst in the Long Term Services and Supports Bureau.

Q. And how long were you in that role for?

A. From August 2017 to January 2018.

Q. Did that role require any knowledge about Medicaid?

A. Yes.

Q. And did that role require any knowledge about rulemaking?

A. Not the promulgation process itself, per Chapter 120; but the development of rule language, yes.

Q. Okay. And when did you start at DOEA?

A. June 2012.

Q. Okay. And so what other positions did you hold there between June 2012 and when you became the senior program management analyst?

A. I held various analyst positions within the

same unit.

Q. Okay. And did those other positions require knowledge of Medicaid?

A. Yes.

Q. And did those other positions require knowledge about rule promulgation?

A. The same as the senior management analyst would have.

Q. In your current role at AHCA, who is your direct supervisor?

A. Currently Brian Meyer is my direct supervisor.

Q. And who is that person's supervisor?

A. Jason Weida.

Q. And what is Brian Meyer's position at the agency?

A. These changes are recent. And I'm not sure of the exact title of his position.

Q. How is his position in relation to Tom Wallace? Or I should ask: What is Tom Wallace's position at the agency?

A. He's a deputy secretary at the agency.

Q. Does Brian Meyer supervise him?

A. No, I believe they're the same position.

Q. Okay.

A. But, again, these are recent changes, and I'm

not quite sure of the exact title.

Q. What was Brian Meyer's role before he changed into the role he currently is in?

A. He was assistant deputy secretary of operations.

Q. Okay. Is Brian within the Bureau of Medicaid Policy?

A. No.

Q. Okay. Is he within any specific bureau at the agency?

A. No.

Q. Describe your current role at the agency for me. What are the responsibilities?

A. I oversee the Bureau of Medicaid Policy. The Bureau of Medicaid Policy is responsible for the federal authorities; which are the contracts between us and the federal government that manage the Medicaid program in Florida. Promulgates -- we oversee the promulgation of all the rules and rule class 59G; which are the Medicaid rules. Oversee the coverage policy development; those coverage policies are promulgated in administrative rule, but outline the specific services and the criteria for reimbursement.

The administration of the CHIP program is also part of the bureau's responsibility. And the managed

care plan contracts -- the drafting of those contracts and policy actions related to the managed care program.

Q. What are coverage policies?

A. Coverage policies are documents that contain the information needed by providers and recipients that describes the service and also provides the information that they would need to be reimbursed -- providers would need to be reimbursed for a service. It describes who can provide the service, who can receive the service, and then any service criteria or details around that service.

Q. What do you mean "service criteria"? Can you explain that further.

A. A description of the service and then any exclusions, if there are any, pertaining to that service. It's different for each coverage policy.

Q. Okay. And what are coverage handbooks?

A. "Handbooks" is a term that we used to use at the agency. A lot of the coverage polices were -- they are now separate coverage policies, but they were contained in bigger handbooks that have since been kind of broken down to be more service specific. And so the term that we use now to describe the information that was previously contained in the handbooks is "coverage policy."

Q. Are the handbooks promulgated into rule?
A. Yes.
Q. And does the agency still rely on those handbooks in determining service eligibility?
A. If the information from a handbook was moved to a coverage policy, the coverage policy would be promulgated in the rule and the handbook would no longer be part of that rule.
Q. Can you give a recent example of the handbook information moving into a coverage policy rule.
A. It's not that recent, but it's the first one that comes to my mind -- is the Home Health Handbook was broken down into three coverage policies, I believe, around 2016. And those three policies are the Home Health Services Coverage Policy, Personal Care Services Coverage Policy, and the Private Duty Nursing Services Coverage Policy.
Q. Okay. And this will seem like a simple question. But where do those coverage policies -- can the public access those coverage policies?
A. Yes.
Q. And where would they access those coverage policies?
A. The agency has an external web page specific to all the coverage policies, fee schedules, reimbursement

policies.

Q. And the policies that are on that public facing website, are they all inclusive of the policies on which the agency relies for determining coverage? Strike that question.

Is it an exhaustive -- is what is contained on the agency's website, is it an exhaustive list of Medicaid coverage policies?

A. All the policies promulgated in class 59G. And the rules or links to the FAR notice are on our website, yes.

Q. Are there any coverage policies not on the website on which AHCA relies to determine coverage of Medicaid services?

A. Not that I'm aware of.

Q. What is a fee schedule?

A. A fee schedule is the document that provides information on billing codes, the description associated with a code, and the amount that Medicaid will reimburse for fee for service.

Q. What is fee for service?

A. Fee for service is a delivery system where the State pays providers directly -- reimburses them directly for the service provided.

Q. Is that in contrast to managed care?

A. It's a different delivery model.

Q. If a Medicaid service is listed on the fee schedule, does that mean Medicaid covers it?

I'll strike that. I think I can ask a question that well help here.

If a Medicaid service is on the fee schedule, does that mean Medicaid does not categorically exclude it?

MR. PERKO: Object to form.

MS. DEBRIERE: You can go ahead and answer if you understand. If you don't understand, please feel free to ask me to rephase.

THE WITNESS: I don't think I understand.

BY MS. DEBRIERE:

Q. If a Medicaid service is listed on a fee schedule, does that mean that Medicaid is willing to pay for it if the recipient meets all eligibility criteria for that service?

A. So the fee schedules have to be used in conjunction with the coverage policy. So, like I said, the fee schedule contains the coding that the provider needs to use in order to get reimbursed, and, in most cases, the amount and description. But the parameters of who can receive the service -- what kind of providers can get reimbursed for the service -- that's in the

coverage policy.

Q. Okay. What would it mean if a Medicaid service was not on the fee schedule?

A. So the fee schedule document and the term as we would use "fee schedule" does not include all of the services. Some of those are going to be found in the reimbursement methodology rules, if there's not a specific fee equated to a specific code. So there's also reimbursement methodology rules and documents as well.

Q. Are there services -- Medicaid services on the fee schedule that AHCA will not cover?

A. I don't know if there's any. But it would be -- any information about how the services covered would be included -- either on the fee schedule or in the coverage policy.

Q. Okay. Do your responsibilities currently include developing coverage policies for the Florida Medicaid program?

A. I oversee the teams that are responsible for that, yes.

Q. And who are those individuals? Or let's start with: Who are the teams?

A. The team primarily responsible for the majority of the coverage policies is the team managed by Jesse

Bottcher; he's the AHCA administrator. And he has three program administrators who report directly to him.

Q. And who are those people?

A. Christine Polacheck [phonetic], and she oversees the specialized services section. John Matson, he's the manager over at the primary and preventative services section. And then Tim Beaner is the manager over the behavioral health and behavioral analysis section.

Q. Are those the only teams over which you manage? Or are there other teams?

A. I have five AHCA administrator direct reports.

Q. Okay.

A. And then one program administrator direct report. So I have six direct management team reports.

Q. So who are the other ones?

A. Catherine Mcgrath is the AHCA administrator over the program authority section. Ashley Peterson is the AHCA administrator over at the pharmacy policy section. One of them is vacant -- the managed care contract AHCA administrator position. Devona Pickle, she is the AHCA administrator over the Canadian Prescription Drug Importation team. And Jesse Bottcher. And then Lakeva Campbell [phonetic] is a program administrator over the administrative unit who does the

administrative functions of the bureau.

Q. Who works under Jesse Bottcher?

A. That was Christine Polacheck, John Matson, and Tim Beaner.

Q. And do you know who Mr. Jeff English is?

A. Yes.

Q. And who is his supervisor?

A. His current supervisor is Cole Giering.

Q. Who is Mr. Giering's supervisor?

A. Catherine Mcgrath.

Q. And Mr. Bottcher -- does he supervise the person who undertakes GAPMS analysis?

A. The position that is designated to do the GAPMS is under Jesse Bottcher.

Q. Okay. And who does Ms. Peterson supervise?

A. The pharmacy policy team, which consists mostly of pharmacists within the bureau.

Q. How many pharmacists are there?

A. In Ashley's section, there are currently three.

Q. Do you know the names of any of those people?

A. Yes. Jessica Forbes, Kelly Rubin, Susan Williams.

Q. Are you familiar with a person named Nai Chen?

A. Yes.

Q. And who is his supervisor?

A. D.D. Pickle.
Q. And was Mr. Chen ever involved in the pharmacy policy? Did Mr. Chen ever work for the pharmacy policy unit?
A. No.
Q. How long has Mr. Chen been in that position?
A. I don't remember.
Q. More than a year?
A. Yes.
Q. More than two years?
A. I'm not sure.
Q. Okay. Does Mr. Chen in his position have any responsibilities over pharmacy coverage policies?
A. None that are currently promulgated.
Q. What about policies that are not promulgated?
A. I don't know if there's going to be the need for a coverage policy or what types of administrative rule we're going to need to implement the Canadian Prescription Drug Importation Program once that's federally approved -- which is why I answered how I did.
Q. Are there any other pharmacy related activities that Mr. Chen engaged in the past year?
A. Yes.
Q. What are those?
A. His -- he's part of the Canadian Prescription

Drug Importation Program team. And there has been pharmacy related activity regarding the SIP approval.

Q. What does SIP stand for? Or you can just describe it if that's easier.

A. It's the proposal or the importation program plan that the federal government authorized states to submit or request approval of in order to develop an importation program. And this was submitted to the FDA.

Q. What does the Canadian Prescription Drug Importation unit do?

A. Their primary responsibility is to implement the Canadian Prescription Drug Importation Program that was statutorily authorized -- and I think it was in 2019 -- which includes seeking that federal approval from the FDA and any implementation activities in managing the contract with LifeScience Logistics -- the agency's vendor who assists with that program.

Q. And did Mr. Chen over the past year have any responsibilities related to pharmacy activities that did not involve the Canadian Prescription Drug Importation Program?

A. Yes.

Q. And what were those?

A. I can't recall all the specific assignments. But he has helped with several research projects. I

think he has assisted Ashley's team with some questions or answering questions. And he's been available to assist with just different research projects.

Q. Was he involved at all with the categorical exclusion of treatment for gender dysphoria in developing the pharmacy coverage decisions related to that?

A. So when you ask that, you're specifically talking about the rule?

Q. I'm talking about the rule and the ways in which AHCA is implementing the rule.

A. I don't know to the extent -- I know that he assisted with research for the GAPMS report.

Q. Okay. And by GAPMS report, is that the report that is related to the categorical exclusion for treatment of gender dysphoria?

A. Yes.

Q. Why did Mr. Chen assist the pharmacy unit with the GAPMS report instead of the other pharmacists in the pharmacy policy unit? I'll strike that.

Why did Mr. Chen -- does the Canadian Prescription Drug Importation unit focus on pharmacy policies unrelated to the Canadian Prescription Drug Importation Program typically?

A. Since there's been such a long delay with the

federal approval of the Canadian Prescription Drug Importation Program, that team has assisted with various other projects within the bureau.

Q. Okay. Is that why Mr. Chen assisted with the GAPMS report for the exclusion of the treatment for gender dysphoria?

A. Yes.

Q. What types of services does AHCA develop coverage policies for? Actually -- I'm sorry; strike that. I apologize.

What does the Pharmacy Policy unit do?

A. Their job entails a lot of duties. Primarily they host and oversee the PNT and DUR meetings -- public meetings and the boards associated with that. They oversee the coverage policies specific to pharmacy. They assist with any contract language for the managed care contacts for pharmacy. They oversee the contract for our PBM contractor Magellan. Those are the primary duties.

Q. What does PBM stand for?

A. Pharmacy benefits manager.

Q. And what is that?

A. PBMs can have various duties. But the contract that I'm referring to is our rebate negotiation contract.

Q. Okay. And you said that PBM contract is with Magellan; is that correct?
A. Yes.
Q. Okay. What's DUR?
A. Drug Utilization Review Board.
Q. And I think you used one other acronym when you were discussing the public facing pharmacy meetings.
A. PNT.
Q. And what does that stand for?
A. I believe it's pharmaceuticals and therapeutics.
Q. Okay. And what is that?
A. All the responsibilities of that board are outlined in statute.
Q. Okay.
A. I can't think off the top of my head. But they meet quarterly. And we host those meetings and schedule them.
Q. Okay. A few more questions about Mr. Chen.
Is Mr. Chen a pharmacist?
A. I believe so.
Q. And is he the only pharmacist in the Canadian Prescription Drug Importation Program unit?
A. None of the other members of that team are pharmacists.

Q. So Mr. Chen is the only one?
A. Yes.
Q. Okay. Did any other pharmacist assist with the 2022 GAPMS relating to exclusion of treatment for gender dysphoria?
A. I don't know.
Q. What types of services does AHCA develop coverage policies for?
A. The coverage policies are -- outline the services that the State covers through the state plan -- Medicaid state plan or Medicaid waivers. So those are just any Medicaid related service.
Q. Does AHCA develop coverage policies for surgeries?
A. Yes.
Q. How about for prescription drugs?
A. Yes.
Q. Does AHCA develop coverage policies for every Medicaid service?
A. I don't know.
Q. Have you ever had a situation where a Medicaid recipient requests coverage for a service and there is no policy?
A. I personally have not, no.
Q. Okay. And what process does AHCA use to decide

whether to provide coverage of a Medicaid service?

A. That really depends on the specifics of what that service is.

Q. Does every service have a different process?

A. The process could vary based on what the service is that we are determining coverage for.

Q. Do you use the same process for developing pharmacy policy coverage?

A. I can't speak to the process or approach of the analysts. The process of promulgating the coverage policies into rule is always going to be in accordance with Chapter 120.

Q. During your time at AHCA, have you developed -- have you been involved in developing or has your team -- those you supervise -- been involved in developing new coverage policies to cover services?

A. Yes.

Q. Can you remember a specific service that you did that for?

A. Yes. We are currently in the process with promulgating the iBudget Waiver handbook. And as part of the updates to the handbook, one of those is to develop a new life skills development for Level 4 service. As part of that process, we also worked with our federal partners at CMS to get a waiver amendment

approved. That's a very recent example of a new service being developed.

Q. Do you have an example of a state plan service that you developed coverage for that's under current development?

A. Yes. We recently added some Puro Meno products to the DME fee schedule.

Q. And so in that instance, did you establish a coverage policy for those specific items of DME?

A. We did a coverage determination to determine if and how they could be included as a covered service as part of the DME service.

Q. And what is DME?

A. Durable medical equipment.

Q. And that includes medical supplies?

A. Yes.

Q. And Puro Meno would be a medical supply?

A. Yes.

Q. And you, to cover that service, incorporated it onto the fee schedule?

A. Yes.

Q. Did you do --

Okay. How did you assess whether to decide to incorporate Puro Meno into the fee schedule?

A. So I can't speak to all the steps that the

analyst -- the specific steps that they took. But just speaking overall, determined if we had the legislative and state plan authority to cover it; determined if it was -- if there would be a fiscal impact.

And we approach coverage like that example to, you know, try and make sure it's budget neutral since we are -- our coverage is driven by our general appropriations and our state general appropriations act. And then determined if and what types of updates would be needed to any of the Medicaid rules. That's the general process for determining that kind of coverage.

Q. So to make a coverage determination you look at your legislative authority -- authority under the state plan -- and you do a fiscal analysis and hope for budget neutrality. You check to see if there's any updates to Medicaid rules. Anything else?

A. Making sure that it's an allowable service under Medicaid, as well; which would entail that it meets all federal, state rules and regulations for coverage. But, like I said, all the details of the research that the team does -- I can't speak to exactly everything that they read or looked at.

Q. And if in that coverage determination you decide to cover that service, do you then incorporate it into the fee schedule?

A. In the example I gave, that's what we did, yes.
Q. Are there any situations where you would not incorporate it into the fee schedule?
A. Yes.
Q. What are those circumstances?
A. That would vary depending on what the actual request or coverage benefit is that we're looking.
Q. Can you think of an example?
A. Yes. Last legislative session, I believe it was, there was a specific language regarding the coverage of human donor milk and milk derivatives for inpatient use. Because it was under inpatient, that is a -- the reimbursement for that is different and isn't included in a fee schedule.
Q. Okay. That makes sense.
Once this coverage determination is made, do your responsibilities include reviewing that to determine whether to approve the decision?
A. Yes.
Q. And how do you go about doing that?
A. We usually meet with the team. We do a walkthrough, have discussions around the proposal and the recommendation. And then we put together -- depending on what the change is, put together a document to get approval from management -- upper management.

Q. Does that document have a specific title -- the same title every time?

A. No.

Q. How would you identify that document?

A. So if a fee schedule change was needed, there is a formal routing process for the rule promulgation process that would be routed through management and signed off on.

Q. Okay. Are there other documents that would be routed through management to be signed off on?

A. Yes.

Q. And what are the titles of those documents?

A. It depends on the situation. For example, we also have a steering committee at the agency for the division of Medicaid. And we call that a decision point that would be to the steering committee.

Q. Okay.

A. And the Medicaid director or agency leadership is part of that committee. And so that is also a way for us to get approval.

Q. For those coverage determinations that you reviewed and put together in a document for administrative review, who in the administration reviews that document?

A. Depends on what that is. So for administrative

rule -- that needs to be signed off by several agency leadership; including the general counsel, the agency secretary for a proposed rule. So it would depend on what the final document is who the final signatory would be.

Q. Distinct from implementation of the coverage determination, is there a review by the administration of just whether to cover the Medicaid service?

A. It depends on what the specific circumstances are.

Q. Okay. Can you think of an example of the administration reviewing a determination of whether to cover a service?

A. Can you be more specific? So the waiver example I used a while back would be signed to submit the waiver -- the iBudget waiver -- with the changes. That would have been signed by the Medicaid director prior to submission to federal CMS.

Q. How long have you been involved in the process of doing coverage determination?

A. Since my time at AHCA.

Q. Okay. So since -- I'm trying to take notes here. So since August of 2018?

A. January of 2018.

Q. January of 2018. Thank you.

And when you're making coverage determinations, you coordinate with AHCA rules unit if a rule change is needed; is that right?

A. Yes.

Q. Okay. Under what bureau does the AHCA rules unit fall?

A. Under the Bureau of Medicaid Policy.

Q. Okay. So under your unit?

A. In the bureau.

Q. I'm sorry. Under you're bureau?

A. Yes.

Q. And you coordinate with AHCA's pharmacy policy unit; which falls under your -- the pharmacy policy unit falls under your bureau as well; is that right?

A. Yes.

Q. Okay. Do you coordinate with other bureaus in developing coverage determinations?

A. Yes.

Q. Which ones?

A. All the bureaus in the division work closely together. And there have been some recent changes with that structure. But speaking prior to those changes, the Bureau of Medicaid Program Finance would be probably be the primary bureau; because they assist with determining or setting our fee schedules and our rates

and the methodologies and doing fiscal impact analyses -- data analytics -- Medicaid data analytics.

As part of the whole development package, we talk to all the bureaus because plan management operations can be affected if there is an update to the contracts. The Bureau of Medicaid Quality who monitors and oversees the provision of services through those contracts -- and they have various other duties. But depending on what the change is, we would communicate with most of the bureaus within the division.

Q. Okay. You just mentioned some recent changes in terms of that structure. What are those recent changes?

A. The Bureau of Medicaid Finance and Medicaid Data Analytics are reporting directly to Tom. And Plan Management Operations, Quality, and Policy are reporting directly to Brian Meyer.

Q. And why is that a change?

A. Previously I had been reporting directly to Tom Wallace.

Q. Is Brian Meyer's position a new one?

A. I don't know all the details of those changes.

Q. Okay. Who made the decision to make those changes?

A. I don't know.

Q. Okay. Who oversees the rules unit?
A. Cole Giering is program administrator of the rules unit.
Q. How long has he been in that position?
A. I'm not sure exactly. But it was since I've been bureau chief.
Q. Okay. So --
A. August of 2021.
Q. Thank you.
Do you coordinate -- in making coverage determinations, do you coordinate with the chief medical officer for AHCA?
A. Yes.
Q. Who is that?
A. Dr. Christopher Cogal.
Q. Can you describe how you coordinate with him, what that process looks like.
A. Again, it really depends on the specific question or policy we're reviewing. But it would consist of meetings or discussions.
Q. What types of things would you discuss?
A. So, for example -- I'm going to go back to the two examples of recent activity. So he wasn't involved in the iBudget Waiver changes at all. But for the human donor milk, he assisted when we had originally done the

legislative bill analysis when the legislation was first proposed. And so for the development of how to implement the changes, he was consulted. I don't know the specific conversation, but I do know that he was involved in that process.

Q. On what kind of expertise do you rely on him for? What kind of input does he provide in the process? Is it medical in nature?

A. I don't know.

Q. Okay.

A. To the extent -- I know he's an available resource for the team. But I don't know to the extent that -- of his involvement.

Q. When he gets involved, is it through a formal process? Or is it just a decision to reach out and ask him for advice? How would you characterize it?

A. From my experience at the bureau level, it's been more informal. I know that there have been -- he's been formally asked to review bill analysis or -- but how that process works, I don't know.

Q. Okay. Are there people under you who are more likely to communicate with Dr. Cogal?

A. I believe there's staff that communicate with him more than others, yes.

Q. What staff are those?

A. Ashley Peterson has been meeting with him on some projects lately. Again, it really depends on the project. But we are working with him on continuous glucose monitoring -- questions around coverage there. And Jesse Bottcher and his team.

Q. When you say Jesse Bottcher and his team, would that include the GAPMS process?

A. His team is responsible for it.

Q. In coordinating with Dr. Cogal -- in the coordination between Mr. Bottcher's team and Dr. Cogal, would that include the GAPMS process?

A. I don't know the extent to which he is involved in that.

Q. Okay. To your knowledge, has he ever been involved in that?

A. I don't know specifically.

Q. Have you and Dr. Cogal and anyone from Mr. Bottcher's team ever met to discuss the GAPMS process?

A. The process, yes. When I first took the role, we had met to talk through the process. But I can't remember the specific conversation.

Q. Okay. Switching gears a bit. When I use the term "Florida Medicaid managed care plan," do you know what it means?

A. Yes.
Q. What does that term mean?
A. Those are the managed care plans that the agency contracts with to provide the services through the managed care delivery model.
Q. Do Medicaid managed care plans have their own coverage policies?
A. The agency's coverage policies are incorporated into the managed care plan contracts by reference. And there are requirements outlined in the contract with how the managed care plans have to provide services.
Q. Are you aware of managed care plans having their own policies that incorporate Florida Medicaid's policies?
A. I don't know.
Q. Have you ever seen a copy of a Florida Medicare managed care plan document that discusses the coverage of a Florida Medicaid service?
A. I reviewed the plans' member handbooks or enrollee handbooks. And I've seen their resources available on their websites that weigh out what they cover. I can't remember if I've ever seen an official document titled "Coverage Policy."
Q. So my question is: Have you ever seen a document from a Medicaid managed care plan -- formal or

informal, it doesn't matter -- with information that contains the criteria used to determine if Florida Medicaid will cover a service?

A. I believe that information is in the handbooks. But I can't recall any specific documents drafted by the plans.

Q. What unit would be responsible for communicating with managed care plans about their coverage of Florida Medicaid services?

A. That would depend if they had a question for the agency on the agency's coverage of a covered service or a contractually required service. Those most likely would be sent to Medicaid policy.

Q. Okay.

A. To review.

MS. DEBRIERE: Okay. Yes. Definitely. Just a couple more questions, if that's okay.

BY MS. DEBRIERE:

Q. Are you okay Ms. Dalton?

A. Yes.

Q. Who would review those questions? Who specific -- like, what specific individuals?

A. It would depend on what the question was.

Q. Okay. If the managed care plan doesn't have a question, is there any process that exists that just

involves overseeing whether a Medicaid managed care plan is covering a Florida Medicaid service?

A. The Bureau of Plan Management Operations is the bureau that oversees the adherence to the contract. All the contract managers for the individual plans are housed there. So if it was a compliance question on if the managed care plan was following the requirements in the contract, that would be Plan Management Operations most likely who would be the first point of contact for the plans.

Q. Okay. Can MCOs create their own guidelines for implementing AHCA coverage policies?

A. I don't know.

Q. Who would know that?

A. It would be in the contracts.

Q. Okay.

A. The parameters around what their materials are allowed to contain and if the materials have to be reviewed and approved by the agency.

Q. Okay. And that would be the Bureau of Planned Management Operations who does that -- takes on that role? And if not, then who?

A. I believe it would depend on what the materials being reviewed are. Just like with reporting -- there are different report owners in different bureaus within

the division of Medicaid that review compliance with the -- the plan's compliance with the contracts. But the first point of contact for submitting those materials and making sure that they're submitted would be through Plan Management Operations.

Q. And who is that bureau chief? Remind me.

A. Pam Hall.

Q. Okay. One last question. Are you aware that MCOs have their own guidelines for specific types of Medicaid services?

A. I can't speak to that. I don't know.

Q. Do you know who would know?

A. Are you asking if it's a required -- or if they're allowed to --

Q. No. I'm just asking if you're aware. So are you aware that they have their own --

MR. PERKO: Asked and answered.

MS. DEBRIERE: -- criteria guidelines?

THE WITNESS: I would have to review the contract.

BY MS. DEBRIERE:

Q. Okay. So is that a no, you are not aware as we sit here today without having anything in front of you?

A. Correct. I don't know without seeing a specific example or reviewing the contract.

Q. Okay. Do you want to take a break?
A. Yes.
(Brief recess.)
BY MS. DEBRIERE:
Q. Ms. Dalton, just briefly -- when we took a break, did you discuss this deposition with anyone?
A. No.
Q. Did you discuss it with your attorneys?
A. Just briefly.
Q. Okay. When I use the term "quality improvement organizations" or QIOs, do you know what I mean?
A. Yes.
Q. What does that term mean?
A. Quality improvement organization.
Q. Yeah. Is eQHealth a QIO?
A. Yes.
Q. And what do they do?
A. I don't know the whole scope. But their main function in their contract with the agency is the -- to do prior authorization for fee for service services.
Q. Okay. What does prior authorization mean?
A. It's a utilization management tool to ensure that the services are in their scope, authorized, and appropriate.
Q. By "appropriate," what do you mean?

A. That the service that's being requested is allowable and delivered within the parameters of the Medicaid program.

Q. Who makes the request for prior authorization?

A. I don't know the details of how the process works.

Q. Okay. By parameters, do you mean the parameters set by AHCA's coverage policies?

A. Yes. And administrative rule.

Q. Okay. Is administrative rule distinct from a coverage policy?

A. Yes. Not all of the administrative rules incorporate a coverage policy by reference.

Q. Okay. So an example of that would be the definition of medical necessity -- would be an administrative rule that sets out the parameters for coverage but does not include a specific coverage policy?

A. The definition of medical necessity is actually in the definitions policy -- which is a document incorporated by reference into the text of the administrative rule.

Q. Okay. Do QIOs like eQHealth -- do they have their own coverage criteria they rely on?

A. Yes.

Q. Do you coordinate with QIOs regarding those coverage criteria?

A. I personally do not.

Q. Does anybody on your team?

A. The eQHealth contract is housed in the Bureau of Medicaid Quality.

Q. Okay.

A. So they would be a lead in managing of that contract and communicating with the vendor. But I do know that we have communicated with them in the past -- the Bureau of Medicaid Policy has.

Q. What types of things have you communicated about in the past?

A. The first example that comes to mind is recently the agency opened the definitions rule policy and did communicate that that rule was being opened with eQHealth.

Q. Okay. Are MCOs and QIOs bound by AHCA's coverage policies?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: As I stated before, the contract for the managed care plans incorporates the coverage policies by reference. And the plans are not allowed to be more restrictive than the coverage

policies. I don't know the specific language off the top of my head with the requirements of how they adhere to the policies. But that is in the contract.

BY MS. DEBRIERE:

Q. Okay. So the MCO's obligation to adhere to AHCA's coverage policies is set forth in the contract?

A. Yes.

Q. Okay. What about QIOs?

A. I don't know the specific language off the top of my head. But that information is also in the contracts on how the managed care plans' contracted QIO vendors are expected to operate.

Q. Okay. Is there a formal approval process for the QIO's coverage criteria?

A. I don't know.

Q. Is Magellan a QIO?

A. I don't know.

Q. Okay. Does Magellan conduct prior authorization of Florida Medicaid services?

A. I don't know.

Q. Does Magellan review the request of a Medicaid recipient to authorize prescription drug services in the Fee for Service program?

A. I don't know.

Q. Do you know what -- do you know if Magellan plays any role in determining coverage of pharmacy services under Florida Medicaid?

A. I believe the agency has a contract with them to adjudicate the claims. But I don't know the scope of that contract.

Q. What do you mean by adjudicate the claims?

A. I don't know the whole scope of that process or the contract.

Q. When you just use that phrase, what did you mean by that?

A. That they're involved in the reimbursement process.

Q. Okay. And would the reimbursement process involve determining the eligibility for the service itself?

A. I don't know the extent of that process.

Q. Would anybody at AHCA know or be able to answer that question?

A. I don't know.

Q. Moving back to coverage determinations undertaken by your bureau, who is the final decisionmaker as to whether AHCA will adopt that coverage determination?

A. Can you repeat the question.

Q. So earlier we were talking about your bureau undertaking coverage determinations of Florida Medicaid services; correct?

A. Yes.

Q. Who is -- before AHCA or anyone at AHCA can act on that determination, who is the final decisionmaker?

A. Again, it depends on the circumstances. And I can only speak to the signatory of who needs to be -- to officially sign off. But the example I used before for a federal authority submission, that would be whoever was designated from the agency as the Medicaid director or the Medicaid state plan approver.

Q. Okay.

A. And then administrative rule to actually complete the promulgation process. That's actually signed off by the head of the agency, which here would be our secretary.

Q. Okay. When coverage policies are promulgated, are there multiple drafts of those policies? Are there ever multiple drafts of those policies?

A. Can you repeat the question.

Q. When you're developing a coverage policy, are there multiple drafts?

A. It would it depend on what the change was.

Q. So there are times when coverage policies have

multiple drafts?

A. Yes.

Q. And how do you track any changes to those policies during the drafting process?

A. So specific to the coverage policy, we typically use a document called a revisions template; which tracks the changes being proposed.

Q. Okay. Is there a limit to the people who can make changes to the revisions document?

I'm sorry; the revision just tracks who has made the changes; is that right?

A. So it tracks what the old policy said, what the new changes are, if there's a reason for the change. I'm not sure if it includes who the requester of the change is.

Q. Okay. Does it record who is making the change?

A. I can't recall if that's on the template.

Q. Is anybody at AHCA allowed to make a change?

A. So for most of the coverage policies, there's a subject matter expert assigned to that program area who any changes would filter through. And then they have to work with the rules unit who is actually making the changes to the coverage policy and promulgating that through the rulemaking process.

Q. Okay. Just switching quickly to some specific

Medicaid services. Are coverage policies regarding surgery adopted into rule?

A. Yes.

Q. And are they in handbooks or a handbook?

A. I don't believe it's one specific handbook.

Q. Do you remember the names of any of the handbooks they are contained in?

A. We have a transplant services coverage policy.

Q. Okay.

A. Which I would consider inclusive of surgical. We have an inpatient services coverage policy. Without seeing the list of policies, I can't recall off the top of my head.

Q. Give me one second.

Would coverage policies about surgeries be in the Ambulatory and Surgical Center Services Policy?

A. I don't know the content of that policy off the top of my head.

Q. Okay. You said inpatient hospital services would contain surgery policies?

A. I don't know all the content in the policy without looking at it. But it...

Q. If it mentions surgery in the handbook, is it going to have a coverage policy related to it?

How would you know if a handbook covered

surgery or contained a surgery coverage policy in it?

A. I would have to read the handbook. Depending on what the specific question was, what type of surgery.

Q. Okay. What about prescription drug coverage policies? Are those adopted into rule?

A. I believe there is a rule specific to pharmacy policies and prescription drugs, yes.

Q. Okay. And then I'm just going to flip my computer around here and go to this page. We're looking at what's titled Agency for Health Care Administration Drug Criteria. AHCA.myFlorida.com/Medicaid/prescribed_drug_criteria.shtml.

And I assume, Ms. Dalton, I'm seeing here -- are you just seeing a list of drug criteria?

A. Yes.

Q. Is this an exhaustive list of the drug criteria that AHCA relies on?

A. I don't know.

Q. Who would know that?

A. Ashley Peterson and her team may be able to confirm.

Q. Okay. And why wouldn't this be an exhaustive list?

MR. PERKO: Object to form.

THE WITNESS: I'm not personally very familiar with this page.

MR. PERKO: Counsel, for the record, can we read the URL.

MS. DEBRIERE: Absolutely. Well, I think I -- Gary, do I not know what a URL is?

MR. PERKO: The website address.

MS. DEBRIERE: So I think we read most of it. But I can start with https://AHCA.myFlorida.com/Medicaid/prescribed_drug/drug_criteria.shtml.

MR. PERKO: Thank you.

MS. DEBRIERE: Absolutely.

BY MS. DEBRIERE:

Q. Do you know what categorical exclusion means?

MR. PERKO: I'm going to object to form. I guess I'm a bit confused, Counsel. You already defined what categorical exclusion means at the beginning of this deposition.

MS. DEBRIERE: Well, that's categorical exclusion -- you're right, Counsel. It contained the statement "categorical exclusion"; just categorical exclusion of a very specific set of services. The treatment for --

MR. PERKO: That wasn't the definition at the

beginning. But go ahead.

BY MS. DEBRIERE:

Q. How about this, Ms. Dalton: Can you provide an example of a categorical exclusion under Medicaid?

A. I can't think of an example. I'm familiar with the term. I cannot think of an example.

Q. Okay. I'm trying to think of one too.

Does AHCA -- does Florida Medicaid cover private duty nursing service for individuals over the age of 21?

A. Not through the state plan.

Q. Okay. Do they cover it through home and community based services with a Medicaid waiver?

A. Yes.

Q. Okay. And if Florida Medicaid does not cover private duty nursing services for individuals over 21 under the Medicaid state plan, is that a categorical exclusion?

A. Yes.

Q. And does the agency categorically exclude any Medicaid service for beneficiaries under the age of 21?

A. Can you repeat the question.

Q. I'm sorry. Bear with me one second, Ms. Dalton. I'll come back to that.

Do your responsibilities include ensuring that

coverage policies meet the standards under EPSDT?

A. The Bureau of Medicaid Policy doesn't oversee the monitoring of the adherence to the policies or the provision of services. In terms of ensuring that the policy language complies with the federal EPSDT requirements, yes.

Q. And how do you ensure that compliance when developing coverage policies?

A. It depends on the specific coverage policy. But the majority of the service specific coverage policies include language incorporating EPSDT by reference and language from the federal regulation.

Q. Generally speaking, what is that EPSDT requirement?

A. That the State must provide all medically necessary services to children ages under 21.

Q. Does the State have to provide a service under EPSDT to a Medicaid recipient under 21 if that service is experimental?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Do you know what I mean when I say experimental?

A. Yes.

Q. So same question. Does the State have to

provide coverage to children under age 21 if that health service is considered experimental?

MR. PERKO: Object to form.

THE WITNESS: The State is allowed to develop its own definition of medically necessary or medical necessity; which Florida has done and promulgated in administrative rule. And part of that definition does include the parameters by which a service would not be determined medically necessary; and, therefore, not required under the EPSDT.

BY MS. DEBRIERE:

Q. Okay. And that definition of medical necessity includes the requirement that the service not be experimental; correct?

A. I cannot recall the exact definition off the top of my head. But that is in -- promulgated in the definition coverage policy.

Q. When you say that is --

A. The definition of medical necessity.

MS. DEBRIERE: Okay. We can mark -- I have a copy of the rule so you can reference it. We can mark that as Exhibit 3. And that's 59G-1.010.

We might have forgotten to put a copy in. If we did, it's my fault.

MS. DUNN: I have a copy right here.

(Plaintiff's Exhibit No. 3 was marked for identification.)

MS. DUNN: Yeah. It's right there. Last definition on that page.

THE WITNESS: It doesn't seem to be the whole --

MS. DUNN: It's not.

MS. DEBRIERE: It's not. We ended it at "N," because it's a very large coverage policy and we are trying to save some trees.

BY MS. DEBRIERE:

Q. So if you look at the definition of "medically necessary" or "medical necessity," does that contain a requirement that the service not be experimental?

A. Yes.

Q. And so under EPSDT, can the agency deny a medical service to a child under 21 if they deem it to be experimental?

A. Yes.

Q. Okay. Who is responsible for compliance with EPSDT? Is it a specific person?

A. I don't know who is responsible.

Q. Is it someone within your bureau regarding EPSDT as it relates to the development of coverage policies?

A. There isn't a specific person in my bureau, no.
Q. Are there any written guidelines about ensuring compliance with EPSDT with developing coverage policies?
A. Can you repeat.
Q. Are there any written guidelines relied on to determine whether a coverage policy complies with EPSDT, other than that contained in the Federal Medicaid Act?
A. I don't know specific -- all the specific documents that the analysts rely on when developing the coverage policy. But as part of that process, the expectation is to review the federal guidelines and statute and other rules and regulations of governing the Medicaid program to ensure that the coverage policy adheres to the Medicaid program federally and state.
Q. And that's an expectation of the staff within your bureau?
A. Yes. It's the common practice when approaching research regarding changes to the policy -- a policy.
Q. Okay. When I use the term "comparability," do you know what I mean as it's laid out in regulations implemented in the Federal Medicaid Act?
A. You may have to give me some more context.
Q. So under the Federal Medicaid Act, there is a requirement that state agencies who administer Medicaid do so in a way that all Medicaid recipients receive

comparable services. Are you familiar with that requirement?

A. Vaguely sounds familiar.

Q. Is your bureau required to be familiar with that requirement in developing coverage policies?

A. I can't speak to that without more information.

Q. Okay. Is there anyone who can speak to the requirement -- is there anyone who can speak to ensuring that the policy comply with comparability under the Federal Medicaid Act?

A. So, again, I think it really would depend on what the specific question is regarding or which specific coverage policy. As I said before, a lot of the coverage policies have a specific subject matter expert with knowledge of that service area. So it just really would depend.

Q. Okay. I'm just going to make myself a note.

What is the purpose -- turning back to Exhibit 3 and the definition of medical necessity -- what's the purpose of AHCA's medical necessity standard?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Does AHCA's medical necessity standard have a purpose?

MR. PERKO: Object to form.

THE WITNESS: I don't know what you mean.
BY MS. DEBRIERE:
Q. What is the purpose of the definition of medical necessity?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. What do you use it for?
A. The definition is relied on a lot. Most of the service specific coverage policies refer and incorporate by reference the definitions policy and make a statement that the service must be medically necessary as part of the requirement for reimbursement.
Q. If a Medicaid recipient makes a request for a Medicaid service, in order for that service to be authorized, does it have to be medically necessary?
A. Yes.
Q. Do managed care plans rely on AHCA's medical necessity standard in their prior authorization process?
A. I can't recall the exact contract language. But, yes.
Q. And what about QIOs?
A. I don't know.
Q. Regardless of the method in which Medicaid is delivering the service -- fee for service or managed care -- in order for that surface to be authorized, does

it have to be medically necessary?

A. I don't know the details of the actual authorization process. I do know that the expectation from policy prospective is that the services have to be provided in accordance with the agency's coverage policies and administrative rules.

Q. And that includes the definition of medical necessity?

A. Yes.

Q. If AHCA finds that a Medicaid service is experimental, would AHCA or a contractor or managed care plan still review whether service meets other portions of AHCA's medical necessity definition?

A. I don't know the extent of their review.

Q. What about your review at AHCA for fee service?

A. Again, I don't know eQHealth or QIO vendors' process.

Q. Do all Florida Medicaid services require prior authorization?

A. I don't know. I don't believe so.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 4, which is the GAPMS Report on Cross-Sex Hormone Therapy, dated May -- I believe we did the May version.

So what I'm showing you is Bates stamped

beginning at Defendant 00126105. I should pull out my own copy.

And that continues through, Court Reporter -- this one is not Bates stamped. It's weird. This one doesn't have a copy. This copy is not Bates stamped. But it is entitled Cross-Sex Hormone Therapy GAPMS Determination Report With Recommendation.

That's very odd. Very odd. I don't think it's a huge deal.

(Plaintiff's Exhibit No. 4 was marked for identification.)

BY MS. DEBRIERE:

Q. So on the last two pages, Ms. Dalton, starting at "Coverage policy" -- and it starts, "Federal regulations."

"Federal regulations for Medicaid..." and continues on through the definition of medical necessity --

MR. PERKO: Can you give a page number.

MS. DEBRIERE: Oh, yes. Thank you, Gary.

So page 8, 9, and a tiny bit of the top of 10.

THE WITNESS: I'm there.

BY MS. DEBRIERE:

Q. Take all the time you need to read it. And

afterwards, if you can tell me if this is an accurate portrayal of the standard used to determine Florida Medicaid coverage for prescription drugs.

MR. PERKO: Do you have another copy?

Thank you.

BY MS. DEBRIERE:

Q. I think it starts at the top of page 8 -- middle of page 8. So reviewing that standard, is that what's used to determine whether Florida Medicaid will cover a prescription drug?

A. Can you direct me more to where you're referring. I read both pages 8 and 9, and I don't think I can speak to the specifics of all this information.

Q. Okay. When reviewing whether to cover a prescription drug, does AHCA look at -- here on page 8 it says AHCA is -- "The program is required to asses data on drug use against predetermined standards consistent with the following compendia." And then it lists three types of compendia and the peer reviewed medical literature. Is that an accurate statement of AHCA policy?

A. I don't know.

Q. Who would know that?

A. I don't know if I can speak for them. But I would ask one of the pharmacists.

Q. Would you ask Ashley Peterson? Or would you ask one of the pharmacists that works under her?

A. I specifically would go to Ashley, as she's my direct report. And then she would research the question for me.

Q. Okay. Would research involve asking one of her pharmacists?

A. I don't know. I can't speak for her process.

Q. So going to page 9, top of the page says, "In order to be reimbursed by Medicaid, a drug must be medically necessary."

Is that the same as the definition contained in the 59G-1.010 that we just reviewed -- Exhibit 3?

A. I don't understand what you mean by the same.

Q. Does medically necessary mean the same as the definition in the definitions policy?

A. I would think so.

Q. Okay. And it is, "Either prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in the Medicaid Act or prior authorized by a qualified clinical specialist approved by that agency."

Is this an accurate recitation of the standard AHCA uses to authorize prescription drug coverage?

A. I don't know.

Q. Would Ashley Peterson know that information -- her or her team?

A. I would think so, yes.

Q. Okay. The next thing it says, "The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows." And then it lists three criteria.

Reading over that statement, are these currently the criteria AHCA uses in authorizing drugs for off label purposes?

A. Again, I don't know.

Q. Would Ashley Peterson know the answer to that question?

A. I would think her team would, yes.

Q. Is this the type of information -- looking at this, is this the type of information that would be contained in a coverage policy adopted in rule?

A. I'm not sure.

Q. Why aren't you sure? What's throwing you about it?

A. I don't know the content of the rules off the top of my head.

Q. But I think my question is a little different. So does this appear to be the type of information that would be contained in a coverage policy adopted into

rule?

A. I can't speak to that. I don't know because of the reason I stated. I will say the coverage policies traditionally do not repeat regulation or requirements or information that are found elsewhere; for example, in Florida statute or in federal regulation. And each coverage policy is structured somewhat similarly, but does contain very different information. So I don't know if this is information that's found off the top of my head in one of our policies.

Q. Okay. I think you -- do all prescription drugs require prior authorization to be reimbursed by Medicaid?

A. I don't know.

Q. Who would know that?

A. I would think Ashley Peterson and her team. Or it might be available on the information on our website regarding pharmacy policy and authorization criteria.

Q. Okay. So Ms. Peterson would be familiar with authorization criteria for prescription drugs?

A. Yes. Or she would know where to look.

Q. Okay. Specifically related to pharmacy coverage policies, how are they developed?

A. The coverage of the pharmacy services is a little different than the other coverage policies. I

don't know all the details that go from the analysts into the developments. But because there is different statutory requirements -- Florida statutory requirements around pharmacy services, including the PNT and DUR board -- the process for overseeing the coverage of pharmacy services is a little different.

Q. In reviewing whether a prescription drug requires a coverage policy -- strike that.

Do you use the GAPMS process to determine pharmacy coverage -- to determine whether coverage of a prescription drug is experimental?

A. I don't know specifically for determining if a prescription drug is experimental. I don't know.

Q. When you develop coverage policies in your bureau, does that include a determination as to whether a service is experimental?

A. So the coverage policies are drafted specific to the covered services that we've been approved to provide.

Q. Okay.

A. By the federal government. So that is the driving factor on how we would initially approach the coverage and organize or draft a coverage policy asserting a service that we are authorized to provide.

Q. So separate and apart from developing coverage

policies, the responsibilities of your bureau also include determining whether a service is experimental; is that correct?

A. So that would be part of the GAPMS process that is outlined in administrative rule.

Q. Okay. Do you use the GAPMS process for prescription drugs?

A. Without researching or consulting others on the team for a specific example, I don't know the interplay between the different authorities and how that works.

Q. Which team is responsible for the GAPMS process?

A. That position is within the Medicaid -- Bureau of Medicaid Policy.

Q. Earlier speaking about teams under the bureau, which teams is responsible for the GAPMS process?

A. Jesse Bottcher is the manager over the position that is primarily responsible for the GAPMS process.

Q. Are there any other teams that are primarily responsible for the GAPMS process? Or is it only Jesse's team?

A. So in terms of listing that as a primary responsibility on a job description, that would be Jesse's team.

Q. Should the people on Jesse's team be aware of

every GAPMS process that's undertaken?

MR. PERKO: I'm going to object to form.

You can answer.

THE WITNESS: So as the bureau chief of Policy, I do try to keep staff within the bureau aware of everything that's happening within the bureau -- especially when a determination has been made. Jesse's team would definitely need to be aware, because there could be potential impacts with a specific service coverage policy. But I do think every circumstance is different. So I can't say just in a general statement to your question.

BY MS. DEBRIERE:

Q. Would it be typical for Jesse's team to not be aware of a GAPMS report being developed?

A. I can't say if it would be typical. I have not overseen very many GAPMS in my time as bureau chief.

Q. So as the bureau chief with Jesse's team being primarily responsible for GAPMS, would you as that chief endeavor to ensure that Jesse's team was aware of all GAPMS reports being written?

A. Yes. We meet the managers on -- my direct reports and I meet regularly at least twice a week for an hour and discuss projects that are going on with each team and provide updates. So the ongoing bureau

activities are regularly discussed with the management team.

Q. Okay. Do you know what a drug compendium is?

A. I recognize the term, but don't think I can define it.

Q. Do you know which compendia are listed in the Federal Medicaid Act?

A. No.

Q. I'm just going to screen share again. I'm showing right now on my screen -- the URL is https://AHCA.myFlorida.com/Medicaid/prescribed_drug/pharm_thera/pdf/PDL.pdf. The title of this document is Preferred Drug List, Effective January 21st, 2023.

Do you know what the preferred drug list is?

A. Yes.

Q. What is it?

A. It's list of drugs developed that the managed care plans must adhere to. And it has to do with rebate negotiations and is recommended by the PMT committee.

Q. Perhaps you just answered this. But who develops the PDL?

A. The agency.

Q. What is the PMT committee's role in it?

A. Per statute, they make recommendations to the agency.

Q. Okay. Does the DUR have any role in developing the PDL?

A. I don't know. I don't believe so.

Q. And this PDL applies to managed care plans; is that correct?

A. And fee for service.

Q. Okay. So on here -- I'm going to have to do Control+F. Pardon; one second.

It's very small. So tell me if you need to make it any bigger.

Okay. On here you will see the drug estradiol -- e-s-t-r-a-d-i-o-l -- listed. And there is many versions here starting at it looks like this line continuing all the way down until we hit norethindrone AC. So the fact that estradiol is lied on the PDL, does that mean Florida Medicaid will cover it if the eligibility criteria are met? Excuse me. Scratch that.

Since estradiol is listed on this PDL, does it mean that Florida Medicare will cover it?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. If any drug is listed on the PDL, does that mean Florida Medicaid will cover it?

A. I don't know the interplay between the PDL and

the other rules and regulations covering pharmacy services.

Q. Okay. Over in this column at the top of page, it reads "Clinical PA required." And it also has a column for a minimum and a maximum age. What does clinical PA required mean?

A. Operationally, I don't know.

Q. Do you know it in any other version?

A. I understand the words. But I don't know in the context of the program or the PA process what that means.

Q. What does "PA" stand for?

A. Prior authorization.

Q. Okay. Is it possible that clinical PA -- so if we scroll down to estradiol -- this version with a minimum of an age of zero, maximum age of 999 -- and it says "no" under the column of clinical PA required, do you know what that means?

A. No.

Q. Who would know that?

A. Ashley Peterson and her team are lead on this.

Q. Do you know what it means to have a minimum age column? Why that's significant or why it's on there?

A. Specific to this document, no.

Q. Same with maximum age?

A. No, I don't know the reason why it's on there.
Q. Since you've been at the agency -- January 2018?
A. Yes.
Q. How many GAPMS processes have you been involved in?
A. Two completed. And maybe one or two discussions.
Q. How many pending?
A. I don't know.
Q. Do you know currently how many GAPMS are pending?
A. Clarify "pending."
Q. Why don't you tell me what you meant by completed.
A. Two that have been signed by agency leadership.
Q. Okay. And how many reports are in the stage of being written and not yet signed?
A. I don't know.
Q. To be clear, though, as bureau chief you meet weekly with Jesse Bottcher and his team who are primarily responsible for GAPMS.
A. I meet weekly with Jesse Bottcher and my team.
Q. Okay.
A. I don't regularly meet with the individual

teams, but with the managers.

Q. When you meet with Jesse, do you discuss GAPMS?

A. Not routinely. We have before.

Q. What are the other responsibilities of Jesse's team?

A. The three managers under Jesse each have units that are responsible for the developments of the service specific coverage policies. His team also oversees the eligibility policy and the provider enrollment policy, updates all the fee schedules -- so works closely with fiscal agent operations to ensure updates are made to the MMIS system and with Medicaid program financing the development of fee schedules. And that's the bulk of their responsibilities.

Q. So when you're meeting with Jesse weekly, what are you discussing about his team?

A. It depends on what -- the highest priority assignments are usually up first; things that are due that week.

Q. Okay. So you do not routinely discuss GAPMS -- that was your testimony just a second ago?

A. Yes. I wouldn't say that it's a subject that we discuss at every meeting or routinely at our individual meetings, no.

Q. And you organize what you discuss based on what

has the highest priority?

A. Yes, typically.

Q. Okay. How familiar with you with the GAPMS process?

A. In terms of all the research and everything that goes into developing, I'm not as familiar. But I am familiar with the routing process, the rule, the authority for that process.

Q. Okay. So just generally, what does AHCA use the GAPMS process for?

A. So if the agency receives a request for coverage -- typically that's how the process would be initiated. If the coverage was determined to not be something that the agency could proceed with -- possibly adding to the fee schedule or incorporating into a service definition -- then the GAPMS process would be used.

Q. Okay. How is the GAPMS process initiated?

A. I believe it's a rule how to.

Q. Would it be helpful if you had the rule in front of you?

A. Yes.

MS. DEBRIERE: Okay. Let's mark that as Exhibit 5. That's Rule 59G-1.035.

(Plaintiff's Exhibit No. 5 was marked for

identification.)
BY MS. DEBRIERE:
Q. So how is GAPMS initiated?
A. A request is submitted to the health services research inbox in the Medicaid Policy Bureau.
Q. Who can submit a request to that inbox?
MR. PERKO: Object to form.
THE WITNESS: I believe anyone can.
BY MS. DEBRIERE:
Q. Okay. Is that the only way that a request is submitted for AHCA to undertake a GAPMS?
A. No.
Q. What are other ways?
A. So in the contracts with the plans, there's also language on how a managed care plan can submit a request to the agency for review -- not necessarily through the health services inbox. I can't recall the exact direction. But there's also the opportunity for the clients to request a review.
Q. When that review is requested, is it -- is the standard process used? Is the standard GAPMS process used?
A. I'm not sure. I believe it may be expedited. But I'm not sure to the specifics of the process.
Q. Who would be most familiar with that process?

A. Either Jesse Bottcher or Jeffrey English.

Q. Okay. So you mentioned managed care plans can submit a request -- or anyone can submit a request through the health services inbox. Are there any other ways that a request can be submitted to the agency to undertake a GAPMS?

A. Yes.

Q. And what are those ways?

A. I don't know all the ways. But I can't think of us not approaching the process if we received a request outside of getting it specifically through the health services research inbox.

Q. How often --

A. Which is -- I'm hesitating because I couldn't see us not -- like, refusing to complete the process if it was received another way.

Q. How often does that happen?

A. So, like I said before, in my time as bureau chief, there haven't very many finalized GAPMS. Or that process has not been a part of my day-to-day work. So I'm not sure.

Q. Okay. So you cannot recall another way that a GAPMS request came to the agency, other than through a managed care plan or the health services inbox?

A. So for the most recent GAPMS report, that was a

request from -- I believe it was the secretary. But I don't know if it went through the inbox specifically or not.

Q. Okay. So that's another way that the GAPMS process can be requested -- is through the secretary?

A. That's the way that it has been.

Q. Okay. How many times?

A. I don't know.

Q. And when you say the most recent GAPMS report, do you mean the GAPMS report related to gender dysphoria?

A. Yes.

Q. When that request came in through the secretary, did the secretary identify why she was making that request?

And, I'm sorry, do you mean Secretary Marstiller?

A. Yes.

Q. Okay. Did she identify why she was making that request?

A. I can't recall the contents of the specific request.

Q. Did the request come -- who did the request from Marstiller go to?

A. I don't know.

Q. How did you find out about it?
A. I just can't remember if I was sent the letter in an email. But it was then discussed by my manager.
Q. And that manager was? Is?
A. At the time was Jason Weida, who is the assistant deputy secretary.
Q. And did you receive the letter from Secretary Marstiller before that discussion occurred?
A. Yes.
Q. And how long between receiving the letter and having -- how long past between receiving that letter and having that conversation with Mr. Weida?
A. I don't remember.
Q. Was it, like, hours? A day? Several days? Within the same week?
A. I don't remember.
Q. Okay. Was that discussion just between you and Mr. Weida? Or were there other people?
A. I don't remember in the initial conversation if there was anybody with me.
Q. Okay. Was it -- where did it take place?
A. I believe it was in Jason's office.
Q. Okay. Did Jason ask you to come to his office to have the conversation? How were you notified of the meeting?

A. I don't remember. We had standing meetings in his office; he was my -- or I was his direct report. So I don't remember if it was part of that when we were talking about assignments and priorities or separate. I can't remember.

Q. What was Mr. Weida's position at the time at the agency?

A. He was the assistant deputy secretary for Medicaid policy and quality.

Q. And then who is in that position prior to him?

A. I think Shevaun Harris.

Q. Okay.

A. There was a gap in between. But I think she was the last person.

Q. Okay. And who took that position after Mr. Weida?

A. That position is currently vacant.

Q. Okay. And has Brian Meyer ever held that position?

A. No.

Q. Okay. Prior to your meeting with Mr. Weida but after your received the request from Secretary Marstiller, did you communicate with anybody else about the request?

A. Can you repeat the question.

Q. Between the time that you received the request from Secretary Marstiller -- the letter -- and meeting with Mr. Weida, did you have a conversation with anyone else about the request?

A. I don't believe so.

Q. Okay. Were you surprised to see the request?

A. No.

Q. Why not?

A. Medicaid Policy -- I think we're unique in that bureau because no one day is exactly the same. There's always something new coming out from the federal government, from legislative action, from leadership. So I think that's kind of part of the job of being the bureau chief of Medicaid policy.

Q. Okay. What was -- when you met with Mr. Weida, did you develop a plan about how to honor the Secretary's request?

A. Yes.

Q. And what was that plan?

A. The team that was going to work on it was the Canadian Prescription Drug Importation Plan team; following the regular GAPMS process in terms of research and report and development.

Q. Did you identify who was going to be on that team?

A. Yes.
Q. And who did you identify?
A. Matt Brackett, Nai Chen, and D.D. Pickle.
Q. As part of that plan -- and to be clear, the secretary's request was specifically a request to undertake a GAPMS investigation?
A. Yes; to review through that process.
Q. Okay. And the team identified was Brackett, Chen -- and I forgot the --
A. Their manager, D.D. Pickle.
Q. D.D. Pickle. Thank you.
So you previously testified that the team primarily responsible for GAPMS was led by Jesse Bottcher. Why was Jesse Bottcher not part of the team to undertake this GAPMS?
A. So there was several factors considered. Matt Brackett has worked with the bureau a long time and previously had the position responsible for -- primarily responsible for the GAPMS. D.D. Pickle has also been with the bureau and agency a very long time. So I would say that the historical knowledge, the bandwidth -- having bandwidth to focus on completing the GAPMS -- were probably the two biggest factors.
Q. When you say bandwidth, what do you mean?
A. So that team -- their primary responsibility is

the Canadian Prescription Drug Importation Program, which is not approved federally. So our ability to move forward with the day-to-day operations and implementation of that program is stalled. Due to that, that team has been available to assist in other areas within the bureau when needed.

Q. Was the team that's primarily responsible for GAPMS -- were they overwhelmed with doing GAPMS at the time?

A. I don't know.

Q. But you used the fact that Mr. Brackett and D.D.'s team generally would have a lot of time to work on GAPMS as a deciding factor to pick the team for this report; is that right?

A. Yes.

Q. But you didn't first check whether the team that's primarily responsible for GAPMS would have the time to do the report?

A. No.

Q. Okay. How long has Mr. Chen been with the agency?

A. I don't remember.

Q. Would you classify him -- as you did Ms. Pickle and Mr. Brackett -- as being with the agency for a long time?

A. No.
Q. So he did not have that historical knowledge that Mr. Brackett and Ms. Pickle have with the agency?
A. No.
Q. And that was a deciding factor in picking the team?
A. Yes.
Q. When you met with Mr. Weida to pick this team, did Mr. Weida suggest the names or did you?
A. I believe I did.
Q. Okay. Other than the length of time at the agency and bandwidth, what criteria -- did Mr. Weida give you any criteria in terms of picking the team?
A. I don't think so, no.
Q. Did you use any other factors other than the length of time at the agency and bandwidth to select this team?
A. I think it's still the same as historical knowledge. But I have worked very closely with D.D. and Matt in my various positions. I knew Matt had some knowledge of previous similar requests, as well extensive knowledge of the standard GAPMS process. And it was a team of three that was available. So I think that still kind of historical knowledge and bandwidth were really the biggest factors.

Q. You said Mr. Brackett had experience with previous similar requests. What were those previous similar requests?

A. I believe there was a GAPMS request in the past before my time with the agency that had to do with hormone treatment.

Q. Would it be -- and it was hormone treatment. When you say a similar request, was it for GAPMS?

A. Yes.

Q. Would it have been the cross-sex hormone therapy GAPMS that is Exhibit 4?

A. No.

Q. How do you know?

A. The date on this. The one I was thinking of was much earlier before my time.

Q. Before your time -- do you have any sense of when that might be?

A. Maybe 2016 or 2017.

Q. Do you know who the Governor of Florida was in 2016 or 2017? I'm sorry. It's not a test, I promise.

Was it Rick Scott?

A. Yes.

Q. Okay. And was the interim secretary at the time at AHCA, was it Justin Senior?

A. Yes.

Q. And was Beth Kidder there at that time at AHCA?
A. Yes.
Q. And all of those people are listed on this Exhibit 4 --
A. So my document has Beth Kidder crossed out and looks to be a draft document from May 20th, 2022.
Q. Is there a name that replaced Beth Kidder on that?
A. Ashley Peterson.
Q. Okay. Do you know when Ashley Peterson joined AHCA?
A. I believe it was 2021.
Q. Okay. And is it --
MR. PERKO: Counsel, it's 1:30. Are we going to stop for lunch?
MS. DEBRIERE: We can if you want to.
MR. PERKO: Do you want to? It's up to you.
THE WITNESS: At some point.
MS. DEBRIERE: That's fine. Can I just finish up here real quick.
BY MS. DEBRIERE:
Q. So is it possible that this document was created in 2017?
A. I'm looking at a document that has track changes that appear to be since then. But I don't know.

Q. Why do those track changes appear to be since then?

A. Since the date was updated to May 20th, 2022.

Q. Okay. There's some editing in the column. It's very faint. Can you see it?

A. Yes.

Q. And the initials of editor appear to be GS.

A. Yes.

Q. Do you have any idea who that would be?

A. No.

Q. Do you know anybody here with the initials GS?

A. I'm sure somebody here has those initials, but I don't know off the top of my head.

Q. So Mr. Brackett was involved with a GAPMS related to cross-sex hormone therapy, but it wasn't necessarily this one; is that right?

A. I don't know the level of his involvement, but I know that he had some knowledge or knew about it.

Q. Okay. Did he do any other GAPMS related to the treatment of gender dysphoria?

A. I don't know.

Q. Mr. Chen -- did he have any previous experience with GAPMS?

A. I don't know.

Q. Ms. Pickle -- has she had any previous

experience with GAPMS?

A. I don't know.

Q. And you've explained why Mr. Brackett, Ms. Pickle, and Mr. Chen were selected for the team. Why was Mr. Bottcher not selected?

A. I can't recall all the details of the decision. But Jesse Bottcher's team is one of the busiest in the bureau, and has a lot of time sensitive work that they are constantly working on. So I think that had something to do with it, since he is the manager of an entire section.

Q. I think you had previously testified there weren't a lot of GAPMS pending at the time this request come through; is that right?

A. I didn't know the bandwidth or the workload.

Q. Okay. You didn't know the bandwidth. So you didn't know if, for example, Mr. English had the bandwidth to handle the GAPMS report?

A. No.

Q. Do you want to take a break?

A. Yes.

(Brief recess.)

BY MS. DEBRIERE:

Q. Previously before break we were talking about the selection of Mr. Brackett to be on the GAPMS report

team for gender dysphoria. And you mentioned that he had drafted previous similar GAPMS in the past. And I believe you used the example of cross-sex hormones.

Were there any other similar requests that he drafted related to gender dysphoria in the past?

MR. PERKO: Object to form.

THE WITNESS: Just to clarify, I'm not sure if he drafted it.

MS. DEBRIERE: I'm sorry; yes.

THE WITNESS: I know he had some historical knowledge of previous GAPMS.

MS. DEBRIERE: Okay.

THE WITNESS: So can you repeat your question.

BY MS. DEBRIERE:

Q. Did he have hysterical knowledge of previous GAPMS related to gender dysphoria?

A. Outside of the one that I referred to earlier?

Q. No, including that one.

A. Yes, I believe he had some historical knowledge of previous GAPMS.

Q. Other than the one you referenced earlier, are you aware of any other GAPMS that he was involved in related to gender dysphoria?

A. I don't know the extent of all the GAPMS he was involved in.

Q. Also earlier when you were discussing your responsibilities under GAPMS, you mentioned routing.

A. Yes.

Q. Can you describe that a little bit.

A. As the bureau chief of Bureau of Medicaid Policy, any official documents that leave the bureau are usually reviewed by me. And so routing process is the hierarchy of reviewers through wherever the final reviewer or signatory or approver. That's what I was referring to by routing process.

Q. Okay. Does every GAPMS report have a routing process?

A. Yes.

MS. DEBRIERE: Okay. Can I have the 2016 GAPMS routing form. And we'll mark it as Exhibit 6.

MS. DUNN: I can tell from this exhibit that when we printed these the Bates numbering got cut off. So I will look it up and read --

MS. DEBRIERE: That's a bummer.

MS. DUNN: I know.

(Plaintiff's Exhibit No. 6 was marked for identification.)

BY MS. DEBRIERE:

Q. Okay. So do you recognize this document?

A. Not this specific document. But this appears

to be a policy routing and tracking form.

Q. And is that form the same as the form you currently use to track -- to route and track?

A. Sometimes.

Q. What other forms do you use?

A. Prior to the pandemic, we used this form primarily. Since returning to the office there have been different variations of routing and tracking forms developed for different teams or documents -- types of documents.

Q. Do you use the same routing and tracking form for GAPMS?

A. So I've only approved two GAPMS in my time. And I can't remember if this was the -- this format was what was used to route it to me.

Q. Okay. But there was a form used to route it to you when you approved -- when you approved your two GAPMS?

A. I believe so.

Q. Okay. And on this GAPMS form, it says prepared by Monique Johnson. What does it mean to be prepared by? Was the form prepared by Ms. Johnson? Or was the GAPMS report prepared by Ms. Johnson?

A. I don't know.

MS. DEBRIERE: Okay. Could I see the 2022

GAPMS. This will be Exhibit 7.

(Plaintiff's Exhibit No. 7 was marked for identification.)

BY MS. DEBRIERE:

Q. So I'm handing you -- and Gary will want to take a look at it too -- again, the first page of the document is entitled "Medicaid Policy Routing and Tracking Form." If you go through the entire document, it should also include the June 20, 2022, GAPMS report on treatment of gender dysphoria.

MR. PERKO: I believe it was June 2nd.

MS. DEBRIERE: June 2nd. Excuse me.

BY MS. DEBRIERE:

Q. So looking at the document -- the first page, is this the Medicaid Policy Routing and Tracking Form that was associated with the GAPMS report on the treatment of gender dysphoria?

A. Yes.

Q. How do you know?

A. These are my initials.

Q. Okay. So you've seen this before?

A. Yes.

Q. I do want to point out "prepared by" here. What does that mean?

A. That Matt Brackett prepared the routing

package.

Q. Okay. Did he also prepare the GAPMS report itself?

A. Yes.

Q. Do you know if the person who prepares the routing and tracking form -- if they are the person who also prepares the GAPMS report?

A. Can you repeat the question.

Q. The person who prepares the Medicaid Policy Routing and Tracking Form, do they also prepare the GAPMS report itself?

A. I don't know how all the team members are instructed to fill out the report or -- I'm sorry -- fill out the tracking form.

Q. Is there any other way to determine who has prepared a GAPMS report?

A. I don't know. But speaking in general assignments -- these forms are used for other assignments. And there are a lot of assignments that are done collaboratively. So, yeah. I don't know specifically how else you would know just looking at documentation.

Q. Would that information be contained on an AHCA shared drive?

A. It's possible.

Q. Okay. Is there a reason the GAPMS report doesn't identify an author on the report?

A. I don't know.

Q. Okay. A couple other things. On the section line here, it says Canadian Prescription Drug Importation Program. But we have established this was the routing and tracking form for the GAPMS report related to the treatment of gender dysphoria. Are those two things related?

A. So the Canadian Prescription Drug Importation Program is the section of who developed the report. And it lets us know how the hierarchy of the routing should go through the management levels within the bureau and outside.

Q. So it was the Canadian Prescription Drug Importation unit who prepared the GAPMS report on the treatment for gender dysphoria?

A. So that's what I would interpret this section -- why it's listed there next to this section. It's the section responsible for routing and lets us know the hierarchy of the management.

Q. Okay. And then just looking down at the "Reviewed by and Routing Timelines," the start date is June 1st, 2022, for everybody except Mr. Wallace; who has a date of June 2nd, 2022. And the end date is June

1st, 2022, except for Mr. Wallace. Does that indicate that you Mr. Weida and Ms. Pickle all reviewed the report and signed off on it on the same day?

A. That the official routing and the signature occurred on the same day, yes.

Q. What do you mean by official routing?

A. So the date that this form and the final routing package was ready for signature.

Q. And what was continued in the final routing package?

A. I believe it was just the report.

Q. Okay. So the final report -- what was being tracked through this routing and tracking form?

A. Yes.

Q. Were there any attachments to the final report that were also reviewed?

A. The expert witness reports were also reviewed. But I can't remember if they were included in this routing package at the same time.

Q. Who reviewed those final expert reports?

A. I don't remember.

Q. Did you review them?

A. I don't remember if I reviewed them all. But I had seen them -- at least some of them. I can't remember if I reviewed them all formally.

Q. Okay. Turning just back to the general GAPMS process. Is the GAPMS process ever initiated to assess existing coverage of Medicaid services?

A. Can you repeat the question.

Q. Is the GAPMS process ever used to assess existing coverage of Medicaid services?

A. I don't know specifically.

Q. Okay. Who would know that?

A. Are you asking if it ever has or ever would?

Q. Ever would.

Would Ms. Pickle know that?

A. So my personal experience with the GAPMS process is somewhat limited. But it is such a unique process. I feel it's hard to answer that without each situation or each request that we would get would be unique, because that process is dealing with questions that fall outside of something that's easily answered policy question.

MS. DEBRIERE: Have we entered the GAPMS rule into evidence yet? Can we do that now. And that's to be 59G-1.0 -- I thought we had. Oh, it's 5. Okay. Sorry. That's my fault.

MR. PERKO: That's fine.

BY MS. DEBRIERE:

Q. So a couple questions about the language of the

rule. First under (1)(b), "health services" is defined as diagnostic tests, therapeutic procedures, or medical devices or technologies.

Under what category would prescription drugs fall in this definition?

A. I don't know.

Q. You are familiar with the GAPMS rule, though; correct?

A. Yes. I've read the GAPMS rule.

Q. Would prescription drugs fall under any of these categories?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I wasn't part of the original drafting of this rule text. So in order to interpret the policy, I would need to do research.

BY MS. DEBRIERE:

Q. Who would you ask?

A. I would probably start with Ashley Peterson.

Q. Okay. And going down to 3, the second sentence -- "The public may request that a health service be considered for coverage under the Florida Medicaid program by submitting a request."

What does this sentence mean to you?

A. There's much room for interpretation. It says

the public may request a public health service be considered for coverage.

Q. Does this sentence mean that the public may request that Florida Medicaid consider whether to exclude a service previously covered?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I think it could. Not only do we update the coverage policies to include new services, but we do change the scope of a service as part of that process. So if there was a question that was not clear within the scope of the service, I can see how that might apply.

Or the example that you used earlier with a service that's only provided to under 21. If that service was -- if we received a request to make that service available for over 21. So I can think of examples where it wouldn't have to be a new service.

BY MS. DEBRIERE:

Q. Does this rule cover a public's request to take a service away?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know?

A. Public -- that would be a legal interpretation

or policy interpretation that would need consultation with the agency for me to answer.

Q. As the bureau chief of Medicaid Policy, you're responsible for developing coverage policies; correct?

A. I oversee the teams that develop coverage policies, yes.

Q. And you are responsible for overseeing the teams that develop administrative rules to implement those coverage policies; correct?

A. Yes.

Q. So you would be responsible for understanding how rules that implement coverage policies should be interpreted.

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Is it your responsibility to understand the content of this rule?

A. Yes.

Q. Okay. But you can't tell me how to interpret that second sentence in Subpart 3?

A. So if we received a request and I wasn't clear on the authority, there's several steps I would take to confirm that the agency's position is we have authority -- which would be to review any other applicable laws or regulations; would be to consult with

my team and with agency management and perhaps with legal if I was not sure whether a specific question or scenario that was received. We may not have the authority to take an action.

Q. So when reading the second sentence in Subpart 3 -- "The public may request a health service be considered for coverage" -- in order to understand what that sentence means, would you undertake any of the steps you just described?

A. It would depend on the exact question. If I wasn't clear with what the request was and how that authority applied, then I would take further steps to make sure that I understood how the rule applied to the request.

Q. Did you do that for -- okay. Okay. Let me make a note.

In the legal consultation part, it trigged me to remember just a housekeeping question. At lunch did you speak with your attorneys --

A. No.

Q. -- about the deposition?

A. No.

Q. Okay. Does the GAPMS process typically look at an individual service when you're undertaking analysis?

A. I don't know.

MS. DEBRIERE: Okay. Can I have either the Van Mol or Van Meter ATF. It doesn't matter. And we'll mark that as Exhibit 8.

(Plaintiff's Exhibit No. 8 was marked for identification.)

BY MS. DEBRIERE:

Q. So at the top of the page you have a -- did you approve this document?

A. Yes.

Q. Okay. So under "Reason for Occurrence," it says, "On April 20th, 2022, the Bureau of Medicaid Policy received a request for a time-sensitive analysis of service coverage. While such requests are typically for a single service or good --" Is that a correct statement?

A. I don't know.

Q. But you wrote this?

A. No. I signed this.

Q. Okay. Were you the one making the request?

A. No.

Q. Who was making the request?

A. Devona Pickle.

Q. Okay. Before you sign something, do you have to agree with the language contained therein?

A. Yes.

Q. So at the time you signed this, you agreed with the statement that such requests are typically for a single service or good?

A. Yes.

Q. Okay. But now you don't know if GAPMS are typically used for a single service or good?

A. My experience with GAPMS is limited. And I trust the expertise of my staff. And one of the reasons I asked or had recommended that this team be responsible was because of their historic knowledge of the GAPMS process.

Q. And when you say that, that includes D.D. Pickle; correct? You trust her expertise on the GAPMS process?

A. Yes.

Q. Okay. Are you aware of a standard operating procedure used for the GAPMS process?

A. I've heard mention of it. But I don't believe I've ever seen it.

Q. Who did you hear mention of it from?

A. I can't remember. Either Matt or Jesse.

MS. DEBRIERE: Okay. Can I have what we'll mark as Exhibit 9, which is the GAPMS Decision Tree Checklist.

(Plaintiff's Exhibit No. 9 was marked for

identification.)

BY MS. DEBRIERE:

Q. Do you recognize this document, Ms. Dalton?

A. I believe I've seen this before.

Q. Do you know what it's used for?

A. I believe this was developed to determine if a request just goes through the coverage determination process or should be handled as a GAPMS.

Q. Okay. And tell me the difference between a coverage determination and something that needs to go through the GAPMS.

A. I don't know everything that goes into how that decision is concluded. But in general, a coverage determination is when it's very clear that the agency has the authority to add a service and that it meets all of the agency's rules and -- for example, an optional state plan service that the agency currently doesn't cover but is clearly allowed through federal CMS would be a coverage determination. Where the GAPMS process is driven by the rule you referenced earlier that describes when it's not clearly meeting all the requirements and laid out in the current coverage policies.

Q. So much earlier in the deposition you gave an example of a coverage determination of a medical supply for -- was it Amino Foods?

A. Puro Meno.

Q. Puro Meno Foods. Why didn't you use the GAPMS process for that? Did you use the GAPMS process for that?

A. No.

Q. Why not?

A. Because the agency already covered similar products.

Q. Okay. Was that the only factor in determining whether to assess it using GAPMS?

A. I don't remember the conversations with the team when I was briefed on the recommendation.

Q. Was a GAPMS Decision Tree Checklist done for Puro Meno Foods?

A. I don't believe so. I never saw one, no.

Q. Okay. Who undertakes the process to fill out the decision tree?

A. I don't know.

MS. DEBRIERE: I apologize. Can we take just a two-minute break.

MR. PERKO: Sure.

(Brief recess.)

BY MS. DEBRIERE:

Q. Do you know how to interpret the answers on a decision tree checklist?

A. No, I don't believe I've ever seen one filled out.

Q. Okay. There's a space here that says "GAPMS Topic." What would go in that space? Do you know?

A. I don't know.

Q. Would a decision tree checklist be generated for every GAPMS request that comes in?

A. I don't know.

Q. Who would know that?

A. I don't know. I don't know if this is still the internal process. I don't know.

Q. Who would know whether it was still the internal process?

A. Jesse Bottcher.

Q. Okay. Would the members of Jesse Bottcher's team also know?

A. No, I don't think anyone currently on his team would know.

Q. How about anybody previously on his team -- I'm sorry; back up.

So no one on Jesse Bottcher's team is in charge of the GAPMS process?

A. The GAPMS position is currently vacant.

Q. Would anybody who was in charge of the GAPMS process at some point know whether the decision tree

checklist is used in the GAPMS process?
A. I don't know.
Q. And there's only one position that would know that, and that is currently vacant; correct?
A. I believe so, yes.
Q. And what is that position called?
A. I believe it's a Government Analyst II.
Q. And so there's just that one position in charge of knowing the GAPMS process?
A. As far as I know, yes.
Q. Okay. We touched on this a bit earlier. Does AHCA use the GAPMS process for prescription drugs?
A. I don't know.
Q. When you were giving an example of similar requests that Mr. Brackett handled for GAPMS, the example you gave was cross hormone therapy; correct?
MR. PERKO: Object to form.
THE WITNESS: I believe that was the example I gave.
BY MS. DEBRIERE:
Q. And what is cross-sex hormone? What is a hormone?
A. I don't think I can recite the clinical definition.
Q. Is the hormone a prescribed drug?

A. I believe so.
Q. So then you're aware of one instance in which GAPMS was used for determining -- for assessing a prescription drug?
A. Yes.
Q. But you don't know generally if GAPMS is used to assess prescription drugs?
A. My knowledge of GAPMS is limited. So to speak in generalities -- but I do see where in 2016 there was the GAPMS on hormone suppression.
Q. Okay. Is GAPMS the only method AHCA relies on to determine whether a Medicaid service is experimental?
A. I don't know. I know we have a clinical trials coverage policy. So there may be circumstances where it's clear that coverage would be -- that coverage policy or the clinical trials rule would apply. And I don't know all the details of how the QIO vendors -- what that process, all that entails.
Q. Whether the QIO venders would determine whether something is experimental?
A. Or if it was clear the clinical trial policy would apply instead. So I don't know to the extent of if there could possibly be.
Q. What is the clinical trials policy?
A. It's a rule that outlines the agency's coverage

for recipients participating in a clinical trial.

Q. And what does that type of authorization entail?

A. I don't know the specifics.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should be excluded?

A. Can you repeat the question.

Q. Is GAPMS the only method that AHCA relies on to determine whether a Medicaid service is experimental and therefore should not be covered?

A. I don't know the specifics. But if, for example, a pharmaceutical is not FDA approved, there would be perhaps, like, a different process where it wouldn't have to go through the process.

Q. What is the significance of a drug being FDA approved for the purposes of coverage?

A. I don't know the details.

Q. What do you know about it?

A. I believe there's federal requirements on if a drug is not FDA approved -- there is certain coverage requirements.

Q. Do you know if that relates to the compendia we were earlier talking about?

A. I don't know.

Q. Okay. If AHCA is determining whether a production drug is experimental, does AHCA consider whether the drug is FDA approved?

A. I believe so.

Q. If a particular use for a drug has been FDA approved, can AHCA deem the drug experimental for that use?

A. Can you repeat the question.

Q. If a particular use for a drug has been FDA approved, can AHCA deem that drug experimental for that use?

MR. PERKO: I'm going to object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. But FDA approval bears on a determination as to whether AHCA will cover a drug; is that correct?

A. Yes, I think it's considered.

Q. If it's not -- if a drug is not FDA approved, are there circumstances under which AHCA will still cover the drug?

A. I don't know. But I think there is federal regulations around what's allowable.

Q. In the Federal Medicaid Act?

A. I believe.

Q. You mentioned just a second ago, a clinical

trials coverage policy. Where does that policy live?

A. In Rule Class 59G on our website.

Q. If it's not there where would we find it?

A. In the Florida Administrative Code.

Q. It should be in Chapter 59G?

A. But it should be on our website.

Q. Okay. And it is adopted as a rule?

A. Yes.

Q. Okay. Once AHCA reaches a decision through the GAPMS process, describe the implementation of that decision.

A. So, again, in my experience -- I've only been bureau chief for two finalized decisions that were different. And I can't remember all the steps to implementation. But once a determination of any coverage is made, then there's a process of how to notify the public. There's a process for notifying the plans of changes if it affects the plans. There's a process of making sure that the -- any other associated rules that may be impacted are updated.

Q. Anything else?

A. If a training is needed, it depends on what it is. But there could be other.

Q. Who would you train?

A. So, again, just speaking generally -- the

managed care plans; the public; if it's fee for service, the providers; especially if it has to do with submitted claims.

Q. What are the two final reports that you have overseen as bureau chief?

A. So it was the GAPMS that we're discussing today.

Q. And, again, that's the one that relates to treatment of gender dysphoria?

A. Yes. And then the -- I can't remember the exact name of the other GAPMS. But it was through a managed care plan request.

Q. Was it an expedited GAPMS?

A. I don't believe so.

Q. Do you remember what the service was at issue?

A. I do not.

Q. Okay. And the process for an expedited GAPMS, that's different from the traditional GAPMS process?

A. I'm not sure of the differences outside of the timeframe.

Q. Is it different as to how you would inform the public about it?

A. I don't know. I can't recall what steps we took after notifying the plans of the final decision.

Q. Okay. Through the traditional GAPMS process --

do you have any GAPMS right now that are in the final stages?

A. No.

Q. Okay. And you don't know how many requests are currently pending?

A. I don't know.

Q. So the last GAPMS that was finalized was in June of 2022?

A. Yes.

Q. Okay. And now we're in February of 2023. And there's no GAPMS that are ready for finalization at this point?

A. I don't know what stages of development they are.

Q. Okay. Is there anything on your desk to review?

A. I don't know. I don't remember if I have anything pending.

Q. Okay. When you were meeting with Mr. Weida about the June 2022 GAPMS report related to the treatment for gender dysphoria, that report had not been drafted; correct?

A. Sorry. Can you repeat that.

Q. Yeah. Absolutely. So earlier you spoke to meeting with Mr. Weida once you received the request

from the secretary to undertake the GAPMS for treatment of gender dysphoria; do you remember?

A. Yes.

Q. During that meeting had the GAPMS report been drafted yet? I know it seems like a silly question. But I'm asking at face value.

At the time you met with Mr. Weida, had the GAPMS report been drafted yet?

A. The GAPMS report I was discussing with him? No.

Q. Okay. But you have a good memory of that report before it was even drafted; is that right? You were able to recount details to me about discussing that report about before it had been drafted; is that right?

A. Throughout the process there had been discussions. But I don't know if I remember all the details.

Q. What I'm wondering is just why that report sticks out in your mind, but now you can't recount any other GAPMS reports that are pending. Is there a reason for that?

A. I have a lot of documentS in my queue at any one time. And it's really on the onus of the analyst -- part of their job responsibilities -- to make sure assignments are completed and finalized and routed and

closed. So because there was discussion and updates on the status and progress of the report -- and it was not that long ago -- I remember having conversations about the report.

Q. There are GAPMS reports pending right now, though; right?

A. I don't know. I don't know what the GAPMS queue is right now.

Q. Okay. So you don't know if there's anything in the queue right now?

A. Correct.

Q. But you do remember details about the GAPMS report related to treatment of gender dysphoria?

A. Details on the process?

Q. Yeah.

A. Yes.

Q. Okay. When I say "rulemaking process," do you understand what I'm referring to?

A. Yes.

Q. And do your current responsibilities at AHCA include the rulemaking process?

A. Yes.

Q. Can you describe those responsibilities.

A. I review drafts of the coverage policy and the documents that go along with the rule promulgation

process. I sometimes participate in the public meetings and review provider alerts or other notices associated with the process.

Q. Anything else?

A. Not that I can think of.

Q. Okay. Do you ever review public comment associated with the rule?

A. It depends.

Q. So you have before?

A. More in my old role as the AHCA administrator.

Q. Okay. Can you remind me the dates you were in that role.

A. August 2018 to August 2021.

Q. And in your previous roles at AHCA as well as DOEA, you had rulemaking responsibilities; is that right?

A. DOEA was more of the drafting of the policy and not the promulgation process.

Q. Okay.

A. And then AHCA has been more on the promulgation process -- administrative process.

Q. So you'd say you had experience with Florida agency rulemaking?

A. Yes.

Q. When I say "rule workshop," do you understand

what I'm referring to?

A. Yes.

Q. When I say "rule hearing," do you understand what I'm referring to?

A. Yes.

Q. What is the difference?

A. Chapter 120 has different public meetings outlined in different stages of the process. The workshop as we use it here is primarily for the rule development stage of the administrative process. And the hearing occurs at the proposed rule stage.

Q. Okay. When you say the development of the rule, does that mean generally the rule language itself has not yet been drafted or proposed?

A. It depends.

Q. Okay. So is there a difference between workshop and hearing?

A. They're both public meetings meant to garner input from the public and make the public aware of the changes. But per Chapter 120, there are differences because of the different stages of the process.

Q. Okay. Why was there no public workshop held for the rule development of the change to Rule 1.050 excluding the treatment for gender dysphoria?

A. I don't know.

Q. Were you here were when that happened?
You were?
A. Yes.
Q. Okay. While here, have you had public comment on rule workshops for other rules?
A. Can you repeat the question.
Q. Since you've been here at AHCA, have you -- let me ask this question: When the rule was developed to exclude treatment of gender dysphoria per 1.050, were the you bureau chief for Medicaid Policy?
A. When the rule was promulgated?
Q. Well, when you were having the -- when you noticed the proposed rule and had the rule hearing.
A. For this specific rule?
Q. Yes.
A. Yes.
Q. Okay. In your role as bureau chief, have you ever -- in your role as bureau chief, have you been involved in rule workshops for other rules?
A. Yes.
Q. So why weren't you involved in the rule workshop for the exclusion of treatment for gender dysphoria; do you know?
A. I can't remember. I believe I was out of town.
Q. Okay. If you weren't out of town, would you

have been involved in it?

A. I don't remember the discussion around that. But I'm not always involved in the workshops or rules.

Q. How is that determined?

A. It depends on the circumstances and the content of the rule. But I can't remember the specific conversation when that was determined.

Q. Was there a public workshop for the exclusion of the treatment for gender dysphoria? There was only a public hearing; correct?

A. I know there was only one public meeting. I can't remember.

Q. Generally what's the process for planning a rule hearing?

A. We determine a date, a location, and who will be in attendance. And the date and location is included in the notice.

Q. And when you say who will be in attendance, who does that mean?

A. Who the subject matter experts or other agency staff will conduct the public meeting.

Q. Okay. And what do you mean by subject matter expert?

A. So I think I described it a little before how for most of the coverage areas there is a specific

analyst responsible for the development of that policy. So, for example, if there was a change to respiratory services, whoever that suggest matter expert or analyst is would typically be present at the workshop since they have the in-depth knowledge on the changes being proposed.

Q. Is that person always a person employed by the agency?

A. The subject matter expert for all our coverage policies are individuals employed with the agency.

Q. Okay. Are there any written protocols regarding the planning of a rule hearing?

A. I know we've developed process maps and procedures. But I don't know the details of planning a hearing specifically and how detailed those documents are on that process.

Q. What's a process map? What does that entail or detail?

A. There's a graphic that was created before my time that -- it's a real nice layout of the administrative rulemaking process.

Q. Okay.

A. And so it has -- it's a graphic, and it's one page. So it's easy to put on your wall.

Q. And your responsibilities include sometimes

attending rule hearings?

A. Yes.

Q. Since you've been the bureau chief, how many rule hearings have you attended?

A. I don't think I've attended any hearings.

Q. As a State agency employee -- either at DOEA or AHCA -- how many rule hearings have you attended?

A. So at DOEA I attended several AHCA rule hearings in the audience. In my previous position with the agency, I think it was only a handful.

Q. Does that mean five?

A. Yes; I'd say five or less.

Q. Okay. Who else from AHCA attends rule hearings? Let me ask this: Are there AHCA staff who attend rule hearings as part of their job description -- they have to be at every rule hearing?

A. I don't know if that's actually in the job descriptions. But Cole and his team -- since they set up the workshop or hearing or the public meeting -- their responsibilities include making sure they have the speaker list, making sure that everybody is escorted into the building, that the speakers can be heard. So they're in attendance for all of the public meetings.

Q. Okay. And do you know if they have any protocol off which they operate -- written protocol for

conducting the hearing?

A. I believe there's an internal process and process map. But I don't know the details off the top of my head what's included in that document.

Q. Is it the rules unit that is in possession of that document?

A. I would think so, yes.

Q. Okay. In your experience, aside from the agency who attends the hearing?

A. From the public?

Q. I mean, I think that would be the only other option; right?

What types of people from the public?

MR. PERKO: Object to form.

THE WITNESS: That would really depend on what the change is and who is impacted.

BY MS. DEBRIERE:

Q. In your experience attending public hearings -- rule hearings -- are there typically more than 25 people from the public that show up at the rule hearing?

A. I would say yes. Especially since the hearings are now -- have a virtual option. The majority of them are virtual and in person.

Q. Are there typically more than 25 people who show up in person?

A. So I haven't participated in all of them. In the last few that I participated in, there was not 25.

Q. In the last one you participated in how many were there?

A. Less than ten.

Q. Does AHCA ever invite specific persons from the public to attend the rule hearings?

A. Yes.

Q. And how do they do that invite?

A. A provider alert is sent out to the providers. Usually that goes along with the FAR notice that was posted and the public was noticed. If it's a sister agency, it might be by email. So if we believe a rule might impact a sister agency, we might reach out specifically.

Q. So other than posting the public notice and the FAR provider alerts and emails to potentially impacted sister agencies, is there any other way the agency invites specific people to attend the hearing?

A. I believe we sent calendar invites before.

Q. To what people? How did you decide on sending calendar invites?

A. The specific example I'm thinking of is a sister agency for the iBudget handbook. We invited ADP to participate and sent them a meeting invite so they

can block that time.

Q. Okay. Have you ever invited Medicaid recipients other than through the public notice to attend a rule hearing?

A. I don't know, outside of the public notice process.

Q. In your experience?

A. I personally have not.

Q. Okay. Do any State agencies in hosting a rule hearing, do they arrange for transportation for individuals from the public to attend that hearing?

MR. PERKO: Object to form.

THE WITNESS: I can't speak for any other agency. I don't know.

BY MS. DEBRIERE:

Q. What about at DOEA? Did that ever happen?

A. I don't believe I ever participated in an actual public meeting hosted by DOEA.

Q. That's right. You said that.

What about AHCA? Are you aware of AHCA ever arranging transportation for individuals from the public to attend a hearing?

A. Not that I'm aware of.

Q. Are you aware of anyone from the public being paid to attend a hearing?

A. No.
Q. Are you aware of anyone who is a subject matter expert being paid to attend a hearing?
A. I know we've reimbursed the subject matter experts. But I'm not sure if that was specifically -- attending the hearing was specifically included.
Q. And these are subject matter experts that are employed with the agency?
A. I don't know how that process works. But they're not full-time employees with the agency. I believe it's like consultants.
Q. Okay. What's the average length of a hearing?
A. I don't know the average. I know our public meetings typically range between 30 minutes and two hours.
Q. Okay. On average how many comments do agencies receive for a rule hearing? Is there an average?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Do you think 100 comments is a lot of public comments to receive at a hearing?
MR. PERKO: Same objection.
THE WITNESS: I really don't know.
BY MS. DEBRIERE:

Q. In your experience, does a State agency ask outside legal counsel to attend and perhaps in rule hearings?

A. Can you repeat the question.

Q. In your experience, does a State agency normally ask that outside legal counsel attend a rule hearing?

A. I don't know.

Q. When you planned this last rule hearing, did you ask outside legal counsel to attend?

A. Can you specify which hearing.

Q. Yeah. There was a hearing a couple of weeks ago on the change to the medical necessity definition.

A. Yes. The workshop.

Q. Workshop. Did you ask outside legal counsel to attend that workshop?

A. I personally did not.

Q. Did outside legal counsel attend that workshop?

A. I don't believe so.

Q. And have you ever attended a rule hearing where outside legal counsel was asked to participate in?

A. I can't recall if that circumstance has ever happened.

Q. So it's not usually -- it's not the standard course of things for outside legal counsel to attend?

A. Correct.

Q. All right. Turning to the exclusion for treatment of gender dysphoria under Rule 59G-1.050. Prior to the adoption of this exclusion, did any coverage policies regarding any of the services listed there -- sorry. Strike that.

Prior to the adoption of the exclusions set forth -- I'm not sure you're looking at the right rule. 59G-1.050. Exhibit 2. It would help me to tell you the exhibit number. And then it's Subpart 7.

So prior to the adoption of that rule -- that Subpart 7 -- did any coverage policies exist regarding the services that are now subject to that exclusion?

A. Can you repeat that question.

MS. DEBRIERE: Court Reporter, can you read back that last question.

(The preceding question was read back by the reporter.)

THE WITNESS: There was not a specific coverage policy for services for the treatment of gender dysphoria.

BY MS. DEBRIERE:

Q. Does that mean those services were never covered to treat gender dysphoria by Florida Medicaid?

A. I don't believe there was any policy language

that specifically outlined coverage of the services listed in this section.

Q. If there was no specific policy language, does that then mean those services were not covered to treat gender dysphoria by Florida Medicaid?

A. I don't know the extent to what providers were reimbursed for providing the services.

Q. So even if there wasn't a coverage policy specifically related to these services, it's possible that Florida Medicaid was covering the services for the treatment of gender dysphoria?

A. It's possible Florida Medicaid reimbursed for these.

Q. Are there circumstances in which AHCA might not have an explicit or affirmative coverage policy, but would consider a request for a service on a case-by-case basis?

A. Can you repeat the question.

Q. Are there circumstance in which AHCA might not have an explicit coverage policy regarding those services -- or any service -- but would consider a request for a service on a case-by-case basis?

A. I don't know specifically if it's case-by-case basis. But I believe that the plans -- that some of the request from the managed care plans may be specific to a

request for a specific coverage. So when plans request for a GAPMS to be provided, it could be being driven by a specific case.

Q. Okay. So even though a coverage policy does not exist regarding the coverage of a specific service, there are circumstances in which AHCA might still cover that service?

A. Yes.

And I apologize. On your last question I think I heard you specific about GAPMS, which is what I answered. So I apologize.

Q. That's okay. No, that's fine. You're referring to not the last question, but the question before that; is that right?

A. Yes.

Q. Okay. But your response on that last question, you understood the question?

A. Yes.

Q. Okay. Will Florida Medicaid cover an EPSDT service if that service is experimental?

A. So in order for an EPSDT service to be covered, it has to meet the definition of medical necessity.

Q. And that medical necessity definition includes the requirement that the service not be experimental?

A. Yes.

Q. Okay. So you received a request from Secretary Marstiller via email to engage in a GAPMS regarding treatment for gender dysphoria; correct?
A. I can't remember if it was email.
Q. Right. But you received the request somehow?
A. Yes.
Q. And roughly when was that; do you remember?
A. I don't remember.
Q. And then the next step was speaking with Mr. Weida about the letter?
A. Yes.
Q. And developing the plan as to who was going to --
A. Yes. Developing how the process would work.
Q. Were all the decisions reached in that one meeting with Mr. Weida?
MR. PERKO: Object to form.
THE WITNESS: No.
BY MS. DEBRIERE:
Q. Okay. So after that meeting with Mr. Weida, what happened next?
A. I can't remember the exact timeline of events. I know we met at some point with the Canadian Prescription Drug Importation team.
Q. And they were the ones who were put in charge

of doing this GAPMS?

A. Yes.

Q. Okay.

A. And there was several conversations following that.

Q. Were those conversations limited to yourself, Mr. Brackett, Mr. Chen, and Ms. Pickle? Or were there other people involved?

A. I can't remember the chronology. I know after the report and then into the rulemaking Cole Giering was brought into the conversation. Legal counsel -- there was conversations with the experts.

Q. Who were the experts?

A. I can't remember all their names. I don't know if we have that list here.

Q. Did you ever personally speak with any of the experts?

A. No.

Q. Are all the experts listed here on what would be will be your Exhibit 7 on page 45?

A. I believe so, yes.

Q. Was a Dr. Von Mol ever involved as an expert?

A. I believe so.

MS. DEBRIERE: And let me just mark this as Exhibit 10.

(Plaintiff's Exhibit No. 10 was marked for identification.)

BY MS. DEBRIERE:

Q. And this is a document -- an After the Fact Request Form Under 35K. This form is indicating what?

A. Consultant services for vendor name Andre Van Mol.

Q. And what kind of consulting services did Dr. Van Mol provide?

A. I don't know all the details of that -- what the contractor provided. But it was as part of the GAPMS process.

Q. Okay. Why was it time sensitive? It indicates on that form it was time sensitive. Why?

A. I don't know why the request was time sensitive.

Q. Who would know that?

A. I don't know.

Q. Okay. At any time throughout the process did you feel like there was an urgency to the development of the report and rule?

A. Yes. The time sensitive nature was communicated.

Q. By?

A. I don't know remember if it was in the original

request or if it was later in conversations with leadership. I can't remember exactly who. But I think the expectation to follow the process but work as quickly as possible was apparent.

Q. Okay. But you cannot provide me an explanation as to why it was identified as time sensitive?

A. Correct.

Q. I believe we already marked ATF to Dr. Van Meter as Exhibit 8.

Dr. Van Mol -- do you know if he attended the rule hearing for the exclusion of treatment for gender dysphoria?

A. I don't know.

Q. Okay. What does this document, Exhibit 8, indicate to you?

A. An approval for consultant services for vendor named Quintan Van Meter.

Q. Okay. And what kind of services did he provide in exchange for that reimbursement?

A. Consultant services.

Q. Consulting on what?

A. As part of the GAPMS process.

Q. Do you know what specific stages he provided consultation on?

A. I don't.

Q. Do you know whose idea it was to use him?
A. I don't.
Q. Do you know whose idea it was to retain any of the outside experts?
A. No.
Q. Was it internal to AHCA, that decision? Did someone at AHCA decide to retain outside experts?
A. I don't know.
Q. Who would have made that decision?
MR. PERKO: Asked and answered.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Are you aware of AHCA retaining outside experts for any other GAPMS report?
A. I don't know.
Q. Other than Dr. Van Meter and Dr. Van Moll -- I'm sorry.
Was there a Dr. Grossman involved in the process?
A. Yes.
Q. And what was Dr. Grossman's role?
A. I believe it was the same -- consultant services.
Q. For the development of the report?
A. Yes.

Q. Okay. Do you know if they were reimbursed to participate in the hearing?

A. I don't know.

Q. Okay. Were any of the -- other than Dr. Van Mol and Dr. Van Meter -- was Dr. Brignardello-Petersen reimbursed by AHCA for consultant services related to the development of the exclusion of treatment for gender dysphoria?

A. I don't know off the top of my head.

Q. What about Dr. James Cantor?

A. I don't know off the top of my head without consulting if there was an invoice.

Q. Is that true for all the experts?

A. I can't remember how exactly the contracts -- the contracted services were reimbursed.

Q. Were they reimbursed?

A. They were.

Q. Looking at Van Meter's form -- why did you sign that form for a $34,000 reimbursement if you didn't know what Van Meter was doing?

MR. PERKO: I'm going to object to form.

THE WITNESS: So I know that Van Meter was consulting as part of the project. I just don't know throughout the process all the specific details of that consultation.

BY MS. DEBRIERE:

Q. Would you assume each expert listed was similarly compensated for the amount that Dr. Van Meter and Van Mol were compensated?

A. I'm not going to assume. Just looking at the two invoices, they are very different.

Q. In what ways?

A. This one has a not to exceed amount. And then this one has as dollar amount.

Q. Okay. Is that the only way they're different?

A. No.

Q. How else are they different?

A. The one for Quinton Van Meter has specific information regarding his MFMP registration.

Q. What is MFMP?

A. My Florida Market Place.

Q. Okay. Any other ways that they're different?

A. Some of the other language is different. The dates are different. But aside from that, no.

Q. How often do you approve an After the Fact Request Form for reimbursement of outside expertise?

A. Not often.

Q. How many times have you done it for expertise not related to the treatment of gender dysphoria?

A. I can't recall if I actually approved the

invoice; but I believe there was a consultant for the Canadian Prescription Drug Importation Program at one point. And I just can't remember the time.

Q. Is that the only time you can remember?

A. Yes.

Q. Okay. So when you were approving these forms that don't come across your desk often, do they strike you as something that needed careful review?

A. The invoice itself?

Q. The reason for reimbursement.

A. Yes. But the invoice itself seems pretty straightforward that a reimbursement based on services provided -- that had already been provided would be signed.

Q. Did you do a carful review of the reason for reimbursement?

MR. PERKO: Object to form.

THE WITNESS: I guess I'm not sure what you mean by careful review. I personally was not involved in all of the consultation services provided. But I did meet with the team and knew that services were provided.

BY MS. DEBRIERE:

Q. Prior to you receiving this request for reimbursement, did you know these experts were being

relied on for consultation?
A. Yes.
Q. Did you have to approve that request?
A. I don't know if there was a request initiating the services. I don't remember.
Q. Was there a need to approve the decision to rely on outside experts?
MR. PERKO: Object to form.
BY MS. DEBRIERE:
Q. Was there a requirement that consulting with outside experts be approved prior to the consultation?
MR. PERKO: Object to form.
THE WITNESS: Can you repeat that question.
BY MS. DEBRIERE:
Q. Was there -- who consulted with the outside experts?
A. Again, I don't know the extent of what the consultation services were or who all was part of that.
Q. In order for them to -- in order for the team to develop the GAPMS report -- who wrote it -- in order for them to consult with outside experts, did it require your approval?
A. I don't recall ever approving them.
Q. And the team relying on outside experts to write the GAPMS report on gender dysphoria, did it

require the approval of D.D. Pickle?

MR. PERKO: Object to form.

THE WITNESS: I can't recall how the formal process was initiated.

And I do want to say relying on experts -- there was a lot of additional research done as well as part of the GAPMS process. So I wanted to clarify that.

BY MS. DEBRIERE:

Q. But part of writing the report was consulting with these outside experts; correct?

A. Yes.

Q. And you don't know who made the decision to consult with those experts; is that right?

A. Correct.

Q. Whoever made the decision -- we don't know who that is. But whoever made the decision, did they require approval before they could implement that decision?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. Okay. As the bureau chief who oversees the team who wrote this GAPMS report, did you have an expectation that they would come to you for approval to

consult with outside experts that would then be paid?
A. Can you repeat that.
Q. As the bureau chief, the person who oversees the team that wrote the GAPMS report on treatment for gender dysphoria, did you have an expectation that they first ask you permission before they consulted with outside experts who charged for their services?
A. No.
Q. Why didn't you have that expectation?
A. I can't really answer that, as I was not part of the decision to consult with the experts.
Q. Who was part of the decision?
A. I don't know.
Q. But you know you were not part of it. Okay.
At the bottom of the After the Request Form, it states -- for Dr. Van Mol, which is Exhibit 10 -- it states supervisor approval is required. What does that mean?
A. In the routing hierarchy for approval.
Q. Approval of what?
A. For invoices for My Florida Marketplace. I'm the direct supervisor of D.D. Pickle.
Q. So your approval is required for D.D. Pickle to pay this bill?
A. Yes.

Q. Okay. But your approval was not required for D.D. Pickle to incur this bill?

MR. PERKO: Object to form.

THE WITNESS: I don't remember if there was a formal approval to initiate the services.

BY MS. DEBRIERE:

Q. Did you have to have approval to authorize this payment to Dr. Van Mol?

A. I can't remember. I don't know where this goes next in the routing.

Q. Okay. Did you ask permission to approve this from anyone?

A. I can't remember a specific conversation. But I knew it was approved by the agency to consult with -- to have the consultant services.

Q. Okay. Related to that, the last sentence is -- how did you know that?

A. How did I know what? Can you repeat that.

Q. I think you had responded that you knew the agency had approved it. And so my question was: How did you know that?

A. I don't remember the specific conversation. But I do know that it was approved by leadership.

Q. And how do you know that?

A. There must have been a conversation. I just

can't remember an exact -- if there was an exact conversation or a document I signed. I can't remember.

Q. Okay. Do you remember who you had the conversation with or had the document signed by?

A. I don't remember.

Q. The last sentence under that first paragraph, it says, "Verification of the availability of funding and approval from executive leadership was obtained prior to any work being conducted for this project."

Who was that executive leadership?

A. The majority of my discussions were with my direct supervisor. But Tom Wallace ultimately signed the report. And I don't know outside of that who all was involved.

Q. Do you need a break?

A. Yeah.

(Brief recess.)

BY MS. DEBRIERE:

Q. Who decided the amount in those forms?

A. I don't know how the amount was negotiated.

Q. Did you follow up on the amount being requested -- ask any questions about it?

A. I can't remember if I asked any questions. But, again, as it states on the form -- the availability of funding approval for leadership.

Q. So you think whoever that leadership was had approved that amount?

A. I don't know how the reimbursement for the services was negotiated.

Q. Okay. So you didn't ask any questions about the amount or what it was being used for?

MR. PERKO: Object to form.

THE WITNESS: I knew what it was being used for. But I can't remember if I asked any questions about the amount.

MS. DEBRIERE: Okay.

THE WITNESS: I can't recall any.

BY MS. DEBRIERE:

Q. Are there any subject matter experts for the services listed in that exclusion that are full-time employees with the agency?

MR. PERKO: Object to form.

THE WITNESS: I don't believe so, since the services outlined in the policy were not clearly outlined in any existing coverage policy that would have had any subject matter expert assigned to the coverage policy.

BY MS. DEBRIERE:

Q. Do you have a subject matter expert in surgery?

A. I don't know if it's one person or more than

one. We have an area that's responsible for the coverage policies we talked about earlier that contain coverage for surgical procedures.

Q. So you have a subject matter expert for outpatient hospital services?

A. Yes.

Q. And do you have a subject matter expert for inpatient hospital services?

A. I don't know if it's the same person.

Q. Okay. But do you have a subject matter expert in inpatient, it just might be the same person?

A. There's a team responsible for oversight of those policies, yes.

Q. Was that team involved in the development of this GAPMS report?

A. Not to my knowledge. But I can't speak to all of the research and activities that were part of the completion of the project.

Q. Who is that team -- that team that are the suggest matter experts in inpatient and outpatient hospital services?

A. That would be John Matson under Jesse Bottcher who is responsible for primary and preventive surgeries, including dental.

Q. Okay. You had mentioned before the break that

you had communications about the development of the GAPMS report with legal counsel; is that correct?

A. I believe so. I can't remember if it was part of the report or part of the rule. I know for sure with the rulemaking process that legal is involved in that process normally. And they were in this instance as well.

Q. Did that legal include outside counsel?

A. I don't know. I don't remember meeting with outside counsel.

Q. Okay. You don't remember with meeting with Holtzman & Vogel, the law firm?

A. No.

Q. Did you communicate with any other State agencies like the Florida Department of Health about the GAPMS report?

A. I personally did not.

Q. Did anybody at the Agency for Health Care Administration?

A. I don't know.

Q. Did you communicate -- were there any communications between AHCA and the Governor about the development of this report?

A. I don't know.

Q. Did you personally communicate with the

Governor's office about the development of this report?

A. No.

Q. Did you personally communicate with the Governor's office about the exclusion of treatment for gender dysphoria?

A. No.

Q. Were there any communications between AHCA and people that provided public comment at the hearing?

A. I'm sorry; can you repeat the question.

Q. Were there any communications between AHCA -- prior to the hearing, were there any communications between AHCA and the people who provided public comment at the hearing?

A. I don't know.

Q. Did you personally communicate with anyone who provided public content at the hearing prior to the hearing?

A. No.

Q. Was anyone at AHCA aware that specific people would provide public content at the hearing prior to the hearing?

A. I don't know.

Q. Were you aware that there were any specific members of the public who would provide public comment at the hearing prior to the hearing?

A. No.
Q. The person who is identified as authoring the GAPMS report on gender dysphoria is Matt Brackett; correct?
A. Yes, he was the primary author.
Q. Do you recall a meeting between you, Mr. Weida, and Mr. Bottcher discussing who the author of the report would be?
A. I don't remember if Jesse was in any of the conversations.
Q. Okay. Did Jesse ever express a concern to you about someone -- anyone on his team drafting the GAPMS report on gender dysphoria treatment?
A. Prior to?
Q. At any time.
A. Can you say that again.
Q. Did Mr. Bottcher ever express to you concerns over someone on his team drafting the GAPMS report on the treatment for gender dysphoria?
A. Not that I can recall.
Q. Was the GAPMS decision tree used before you decided to undertake the GAPMS analysis that is contained in the June 2022 report?
A. I don't know.
Q. Who would have that information?

Did Secretary Marstiller in her letter to Tom Wallace -- did she direct Tom Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.

THE WITNESS: I can't recall the details of the letter.

MS. DEBRIERE: Me neither. Do we have a copy?

MS. CHRISS: It's the last page right there. It's Attachment A.

MS. DEBRIERE: Oh. It's the very back of Exhibit --

MR. PERKO: It's not attached to ours.

MS. DEBRIERE: Okay.

MS. DUNN: Why don't you pull it off and mark it as a separate exhibit.

MS. DEBRIERE: So we'll mark the letter from Simone Marstiller dated April 10th, 2022, as Exhibit 11. And that's Attachment A to the June 2022, GAPMS report related to the treatment for gender dysphoria.

(Plaintiff's Exhibit No. 11 was marked for identification.)

BY MS. DEBRIERE:

Q. So in this letter is Secretary Marstiller directing Mr. Wallace to undertake the GAPMS process?

MR. PERKO: Object to form.
THE WITNESS: Yes.
BY MS. DEBRIERE:
Q. Do you think that Secretary Marstiller undertook a decision tree prior to writing this letter and sending it to Mr. Wallace?
MR. PERKO: Object to form.
THE WITNESS: I don't know.
BY MS. DEBRIERE:
Q. Has the secretary of AHCA ever personally completed a decision tree on the GAPMS process?
A. I don't know.
Q. Would it be unusual if the secretary of AHCA completed a decision tree on the GAPMS process?
A. I don't know.
Q. Looking at the GAPMS report itself, does it contain a fiscal analysis?
A. I don't know off the top of my head.
Q. Yeah. No, take your time.
A. No, I do not see a fiscal analysis.
Q. Do you see anything related to cost effectiveness?
A. No.
Q. Do you know why that was not included?
A. No.

Q. Is budget neutrality in reaching a GAPMS decision important?

MR. PERKO: Object to form.

THE WITNESS: I don't know. I know that that's something when determining a coverage determination that is taken into consideration. But specific to the GAPMS process, I don't know.

BY MS. DEBRIERE:

Q. Okay. Who would know that? Would the person responsible for writing GAPMS reports know that?

A. Yes. Or Jesse Bottcher or Matt Brackett.

Q. Or Jeff English?

A. Yes.

Q. Who decided which services would be assessed in the GAPMS report?

A. I don't know.

Q. So typically a request comes in from the public for a specific service. In this instance, the request came from the secretary; correct?

A. Yes.

Q. So would it have been the secretary who decided which services should be assessed?

A. I can't recall how the decision was made. I do know that that was part of conversations we had during this process. But I can't recall exactly how the

decision was finalized.

Q. Was there ever a discussion about narrowing the types of services to be included?

A. I don't recall specifically. I know that the coverage of behavioral health services was something that was always covered. But outside of that specifically, I can't remember.

Q. Was there ever any discussion about undertaking the GAPMS process for a set of services simultaneously as opposed to a single service?

A. Can you clarify.

Q. In the discussions about writing the report or assessing the services, were there ever any concerns raised about undertaking the process for a set of services as opposed to a single one?

A. I don't recall specifically.

Q. Was there any discussion about EPSDT?

A. I can't remember if it was specific to the development of the report or the rulemaking more specifically. But I believe there was.

Q. And what was discussed?

MR. PERKO: I'm going to object for a second. Did that include counsel? Did those discussions include counsel?

THE WITNESS: Yes.

MR. PERKO: And who was that?
THE WITNESS: I don't remember.
MR. PERKO: But it did include counsel?
THE WITNESS: I believe it was a discussion on the rulemaking with counsel.
MR. PERKO: I'm going to instruct the witness not to answer.
BY MS. DEBRIERE:
Q. Were all discussions had in front of counsel about EPSDT?
A. I don't remember.
Q. How about comparability?
MR. PERKO: I'll ask you the same thing.
THE WITNESS: Can you remind me what you're referencing when you say comparability. I think you mentioned that at the very beginning of the day.
MS. DEBRIERE: Comparability is a requirement under the Federal Medicaid Act in the administration of the coverage of the Medicaid services.
THE WITNESS: I don't recall.
BY MS. DEBRIERE:
Q. Were there communications with the Centers for Medicare and Medicaid Services about AHCA's decision to assess whether the services listed in the exclusion were experimental?

A. I don't know. I personally did not have any conversations.

Q. Who communicates with CMS about those kinds of things?

A. Those kinds of things, you mean changes in coverage?

Q. Does CMS ever reach out to AHCA about concerns they have about an action that they're taking related to Medicaid coverage?

A. Yes.

Q. Who would be the point person at AHCA to have those conversations?

A. So if an update to a federal authority were needed, that would be either Catherine Mcgrath or myself.

Q. Okay. You would not have had -- have you had any conversations with CMS about the GAPMS report related to the treatment of gender dysphoria?

A. No.

Q. Has Catherine?

A. Not to my knowledge.

Q. Have you had any conversations with CMS about the exclusion of the treatment for gender dysphoria as contained in Rule 59G-1.050?

A. I have not.

Q. Has Catherine?
A. Not to my knowledge.
Q. Has anybody else at AHCA?
A. I don't know.
Q. Okay. You mentioned a second ago that you weren't sure if you were talking about EPSDTs as it related to the report or the rulemaking. When you make that distinction, are you referring the writing of the report versus the adoption of the rule?
A. Yes.
Q. Okay. How was it decided that the conclusions from the GAPMS report should be adopted into rule?
A. I'm trying to remember the specific conversations. But I do believe those were conversations with counsel as well.
Q. Okay. The expedited GAPMS that you were involved in from start to finish, was that decision adopted into rule?
A. It was just one other GAPMS. And I don't believe any rule update was needed for that one.
Q. Why was a rule update needed for this GAPMS report?
MR. PERKO: If that's discussion with counsel, I will instruct you not to answer.
THE WITNESS: Because there was not any policy

language that clearly explained the coverage, it was determined that developing policy language was the best approach. Anything past that was -- how that process went was conversation with counsel.

BY MS. DEBRIERE:

Q. How often in your day-to-day in making decisions in your job do you have to consult with legal counsel?

A. Often.

Q. Okay. So does that mean -- okay. Like, every day?

A. I would say the majority of days.

Q. Okay.

A. And I'll just specify. I have some sort of contact or interaction with legal counsel.

Q. On most days?

A. Yes. And, again, because the rule promulgation does require review and some other documents we route are managed care contracts also route through legal. Just to give you examples of why it's quite often.

Q. They're all contacts with legal counsel about things related to the doing of your job?

A. The development of policy and -- yes.

Q. Okay. So there was -- you said there was -- the reason that it needed to be adopted into rule is

because there was no clear coverage policy on the services at issue; is that correct?

A. I can't remember all the factors that went into the decision. But I believe that was one of the factors when it was assessed that there was no coverage policy specific to the treatment of gender dysphoria.

Q. Were there existing coverage guidelines?

A. Not to my knowledge.

Q. At the time were you aware of existing pharmacy policies related to the treatment of gender dysphoria?

A. At what time? Can you specify.

Q. It was 2017/2016.

A. I was not with the agency in 2016. So I would not have been part of any development of policy at that time.

Q. But when you were deciding whether to adopt this exclusion into the rule, did you do any review of existing coverage guidelines or past coverage decisions?

A. I believe we did. But I can't recall the specifics.

Q. Did you review past GAPMS reports regarding the treatment of gender dysphoria?

A. I believe we did.

Q. And why weren't they enough to establish the coverage policy?

MR. PERKO: Object to form.

THE WITNESS: I don't know.

BY MS. DEBRIERE:

Q. 59G-1.050, Subpart 7 -- it bans Medicaid coverage for puberty blockers, hormones and surgery if done so to treat gender dysphoria; correct?

A. It covers that Medicaid does not cover those services for the treatment of gender dysphoria; correct.

Q. Does it distinguish between adults and children?

A. No.

Q. So the exclusion applies equally to both children and adults; is that correct?

A. Yes.

Q. Okay. And it excludes Medicaid coverage for puberty blockers and hormones and surgery to treat gender dysphoria, but it does not exclude Medicaid coverage for those services to treat other diagnoses; is that correct?

A. Correct.

Q. And I just forgot you answer; I apologize. Were you involved in the rule hearing held on July 8th regarding the exclusion set forth in 1.050?

A. No.

Q. Were you aware that outside legal counsel

participated in that hearing?

A. I don't know if I was made aware prior to today. I can't remember.

Q. At rule hearings you've been in in the past, do the State agencies have a panel of subject matter experts who respond to public comment during the hearing?

A. I can't cite the specific language, but it's actually required per Chapter 120 that the agency has subject matter experts who can speak to the contents of whatever is being discussed at a public meeting available.

Q. Other than the July 8th hearing, are you aware of any time that any agency has retained outside subject matter experts to participate on that panel?

A. I'm not aware of any.

Q. To your knowledge is this the only time AHCA has created a slogan to advertise the conclusion in its GAPMS memo?

MR. PERKO: Object to form.

BY MS. DEBRIERE:

Q. Are you aware of the slogan "Let kids be kids"?

A. I've seen the website, yes.

Q. In your experience has AHCA ever designed a website page for any other rule adoption?

A. I can't remember if it was specific to rule adoption. But I can think of a couple of examples where we created web pages for policy updates; for example, for home and community based settings rule that was an administrative rule as well as a federal rule. There's a specific external web page for updates regarding that and information on that rule.

When we received the American Rescue Act funding approval, we created a web page with information on that funding and what those funding could be used for. So I feel like it's pretty common for us to update our external website when there's important information to communicate.

Q. In those other examples, did AHCA ever develop a slogan to go along with those web pages?

A. Not in the examples that I used, I don't think.

Q. Did they issue press releases?

A. The American Rescue Act funding may have had one. But I can't remember.

Q. Okay. Just going back quickly. My co-counsel has pointed out to me that in Chapter 120 it says that at the rule hearing agency staff must be available but not an expert. Do you think maybe you were confusing that requirement that an expert needs to be available under 120?

A. I think it says an agency staff with knowledge.

Q. Okay. "Ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule." Is that the provision you were --

A. Yes.

Q. -- thinking of? Okay.

Typically when AHCA decides not to cover a particular service, where is that information included?

MR. PERKO: Object to form.

THE WITNESS: I think it depends on the policy. Each policy has different exclusions, if there are any, with the service. Or most of the coverage policies include a section specific to exclusions.

MS. DEBRIERE: Most of the policies? Is that what you said? I apologize.

THE WITNESS: Most of the coverage policies.

BY MS. DEBRIERE:

Q. Okay. And those coverage policies are service specific policies?

A. The examples I was thinking of, yes, were service specific coverage policies and include -- I can't remember exactly what section in the example of where to find that in the coverage policy. But, yes, it would include exclusion specific to the coverage that's

being described in the policy.

Q. Okay. The exclusion on the treatment of gender dysphoria, is it in a service specific coverage policy?

A. No. This is a general Medicaid policy. But it does include coverage information including what Florida Medicaid reimburses for and what it does not.

Q. Does it speak to the exclusion of any other services under Florida Medicaid but those services excluded for the treatment of gender dysphoria?

A. Yes.

Q. Which ones?

A. No. 4 is an example. (4)(b), that speaks to that Florida Medicaid does not cover continuous services after the emergency has been alleviated.

Q. Is that a specific service? Or is that the length of time for any service?

A. I apologize. It's emergency service. It's under the section for emergency Medicaid.

Q. But, again, is that speaking to the coverage of any service deemed emergency?

A. It's specific to emergency services provided to aliens who meet all Florida Medicaid eligibility requirements except for citizenship.

Q. It says an exclusion under Subpart 7 speaks specifically to the exclusion of sex reassignment

surgeries; correct?

A. Services for the treatment of gender dysphoria.

Q. But only three services.

A. Four.

Q. What are examples of procedures that alter primary or secondary sexual characteristics that are not related to surgery?

A. I don't know.

Q. Just going back to the surgery, why not include that in service specific policies that discuss surgery?

A. Can you repeat the question.

Q. Looking at the exclusion of sex reassignment surgeries, why was that not included in the coverage policies related to surgeries that we discussed earlier?

A. I don't recall the specific conversation on how it was decided that this was the most appropriate policy. And I do believe that most of that conversation was with counsel.

Q. So same question for puberty blockers. Why wouldn't you include that in a pharmacy coverage policy?

A. I don't know.

Q. And Subpart 7's subject line is "Gender Dysphoria"; correct?

A. Yes.

Q. And that's a diagnosis?

A. I don't know clinically the definition.
Q. We've been talking about the treatment of gender dysphoria; right?
A. Yes.
Q. So in order to exclude treatment of gender dysphoria, it would be the exclusion of a treatment for a diagnosis; correct?
A. Yes. But I can't speak to the specifics of the diagnosis or what that means in clinical terms.
Q. Okay. For the July 8th hearing, do you know how many public comments were submitted?
A. I don't know.
Q. Do you know if it was more than 100?
MR. PERKO: Asked and answered.
THE WITNESS: I know it was a lot.
BY MS. DEBRIERE:
Q. Okay. And do you know how long it took AHCA to review and consider the comments before adopting the final rule?
A. I don't know the length of time. But I know that all the public comments were reviewed.
Q. Who reviewed them?
A. I know Cole Giering did. I don't know if anybody else -- if anybody else did.
Q. Okay. So after the July 8th hearing up until

the final adoption of the rule, other than reviewing and considering public comment, what else did AHCA do before adopting the rule?

A. Can you repeat the question.

Q. So after the July 8th hearing up until the final adoption of the rule, other than reviewing public comment, what other activities did AHCA undertake in deciding to adopt the rule?

A. I don't know. I can't remember specific to this rule. But after it's been determined there's no changes needed to the rule, the filing for adoption would be the next step.

Q. How do you reach that decision that no changes should be made?

MR. PERKO: Object to form.

THE WITNESS: There's various factors involved in that decision. And it really depends on the specific circumstances.

MS. DEBRIERE: Okay. I don't know what it would be labeled, but do you have an exhibit -- it's an email from Ms. McGriff to Magellan.

MS. CHRISS: Yes. The email exchange between Magellan and AHCA.

MS. DEBRIERE: Thank you.

Court Reporter, just for your reference what we

just marked as Exhibit 12 is Bates stamped DEF_00288753 to 000288756.

(Plaintiff's Exhibit No. 12 was marked for identification.)

BY MS. DEBRIERE:

Q. So Magellan is emailing several people at AHCA. And she says, "Attached are the internal criteria not publicly posted."

What are the internal criteria?

A. I don't know.

Q. Does Magellan rely on internal criteria for the coverage of Medicaid services?

A. I don't know.

Q. What does "CCM" mean? It's right after that sentence. "Attached are the internal criteria 'not publicly posted' CCM."

A. I don't know.

Q. What does gender code mean?

A. I don't know.

Q. Do you know hot had significance of "B for both" is?

A. I do not.

Q. Who is Linda Simone Moore?

A. Who?

Q. So there's a sender up top here -- I'm sorry.

Leslie.

A. Moore-Simons.

Q. I need reading glasses. Leslie Moore-Simons. That's exactly right.

A. I don't know.

Q. Okay. Who is Susan Williams?

A. She works for Ashley Peterson in the pharmacy unit in the Bureau of Medicaid Policy.

Q. Okay. And who is Arlene Elliott? I'll just note the date that Arlene's email was sent was 8/21/2017.

A. Currently Arlene Elliott is in a different division at the Agency for Health Care Administration. But at this time, she was the AHCA administrator over the pharmacy policy section of the Bureau of Medicaid Policy.

Q. And what unit is she in now?

A. I don't know. She's no longer in the division of Medicaid.

Q. What division is she in?

A. I believe it's Health Quality Assurance.

Q. Do you know when she left her position in the Bureau of Medicaid Policy?

A. I believe it was spring or summer 2021. I'm not sure the exact date.

Q. Okay. Earlier in the exchange -- and yet dated later -- is the email dated April 20th, 2022, from Elica King-Wilson at Magellan. And she's included some language which she underlined and bolded. And it says, "All requests require vetting by AHCA before a final determination is made."

And it appears this is related to a final determination as to whether -- well, it says -- Leslie noted, "MMA does have an internal gender dysphoria criteria, which is attached."

MMA stands for?

A. I don't know in what context she's using it.

Q. Okay.

A. But to me, MMA would normally stand for managed medical assistance.

Q. I assume you're confused because this is coming from Magellan which is not a managed medical assistance program; is that right?

A. Yes. So I don't know if that's what she's referring to.

Q. And it says, "This internal document serves for GnRH analog use to delay puberty in adolescents with gender dysphoria." This document was provided by AHCA due to a fair hearing request received for Lupron for a recipient with this diagnosis" -- meaning gender

dysphoria. And it goes on with the underlying language that all of those requests -- coverage of Lupron for gender dysphoria -- need to be vetted by AHCA before a final determination is made.

Were you familiar with that process at all?

A. No. I don't know what process they were referring to.

Q. Would Ashley Peterson know?

A. I don't know. But she does work closely with Magellan.

Q. Okay. Did AHCA work with managed care plans to implement the exclusion in 1.050?

A. They were notified. But the specifics of how that communication happened, I can't recall.

MS. DEBRIERE: Okay. Can I have the SMMC Policy Transmittal relating to the Non-Coverage of Gender Dysphoria Treatment.

MS. DUNN: Do you want the policy or the emails?

MS. DEBRIERE: Could you do both.

MS. DUNN: Do you want them together?

MS. DEBRIERE: That would be great. But separate exhibits.

(Plaintiff's Exhibit No. 13 was marked for identification.)

(Plaintiff's Exhibit No. 14 was marked for identification.)

BY MS. DEBRIERE:

Q. So right now we're looking at an email that's Bates stamped DEF_000258835 to 000258838. It's an email from D.D. Pickle CC-ing you. And it's to Jason Weida.

In this -- I'm sorry. Looking specifically at an email dated August 22, 2022, from D.D. to Ashley Peterson and Matt Brackett. It states, "Ashley, Ann wants to include the 60-day language in the alert?"

What alert is D.D. Pickle referring to?

A. I believe it was the provider alert.

Q. And what's a provider alert?

A. It's the main way -- one of the main ways we communicate information to our providers and external stakeholders.

(Plaintiff's Exhibit No. 15 was marked for identification.)

BY MS. DEBRIERE:

Q. I'm handing you a document that's marked as Exhibit 15, called Florida Medicaid Health Care Alert Sign-Off Form, starting at Bates stamp DEF_000258839.

Is this the provider alert you were referring to?

A. Yes. It looks to be a provider alert regarding

the coverage of treatment for gender dysphoria.

MS. DEBRIERE: Okay. And then what was the transmittal?

MS. DUNN: It was 14.

BY MS. DEBRIERE:

Q. No. 14 -- can you look at that document. And that's Bates stamped DEF_000258833.

What is this document?

A. It looks to be a draft -- a policy transmittal.

Q. And who does that go to?

A. This specific one is marked to be sent to the medical assistance and specialty plans.

Q. Is that the final that was sent?

A. It does not appear so, no.

Q. Okay. How do you know that?

A. The policy transmittal number is not completed and it's not signed.

Q. Okay. Going back to the provider alert, was that the final that was sent?

A. I can't tell from this document if this was the final that was sent.

Q. Okay. Would you be able to tell from any of the versions whether it was the final?

A. Seeing the actual email alert would be how I would make sure. My team actually does not send out the

final provider alerts. So that's typically how I would look at the final version.

Q. Okay. And the policy transmittals and the provider alerts -- are those available on the agency's website? The finals?

A. Yes.

Q. Okay. So turning back to that email exchange where D.D. mentions you by name.

What is 60-day language?

A. I believe she's referring to the continuity of care.

Q. What is continuity of care?

A. It's a contract requirement for the plans to provide services for a period of time. I don't know if it's specific to when they change plans. I can't recall the exact contract language, but it's a contract provision.

Q. And are services previously being covered supposed to be continue being covered for 60 days according to the 60-day language?

A. I can't recall the exact parameters of the requirement.

Q. Do you recall why --

MR. PERKO: Counsel, we're getting on seven hours here.

BY MS. DEBRIERE:

Q. Do you recall why the 60-day language -- you wanted the 60-day language included in this alert?

A. I can't remember the conversation around this. And I can't speak for D.D.

Q. Well, D.D. is speaking for you; right?

The subject is "GD Policy Transmittal"; correct?

A. Yes.

Q. And what does "GD" stand for?

A. Based on the attachments, I would conclude that it is for gender dysphoria.

Q. Okay. And this would be discussion had after the rule was adopted excluding coverage of services for the treatment of gender dysphoria; correct?

A. Can you repeat that question.

Q. The date of this email is after the rule was adopted to exclude coverage of services for treatment of gender dysphoria.

A. I believe so.

Q. You don't recall why you thought it was important to have the 60-day language included in the alert?

A. I don't recall the specifics of the conversation. But I believe it was to ensure if there

was any current reimbursement or authorization that would apply.

Q. Current authorization of treatment of gender dysphoria?

A. Of the services listed in Rule 1.050, No. 7.

Q. Did any plans state to AHCA that they would continue coverage of the services excluded in the rule even though that rule had been adopted?

A. I don't know.

Q. Who would know that?

A. I don't know who it would have gone to. If there was a question, the communications typically go through the contract managers.

Q. Okay. Do you know if all plans have implemented the exclusion contained in the rule?

A. I don't know.

Q. Are you familiar with the variance and waiver process under Chapter 120?

A. Yes.

Q. Okay. What is the purpose of that statute?

MR. PERKO: Object to form; calls for a legal conclusion.

BY MS. DEBRIERE:

Q. What it the purpose of the variance and waiver process?

MR. PERKO: Object to form.
THE WITNESS: I don't know.
MR. PERKO: Counsel, we're getting on seven hours here.
MS. DEBRIERE: All right. Let me just consult with my team for just a second.
(Brief recess.)
MS. DEBRIERE: We'll all set with direct.
Thank you for your time, Ms. Dalton.
MR. PERKO: I don't have any questions.
THE COURT REPORTER: Would you like to read or waive?
THE WITNESS: Read.
THE COURT REPORTER: Would you like to order at this time?
MS. DEBRIERE: Yes.
THE COURT REPORTER: Would anybody like to order a copy?
MR. PERKO: Yes.
(This deposition was concluded at 6:05 p.m.)

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CERTIFICATE OF OATH

STATE OF FLORIDA:
COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, do hereby certify that ANN DALTON personally appeared before me on January 24, 2023 and was duly sworn and produced her ID badge as identification.

Signed this 30TH day of JANUARY, 2023.

GREG T. SMITH

Notary Public, State of Florida
My Commission No.: GG933698
Expires: March 21, 2024

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, GREG T. SMITH, Notary Public, State of Florida, certify that I was authorized to and did stenographically report the deposition of ANN DALTON; that a review of the transcript was requested; and that the foregoing transcript, pages 6 through 175, is a true and accurate record of my stenographic notes.

I further certify that I am not a relative, employee, or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 30TH day of JANUARY, 2023.

Greg T. Smith

GREG T. SMITH

KATHERINE J. DEBRIERE, ESQUIRE
DEBRIERE@FLORIDAHEALTHJUSTICE.ORG

January 30, 2023

RE: Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

The above-referenced transcript is available for review.

(The witness/You) should read the testimony to verify its accuracy. If there are any changes, (the witness/you) should note those with the reason on the attached Errata Sheet.

(The witness/You) should, please, date and sign the Errata Sheet and email to the deposing attorney as well as to Veritext at Transcripts-fl@veritext.com and copies will be emailed to all ordering parties.

It is suggested that the completed errata be returned 30 days from receipt of testimony, as considered reasonable under Federal rules*, however, there is no Florida statute to this regard.

If the witness fails to do so, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

*Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e).

Dekker, August v Marstiller, Simone
1-24-23 Ann Dalton, Job# 5662663

E R R A T A S H E E T

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REASON_____

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

(WITNESS NAME) DATE

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Governor Ron DeSantis Urges Swift Approval of Florida's Canadian Prescription Drug Importation Program

On July 9, 2021, in News Releases, by Staff

FDA directed to work with states on importation program plans

TALLAHASSEE, Fla. – Nearly eight months ago, under the leadership of Governor Ron DeSantis, Florida submitted its Section 804 Importation Proposal (SIP) to the U.S. Department of Health and Human Services (HHS) for our state's Canadian Prescription Drug Importation Program – the first in the nation to do so. Today, President Biden directed the U.S. Food and Drug Administration (FDA) to work with states and tribes to safely import prescription drugs from Canada as outlined in the FDA's implementing regulations based in part off Florida's 2019 importation concept paper.

Since taking office, Governor Ron DeSantis has prioritized lowering the cost of prescription drugs for Floridians. In 2019, the Florida Legislature passed several pieces of legislation, including Florida's Canadian Drug Importation Program, to reform Florida's health care market by increasing transparency, empowering patients, and reducing costs. Florida's Canadian Drug Importation Program will improve access to essential medications to vulnerable citizens and potentially save the state between $80 to $150 million in the first year alone.

"In Florida, we've led the nation in creating a program to lower prescription drug costs through their importation from Canada," **said Governor Ron DeSantis**. "With the issuance of this new executive order directing the FDA to work with states, I expect no further delay in the approval of Florida's plan to import safe and effective prescription drugs. While Big Pharma and federal bureaucracy have continued to stand in the way, it's past time Florida taxpayers realized savings on these drugs."

In May of this year, Governor Ron DeSantis toured the facility secured by Florida to warehouse drugs procured through this program and called on the Biden Administration and leadership at HHS to approve Florida's SIP. Further, on June 1, 2021, Florida filed an Amicus brief in support of the HHS final rule implementing Section 804 of the Federal Food, Drug and Cosmetic Act, to facilitate the importation of prescription drugs.

Within 90 days of approval by the FDA, the Agency for Health Care Administration will finally be able to physically import prescriptions drugs, ensure customs inspections are complete and proper testing has taken place, and then fulfilling state agency orders. The state will begin by providing prescription drugs in a small number of drug classes which will include maintenance medications to help individuals that have chronic health conditions such as asthma, COPD, diabetes, HIV/AIDS and mental illness. These drugs will be for individuals who are under the care of the Agency for Persons with Disabilities (APD), Department of Children and Families (DCF), Department of Corrections (FDC), and Department of Health (DOH).

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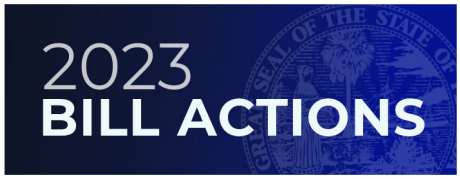
Comments are closed.



Contact Governor DeSantis

Executive Office of Governor Ron DeSantis
400 S Monroe St
Tallahassee, FL 32399
(850) 488-7146

Email Governor DeSantis

Email First Lady DeSantis

Email Lt. Governor Nuñez

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Scheduling Requests

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,	)	
	)	
Plaintiffs,	)	Case No: 4:22cv325
	)	
v.	)	Tallahassee, Florida
	)	October 12, 2022
SIMONE MARSTILLER, et al.,	)	
	)	9:33 AM
Defendants.	)	
_____	)	

TRANSCRIPT OF PRELIMINARY INJUNCTION PROCEEDINGS
BEFORE THE HONORABLE ROBERT L. HINKLE
UNITED STATES CHIEF DISTRICT JUDGE
(Pages 1 through 120)

Court Reporter: MEGAN A. HAGUE, RPR, FCRR, CSR
111 North Adams Street
Tallahassee, Florida 32301
megan.a.hague@gmail.com

Proceedings reported by stenotype reporter.
Transcript produced by Computer-Aided Transcription.

Q. Psychological conditions?
A. I do not make diagnoses, but we're trained in psychology and psychiatry. It's part of our medical licensing.
Q. Okay. But you are not a practicing psychologist?
A. That's correct.
Q. And you're not a practicing psychiatrist?
A. That's correct.
Q. And you have not met with any of the plaintiffs in this matter --
THE COURT: Mr. Charles, I sat through the voir dire. I'm not going to sit through it again on cross. You get one chance to ask some questions. You've asked those. Let's ask some new ones.
MR. CHARLES: Thank you, Your Honor.
BY MR. CHARLES:
Q. Dr. Laidlaw, you stated you don't follow the WPATH standards of care; is that right?
A. Yes.
Q. But you testified earlier you don't treat gender dysphoria; is that correct?
A. I don't treat gender dysphoria with hormones and surgeries.
Q. Dr. Laidlaw, are you aware that your opposition to gender-affirming care for the treatment of gender dysphoria in youth and adults is contrary to the vast majority of medical associations' recommendations?

A. Yes.
Q. Dr. Laidlaw, can you see the screen share that I've just enabled?
A. Yes, I can.
MR. CHARLES: Your Honor, can you see that as well?
THE COURT: I can. It's hiding under the table up here, but I've got it.
MR. CHARLES: Okay.
BY MR. CHARLES:
Q. Dr. Laidlaw, are you aware that the American Academy of Child and Adolescent Psychiatry supports gender-affirming care for youth?
A. I haven't looked at that specifically.
Q. Okay. And looking at the document here, I'll --
MR. CHARLES: Let me ensure -- Defense Counsel, can you view this document?
MR. PERKO: Yes.
MR. CHARLES: Okay. So I'd like to enter this as Exhibit P1.
BY MR. CHARLES:
Q. This is the -- Dr. Laidlaw, this is the "American Academy of Child and Adolescent Psychiatry Statement Responding to Efforts to Ban Evidence-Based Care for Transgender and Gender-Diverse Youth."
Do you see that?

A. Yes.
Q. And it's dated November 8, 2019?
A. Yes.
Q. And if you could, just read aloud for me that highlighted portion, please.
A. Sure.

Many reputable professional organizations, including the American Psychological Association, the American Psychiatric Association, the American Academy of Pediatrics, and the Endocrine Society, which represent tens of thousands of professionals across the United States, recognize natural variations in gender identity and expression and have published clinical guidance that promotes nondiscriminatory, supportive interventions for gender-diverse youth based on the current evidence base. These interventions may include, and are not limited to, social gender transition, hormone-blocking agents, hormone treatment, and affirmative psychotherapeutic modalities.

The American Academy of Child and Adolescent Psychiatry supports the use of current evidence-based clinical care with minors. AACAP strongly opposes any efforts -- legal, legislative, and otherwise -- to block access to these recognized interventions.

Q. Thank you.

THE COURT: You apparently asked to have this admitted into evidence. I don't think I've seen this, so this may not

have been in the record previously.

MR. CHARLES: Just one moment, Your Honor.

It wasn't, Your Honor, but I do have copies I can provide to the Court to so enter.

THE COURT: Didn't I require disclosures before today? If I didn't, it would certainly depart from the standard of care for judges.

MR. CHARLES: I apologize, Your Honor. I wasn't -- I didn't see that designation so -- in your order.

THE COURT: I may not have.

Do you object to the admission of this?

MR. PERKO: Yes, Your Honor, for the reasons you just stated.

Also, I would suggest that it's really irrelevant to this witness's testimony because it talks about the American Psychological Association. He's already testified he's not a psychologist.

THE COURT: You can't have it both ways.

I'll admit it subject to going back and looking at the scheduling orders and --

(Discussion was held.)

BY MR. CHARLES:

Q. Dr. Laidlaw, is what you just read consistent with your understanding of the position of these organizations?

A. Are you talking about the AACAP?

Q. Yes, let's start with that one.
A. Well, I'm just reading it now for the first time, so it must be -- it was 2019 -- unless they have changed their opinion.
Q. Okay. But you don't have any --
THE COURT: Let me just back up. I'm going to exclude the exhibit. I did require things to be disclosed, and you can't come up to the hearing and bring up a new exhibit that you didn't timely disclose.
MR. CHARLES: Okay.
THE COURT: So Plaintiffs' 1 is excluded.
The scheduling order is ECF No. 32.
MR. CHARLES: Okay. Thank you, Your Honor.
Ms. Markley, you can unpublish, please. Thank you.
BY MR. CHARLES:
Q. Dr. Laidlaw, are you aware that the American Academy of Family Physicians supports gender-affirming care for youth and adults?
A. Supports gender-affirming care for youth and adults?
Q. Yes. Do you need to me to repeat? Did you hear that?
A. They probably do. I don't know their exact statement.
Q. Okay. Are you aware that the American Academy of Family Physicians published a policy statement in July of 2022, approved by their board of directors, entitled "Care for the Transgender and Gender Nonbinary Patient"?

A. I have not read that particular document -- Family Practice Document.
Q. Okay. Are you aware that the American Academy of Family Physicians supports gender-affirming care as an evidence-informed intervention that can promote permanent health equity for gender-diverse individuals?
MR. PERKO: Your Honor, I would object for the same reasons. He's essentially reading from an exhibit that was not disclosed.
THE COURT: He's now exploring the witness's knowledge of the situation in the field. The objection is overruled.
BY MR. CHARLES:
Q. Dr. Laidlaw --
A. I'm not a family practice physician, so I don't keep up with --
Q. Just a moment. Sorry. Let me start over.
A. -- the literature of that organization.
Q. I'm sorry. Can you please repeat that?
A. I said I'm not a family practice physician; I'm an endocrinologist, so I don't keep up with whatever they're publishing.
Q. Okay. So I -- let me just ask you one more question about that brief -- or policy statement. Excuse me.
Are you aware that the American Academy of Family Physicians asserts the full spectrum of gender-affirming health

care should be legal and should remain a treatment decision between a physician and their patient?
A. I'm not surprised.
Q. Can -- so does that mean you are or are not aware?
A. I don't read the Family Practice documents, unless they are provided to me.
Q. Dr. Laidlaw, are you aware the American Academy of Pediatrics supports gender-affirming care for youth?
A. Yes.
Q. Dr. Laidlaw, are you aware that the American College of Obstetricians and Gynecologists has recommendations and conclusions that support gender-affirming care for youth and adults?
A. I'm not -- again, I'm not surprised, but I don't read their literature regularly for that purpose.
Q. Okay. Are you aware that the American College of Obstetricians and Gynecologists has conclusions that gender-affirming hormone therapy is not effective contraception?
A. That gender-affirming therapy is not effective contraception?
Q. Correct.
A. I have read that. I'm not sure if it was theirs or someone else who is publishing that. I'm aware of that concept.
Q. Can you repeat your answer? I didn't understand you.
A. I said I haven't read their statements specifically, but

I'm aware of the concept or proposition that gender-affirming hormones are not effective contraception.

Q. Okay. So you're not aware of the American College of Obstetricians and Gynecologists conclusion that it is not effective contraception?

A. I have not read their particular conclusion.

Q. Are you aware that the American College of Physicians, the largest medical specialty society in the world with 160,000 internal medicine and subspecialty members, supports public and private health care coverage of gender-affirming care?

A. I'm not aware that all 160,000 members voted to approve such a thing, but I'm aware that they have issued a statement like that.

Q. You are aware they issued such a statement?

A. Yes.

Q. Are you aware that in 2022, the American College of Physicians issued a brief supporting access to gender-affirming care and opposing discriminatory policies enforced against LGBTQ people and objected, in particular, to the interference with the physician-patient relationship and the penalization of evidence-based care?

A. I may have read that particular statement from that organization.

Q. Are you aware that the American Medical Association supports gender-affirming medical care for youth and adults?

A. Yes.
Q. Are you aware that in April of 2021, the American Medical Association wrote a letter to the National Governors Association objecting to the interference with health care of transgender children?
A. I believe I had come across that headline.
Q. Are you aware that the American Medical Association, in conjunction with GLMA, has issued a brief in support of public and private insurance coverage of gender-affirming care?
A. I'm not a member of the American Medical Association. I think only 20 percent of physicians in the nation are even a member. So I don't follow everything they say, but I do believe I read that document.
Q. Do you have evidence to support your assertion that only 20 percent of medical practitioners in the United States are members of the AMA?
A. I don't have a piece of paper with evidence, but that's my general understanding. I'm not a member.
Q. But you don't have any evidence today to point to to support that assertion?
A. No.
Q. Are you aware that in 2022, the American Medical Association reaffirmed it's resolution in support of private and public health care coverage for the treatment of gender dysphoria as recommended by a patient's physician in Resolution

Number 158.950?
A. I have not read that resolution.
Q. Are you aware, Dr. Laidlaw, that the American Psychological Association has guidelines that support access to gender-affirming care for youth and adults?
A. Yes.
Q. Are you aware that the American Psychological Association opposes gender-identity change efforts as a broad practice described as a range of techniques used by mental health professionals and nonprofessionals with the goal of changing gender identity, gender expression, or associated components of these, to be in alignment with gender role behaviors stereotypically associated with their sex assigned at birth?
A. Yes, I am aware.
Q. Are you aware that the American Psychiatric Association supports gender-affirming medical care for youth specifically?
A. Yes.
Q. Are you aware that the American Psychiatric Association has a position statement from 2018, supporting access to care for transgender and gender-variant individuals broadly?
A. Yes, I believe so.
Q. Are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that there is a durable biological underpinning to gender identity that should be considered in policy determinations?

A. I would have to read -- I have not read that particular statement from the Endocrine Society. I would like to see that before I make a -- conclude anything.
Q. Okay. Are you aware this determination was included in a position statement published in December of 2020?
A. I have read that position statement.
Q. And are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that medical intervention for transgender youth and adults is effective, relatively safe when appropriately monitored, and has been established as the standard of care?
A. Well, they wrote that it was not the standard of care in 2017, so they're contradicting themselves.
Q. Dr. Laidlaw, are you aware that that statement is contained in the transgender health position statement issued December 2020?
A. I believe I read that.
Q. And are you aware that the Endocrine Society and the Pediatric Endocrine Society take the position that federal and private insurers should cover such interventions as prescribed by a physician, as well as the appropriate medical screenings that are recommended for all body tissues that a person may have?
A. I believe I read something along those lines.
Q. Are you aware that the Pediatric Endocrine Society supports

gender-affirming care for youth?
A. Yes.
Q. Are you aware they published a position statement to that effect in April of 2021?
A. Yes. I wrote an article describing why their conclusions are false or incorrect.
Q. Are you aware the Pediatric Endocrine Society recommends an affirmative model of care that supports one's gender identity and follows a multidisciplinary approach that includes involvement of mental health professionals, patients and their families. Puberty suppression and/or gender-affirming hormone therapy is recommended within this evidence-based approach on a case-by-case basis as medically necessary and potentially lifesaving.
Are you aware that was contained in the Pediatric Endocrine Society statement?
A. I am aware that it's contained. I don't agree with it, but, yes, I'm aware.
THE COURT: If we're leading up to something, you can go ahead with all of this. If all you're doing is publishing stuff I've already read --
MR. CHARLES: No, Your Honor.
THE COURT: You're welcome to make a closing argument later and to go through all of this, but if -- this is an incredibly inefficient way to publish material.

MR. CHARLES: Your Honor --

THE COURT: So if that's all we are doing, let's move on.

MR. CHARLES: Thank you, Your Honor. I'm -- I do have a final comment for Dr. Laidlaw related to --

THE COURT: I've been patient through all that, and if you're setting up another question, that's fine.

MR. CHARLES: Okay. Thank you, Your Honor.

Just two more documents. I appreciate your patience.

BY MR. CHARLES:

Q. Dr. Laidlaw, are you aware the Society for Adolescent Health and Medicine supports gender-affirming care for youth?

A. No.

Q. Are you aware the Society for Adolescent Health and Medicine issued a statement in opposition to state legislation barring evidence-based treatment?

A. No.

Q. And, Dr. Laidlaw, are you aware that the World Medical Association, which includes 115 national medical associations, supports gender-affirming care?

A. No.

Q. So, Dr. Laidlaw, you're aware that your opinions related to gender-affirming care are in contrast to all of those medical associations' statements that we just reviewed?

MR. PERKO: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: Yeah. Sorry. Could you repeat the question?

BY MR. CHARLES:

Q. You are aware that your opinions against gender-affirming care for the treatment of gender dysphoria are contrary to the positions of the medical associations' statements we just reviewed?

A. Yes.

MR. CHARLES: Just one moment, Your Honor.

(Discussion was held.)

MR. CHARLES: No further questions, Your Honor.

THE COURT: Redirect?

MR. PERKO: Very briefly, Your Honor.

May it please the Court.

REDIRECT EXAMINATION

BY MR. PERKO:

Q. Dr. Laidlaw, you testified that you consider mental health effects of hormone therapy in your practice; is that correct?

A. That is correct.

Q. Okay. And why do you consider the potential mental health effects of hormone therapy in your practice?

MR. CHARLES: Objection, Your Honor.

THE COURT: Overruled.

THE WITNESS: To give you maybe a more concrete

This is not quite an administrative review, but it's not that far off from it.

Tell me how long do you think -- I probably should have asked before I told you I was going to deny the preliminary injunction because answers change depending on which side thinks they won the preliminary injunction motion.

How long do you think you need to present this case fully? And if the answer is "I don't know," I guess I can just tell you to go talk to each other. But if you can give me a rough ballpark at this point, it will help.

MR. JAZIL: Your Honor, I'm happy to confer with my colleagues for the other side and get back to the Court.

THE COURT: It seems to me that you want to find out about the plaintiffs and their doctors and that's about it; right? I mean, you had all you had when you adopted the rule.

MR. JAZIL: Yes, Your Honor. I suppose -- there's a footnote in *Rush v. Parham* that discusses -- well, in my mind it opens up the possibility of additional evidence to provide to the Court on whether or not this is or isn't experimental, but --

THE COURT: At least tentatively I think that's right. I think the question is for me to decide based on the federal trial whether the State's determination is reasonable or not, and I think *Rush* says that's not an administrative review of what the State knew at the time. It's the question at the --

based on the evidence presented at the trial. So, yes, I think that's right.

MR. JAZIL: That's right.

THE COURT: And that goes back to my questions about the Florida administrative procedure. In a rule challenge in state court, they might be stuck with the record they put together to adopt the rule, but I don't think that's the case here.

MR. GONZALEZ-PAGAN: Your Honor, if I may, I just have a question on the Court's ruling.

Will the Court include in its order for representation as to what counsel has stated here today that there is a waiver procedure?

THE COURT: Yes, I will.

MR. GONZALEZ-PAGAN: Thank you, Your Honor.

THE COURT: I hope I express it accurately. I'll try to have it in -- an accurately narrow statement of the availability of an exception.

MR. JAZIL: Thank you, Your Honor.

THE COURT: You gave me a cite, and I didn't --

MR. JAZIL: Yes, Your Honor. It's 120.542.

THE COURT: 120.54(2)?

MR. JAZIL: No, Your Honor. It's, I think, 120.542.

Your Honor, with the Court's indulgence, I have one other issue. The trial date is set for August 7th. I'm in a

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF STEPHEN B. LEVINE, M.D.

TABLE OF CONTENTS

I. CREDENTIALS

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters' and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have published *Psychotherapeutic Approaches to*

Sexual Problems (2020). The book has a chapter titled "The Gender Revolution."

4. In total I have authored or co-authored over 180 journal articles and book chapters, 27 of which deal with the issue of gender dysphoria. I was an invited member of a Cochrane Collaboration subcommittee that sought to publish a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a

new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation").

9. In 2019, I provided written expert testimony in the landmark case in the United Kingdom in the case of *Bell v. The Tavistock and Portman NHS Foundation Trust*. I have provided expert testimony in other litigation as listed in

my curriculum vitae, which is attached as Exhibit "A".

10. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. In May 2022, I organized and co-presented a symposium on the management of adolescent-onset transgender identity at American Psychiatric Association's Annual Meeting.

11. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit "A".

12. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMARY

1. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section III.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeconomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section III.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children or adolescents. There are no generally accepted "standards of care" and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. The scientific basis for affirmative care is uncertain. (Section III.)

d. Transgender identity is not biologically based. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections V.A, IV.B.)

e. Disorders of sexual development ("DSDs") are biological phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections V.C, V.D.)

f. The large majority of children who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by

puberty or adulthood. Desistance is also increasingly observed among teens and young adults who have experienced "rapid onset gender dysphoria" — first manifesting gender dysphoria during or shortly after adolescence. (Section VI.A., VI.B.)

g. "Social transition" —the active affirmation of transgender identity—in young children is a powerful psychotherapeutic intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of "affirmative" treatment—which include taking puberty blockers and cross-sex hormones—must be taken into account where social transition is being considered. (Section VII.A,, VII.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VII.C.)

i. The knowledge base concerning the "affirmative" treatment of gender dysphoria available today has very low scientific quality with many relevant long-term implications remaining unknown. (Section VIII.A)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves

long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section IX.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and life- long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BACKGROUND ON THE FIELD

A. The biological baseline of the binary sexes

19. Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

20. Sex is not "assigned at birth" by humans visualizing the genitals of a newborn; it is not imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. A publication of the federal government's National Institute of Health accurately summarizes the scientific facts:

> "Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex— making up tissues and organs, like your skin, brain, heart, and
> stomach. Each cell is either male or female depending on whether you are a man or a woman." (NIH 2022.)

21. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014 the NIH has required all funded research on humans or vertebrate animals to include

"sex as a biological variable" and give "adequate consideration of both sexes in experiments." (NIH 2015). In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that "Sex is a biological concept . . . all mammals have 2 distinct sexes;" that "biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;" and that "In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits." (Bhargava et al. 2021 at 221, 229.)

22. The Endocrine Society emphasized that "The terms sex and gender should not be used interchangeably," and noted that even in the case of those "rare" individuals who suffer from some defect such that they "possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or female." They concluded, "Sex is an essential part of vertebrate biology, but gender is a human phenomenon. Sex often influences gender, but gender cannot influence sex." (Bhargava et al. 2021 at 220-221, 228.)

23. As these statements and the NIH requirement suggest, biological sex pervasively influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine

Society and countless other researchers have

determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava et al. 2021 at 225, 229; Blakemore et al. 2010 at 926-927, 929; NIH

2001.).

24. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of "gender identity" as something distinct from sex is a rather recent innovation whose earliest manifestations likely began in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual-centric and subjective. In a statement on "Gender and Health," the World Health Organization defines "gender" as "the characteristics of women, men, girls and boys that are socially constructed" and that "var[y] from society to society and can change over time," and "gender identity" as referring to "a person's deeply felt, internal and individual experience of gender." (WHO Gender and Health.) As these definitions indicate, a person's "felt" "experience of gender" is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual's *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically,

gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

25. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated

gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Is it a product of the quality of early life caregiver attachments? Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma? Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse? Is it a symptom of another, as of yet, unrevealed, emotional disturbance or neuropsychiatric condition (autism)? The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult.

26. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies

continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, internal organ size, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the evolution and consolidation of gender identity during childhood, adolescence, and adulthood.

27. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail

later.

B. Definition and diagnosis of gender dysphoria

28. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5-TR") employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

29. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. (Levine 2021.)

30. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018 at 10.) The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to

another.

31. The criteria used in DSM-5-TR to identify Gender Dysphoria include a number of signs of discomfort with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings. The symptoms must persist for at least six months.

32. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child's—or even an adolescent's—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile (Levine et al, 2022). These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

33. Given that, as I discuss later, a diagnosis of gender dysphoria is now

frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups are receiving this diagnosis at disproportionately high rates. These include: children of color (Rider et al. 2018), children with mental developmental disabilities (Reisner et al. 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer et al. 2016; van der Miesen et al. 2018), children with ADHD (Becerra-Culqui et al. 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer et al. 2017), victims of childhood sexual or physical abuse or other "adverse childhood events" (Thoma 2021 et al.; Newcomb et al. 2020; Kozlowska et al.,2021), children with a prior history of psychiatric illness (Edwards-Leeper et al. 2017; Kaltiala- Heino et al. 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider et al. 2018 at 4).

D. Three competing conceptual models of gender dysphoria and transgender identity

34. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the

distinctions.

35. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable to diseases that are curable before it spreads, such as melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

36. Gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in DSM-III in 1983, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

37. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this

axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play and adolescents work out their issues by adopting various interests and identity labels.

38. There is evidence among adolescents that peer social influences through "friend groups" (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being "tried on" by the youth as part of the adolescent process of self-exploration and self-definition.

39. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes

gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I review later, however, this assertion is not supported by science.[1]

40. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful perspective that exists in the public, non- scientific debate.

E. Four competing models of therapy

41. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of childhood and adolescent development equally applies to

[1] Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." https://www.hrc.org/resources/glossary-of-terms.

trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long term outcomes. They have not been. When we add to this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The "watchful waiting" therapy model

42. In Section V.A below I review the uniform finding of eleven follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated by social transition approaches.

43. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve— that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. Treating any other psychological co-morbidities—that is, other mental illnesses as defined by DSM-5-TR (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive

compulsive disorder, etc), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender (**model #1**); and

b. No treatment at all for anything but a regular follow-up appointment. This might be labeled a "hands off" approach **(model #2**).

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

44. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

45. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine 2017 at 8; Spiliatis 2019; Levine 2021.Levine et al, 2022) I and others have reported success in alleviating distress in this way for at least some patients, whether the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared or not. Relieving

accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

46. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others' feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

47. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. They may enable the patient

to understand the commonality of discomfort with the body's physiology, the growth process, and the struggle to accept oneself during the pubertal developmental process. Patients need to understand that this discomfort with one's body, per se, and one's attractiveness relative to others, typically lasts for several years. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

48. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

49. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male

gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. There are now a series of articles and at least one major book on the psychological treatment of adolescents. (D'Angelo et al. 2021 at 7-16; Evans & Evans 2021.) Among detransitioners, a large percentage express regret that their affirmative therapists did not recommend psychotherapy before encouraging hormonal treatment (*Littman, (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. Archives of Sexual Behavior, 50(8)3353-3369). Exposito-Campos pointed out the large amount reports on detransition and the far greater traffic on various nonprofessional websites (Exposito-Campos, 2021)*

(3) The affirmation therapy model (model #4)

50. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively re-socialized in grade school in their aspired-to gender. As I understand it, this is asserted as a reason why male students who assert a female gender identity must

be permitted to compete in girls' or women's athletic events. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

51. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. This claim is simply not supported by the clinical data we have available to us. Indeed, available long-term data contradicts this claim. I address physical and mental health outcomes in Section VII below, and suicide in Section VIII below.

52. The commonly referenced scientific basis for affirmative care of both early life onset and adolescent onset gender dysphoria are two reports from deVries et al (2011, 2014) that seemingly demonstrated the resolution of gender dysphoria after a sequence of puberty blocking hormones, cross-sex hormones, and breast removal or vaginoplasty. However, recently three articles describing the distinct limitations of the "Dutch Protocol have been widely circulating throughout the world (Levine et al, 2022; Biggs, 2022, Abbruzzese et al, 2023) It is now apparent that the basis for such affirmative care is not scientifically solid. Rapid diffusion of the innovative Dutch Protocol occurred without the scientifically

required confirmatory more rigorous studies. The one attempt to repeat their protocol in the UK failed to demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021).

53. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with by each of them.

54. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. This, however, requires time and effort and for many parents, a challenge to find a therapist to do such work with them.

IV. THERE IS NO CONSENSUS OR AGREED "STANDARD OF CARE" CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

55. There is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither surprising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria.

56. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people." (RANZCP, 2021.) Similarly, a few years earlier prominent Dutch researchers noted: "[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child — such as social transition." (Ristori & Steensma 2016 at 18.)[2] In this Section, I comment on some of the more important areas of disagreement within the field.

[2] *See also* Zucker 2020 which questions the merit of social transition as a first-line treatment.

A. Experts and organizations disagree as to whether "distress" is a necessary element for diagnoses that justifies treatment for gender identity issues.

57. As outlined in Section II.B above, "clinically significant distress" is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and their gender identity choose not to take hormones; their incongruence is quite tolerable as they further clarify their sexual identity elements. This population raises the questions of what distress is being measured when DSM-5-TR criteria are met and what else might be done about it.

58. I note that there is no "clinically significant distress" requirement in World Health Organization's International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates "a marked and persistent incongruence between an individual´s experienced gender and the assigned sex." (World Health Organization 2019.)

59. Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the DSM-5-TR criteria, prescribing transition for children, hormonal

interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity whether or not they are exhibiting "clinically significant distress." Others adhere to the DSM-5 diagnostic standard.

60. It is ironic that affirmative care is said by advocates to be life enhancing and often to be lifesaving because of the risk of suicide. Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical treatments. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of Gender Incongruence do not require distress, just the wish to have the characteristics of the other sex and to change their own sex demarcating features. It seems that as the field moves on in time, the emphasis is on desire rather than distress, pain, or suffering.

61. I will add that even from within one "school of thought," it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans identified youth must be treated in a particular manner

to avoid harm for two reasons: first, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary.

B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

62. The World Professional Association for Transgender Health (WPATH) has published a guidance document under the title of "standards of care." Below, I will provide some explanation of WPATH and its "Standards of Care," which are not the product of a strictly scientific organization, and are by no means accepted by all or even most practitioners as setting out best practices.

63. Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH "Standards of Care version 7" states that the question of social transition for children is a "controversial issue" and calls for mental health professionals to support families in what it describes as "difficult decisions" concerning social transition. Its version 8, however, no longer uses the word "controversial" even though it extensively discusses the dangers of harms versus the possibility of benefits of early transition (Coleman et al, 2022).

64. Dr. Erica Anderson is a prominent practitioner in this area who

identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that "adolescents . . . are notoriously susceptible to peer influence," that transition "doesn't cure depression, doesn't cure anxiety disorders, doesn't cure autism-spectrum disorder, doesn't cure ADHD," and instead that "a comprehensive biopsychosocial evaluation" should proceed allowing a child to transition. (Davis 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

C. The WPATH "Standards of Care" is not an impartial or evidence-based document.

65. Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its "Standards of Care."

66. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its

recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Harry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health (WPATH).

67. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.

68. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately

reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

69. The reviews of WPATH's 7th edition of standards of care published in 2021 by Dahlen et al and Sapir in 2022 have clarified the low quality, low reliability, and bias inherent in its recommendations. (Dahlen et al 2022) Its 8th edition, which is three times the length of the 7th, has not gained additional confidence in its scientific merit. The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. It articulates policy. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger 2015.McNamarra et al 2022) .

70. In recent years, WPATH has fully adopted some mix of the medical

and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In actual practice, that thoughtful person may be as young as age 11!

71. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self- selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

72. In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be

identified in the DSM as a pathology.[3] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

73. In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric co- morbidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. The 8th version of the SOC continues this tradition. When this document recommends a comprehensive psychiatric evaluation, it fails to elaborate its duration, the topics to be covered, and necessary treatment results of the commonly found previous and co-current psychiatric conditions.

[3] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

74. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology. Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper & Anderson 2021; Davis 2022.)

75. In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing "the importance of the psychiatrist's role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating." The

Royal College also emphasized the importance of assessing the "psychological state and context in which Gender Dysphoria has arisen," before any treatment decisions are made. (RANZCP, 2021.)

76. Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, "The WPATH has rejected psychological counseling as a viable means to address sex– gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful (Coleman et al. 2012). Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984)." (Hruz 2020.)

77. In several recent publications, my colleagues and I have demonstrated that both the Endocrine Society's and WPATH's citations for the scientific basis of affirmative care of adolescents reference the same two Dutch studies. We have demonstrated in considerable details the limitations of these studies, their lack of applicability to today's transgendered youth, and the dangers of following therapeutic fashion rather than evidence-based medicine (Levine et al, 2022; Abbruzzese et al, 2023).

E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

78. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standards of Care explicitly recognize the

lack of any consensus on this important point, stating: "Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings."

79. The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the "Dutch Protocol" allows. (Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross gender identity from early childhood; dysphoria that worsened with the onset of puberty; were otherwise psychologically healthy; had healthy families; the patient and family agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact (de Vries 2020).

80. However, Zucker notes that "it is well known" that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by that "Dutch Protocol." (Zucker 2019 at 5.)

81. Similarly, at least one prominent clinic—that of Dr. Safer at Columbia's Mt. Sinai Medical Center—is quite openly admitting patients for even *surgical* transition who are not eligible under the criteria set out in WPATH's Standards of Care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery "immediately" under the center's own criteria, while only 15% were eligible under WPATH's criteria. That is, *three times* as many patients immediately qualified for surgery under the center's loose standards than would have qualified under WPATH criteria. (Lichenstein et al. 2020.)

82. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden has declared that it will no longer authorize use of puberty blockers for minors below the age of 16. Finland has similarly reversed its course, issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK's National Health Service in 2020 by "detransitioner" Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as

prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE 2021a; NICE 2021b).[4] That review in 2022 reorganized trans adolescent care throughout the UK and emphasized the need to focus on the patients' psychological state rather than treat first the gender incongruence. Puberty blockers are not to be initially employed.

83. In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (Ghorayshi 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper & Anderson 2021; Davis 2022.) It is evident that opinions and practices are all over the map.

1. In 2018, committee of the American Academy of Pediatricians issued a policy statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. No other American medical association has endorsed the use of puberty blockers. Pediatricians are neither endocrinologists nor psychiatrists. Many pediatricians were horrified by the recommendation. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement was not

[4] The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

evidence- based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor's analysis. But this is all part of ongoing debate, simply highlighting the absence of any generally agreed standard of care. In 2022, the same committee of the AAP modified their recommendation supporting alternative treatments but still held out that affirmative care is still a viable option. Evidence after all is required for policy decisions and the 2018 evidence base is now widely appreciated as insubstantial.

84. The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* "standards of care." The document states: "The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care*. The guidelines are not intended to dictate the treatment of a particular patient." (Hembree et al. 2017 at 3895 (emphasis added).) Nor do the Guidelines claim to be the result of a rigorous scientific process. Rather, they expressly advise that their recommendations concerning use of puberty blockers are based only on "low quality" evidence.

85. The 2017 Guidelines assert that patients with gender dysphoria often must be treated with "a safe and effective hormone regimen. . ." Notably, however, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than "suggest[ing]" use of puberty blockers—language the Guidelines warn represents

only a "weak recommendation." (Hembree 2017 at 3872.) Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of "low quality" evidence, but its not-quite claims of 'safety' and 'efficacy' are starkly contradicted by several in-depth evidence reviews. (Laidlaw et al., 2019; Malone et al. 2021.) The most recent systematic independent review of hormonal treatment of adolescents reaffiremed the poor quality of evidence making their use questionionalble (Brignardello-Peterson, & Wiercioch 2022). I detail these contradictory findings in more detail in Section VII below.

86. While there is too little meaningful clinical data and no consensus concerning best practices or a "standard of care" this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

87. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, principles of medical ethics prohibit the treatment.

V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

88. There is no medical consensus that transgender identity has any biological basis. Furthermore, there is considerable well-documented evidence that is inconsistent with the hypothesis of a biological basis for gender identity—at least in the large majority of currently-presenting patients.

A. No theory of biological basis has been scientifically validated.

89. At the outset, the attempt to identify a single, biological cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as "out of step with the rest of medicine" and as a lingering "ghost" of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition. Courts need to have clarified that just because some physicians use medication and surgery to treat gender dysphoria does not make it a "medical condition" or that the psychological identity has been determined by a biological mechanism.

90. While some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat et al. 2015 at 202; Frigerio et al. 2021.)

91. Indeed, the Endocrine Society 2017 Guidelines recognizes: "With

current knowledge, we cannot predict the psychosexual outcome for any specific child" and "there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty." (Hembree et al. 2017 at 3876.)

92. In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse the two.

B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

93. In fact, there is substantial evidence that the "biological basis" theory is incorrect, at least with respect to the large majority of patients presenting with gender dysphoria today.

94. **Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations.

Recent surveys estimate that between 2-9% of high school students self- identify as transgender or "gender non-conforming." with a significantly large increase in adolescents claiming "nonbinary" gender identity as well. (Johns et al. 2019; Kidd et al. 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino et al. 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

95. **Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019 at 2.) This phenomenon has been noted by Dr. Erica Anderson, who said: "The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a change in the last couple of years. And it's an open question: What do we make of that? We don't really know what's going on. And we should be concerned about

it." (Davis 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

96. **Clustering**: Dr. Littman's recent study documented "clustering" of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2018.)

97. **Desistance:** As I discuss later, there are very high levels of desistance among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to "affirm" that trans-identity, and then "desisted" and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

98. **"Fluid" gender identification:** Advocates and some practitioners assert that gender identity is not binary but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.[5]) I have not heard any theory offered for how there is or could be a biological basis for gender identity as now expansively

[5] Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.html

defined.

99. I frequently read attempts to explain away the points in this Section V. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their trans identity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all mere hypotheses unsupported by concrete evidence. One set of unproven hypotheses cannot provide support for the unproven hypothesis of biological basis. And none of these hypotheses could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification.

100. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a "unique predictor of

persistence." (See Section VI.B below.) Again, this observation cuts against the hypothesis of biological origin.

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

101. Some have pointed individuals who suffer from disorders of sexual development (DSDs) as evidence that sex is not binary or clearly defined, or as somehow supporting the idea that transgender identification has a biological basis. I have extensively detailed that sex is clear, binary, and determined at conception. (Section III.) Here I explain that gender dysphoria is an entirely different phenomenon than DSDs—which unlike transgender identity are indeed biological phenomena. It is an error to conflate the two distinct concepts.

102. Every DSD reflects a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: "Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in sexual development*." Gender Identity on the other hand is uniformly defined as a subjective "sense" of being, a feeling or state of mind. (Section II.C.)

103. The vast majority of those who experience gender dysphoria, or a

transgender identity, do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those who suffer from a DSD, nor are those who suffer from a DSD a subset of those

who suffer from gender dysphoria. The two are simply different phenomena, one physical with psychological effects , the other mental with physical effects only if treated medically or surgically. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

104. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have "normal endocrine function and karyotype consistent with birth registered sex." (Carmichael et al. 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, to ensure the study was focused only on individuals experiencing the psychological effects of what we might call "ordinary" gender dysphoria.

D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but provide no support for a biological basis for *trans*gender identification.

105. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support.

106. One well-known study by Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals born with severe DSDs who were surgically "feminized" in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental "affirmation" in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male

gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

107. Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *trans*gender identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for

*trans*gender identity. A second study in this area (Reiner & Gearhart 2004) likewise considered exclusively XY subjects, and similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions. None of this provides any evidence at all of a biological basis for transgender identity.

VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

108. There is extensive evidence that gender identity changes over time for many individuals.[6] That evidence is summarized below.

A. Most children who experience gender dysphoria ultimately "desist" and resolve to cisgender identification.

109. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

110. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition."

[6] See n1 *supra*.

(Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." (Adelson et al. 2012 at 963; see also Cohen-Kettenis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to initiate puberty blockers was that it was well known that many children would desist if left free of hormonal intervention until that age.

111. Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2018.)

112. As I explained in detail in Section V above, it is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

113. It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile's gender dysphoria. A 2016 study reviewing the follow-up literature noted that "the period between 10 and 13 years" was "crucial" in that "both persisters and desisters stated that the changes in their social environment, the anticipated and

actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort." (Ristori & Steensma 2016 at 16.) As I discuss in Section VII below, there is considerable evidence that early transition and affirmation causes far more children to persist in a transgender identity.

B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

114. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I have observed an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young "detransitioners" (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels.

115. Almost all scientific articles on this topic have appeared within the last few years.

Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was "socially controversial" in that it "poses significant

professional and bioethical challenges for those clinicians working in the field of gender dysphoria." (Expósito Campos 2021 at 270.) This review reported on the multiple reasons for why individuals were motivated to detransition, which included coming to "understand[ ] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD."

116. In 2021, Lisa Littman of Brown University conducted a ground-breaking study of 100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then "detransitioned" or changed back to a gender identity matching their sex. Littman noted that the "visibility of individuals who have detransitioned is new and may be rapidly growing." (Littman 2021 at 1.) Of the 100 detransitioners included in Littman's study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their natal sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. (Littman 2021 at 9.)

117. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021 at 11.)

118. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for detransitioning was the subject's

conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

119. The existence of increasing numbers of youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper & Anderson 2021.) Edwards-Leeper and Anderson noted "the rising number of detransitioners that clinicians report seeing (they are forming support groups online)" which are "typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it." Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

120. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle 2020; Littman 2021; Vandenbussche 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

121. A recent study from a UK adult gender clinic observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding

a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." (Hall et al. 2021).

122. Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for an average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd et al. 2022 at 15.) Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 both report that detransitioners from the recently transitioning cohorts feel they were rushed into medical gender-affirmative interventions with irreversible effects, often without

the benefit of appropriate, or in some instances any, psychologic exploration.

VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.

A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral.

123. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistance, if it is ever considered, more difficult to accomplish.

124. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing pharmaceutical maintenance and will not have their fertility destroyed post-puberty.

125. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail in Section IX below), as well as being irreversibly sterilized chemically and/or surgically. The child is therefore rendered a "patient for life" with complex medical implications further to a scientifically

unproven course of treatment.

B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.

126. Social transition has a critical effect on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a psychotherapeutic intervention that dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." (Guss et al. 2015 at 421.) Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker 2018 at 7.)

127. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent

study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7[7]; Steensma et al. 2013.)[8] Another researcher observed that a partial or complete gender social transition prior to puberty "proved to be a unique predictor of persistence." (Singh et al. 2021 at 14.)

128. Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross- gender identification desist in that identification and return to a gender identity consistent with their biological sex.[9] This is a very large change as compared to the desistance rates documented apart from social transition.

129. Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: "If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty. . .

[7] Zucker found social transition by the child to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.)

[8] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

[9] *See, e.g.,* Ehrensaft 2015 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

[S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence." (Hembree et al. 2017 at 3879.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker 2020 at 1.)

130. Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a "conveyor belt" path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well- documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into account even where "only" social transition is being considered or requested by the child or family. As a result, there are a number of important "known risks" associated with social transition.

C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

131. It should be understood that puberty blockers are usually administered to early-stage adolescents as part of a path that includes social transition. Yet medicine does not know what the long- term health effects on

bone, brain, and other organs are of a "pause" between ages 11-16. Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this "pause" while one's peers are undergoing their maturational gains in these vital arenas of future mental health. I address medical, social, and mental health risks associated with the use of puberty blockers in Section X. Here, I note that the data strongly suggests that the administration of puberty blockers, too, must be considered to be a component of a "psychosocial treatment" with complex implications, rather than simply a "pause."

132. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world's largest gender clinic—found that 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. (Carmichael et al 2021 at 12.)[10]

133. These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Rather than a "pause," puberty

[10] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

blockers appear to act as a psychosocial "switch," decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

134. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Section III.C.) Whether the gender dysphoria is cause or effect of other diagnosed or undiagnosed mental health conditions, or whether these are merely coincident comorbidities, is hotly disputed, but the basic fact is not.

135. It is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data

comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future. Reliance on a well-known, or well-credentialled "experts" or head of a gender clinic is sometimes referred to as eminence-based medicine. Their opinions do not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

136. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment [T]he proposed benefits of

treatment to eliminate gender discordance … must be carefully weighed against … possible deleterious effects." (Adelson et al. at 968–69.) Similarly, the American Psychological Association has stated, "because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children." (APA 2015 at 842.)

137. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

138. Within the last two years, at least four formal, independent, systematic evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All four found all of the available clinical evidence to be very low quality.

139. The British National Health Service (NHS) commissioned formal "evidence reviews" of all clinical papers concerning the efficacy and safety of puberty blockers and cross- sex hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected "GRADE" criteria for

evaluating the strength of clinical evidence.

140. Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was "very low quality" according to the GRADE criteria. (NICE 2021a; NICE 2021b.) This work is sometimes referred to as the Cass Report.[11] "Very low quality" according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem et al. 2011.)

141. Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to "transitioning transgender women" (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 2.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments. Similarly, McMasters University's skillful

[11] https://cass.independent-review.uk/publications/ interim-report/

methodological unit recently reached the same conclusion (Brignardello-Peterson, & Wiercioch, 2022).

142. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. And for some, surgery before the age of majority. A decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected future interventions. Social transition, therefore, is not merely reversible behavioral change. It is the beginning of a medically dependent future and should be explained as such.

143. I discuss safety considerations in Section IX below. Here, I detail what is known about the effectiveness of social and hormonal transition and affirmation to improve the mental health of individuals diagnosed with gender dysphoria.

B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

144. As I noted above, the evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is "a high likelihood that the patient will not experience the hypothesized benefits of the treatment." There is now some concrete evidence that

on average they do not experience those benefits.

145. An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first longitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they "found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm" as compared to the pre-puberty-blocker baseline evaluations. "Outcomes that were not formally tested also showed little change." (Carmichael at al. 2021 at 18-19.) Similarly, a study by Bränström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

146. A cohort study by authors from Harvard and Boston Children's Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner et al. 2015 at 6.)

Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse "substantially higher than those reported by large population-based studies of youth and adults." (Newcomb et al. 2020 at 14.) Members of the clinical and research team at the prominent Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it "can . . . not provide evidence about . . . long-term mental health outcomes," and that based on what continues to be extremely limited scientific data, "Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution." In other words, we just don't know. (van der Miesen et al. 2020 at 703.)

147. Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and treated by mastectomy, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated "like guinea pigs," experimental subjects. They are not wrong.

148. A recent two-year prospective uncontrolled multisite NIMH study of 315 adolescents found that at the average age of 18 the primary benefit of hormones was happiness with their aesthetic appearance. The effects on

depression and anxiety were very small and highly variable. There were two suicides in the study population. (Chen et al, 2023). This work did not address the relevant long term mental health outcomes of such treatment before their two-year finding.

C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.

149. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient, but must instead consider the happiness and health of the patient from a "life course" perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

150. In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017 at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne et al. 2011; Simonsen et al. 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017 at 10.)

151. A study in the American Journal of Psychiatry reported high mental

health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Pachankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be provided very long-term psychiatric care as the "final" transition step of SRS. (Dhejne et al. 2011, at 6-7.) Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

152. The most recent all-cause mortality study from the UK found a significant excess of deaths among trans individuals compared to age matched controls of both sexes. External causes of death (suicide, homicide, accidental poisoning) were particularly higher than control groups (Jackson et al, 2023).

153. I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautious.

154. Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy.

155. The many studies that I have cited here warn us that as we look ahead to the patient's life as a young adult and adult, the prognosis for the physical health, mental health, and social well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not "easily managed" when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations.

IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

156. While suicide is closely linked to mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria.

157. At the outset, I will note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

158. Some authors have reported rates of suicidal thoughts and behaviors among trans- identifying teens or adults ranging from 25% to as high as 52%,

generally through non- longitudinal self-reports obtained from non-representative survey samples. (Toomey et al. 2018.) Some advocates of affirmative care assert that the only treatment to avoid this serious harm is to affirm gender identity. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response, as I have described above. Rhetorical references to figures such as 40%—and some published studies—confuse suicidal thoughts and actions that represent a cry for help, manipulation, or expression of rage with serious attempts to end life. Such statements or studies ignore a crucial and long-recognized distinction.

159. I have included suicidality in my discussion of mental health above. Here, I focus on actual suicide. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

160. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world's largest gender clinic—found a total of only four completed suicides across 11 years' worth of patient data, reflecting an estimated cumulative 30,000 patient-years spent by patients under the clinic's care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual

patients who died by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

161. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent "suicidality" commit suicide. I agree with Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are "alarmingly high" "has no formal and systematic empirical basis." (Zucker 2019 at 3.)

162. Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock clinic patients, rightly cautions that it is "irresponsible to exaggerate the prevalence of suicide." (Biggs 2022b at 4.) It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between "a live son or a dead daughter" is both factually wrong and unethical. Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply do not know the truth; they are ill-informed.

B. Transition of any sort has not been shown to reduce levels of suicide.

163. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults

before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that "solves the problem." Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016 at 242.)

164. This is all the more true because there is in fact no evidence that social and/or medical transition reduces the risk or incidence of actual suicide. As there are no long-term comparative studies of gender dysphoric adolescents with suicidal ideation, per se, let alone a comparative study of those who were given hormones and those who did not take hormones, there is no scientific basis for declaring affirmative care as reducing suicidal risk. In his analysis of those who were patients of or on the waiting list of the Tavistock clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic's waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022b.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients "demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts." (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to

predict a high rate of future suicide if not successfully addressed.")[12] Long-term life in a transgender identity, however, correlates with very high rates of completed suicide.

165. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

166. There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne reported a long-term follow-up study of subjects after sex reassignment surgery. Across the multi-year study, subjects who had undergone SRS committed suicide at 19.1 times the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9 times the expected rate, and FtM subjects committed suicide at 40.0 times the expected rate. (Dhejne et al. 2011 Supplemental Table S1.)

167. Asscheman, also writing in 2011, reported results of a long-term follow-up of all transsexual subjects of the Netherlands' leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331

[12] Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age- matched general population. (Asscheman et al. 2011.)

168. Importantly, Asscheman et al. found that "No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years." (Asscheman et al. 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al.'s data suggest that such short-term follow-up is engaging only with an initial period of optimism, and will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

169. A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was "three to four times higher than the general Dutch population." "[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment." The authors concluded that "vulnerability for suicide occurs similarly in the different stages of transition."

(Wiepjes et al. 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

170. As with Asscheman et al., Wiepjes et al. found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

171. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were "discharged" (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were "discharged" because they committed suicide *during* treatment. (Hall et al. 2021, Table 2.)

172. None of these studies demonstrates that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and "affirmation" resolve their underlying problems and put them on the path to a stable and healthy life.

173. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine 2016 at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

174. A number of voices in the field assert that puberty blockers act merely as a "pause" in the process of puberty-driven maturation, suggesting that this hormonal intervention has been proven to be fully reversible. This is also an unproven belief.

175. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones, as prescribed for gender dysphoria, are safe in other than the short run. No studies have attempted to determine whether the effects of puberty blockers, as currently being prescribed for gender dysphoria, are fully reversible. There are only pronouncements. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed concern that the full range of possible harms have not even been correctly conceptualized.

176. Because, as I have explained in Section VI, recent evidence demonstrates that pre- pubertal social transition almost always leads to progression

on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

177. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to "safety outcomes" from administration of puberty blockers for gender dysphoria is of "very low certainty." (NHS 2020a at 6.)

178. In its 2017 Guidelines, the Endocrine Society cautioned that "in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols" including "careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development)." (Hembree et al. 2017 at 3874.) No such "careful" or

"rigorous" evaluation of these very serious safety questions has yet been done.

179. Some advocates assume that puberty blockers are "safe" because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the "label" for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the "age was appropriate for entry into puberty." The study provides no information at all as to the safety or reversibility of instead *blocking* healthy, normally-timed puberty's beginning, and *throughout* the years that body-wide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state like their peers without a high incidence of significant side effects—that is, they are "safe" to reverse the condition. But use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated.

180. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations Without quoting extensively from the reviews done by Sweden, Finland, UK, and McMasters University, suffice it to say that their conclusions agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits. They also point to the great unexplained increase in incidence of gender dysphoria, the

increased incidence of detransition and regret, and the lack of evidence of efficacy.[13](Swedish National Board of Health and Welfare, 2022).

181. **Fertility**: The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on "gonadal function" and "sexual development." The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are "fully reversible," there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a "prolonged delay of puberty." The 2017 Endocrine Society Guidelines are correct that are no data on achievement of fertility "following prolonged gonadotropin suppression" (that is, puberty blockade). (Hembree et al. 2017 at 3880.)

182. **Bone strength**: Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink et al. 2015; Vlot et al. 2016; Joseph et al. 2019.) The most recent found that after two years on puberty blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021.) Some other studies have

[13] https:/www.sociialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-7799.pdf

found less concerning effects on bone density. While the available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

183. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that "no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation." (Kozlowska et al. 2021 at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative impact. For the purpose of protecting patients all over the world, the burden of proof should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affected. This recalls the ethical principle: Above All Do No Harm.

184. The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression "may include . . . unknown effects on brain development," that "we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development)," and stating that "animal

data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function." (Hembree et al. 2017 at 3874, 3882, 3883.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

185. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient's "global IQ," measured an anomalous absence of certain structural brain development expected during normal male puberty, and hypothesized that "a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression." (Schneider et al. 2017 at 7.) This should cause parents and practitioners serious concern.

186. Whether any impairment of brain development is "reversed" upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is "fully reversible" are unjustified and based on hope rather than science.

187. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Are there brain anatomic or functional impairment from puberty blockers? And are the documented changes reversed over time when puberty blockers are stopped? With

these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are "fully reversible." Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

188. **Psycho-social harm**: Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the young person's coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one's peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting internal consequences? Do we ignore Adolescent Psychiatry's knowledge of the importance of peer groups among adolescents?

189. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is "fully reversible."

190. In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of "psychological irreversibility" in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho- social realities mean that very few patients well ever be able to make that choice once they have started down the road of social transition and puberty blockers.

B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

191. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of "very low quality." The U.K. NICE evidence review cautioned that "the safety profiles" of cross-sex hormone treatments are "largely unknown," and that several of the limited studies that do exist reported high numbers of subjects "lost to follow-up," without explanation—a worrying indicator. (NICE 2020b.)

192. The 2020 Cochrane Review reported that: "We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for

transgender women in transition." (Haupt et al. 2020 at 4.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on "low quality evidence." (Hembree et al. 2017 at 3889.)

193. **Sterilization**: It is undisputed, however, that harm to the gonads is an expected effect, to the extent that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that "[p]rolonged exposure of the testes to estrogen has been associated with testicular damage," that "[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied," and that "[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain." (Hembree et al. 2017 at 3880.) [14]

194. The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender

[14] *See also* Guss et al. 2015 at 4 ("a side effect [of cross-sex hormones] may be infertility") and at 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al. 2015 at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

transition for any patient. What has been documented is te low rate of acceptance of banking sperm or ova in this population.

195. **Sexual response**: Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females, prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018 at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients. And these young often interpersonally sexually inexperienced patients are both too embarrassed to talk about the subject and too young to seriously consider the topic.

196. **Cardiovascular harm**: Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun et al. 2018; Guss et al. 2015; Asscheman et al. 2011.) With that said, I agree with the

conclusion of the Endocrine Society committee (like that of the NICE Evidence Review) that: "A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is needed to ascertain the potential harm of hormonal therapies." (Hembree et al. 2017 at 3891.) Future research questions concerning long-term harms need to be far more precisely defined. The question of whether cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

197. Further, in contrast to administration for menopausal women, hormones begun in adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones "are safe."

198. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017 at 5.) My concerns about this are based on decades of observations in my professional work with patients and their families. It is important to recognize that the tradition throughout medicine is the focus on the patient. This is true in adolescent medicine as well and seems natural and self-evident. However, when a trans identity occurs in a family, every member—parents, siblings, grandparents, etc—is affected. I am used to watching parents become depressed, siblings take sides, and family dysfunction increase. It is rare to find a medical or mental health professional whose work reflects that each of these family members are deeply connected and share in the uncertainties that are embedded in any trans identity.

199. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017 at 5, 13; Levine 2013 at 40.)

C. The timing of harms.

200. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data (as discussed in Section VIII above) warns us that the safety and beneficence of these treatments cannot be judged based on short- term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking. Regret over sterilization or over an inability to form a stable romantic relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in

many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent "detransitioner" research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

201. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine 2016 at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view. Hopefully, so will the child's physician.

202. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly

addressing conditions that require treatment. When the hoped-for "vanishing" of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger "detransitioner" survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those with previous and co-existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

203. In sum, whether we consider physical or mental health, science does not permit us to say that either puberty blockers or cross-sex hormones are "safe," and the data concerning the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is "easily managed."

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 16th day of February, 2023.

Stephen B. Levine, M.D.

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Wiepjes, C. M., den Heijer, M., Bremmer, M. A., Nota, N. M., Blok, C. J. M., Coumou, B. J. G., & Steensma, T. D. (2020). *Trends in suicide death risk in transgender people: Results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017)*. ACTA PSYCHIATRICA SCANDINAVICA *141*(6) 486–491.

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Zucker, K. (2019). *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*. ARCHIVES OF SEXUAL BEHAVIOR 48(7) 1983–1992.

Zucker, K. (2020). *Different strokes for different folks.* CHILD ADOLESC MENT HEALTH 25(1): 36–37. https://doi: 10.1111/camh.12330.

Exhibit “A”

Stephen B. Levine, M.D. **Curriculum Vita**
February, 2022

Brief Introduction

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the author or coauthor of numerous books on topics relating to human sexuality and related relationship and mental health issues. Dr. Levine has been teaching, providing clinical care, and writing since 1973, and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. Dr. Levine has been co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992 to the present. He received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

Personal Information

Date of birth 1/14/42

Medical license no. Ohio 35-03-0234-L

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973- Assistant Professor of Psychiatry

1979- Associate Professor

1982- Awarded tenure

1985- Full Professor

1993- Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award-1990 and 2010 (Residency program)

Visiting Professorships

- Stanford University-Pfizer Professorship program (3 days)–1995
- St. Elizabeth's Hospital, Washington, DC –1998
- St. Elizabeth's Hospital, Washington, DC--2002

Named to America's Top Doctors consecutively since 2001

Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops

Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof

2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit

2018—Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (Exceling in one's field for at least twenty years)

Professional Societies

1971- American Psychiatric Association; fellow; #19909

2005- American Psychiatric Association, Distinguished Life Fellow

1973- Cleveland Psychiatric Society

1973- Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974-Society for Sex Therapy and Research

- 1987-89-President

1983- International Academy of Sex Research

1983- Harry Benjamin International Gender Dysphoria Association

- 1997-8 Chairman, Standards of Care Committee

1994- 1999 Society for Scientific Study of Sex

Community Boards

1999-2002 Case Western Reserve University Medical Alumni Association

1996-2001 Bellefaire Jewish Children's Bureau

1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

a. Archives of Sexual Behavior
b. Annals of Internal Medicine
c. British Journal of Obstetrics and Gynecology
d. JAMA
e. Diabetes Care
f. American Journal of Psychiatry
g. Maturitas
h. Psychosomatic Medicine
i. Sexuality and Disability
j. Journal of Nervous and Mental Diseases
k. Journal of Neuropsychiatry and Clinical Neurosciences
l. Neurology
m. Journal Sex and Marital Therapy
n. Journal Sex Education and Therapy
o. Social Behavior and Personality: an international journal (New Zealand)
p. International Journal of Psychoanalysis
q. International Journal of Transgenderism
r. Journal of Urology
s. Journal of Sexual Medicine
t. Current Psychiatry
u. International Journal of Impotence Research
v. Postgraduate medical journal
w. Academic Psychiatry

Prospectus Reviewer

a. Guilford

b. Oxford University Press

c. Brunner/Routledge

d. Routledge

Administrative Responsibilities

Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

Co-leader of case conferences at DELRLLC.com

Expert testimony at trial or by deposition within the last 4 years

Provided expert testimony for Massachusetts Dept. of Corrections in its defense of a lawsuit brought by prisoner Katheena Soneeya, including by deposition in October 2018, and in-court testimony in 2019.

Provided expert testimony by deposition and at trial in *In the Interests of the Younger Children* (Dallas, TX), 2019.

Testified in an administrative hearing in *In the matter of Rhys & Lynn Crawford* (Washington State), March 2021.

Testified multiple times in juvenile court in *In the matter of Asha Kerwin* (Tucson, Arizona), 2021.

Provided expert testimony by deposition in *Kadel et al v. Folwell et al.* (North Carolina), 2021.

Consultancies

Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010.

California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies.

Virginia Department of Corrections –evaluation of an inmate.

New Jersey Department of Corrections—evaluation of an inmate.

Idaho Department of Corrections—workshop 2016.

Grant Support/Research Studies

TAP–studies of Apomorphine sublingual in treatment of erectile dysfunction.

Pfizer–Sertraline for premature ejaculation.

Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction.

NIH- Systemic lupus erythematosis and sexuality in women.

Sihler Mental Health Foundation

a. Program for Professionals
b. Setting up of Center for Marital and Sexual Health
c. Clomipramine and Premature ejaculation
d. Follow-up study of clergy accused of sexual impropriety
e. Establishment of services for women with breast cancer

Alza–controlled study of a novel SSRI for rapid ejaculation.

Pfizer–Viagra and self-esteem.

Pfizer- double-blind placebo control studies of a compound for premature ejaculation.

Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation.

Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement.

Lilly-Icos—study of Cialis for erectile dysfunction.

VIVUS – study for premenopausal women with FSAD.

Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration.

Medtap – interview validation questionnaire studies.

HRA- quantitative debriefing study for Female partners os men with premature ejaculation, Validation of a New Distress Measure for FSD.

Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder.

Biosante- studies of testosterone gel administration for post menopausal women with HSDD.

J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.

UBC-Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD.

National registry trial for women with HSDD.

Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women.

Palatin—study of SQ Bremelanotide for HSDD and FSAD.

Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.

S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD.

HRA – qualitative and cognitive interview study for men experiencing PE.

Publications

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985

2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988; Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997

3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992

4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998

5) Editor, Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.

6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003

1. 2006 SSTAR Book Award: Exceptional Merit

7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006

8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals, 2nd edition. Routledge, New York, 2010.

9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.

10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016

B) Research and Invited Papers

When his name is not listed in a citation, Dr. Levine is either the solo or the senior author.

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73

2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26

3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2

4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

12) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

13) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the dysfunction? Sexual Medicine Today 1977;1:13

14) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

15) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

16) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977;3:177-186

17) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

18) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978;4:235-258

19) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978;113-958-962

20) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981;6:102-108

21) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

22) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

23) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

24) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983;12:247-61

25) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

26) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982;9:21-28

27) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982;8:316-324

28) Nymphomania. Female Patient 1982;7:47-54

29) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982;16:135-9

30) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

31) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

32) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

33) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984;86:412-418

34) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984;10:176-184

35) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984;13:287-9

36) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

37) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

38) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

39) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI.

External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

40) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

41) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987;13:35-44

42) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

43) Lets talk about sex. National Hemophilia Foundation January, 1988

44) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

45) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

46) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630

47) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. Archives of Sexual Behavior 1991;;20(4):333-43.

48) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19

49) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. Journal of Sex & Marital Therapy 1987**;** 13:155-167

50) Althof SE, Turner LA, Risen CB, Bodner DR, Kursh ED, Resnick MI. Side effects of self-administration of intracavernosal injection of papaverine and phentolamine for treatment of impotence. Journal of Urology 1989;141:54-7

51) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989

52) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989

53) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. Journal of Sex & Marital Therapy

54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? Journal of Sex & Marital Therapy. 1989;15:121-9

55) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. Journal of Sex & Marital Therapy. 1989; 15(3):163-78

56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. Journal of Urology 1990;141(1):79-82

57) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia Journal of Sex & Marital Therapy 1990; 16(2):89-102.

58) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. International Journal of Impotence Research (supplement 2)1990;346-7.

59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. A comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. . International Journal of Impotence Research (supplement 2)1990;289-90

60) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence.International Journal of Impotence Research (supplement 2)1990;340-1.

61) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in Journal of Sex & Marital Therapy 1991; 17(2):101-112

62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dsyfunction in Journal of Sex & Marital Therapy 1991;17(2):81-93

63) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. Urology 1992;39(2):139-44

64) Althof SE, The pathogenesis of psychogenic impotence. J. Sex Education and Therapy. 1991; 17(4):251-66

65) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. Clinical Pediatrics 1991; 30(4):259-260

66) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic

Services), Autumn, 1991

67) Psychological intimacy. Journal of Sex & Marital Therapy 1991; 17(4):259-68

68) Male sexual problems and the general physician, Georgia State Medical Journal 1992; 81(5): 211-6

69) Althof SE, Turner LA, Levine SB, Bodner DB, Kursh E, Resnick MI. Through the eyes of women: The sexual and psychological responses of women to their partner's treatment with self-injection or vacuum constriction devices. Journal of Urology 1992; 147(4):1024-7

70) Curry SL, Levine SB, Jones PK, Kurit DM. Medical and Psychosocial predictors of sexual outcome among women with systemic lupus erythematosis. Arthritis Care and Research 1993; 6:23-30

71) Althof SE, Levine SB. Clinical approach to sexuality of patients with spinal cord injury. Urological Clinics of North America 1993; 20(3):527-34

72) Gender-disturbed males. Journal of Sex & Marital Therapy 19(2):131-141, 1993

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, legally known as KORI DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents and next friends, JANE DOE and JOHN DOE; and K.F., a minor, by and through his parent and next friend, JADE LADUE,

Plaintiffs,

JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration; and FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendants.

Civil Action No. 4:22-cv-00325-RH-MAF

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Expert Report of Paul W. Hruz, M.D., Ph.D.

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this report.

2. I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as Chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016. I am currently serving as Associate Fellowship Program Director at Washington University in St. Louis.

3. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

4. I have published 62 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading

journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See Exhibit A.

5. I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne, assessing the quality of evidence that is put forward for publication. I have also been involved in the evaluation of clinical trials with colleagues. I have received over $4.6 million in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J. Quick Award for Excellence in Biochemistry, the Eli Lilly Award for Outstanding Contribution to Drug Discovery, and the Julio V. Santiago Distinguished Scholar in Pediatrics Award.

6. During the more than 22 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington

University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.

7. My CV (Exhibit A) contains a complete list of the cases I have testified in as an expert witness either at trial or in deposition. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in Joaquín Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina), Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-524), Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT), Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943), Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080), Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA), Brandt v Rutledge (The United States District Court Eastern District

of Arkansas Central Division, Case No. 4:21-CV-00450-JM), Eknes-Tucker vs Ivy (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW), D.H. et al. v. Snyder (United States District Court of Arizona, Case No. 4:20-cv-00335-SHR), Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children, and Bo v. Marshall (United States District Court For The Middle District Of Alabama Northern Division). I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v. Tavistock).

8. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

9. In my role as a scientist and as the Director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local, national, and international meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually

and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

10. In my 25 years of clinical practice, I have cared for children from birth to the completion of college in their early twenties who have a variety of hormone related diseases. This includes disorders of growth, puberty (both precocious and delayed), glucose homeostasis (both hypoglycemia and diabetes mellitus), adrenal function (both adrenal insufficiency and steroid excess), thyroid function, skeletal abnormalities, gonadal dysfunction (including polycystic ovarian syndrome and ovarian failure), hypopituitarism, and disorders of sexual development. Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for

this role based upon a special interest and professional knowledge and training in this patient population.

11. My opinions as detailed in this report are based upon my:

a. knowledge, training, and clinical experience in caring for thousands of patients over many years;
b. detailed methodological reviews of hundreds of relevant peer-reviewed science publications;
c. consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences;
d. publications in peer reviewed scientific journals;
e. editorial work for peer reviewed scientific journals; and,
f. peer reviewed research grant receipt and review work.

The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject, including hundreds of published, peer reviewed scientific research (and professional) articles.

12. My opinions and hypotheses in this matter are—as all expert reports—subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, and the limitations of social, biological, and medical science. I have not met with, or personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may

or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information.

Background on Sex and Gender

13. Sex is an objective biological trait intrinsically oriented toward specific roles in the conception and development of new members of a species. Both males and females contribute genetic information in distinct yet complimentary ways. Males have the role of delivering sperm produced by testes and the unique paternal DNA contained therein to a female. Females have the role of receiving this male genetic information to join with the maternal genetic information contained in ova produced by ovaries. Sex is not "assigned at birth"; it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades.

14. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to

recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized. The measurement and assessment of biological sex has been documented by valid and reliable research published in credible journals, and is accepted by the relevant scientific community. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females).

15. For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality.

16. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e., reproduction). Internal structures (e.g., gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans.

17. Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births).[1] Defects can occur through either inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community.

18. The medical care of persons with DSDs is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g., assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict the sex chromosomes present nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert

[1] See Sax, How common is Intersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139 (2002).

medical providers. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with confidence, a presumptive sex assignment is made. Factors used in making such decisions include karyotype (46XX, 46XY, or other), phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to a change in sex determination. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent.[2]

19. "Gender," a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, not biology. The reliability and validity of various usages of the term "gender" is currently controversial and the relevant scientific community

[2] See Lee et al., Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care, Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016).

has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The dangers of incorrectly using the term "gender" in place of "sex" have been acknowledged by the Endocrine Society.[3]

20. "Gender identity" refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is controversial. There is no current worldwide definition of "gender identity" accepted by the relevant clinical communities. The measurement error rate for non-biological "gender identity" is unknown.

21. People who identify as "transgender" transiently or persistently experience a sex-discordant gender identity.[4]

Puberty

22. Puberty is "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in

[3] See Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, 42 *Endocrine reviews*, No. 3, pp. 219-58, https://doi.org/10.1210/endrev/bnaa034 (2021).
[4] APA, DSM-5, 451.

all individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[5]

23. The principal manifestations of puberty are:

- The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.
- The development of the gonads.
- The development of the secondary reproductive organs and the secondary sex characters.
- Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
- Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[6]

24. The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the ovaries, uterus, and

[5] William A. Marshall and James M. Tanner, "Puberty," in Human Growth: A Comprehensive Treatise, Second Edition, Volume 2, eds. Frank Falkner and James M. Tanner (New York: Springer, 1986), 171.
[6] *Id.* at 171–72.

vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop during puberty — the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis" and in boys "the appearance of facial hair and the broadening of shoulders," while other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[7]

25. Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche"; it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[8] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[9] "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[10] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen,

[7] Robert V. Kail and John C. Cavanaugh, Human Development: A Life-Span View, Seventh Edition (Boston, Mass.: Cengage Learning, 2016), 276.
[8] Jamie Stang and Mary Story, "Adolescent Growth and Development," in Guidelines for Adolescent Nutrition Services, eds. Jamie Stang and Mary Story (Minneapolis, Minn.: University of Minnesota, 2005), 4.
[9] *Id.* at 3.
[10] Marshall and Tanner, "Puberty," 191–192.

which also typically occurs around 13.[11] (The "-arche" in the terms for these milestones comes from the Greek for beginning or origin.)

26. Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration. "Adrenarche"—the beginning of adrenal maturation—begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[12]

27. "Gonadarche"—the beginning of the process of gonadal maturation—normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[13] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[14] This hormone is secreted in a cyclical or "pulsatile" manner—the hypothalamus releases bursts of GnRH,

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[11] *Id.* at 185.
[12] Sharon E. Oberfield, Aviva B. Sopher, and Adrienne T. Gerken, "Approach to the Girl with Early Onset of Pubic Hair," Journal of Clinical Endocrinology and Metabolism 96, no. 6 (2011): 1610–1622, http://dx.doi.org/10.1210/jc.2011-0225.
[13] Selma Feldman Witchel and Tony M. Plant, "Puberty: Gonadarche and Adrenarche," in Yen and Jaffe's Reproductive Endocrinology, Sixth Edition, eds. Jerome F. Strauss III and Robert L. Barbieri (Philadelphia, Penn.: Elsevier, 2009), 395.
[14] Allan E. Herbison, "Control of puberty onset and fertility by gonadotropin-releasing hormone neurons," Nature Reviews Endocrinology 12 (2016): 452, http://dx.doi.org/10.1038/nrendo.2016.70.

and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones.[15] These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in women and testes in men).[16] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these two hormones also play an important role in regulating aspects of human fertility.[17]

28. As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[18] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as

[15] *Id.* at 453.
[16] *Id.* at 454.
[17] *Id.* at 452.
[18] Michael A. Preece, "Prepubertal and Pubertal Endocrinology," in Human Growth: A Comprehensive Treatise, Volume 2, 212.

well as estrogens, however the testes secrete more androgens and the ovaries more estrogens.[19]

29. The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[20] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproductive capacity and the external sex characteristics that distinguish the sexes.[21]

30. The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus induces the pituitary gland to secrete FSH and LH, in this case short

[19] Rex A. Hess, "Estrogen in the adult male reproductive tract: A review," Reproductive Biology and Endocrinology 1, (2003), https://dx.doi.org/10.1186/1477-7827-1-52; Henry G. Burger, "Androgen production in women," Fertility and Sterility 77 (2002): 3–5, http://dx.doi.org/10.1016/S0015-0282(02)02985-0.
[20] Russell D. Romeo, "Neuroendocrine and Behavioral Development during Puberty: A Tale of Two Axes," Vitamins and Hormones 71 (2005): 1–25, http://dx.doi.org/10.1016/S0083-6729(05)71001-3.
[21] Margaret E. Wierman and William F. Crowley, Jr., "Neuroendocrine Control of the Onset of Puberty," in Human Growth, Volume 2, 225.

pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[22] This process is augmented by testosterone and estrogen. Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[23]

31. The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental factors like social conditioning), are all matters of debate.

32. Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens

[22] Preece, *supra*, at 218–19.
[23] Udo J. Meinhardt and Ken K. Y. Ho, "Modulation of growth hormone action by sex steroids," Clinical Endocrinology65, no. 4 (2006): 414, http://dx.doi.org/10.1111/j.1365-2265.2006.02676.x.

and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[24]

33. In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. During this period of life, adrenarche and changes in the secretion of growth hormone contribute to the child's growth and development. With gonadarche, the maturation of sex organs begins and with normal maturation will lead to the emergence of reproductive capacity, as well as the development of the other biological characteristics that distinguish males and females.

Pediatric Endocrine Disorders and Treatments

34. The field of endocrinology is directed toward the care of hormone related diseases. Pediatric endocrine diseases include disorders of glucose regulation (hypoglycemia and diabetes mellitus), disorders of thyroid function (hyper and hypothyroidism), disorders of growth (e.g. short stature, acromegaly, obesity and poor weight gain), disorders of sexual development and function (e.g. genital am-

[24] Herting MM, Sowell ER. Puberty and structural brain development in humans. Front Neuroendocrinol. 2017 Jan;44:122-137. doi: 10.1016/j.yfrne.2016.12.003; Hornung J, Lewis CA, Derntl B. Sex hormones and human brain function. Handb Clin Neurol. 2020;175:195-207. doi: 10.1016/B978-0-444-64123-6.00014-X

biguity, precocious and delayed puberty, hypogonadism, polycystic ovarian syndrome), disorders of adrenal function (e.g. adrenal insufficiency and Cushing's syndrome), disorders of pituitary function, lipid disorders, and disorders of bone and mineral metabolism. For all of these conditions, there are objective physical and biochemical criteria for diagnosis and treatment with well-established normal reference ranges for hormones and metabolites.

35. Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria. Rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

36. For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before age 9.[25] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is

[25] Karen Oerter Klein, "Precocious Puberty: Who Has It? Who Should Be Treated?," Journal of Clinical Endocrinology and Metabolism 84, no. 2 (1999): 411, http://doi.org/10.1210/jcem.84.2.5533. See also: Frank M. Biro et al., "Onset of Breast Development in a Longitudinal Cohort," Pediatrics 132, no. 6 (2013): 1019–1027, http://dx.doi.org/10.1542/peds.2012-3773; Carl-Joachim Partsch and Wolfgang G. Sippell, "Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens," Human Reproduction Update 7, no. 3 (2001): 293, http://dx.doi.org/10.1111/j.1600-0463.2001.tb05760.x.

marked by premature testicular enlargement.[26] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[27]

37. Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[28] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment. Effects of androgen or estrogen hypersecretion can be reduced by administration of drugs that block the activity of the sex hormone receptors. If a tumor is causing the disorder, surgical removal may be necessary.

38. Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000

[26] Anne-Simone Parent et al., "The Timing of Normal Puberty and the Age Limits of Sexual Precocity: Variations around the World, Secular Trends, and Changes after Migration," Endocrine Reviews 24, no. 5 (2011): 675, http://dx.doi.org/10.1210/er.2002-0019.
[27] Jean-Claude Carel et al., "Precocious puberty and statural growth," Human Reproduction Update 10, no. 2 (2004): 135, http://dx.doi.org/10.1093/humupd/dmh012.
[28] Partsch and Sippell, *supra*, at 294–95.

(37 in 100,000 girls affected, and 0.46 in 100,000 boys).[29] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[30]

39. To diagnose central precocious puberty, hormones from the pituitary gland, LH and FSH, are objectively measured. This can sometime be done by measurement of baseline levels but often requires assessment after transient stimulation with GnRH. As discussed, these are two hormones that are made in the pituitary gland that signal to the gonads. In males, they lead to production of testosterone. In females, they lead to the production of estrogen. LH and FSH signaling are essential for normal sperm production and ovarian maturation in males and females, respectively.

40. Also subject to objective measurement when diagnosing and treating central precocious puberty are sex steroid hormones, either testosterone or estrogen, and bone growth.

41. Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production of GnRH, physicians actually provide patients

[29] Leandro Soriano-Guillén et al., "Central Precocious Puberty in Children Living in Spain: Incidence, Prevalence, and Influence of Adoption and Immigration," Journal of Clinical Endocrinology and Metabolism 95, no. 9 (2011): 4307, http://dx.doi.org/10.1210/jc.2010-1025. In some cases, peripheral precocious puberty is caused by an underlying condition, such as a tumor, that can be treated.

[30] Grete Teilmann et al., "Prevalence and Incidence of Precocious Pubertal Development in Denmark: An Epidemiologic Study Based on National Registries," Pedriatics 116, no. 6 (2005): 1323, http://dx.doi.org/10.1542/peds.2005-0012.

more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[31] As discussed above, when produced endogenously (that is, by the body naturally), GnRH stimulates the pituitary gland to release gonad-stimulating hormones (gonadotropins, LH and FSH). When added exogenously, the additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins, which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The intent and effect of giving puberty blockers is identical when it is given to a male as when it is given to a female in this context: suppressing the secretion of gonadotropin hormones. Even the dosing is the same for males and females, and depends on the person's weight.

42. The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[32] In the time since GnRH analogues were first proposed, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that use by the FDA in 1993.[33] However, there remain some questions concerning the ef-

[31] William F. Crowley, Jr. et al., "Therapeutic use of pituitary desensitization with a long-acting LHRH agonist: a potential new treatment for idiopathic precocious puberty," Journal of Clinical Endocrinology and Metabolism 52, no. 2 (1981): 370–372, http://dx.doi.org/10.1210/jcem-52-2-370. (LHRH refers to "lutenizing hormone releasing hormone," another term for GnRH.)
[32] Crowley et al., *supra*, at 370–72.
[33] "Full Prescribing Information" for Lupron Depot-Ped, FDA.gov (undated), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf.

fectiveness of treatment with GnRH analogues. A 2009 consensus statement of pediatric endocrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who have compromised height potential.[34] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[35] Puberty blockers have recently been recognized to carry a risk of increased brain pressure that can adversely affect vision and cause severe headaches.[36]

43. When used to treat precocious puberty, the process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that

[34] Jean-Claude Carel et al., "Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children," Pediatrics 123, no. 4 (2009): e753, http://dx.doi.org/10.1542/peds.2008-1783.
[35] *Id.*
[36] *Risk of pseudotumor cerebri added to labeling*, AAP (July 1, 2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for.

children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[37]

44. The goal of this treatment is to allow the child to have pubertal development enter the normal quiescence that is present at that age. This treatment helps to preserve their final adult height, by slowing the rate of bone age advancement. The goal is *not* to delay puberty beyond other children, as delaying too long can be adverse effects, including reduced bone marrow density, as discussed below.

45. In addition to being prescribed for children with precocious puberty, GnRH analogues have also been used in adults for a variety of indications, including hormone-sensitive tumors.[38] GnRH analogues have also been given to post-pubertal adolescents undergoing chemotherapy with drugs that can have toxic effects on the gonads.[39]

[37] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.
[38] See Kumar & Sharma, Gonadotropin-Releasing Hormone Analogs: Understanding Advantages and Limitations, Journal of Human Reproductive Sciences 7, no. 3 (2014).
[39] Meli M, et al. Triptorelin for Fertility Preservation in Adolescents Treated With Chemotherapy for Cancer. J Pediatr Hematol Oncol. 40(4):269-276 (2018).

46. Sex steroids such as testosterone and estrogen are frequently used in the treatment of disorders of normal gonadal function. This includes hypogonadotropic hypogonadism, primary gonadal failure and delayed puberty.[40] In each of these conditions, there are objective laboratory tests that are used to diagnose these conditions and monitor response to treatment. Deficiency of sex steroids has bodily effects that extend beyond sexual function.[41] This includes significant effect on bone density, lean body mass, metabolism, immunity, and neural function.

47. There are major and highly significant differences between male and female responses to sex hormones.[42] Giving estrogen to a biological male is not equivalent to giving the same hormone to a biological female. Likewise, giving testosterone to a biological female is not equivalent to giving the same hormone to a biological male.[43] Differences are not limited to pharmacokinetic effect (i.e. how

[40] Kumar P, Kumar N, Thakur DS, Patidar A. Male hypogonadism: Symptoms and treatment. J Adv Pharm Technol Res. 2010 Jul;1(3):297-301. doi: 10.4103/0110-5558.72420. PMID: 22247861; PMCID: PMC3255409; Voutsadaki K, Matalliotakis M, Ladomenou F. Hypogonadism in adolescent girls: treatment and long-term effects. Acta Biomed. 2022 Oct 26;93(5):e2022317. doi: 10.23750/abm.v93i5.13719. PMID: 36300209; PMCID: PMC9686158.
[41] Alemany M. The Roles of Androgens in Humans: Biology, Metabolic Regulation and Health. Int J Mol Sci. 2022 Oct 8;23(19):11952. doi: 10.3390/ijms231911952. PMID: 36233256; PMCID: PMC9569951; Patel S, Homaei A, Raju AB, Meher BR. Estrogen: The necessary evil for human health, and ways to tame it. Biomed Pharmacother. 2018 Jun;102:403-411. doi: 10.1016/j.biopha.2018.03.078. Epub 2018 Mar 22. PMID: 29573619.
[42] See Madla et al., Let's talk about sex: Differences in drug therapy in males and females, *Advanced drug delivery reviews*, 113804. Advance online publication. https://doi.org/10.1016/j.addr.2021.05.014 (2021).
[43] See Soldin et al., Sex differences in pharmacokinetics and pharmacodynamics, Clinical pharmacokinetics, 48(3), 143–157 (2009); Pogun et al., Sex Differences in Drug Effects. In: Stolerman I.P. (eds) Encyclopedia of Psychopharmacology, Springer, Berlin, Heidelberg (2010).

drugs are absorbed, distributed throughout the body and metabolized) but are present even at the cellular level.[44] Sex steroids act by altering the expression of the genetic information present in all nucleated cells of the body. Epigenetic differences (i.e. chemical changes to DNA structure) result in sex-differential expression of over 6,500 genes in the body.[45] Consequences of a failure to recognize these differences can result in drug overdose, lack of treatment response, or serious side effects.

48. Several conditions in minors may indicate endocrinologic treatment with testosterone. For instance, primary hypogonadism from gonadal failure is caused damage or impaired function of the male testes. Secondary hypogonadism is caused by abnormalities in pituitary structure or function. Hypogonadism can be objectively diagnosed by measurement of testosterone (or its derivatives) and gonadotropin (LH and FSH) levels. When used for the treatment of affected males with hypogonadism, testosterone is administered to achieve levels that are normal

[44] See, e.g., Walker et al., Matters of the heart: Cellular sex differences, *Journal of molecular and cellular cardiology*, S0022-2828(21)00087-0. Advance online publication. https://doi.org/10.1016/j.yjmcc.2021.04.010 (2021).
[45] Gershoni, M., Pietrokovski, S. The landscape of sex-differential transcriptome and its consequent selection in human adults. *BMC Biol* **15**, 7 (2017). https://doi.org/10.1186/s12915-017-0352-z

for the individual's age. This requires careful monitored of serum testosterone levels, as excess levels can have serious adverse effects, including elevations of red blood cell counts, changes in blood pressure, and brain changes.[46]

49. Testosterone may also be used in males to treat delayed puberty. To treat the condition of constitutional delay (where the person has means to progress through puberty, but onset was delayed), the male would normally be given low doses of testosterone for 3-4 months to "prime the pump" for normal puberty. Assessment of this condition includes measuring levels of LH, FSH, and testosterone, as well as observation of testicular size. Once puberty has been initiated and is progressing, there is no need to administer ongoing testosterone therapy. The normal signals present within the body with the pituitary gland signaling to the testicles continue with maturation of the gonad leading to reproductive capacity.

50. Continuing to give external testosterone to a male in normal puberty would suppress the normal function of the testes and can lead to infertility—a result contrary to the goal of endocrinology, which is to restore health. Thus, for instance, a male adolescent undergoing normal puberty who simply desired increased

[46] Ohlander SJ, Varghese B, Pastuszak AW. Erythrocytosis Following Testosterone Therapy. Sex Med Rev. 2018 Jan;6(1):77-85. doi: 10.1016/j.sxmr.2017.04.001; Kienitz T, Quinkler M. Testosterone and blood pressure regulation. Kidney Blood Press Res. 2008;31(2):71-9. doi: 10.1159/000119417; Scarth M, Bjørnebekk A. Androgen abuse and the brain. Curr Opin Endocrinol Diabetes Obes. 2021 Dec 1;28(6):604-614. doi: 10.1097/MED.0000000000000675.

lean body mass (i.e., higher muscle mass) should not normally be given testosterone for that purpose, both because it is considered medically unnecessary and because of the adverse effects of extra testosterone. Among other reasons, these effects explain why testosterone is a controlled substance.

51. Outside the context of gender dysphoria, testosterone is not an indicated treatment for a female child or adolescent. Testosterone, or any androgen, would lead to virilization, which can come with serious adverse effects. This includes impaired fertility, alopecia (hair loss), disfiguring acne, and metabolic changes that increase risk of heart disease and diabetes.[47]

52. Estrogen can be given to young females for the same types of indications in males of either constitutional delay or hypogonadism, which could be either primary or secondary. Primary hypogonadism is caused by a defect in the presence or function of the ovaries. Secondary hypogonadism is caused by a defect in the structure or function of the pituitary gland. A female can experience premature ovarian insufficiency where the ovaries become inactive over time, both genetically and through environmental incidents. To diagnose these conditions, hormone levels can be objectively measured. This includes LH, FSH, estradiol, and

[47] Yang R, Yang S, Li R, Liu P, Qiao J, Zhang Y. Effects of hyperandrogenism on metabolic abnormalities in patients with polycystic ovary syndrome: a meta-analysis. Reprod Biol Endocrinol. 2016 Oct 18;14(1):67. doi: 10.1186/s12958-016-0203-8. PMID: 27756332; PMCID: PMC5069996

other levels. (Estradiol is a form of estrogen, and generally the main hormone followed and measured in female endocrinologic practice.) The physical response to the intervention can also be measured.

53. Estrogen treatments carry risks, including stroke, elevated blood pressure, and changes to bone development. Males are not generally prescribed estrogen (again, outside the context of gender dysphoria), and there is concern that the risks of estrogen are even higher in males.

Gender Dysphoria and Treatments

I. Diagnosis

54. In contrast to the conditions discussed above, gender dysphoria is not an endocrine disorder. Instead, it is a diagnostic term for "the distress that may accompany the incongruence between one's experienced or expressed gender and one's" biological sex.[48] Gender dysphoria is associated with high rates of comorbidity, including suicidal ideation, depression, anxiety, poverty, homelessness, eating disorders, and HIV infection.[49] Gender dysphoria as a psychiatric disorder should be distinguished from identifying as transgender and transsexual. As noted,

[48] APA, DSM-5, 451.
[49] M. D. Connolly et al., "The Mental Health of Transgender Youth: Advances in Understanding," J Adolesc Health 59, no. 5 (2016); Pinna F, et al. Italian Working Group on LGBTQI Mental Health. Mental health in transgender individuals: a systematic review. Int Rev Psychiatry.34(3-4):292-359 (2022).

people who identify as transgender "transiently or persistently identify with a gender different from their natal gender." Transsexual has an even more specific meaning; it "denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involved a somatic transition by cross-sex hormone treatment and genital surgery."[50]

55. The clinical assessment methodology in sex discordant gender medicine is currently limited to self-reported information from patients without objective scientific markers or medical tests. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes.

56. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition.

[50] APA, DSM-5, 451.

57. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors"—often no more reliable in discerning false reports than flipping a coin—and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors," many health professionals personally—and falsely—believe they are "experts" at this complex and difficult task.[51]

58. Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals report experiencing discordance in these distinct traits. Specifically, for example, biological females may report experiencing that they identify as males and biological males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no

[51] See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861.

known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity." There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments.

II. Treatments

59. Moving from diagnosis to treatment, three approaches have been proposed for treating children with gender dysphoria.[52]

A. Reparative Therapy

60. The first approach, sometimes called "reparative therapy," is directed toward actively supporting and encouraging children to identify with their biological sex. Reparative therapy views sex/gender identity discordance as a pathologic condition. Accordingly, understanding and addressing factors that lead to this condition form the primary focus of reparative therapy, with an explicit goal of realigning one's gender identity with one's biological sex. Components of this approach have included play therapy for children and adolescents, counseling for patients and their families to help them understand and address underlying psycho-

[52] See Zucker, On the "natural history" of gender identity disorder in children, J. Am. Acad. Child Adolesc. Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).

logical dysfunction, and instruction on setting specific boundaries for behavior according to stereotypical gender norms.[53] Some have used the term conversion therapy to label efforts to realign gender identity with biological sex, but this ideologically loaded label has been used extensively in reference to same-sex attraction.[54]

B. Watchful Waiting

61. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing existing evidence (discussed next) showing that the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex. This realignment of expressed gender identity to be concordant with sex is sometimes called "desistance."

62. The "watchful waiting" approach does not advocate doing nothing. Rather, it focuses on affirming the inherent dignity of affected people and supporting them in other aspects of their lives, including the diagnosis and treatment of any comorbidities, as individuals proceed through the various stages of physical and psychological development. For instance, the approach may include the use of

[53] Kenneth J. Zucker et al., "A Developmental, Biopsychosocial Model for the Treatment of Children with Gender Identity Disorder," Journal of Homosexuality 59, no. 3 (2012).
[54] D. C. Haldeman, "The Practice and Ethics of Sexual Orientation Conversion Therapy," J Consult Clin Psychol 62, no. 2 (1994)Kenneth J. Zucker, "Editorial: The Politics and Science of "Reparative Therapy"," Archives of Sexual Behavior 32, no. 5 (2003).

scientifically validated treatments (e.g., cognitive behavioral therapy) for the patient's anxiety, depression, social skills deficits, or other issues.[55]

63. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than gender discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children before the widespread adoption of the "affirming" model discussed below.[56] In 2018, for instance, studies found that 67% of children meeting the diagnostic criteria for gender dysphoria no longer had the diagnosis as adults, with an even higher rate (93%) of natural resolution of gender-related distress for the less significantly impacted

[55] See van Bentum et al., Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression, 38 Depression & Anxiety 940 (2021).
[56] T. D. Steensma et al., "Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-up Study," J Am Acad Child Adolesc Psychiatry 52, no. 6 (2013); K. D. Drummond et al., "A Follow-up Study of Girls with Gender Identity Disorder," Dev Psychol 44, no. 1 (2008); M. S. Wallien and P. T. Cohen-Kettenis, "Psychosexual Outcome of Gender-Dysphoric Children," J Am Acad Child Adolesc Psychiatry 47, no. 12 (2008); K. J. Zucker and S. J. Bradley, Gender Identity Disorder and Psychosexual Problem in Children and Adolescents (New York: Guilford Press., 1995).

cases.[57] A March 2021 study, with one of the largest samples in the relevant literature, suggests that most young gender dysphoric children grow out of the condition without medical interventions.[58] Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation.

64. Decades of peer-reviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of the psychological approaches for the majority of patients experiencing gender dysphoria.[59] Cognitive therapy and interpersonal psychotherapy have been found to reduce suicidal ideation independent of their effect on depression.[60] Within the "watchful

[57] See, e.g., Zucker, K. J. (2018). The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children" by Temple Newhook et al. (2018). International Journal of Transgenderism, 19(2), 231–245.
[58] See Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.
[59] See Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 YearsG. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.).
[60] van Bentum JS et al. Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. Depress Anxiety. 9:940-949 (2021). doi: 10.1002/da.23151.; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. *Psychotherapy (Chicago, Ill.)*, *57*(3), 379–390. https://doi.org/10.1037/pst0000283.

waiting" model, these data support the investigative use of modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria.

C. Gender Affirming

65. The third, so-called "gender affirming," approach is to affirm the child's present gender identity. This affirmation may have social, medical, legal, and behavioral dimensions. Typically, the "affirming" approach encourages children to embrace transgender identity with social transitioning followed by puberty blockage and hormonal therapy (cross-sex hormones), and potential surgical interventions.[61] This approach is considered below.

66. Before analyzing this course of treatment, it is important to understand that underlying biology is not changed by altering bodily features to appear as the opposite sex, and such alterations do not change disease vulnerabilities associated with genetically defined sex. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities

[61] See Walch et al., Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective, J. Clin. Endocrinol Metab. 106(2):305-308. doi:10.1210/clinem/dgaa816 (2021).

associated with that chromosomally-defined sex.[62] For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks.[63] And their underlying biology does not change.

Puberty Blockers

67. Only in the 1990s did GnRH analogues begin being used to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient, on whom a GnRH analogue was used to suppress puberty before the patient received a definitive diagnosis of gender identity disorder at age 16. At age 18, the patient underwent sex-reassignment surgery.[64]

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[62] See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.

[63] See S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

[64] Cohen-Kettenis and van Goozen, "Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent," 246. See also Peggy T. Cohen-Kettenis, Thomas D. Steensma, and Annelou L.C. de Vries, "Treatment of Adolescents With Gender Dysphoria in the Netherlands," Child Adolescent Psychiatric Clinics of North America 20, (2011): 689–700, http://dx.doi.org/10.1016/j.chc.2011.08.001.

68. The clinic's scientists developed an influential protocol, often referred to as the "Dutch protocol," which involved puberty suppression followed by cross-sex hormones and potential surgical interventions. In many clinics that adhere to the gender affirmation model, the ages for initiating sex-discordant gender affirming sex steroid hormones has deviated substantially from the original Dutch protocol. The typical protocol is to initiate puberty blockers (GnRH analogs) as soon as puberty begins (Tanner stage 2) which can occur as early as 8 years in females and 9 years in males. While in the Dutch protocol, cross-sex hormones are started at 16 years, many programs in the United States offer these hormones earlier to coincide with the start of normal pubertal development in males (13-14 years) and females (12-13 years). Gender-affirming surgery in the Dutch model was reserved to patients 18 years or older. Again, programs in the United States have advocated for individualization of decisions on ages for surgery in minors. GnRH analogs are discontinued after gonadectomy is performed as this medication is no longer needed to suppress gonads that are no longer present. Due to the suppressive effect of exogenous sex-steroids on gonadal function, GnRH analogs are often stopped after gender affirming hormone administration has been titrated to maximal doses required to achieve the desired change in secondary sex characteristics.

69. This gender "affirming" model would make gender dysphoria unique: it would be "the only psychiatric condition to be treated by surgery, even though

no endocrine or surgical intervention package corrects any identified biological abnormality."[65]

70. These scientists, along with others, have claimed that puberty suppression is "fully reversible."[66] On this view, puberty suppression "give[s] adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved."[67]

71. This claim appears to presume that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It is based upon an untested scientific premise that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gender identity of the child. It seems equally plausible that the interference with normal pubertal development will influence the gender identity

[65] S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law, 44, 236 at 238 ("Reflections"), at 240.
[66] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, "Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects," European Journal of Endocrinology 155 (2006): S133, http://dx.doi.org/10.1530/eje.1.02231.
[67] Peggy T. Cohen-Kettenis, Henriette A. Delemarre-van de Waal, and Louis J.G. Gooren, "The Treatment of Adolescent Transsexuals: Changing Insights," Journal of Sexual Medicine 5, no. 8 (2008): 1894, http://dx.doi.org/10.1111/j.1743-6109.2008.00870.x.

of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex.

72. Given their potential importance in the lives of the affected children, claims about reversibility are worth careful examination. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

73. A more relevant question is whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development

gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[68] The evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much rarer in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[69]

74. Unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at age 12 will simply resume normal pubertal development down the road if they choose to withdraw from the puberty-suppressing treatment and choose not

[68] Marisa M. Fisher, Deborah Lemay, and Erica A. Eugster, "Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant," The Journal of Pediatrics 164, no. 4 (2014): 3, http://dx.doi.org/10.1016/j.jpeds.2013.12.009.

[69] Silvano Bertelloni and Dick Mul, "Treatment of central precocious puberty by GnRH analogs: long-term outcome in men," Asian Journal of Andrology 10, no. 4 (2008): 531, http://dx.doi.org/10.1111/j.1745-7262.2008.00409.x.

to undergo other sex-reassignment procedures. Interrupting puberty in this manner may have significant effects on final stature and bone density.[70]

75. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.[71] Once puberty is blocked, even if eventually unblocked (and assuming signaling from the pituitary gland resumes), the person cannot "buy back" the time when the physical process of puberty has been disrupted at the time when it would normally occur with complementary psychological processes in that stage in the person's life.

76. A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation.[72]

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[70] Joseph T, Ting J, Butler G. The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort. J Pediatr Endocrinol Metab. 32(10):1077-1081 (2019); Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[71] See Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36; see also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123; see also Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, *Social Cognitive and Affective Neuroscience*, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030.

[72] See Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, *9*, 449–461. https://doi.org/10.2147/NDT.S39776.

77. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

78. In addition to the reasons to suspect that puberty suppression may have side effects on physiological, psychological, and brain development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak.

Cross-Sex Hormones

79. Rather than resuming biologically normal puberty, adolescents treated on the "affirming" model overwhelmingly go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones. Specifically, exogenous estrogen is administered to biological men to induce gynecomastia (i.e., the enlargement of breast tissues), and testosterone is administered to biological women to induce virilization (i.e., the development of facial hair and other desired male features) and to interfere with normal ovarian function. Nearly all of the children that have been studied that have received puberty blockers go on to cross-sex hormones.[73]

[73] https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00254-1/fulltext

80. Along with (and often before) estrogen is administered to biological males in this treatment, spironolactone may be used as an androgen blocker. Spironolactone is primarily used for the treatment of blood pressure and heart failure. It is a mineralocorticoid antagonist. But it also has effects in blocking the action of androgens. As discussed, androgens are masculinizing hormones that lead to virilization. Testosterone is a prime androgen, but other androgens are also made in the gonads and adrenal gland. Spironolactone is sometimes used in the treatment of polycystic ovarian syndrome, in which females will undergo virilization due to excess androgen production in the ovaries. This syndrome can have adverse effects on fertility, metabolic health, and cardiovascular health.[74] The diagnosis of polycystic ovarian syndrome is a clinical diagnosis based upon the physical evidence of virilization or androgen effects, insulin resistance, and irregular periods. There are objective biological measures to assess those androgen levels, most notably elevated free testosterone levels. And there are objective measures of dysregulation of relevant signals from the pituitary gland, the LH and the FSH, to complement the clinical diagnosis by looking at the degree of virilization that is present in the patient.

[74] Hunter MH, Sterrett JJ. Polycystic ovary syndrome: it's not just infertility. Am Fam Physician. 2000 Sep 1;62(5):1079-88, 1090

81. Spironolactone would not be prescribed to male patients for an endocrinologic purpose related to androgen production. Once again, this reflects a fundamental biological difference between males and females. Though spironolactone can be used to regulate the levels of potassium and sodium in the body, such treatment would be based on objective markers of those levels.

82. Likewise, the administration of the sex steroid hormones differ by the sex of the individual. It is not identical to give testosterone to a male as it is to give it to a female, nor is it the same treatment to give estrogen to a male versus female. This difference has an established scientific basis. The differences between males and females occurs in every nucleated cell of the body, for males and females have different genetic programming. This is a process known as epigenetics, meaning that there are modifications of the DNA itself that alter the expression of genes when exposed to the same stimulus. There are over 6,000 sex-differentially expressed genes. So, if one gives testosterone to a male, the physiologic effects of that treatment, even in the measurement at which genes are turned on and turned off, will be different than if one gives testosterone to a female.[75]

83. When a patient with gender dysphoria is placed on cross-sex hormones, per the Dutch protocol, puberty-suppressing GnRH analogues continue to

[75] Gershoni M, Pietrokovski S. The landscape of sex-differential transcriptome and its consequent selection in human adults. BMC Biol. 2017 Feb 7;15(1):7

be administered until exogenous administration of cross-sex hormones (i.e. sex hormones normally produced the gonads of the opposite sex) leads to sufficient suppression of endogenous sex hormone production or the gonads are surgically removed. Sex hormones that are normally secreted by the maturing gonads are not produced. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of sexual maturation—the maturation of their reproductive organs.

84. Patients undergoing gender affirming surgery discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible. These patients are then sterile, as loss or alteration of primary sexual organs leads directly to impairment of reproductive potential.

85. Although the long-term effect of exposing immature gonads to cross-sex hormones is currently unknown, it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility, which may be irreversible.[76] Specifically, estrogen administration to males who identify as women results in impaired spermatogenesis and an absence of Leydig cells in the

[76] See Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health 61, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017).

testis.[77] Exogenous testosterone administration to females who identify as men causes ovarian stromal hyperplasia and follicular atresia.[78] Recognition of these consequences is the basis for the development of new arenas of medical practice where there is an attempt to restore fertility that has been intentionally destroyed.[79]

86. Gametes (sperm and ova) require natural puberty to mature to the point that they are viable for reproduction.[80] While it is expected that the exposure of immature gonads to cross-sex hormones will lead to infertility, whether affected individuals have permanent sterility has not been established. Much of the uncertainty arises from the novelty of this intervention and the lack of long term follow up. There are limited reports of successful pregnancies after cross-sex hormones, but all of the subjects started gender affirming hormones as adults after completing

[77] Schulze C. Response of the human testis to long-term estrogen treatment: Morphology of Sertoli cells, Leydig cells and spermatogonial stem cells. Cell Tissue Res 251:31e43 (1988)..
[78] [2] Pache TD, Chadha S, Gooren LJ, et al. Ovarian morphology in long-term androgen-treated female to male transsexuals. A human model for the study of polycystic ovarian syndrome? Histopathology 19: 445e52 (1991); Ikeda K, Baba T, Noguchi H, et al. Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology. Hum Reprod 28:453e61 (2013).
[79] See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: A Review. Mayo Clin Proc. 2020 Apr; 95(4):784-792. doi: 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195.
[80] Howard E. Kulin, et al., "The Onset of Sperm Production in Pubertal Boys. Relationship to Gonadotropin Excretion," American Journal of Diseases in Children 143(2), 190-193 (1989).

puberty.[81] I am not aware of any reports that show this for children who were exposed to puberty blockers before completing puberty followed by cross-sex hormones.

87. There are many other known risks to puberty suppression followed by cross-sex hormones beyond fertility concerns. As noted, emerging data show that treated patients have lower bone density, which may lead to increased fracture risk later in life.[82] Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.[83] In addition, non-physiological levels of

[81] de Nie I, van Mello NM, Vlahakis E, Cooper C, Peri A, den Heijer M, Meißner A, Huirne J, Pang KC. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. Cell Rep Med. 2023 Jan 17;4(1):100858. doi: 10.1016/j.xcrm.2022.100858.

[82] See Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015).

[83] See Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. *Hypertension (Dallas, Tex.: 1979)*, HYPERTENSIONAHA12016839. Advance online publication. https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Annals of internal medicine*, *169*(4), 205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

estrogen in males has been shown to increase the risk of thromboembolic stroke above the incidence observed in females.[84]

Endocrine Society and WPATH Guidelines

88. A reasonable understanding of relative risk versus benefit for medical products or procedures is a fundamental obligation in providing appropriate clinical care. This is the bedrock standard of "evidence based medical practice." When considering clinical practice guidelines, it is essential that physicians recognize the relative risks and benefits of such documents. If done properly, they can distill large data sets into actionable clinical recommendations. However, there is a long history of clinical practice guidelines that have later been found to be deficient, resulting in wasted medical resources, have failed to achieve desired benefits, or have caused substantial harm to patients.[85]

89. As detailed throughout this report, this foundational standard of "evidence based medical practice" has never been met as to so-called gender affirming care. The field of "affirming care" is characterized by a poor quality of evidence

[84] E.g. Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. Annals of internal medicine, 169(4), 205–213. https://doi.org/10.7326/M17-2785.

[85] See Woolf et al., Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ (Clinical research ed.)*, 318(7182), 527–530, https://doi.org/10.1136/bmj.318.7182.527 (1999).

regarding safety and efficacy, as well as attempts to silence standard scientific discussion and consideration of alternative hypotheses, failures to acknowledge existing data showing persistence of suicidality after intervening, the intentional impairment and destruction of normally formed and functioning male and female sexual organs to address psychological-psychiatric distress, the manipulation of language from standard medical definitions, and widespread failures to properly report research data related to gender transitioning.

90. Because of ideological and political pressure, health providers in many fields are now not permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of gender dysphoric patients.[86] Providers are instead compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of confirmation bias—one of the most serious of all methodological diagnostic failures. As one paper explained, "physicians' desire to confirm a preliminary diagno-

[86] See https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4928.pdf and https://williamsinstitute.law.ucla.edu/publications/conversion-therapy-and-lgbt-youth/

sis while failing to seek contradictory evidence" appears to be "an important reason for wrong diagnoses."[87] Such "[d]iagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions."[88]

91. Despite the dangers of confirmation basis, existing guidelines base recommendations for "affirming" medical interventions on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories," with no alternative treatments offered, and no alternative explanations (e.g., social contagion) explored. Clinicians tasked with providing GnRH analogs to suppress normally timed puberty and gender affirming cross-sex hormones to induce secondary sexual characteristics coinciding with a sex-discordant gender identity rely upon subjective criteria to establish a diagnosis of sex-gender incongruence. There is no biological test to verify the diagnosis.

[87] Mendel et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press (2011).
[88] *Id.*; see also Doherty et al., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics 22(9):E773-778 (2020) ("Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them."); Hershberger et al., Teaching awareness of cognitive bias in medical decision making. *Acad Med*. 70(8):661 (1995).

I. Endocrine Society

92. In 2009, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.[89] The recommendations include temporary suppression of pubertal development of children with GnRH agonists followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low." According to the GRADE system, low recommendations indicate that "[f]urther research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that **"**any estimate of effect is very uncertain."[90]

[89] See Hembree et al., Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline, *The Journal of clinical endocrinology and metabolism*, *94*(9), 3132–3154, https://doi.org/10.1210/jc.2009-0345 (2009).
[90] Guyatt et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, BMJ; 336:924 doi:10.1136/bmj.39489.470347 (2008).

93. The Endocrine Society published an updated set of guidelines in September 2017.[91] Those guidelines show that all recommendations as to "affirming" treatment of adolescents are supported by low or very low quality evidence.

94. It is highly misleading to imply that the current Endocrine Society guidelines represent the opinions of the Society's 18,000 members. The committee that drafted these guidelines was composed of *less than a dozen* members. The guidelines were never submitted to the entire Endocrine Society membership for comment and approval prior to publication. They also did not undergo external review. Such methodologies are common in association "statements" and "endorsement"; they are not scientific or generally reliable.

95. The panel that drafted the Endocrine Society guidelines was heavily composed of individuals who have significant associations with WPATH. Specifically, all but one of the committee members were leaders in WPATH. Two of the authors served as WPATH's president (Walter J. Meyer and Vin Tangpricha); at least four have served, or are serving, on WPATH's Board of Directors (Peggy Cohen-Kettenis, Louis Gorren, Stephen Rosenthal, Guy T'Sjoen); and at least four (Stephen Rosenthal, Joshua Safer, Vin Tangpricha, and Guy T'Sjoen) were authors

[91] See Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of clinical endocrinology and metabolism*, *102*(11), 3869–3903, https://doi.org/10.1210/jc.2017-01658 (2017).

of WPATH SOC 8. Three (Peggy Cohen-Kettenis, Walter Meyer, and Vin Tangpricha) were authors of WPATH SOC 7.

II. WPATH

96. The World Professional Association for Transgender Health (WPATH) has also issued several iterations of guidelines. The first set of clinical practice guidelines was published in 1979. WPATH published its latest version of their "Standards of Care for the Health of Transgender and Gender Diverse People" (SOC 8) in September of 2022. [92] While this document has been presented as "authoritative" and "evidenced based", numerous concerns have been raised about the updated recommendations. This includes removal of age limits for initiation of cross sex hormones and gender affirming surgery, recommendations for excluding parents in the decision making process if they question or challenge medical interventions, elimination of safeguards for addressing underlying mental health illness before the start of gender affirming medical interventions, and the addition of a section on "eunuch-identified" people. [93] Many of the recommendations made reflect WPATH's acknowledged agenda as an advocacy group. In SOC8 they specifically state "Health is promoted through public policies and legal reforms that ad-

[92] ibid

[93] Coleman et al, Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644..

vance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy." Despite the claim that the SOC8 guidelines are based upon solid scientific evidence, such recommendations represent ideological positions devoid of rigorous scientific evidence. Scientific data on long-term outcomes in adolescents who are exposed to the U.S. affirmation model simply do not exist.

97. In sum, clinical guidelines or standards of care should provide practitioners with evidence-based standards by which they may reliably inform the patient of projected outcomes, and do so with a known error rate. Such data is the starting point for obtaining informed consent. This information is not provided by either WPATH or Endocrine Society's guidelines.

Informed Consent

98. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. As discussed above, relying on clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. Using "affirming"

treatments on minors violates this essential principle by using experimental treatments on vulnerable populations without properly informing them of the actual risks and limitations of the treatments.[94]

99. It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment.[95]

100. Essential requirements for informed consent include the ability of the patient or study subject to understand the proposed procedure, full disclosure of known and potential risks and benefits, discussion of alternative treatments, and freedom to act voluntarily. This information is presented verbally and in written form with allowance of sufficient time for the patient to ask questions and for the provider to assess adequate comprehension by the patient. It is well recognized that

[94] See Jonson et al., Clinical Ethics, New York: McGraw Hill (1998).
[95] See Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ("Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits.") See also Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, Pediatrics, August 2016, 138 (2) e20161485; DOI: https://doi.org/10.1542/peds.2016-1485 at https://pediatrics.aappublications.org/content/138/2/e20161485.

the signing of a formal consent form does not guarantee that informed consent has been obtained.

101. Several aspects of the care of individuals with gender dysphoria may substantially interfere with proper application of these foundational principles.[96] For adolescent children seeking medical gender affirmation medical, well established limitations in decision making ability raise serious concerns about their ability to consent to hormonals and surgical interventions. Adolescents have a known tendency to engage in risky behaviors, exercise poor impulse control, and show frequent failure to appreciate long-term consequences of current choices.[97]

102. For example, the ability of a child to understand implications for future fertility while still developmentally immature can pose a significant barrier to meeting the criterion of appreciating decision consequence. Children are often unlikely to be capable of giving truly informed consent, particularly when it comes to hormonal or surgical treatments that will result in lifelong sterility.[98] Adolescents' inability to adequately weigh potential short-term benefits against long-term risks

[96] Paul S. Appelbaum and Thomas Grisso, "Assessing Patients' Capacities to Consent to Treatment," New England Journal of Medicine 319, no. 25 (1988).
[97] Sarah-Jayne Blakemore and Trevor W. Robbins, "Decision-Making in the Adolescent Brain," *Nature Neuroscience* 15 (2012); Neuroscientists have found that the adolescent brain is too immature to make reliably rational decisions. B.J. Casey, Rebecca M. Jones, and Todd A. Hare, "The Adolescent Brain," Annals of the New York Academy of Sciences 1124 (2008): 111, http://dx.doi.org/10.1196/annals.1440.010.
[98] See Geier, Adolescent cognitive control and reward processing: Implications for risk taking and substance use, Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013).

seems supported by the observation that few adolescents express concern over loss of fertility even when directly told of the potential sterilizing effect of medical intervention.[99]

103. Similarly, individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weight proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria.[100]

104. In addition, a study subject's underlying belief that he or she was born in the wrong body is the primary reason for seeking medical intervention. Thus any challenge to this underlying premise is seen as a threat to the affected individual. Under such conditions, an individual will find it difficult, if not impossible, to give truly informed consent.

105. A model relying on parental consent with child assenting to affirmative medical interventions does not remove concerns about the difficulty in obtaining truly informed consent. Since many of the long-term outcomes of gender affirming interventions are unknown, prospective patients are being asked to consent

[99] Leena Nahata et al., "Low Fertility Preservation Utilization among Transgender Youth," Journal of Adolescent Health 61, no. 1 (2017).
[100] H. Helmchen, "Ethics of Clinical Research with Mentally Ill Persons," Eur Arch Psychiatry Clin Neurosci 262, no. 5 (2012).

without sufficient knowledge of inherent risk versus benefit. Without understanding that nearly all adolescents who are put on puberty blockers will proceed to gender affirming hormones, with many subsequently opting for gender affirming surgeries, focus on gaining consent for this first stage of the affirmative model is difficult if not impossible.

106. Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child to medically transition will result in suicide. These "threats" ignore data that challenge this biased assumption.[101]

107. While any cases of suicide are of utmost concern, suicide rates in children with sex-discordant gender identity must be put in context of overall suicidality in the pediatric population independent of gender dysphoria. When considered in this context, the rates of suicidal ideation and attempt in transgender adolescents are similar to those found in adolescents without gender dysphoria who present for psychological care (ref). Furthermore, it is necessary to critically assess, with rigorous scientific data, whether gender affirming medical interventions succeed in preventing suicides. While long-term data are not available for pediatric patients,

[101] See D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Arch Sex Behav* 50**,** 7–16, https://doi.org/10.1007/s10508-020-01844-2 (2021).

the adult literature consistently reports continued elevated suicidality after undergoing gender affirming medical interventions.[102]

108. Researchers have noted that in the "affirming" context, "the informed consent process rarely adequately discloses" either "the uncertain permanence of a child's or an adolescent's gender identity" or "the uncertain long-term physical and psychological health outcomes of gender transition."[103] Levine et al. recently noted the following major deficiencies in the informed consent process under existing "affirming" guidelines and approaches:

- "High rate of desistance/natural resolution of gender dysphoria in children is not disclosed";
- "Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained"; and,
- "The question of suicide is inappropriately handled".[104]

As discussed above, the informed consent process for "affirming" treatments is further "limited by" "erroneous professional assumptions" and "poor quality of the initial evaluations."[105]

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[102] Adams N, Hitomi M, Moody C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health. 2017 Apr 1;2(1):60-75. doi: 10.1089/trgh.2016.0036; Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).
[103] Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, *Journal of sex & marital therapy*, 1–22, https://doi.org/10.1080/0092623X.2022.2046221 (2022).
[104] *Id.*
[105] *Id.*

109. Using experimental procedures on uninformed, vulnerable patients is unethical and improper. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science—such is the case with the gender transition industry. The infamous Tuskegee studies, Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia[106]), recovered memory therapy-multiple personality disorders, rebirthing therapy,[107] coercive holding therapy,[108] and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions.

Existing Literature and Its Limitations

110. Before turning to the existing literature on gender dysphoria and its treatments, it is important to understand the varying types of studies conducted in this and other medical fields, as well as the general approach to scientific testing.

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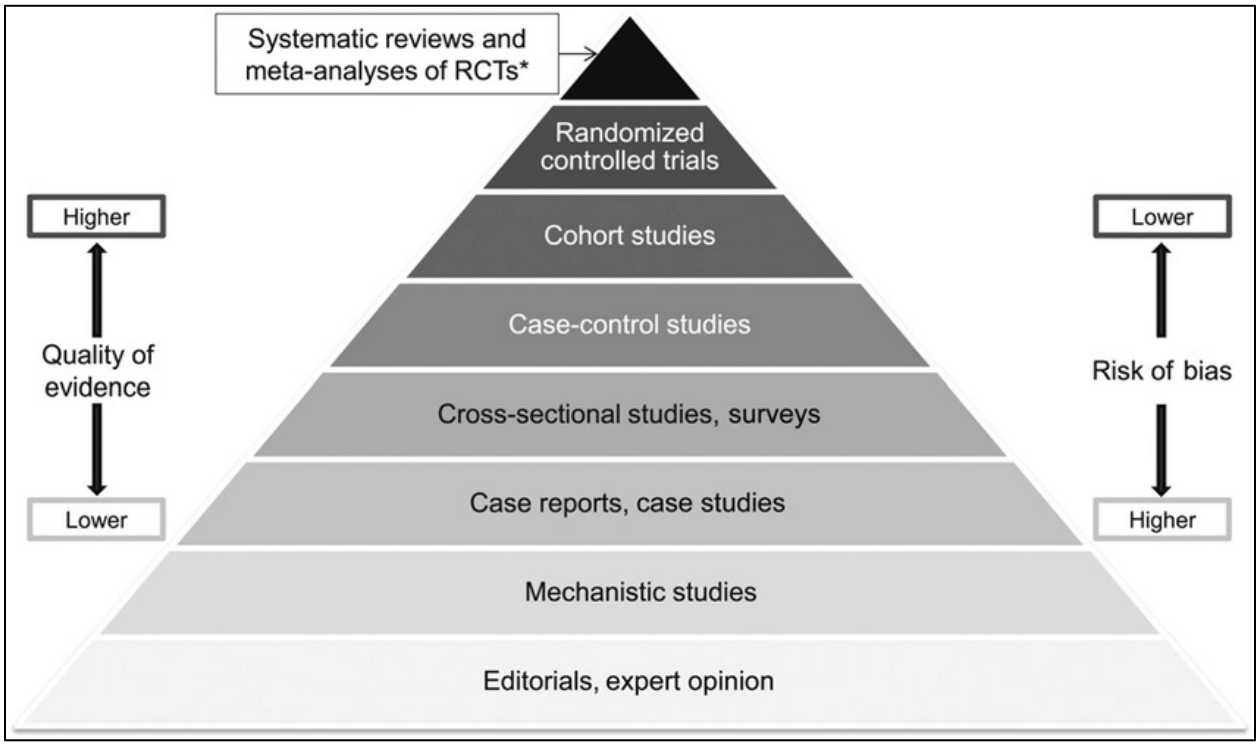
[106] See https://www.nobelprize.org/prizes/medicine/1949/moniz/article.
[107] See, e.g., Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001; see also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001.
[108] See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005.

Appropriate testing of medical and other scientific hypothesis requires proper study design. First, the research formulates a hypothesis as to whether there is a difference—a cause and effect relationship—from the studied intervention. The study starts by assuming the "null hypothesis"—there is no difference—and then one looks for evidence sufficient to disprove the null hypothesis. When conducting the study, statistical significance is of central importance, for it states the likelihood that the observation would exist if the null hypothesis were true. Only if there is a very small likelihood that the null hypothesis is true is it generally appropriate to treat a study as providing evidence that the null hypothesis is, in fact, false. Accordingly, if a study finding does not reach statistical significance, it would be improper to use the finding as a rejection of the null hypothesis.

111. Case reports or experts' opinions are recognized as the lowest level of evidence. Those are based upon general experiences, not scientific testing. They can be useful for generating a novel hypotheses, which can then be tested through experimental testing to establish if there are cause/effect relationships. Next up on the pyramid of quality of evidence would be, for example, cross-sectional studies that are done where one looks at a condition at one point in time. One can merely infer associations from these types of studies. Randomized longitudinal studies can permit, to some extent, the elimination of unrecognized variables that may distort the results. The highest part of the evidence-based pyramid (for individual studies)

is randomized controlled trials, in which the investigator attempts to control all aspects of the study with the exception of the independent variable that is being tested. When done properly, this type of study can provide strong evidence of causation. The following illustrates this pyramid:[109]



112. Since the "affirming" model of treating transgender children, as summarized by the World Professional Association for Transgender Health (WPATH) and Endocrine Society guidelines discussed below, are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions

[109] https://www.researchgate.net/figure/Hierarchy-of-evidence-pyramid-The-pyramidal-shape-qualitatively-integrates-the-amount-of_fig1_311504831

in psychological distress following social transition in a "gender affirming" environment remains inconclusive. Multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.[110] No randomized control trials have been performed, and the existing longitudinal studies have serious limitations—most significantly, that they follow cohorts of patients in a non-controlled, unrandomized manner. This design severely limits any conclusions that can be drawn.

113. Moreover, many studies find no improvement—or negative effects—from "affirming" care. For instance, a 2020 British study (Carmichael et al.[111]) found "no evidence of change (no improvement) in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm." Puberty blockers used to treat children aged 12 to 15 who had severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age

[110] See Hruz, P. W. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* 87, 34-42, doi:10.1177/0024363919873762 (2020).
[111] Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653.

16. As Oxford's Professor Michael Biggs summarized the study's findings, "After a year on GnRHa [puberty blockers] children reported greater self-harm, and girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria."[112]

114. The widely respected Cochrane Review examined hormonal treatment outcomes for male-to-female transitioners over 16 years.[113] They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." Thus, decades after the first transitioned male-to-female patient, quality evidence for the benefit of transitioning remains lacking.

115. Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia

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[112] https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/; Dyer, C. Puberty blockers: children under 16 should not be referred without court order, says NHS England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453. See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021); see also Dyer, C. Puberty blockers do not alleviate [suicidal] negative thoughts in children with gender dysphoria, finds study. BMJ 372, n356, doi:10.1136/bmj.n356 (2021). https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1; BBC summary: https://www.bbc.com/news/uk-55282113

[113] See Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 and https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full.

continue to have rates of depression, anxiety, substance abuse and suicide far above the background population.[114]

A. Change in Patient Population

116. One important (and contentious) issue requiring more study is the recent trend of adolescent female to male gender discordant patients. In the United Kingdom, where centralized medical care provides data to track health care phenomenon, the number of adolescent girls seeking sex transitioning exploded over 4,000% in the last decade. Similarly, in the United States, where we lack the same kinds of centralized health care data, it has been reported that in 2018, 2% of high school students identified on surveys as "transgender"—this is 200 times greater response, a 20,000% increase—over reports during past decades which showed a rate of only .01 percent.[115]

117. Along with this increase in transgender patients and identifiers has come a radical and recent transformation of the patient population from early onset males to rapid onset adolescent girls. Currently the majority of new patients with

[114] See Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); see also Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011).

[115] See Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019; 68:67–71.

sex-gender discordance are not males with a long, stable history of gender dysphoria since early childhood—as they were for decades, and under the Dutch protocols—but instead adolescent females with no documented long-term history of gender dysphoria. One might say, as Dr. Lisa Littman has theorized, [116] that these females experienced "rapid onset" transgender identification.

118. This recent change in the typical patient raises questions about our understanding of the origins of transgender identity. For instance, a genetics or "immutable" theory of transgender identity cannot explain the rapid expansion of new GD cases (a 4,000% to 20,000% increase), given that our genome is simply not changing that fast. Nor can that theory explain the explosion of adolescent females presented with GD. A "brain structures" theory has only weak medical evidence, and it also cannot explain the rapid expansion of new gender dysphoria cases. As for the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why males and older women are not also coming out in the same large numbers and not coming out in "social peer group clusters," as adolescent females are reportedly doing.

[116] See Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

B. Methodological Problems with "Affirming" Literature

119. The published literature relied on to advocate for the use of puberty blockers, cross-sex hormones and gender affirming surgeries in minors consists almost entirely of studies with major methodological limitations.[117] As detailed next, these include:

- Significant recruitment biases, including internet-based convenience sampling;
- Relatively small sample sizes for addressing a condition that is likely to be multifactorial;
- Short term follow-up;
- Lack of randomization to different treatment arms;
- Failure to consider alternate hypotheses;
- Failure to include proper control groups;
- Reliance on cross sectional sampling that may identify associations, but cannot establish causal relationships between intervention and outcome;
- A high rate of patients lost to follow up in longitudinal analyses, which is relevant to questions of regret, desistance and completed suicide;
- Biased interpretation of study findings with a goal of validating *a priori* conclusions rather than seeking evidence to disprove the null hypothesis; and
- Ignoring starkly contradictory research documenting the lack of effectiveness of "transitioning" procedures, the low quality of research in this area, and the ongoing contentions and disagreements over this highly controversial, experimental medical field.

[117] See generally Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, Linacre Q 87(1), 34-42, doi:10.1177/0024363919873762 (2020).

120. Some or all of these methodological and statistical flaws are present in the following studies, which are commonly relied on by advocates of "affirming" treatments.

The Branstrom Long-Term Treatment Outcome Study: The historic Branstrom study is a long-term treatment (10+ years) outcome research investigation testing the effects of hormonal and surgical "transitioning" treatments on patients. This historic research found no reliable benefits from these treatments, as well as evidence suggesting *increased* suicide attempts and anxiety disorders following the "gender transitioning" treatments. In addition, detailed methodological critiques discovered significant research errors by the authors that appear to support the investigative theory that the authors had initially attempted to manipulate and misreport the findings of the study. The authors ultimately recanted their initial misreporting and agreed that their study produced *no reliable evidence* of benefits for gender reassignment hormone and surgical treatments. This historic investigation has helped to generate a profound collapse of support for these experimental procedures across Europe.[118]

[118] See SEGM, *Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health*, https://segm.org/ajp_correction_2020 (Aug. 30, 2020); Van Mol et al., *Gender-Affirmation Surgery Conclusion Lacks Evidence.* Am. J. Of Psych., 177(8), 765-766 (2020).

A 2011 Dutch study by de Vries et al.[119] is often cited to support longitudinal evidence of benefit from pubertal blockade. Although the study found slight improvements in mood improved and the risk of behavioral disorders with pubertal blockade over baseline, the study included no control group, and all 70 participants received ongoing psychological support. Thus, the authors were unable to determine the basis of the limited observed improvement. The authors acknowledge that psychological support or other reasons may have contributed to (or wholly caused) this observation. By the very nature of the trial, at best the study can provide a rationale for doing further studies that could show whether "affirming" interventions provide a benefit. The study does not (and cannot) answer the central question: whether the administration of puberty blockers is the solution to the problem and whether alternative approaches that do not carry the same risks relative to purported benefits (i.e., psychological interventions) may have the same or superior benefits.

Moreover, there remain questions about the extent to which the protocol used in these early Dutch studies may be relevant to the patient population presenting today. For decades transgender patients were mostly older adults or very young boys. As noted, over the last few years, a tsunami of teenaged girls has

[119] de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. *J Sex Med*. 8(8):2276-2283 (2011).

flipped the demographics of transgender patients—now up to 7 to 1 teen girls. The newly presenting cases are vastly overrepresented by adolescent females, the majority of whom also have significant mental health problems and neurocognitive comorbidities such as autism-spectrum disorder or ADHD.[120] Furthermore, estimates of gender dysphoria-transgenderism are rocketing upwards from 1 in 10,000 to "the number of U.S. transgender-identified youth may be as high as 9%."[121] This unexplained, radical transformation of patient demographics raises questions about the applicability even of the limited existing literature on this issue, particularly as to the Dutch protocol. Dr. Thomas Steensma, a prominent investigator of the Dutch protocol—the original model for transitioning treatments—has recently noted that "[w]e don't know whether studies we have done in the past can still be applied to this time," specifically because of the unexplained surge in female adolescents reporting gender dysphoria. "Many more children are registering, but also of a different type… Suddenly there are many more girls applying who feel like a boy." He concluded with the warning that "[w]e conduct structural

[120] See de Graaf, Nastasja M., and Polly Carmichael. "Reflections on Emerging Trends in Clinical Work with Gender Diverse Children and Adolescents." Clinical Child Psychology and Psychiatry, vol. 24, no. 2, Apr. 2019, pp. 353–64.
[121] See Kidd, Kacie M., et al. "Prevalence of Gender-Diverse Youth in an Urban School District." Pediatrics, vol. 147, no. 6, June 2021, p. e2020049823.

research in the Netherlands. But the rest of the world is blindly adopting our research."[122]

A 2014 follow-up study by de Vries et al.[123] encompassed 55 of the original 70 patients; 15 were lost to follow-up or not included. It has the same limitations that was present in assessing the original 2011 study, including a carefully selected patient population that is not representative of the broader population, especially now. Having a longer study does not obviate the limitations of the study design in making a conclusion that can be applied to the gender clinics that are operating in the United States.

In addition to the concerns of the Dutch studies already exposed, "[t]he linchpin result of the Dutch studies is the reported resolution of gender dysphoria, as measured by the Utrecht Gender Dysphoria Scale (UGDS)." Yet, as several researchers recently explained, the observed "drop was an artifact of switching the scale from 'female' to 'male' versions (and vice versa) before and after treatment, prompting a problematic reversal in the scoring."[124] "The same gender dysphoric

[122] See https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/.
[123] de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics. 2014 Oct;134(4):696-704. doi: 10.1542/peds.2013-2958
[124] Abbruzzese E, Levine SB, Mason JW. The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies-and research that has followed. J Sex Marital Ther. 2023 Jan 2:1-27. doi: 10.1080/0092623X.2022.2150346.

individual, effectively answering the same question (albeit linguistically inverted)"—e.g., "Every time someone treats me like a girl [or boy] I feel hurt"—"results in either the maximum or the minimum 'gender dysphoria' score—depending on which sexed version of the scale was used." Thus, because researches used different scales of the UGDS before and after treatment, "it is impossible to determine if [the result shows] a real difference in gender dysphoria between groups or if this is an artifact of measurement error." Indeed, if anything, "[t]he fact that after gender reassignment, the UGDS scores were low on the opposite-sex scale indicates that the subjects would have scored high on the natal sex scale, which corresponds to a *persistence in transgender identity*." This, of course, is the opposite result purportedly reached by the study.

The 2018 paper by Wiepjies, et al.[125] is a retrospective review of records from all patients of the Center of Expertise on Gender Dysphoria gender clinic in Amsterdam from 1972-2015. While the study appears to report on the regret rates among a large cohort of adolescents (812) and children (548), regret is only reported for children and adolescents who had undergone gonadectomy once over 18 years of age. Of the adolescents, 41% started puberty suppression. Of those who started GnRH agonists, only 2% stopped this intervention (meaning that 98% of

[125] Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, *The Journal of Sexual Medicine*, *15*(4), 582–590 (2018).

those who started puberty suppression progressed to cross-sex hormone therapy). An additional 32%, having already completed puberty, started cross-sex hormone therapy without use of a GnRH agonist. Classification of regret was very stringent, requiring physician documentation of patient verbalized regret after gonadectomy and start of sex-concordant hormones to treat the iatrogenic hypogonadism. This means there are significant limitations to the conclusions that can be drawn from this paper. There is no discussion in the paper regarding adolescent regret of use of puberty blockers, cross-sex hormones or mastectomies. Importantly, 36% of patients were lost to follow up. This is notable given that gonadectomy iatrogenically induces the pathologic state of primary hypogonadism. Affected patients have a lifelong dependency for exogenously administered sex-steroid hormones, and thus an acute need for ongoing follow-up. Their failure to return to the physicians who provided gender affirming interventions raises serious questions about their outcome. It is reasonable to hypothesize that some may have experienced regret or completed suicide. Yet due to missing data, their fate remains unknown. It is also significant that the average time to regret was 130 months. The authors themselves acknowledge that it may be too early to predict regret in patients who started hormone therapy in the past 10 years.

The 2018 Olson-Kennedy et al. paper[126] presents the results of a survey of biologically female patients with male gender identity at the lead author's institution using a novel rating system for "chest dysphoria" created by the study authors. There were an equal number (68) of nonsurgical and post-surgical subjects surveyed. Those who had undergone bilateral mastectomies were reported to have less chest dysphoria than those who did not receive this intervention. Limitations of this study include convenience sampling of nonsurgical study subjects with high potential for selection bias, cross-sectional design, lack of validation of the primary outcome measure, and short follow-up time (about 2 years). Test validation is particularly relevant in assessing adolescent questionnaires due to a variety of cognitive and situational factors in this population.[127] Rigorous validation methods have been previously used in several other established questionnaires addressing adolescent self-perception.[128] As previously noted, this study cannot provide information about a causal relationship between the intervention and outcomes observed.

[126] Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, *JAMA Pediatr.* 172(5):431–436 (2018).
[127] See Brener et al., Assessment of Factors Affecting the Validity of Self-Reported Health-Risk Behavior among Adolescents: Evidence from the Scientific Literature, *Journal of Adolescent Health* 33 (6): 436–57 (2003).
[128] See Palenzuela-Luis et al., Questionnaires Assessing Adolescents' Self-Concept, Self-Perception, Physical Activity and Lifestyle: A Systematic Review, *Children (Basel, Switzerland)*, *9*(1), 91 (2022).

A 2019 study by Allen et al.[129] considered suicidality after cross-sex hormones. It was limited by a very small patient population (47), had no control group, had a short follow-up period (mean < 1 year), and again ignored that patients receiving the interventions also received psychological support.

A 2020 study by Turban et al.[130] is often cited as proof that pubertal blockade prevents suicide in transgender youth. However, this study used an unreliable, biased sampling methodology. As stated in the paper, the authors considered "a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years" from the 2015 U.S. Transgender Survey. This was an online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. Among the many problems with this sampling methodology, there is no evidence of study subject identities, no way to assess for potential false subjects, and no medical diagnosis for entry. No causation can be determined from this retrospective, cross-sectional design. Furthermore, the study failed to even assess individuals who may have desisted or regretted transitions. Turban claimed that desisters and regretters would "not be likely" in this study group, which also only included

[129] Allen, L. R., Watson, L. B., Egan, A. M., & Moser, C. N. (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. Clinical Practice in Pediatric Psychology, 7(3), 302–311. https://doi.org/10.1037/cpp0000288

[130] Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, *145*(2), e20191725 (2020).

adults. Thus, the study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender."

Turban's misleading claim of lower suicidal ideation for treated patients is based upon "lifetime suicidality". It fails to recognize or acknowledge that the decision to grant the wish to provide puberty blockers was likely influenced by the mental health of the subjects at the time of presentation. Specifically, the most seriously mentally ill patients would have been denied affirmation treatment. Those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6). In Table 3 of the paper, under "Suicidality (past 12 months)" reductions for suppressed group versus non-suppressed were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). However, it is important to note that differences in suicidal "ideation with plan and suicide attempt" and "attempt resulting for inpatient care" did not reach statistical significance. This was ignored by the authors. It would be reasonable to be concerned from an observation of over 40% attempted suicide in the treated group that the intervention was unsuccessful in improving health.[131]

[131] See generally Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, DOI: 10.1007/s10508-020-01743-6 (2020) and the multiple Letters to the Editor that criticized the multiple methodological errors in this study,

A 2020 study by van der Miesen, et al.[132] was a cross-sectional Dutch study that measured some patients who received puberty blockers and some who did not. The study had three populations of subjects: One was patients presenting to the gender clinic who had not received any intervention. The second was patients who had received puberty blockers. The third was adolescents from the general population. Because of this study's cross-sectional nature, it cannot establish a causal relationship between intervention and effect. It also represents a non-probability sample with potential for significant biases in subject recruitment. In addition, the subjects assessed before and after treatment are difference populations. Among the differences between these groups is patient age (mean of 14.5 and 16.8 years before and after treatment, respectively). This two year age difference is important as developmental progress during adolescence is known to influence psychological well-being.[133] There was also the same limitation noted in the 2011 de Vries study, that the treated population also received psychological support.

https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation.

[132] van der Miesen AIR, Steensma TD, de Vries ALC, Bos H, Popma A. Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers. J Adolesc Health. 2020 Jun;66(6):699-704. doi: 10.1016/j.jadohealth.2019.12.018

[133] He J, Sun S, Zickgraf HF, Lin Z, Fan X. Meta-analysis of gender differences in body appreciation. Body Image. 2020 Jun;33:90-100. doi: 10.1016/j.bodyim.2020.02.011.

A 2021 study by Bustos, et al.[134] attempts to provide a systematic review of 27 observational or interventional studies that report on regret or detransition following gender-transition surgeries. A total of 7,928 subjects were included in their meta analysis. The authors concluded that only 1% or less of those who had gender-transition surgeries expressed regret. It is important to understand the serious methodological limitations and high risk of bias contained within this study's analysis.[135] This includes failure to include major relevant studies addressing this question,[136] inaccurate analysis within one of the studies considered,[137] and the general lack of controlled studies, incomplete and generally short-term follow-up, large numbers of lost subjects, and lack of valid assessment measures in the published literature addressing this question. As noted by Expósito-Campos and D'Angelo (2021), moderate to high risk of bias was present in 23 of the 27 studies included in the analysis. Furthermore, 97% of subjects analyzed were found

[134] Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(3), e3477 (2021).
[135] See Expósito-Campos, P., & D'Angelo, R. (2021). Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(11), e3951.
[136] E.g. Dhejne, C., Öberg, K., Arver, S., & Landén, M. (2014). An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. *Archives of sexual behavior*, *43*(8), 1535–1545.
[137] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med 2018; 15: 582–590.

within studies deemed to be of fair to poor scientific quality. Thus, this study cannot be used as strong support for the contention that regret is rare.

The 2021 study by Narayan et al.[138] examines anonymous survey results from 154 surgeons affiliated with WPATH. The response rate for this survey was 30%. Of the respondents, 57% had encountered patients with surgical regret. It is important to recognize that this study was specifically directed toward patients who had undergone surgical transition. Acknowledged biases of this study include selection bias, recall bias, and response bias. This type of study cannot accurately identify the prevalence in the transgender population as a whole, and is particularly limited in the ability to assess potential for regret in the pediatric population.

The 2021 Almazan study[139] attempts to address mental health outcomes in relation to gender-transition surgery. This study relies upon data from the 2015 US Transgender Survey. Limitations and weaknesses of this survey tool includes convenience sampling, recruitment of patients through transgender advocacy organizations, demand bias (i.e., the good subject effect[140]), a high number of respondents

[138] Narayan et al., Guiding the conversation-types of regret after gender-affirming surgery and their associated etiologies, *Annals of translational medicine*, *9*(7), 605 (2021).
[139] Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes. *JAMA Surgery, 156*(7): 611–618 (2021).
[140] Nichols AL, Maner JK. The good-subject effect: investigating participant demand characteristics. J Gen Psychol. 2008 Apr;135(2):151-65. doi: 10.3200/GENP.135.2.151-166. PMID: 18507315.

who reported having not transitioned medically or surgically (and reported no desire to do so in the future), and several data irregularities. One notable data irregularity was that a high number of respondents reported that their age was exactly 18 years. As noted by D'Angelo and colleagues, these irregularities raise serious questions about the reliability of the USTS data and therefore the reliability of conclusions based on that data.[141]

The **2022 van der Loos** study[142] is a Dutch cohort study that investigates the continuation rate of gender affirming interventions in people who began puberty blockers and gender affirming hormones during adolescence. The authors claim that the study provides evidence against desistance after receiving gender affirming hormones. While the paper gives the impression that subjects represent a period of study extending from 1972 to 2018, the majority of subjects recently started hormone interventions. The length of time for follow-up (mean of 3.5 years for males and 2.3 years for females) and the average age at follow-up (20.2 years for males and 19.3 years for females) are inadequate to support the authors' claim. Notably,

[141] D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, *Archives of sexual behavior*, *50*(1): 7–16. https://doi.org/10.1007/s10508-020-01844-2 (2021).

[142] van der Loos MATC, Hannema SE, Klink DT, den Heijer M, Wiepjes CM. Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: a cohort study in the Netherlands. Lancet Child Adolesc Health. 2022 Dec;6(12):869-875. doi: 10.1016/S2352-4642(22)00254-1.

research from these same investigators has suggested that the average time to de-transition is over 10 years.[143] Thus, it would be necessary for the study to assess patients at least a decade after starting gender affirming hormones to make any meaningful conclusions on desistance. Furthermore, as a retrospective cohort study without a control group, the study design cannot determine the effect of gender affirming therapy on whether or not the intervention influences the rate of desistance that would have occurred without the provision of gender affirming hormones.

The **2022 Nos** study[144] is a retrospective cohort study that reports on the likelihood of starting on gender affirming hormones (GAH) based upon whether or not subjects were treated with puberty blockers. While the title and abstract give the impression that puberty blocker use is not linked to subsequent GAH, the data fail to support this conclusion. Since nearly all of the patients in this study who did not receive GnRHa were given GAH, it is not possible to determine whether GnRHa could increase this outcome. The comparison groups differed by age at time of initial presentation (age 10-13 years versus 14-17 years). GnRHa use was higher among the younger patients owing to the fact that they had not completed

[143] Wiepjes CM, Nota NM, de Blok CJM, Klaver M, de Vries ALC, Wensing-Kruger SA, de Jongh RT, Bouman MB, Steensma TD, Cohen-Kettenis P, Gooren LJG, Kreukels BPC, den Heijer M. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med. 2018 Apr;15(4):582-590. doi: 10.1016/j.jsxm.2018.01.016.
[144] Nos AL, Klein DA, Adirim TA, Schvey NA, Hisle-Gorman E, Susi A, Roberts CM. Association of Gonadotropin-Releasing Hormone Analogue Use With Subsequent Use of Gender-Affirming Hormones Among Transgender Adolescents. JAMA Netw Open. 2022 Nov 1;5(11):e2239758. doi: 10.1001/jamanetworkopen.2022.39758.

puberty at the time of first visit. A lag in progression to GAH use in this group is heavily influenced by the difference in age at time of initial presentation. The older group was eligible to start GAH at the time of study entry while those in the younger group were not. When adjusted for age, the rates of progression to GAH use is nearly identical. Importantly, among the patients who received GnRHa, **94% (64 out of 70)** went on to take gender affirming hormones. Thus, the study further confirms that rather than serving as a "pause button" for gender dysphoric adolescents, it is an intervention that will lead to progression to gender affirming hormones.

The 2022 Green at al. study[145] purported to measure suicide attempts and access to cross-sex hormones. Though this study had a large cohort of patients, it suffered many biases in patient recruitment—which was done over the Internet and provided a cross-sectional analysis which can, at best, demonstrate correlation but not causation. Similar to other studies, it not assess the effect of psychiatric medications or psychotherapy on outcomes. It also failed to include variables to assess at what age youth began puberty blockers or the duration which they had received gender affirming hormones.

[145] Green AE, DeChants JP, Price MN, Davis CK. Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. J Adolesc Health. 2022 Apr;70(4):643-649.

The 2022 Turban et al. study[146] is retrospective cross-sectional investigation to assess whether there is an association between adolescent access to gender affirming hormones and mental health. The authors claim that there is an association between getting gender affirming hormones and favorable mental health outcomes compared to those who desired but did not receive this intervention. The methodology used is similar to the author's 2020 study on the effects of access to puberty blockers on lifetime suicidality already discussed above. Specifically, it used the same 2015 U.S. Transgender Survey (USTS), with all of the associated limitations and biases.[147] Participants in the USTS were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. Thus, there are serious concerns of selection bias.[148] It also suffers from recall bias[149] and an inability to verify the veracity of the claims of treatments given to the study respondents. Even if one dis-

[146] Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Erratum in: JAMA Netw Open. 2022 Jul 1;5(7):e2229031.

[147] D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50**, 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2

[148] Tyrer S, Heyman B. Sampling in epidemiological research: issues, hazards and pitfalls. BJPsych Bull. 2016 Apr;40(2):57-60. doi: 10.1192/pb.bp.114.050203. PMID: 27087985; PMCID: PMC4817645.

[149] Coughlin SS. Recall bias in epidemiologic studies. J Clin Epidemiol. 1990;43(1):87-91. doi: 10.1016/0895-4356(90)90060-3. PMID: 2319285.

misses these concerns, by design, the study is not able to make any conclusions regarding a causal relationship between GAH access and mental health. Review of the data contained within the paper leads to conclusions that are far different than those stated by the study authors regarding mental health of the study participants. While the odds ratio for past year suicidal ideation was statistically different between those who did and those who did not get GAH, there was no difference in those who had a suicide plan, actually attempted suicide, or were hospitalized for a suicide attempt. This is important since the rationale for accepting the attendant risks of gender affirming hormones is to prevent suicide. Those with a suicide plan or attempt are far more likely to succumb to suicide than those who merely contemplated suicide. As pointed out by Michael Biggs in a commentary of this article,[150] the data presented in this study negate the purported significance of effects of puberty blocker access on mental health as reported in Turban's 2020 Pediatric article.

The 2022 Tordoff study is a prospective observational cohort study that assessed the mental health of patients presenting to the Seattle Children's gender clinic over a one year period of follow up. The authors claimed that access to gender affirming care had significantly improved mental health with lower odds ratios

[150] https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6

of depression and suicidality. This purported finding was widely publicized by the University of Washington and was featured on several news media sites. A detailed critique of the paper's data and flawed conclusions have been posted online.[151] Contrary to the claims, data contained in the paper did not show improvement in mental health over the one year study period. At entry into the study, 59% of the subjects had moderate to severe depression. At the end of the study, 56% had moderate to severe depression. Self-harm or suicidal thoughts were 45% and 37% at baseline and 12 months, respectively. These are alarmingly high numbers for an intervention that is touted to be lifesaving. The reported statistical difference in odds ratios were comparisons between those who started on puberty blockers and cross-sex hormones and those who did not receive hormones. Importantly, there was a marked difference in the number of dropout subjects in the treated and non-treated groups (17.5% versus 80%, respectively). It is reasonable to speculate that the small number of subjects who remained in the study but did not receive hormones had significant co-morbidities that prevented them from accessing this intervention. In any event, the actual data from this study demonstrates that access to puberty blockers and gender affirming hormones did not improve mental health over the first year of treatment. This is drastically different from what the authors and the media claimed.

[151] See https://jessesingal.substack.com/p/researchers-found-puberty-blockers?s=r

The 2022 Chen study[152] is a longitudinal observational study of patients receiving care at four gender centers in the United States. The primary conclusion made by the authors is that "GAH improved appearance congruence and psychosocial functioning." However, there are major limitations and weaknesses in the data that limit the conclusions that can be made. A revealing critique of the paper by de Vries and Hannema that was published alongside this article exposes some of these concerns.[153] The most glaring problem is that the study was observational and did not include a control group. Thus, there is no ability to draw causal conclusions. At best, the authors can find associations. Akin to many of the other papers in this field, there is no way to determine whether any of the changes were contributed by or due solely to psychiatric interventions. It is also notable that even though the study was designed to recruit only subjects in with good mental health at baseline, 48 of the 307 study subjects (15.6%) were described as having severe depression at this time point. At the end of the two year follow up, 30 of the 219 remaining subjects (13.7%) were reported to have major depression. Furthermore, two patients committed suicide during the time of observation. This is an outcome that in most

[152] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297.
[153] de Vries ALC, Hannema SE. Growing Evidence and Remaining Questions in Adolescent Transgender Care. N Engl J Med. 2023 Jan 19;388(3):275-277. doi: 10.1056/NEJMe2216191

other situations would lead to a halt in study and detailed inquiry by an institutional review board.[154] The paper claims to present two year follow up data in this cohort. However, only half of the study participants were assessed at each study time point and 30% did not have 24 month data collected. Even if one accepted the follow up period, this is likely not long enough to make firm conclusions about long-term efficacy. Most of the measures are based upon subjective experience. There is no inclusion of more robust measures of psychological well-being such as the number on antidepressants and other psychotropic medications. The study effects for many of the measured parameters was very modest at best and, while statistically significant, do not have any meaningful clinical significance. For example, the depression scores, showed little change over two years in the highest severity group. There is also significant heterogeneity in responses with some subjects showing improvement, some no change, and others worsening. Despite the spin provided by the authors and media, these data do not alleviate the serious concerns raised regarding the safety and efficacy of gender affirming medical interventions.

121. Many conclusions in the above studies are drawn or characterized in fundamentally unscientific ways without apparent regard to the scientific process of disproving a null hypothesis. Instead, these studies suggest that the authors began with a conclusion and then looked for data to support that conclusion. That is

[154] https://grants.nih.gov/grants/guide/notice-files/NOT99-107.html

a vastly unsound way of doing science, and patients will not be aware of these methodological limitations and distortions when informed of these purported conclusions.

122. There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals, as well as the long-term effects of "affirming" interventions.[155] In particular, there is a concerning lack of randomized controlled trials or adequately controlled longitudinal studies comparing outcomes of youth with gender dysphoria who received psychological support, were encouraged to socially transition, or were put on medical interventions, and how these differential treatments affect the usual and natural progression to resolution of gender dysphoria and other variables. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to all treatment groups.[156] But they have not been performed in the existing literature, leaving that literature in a state insufficient to enable sound conclusions about the efficacy of "affirming" treatments.

[155] Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity 23, 172-179, (2016).
[156] See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html.

International Responses

123. Recognizing the paucity of evidence supporting "affirming" treatments, along with the proven risks of those treatments, other countries are increasingly limiting use of those treatments.

124. **Finland**: The National Science Review in Finland carefully examined all relevant science and suspended transition treatments for minors under age 16.[157] The review determined that "[t]he first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders." According to the review, "[c]ross-sex identification in childhood, even in extreme cases, generally disappears during puberty." The review also found: "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system"; "there are no medical treatments (for transitioning) that can be considered evidence-based"; and, "[t]he reliability of the existing studies with no control groups is highly uncertain." Thus, "because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development," and "[n]o gender confirmation surgeries are performed on

[157] See 2020 Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors.

minors." "Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood…. In light of available evidence, gender reassignment of minors is an experimental practice."

125. **Sweden**: The world-renowned Karolinska Hospital reviewed the current research and suspended pediatric gender transitions for patients under 16 outside of experimental, monitored clinical trials settings as of May 2021. Treatment will focus on psychotherapy and assessment[158]. The "Dutch protocol" for treating gender dysphoric minors has been discontinued over concerns of medical harm and uncertain benefits.

Moreover, in a national policy review, a report commissioned by the Swedish government concluded that:

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.

[158] See Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies. https://segm.org/Sweden_ends_use_of_Dutch_protocol. See also, Karolinska Policy Change K2021-3343 March 2021 (in English).pdf; Karolinska Hospital Ends the Use of Puberty Blockers for patients under 16: New policy statement from the Karolinska Hospital.

- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria. There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium…
- No relevant randomized controlled trials in children and adolescents were found.[159]

From these findings, the Swedish National Board of Heath in December of 2022 issued updated guidelines for the care of adolescents and children with gender dysphoria.[160] This medical board concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatment". Noting that there is uncertainty about the cause for the rapid rise in number of people being diagnosed with gender dysphoria, documented evidence of detransitioning young adults with uncertainty regarding the prevalence of this outcome, and lack of uniformity in experience-based knowledge among providers, GnRH analogues, gender affirming hormones and mastectomy should be provided only in exceptional cases and ideally as part of an experimental trial.

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[159] See Sweden Policy Review, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e).
[160] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

126. **United Kingdom**: The British official medical review office (National Institute of Health and Care Excellence, NICE) published reports on the use of both puberty blockers and hormones for transitioning purposes. The assessment of the evidence into the drugs was commissioned by NHS England. The review found that the evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low certainty."[161] The review found that "all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly."

NICE also reviewed the evidence base for cross-sex hormones.[162] The review found the evidence of clinical effectiveness and safety of cross-sex hormones was also of "very low" quality. The review concluded: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."

[161] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf
[162] https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf

A recent independent review of gender identity services in the United Kingdom, by Dr. Hillary Case, concluded that "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."[163] Dr. Cass notes that "[t]here is lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response."

Citing concerns from the Cass report that the Tavistok model of care placed affected youth at considerable risk of poor mental health, and is therefore "not a safe or viable long-term option," this clinic is being shut down. It will be replaced by a new regional hospital-based service where related services for mental health and autism can be provided by clinicians who have expertise in safeguarding, supporting looked-after children and children who have experienced trauma. Thus, gender-related distress will be addressed "within a broader child and adolescent health context."

This new model is in sharp contrast to recommendations made by WPATH in their "standards of care" (SOC8). Differences in approach include the prioritization of parent versus child expectations for care, recommendations against social

[163] https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf

affirmation of pre-pubertal youth, the provision of puberty blockers within the experimental setting, initial focus on exploration and treatment of mental health problems, and use of psychological support as a primary intervention.

Conclusions

127. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

128. There are no long-term, peer-reviewed published, reliable, and valid research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological or other objective assessment of gender identity or gender dysphoria.

129. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

130. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

131. A currently unknown percentage and number of patients reporting gender dysphoria may be manipulated by a social contagion and social pressure

processes, including peer group, social media, YouTube role modeling, and parental pressures.

132. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

133. There are no long-term, peer-reviewed published, reliable and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

134. "Affirming" treatments have no known, peer reviewed and published error rates.

135. The gender affirming approach has limited, very weak scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches.

136. Because of the major methodological limitations and weaknesses of the extent published literature in the field of gender dysphoria, one cannot make a conclusion that "affirming" treatments are justified as a safe and effective long-term solution to gender dysphoria in consideration of the significant risks and unsubstantiated long-term benefits.

137. With the limited and poor-quality data currently available about the purported efficacy of blocking normally timed puberty, administering cross-sex

hormones, and gender affirming surgeries in alleviating psychological morbidity for youth who experience sex-discordant gender identity and the associated serious medical risks associated with these interventions, it cannot be concluded that this approach is "medically necessary." Use of such medical interventions remains a largely experimental approach.

138. Experimentation on gender discordant youths is especially likely to cause harm to patients from historically marginalized communities. That is because children in such communities are disproportionally affected by gender discordance. These include:

- children with a history of psychiatric illness;[164]
- children of color;[165]
- children with mental developmental disabilities;[166]
- children on the autistic spectrum;[167] and,

[164] See, e.g., Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y.

[165] See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.

[166] See, e.g., Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* 28**,** 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7.

[167] See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender dysphoric children and adolescents. *J Autism Dev Disord* 40, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

- children residing in foster care homes and adopted children.[168]

139. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable, valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

140. The treatment protocols and recommendations of politically influenced, non-science associations like WPATH and the American Academy of Pediatrics that engage in consensus-seeking methodologies by vote rather than science are not based on competent, credible, methodologically sound science, and have no known or published error rate.

141. Administering hormones to a child whose gender dysphoria is highly likely to resolve is risky, unscientific, and unethical. Iatrogenic damages from these interventions, including infertility, stunted growth, increased heart attack risk, and many more, are often irreversible.

142. Because of these concerns about the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the

[168] See, e.g., See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures.

143. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 15, 2023.

Paul W Hruz

Paul W. Hruz, M.D., Ph.D.

Exhibit "A"

Curriculum Vitae

Date: 2/15/2023
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: hruz_p@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 3-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO Stae License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry

1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute
2021	Linacre Award

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014 - 2015	Endocrinology and Metabolism Clinics of North America

National Panels, Committees

2017 - Pres	Consultant, Catholic Health Association
2021 - Pres	Consulting Fellow, National Catholic Bioethics Center

National Boards

2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Community Service Contributions

Professional Societies and Organizations

American Diabetes Association
Endocrine Society
Pediatric Endocrine Society

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children's Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting,, Vancouver, Canada
2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN

2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN
2022	The World Federation of Catholic Medical Associations (*FIAMC*), Rome, Italy

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator
2008 - 2011	II Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure Role: Co-Investigator PI: Hruz Total cost: $249,999.00
2009 - 2012	Research Program Regulation of GLUT4 Intrinsic Activity Role: Principal Investigator Total cost: $268,262.00
2010 - 2011	Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function Role: Principal Investigator
2012 - 2015	II Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins Role: Principal Investigator Total cost: $375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8
Role: Co-Principal Investigator
PI: DeBosch
Total cost: $450,000.00

2017 - 2021 Matching Micro Grant
Novel Treatment of Fatty Liver Disease (CDD/LEAP)
Role: Principal Investigator
Total cost: $68,500.00

2018 - 2021 LEAP Innovator Challenge
Novel Treatment of Fatty Liver Disease
Role: Principal Investigator
Total cost: $68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation
Novel Treatment of Non-Alcoholic Fatty Liver Disease
Role: Principal Investigator
Total cost: $379,000.00

Current Governmental Support

2021 - 2025 R-01 DK126622 (Co-investigator), 8/25/2021-7/31/2025, NIH-NIDDK, , NIH
Leveraging glucose transport and the adaptive fasting response to modulate hepatic metabolism
Role: Co-Investigator
PI: DeBosch

Trainee/Mentee/Sponsorship Record

2002 - 2002 Nishant Raj- Undergraduate Student, Other
Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009 Stephanie Scherer, Graduate Student
Study area: Research

2010 - 2014 Lauren Flessner, PhD, Postdoctoral Fellow
Present position: Instructor, Syracuse University

2010 - 2010 Constance Haufe- Undergraduate Student, Other
Study area: Researcher

2010 - 2011 Corinna Wilde- Undergraduate Student, Other
Study area: Researcher

2010 - 2010 Samuel Lite- High School Student, Other
Study area: Research

2011 - 2016 Thomas Kraft, Graduate Student
Study area: Glucose transporter structure/function
Present position: Postdoctoral Fellow, Roche, Penzberg, Germany

2011 - 2011 Amanda Koenig- High School Student, Other
Study area: Research

2011 - 2012 Lisa Becker- Undergraduate Student, Other

2011 - 2011 Melissa Al-Jaoude- High School Students, Other

2019 Ava Suda, Other, Pre-med

Bibliography

A. Journal Articles

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C2. Chapters

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C4. Invited Publications

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7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Expert Witness Testimony

2009 Rosas v. Astrazeneca

2012 O'Connor v. Stamford

2016 Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina)

2016 Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-, 524)

2017 Ward v. Janssen (Circuit Court of St Louis, Division 16, MO, Case No. 1522-CC00213-01)

2017 Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT)

2017 Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943)

2018 Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080)

2019 Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children

2021 Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA)

2022 Brandt v Rutledge (The United States District Court Eastern District of Arkansas Central Division, Case No. 4:21-CV-00450-JM)

2022 Eknes-Tucker vs Ivey (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW)

2022 D.H. et al. v. Snyder (United States District Court For the District Court of Arizona, Case No. 4:20-cv-00335-SHR)

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Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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REPORT

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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ABSTRACT

Background: Transgender healthcare is a rapidly evolving interdisciplinary field. In the last decade, there has been an unprecedented increase in the number and visibility of transgender and gender diverse (TGD) people seeking support and gender-affirming medical treatment in parallel with a significant rise in the scientific literature in this area. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for TGD people through the Standards of Care (SOC). The SOC was initially developed in 1979 and the last version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8.

Aim: The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.

Methods: The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

Results: A total of 18 chapters were developed as part of the SOC-8. They contain recommendations for health care professionals who provide care and treatment for TGD people. Each of the recommendations is followed by explanatory text with relevant references. General areas related to transgender health are covered in the chapters Terminology, Global Applicability, Population Estimates, and Education. The chapters developed for the diverse population of TGD people include Assessment of Adults, Adolescents, Children, Nonbinary, Eunuchs, and Intersex Individuals, and people living in Institutional Environments. Finally, the chapters related to gender-affirming treatment are Hormone Therapy, Surgery and Postoperative Care, Voice and Communication, Primary Care, Reproductive Health, Sexual Health, and Mental Health.

Conclusions: The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and guidance for the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria set forth in this document for gender-affirming medical interventions are clinical guidelines; individual health care professionals and programs may modify these in consultation with the TGD person.

KEYWORDS

adolescents; assessment; children; communication; education; endocrinology; eunuch; gender diverse; health care professional; institutional settings; intersex; mental health; nonbinary; population; postoperative care; primary care; reproductive health; sexual health; SOC8; Standards of Care; surgery; terminology; transgender; voice

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INTRODUCTION

Purpose and use of the Standards of Care

The overall goal of the World Professional Association for Transgender Health's (WPATH) Standards of Care—Eighth Edition (SOC-8) is to provide clinical guidance to health care professionals to assist transgender and gender diverse (TGD) people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment. This assistance may include but is not limited to hormonal and surgical treatments, voice and communication therapy, primary care, hair removal, reproductive and sexual health, and mental health care. Healthcare systems should provide medically necessary gender-affirming health care for TGD people: See Chapter 2—Global Applicability, Statement 2.1.

WPATH is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. Founded in 1979, the organization currently has over 3,000 health care professionals, social scientists, and legal professionals, all of whom are engaged in clinical practice, research, education and advocacy that affects the lives of TGD people. WPATH envisions a world wherein people of all gender identities and gender expressions have access to evidence-based health care, social services, justice, and equality.

One of the main functions of WPATH is to promote the highest standards of health care for individuals through the Standards of Care (SOC) for the health of TGD people. The SOC-8 is based on the best available science and expert professional consensus. The SOC was initially developed in 1979, and the last version was published in 2012.

Most of the research and experience in this field comes from a North American and Western European perspective; thus, adaptations of the SOC-8 to other parts of the world are necessary. Suggestions for approaches to cultural relativity and cultural competence are included in this version of the SOC.

WPATH recognizes that health is not only dependent upon high-quality clinical care but also relies on social and political climates that ensure social tolerance, equality, and the full rights of citizenship. Health is promoted through public policies and legal reforms that advance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy and legal changes. Thus, health care professionals who provide care to TGD people are called upon to advocate for improved access to safe and licensed gender-affirming care while respecting the autonomy of individuals.

While this is primarily a document for health care professionals, individuals, their families, and social institutions may also use the SOC-8 to understand how it can assist with promoting optimal health for members of this diverse population.

The SOC-8 has 18 chapters containing recommendations for health care professionals working with TGD people. Each of the recommendations is followed by explanatory text with relevant references. The recommendations for the initiation of gender-affirming medical and/or surgical treatments (GAMSTs) for adults and adolescents are contained in their respective chapters (see Assessment for Adults and Adolescent chapters). A summary of the recommendations and criteria for GAMST can be found in Appendix D.

Populations included in the SOC-8

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities that exist globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, which may or may not be based on or encompassed by Western conceptualizations of gender or the language used to describe it.

WPATH SOC-8 expands who is included under the TGD umbrella, and the settings in which these guidelines should be applied to promote equity and human rights.

Globally, TGD people encompass a diverse array of gender identities and expressions and have differing needs for gender-affirming care across their lifespan that is related to individual goals and characteristics, available health care resources, and sociocultural and political contexts. When standards of care are absent for certain groups this vacuum can result in a multiplicity of therapeutic approaches, including those that may be counterproductive or harmful. The SOC-8 includes recommendations to promote health and well-being for gender diverse groups that have often been neglected and/or marginalized, including nonbinary people, eunuch, and intersex individuals.

The SOC-8 continues to outline the appropriate care of TGD youth, which includes, when indicated, the use of puberty suppression and, when indicated, the use of gender-affirming hormones.

Worldwide, TGD people commonly experience transphobia, stigmatization, ignorance, and refusal of care when seeking health care services, which contributes to significant health disparities. TGD people often report having to teach their medical providers how to care for them due to the latter's insufficient knowledge and training. Intersectional forms of discrimination, social marginalization, and hate crimes against TGD people lead to minority stress. Minority stress is associated with mental health disparities exemplified by increased rates of depression, suicidality, and non-suicidal self-injuries than rates in cisgender populations. Professionals from every discipline should consider the marked vulnerability of many TGD people. WPATH urges health care authorities, policymakers, and medical societies to discourage and combat transphobia among health care professionals and ensure every effort is made to refer TGD people to professionals with experience and willingness to provide gender-affirming care.

Flexibility in the SOC

The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve.

The SOC-8 supports the role of informed decision-making and the value of harm reduction approaches. In addition, this version of the SOC recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Health care professionals can use the SOC to help patients consider the full range of health services open to them in accordance with their clinical needs for gender expression.

Diversity versus Diagnosis

The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. Unfortunately, gender nonconformity and diversity in gender identity and expression is stigmatized in many societies around the world. Such stigma can lead to prejudice and discrimination, resulting in "minority stress." Minority stress is unique (additive to general stressors experienced by all people), socially based, and chronic, and may make TGD individuals more vulnerable to developing mental health concerns such as anxiety and depression. In addition to prejudice and discrimination in society at large, stigma can contribute to abuse and

neglect in one's interpersonal relationships, which in turn can lead to psychological distress. However, these symptoms are socially induced and are not inherent to being TGD.

While Gender Dysphoria (GD) is still considered a mental health condition in the Diagnostic and Statistical Manual of Mental Disorders, (DSM-5-TR) of the American Psychiatric Association. Gender incongruence is no longer seen as pathological or a mental disorder in the world health community. Gender Incongruence is recognized as a condition in the International Classification of Diseases and Related Health Problems, 11th Version of the World Health Organization (ICD-11). Because of historical and current stigma, TGD people can experience distress or dysphoria that may be addressed with various gender-affirming treatment options. While nomenclature is subject to change and new terminology and classifications may be adopted by various health organizations or administrative bodies, the medical necessity of treatment and care is clearly recognized for the many people who experience dissonance between their sex assigned at birth and their gender identity.

Not all societies, countries, or health care systems require a diagnosis for treatment. However, in some countries these diagnoses may facilitate access to medically necessary health care and can guide further research into effective treatments.

Health care services

The goal of gender-affirming care is to partner with TGD people to holistically address their social, mental, and medical health needs and well-being while respectfully affirming their gender identity. Gender-affirming care supports TGD people across the lifespan—from the very first signs of gender incongruence in childhood through adulthood and into older age—as well as people with concerns and uncertainty about their gender identity, either prior to or after transition.

Transgender health care is greater than the sum of its parts, involving holistic inter- and multidisciplinary care between endocrinology, surgery, voice and communication, primary care, reproductive health, sexual health and mental health disciplines to support gender-affirming interventions as well as preventive care and chronic disease management. Gender-affirming interventions include puberty suppression, hormone therapy, and gender-affirming surgeries among others. It should be emphasized there is no 'one-size-fits-all' approach and TGD people may need to undergo all, some, or none of these interventions to support their gender affirmation. These guidelines encourage the use of a patient-centered care model for initiation of gender- affirming interventions and update many previous requirements to reduce barriers to care.

Ideally, communication and coordination of care should occur between providers to optimize outcomes and the timing of gender-affirming interventions centered on the patient's needs and desires and to minimize harm. In well-resourced settings, multidisciplinary consultation and care coordination is often routine, but many regions worldwide lack facilities dedicated to transgender care. For these regions, if possible, it is strongly recommended that individual care providers create a network to facilitate transgender health care that is not available locally.

Worldwide, TGD people are sometime forced by family members or religious communities to undergo conversion therapy. WPATH strongly recommends against any use of reparative or conversion therapy (see statements 6.5 and 18.10).

Health care settings

The SOC-8 are guidelines rooted in the fundamental rights of TGD people that apply to all settings in which health care is provided regardless of an individual's social or medical circumstances. This includes a recommendation to apply the standards of care for TGD people who are incarcerated or living in other institutional settings.

Due to a lack of knowledgeable providers, untimely access, cost barriers and/or previous stigmatizing health care experiences, many TGD people take non-prescribed hormone therapy. This poses health risks associated with the use of unmonitored therapy in potentially supratherapeutic doses and the potential exposure to blood-borne illnesses if needles are shared for administration. However, for many individuals, it is the only means of acquiring medically necessary

gender-affirming treatment that is otherwise inaccessible. Non-prescribed hormone use should be approached with a harm-reduction lens to ensure individuals are connected with providers who can prescribe safe and monitored hormone therapy.

In some countries, the rights of TGD are increasingly being recognized, and gender clinics are being established that can serve as templates for care. In other countries, however, such facilities are lacking and care may be more fragmented and under-resourced. Nonetheless, different models of care are being pioneered, including efforts to decentralize gender-affirming care within primary care settings and establish telehealth services to reduce barriers and improve access. Regardless of the method of care delivery, the principles of gender-affirming care as outlined in the SOC-8 should be adapted to align with local sociocultural, political, and medical contexts.

Methodology

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility.

While evidence-based research provides the basis for sound clinical practice guidelines and recommendations, it must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated the recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process.

The SOC-8 guidelines committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers, and stakeholders with diverse perspectives and geographic representation. A guideline methodologist assisted with the planning and development of questions and systematic reviews with additional input provided by an international advisory committee and during the public comment period. All committee members completed conflict of interest declarations. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. A detailed overview of the SOC-8 Methodology is included in Appendix A.

SOC-8 Chapters Summary

The SOC-8 represents a significant advancement from previous versions. Changes in this version are based upon a fundamentally different methodology, significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for TGD people beyond hormone therapy and surgery.

These updated guidelines continue the process started with the SOC-7 in 2011 to broaden in scope and move from a narrow focus on psychological requirements for "diagnosing transgenderism" and medical treatments for alleviation of gender dysphoria to gender-affirming care for the whole person. WPATH SOC-8 expands guidelines specifying who is included under the TGD umbrella, what should and should not be offered with gender-affirming care, and the settings in which these guidelines should be applied to promote equity and human rights.

The SOC-8 has several new chapters such as the Assessment of Adults, Education, Eunuchs, and a Nonbinary chapter. In addition, the chapter for children and adolescents of the SOC-7 has been divided into two different chapters. Overall, the SOC-8 is considerably longer than previous versions and provides a more in-depth introduction and recommendations for health care professionals. A summary of every chapter of the SOC-8 can be found below:

Chapter 1—Terminology
This new chapter lays the framework for language used in the SOC-8 and offers consensually agreed upon recommendations for the use of terminology. The chapter provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary (see Appendix B) of common terms and language to provide a framework for use and interpretation of the SOC-8.

Chapter 2—Global Applicability
This chapter references key literature related to development and delivery of health care services, broader advocacy care for TGD people from beyond Western Europe and North America and provides recommendations for adapting and translating the SOC-8 to varied contexts.

Chapter 3—Population Estimates
This chapter updates the population estimates of TGD people in society. Based on the current evidence, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location.

Chapter 4—Education
This new chapter provides a general review of the literature related to education in TGD health care. It offers recommendations at governmental, nongovernmental, institutional and provider levels to increase access to competent, compassionate health care. The intent is to lay the groundwork in the education area and invite a much broader and deeper discussion among educators and health care professionals.

Chapter 5—Assessment of Adults
This new chapter provides guidance on the assessment of TGD adults who are requesting gender-affirming medical and surgical treatments (GAMSTs). It describes and updates the assessment process as part of a patient-centered approach and the criteria that health care professionals may follow in order to recommend GAMSTs to TGD adults.

Chapter 6—Adolescents
This new chapter is dedicated to TGD adolescents, is distinct from the child chapter, and has been created for this 8th edition of the Standards of Care given (1) the exponential growth in adolescent referral rates; (2) the increase in studies available specific to adolescent gender diversity-related care; and (3) the unique developmental and gender-affirming care issues of this age group. This chapter provides recommendations regarding the assessment process of adolescents requiring GAMSTs as well as recommendations when working with TGD youth and their families.

Chapter 7—Children
This new chapter pertains to prepubescent gender diverse children and focuses on developmentally appropriate psychosocial practices and therapeutic approaches.

Chapter 8—Nonbinary
This new chapter in the SOC-8 consists of a broad description of the term nonbinary and its usage from a biopsychosocial, cultural, and intersectional perspective. The need for access to gender-affirming care, specific gender-affirming medical interventions, as well as an appropriate level of support is discussed.

Chapter 9—Eunuchs
This new chapter describes the unique needs of eunuchs, and how the SOC can be applied to this population.

Chapter 10—Intersex
This chapter focuses on the clinical care of intersex individuals. It addresses the evolving terminology, prevalence, and diverse presentations of such individuals and provides recommendations for providing psychosocial and medical care with their evidence-based explanations.

Chapter 11—Institutional Environments
This chapter has been expanded to include both carceral and non-carceral settings and has been built upon the last 3 versions of the SOC. This chapter describes how the SOC-8 can be applied to individuals living in these settings.

Chapter 12—Hormone Therapy

This chapter describes the initiation of gender-affirming hormone therapy, the recommended regimens, screening for health concerns before and during hormone therapy, and specific considerations regarding hormone therapy prior to surgery. It includes an expanded discussion about the safety of gonadotropin releasing hormone (GnRH) agonists in youth, various hormone regimens, monitoring to include the development of potential therapy-related health concerns, and guidance on how hormone providers should collaborate with surgeons.

Chapter 13—Surgery and Postoperative Care

This chapter describes a spectrum of gender-affirming surgical procedures for the diverse and heterogeneous community of individuals who identify as TGD. It provides a discussion about the optimal surgical training in GAS procedures, post-surgical aftercare and follow-up, access to surgery by adults and adolescents, and individually customized surgeries.

Chapter 14—Voice and Communication

This chapter describes professional voice and communication support and interventions that are inclusive of and attentive to all aspects of diversity and no longer limited only to voice feminization and masculinization. Recommendations are now framed as affirming the roles and responsibilities of professionals involved in voice and communication support.

Chapter 15—Primary Care

This chapter discusses the importance of primary care for TGD individuals, including topics of cardiovascular and metabolic health, cancer screening, and primary care systems.

Chapter 16—Reproductive Health

This chapter provides recent data on fertility perspectives and parenthood goals in gender diverse youth and adults, advances in fertility preservation methods (including tissue cryopreservation), guidance regarding preconception and pregnancy care, prenatal counseling, and chest feeding. Contraceptive methods and considerations for TGD individuals are also reviewed.

Chapter 17—Sexual Health

This new chapter acknowledges the profound impact of sexual health on physical and psychological well-being for TGD people. The chapter advocates for sexual functioning, pleasure, and satisfaction to be included in TGD-related care.

Chapter 18—Mental Health

This chapter discusses principles of care for managing mental health conditions in TGD adults and the nexus of mental health care and transition care. Psychotherapy may be beneficial but should not be a requirement for gender-affirming treatment, and conversion treatment should not be offered.

CHAPTER 1 Terminology

This chapter will lay the framework for language used in the SOC-8. It offers recommendations for use of terminology. It provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary of common terms and language to provide a framework for use and interpretation of the SOC-8. See Appendix B for glossary.

Terminology

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, and/or that are not based on or encompassed by Western conceptualizations of gender, or the language used to describe it. TGD is used for convenience as a shorthand for transgender and gender diverse.

The decision to use transgender and gender diverse resulted from an active process and was not without controversy. Discussions centered on avoiding over-emphasis on the term transgender, integrating nonbinary gender identities and experiences, recognizing global variations in understandings of gender, avoiding the term gender nonconforming, and recognizing the changing nature of language because what is current now may not be so in coming years. Thus, the term transgender and gender diverse was chosen with the intent to be most inclusive and to highlight the many diverse gender identities, expressions, experiences, and health care needs of TGD people. A Delphi process was used wherein SOC-8 chapter authors were anonymously and iteratively surveyed over several rounds to obtain consensus on terms. The SOC-8 presents standards of care that strive to be applicable to TGD people globally, no matter how a person self-identifies or expresses their gender.

Context

The language selected in this chapter may not be (nor ever could be) comprehensive of every culture and geographic region/locale. Differences and debates over appropriate terms and specific terminologies are common, and no single term can be used without controversy. The goal of this chapter is to be as inclusive as possible and offer a shared vocabulary that is respectful and reflective of varied experiences of TGD people while remaining accessible to health practitioners and providers, and the public, for the purposes of this document. Ultimately, access to transition-related health care should be based on providing adequate information and obtaining informed consent from the individual, and not on what words TGD people, or their service providers, use to describe their identities. Using language and terminology that is respectful and culturally responsive is a basic foundation in the provision of affirming care, as is reducing the stigma and harm experienced by many TGD people seeking health care. It is vital for service providers to discuss with service users what language is most comfortable for them and to use that language whenever possible.

This chapter explains why current terms are being used in preference to others. Rather than use specific terms for medical, legal, and advocacy groups, the aim is to foster a shared language and understanding in the field of TGD health, and the many related fields (e.g., epidemiology, law), in order to optimize the health of transgender and gender diverse people.

Sex, gender, gender identity, and gender expression are used in the English language as descriptors that can apply to all people—those who are TGD, and those who are not. There are complex reasons why very specific language may be the *most* respectful, *most* inclusive, or *most* accepted by global TGD communities, including the presence or absence of words to describe these concepts in languages other than English; the structural relationship between sex and gender; legal landscapes at the local, national, and international levels; and the consequences of historical and present-day stigma that TGD people face.

Statements of Recommendations

1.1- We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.
1.2- We recommend health care professionals use language in health care settings that uphold the principles of safety, dignity, and respect.
1.3- We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

Because at present, the field of TGD health is heavily dominated by the English language, there are two specific problems that constantly arise in setting the context for terminology. The first problem is that words exist in English that do not exist in other languages (e.g., "sex" and "gender" are only represented by one word in Urdu and many other languages). The second problem is that there are words that exist outside of English that do not have a direct translation into English (e.g., *travesti*, *fa'afafine*, *hijra*, *selrata*, *muxe*, *kathoey*, *transpinoy*, *waria*, *machi*). Practically, this means the heavy influence of English in this field impacts both what terms are widely used and which people or identities are most represented or validated by those terms. The words used also shape the narratives that contribute to beliefs and perceptions. While in past versions of the Standards of Care, World Professional Association for Transgender Health (WPATH) has used only transgender as a broadly defined umbrella term, version 8 broadens this language to use TGD as the umbrella term throughout the document (see Chapter 2—Global Applicability).

Furthermore, the ever-evolving nature of language is impacted by external factors and the social, structural, and personal pressures and violence enacted on TGD people and their bodies. Many of the terms and phrases used historically have been marred by how, when, and why they were used in discussing TGD people, and have thus fallen out of use or are hotly contested among TGD people, with some individuals preferring terms others find offensive. Some wish that these Standards of Care could provide a coherent set of universally accepted terms to describe TGD people, identities, and related health services. Such a list, however, does not and cannot exist without exclusion of some people and without reinforcing structural oppressions, with regards to race, national origin, Indigenous status, socioeconomic status, religion, language(s) spoken, and ethnicity, among other intersectionalities. It is very likely that at least some of the terminology used in SOC-8 will be outdated by the time version 9 is developed. Some people will be frustrated by this reality, but it is hoped it will be seen instead as an opportunity for individuals and communities to develop and refine their own lexicons and for people to develop a still more nuanced understanding of the lives and needs of TGD people, including TGD people's resilience and resistance to oppression.

Finally, law and the work of legal professionals are within the remit of these Standards of Care. As such, language used most widely in international law is included here to help with the development of the functional definitions of these terms and encourage their usage in legal contexts in lieu of more antiquated and/or offensive terms. The currently most thorough document in international human rights law uses the term "gender diverse."[1]

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 1.1

We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.

Culturally relevant language is used to describe TGD people in different global settings. For example, the concepts of sex, gender, and gender diversity differ across contexts, as does the language used to describe them. Thus, the language used when caring

for TGD people in Thailand is not going to be the same as that used for TGD care in Nigeria. When applying the Standards of Care globally, we recommend health care professionals (HCPs) utilize local language and terms to deliver care in their specific cultural and/or geographical locale.

Gender affirmation refers to the process of recognizing or affirming TGD people in their gender identity—whether socially, medically, legally, behaviorally, or some combination of these (Reisner, Poteat et al., 2016). Health care that is gender-affirming or trans-competent utilizes culturally specific language in caring for TGD people. Gender-affirming care is not synonymous with transition-related care. Provision of transition-related care, such as medical gender affirmation via hormones or surgery, does not alone ensure provision of gender-affirming care, nor does it indicate the quality or safety of the health care provided.

Consultation and partnerships with TGD communities can help to ensure relevancy and inclusivity of the language used in providing health care locally in a particular context and setting.

Statement 1.2

We recommend health care professionals use language in health care settings that upholds the principles of safety, dignity, and respect.

Safety, dignity, and respect are basic human rights (International Commission of Jurists, 2007). We recommend HCPs utilize language and terminology that uphold these human rights when providing care for TGD people. Many TGD people have experienced stigma, discrimination, and mistreatment in health care settings, resulting in suboptimal care and poor health outcomes (Reisner, Poteat et al., 2016; Safer et al., 2016; Winter, Settle et al., 2016). Such experiences include misgendering, being refused care or denied services when sick or injured and having to educate HCPs to be able to receive adequate care (James et al., 2016). Consequently, many TGD people feel unsafe accessing health care. They may avoid health care systems and seek other means of getting health-related needs met, such as taking hormones without a medical prescription or monitoring and relying on peers for medical advice. Furthermore, previous negative experiences in health care settings are associated with future avoidance of care among TGD people.

Many TGD people have been treated unjustly, with prejudice, and without dignity or respect by HCPs, and lack of trust is often a barrier to care. Using language grounded in the principles of safety, dignity, and respect in health care settings is paramount to ensure the health, well-being, and rights of TGD people globally. Language is a significant component of gender-affirming care, but language alone does not resolve or mitigate the systematic abuse and sometimes violence TGD people face globally in care settings. Language is but one important step toward patient/client-centered and equitable health care among TGD people. Other concrete actions HCPs can take include obtaining informed consent and refraining from making assumptions about a person's needs based on their gender or TGD status.

Statement 1.3

We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

In providing health care to TGD people, we recommend HCPs discuss with their patients what language or terminology they prefer be used when referring to them. This discussion includes asking TGD people how they would like to be addressed in terms of name and pronouns, how they self-identify their gender, and about the language that should be used to describe their body parts. Utilizing affirming language or terminology is a key component of TGD-affirming care (Lightfoot et al., 2021; Vermeir et al., 2018). Furthermore, these discussions and communications can serve to build rapport and reduce the mistrust many TGD people feel toward HCPs and experience within health care systems. Discussions and usage of language or terminology can also facilitate engagement and retention in care that is not specifically TGD-related, such as uptake of routine preventive screenings and any necessary medical follow-up of findings. In electronic health records, organ/anatomical inventories can be standardly used to inform appropriate clinical care, rather than relying solely on assigned sex at birth and/or gender identity designations.

HCPs and health care settings can implement standardized procedures to facilitate these conversations such as: using intake forms that include chosen pronouns and name, inviting

all staff (regardless of gender, i.e., cisgender, TGD) to use pronouns in introductions, having pronouns accompany names on a document for all patients, and not using gendered honorifics (e.g., Ms., Mr.). Policies for HCPs and health care settings can be put in place to ensure a TGD person's privacy and right to confidentiality, including when they disclose being a TGD person, and if/how to appropriately document. For example, a clinic policy may be to record this information as private and confidential between HCPs and patients/clients, and that it should only be disclosed on a "need to know" basis.

Note

1. A/73/152, Report of the Independent Expert on protection against violence and discrimination based on sexual orientation and gender identity

CHAPTER 2 Global Applicability

People who defy cultural boundaries of sex and gender have existed in cultures worldwide since ancient times, sometimes acknowledged in local language terms (Feinberg, 1996). In contrast to the more recent pathologization of gender diversity as an illness, some cultures traditionally celebrated and welcomed this diversity (e.g., Nanda, 2014; Peletz, 2009). Today, the English language umbrella term transgender and gender diverse (TGD) describes a huge variety of gender identities and expressions, and therefore a population with diverse health care experiences and needs. Together, TGD people represent important aspects of human diversity the World Professional Association for Transgender Health (WPATH) asserts should be valued and celebrated. TGD people continue to make vital contributions to the societies in which they live, although often these are unrecognized.

Disturbingly, many TGD people in the modern world experience stigma, prejudice, discrimination, harassment, abuse and violence, resulting in social, economic and legal marginalization, poor mental and physical health, and even death—a process that has been characterized as a stigma-sickness slope (Winter, Diamond et al., 2016). Experiences such as these (and the anticipation or fear of encountering such experiences) leads to what Meyer has described as minority stress (Meyer, 2003; see also Bockting et al., 2013 writing specifically about TGD people), and are associated with poor physical (e.g. Rich et al, 2020) and psychological (e.g., Bränström et al., 2022; Scandurra et al., 2017; Shipherd et al., 2019, Tan et al., 2021) health outcomes.

Violence against TGD people is a particular problem. Seen from a global perspective, it is widespread, diverse in nature (emotional, sexual and physical, e.g., see Mujugira et al., 2021), and involves a range of perpetrators (including State actors). Statistics on murder, the form of violence most extreme in its consequences, are alarming. Worldwide, there were over 4,000 documented killings between January 2008 and September 2021; a statistic widely regarded as flawed by under-reporting (TGEU, 2020).

Since the publication of the Standards of Care Version 7 (SOC-7), there have been dramatic changes in perspectives on TGD people and their health care. Mainstream global medicine no longer classifies TGD identities as a mental disorder. In the Diagnostic and Statistical Manual Version 5 (DSM-5) from the American Psychiatric Association (APA, 2013), the diagnosis of *Gender Dysphoria* focuses on any distress and discomfort that accompanies being TGD, rather than on the gender identity itself. A text revision (DSM-5-TR) was published in 2022. In the International Classification of Diseases, Version 11 (ICD-11), the diagnostic manual of the World Health Organization (WHO, 2019b), the *Gender Incongruence* diagnosis is placed in a chapter on sexual health and focuses on the person's experienced identity and any need for gender-affirming treatment that might stem from that identity. Such developments, involving a depathologization (or more precisely a de-psychopathologization) of transgender identities, are fundamentally important on a number of grounds. In the field of health care, they may have helped support a care model that emphasizes patients' active participation in decision-making about their own health care, supported by primary health care professionals (HCPs) (Baleige et al., 2021). It is reasonable to suppose these developments may also promote more socially inclusive policies such as legislative reform regarding gender recognition that facilitates a rights-based approach, without imposing requirements for diagnosis, hormone therapy and/or surgery. TGD people who have changed gender markers on key documents enjoy better mental health (e.g., Bauer et al., 2015; Scheim et al., 2020). A more rights-based approach in this area may contribute greatly to the overall health and well-being of TGD people (Arístegui et al., 2017).

Previous editions of the SOC have revealed much of the recorded clinical experience and knowledge in this area is derived from North American and Western European sources. They have focused on gender-affirming health care in high income countries that enjoy relatively well-resourced health care systems (including those with trained mental health providers, endocrinologists, surgeons and other specialists) and where services are often funded publicly or (at least for some patients) through private insurance.

For many countries, health care provision for TGD people is aspirational; with resourcing in this area limited or non-existent, and services often unavailable, inappropriate, difficult to access and/or unaffordable. Few if any HCPs (primary or specialist) may exist. Funding for gender-affirming health care may be absent, with patients often bearing the full costs of whatever health care they access. Health care providers often lack clinical and/or cultural competence in this area. Training for work with these patients may be limited (e.g., Martins et al., 2020). For all these reasons and because of mainstream "Western" medicine's historical view of TGD people as mentally disordered (a perspective that has only recently changed), TGD people have commonly found themselves disempowered as health care consumers.

Health care providers have found the relevant literature is largely North American and European, which present particular challenges for persons working in health care systems that are especially poorly resourced. Recent initiatives that often involve TGD stakeholders as partners are changing this situation somewhat by providing a body of knowledge about good practice in other regions, including how to provide effective, culturally-competent TGD health care in low- and middle-income countries outside the global north.

Within the field, a wide range of valuable health care resources have been developed in recent years. Dahlen et al (2021) review twelve international clinical practice guidelines; over half those reviewed originate from professional bodies based in North America (e.g., Hembree et al., 2017) or Europe (e.g., T'Sjoen et al., 2020). Three are from WHO (the most recent being WHO, 2016). Nowadays, there are numerous other resources, not on Dahlen et al.'s list, that explicitly draw on expertise from regions outside North America and Europe. Examples can be found in Asia and the Pacific (APTN, 2022; Health Policy Project et al., 2015), the Caribbean (PAHO, 2014), Thailand, Australia (Telfer et al., 2020), Aotearoa New Zealand (Oliphant et al., 2018), and South Africa (Tomson et al., 2021) (see also TRANSIT (UNDP et al., 2016)). These resources have commonly been created through the initiatives of or in partnership with TGD communities locally or internationally. This partnership approach, focused on meeting local needs in culturally safe and competent ways, can also have broad international relevance. Some of these publications may be of particular value to those planning, organizing and delivering services in low-income, low-resource countries. There are likely to be other resources published in languages other than English of which we are unaware.

Globally, TGD identities may be associated with differing conceptual frameworks of sex, gender, and sexuality and exist in widely diverse cultural (and sometimes spiritual) contexts and histories. Considering the complex relationships between social and cultural factors, the law, and the demand for and provisions of gender-affirming health care, the SOC-8 should be interpreted through a lens that is appropriate for and within the context of each HCP's individual practice while maintaining alignment to the core principles that underscore it (APTN and UNDP, 2012; Health Policy Project et al., 2015; PAHO, 2014).

It is within this context and by drawing broadly on the experiences of TGD people and health care providers internationally that we consider the global applicability of SOC-8 within this chapter. We set out key considerations for HCPs and conclude by recommending core principles and practices fundamental to contemporary health care for TGD people, regardless of where they live or whether there are resources available to those who seek to provide such health care.

Statement 2.1

We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.

Medical necessity is a term common to health care coverage and insurance policies globally. A common definition of medical necessity as used by insurers or insurance companies is "Health care services that a physician and/or health care professional, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with generally accepted standards of medical practice; (b) clinically

Statements of Recommendations

2.1- We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.
2.2- We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.
2.3- We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.
2.4- We recommend translations of the SOC focus on cross-cultural, conceptual, and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.
2.5- We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles
- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights including the right to bodily and mental integrity, autonomy and self-determination; freedom from discrimination, and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care
- Involve transgender and gender diverse people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and the capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion and avoid providing any direct or indirect support for such approaches or services.

Principles around delivering competent services
- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services including those related to administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches
- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease." The treating HCP asserts and documents that a proposed treatment is medically necessary for treatment of the condition (American Medical Association, 2016).

Generally, "accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, designated Medical Specialty Societies and/or legitimate Medical Colleges' recommendations, and the views of physicians and/or HCPs practicing in relevant clinical areas.

Medical necessity is central to payment, subsidy, and/or reimbursement for health care in parts of the world. The treating HCP may assert and document that a given treatment is medically necessary for the prevention or treatment of the condition. If health policies and practices challenge the medical necessity of a treatment, there may be an opportunity to appeal to a governmental agency or other entity for an independent medical review.

It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical

interventions. In many countries, medically necessary gender-affirming care is documented by the treating health professional as treatment for Gender Incongruence (HA60 in ICD-11; WHO, 2019b) and/or as treatment for Gender Dysphoria (F64.0 in DSM-5-TR; APA, 2022).

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments (e.g., Ainsworth & Spiegel, 2010; Aires et al., 2020; Aldridge et al., 2020; Almazan & Keuroghlian, 2021; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Buncamper et al., 2016; Cardoso da Silva et al., 2016; Eftekhar Ardebili, 2020; Javier et al., 2022; Lindqvist et al., 2017; Mullins et al., 2021; Nobili et al., 2018; Owen-Smith et al., 2018; Özkan et al., 2018; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Yang, Zhao et al., 2016). Gender-affirming interventions may also include hair removal/transplant procedures, voice therapy/surgery, counseling, and other medical procedures required to effectively affirm an individual's gender identity and reduce gender incongruence and dysphoria. Additionally, legal name and sex or gender change on identity documents can also be beneficial and, in some jurisdictions, are contingent on medical documentation that patients may call on practitioners to produce.

Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria (e.g., Aires et al., 2020; Aldridge et al., 2020; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Bertrand et al., 2017; Buncamper et al., 2016; Claes et al., 2018; Eftekhar Ardebili, 2020; Esmonde et al., 2019; Javier et al., 2022; Lindqvist et al., 2017; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Mullins et al., 2021; Nobili et al., 2018; Olson-Kennedy, Rosenthal et al., 2018; Özkan et al., 2018; Poudrier et al., 2019; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Wolter et al., 2015; Wolter et al., 2018).

Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of TGD individuals. In other words, governments should ensure health care services for TGD people are established, extended or enhanced (as appropriate) as elements in any Universal Health Care, public health, government-subsidized systems, or government-regulated private systems that may exist. Health care systems should ensure ongoing health care, both routine and specialized, is readily accessible and affordable to all citizens on an equitable basis.

Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

Statement 2.2

We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.

TGD people identify in many different ways worldwide, and those identities exist within a cultural context. In English speaking countries, TGD people variously identify as *transsexual,*

trans, gender nonconforming, gender queer or diverse, nonbinary, or indeed *transgender and/or gender diverse,* as well as by other identities; including (for many identifying inside the gender binary) *male* or *female.* (e.g., James et al., 2016; Strauss et al., 2017; Veale et al., 2019).

Elsewhere, identities include but are not limited to *travesti* (across much of Latin America), *hijra* (across much of South Asia), *khwaja sira* (in Pakistan), *achout* (in Myanmar), *maknyah, paknyah* (in Malaysia), *waria* (Indonesia) *kathoey, phuying kham phet, sao praphet song* (Thailand), *bakla, transpinay, transpinoy* (Philippines), *fa'afafine* (Samoa), *mahu* (French Polynesia, Hawai'i), *leiti* (Tonga), *fakafifine* (Niue), *pinapinaaine* (Tuvalu and Kiribati), *vakasalewalewa* (Fiji), *palopa* (Papua Niugini), *brotherboys* and *sistergirls* (Aboriginal and Torres Strait Islander people in Australia), and *akava'ine* (Cook Islands) (e.g., APTN and UNDP, 2012; Health Policy Project et al., 2015; Kerry, 2014). There are also a large number of *two spirit* identities across North America (e.g., *nadleehi* in Navajo (Diné) culture) (Sheppard & Mayo, 2013). The identities to which each of these terms refer are often culturally complex and may exist in a spiritual or religious context. Depending on the cultures and the identities concerned, some may be regarded as so-called "third genders" lying beyond the gender binary (e.g., Graham, 2010; Nanda, 2014; Peletz, 2009). Some TGD identities are less firmly established than others. In many places worldwide, the visibility of transgender men and nonbinary trans masculine identities is relatively recent, with few or no applicable traditional terms in local languages (Health Policy Project et al., 2015). Regardless of where or with whom HCPs work (including those working with ethnic minority persons, migrants and refugees), they need to be aware of the cultural context in which people have grown up and live as well as the consequences for health care.

Worldwide the availability, accessibility, acceptability and quality of health care vary greatly, with resulting inequities within and across countries (OECD, 2019). In some countries, formal health care systems exist alongside established traditional and folk health care systems, with indigenous models of health underpinning the importance of holistic health care (WHO, 2019a). HCPs should be aware of the traditions and realities within which health care is available and provide support that is sensitive to the local needs and identities of TGD people and provide them with culturally competent and safe care.

Statement 2.3

We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.

TGD people's lived experiences vary greatly, depending on a range of factors, including social, cultural (including spiritual), legal, economic and geographic. When TGD people live in environments that affirm their gender and/or cultural identities, then these experiences can be very positive. Families are particularly important in this regard (e.g., Pariseau et al., 2019; Yadegarfard et al., 2014; Zhou et al., 2021). However, when viewed from a global perspective, the circumstances in which TGD people live are often challenging. They are commonly denied widely accepted rights in international human rights law. These include rights to education, health and protection from medical abuses, work and an adequate standard of living, housing, freedom of movement and expression, privacy, security, life, family, freedom from arbitrary deprivation of liberty, fair trial, treatment with humanity while in detention, and freedom from torture, inhuman or degrading treatment or punishment (International Commission of Jurists, 2007, 2017).

It is widely accepted that denial of rights can impact sexual and gender minority health and well-being (e.g., OHCHR et al., 2016; WHO, 2015). We therefore reaffirm here the importance of the rights listed above for TGD people and note WPATH's previous rights advocacy, including through numerous policy documents (e.g., WPATH, 2016, 2017, 2019). HCPs can play an important role in rights advocacy, including the right to quality gender-affirming health care that is appropriate, affordable, and accessible.

Across the world, a large number of studies detail the challenges TGD people face in their lives, and the impact on their health and well-being (e.g., Aurat Foundation, 2016;

Bhattacharya & Ghosh, 2020; Chumakov et al., 2021; Coleman et al., 2018; Heylens, Elaut et al., 2014; Human Rights Watch, 2014; James et al, 2016; Lee, Operario et al., 2020; Luz et al., 2022; McNeil et al., 2012, 2013; Motmans et al., 2017; Muller et al., 2019; Scandurra et al., 2017; Strauss et al., 2019; Suen et al., 2017; Valashany & Janghorbani, 2019; Veale et al., 2019; Wu et al., 2017). The research shows TGD people often experience stigma and prejudice as well as discrimination and harassment, abuse and violence, or they live in anticipation and fear of such actions. Social values and attitudes hostile to TGD people, often communicated to young people in school curricula (e.g., Olivier & Thurasukam, 2018), are also expressed in family rejection (e.g., Yadegarfard et al., 2014), and perpetuated in laws, policies and practices that limit freedom to express one's gender identity and sexuality and hinder access to housing, public spaces, education, employment and services (including health care). The end result is TGD people are commonly deprived of a wide range of opportunities available to their cisgender counterparts and are pushed to the margins of society, without family supports. To make matters worse, across much of the world TGD people's access to legal gender recognition is restricted or non-existent (e.g., ILGA World, 2020a; TGEU, 2021; UNDP and APTN, 2017). In some countries, such barriers nowadays draw on support from "gender-critical theorists" (as critiqued by e.g., Madrigal-Borloz, 2021; Zanghellini, 2020).

Gender identity change efforts (gender reparative or gender conversion programs aimed at making the person cisgender) are widespread, cause harm to TGD people (e.g., APTN, 2020a, 2020b, 2020c, 2021; Bishop, 2019; GIRES et al., 2020; Turban, Beckwith et al., 2020), and (like efforts targeting sexual orientation) are considered unethical (e.g., APS, 2021; Trispiotis and Purshouse, 2021; Various, 2019, 2021). These efforts may be viewed as a form of violence. The UN independent expert on protection against violence and discrimination based on sexual orientation and gender identity has called for a global ban on such practices (Madrigal-Borloz, 2020). An increasing number of jurisdictions are outlawing such work (ILGA World, 2020b).

Inequities arise from a range of factors, including economic considerations and values underpinning the provision of health care systems, particularly with regard to the emphasis placed on public-, private- and self-funding of health care. Lack of access to appropriate and affordable health care can lead to a greater reliance on informal knowledge systems. This includes information about self-administration of hormones, which, in many cases, is undertaken without necessary medical monitoring or supervision (e.g., Do et al., 2018; Liu et al., 2020; Rashid et al., 2022; Reisner et al., 2021; Winter & Doussantousse, 2009).

In some parts of the world, large numbers of transgender women employ silicone as a means of modifying their bodies, drawing on the services of silicone "pumpers" and/or attending pumping "parties", often within their communities. The immediate results of silicone pumping contrast with significant downstream health risks (e.g., Aguayo-Romero et al., 2015; Bertin et al., 2019; Regmi et al., 2021), particularly where industrial silicone or other injectable substances have been used and where surgical removal may be difficult.

Finally, sexual health outcomes for TGD people are poor. HIV prevalence for transgender women reporting to clinical organizations in metropolitan areas is approximately 19% worldwide, which is 49 times higher than the background prevalence rate in the general population (Baral et al., 2013). Sexual health outcomes for transgender men are also problematic (e.g., Mujugira et al., 2021).

Statement 2.4

We recommend translations of the SOC focus on cross-cultural, conceptual and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.

Much of the research literature on TGD people is produced in high-income and English-speaking countries. global northern perspectives about TGD people (including those related to health care needs and provision) dominate this literature. A May 2021 Scopus database search undertaken by the current authors shows 99% of the literature on transgender health care comes out of Europe, North America, Australia, or New Zealand. Overall, 96% of the literature is in the English language. TGD people of the Global

South have received relatively little attention in the English language literature, and the work of those HCPs who interact with them has often gone unrecognized and unpublished or has not been translated into English. Applying resources produced in the global north risks overlooking the relevance and nuance of local knowledge, cultural frameworks and practices, and missed opportunities to learn from the work of others.

When translating the principles set out in the SOC, we recommend following best practice guidelines for language translation to ensure high quality written resources are produced that are culturally and linguistically appropriate to the local situation. It is important translators have knowledge about TGD identities and cultures to check that literal translations are culturally competent and safe for local TGD people. It is also important translation should follow established processes for quality assurance (Centers for Medicare & Medicaid Services, 2010; Sprager & Martinez, 2015)

Statement 2.5

We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles

- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care, for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights, including the right to bodily and mental integrity, autonomy, and self-determination; freedom from discrimination and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care

- Involve TGD people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion, and avoid providing any direct or indirect support for such approaches or services

Principles around delivering competent services

- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services, including those associated with administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches

- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

We have already cited research detailing the broad range of challenges TGD people may face; social economic and legal obstacles, as well those related to health care access. While overall health care services are diverse across the world (in terms of availability, accessibility, and quality), those services available to TGD people are often inadequate. Numerous reports from diverse regions worldwide show, while TGD people may report positive health care experiences, many others do not (e.g., Callander et al., 2019; Costa, da Rosa Filho et al., 2018; Do et al., 2018; Gourab et al., 2019; Health Policy Project et al., 2015; Liu et al., 2020; Motmans et al., 2017; Muller et al., 2019; PAHO, 2014; Reisner et al., 2021; Strauss et al., 2017; TGEU, 2017). Mainstream health care options often do not meet their needs for general, sexual, or gender-affirming health care. Standard patient management procedures at clinics and hospitals often fail to recognize the gender identities of their TGD patients (including where outside of the binary their patients identify). Patients may be housed in wards that are gender inappropriate for them, putting them at risk of sexual harassment. TGD patients often encounter unsupportive or hostile attitudes from HCPs and ancillary staff and may even be refused service. Of great concern, HCPs in some parts of the world are involved in gender identity change efforts of the sort described earlier in this chapter.

Throughout the world, there are many other barriers to the provision of gender-affirming health care. Health care professionals may often be unwilling to provide the services TGD people seek. In some countries, there may be laws or regulations inhibiting or preventing them from doing so. When general practitioners and other health care providers do not have access to clear guidelines in their own language, they may be deterred from providing services. Even in situations where health care is available, patients may find it is difficult to access because of distance, gatekeeping practices, supply and demand issues that result in long wait lists or cost increases. Indeed, gender-affirming procedures may not be incorporated into a universal health care provision or be covered by private insurance, even though similar procedures may be covered for cisgender patients.

For all these reasons, many TGD people avoid formal health care services whenever they can. Their own communities commonly fill the void, acting as important resources for their members. They provide social and emotional support, often in an otherwise hostile environment. In addition, they often act as reservoirs of shared information about available options for health care, including parallel and informal health care options outside of (and more accessible and affordable than) mainstream medicine. As we saw earlier in this chapter, this often includes sharing of information about silicone and other injectable substances for bodily transformation and about hormones that are self-administered without necessary medical monitoring or supervision. WHO notes TGD individuals who self-administer gender-affirming hormones would benefit from access to evidence-based information, quality products, and sterile injection equipment (WHO, 2021). Access to such information can form part of a broader harm reduction approach (e.g., Idrus & Hyman, 2014).

Putting the important core principles outlined above into practice can improve health care experiences and promote respect for TGD people in all local contexts. This can occur regardless of the realities of a health care system (including the cultural, social, legal, economic context in which health care is provided), the level of provision available, or the TGD people seeking such services.

CHAPTER 3 Population Estimates

In the previous edition of its Standards of Care, Version 7, World Professional Association for Transgender Health (WPATH) identified only a small number of articles attempting to estimate the size of the transgender and gender diverse (TGD) population and characterized the state-of-the-science as "a starting point" requiring further systematic study (Coleman et al., 2012). Since then, the literature on this topic has expanded considerably as evidenced by a number of recent reviews that have sought to synthesize the available evidence (Arcelus et al., 2015; Collin et al., 2016; Goodman et al., 2019; Meier & Labuski, 2013; Zhang et al., 2020).

In reviewing epidemiologic data pertaining to the TGD population, it may be best to avoid the terms "incidence" and "prevalence." Avoiding these and similar terms may preclude inappropriate pathologizing of TGD people (Adams et al., 2017; Bouman et al., 2017). Moreover, the term "incidence" may not be applicable in this situation because it assumes TGD status has an easily identifiable time of onset, a prerequisite for calculating incidence estimates (Celentano & Szklo, 2019). For all the above reasons, we recommend using the terms "number" and "proportion" to signify the absolute and the relative size of the TGD population.

Perhaps the most important consideration in reviewing this literature is the variable definition applied to the TGD population (Collin et al., 2016; Meier & Labuski, 2013). In clinic-based studies, the data on TGD people are typically limited to individuals who received transgender-related diagnoses or counseling or those who requested or underwent gender-affirming therapy, whereas survey-based research typically relies on a broader, more inclusive definition based on self-reported gender identities.

Another methodological consideration in assessing the size and distribution of the TGD population is the need to understand what constitutes the sampling frame. As noted in recent reviews (Goodman et al., 2019; Zhang et al., 2020), many of the published studies, especially those conducted more than a decade ago, first assessed the number of patients seen at a particular clinical center and then divided that number by an approximated population size. This was unlikely to produce an accurate estimate because the numerator in the calculations is not necessarily included in the denominator, and the true size of the denominator often remains unknown.

With these considerations in mind, it is advisable to focus specifically on recent (published within the last decade) peer-reviewed studies that utilized sound methodology in identifying TGD people within a well-defined sampling frame. For all of the above reasons, the present chapter is focused on studies that met the following inclusion criteria 1) appeared in press in 2009 or later; 2) used a clear definition of TGD status; 3) calculated proportions of TGD people based on a well-defined population denominator; and 4) were peer-reviewed. These types of studies can provide more accurate contemporary estimates.

The available studies can be assigned into three groups 1) those that reported proportions of TGD people among individuals enrolled in large health care systems; 2) those that presented results from population surveys of predominantly adult participants; and 3) those that were based on surveys of youth conducted in schools. Of these three categories, the most informative and methodologically sound studies are summarized below. Additional details about these and other similar studies can be found in recent literature reviews (Goodman et al., 2019; Zhang et al., 2020).

Among studies that estimated the size of the TGD population enrolled in large health care systems, all were conducted in the US, and all relied on information obtained from electronic health records. Four of those health system-based studies relied exclusively on diagnostic codes to ascertain the TGD population; two studies (Blosnich et al., 2013; Kauth et al., 2014) used data from the Veterans Health Affairs system, which provides care to over 9 million people, and two studies (Dragon et al., 2017; Ewald et al., 2019) used claims data from Medicare, the federal health insurance program that primarily covers people 65 years of age or older. The proportions of TGD people reported in these diagnostic code-based studies ranged from approximately 0.02% to 0.03%. Another more recent publication also used Medicare data along with commercial insurance claims to identify TGD people and applied expanded inclusion criteria to supplement

diagnostic codes with information on procedures and hormone therapy (Jasuja et al., 2020). Using this methodology, the proportion of TGD people among all persons enrolled in the participating health plans was 0.03%. The sixth health systems-based study (Quinn et al., 2017) was conducted at Kaiser Permanente plans in the states of Georgia and California; these plans provide care to approximately 8 million members enrolled through employers, government programs, or individually. The TGD population in the Kaiser Permanente study was ascertained across all age groups using both diagnostic codes and free-text clinical notes. The proportions of TGD people identified at Kaiser Permanente were higher than the corresponding proportions reported in the Veterans Health Affairs and Medicare studies with the most recent estimates ranging from 0.04 to 0.08%.

In contrast to results from the health system-based studies, findings from surveys that relied on self-reported TGD status produced much higher estimates. Two US studies took advantage of the Behavioral Risk Factor Surveillance Study (BRFSS), which is an annual telephone survey conducted in all 50 states and US territories (Conron et al., 2012; Crissman et al., 2017). The first study used data from the 2007–2009 BRFSS cycles in the state of Massachusetts, and the second study used the 2014 BRFSS data from 19 states and the territory of Guam. Both studies reported that approximately 0.5% of adult participants (at least 18 years of age) responded *"Yes"* to the question *"Do you consider yourself to be transgender?"*

An internet-based survey administered to a sample of the Dutch population 15–70 years of age (Kuyper & Wijsen, 2014) asked participants to score the following two questions using a 5-point Likert scale: *"Could you indicate to which degree you psychologically experience yourself as a man?"* and *"Could you indicate to which degree you psychologically experience yourself as a woman?"* The respondents were considered "gender ambivalent" if they gave the same score to both statements and "gender incongruent" when they reported a lower score for their sex assigned at birth than for their gender identity. The proportions of participants reporting incongruent and ambivalent gender identity were 1.1% and 4.6%, respectively, for persons who were assigned male at birth (AMAB), and 0.8% and 3.2%, respectively, for persons assigned female at birth (AFAB).

A similarly designed study estimated the proportion of TGD residents in the Flanders region of Belgium using a sample drawn from the country's National Register (Van Caenegem, Wierckx et al., 2015). Participants were asked to score the following statements: *"I feel like a woman"* and *"I feel like a man"* on a 5-point Likert scale. Using the same definitions applied in the Dutch study (Kuyper & Wijsen, 2014), the proportion of gender incongruent individuals was 0.7% for AMAB people and 0.6% for AFAB people. The corresponding estimates for gender ambivalence among AMAB and AFAB people were 2.2% and 1.9%, respectively.

A more recent population-based study evaluated the proportion of TGD people among approximately 50,000 adult residents of Stockholm County, Sweden (Åhs et al., 2018). The numerator was determined by asking participants the following question: *"I would like hormones or surgery to be more like someone of a different sex."* Two additional items were designed to identify individuals experiencing gender incongruence: *"I feel like someone of a different sex"* and *"I would like to live as or be treated as someone of a different sex."* The need for either hormone therapy or gender-affirming surgery was reported by 0.5% of participants. Individuals who expressed feeling like someone of a different sex and those who wanted to live as or be treated as a person of another sex constituted 2.3% and 2.8% of the total sample, respectively.

Population-based data outside of North America and Western Europe are less common. One recent study offers valuable data from a large representative survey of 6,000 adults in Brazil (Spizzirri et al., 2021). Gender identity of participants was assessed based on the following three questions 1) *"Which of the following options best describes how you currently feel?"* (Options: I feel I am a man, I feel I am a woman, and I feel I am neither a man nor a woman); 2) *"What is the sex on your birth certificate?"* (Options: male, female, and undetermined); and 3) *"Which of*

these situations do you most closely relate to?" (Options: I was born male, but I have felt female since childhood; I was born female, but I have felt male since childhood; I was born male, and I feel comfortable with my body; I was born female, and I feel comfortable with my body). Based on the responses to these three questions, the authors determined 1.9% of the survey respondents were TGD (0.7% defined as transgender, and 1.2% defined as nonbinary).

The literature on the population proportions of TGD youth (persons under 19 years of age) includes several survey studies conducted in schools. A 2012 national cross-sectional survey in New Zealand collected information on TGD identity among high school students (Clark et al., 2014). Among over 8,000 survey participants, 1.2% self-identified as TGD and 2.5% reported they were not sure. Another study of schoolchildren was based on a 2016 survey of 9th and 11th grade students (ages 14–18 years) in the US state of Minnesota (Eisenberg et al., 2017). Of the nearly 81,000 survey respondents, 2.7% reported being TGD. A more recent study (Johns et al., 2019) presented results of the Youth Risk Behavior Survey (YRBS), which is conducted biennially among local, state, and nationally representative samples of US high school students in grades 9–12 (approximate age range 13–19 years). The 2017 YRBS cycle was carried out in 10 states and 9 large urban areas and included the following sequence: "*Some people describe themselves as transgender when their sex at birth does not match the way they think or feel about their gender. Are you transgender?*" Among nearly 120,000 participants across the 19 sites, 1.8% responded "*Yes, I am transgender,*" and 1.6% responded "*I am not sure if I am transgender.*"

Another recently published school-based study in the US presented results of a 2015 survey conducted in Florida and California with the aim of identifying gender diverse children and adolescents in a sample of just over 6,000 students in grades 9–12 (Lowry et al., 2018). "High gender-nonconforming" was used to define AMAB children who reported being very/mostly/somewhat feminine or AFAB children who reported being very/mostly/somewhat masculine. Based on these definitions, the proportions of TGD participants were reported to be 13% among AMAB students, 4% among AFAB students, and 8.4% overall.

Only one study examined the proportion of self-identified TGD children in a younger age group. Shields et al. analyzed the data from a 2011 survey of 2,700 students in grades 6–8 (age range 11–13 years) across 22 San Francisco public middle schools (Shields et al., 2013). Thirty-three children self-identified as TGD based on the question "*What is your gender?*" where the possible responses were "*female, male, or transgender.*" The resulting proportion of transgender survey respondents was 1.3%. However, this definition would exclude TGD persons self-identifying as nonbinary and those who do not explicitly identify as transgender.

Taken together, these data indicate among health system-based studies that relied on diagnostic codes or other evidence documented in the medical records (Blosnich et al., 2013; Dragon et al., 2017; Ewald et al., 2019; Kauth et al., 2014; Quinn et al., 2017), the proportions of TGD people reported in recent years (2011–2016) ranged from 0.02% to 0.08%. By contrast, when the TGD status was ascertained based on self-report, the corresponding proportions were orders of magnitude higher and reasonably consistent, if the studies used similar definitions. When the surveys specifically inquired about "transgender" identity, the estimates ranged from 0.3% to 0.5% among adults and from 1.2% to 2.7% in children and adolescents. When the definition was expanded to include broader manifestations of gender diversity, such as gender incongruence or gender ambivalence, the corresponding proportions were higher: 0.5% to 4.5% among adults and 2.5% to 8.4% among children and adolescents.

As reviewed elsewhere (Goodman et al., 2019), another noteworthy observation is the continuous increase in both the size and the composition of the TGD population with upward trends in the proportion of TGD people observed in health care systems, through population-based surveys, as well as in the data on legal gender recognition. The higher estimates observed in more recent literature support some of the previous publications indicating the size of TGD population was

Summary of reported proportions of TGD people in the general population

Health systems-based studies: 0.02–0.1%
Survey-based studies of adults: 0.3–0.5% (transgender), 0.3–4.5% (all TGD)
Survey-based studies of children and adolescents: 1.2–2.7% (transgender), 2.5–8.4% (all TGD)

likely underestimated in earlier studies (Olyslager & Conway, 2008).

The temporal trends in AMAB to AFAB ratio have also been reported in studies analyzing referrals to clinics as well as data from integrated health systems; this ratio has changed from predominantly AMAB in previous decades to predominantly AFAB in recent years, especially among TGD youth (Aitken et al., 2015; de Graaf, Carmichael et al., 2018; de Graaf, Giovanardi et al. 2018; Steensma et al., 2018; Zhang et al., 2021). The trend towards a greater proportion of TGD people in younger age groups and the age-related differences in the AMAB to AFAB ratio likely represent the "cohort effect," which reflects sociopolitical advances, changes in referral patterns, increased access to health care and to medical information, less pronounced cultural stigma, and other changes that have a differential impact across generations (Ashley 2019d; Pang et al., 2020; Zhang et al., 2020).

Despite recent improvements in the quality of published studies, an important limitation of the existing literature is the relative paucity of peer-reviewed publications from regions outside of Western Europe or North America. Some of the relevant information on global estimates can be obtained from reports supported by the governments or non-governmental organizations (Fisher et al., 2019; Kasianczuk & Trofymenko, 2020), but these reports may be difficult to systematically identify and evaluate until they appear in peer-reviewed literature. Other barriers to evaluating the global distribution of the TGD populations include inadequate access to demographic data and over-representation of English-language journals in the world literature.

These limitations notwithstanding, the available highest-quality data clearly indicate TGD people represent a sizable and growing proportion of the general population. Based on the credible evidence available to date, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location. Accurate estimates of the proportion, distribution, and composition of the TGD population as well as a projection of resources required to adequately support the health needs of TGD people should rely on systematically collected high-quality data, which are now increasingly available. Continuous and routine collection of these data is needed to decrease variability and minimize over- and under-estimation of the reported results. For example, far more accurate and precise estimates should become available when population censuses begin systematically collecting and reporting data on sex assigned at birth and gender identity, including asexual and nonbinary categories, using the now well-validated two-step method. The first such census-based estimate was released by the national statistical office of Canada. Based on the 2021 census data, 100,815 of 30.5 million Canadians self-identified as transgender or nonbinary; this accounted for 0.33% of the population 15 years of age or older (Statistics Canada, 2022). Consistent with the published literature, the proportions of transgender and nonbinary people were much higher for Generation Z (born between 1997 and 2006, 0.79%) and millennials (born between 1981 and 1996, 0.51%) than for Generation X (born between 1966 and 1980, 0.19%), baby boomers (born between 1946 and 1965, 0.15%), and the Interwar and Greatest Generations (born in 1945 or earlier, 0.12%). While these results represent the highest quality data available to date, it is not clear how the population proportions reported in Canada may compare with those in other countries. The variability in the definitions of what constitutes the TGD population and the differences in data collection methods can be reduced further by improving international collaborations.

CHAPTER 4 Education

This chapter will provide a general review of the literature related to education in transgender and gender diverse (TGD) health care. Recommendations are offered at governmental, nongovernmental, institutional, and provider levels with the goal of increasing access to competent, compassionate health care. In turn, this increased access should improve health outcomes in TGD populations. As this is a novel chapter in the World Professional Association for Transgender Health (WPATH) Standards of Care, the intent is to lay the groundwork for the education area and invite a broader and deeper discussion among educators and health professionals.

Health professionals involved in transgender care encompass a broad range of disciplines. Health professional education varies considerably by country or region in terms of structure, licensure, and policy. Published literature on education in TGD health care is predominantly from North America, Europe, Australia and New Zealand. This chapter does not provide a review of the education literature for each discipline, the needs specific to each discipline (which can be found in the relevant chapters), or the needs specific to each country/region's health education system. Greater understanding and research are needed on the intersection of health education systems, licensure, and transgender health across the world.

On a global level, TGD health education is imperative if national and international health disparities are to be addressed. Cultural competency related to TGD communities continues to be lacking. The World Bank Group (2018) reports widespread discrimination, harassment, violence, and abuse affecting TGD people. They also report TGD people face the highest rates of violence and discrimination (World Bank Group, 2018). Although many higher income countries have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018).

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing education—historically have ignored TGD cultural or clinical education. The Joint Commission (US) has recommended health care organizations "provide educational programs and forums that support the unique needs of the LGBT community" and "offer educational opportunities that address LGBT health issues" (The Joint Commission, 2011). However, this is not enforced.

On an individual level, several questions need answers. What type of education interventions can most effectively address transphobia and lead to long-standing changes in attitudes? What interventions translate into increasing the number of care providers in this area as well as the number of TGD people receiving care? Does clinical exposure increase the confidence of providers over time? What educational interventions lead to improved health outcomes in the TGD population and, if so, when and how did these interventions accomplish this? Although health professions have begun to incorporate TGD health into education using a variety of modalities and at varying levels of training, efforts differ by health profession and are neither systemic nor systematic in nature (e.g., Brennan et al., 2012; Chinn, 2013; Eliason et al., 2010; Lim et al., 2015; Obedin-Maliver et al., 2011; Rondahl, 2009).

Attaining cultural humility with the full appreciation of the intersectionality of humanity is an ultimate educational goal. That said, this initial call for education is focused on building the foundation in cultural awareness and cultural competency that is currently weak or non-existent in much of the world.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

4.1- We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity and respect.
4.2- We recommend all members of the health care workforce receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.
4.3- We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Recommendation 4.1

We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity and respect.

Article 1 of the United Nations Universal Declaration of Human Rights states, "All human beings are born free and equal in dignity and rights" (United Nations, 1948). Only recently has this fundamental statement included the recognition that TGD rights are human rights (UNOCHR, 2018). Globally, training at all levels about TGD communities continues to be lacking. As recently as 2002, only 3% of Fortune 500 companies had antidiscrimination protection for TGD employees, and none offered insurance coverage for gender-affirming health care (Human Rights Campaign Foundation, 2017). By 2022, 91% of Fortune 500 companies included gender identity in US non-discrimination policies, and 66% offered TGD-inclusive insurance coverage. However, only 72% provide any form of lesbian, gay, bisexual, transgender and queer/questioning (LGBTQ) cultural knowledge training for their workforce (Human Rights Campaign Foundation, 2022). This lack of understanding fosters discrimination across the board. Taken together, these inconsistencies negatively affect the health of individuals and communities and exacerbate the health disparities and inequities they face. In Britain, only 28% of TGD workers felt the senior leadership were committed to TGD equality; only 21% of TGD employees would consider reporting transphobic harassment in the workplace (Stonewall, 2018). For those who are openly TGD, 34% were excluded by their co-workers, 35% were abused by customers, 24% were denied promotion due to their gender identity, and 11% were fired (Stonewall, 2018). In southeastern Europe, the World Bank stated there is widespread discrimination, harassment, violence, and abuse, and TGD people in that region faced the highest rates of violence and discrimination (World Bank Group, 2018). Often the discrimination went unreported with 60% of individuals not filing a report because of a lack of faith the complaint would be addressed, a fear of further discrimination or ridicule, and a reluctance to be outed (World Bank Group, 2018). Although many countries in the region have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018). It is the responsibility of the governmental, nongovernmental, and private agencies in these countries with anti-discrimination laws to ensure the rights of the TGD population. They are, therefore, obligated to find ways in which discrimination and stigma can be decreased. One of these is through education. Local cultures that foster anti-TGD attitudes are often a barrier to this needed education. Although cultural competency trainings have led to equivocal results, Shepherd (2019) recommends that providing cultural knowledge training that prioritizes local cultural issues and focuses on the values of openness, non-judgment, and responsiveness may lead to the desired results. Implementing cultural knowledge training requires a leadership willing to prioritize the training and to dedicate the time, money, and human capital to delivering initial and ongoing training.

Recommendation 4.2

We recommend all members of the health care workforce receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing

education—historically have ignored TGD cultural or clinical education. Factors contributing to this lack of inclusion include lack of faculty knowledge, experience, comfort with the subject matter, faculty bias, limited space within the existing curriculum, and lack of guidance on how to integrate the topics (McDowell & Bower, 2016). Research into the lack of and the need for such education does not specifically address TGD health concerns. Rather, the existing literature subsumes TGD health education within the broader discussion of the lack of LGBTQ-focused cultural and clinical-competency training. As an example, nursing baccalaureate programs included only an average of 2.12 hours of instruction on LGBTQ health (Lim et al., 2015). A fair assumption is that the amount of time devoted to TGD-specific health issues constituted only a fraction of this time.

Within the broader context of LGBTQ competency, the lack of TGD cultural- and clinical-competency training is a long-known shortfall of health care education (Aldridge et al., 2021). In the US, the Department of Health and Human Services' *Healthy People 2020,* (United States Department of Health and Human Services (2013, April 10)), the National Academy of Medicine (The Institute of Medicine, 2011), and the Joint Commission (The Joint Commission, 2011) all recognized lack of education negatively impacts the ability of LGBTQ people, including TGD individuals, to obtain appropriate, medically necessary care. The UK's House of Commons Women and Equalities Committee found lack of education contributed to TGD health disparities in the National Health Service (House of Commons Women and Equalities Committee, 2015, December 8). The lack of TGD health care education has been identified in the US (Obedin-Maliver et al., 2011), UK (Tollemache et al., 2021), South Africa (de Vries et al., 2020; Taylor et al., 2018; Wilson et al., 2014), Canada (Bauer et al., 2014), Australia (Riggs & Bartholomaeus, 2016), Sweden, Spain, Serbia, Poland (Burgwal et al., 2021), and Pakistan (Martins et al., 2020) among other countries.

In addition to developing curriculum, Shepherd (2022) states both clinical and organizational components are necessary to improve clinical encounters and consumer satisfaction. On an organizational level, it must be feasible as well as locally and practically oriented (Shepherd, 2022). On an individual level, in addition to knowledge training, health care professionals are better served employing generic traits that focus on the values of openness, non-judgment, and responsiveness (Shepherd, 2018).

Recommendation 4.3.

We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Each health profession has its own educational institutions, administrative, and licensing bodies, which vary by country and specialization within the profession. No major health professional organizations, educational institutions, or licensing bodies appear to require training in TGD health. While these organizations increasingly recommend including LGBTQ intersex health, rarely do they specify competencies, skills, or learning objectives for working with TGD people within their specialty. Published material on health professional education in TGD health is focused primarily on nursing, medicine, and mental health and is predominantly from North America, Europe, Australia, and New Zealand. An increased understanding of transgender health and medical/health professional education systems and requirements globally is essential.

Despite the increasing visibility of TGD people, access to knowledgeable and culturally- competent health professionals remain an overwhelming need around the world (James et al., 2016; Lerner et al., 2020; Müller, 2017). Lack of knowledgeable providers is a major barrier to gender-affirming care for transgender persons (Puckett et al., 2018; Safer et al., 2016) and contributes to large health disparities (Giffort & Underman, 2016; Reisman et al., 2019). The lack of adequate professional education in TGD health is a global problem (Do & Nguyen, 2020; Martins et al., 2020; Parameshwaran et al., 2017) that occurs at all levels of training (Dubin et al., 2018) and traverses health disciplines (Glick et al., 2020; Gunjawate et al., 2020; Johnson & Federman,

2014) and medical specialties (Fung et al., 2020; Korpaisarn and Safer, 2018).

Challenges remain as studies to date have small sample sizes, involve one-time training, include multiple disciplines at multiple career levels, focus on short-term outcomes, and often cover all LGBTQI topics rather than TGD-specific ones that are usually acquired post-licensure and are not the focus of most currently studied educational interventions (Dubin et al., 2018).

To successfully implement the recommendations, institutions may need to consider developing 1) systemic and systematic approaches to developing and implementing competencies for each health discipline across the professional lifespan; 2) standardized assessments for learners, with input from the TGD community; and 3) allotment of curricular resources, including trained faculty, as well as time in accordance with clear, consensual learning objectives (Dubin et al., 2018; Pratt-Chapman, 2020). In addition, evaluations of these interventions should not only focus on outcomes but also strive to understand how, when, and why these outcomes are occurring (Allen et al., 2021).

CHAPTER 5 Assessment of Adults

This chapter provides guidance for the assessment of transgender and gender diverse (TGD) adults who are requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs) to better align their body with their gender identity (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1).

TGD adults are people at or above the age of majority in their country, who have some form of gender diversity. The developmental elements of the adolescent chapter, including the importance of parental/caregiver involvement, may be relevant for the care of young adults too, even if they are above the age of majority.

This chapter includes all forms of gender identities and transitions including, but not limited to, male, female, gender diverse, nonbinary, agender, and eunuch. The population of TGD adults is heterogeneous and will vary according to their clinical need, biological, psychological, and social situations, as well as their access to health care. As such, any assessment for GAMSTs will need to be adapted to the scientific, clinical, and community knowledge base of the presenting gender identity as well as local circumstances. This chapter recognizes individuals may experience different local levels of clinical or regulatory oversight when the state or others are providing health care.

An individual's gender identity is an internal identification and experience. The role of the assessor is to assess for the presence of gender incongruence and identify any co-existing mental health concerns, to offer information about GAMSTs, to support the TGD person in considering the effects/risks of GAMSTs, and to assess if the TGD person has the capacity to understand the treatment being offered and if the treatment is likely to be of benefit. The assessor can also assist a TGD person to consider choices that could improve their GAMST outcomes. The GAMST assessment approach described in this chapter recognizes the lived experience and self-knowledge of the TGD person and the clinical knowledge of the assessing health care professional (HCP). Consequently, with this approach, the decision to move forward with GAMSTs is shared between the TGD person and the assessing HCP, with both playing a key part in collaborative decision-making.

Some systems use a model of care for TGD adults seeking GAMSTs that prioritizes the TGD adult as the decision maker with the HCP acting as an advisor, barring serious contraindications. These models are used when considering hormone therapy rather than surgery and are often called "informed consent" models (Deutsch, 2011, 2016a). Many such models utilize an abbreviated assessment that focuses primarily on the ability of a TGD person to grant informed consent and to utilize information about GAMSTs to inform their medical decision-making. There is significant variability in such models across jurisdictions, systems, and HCPs (Deutsch, 2011; Morenz et al., 2020). Informed consent models have been used for some time for hormone prescription in many local settings.

This chapter is intended to offer flexible global guidance that must be adapted to local circumstances. HCPs will need to determine which assessment approaches best meet the needs in their local settings. The evaluation of these approaches is best undertaken in collaboration with TGD people.

Since TGD people represent a diverse array of gender identities and expressions and have differing needs for GAMSTs, no single assessment process will fit every person or every situation. Some TGD people may need a comparatively brief assessment process for GAMSTs. For TGD adults with a complex presentation or for those who are requesting less common treatments or treatments with limited research evidence, more comprehensive assessments with different members of a multidisciplinary team will be required. Assessments may be in person or through telehealth. While psychometric assessment tools have been used in some instances, they are not a required part of the assessment for GAMSTs. Counseling or psychotherapy can be helpful when requested by a TGD person. However, counseling or psychotherapy specifically focused on their TGD identity is not a requirement for the assessment or initiation of GAMSTs. Genital exams are not a prerequisite for initiation of GAMTs and should be performed only when clinically indicated.

GAMSTs can be delivered in diverse settings. Settings will depend on available health care systems within each country and may include nationalized/public health care, private sector settings, community health care settings, and charitable institutions. Local and regional circumstances may therefore influence the availability of health care. Regardless of the setting, health care offered to TGD people should be of the highest possible quality. World Professional Organization for Transgender Health (WPATH) advocates for assessment and treatment to be readily available. Access to assessment and treatment for TGD people seeking GAMSTs is critical given the clear medical necessity of these interventions and the profound benefits they offer to TGD people (Aldridge et al., 2020; Byne et al., 2012). The guidance in this chapter will need to be adapted according to local, as well as individual, clinical, and social circumstances.

The statements below are based on significant background literature, including literature demonstrating the strong positive impact of access to GAMSTs; available empirical evidence; a favorable risk-benefit ratio; and consensus of professional best practice. The empirical evidence base for the

Statements of Recommendations

5.1- We recommend health care professionals assessing transgender and gender diverse adults for physical treatments:
5.1.a- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.
5.1.b- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.
5.1.c- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.
5.1.d- Are able to assess capacity to consent for treatment.
5.1.e- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.
5.1.f- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.
5.2- We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):
5.3- We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:
5.3.a- Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.
5.3.b- Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.
5.3.c- Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.
5.3.d- Ensure that any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.e- Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.f- Assess the capacity to consent for the specific physical treatment prior to the initiation of this treatment.
5.3.g- Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.
5.4- We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.
5.5- We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.
5.6- We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).
5.7- We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professional in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

assessment of TGD adults is limited. It primarily includes an assessment approach that uses specific criteria that are examined by an HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research (Olsen-Kennedy et al., 2016). This is understandable given the complexity and ethical considerations of allocating patients in need of care to different assessment groups and the lack of funding for research and other resources to assess long-term outcomes of assessment approaches.

The creation of this guidance has been a complex undertaking. The criteria in this chapter have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to care. It is hoped that future research will explore the effectiveness of this model as well as evolving assessment models for hormone therapy and for surgery that will allow continued improvements to be made.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 5.1.

We recommend health care professional assessing transgender and gender diverse adults for gender-affirming treatments:

Statement 5.1.a

Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.

TGD people, as with all other people seeking health care, should have the highest quality of care accessible that is commensurate with the quality of care provided to all people utilizing health services (The Yogyakarta Principles, 2017). As this will vary around the globe, the nature of the professional completing an assessment for GAMSTs will vary according to the nature of health care in the local setting as well as the regulatory requirements set by licensing and registration boards. It is important the health care provided includes an assessment conducted by a competent, statutorily regulated HCP who has the competence to identify gender incongruence and conditions that can be mistaken for gender incongruence and who can support the TGD person throughout the assessment process (RCGP, 2019). Assessors must be able to refer to HCPs licensed to provide GAMSTs.

HCPs should have at a minimum a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training and be statutorily regulated; examples include a mental health professional (MHP), general medical practitioner, nurse, or other qualified HCP. In some settings, statutorily regulated HCPs with lower levels of qualification may practice under the clinical supervision of a qualified HCP who takes ultimate clinical responsibility for the quality and accuracy of the completed GAMST assessment. For additional information see Chapter 4—Education.

Accessing a competent, statutorily regulated, HCP with expertise in GAMST assessment can sometimes be difficult. Consequently, ensuring continuity of care and minimizing gaps in accessible care or significantly delayed care (e.g., a long waiting list) may require that a statutorily regulated HCP without expertise provide care and support the assessment of a TGD person for GAMSTs. Avoiding unnecessary delays in care is critically important. However, TGD people should be supported to access care with an experienced HCP as soon as possible (RCGP, 2019).

Established practice requires the competence to identify and diagnose gender incongruence (Hembree et al., 2017; Reed et al., 2016; T'Sjoen et al., 2020) and the ability to identify differentials or conditions that may be mistaken as gender incongruence (Byne et al., 2018; Dhejne et al., 2016; Hembree et al., 2017). Established practice also strongly emphasizes the need for ongoing continuing education in the assessment and provision of care of TGD people (American Psychological Association, 2015; T'Sjoen et al., 2020). For more information see Chapter 4—Education.

Statement 5.1.b

For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health

Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.

In some countries, a diagnosis of gender incongruence may be necessary to access GAMSTs (as described below). HCPs assessing TGD people in those countries should be competent to diagnose gender incongruence using the most current classification system necessary for TGD people to access GAMSTs. The ICD-11 (WHO, 2019a) is a classification system that focuses on the TGD person's experienced identity and any need for GAMSTs and does not consider a TGD identity to be a mental illness.

Statement 5.1.c

Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.

Gender diversity is a natural variation in people and is not inherently pathological (American Psychological Association, 2015). However, assessment is best provided by an HCP who possesses some expertise in mental health in order to identify conditions that can be mistaken for gender incongruence. Such conditions are rare and, when present, are often psychological in nature (Byne et al., 2012; Byne et al., 2018; Hembree et al., 2017).

The need to include an HCP with some expertise in mental health does not require the inclusion of a psychologist, psychiatrist, or social worker in each assessment. Instead, a general medical practitioner, nurse, or other qualified HCP could also fulfill this requirement if they have sufficient expertise to identify gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity, assist a TGD person in care planning and preparation for GAMSTs, and refer to a mental health professional (MHP), if needed. As discussed in greater depth in the mental health chapter, MHPs have an important role to play in the care of TGD people. For example, the prejudice and discrimination experienced by some TGD people (Robles et al., 2016) can lead to depression, anxiety, or worsening of other mental health conditions. In such cases, an MHP can diagnose, clarify, and treat mental health conditions. MHPs and HCPs with expertise in mental health are well-placed to assess for GAMSTs, as well as to support TGD people who require or request mental health input or support during their transition. For additional information see Chapter 18—Mental Health.

Statement 5.1.d

Are able to assess capacity to consent for treatment.

An assessment for GAMSTs must include an examination of the TGD person's ability to consent to the proposed treatment. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes. It also requires the ability to retain that information for the purposes of making the decision (using aids as necessary) as well as the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007).

Some TGD individuals will have the capacity to grant consent immediately during the assessment. Some TGD individuals may need a longer process to be able to consent through ongoing discussion and the practice of medical decision-making skills. The presence of psychiatric illness or mental health symptoms do not pose a barrier to GAMSTs unless the psychiatric illness or mental health symptoms affect the TGD person's capacity to consent to the specific treatment being requested or affect their ability to receive treatment. This is especially important because GAMSTs have been found to reduce mental health symptomatology for TGD people (Aldridge et al., 2020).

Health care systems can consider GAMSTs for individuals who may not be able to directly consent if an appropriate legal guardian or regulator-approved independent decision maker with the power to determine health care treatment grants consent and confirms the proposed treatment is in alignment with the TGD individual's needs and wishes.

Statement 5.1.e

Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity. For supporting text, see Statement 5.1.f.

Statement 5.1.f

Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.

As in any other area of clinical practice, it is vital HCPs who are providing assessment for the initiation of GAMSTs are knowledgeable and experienced in the health care of TGD people. If this is not possible in the local context, the HCP providing the assessment should work closely with an HCP who is knowledgeable and experienced. As part of their clinical practice, HCPs should commit to ongoing training in TGD health care, become a member of relevant professional bodies, attend relevant professional meetings, workshops or seminars, consult with an HCP with relevant experience, and/or engage with the TGD community. This is particularly important in TGD health care as it is a relatively new field, and the knowledge and terminology are constantly changing (American Psychological Association, 2015; Thorne, Yip et al., 2019). Consequently, keeping up to date in the areas of TGD health is vital for anyone involved in an assessment for GAMSTs.

Statement 5.2

We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

If required and if possible, assessment for GAMST should be conducted by a multidisciplinary team (Costa, Rosa-e-Silva et al., 2018; Hembree et al., 2017; Karasic & Fraser, 2018; T'Sjoen et al., 2020) with team members who have timely and adequate contact with one another. This could include an MHP, an endocrinologist, a primary care provider, a surgeon, a voice and communication specialist, TGD peer navigator, and others. In some cases, a multidisciplinary team may not be required; however, should a multidisciplinary team be needed, it is critical HCPs be able to access colleagues from different disciplines in a timely manner to complete the GAMST assessment and best support the needs of the TGD person. It is also critical TGD people be supported with follow-up appointments with any HCP who was involved during the assessment for GAMSTs, prior to, during, and after the initiation of gender-affirming treatments.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):

Statement 5.3

We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:

Statement 5.3.a

Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.

To access GAMSTs, a TGD person's gender incongruence must be marked and sustained. This can include a need for GAMSTs and a desire to be accepted as a person of the experienced gender. Consequently, a consideration of the nature, length and consistency of gender incongruence is important. This can include such factors as a change of name and identity documents, telling others about one's gender, health care documentation, or changes in gender expression. However, marked and sustained gender incongruence can exist in the absence of disclosure to others by the TGD person (Brumbaugh-Johnson & Hull, 2019; Saeed et al., 2018; Sequeira et al., 2020). An abrupt or superficial change in gender identity or lack of persistence is insufficient to initiate gender- affirming treatments, and further assessment is recommended. In such circumstances, ongoing assessment is helpful to ensure the consistency and persistence of gender incongruence before GAMSTs are initiated.

While marked and sustained gender incongruence should be present, it is not necessary for TGD people to experience severe levels of distress regarding their gender identity to access gender- affirming treatments. In fact, access to gender-affirming treatment can act as a prophylactic measure to prevent distress (Becker et al., 2018; Giovanardi et al., 2021; Nieder et al., 2021; Nobili et al., 2018; Robles et al., 2016). A TGD adult can have sustained gender incongruence without significant distress and still benefit from GAMSTs.

Established clinical practice examines the persistence of gender incongruence when considering the initiation of GAMSTs (Chen & Loshak, 2020). In a review of 200 clinical notes, Jones, Brewin et al. (2017) identified the importance of the "stability of gender identity" when planning care. Providing GAMSTs to TGD people with persistent gender incongruence has been associated with low rates of patient regret and high rates of patient satisfaction (Becker et al., 2018; El-Hadi et al., 2018; Staples et al., 2020; Wiepjes et al., 2018). However, while the ICD 11 (WHO, 2019a) requires the presence of marked and persistent gender incongruence for a diagnosis of gender incongruence to be made, there is little specific evidence concerning the length of persistence required for treatment in adults. HCPs involved in an assessment of a TGD person for GAMSTs are encouraged to give due consideration to the life stage, history, and current circumstances of the adult being assessed.

Statement 5.3.b

Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.

A diagnosis of gender incongruence may be necessary in some regions to access transition-related care. When a diagnosis is necessary to access GAMSTs, the assessment for GAMSTs will involve determining and assigning a diagnosis. In these instances, HCPs should have competence using the latest International Classification of Diseases and Related Health Problems (ICD) (WHO, 2019a). In regions where a diagnosis is necessary to access health care, a diagnosis of HA60 *Gender Incongruence of Adolescence or Adulthood* should be determined prior to gender-affirming interventions. Gender-affirming interventions secondary to a diagnosis of *HA6Z Gender Incongruence, Unspecified* may be considered in the context of a more comprehensive assessment by the multidisciplinary team.

There is evidence the use of rigid assessment tools for "transition readiness" may reduce access to care and are not always in the best interest of the TGD person (MacKinnon et al., 2020). Therefore, in situations where the assignment of a diagnosis is mandatory to access care, the process should be approached with trust and transparency between the HCP and the TGD individual requesting GAMST, with the needs of the TGD individual in mind. Indeed, high quality relationships between TGD people and their HCPs are associated with lower emotional distress and better outcomes (Kattari et al., 2016). Because many TGD people fear HCPs will erroneously conflate transgender identity with mental illness (Ellis et al., 2015), a diagnostic assessment should be undertaken with sensitivity to facilitate the best relationship between the provider and the TGD individual.

Statement 5.3.c

Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.

In rare cases, TGD individuals might have a condition that may be mistaken for gender incongruence or may have another reason for seeking treatment aside from the alleviation of gender incongruence. In these cases, and when there is ambiguity regarding the diagnosis of gender incongruence, a more detailed and comprehensive assessment is important. For example, further assessment might be required to determine if gender incongruence persists outside of an acute psychotic episode. If gender incongruence persists after an acute psychotic episode resolves, GAMSTs may be considered as long as the TGD person has the capacity to consent to and undergo the specific treatment. If gender incongruence does not persist and only occurs during such an episode, treatment should not be considered. It is important such circumstances be identified and excluded prior to the initiation of GAMSTs (Byne et al., 2012, 2018; Hembree et al., 2017). It is important to understand, however, TGD people may present with gender incongruence and with a mental health condition, autistic spectrum disorder, or other neurodiversity (Glidden et al., 2016). Indeed, some mental health conditions, such as anxiety (Bouman et al., 2017), depression (Heylens, Elaut et al., 2014; Witcomb et al., 2018), and self-harm (Arcelus et al., 2016; Claes et al., 2015) are more prevalent in TGD people who have not accessed GAMSTs. Recent longitudinal studies suggest mental health symptoms experienced by TGD people tend to improve following GAMSTs (Aldridge et al., 2020; Heylens, Verroken et al., 2014;

White Hughto & Reisner, 2016). There is no evidence to suggest a benefit of withholding GAMSTs from TGD people who have gender incongruence simply on the basis that they have a mental health or neurodevelopmental condition. For more information see Chapter 18—Mental Health.

Statement 5.3.d

Ensure any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

Like their cisgender counterparts, TGD people may have mental health problems. Treatment for mental health problems can and should occur in conjunction with GAMSTs when medical transition is needed. It is vital gender-affirming care is not impeded unless, in some extremely rare cases, there is robust evidence that doing so is necessary to prevent significant decompensation with a risk of harm to self or others. In those cases, it is also important to consider the risks delaying GAMSTs poses to a TGD person's mental and physical health (Byne et al., 2018).

In general, social and medical transition of TDG people are both associated with a reduction in mental health problems (Aldridge et al., 2020; Bouman et al., 2017; Durwood et al., 2017; Glynn et al., 2016; Hughto & Reisner, 2016; Wilson et al., 2015; Witcomb et al., 2018). Unfortunately, the loss of social support and the physical and financial stress that can be associated with the initiation of GAMSTs may exacerbate pre-existing mental health problems and warrant additional support from the treating HCP (Budge et al., 2013; Yang, Wang et al., 2016). An assessment of mental health symptoms can improve transition outcomes, particularly when the assessment is used to facilitate access to psychological and social support during transition (Byne et al., 2012). A delay of transition in rare circumstances may be considered if, for example, the TGD person is unable to engage with the process of transition or would be unable to manage aftercare following surgery, even with support. Where a delay in GAMST as a last resort has been found to be necessary, the HCP should offer resources and support to improve mental health and facilitate re-engagement with the GAMST process as soon as practicable. It should be noted access to medical transition for TGD people facilitates social transition and improves safety in public (Rood et al., 2017). In turn, the degree to which TGD people's appearance conforms to their gender identity is the best predictor of quality of life and mental health outcomes following medical transition (Austin & Goodman, 2017). Delaying access to GAMSTs due to the presence of mental health problems may exacerbate symptoms (Owen-Smith et al., 2018) and damage rapport; consequently, this should be done only when all other avenues have been exhausted.

Statement 5.3.e

Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

In rare cases, GAMSTs, such as hormonal and surgical interventions, may have iatrogenic consequences or may exacerbate pre-existing physical health conditions (Hembree et al., 2017). In these instances, care should be taken, whenever possible, to manage pre-existing physical health conditions while initiating (if appropriate) or continuing gender-affirming treatments. Any interruptions in treatment should be as brief as possible and with treatment re-initiated as soon as practicable. Limited data and inconsistent findings suggest an association between cardiovascular and metabolic risks and hormone therapy in TGD adults (Getahun, 2018; Iwamoto, Defreyne et al., 2019; Iwamoto et al., 2021; Spanos et al., 2020). Because of the possible harm related to long-term treatment and the probable benefits expected from the preventive measures applied before and during hormone treatment, a careful assessment of physical health conditions prior to initiation of treatment is important. Some specific conditions, such as a history of hormone-sensitive cancer, may require further assessment and management that may preclude hormone treatment (Center of Excellence for Transgender Health, 2016; Hembree et al., 2017).

Similar concerns may be present for TGD adults who wish to access surgical interventions. Each gender-affirming surgical intervention has specific risks and potentially unfavorable consequences (Bryson & Honig, 2019; Nassiri et al., 2020; Remington et al., 2018). However, intervention-specific risks associated with the presence of specific physical conditions have not been well researched. Thus, the kinds of medical concerns raised by TGD people during the assessment are typically no different from those of any other surgical candidate.

Taking into consideration the mental and physical health disparities (Brown & Jones, 2016) and barriers to health care (Safer et al., 2016) experienced by TGD people, the assessment of physical conditions by HCPs should not be limited to a history of medical interventions. If the TGD person has physical health conditions, it is important these conditions are managed while initiating or continuing GAMSTs whenever possible. Any interruption in treatment should be made with a view toward re-initiating treatment as soon as practicable. It is also important HCPs develop a treatment strategy for managing physical conditions that facilitates health and promotes consistent adherence to a treatment plan.

Statement 5.3.f

Assess the capacity to consent for the specific gender-affirming treatments prior to the initiation of this treatment.

The practice of informed consent to treatment is central to the provision of health care. Informed consent is couched in the ethical principle that recipients of health care should understand the health care they receive and any potential consequences that could result. The importance of informed consent is embedded in many legislative and regulatory practices that guide HCPs around the world (Jefford & Moore, 2008). It is not possible to know all the potential consequences of a health care treatment; instead, considering what would be "reasonable" to expect is often used as a minimum criterion for consent (Jefford & Moore, 2008; Spatz et al., 2016) and remains the case with GAMSTs. Being able to consent to a health care procedure or clinical intervention requires several complex cognitive processes. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes in addition to the ability to retain that information for the purposes of making the decision (using aids as necessary) and the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007). It is vital the TGD person and the assessing HCP consider a priori the nature of the treatment sought and the potential positive and negative effects it may have on the biological, psychological, and social domains of the TGD person's life.

It is important to recognize mental illness, in particular symptoms of cognitive impairment or psychosis, can impact a person's ability to grant consent for GAMSTs (Hostiuc et al., 2018). However, the presence of such symptoms does not necessarily equate to an inability to give consent because many people with significant mental health symptoms are able to understand the risks and benefits of treatment enough to make an informed decision (Carpenter et al., 2000). Instead, it is important a careful assessment is carried out that examines each TGD person's ability to comprehend the nature of the specific GAMST being considered, consider treatment options, including risks and benefits, appreciate the potential short- and long-term consequences of the decision, and communicate their choice in order to receive the treatment (Grootens-Wiegers et al., 2017).

There may be instances in which an individual lacks the capacity to consent to health care, such as during an acute episode of psychosis or in situations where an individual has long-term cognitive impairment. However, limits to capacity to consent to treatment should not prevent individuals from receiving appropriate GAMSTs. For some, understanding the risks and benefits may require the use of repeated explanations in jargon-free language over time or the use of diagrams to facilitate explanation and aid comprehension. A comprehensive and thorough assessment undertaken by the multidisciplinary health care team can further inform this process. For others, an alternative decision maker, such as a legal guardian or regulator-approved,

independent decision maker may need to be appointed. These situations need to be considered on a case-by-case basis with the aim of ensuring the most affirmative and least restrictive health care is provided to the individual. Also see Chapter 11—Institutional Environments.

Statement 5.3.g

Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.

As gender-affirming medical interventions often affect reproductive capacity, HCPs should ensure a TGD person is aware of the implications for reproduction of the treatments and is familiar with gamete storage and assistive reproductive options. Gender-affirming hormone treatments have been shown to impact reproductive functions and fertility, although the consequences are heterogenous for people of all birth-assigned sexes (Adeleye et al., 2019; Jindarak et al., 2018; Taub et al., 2020). There may be individual differences and fluctuations in these effects on TGD adults. It is therefore essential that HCPs inform a TGD person about the possible impact of the treatment on their reproductive potential during the assessment and as part of the evaluation of the person's capacity to consent for GAMSTs. Reproductive options should be considered and discussed prior to the initiation of gender-affirming treatments. Because the literature is unclear about the possibility of conception while on hormone therapy, information about the necessity of using contraception to avoid unwanted pregnancy and the different methods of contraception available may need to be provided (Light et al., 2014; Schubert & Carey,2020).

Cross-sectional studies in clinical and nonclinical samples from different populations consistently report TGD adults express parental desire and wish to pursue fertility preservation with varying rates that are related to age, gender, and the duration of gender-affirming hormone treatment (Auer et al., 2018; De Sutter et al., 2002; Defreyne, Van Schuvlenbergh et al., 2020; Wierckx, Stuyver et al., 2012). In a small sample, provision of fertility information was found to have an influence on decision-making related to the use of fertility preservation (Chen et al., 2019). Although there was no comparison made between groups who did and did not receive fertility counseling, high fertility preservation rates occurred following comprehensive fertility counseling among transgender individuals (Amir et al., 2020). Further, one study suggested consultation with a specialist reduced regret related to the decision about whether to pursue fertility preservation procedures (Vyas et al., 2021). For more information see Chapter 16—Reproductive Health.

Statement 5.4

We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.

Social transition can be extremely beneficial to many TGD people although not all TGD people are able to socially transition or wish to socially transition (Bränström & Pachankis, 2021; Koehler et al., 2018; Nieder, Eyssel et al., 2020). Consequently, some TGD people seek gender-affirming interventions after social transition, some before, some during, and some in the absence of social transition.

Social transition and gender identity disclosure can improve the mental health of a TGD person seeking gender-affirming interventions (Hughto et al., 2020; McDowell et al., 2019). In addition, chest and facial surgeries prior to hormone therapy can facilitate social transition (Altman, 2012; Davis & Colton Meier, 2014; Olson-Kennedy, Warus et al. 2018; Van Boerum et al., 2019). As part of the assessment process, HCPs should discuss which social role is most comfortable for the TGD person, if a social transition is planned, and the timing for any planned social transition (Barker & Wylie, 2008). It is imperative during the assessment process, HCPs are respectful of the wide diversity of gendered social roles, including nonbinary as well as binary identities and presentations, which vary

according to cultural, local community, and individual understandings.

Not everyone who requests GAMSTs will wish to or be able to socially transition. Little is known about TGD people who do not socially transition before, during, or after medical treatment, as this has not been systematically studied. The most frequent reasons that have been identified for avoiding social transition are fear of being abandoned by family or friends, fearing economic loss (Bradford et al., 2013), and being discriminated against and stigmatized (Langenderfer-Magruder et al., 2016; McDowell et al., 2019; White Hughto et al., 2015). However, some people do not pursue social transition because they feel hormonal or surgical treatments offer enough subjective improvement to reduce gender dysphoria.

If there is no clear plan for social transition or if social transition is unwanted, additional assessment is important to determine the specific nature and advisability of the treatment request, especially if surgical treatment is requested. Additional assessment can offer the TGD person an opportunity to consider the possible effects of not socially transitioning while still obtaining GAMSTs. Given the lack of data on health outcomes for TGD people who do not socially transition (Evans et al., 2021; Levine, 2009; Turban, Loo et al., 2021), GAMSTs should be approached cautiously in such circumstances.

Statement 5.5

We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.

Previous versions of the SOC guidelines have required TGD individuals to be assessed for GAMSTs by two qualified HCPs. It was believed having two independent opinions was best practice as it ensured safety for both TGD people and HCPs. For example, it was assumed that seeing two HCPs offered assuredness for both TGD people and their assessing HCPs when pursuing irreversible medical interventions.

However, the limited research in the area indicates two opinions are largely unnecessary. For example, Jones, Brewin et al. (2017) reviewed the case notes of experienced HCPs working within a state-funded gender service and found there was an overwhelming correlation between both opinions—arguably making one of them redundant. Further, Bouman et al. (2014) determined the requirement for two independent assessors reflected paternalism in health care services and raised a potential breach of the autonomy of TGD individuals. The authors posited when clients are adequately prepared and assessed under the care of a multidisciplinary team, a second independent assessment is unnecessary.

Consequently, if written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), TGD people seeking treatments including hormones, and genital, chest, facial and other gender-affirming surgeries require a single written opinion/signature from an HCP competent to independently assess and diagnose (Bouman et al., 2014; Yuan et al, 2021). Further written opinions/signatures may be requested where there is a specific clinical need.

Statement 5.6

We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

The Endocrine Society Clinical Practice Guidelines advise a period of consistent hormone treatment prior to genital surgery (Hembree et al., 2017). While there was limited supportive research, this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery. For example, there can be changes in sexual desire after genital surgery that removes the testicles (Lawrence, 2005; Wierckx, Van de Peer et al., 2014). In this context, reversible testosterone suppression can offer a TGD person a period of time to experience the absence of testosterone and decide if this feels right for

them. It should be noted the effects of reduced estrogen on a TGD person's sexual desire and functioning following an oophorectomy is less well documented.

Surgery that removes gonads is an irreversible procedure that leads to loss of fertility and loss of the effects of endogenous sex steroids. Both effects must be discussed as a component of the assessment process. For additional information see Chapter 16—Reproductive Health. Of course, hormones are not clinically indicated for TGD adults who do not want them or in cases where they are contraindicated due to health reasons. For more information see Chapter 13—Surgery and Postoperative Care.

Statement 5.7

We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professionals in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

Many TGD adults may consider a range of identities and elements of gender presentation while they are exploring their gender identity and are considering transition options. Accordingly, people may spend some time in a gender identity or presentation before they discover it does not feel comfortable and later adapt it or shift to an earlier identity or presentation (Turban, King et al., 2021). Some TGD adults may also experience a change in gender identity over time so that their needs for medical treatment evolve. This is a healthy and reasonable process for determining the most comfortable and congruent way of living, which is informed by the person's gender identity and the context of their life. This process of identity exploration should not necessarily be equated with regret, confusion, or poor decision-making because a TGD adult's gender identity may change without devaluing previous transition decisions (MacKinnon et al., 2021; Turban, Loo et al., 2021). TGD adults should be assisted in this exploration and any other changes in their identity (Expósito-Campos, 2021). While exploration continues, gender-affirming treatments that are irreversible should be avoided until clarity about long-term goals and outcomes is achieved.

The decision to detransition appears to be rare (Defreyne, Motmans et al., 2017; Hadje-Moussa et al., 2019; Wiepjes et al., 2018). Estimates of the number of people who detransition due to a change in identity are likely to be overinflated due to research blending different cohorts (Expósito-Campos, 2021). For example, detransition research cohorts often include TGD adults who chose to detransition because of a change in their identity as well as TGD adults who chose to detransition without a change in identity. While little research has been conducted to systematically examine variables that correlate with a TGD adult's decision to halt a transition process or to detransition, a recent study found the vast majority of TGD people who opted to detransition did so due to external factors, such as stigma and lack of social support and not because of changes in gender identity (Turban, King et al., 2021). TGD adults who have not experienced a change in identity may choose to halt transition or to detransition because of oppression, violence, and social/relational conflict, surgical complications, health concerns, physical contraindications, a lack of resources, or dissatisfaction with the results (Expósito-Campos, 2021). In such cases, MHPs are well placed to assist the TGD person with these challenges.

While the choice to detransition is proportionally rare, it is expected an overall increase in the number of adults who identify as TGD would result in an increase in the absolute number of people seeking to halt or reverse a transition. However, while the absolute numbers may increase, the percentage of people seeking to halt or reverse permanent physical changes should remain static and low. The existence of these rare requests must not be used as a justification to interrupt critical, medically necessary care, including hormone and surgical treatments, for the vast majority of TGD adults.

Due to the limited research in this area, clinical guidance is based primarily on individual case studies and the expert opinion of HCPs

working with TGD adults (Expósito-Campos, 2021; Richards & Barrett, 2020). Accordingly, if a TGD adult has undergone permanent physical changes and seeks to undo them, the assessing HCP should be a member of a comprehensive multidisciplinary assessment team. A multidisciplinary team allows for the contribution of additional viewpoints from HCPs experienced in transgender health. In collaboration with the TGD adult, the multidisciplinary team is encouraged to thoroughly understand the motivations for the original treatment and for the decision to detransition. Any concerns with the previous physical changes should be carefully explored and a significant effort made to ensure similar concerns are not replicated by the reversal.

To ensure the greatest likelihood of satisfaction and comfort with a reversal of permanent physical changes, the TGD adult and the multidisciplinary team should explore the role of social transition in the assessment and in preparation for the reversal. In such instances, it is highly likely a prolonged period of living in role will be necessary before further physical changes are recommended. HCPs should support the TGD adult through any social changes, as well as any feelings of failure, shame, depression, or guilt in deciding to make such a change. In addition, people should be supported in coping with any prejudice or social difficulties they may have experienced that could have led to a decision to detransition or that may have resulted from such a decision. It is also important to help the person remain engaged with health care throughout the process (Narayan et al., 2021).

While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition (Aldridge et al., 2020; Byne et al., 2012; Gorin-Lazard et al., 2012; Owen-Smith et al., 2018; White Hughto & Reisner, 2016), some TGD adults may decompensate or experience a worsened condition following transition. Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition (Hall et al., 2021; Littman, 2021); however, this occurrence appears to be rare (Hall et al., 2021; Wiepjes et al., 2018). In cases where people decompensate after physical or social transition and then remain in a poorer biological, psychological, or social state than they were in prior to transition, serious consideration should be given as to whether transition is helpful at this time, for this person, or both. In cases where treatment is no longer supported, assistance should be arranged to support the person to manage the process of stopping treatment and to manage any concomitant difficulties (Narayan et al., 2021).

It is vital that people who detransition, for any reason, be supported. It should be remembered, however, this is a rare occurrence and the literature shows consistently positive outcomes for the vast majority of TGD adults who transition to a gender that is comfortable for them, including those who receive GAMSTs (Byne et al., 2012; Green & Fleming, 1990; Lawrence, 2003; Motmans et al., 2012; Van de Grift, Elaut et al., 2018).

CHAPTER 6 Adolescents

Historical context and changes since previous Standards of Care

Specialized health care for transgender adolescents began in the 1980s when a few specialized gender clinics for youth were developed around the world that served relatively small numbers of children and adolescents. In more recent years, there has been a sharp increase in the number of adolescents requesting gender care (Arnoldussen et al., 2019; Kaltiala, Bergman et al., 2020). Since then, new clinics have been founded, but clinical services in many places have not kept pace with the increasing number of youth seeking care. Hence, there are often long waitlists for services, and barriers to care exist for many transgender youth around the world (Tollit et al., 2018).

Until recently, there was limited information regarding the prevalence of gender diversity among adolescents. Studies from high school samples indicate much higher rates than earlier thought, with reports of up to 1.2% of participants identifying as transgender (Clark et al., 2014) and up to 2.7% or more (e.g., 7–9%) experiencing some level of self-reported gender diversity (Eisenberg et al., 2017; Kidd et al., 2021; Wang et al., 2020). These studies suggest gender diversity in youth should no longer be viewed as rare. Additionally, a pattern of uneven ratios by assigned sex has been reported in gender clinics, with adolescents assigned female at birth (AFAB) initiating care 2.5–7.1 times more frequently as compared to adolescents who are assigned male at birth (AMAB) (Aitken et al., 2015; Arnoldussen et al., 2019; Bauer et al., 2021; de Graaf, Carmichael et al., 2018; Kaltiala et al., 2015; Kaltiala, Bergman et al., 2020).

A specific World Professional Association for Transgender Health's (WPATH) Standards of Care section dedicated to the needs of children and adolescents was first included in the 1998 WPATH Standards of Care, 5th version (Levine et al., 1998). Youth aged 16 or older were deemed potentially eligible for gender-affirming medical care, but only in select cases. The subsequent 6th (Meyer et al., 2005) and 7th (Coleman et al., 2012) versions divided medical-affirming treatment for adolescents into three categories and presented eligibility criteria regarding age/puberty stage—namely fully reversible puberty delaying blockers as soon as puberty had started; partially reversible hormone therapy (testosterone, estrogen) for adolescents at the age of majority, which was age 16 in certain European countries; and irreversible surgeries at age 18 or older, except for chest "masculinizing" mastectomy, which had an age minimum of 16 years. Additional eligibility criteria for gender-related medical care included a persistent, long (childhood) history of gender "non-conformity"/dysphoria, emerging or intensifying at the onset of puberty; absence or management of psychological, medical, or social problems that interfere with treatment; provision of support for commencing the intervention by the parents/caregivers; and provision of informed consent. A chapter dedicated to transgender and gender diverse (TGD) adolescents, distinct from the child chapter, has been created for this 8th edition of the Standards of Care given 1) the exponential growth in adolescent referral rates; 2) the increased number of studies specific to adolescent gender diversity-related care; and 3) the unique developmental and gender-affirming care issues of this age group.

Non-specific terms for gender-related care are avoided (e.g., gender-affirming model, gender exploratory model) as these terms do not represent unified practices, but instead heterogenous care practices that are defined differently in various settings.

Adolescence overview

Adolescence is a developmental period characterized by relatively rapid physical and psychological maturation, bridging childhood and adulthood (Sanders, 2013). Multiple developmental processes occur simultaneously, including pubertal-signaled changes. Cognitive, emotional, and social systems mature, and physical changes associated with puberty progress. These processes do not all begin and end at the same time for a given individual, nor do they occur at the same age for all persons. Therefore, the lower and upper borders of adolescence are imprecise and cannot be defined exclusively by age. For example, physical pubertal changes may

begin in late childhood and executive control neural systems continue to develop well into the mid-20s (Ferguson et al., 2021). There is a lack of uniformity in how countries and governments define the age of majority (i.e., legal decision-making status; Dick et al., 2014). While many specify the age of majority as 18 years of age, in some countries it is as young as 15 years (e.g., Indonesia and Myanmar), and in others as high as 21 years (e.g., the U.S. state of Mississippi and Singapore).

For clarity, this chapter applies to adolescents from the start of puberty until the legal age of majority (in most cases 18 years), however there are developmental elements of this chapter, including the importance of parental/caregiver involvement, that are often relevant for the care of transitional-aged young adults and should be considered appropriately.

Cognitive development in adolescence is often characterized by gains in abstract thinking, complex reasoning, and metacognition (i.e., a young person's ability to think about their own feelings in relation to how others perceive them; Sanders, 2013). The ability to reason hypothetical situations enables a young person to conceptualize implications regarding a particular decision. However, adolescence is also often associated with increased risk-taking behaviors. Along with these notable changes, adolescence is often characterized by individuation from parents and the development of increased personal autonomy. There is often a heightened focus on peer relationships, which can be both positive and detrimental (Gardner & Steinberg, 2005). Adolescents often experience a sense of urgency that stems from hypersensitivity to reward, and their sense of timing has been shown to be different from that of older individuals (Van Leijenhorst et al., 2010). Social-emotional development typically advances during adolescence, although there is a great variability among young people in terms of the level of maturity applied to inter- and intra-personal communication and insight (Grootens-Wiegers et al., 2017). For TGD adolescents making decisions about gender-affirming treatments—decisions that may have lifelong consequences—it is critical to understand how all these aspects of development may impact decision-making for a given young person within their specific cultural context.

Gender identity development in adolescence

Our understanding of gender identity development in adolescence is continuing to evolve. When providing clinical care to gender diverse young people and their families, it is important to know what is and is not known about gender identity during development (Berenbaum, 2018). When considering treatments, families may have questions regarding the development of their adolescent's gender identity, and whether or not their adolescent's declared gender will remain the same over time. For some adolescents, a declared gender identity that differs from the assigned sex at birth comes as no surprise to their parents/caregivers as their history of gender diverse expression dates back to childhood (Leibowitz & de Vries, 2016). For others, the declaration does not happen until the emergence of pubertal changes or even well into adolescence (McCallion et al., 2021; Sorbara et al., 2020).

Historically, social learning and cognitive developmental research on gender development was conducted primarily with youth who were not gender diverse in identity or expression and was carried out under the assumption that sex correlated with a specific gender; therefore, little attention was given to gender identity development. In addition to biological factors influencing gender development, this research demonstrated psychological and social factors also play a role (Perry & Pauletti, 2011). While there has been less focus on gender identity development in TGD youth, there is ample reason to suppose, apart from biological factors, psychosocial factors are also involved (Steensma, Kreukels et al., 2013). For some youth, gender identity development appears fixed and is often expressed from a young age, while for others there may be a developmental process that contributes to gender identity development over time.

Neuroimaging studies, genetic studies, and other hormone studies in intersex individuals demonstrate a biological contribution to the development of gender identity for some

individuals whose gender identity does not match their assigned sex at birth (Steensma, Kreukels et al., 2013). As families often have questions about this very issue, it is important to note it is not possible to distinguish between those for whom gender identity may seem fixed from birth and those for whom gender identity development appears to be a developmental process. Since it is impossible to definitively delineate the contribution of various factors contributing to gender identity development for any given young person, a comprehensive clinical approach is important and necessary (see Statement 3). Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups. Conceptualization of gender identity by shifting from dichotomous (e.g., binary) categorization of male and female to a dimensional gender spectrum along a continuum (APA, 2013) would also be necessary.

Adolescence may be a critical period for the development of gender identity for gender diverse young people (Steensma, Kreukels et al., 2013). Dutch longitudinal clinical follow-up studies of adolescents with childhood gender dysphoria who received puberty suppression, gender-affirming hormones, or both, found that none of the youth in adulthood regretted the decisions they had taken in adolescence (Cohen-Kettenis & van Goozen, 1997; de Vries et al., 2014). These findings suggest adolescents who were comprehensively assessed and determined emotionally mature enough to make treatment decisions regarding gender- affirming medical care presented with stability of gender identity over the time period when the studies were conducted.

When extrapolating findings from the longer-term longitudinal Dutch cohort studies to present-day gender diverse adolescents seeking care, it is critical to consider the societal changes that have occurred over time in relation to TGD people. Given the increase in visibility of TGD identities, it is important to understand how increased awareness may impact gender development in different ways (Kornienko et al., 2016). One trend identified is that more young people are presenting to gender clinics with nonbinary identities (Twist & de Graaf, 2019). Another phenomenon occurring in clinical practice is the increased number of adolescents seeking care who have not seemingly experienced, expressed (or experienced and expressed) gender diversity during their childhood years. One researcher attempted to study and describe a specific form of later-presenting gender diversity experience (Littman, 2018). However, the findings of the study must be considered within the context of significant methodological challenges, including 1) the study surveyed parents and not youth perspectives; and 2) recruitment included parents from community settings in which treatments for gender dysphoria are viewed with scepticism and are criticized. However, these findings have not been replicated. For a select subgroup of young people, susceptibility to social influence impacting gender may be an important differential to consider (Kornienko et al., 2016). However, caution must be taken to avoid assuming these phenomena occur prematurely in an individual adolescent while relying on information from datasets that may have been ascertained with potential sampling bias (Bauer et al., 2022; WPATH, 2018). It is important to consider the benefits that social connectedness may have for youth who are linked with supportive people (Tuzun et al., 2022)(see Statement 4).

Given the emerging nature of knowledge regarding adolescent gender identity development, an individualized approach to clinical care is considered both ethical and necessary. As is the case in all areas of medicine, each study has methodological limitations, and conclusions drawn from research cannot and should not be universally applied to all adolescents. This is also true when grappling with common parental questions regarding the stability versus instability of a particular young person's gender identity development. While future research will help advance scientific understanding of gender identity development, there may always be some gaps. Furthermore, given the ethics of self-determination in care, these gaps should not leave the TGD adolescent without important and necessary care.

Research evidence of gender-affirming medical treatment for transgender adolescents

A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical

and surgical treatments (GAMSTs) (see medically necessary statement in the Global chapter, Statement 2.1), over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment in adolescents is not possible. A short narrative review is provided instead.

At the time of this chapter's writing, there were several longer-term longitudinal cohort follow-up studies reporting positive results of early (i.e., adolescent) medical treatment; for a significant period of time, many of these studies were conducted through one Dutch clinic (e.g., Cohen-Kettenis & van Goozen, 1997; de Vries, Steensma et al., 2011; de Vries et al., 2014; Smith et al., 2001, 2005). The findings demonstrated the resolution of gender dysphoria is associated with improved psychological functioning and body image satisfaction. Most of these studies followed a pre-post methodological design and compared baseline psychological functioning with outcomes after the provision of medical gender-affirming treatments. Different studies evaluated individual aspects or combinations of treatment interventions and included 1) gender-affirming hormones and surgeries (Cohen-Kettenis & van Goozen, 1997; Smith et al., 2001, 2005); 2) puberty suppression (de Vries, Steensma et al., 2011); and 3) puberty suppression, affirming hormones, and surgeries (de Vries et al., 2014). The 2014 long-term follow-up study is the only study that followed youth from early adolescence (pretreatment, mean age of 13.6) through young adulthood (posttreatment, mean age of 20.7). This was the first study to show gender-affirming treatment enabled transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with satisfactory objective and subjective outcomes in adulthood (de Vries et al., 2014). While the study employed a small (n = 55), select, and socially supported sample, the results were convincing. Of note, the participants were part of the Dutch clinic known for employing a multidisciplinary approach, including provision of comprehensive, ongoing assessment and management of gender dysphoria, and support aimed at emotional well-being.

Several more recently published longitudinal studies followed and evaluated participants at different stages of their gender-affirming treatments. In these studies, some participants may not have started gender-affirming medical treatments, some had been treated with puberty suppression, while still others had started gender-affirming hormones or had even undergone gender-affirming surgery (GAS) (Achille et al., 2020; Allen et al., 2019; Becker-Hebly et al., 2021; Carmichael et al., 2021; Costa et al., 2015; Kuper et al., 2020, Tordoff et al., 2022). Given the heterogeneity of treatments and methods, this type of design makes interpreting outcomes more challenging. Nonetheless, when compared with baseline assessments, the data consistently demonstrate improved or stable psychological functioning, body image, and treatment satisfaction varying from three months to up to two years from the initiation of treatment.

Cross-sectional studies provide another design for evaluating the effects of gender-affirming treatments. One such study compared psychological functioning in transgender adolescents at baseline and while undergoing puberty suppression with that of cisgender high school peers at two different time points. At baseline, the transgender youth demonstrated lower psychological functioning compared with cisgender peers, whereas when undergoing puberty suppression, they demonstrated better functioning than their peers (van der Miesen et al., 2020). Grannis et al. (2021) demonstrated transgender males who started testosterone had lower internalizing mental health symptoms (depression and anxiety) compared with those who had not started testosterone treatment.

Four additional studies followed different outcome designs. In a retrospective chart study, Kaltiala, Heino et al. (2020) reported transgender

adolescents with few or no mental health challenges prior to commencing gender-affirming hormones generally did well during the treatment. However, adolescents with more mental health challenges at baseline continued to experience the manifestations of those mental health challenges over the course of gender-affirming medical treatment. Nieder et al. (2021) studied satisfaction with care as an outcome measure and demonstrated transgender adolescents were more satisfied the further they progressed with the treatments they initially started. Hisle-Gorman et al. (2021) compared health care utilization pre- and post-initiation of gender-affirming pharmaceuticals as indicators of the severity of mental health conditions among 3,754 TGD adolescents in a large health care data set. Somewhat contrary to the authors' hypothesis of improved mental health, mental health care use did not significantly change, and psychotropic medication prescriptions increased. In a large non-probability sample of transgender-identified adults, Turban et al. (2022) found those who reported access to gender-affirming hormones in adolescence had lower odds of past-year suicidality compared with transgender people accessing gender- affirming hormones in adulthood.

Providers may consider the possibility an adolescent may regret gender-affirming decisions made during adolescence, and a young person will want to stop treatment and return to living in the birth-assigned gender role in the future. Two Dutch studies report low rates of adolescents (1.9% and 3.5%) choosing to stop puberty suppression (Brik et al., 2019; Wiepjes et al., 2018). Again, these studies were conducted in clinics that follow a protocol that includes a comprehensive assessment before the gender-affirming medical treatment is started. At present, no clinical cohort studies have reported on profiles of adolescents who regret their initial decision or detransition after irreversible affirming treatment. Recent research indicate there are adolescents who detransition, but do not regret initiating treatment as they experienced the start of treatment as a part of understanding their gender-related care needs (Turban, 2018). However, this may not be the predominant perspective of people who detransition (Littman, 2021; Vandenbussche, 2021). Some adolescents may regret the steps they have taken (Dyer, 2020). Therefore, it is important to present the full range of possible outcomes when assisting transgender adolescents. Providers may discuss this topic in a collaborative and trusting manner (i.e., as a "potential future experience and consideration") with the adolescent and their parents/caregivers before gender-affirming medical treatments are started. Also, providers should be prepared to support adolescents who detransition. In an internet convenience sample survey of 237 self-identified detransitioners with a mean age of 25.02 years, which consisted of over 90% of birth assigned females, 25% had medically transitioned before age 18 and 14% detransitioned before age 18 (Vandenbussche, 2021). Although an internet convenience sample is subject to selection of respondents, this study suggests detransitioning may occur in young transgender adolescents and health care professionals should be aware of this. Many of them expressed difficulties finding help during their detransition process and reported their detransition was an isolating experience during which they did not receive either sufficient or appropriate support (Vandenbussche, 2021).

To conclude, although the existing samples reported on relatively small groups of youth (e.g., n = 22-101 per study) and the time to follow-up varied across studies (6 months–7 years), this emerging evidence base indicates a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment. Further, rates of reported regret during the study monitoring periods are low. Taken as a whole, the data show early medical intervention—as part of broader combined assessment and treatment approaches focused on gender dysphoria and general well-being—can be effective and helpful for many transgender adolescents seeking these treatments.

Ethical and human rights perspectives

Medical ethics and human rights perspectives were also considered while formulating the

Statements of Recommendations

6.1- We recommend health care professionals working with gender diverse adolescents:
6.1.a- Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.
6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.
6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.
6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.
6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.
6.2- We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.
6.3- We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.
6.4- We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.
6.5- We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.
6.6- We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including a review of the benefits and risks.
6.7- We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.
6.8- We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender- related surgery until the transition is made to adult care.
6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.
6.10- We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.
6.11- We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):
6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:
6.12.a- The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.
6.12.b- The experience of gender diversity/incongruence is marked and sustained over time.
6.12.c- The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.
6.12.d- The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.
6.12.e- The adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.
6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.
6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

adolescent SOC statements. For example, allowing irreversible puberty to progress in adolescents who experience gender incongruence is not a neutral act given that it may have immediate and lifelong harmful effects for the transgender young person (Giordano, 2009; Giordano & Holm, 2020; Kreukels & Cohen-Kettenis, 2011). From a human rights perspective, considering gender diversity as a normal and expected variation within the broader diversity of the human experience, it is an adolescent's right to participate in their own decision-making

process about their health and lives, including access to gender health services (Amnesty International, 2020).

Short summary of statements and unique issues in adolescence

These guidelines are designed to account for what is known and what is not known about gender identity development in adolescence, the evidence for gender-affirming care in adolescence, and the unique aspects that distinguish adolescence from other developmental stages.

Identity exploration: A defining feature of adolescence is the solidifying of aspects of identity, including gender identity. Statement 6.2 addresses identity exploration in the context of gender identity development. Statement 6.12.b accounts for the length of time needed for a young person to experience a gender diverse identity, express a gender diverse identity, or both, so as to make a meaningful decision regarding gender-affirming care.

Consent and decision-making: In adolescence, consent and decision-making require assessment of the individual's emotional, cognitive, and psychosocial development. Statement 6.12.c directly addresses emotional and cognitive maturity and describes the necessary components of the evaluation process used to assess decision-making capacity.

Caregivers/parent involvement: Adolescents are typically dependent on their caregivers/parents for guidance in numerous ways. This is also true as the young person navigates through the process of deciding about treatment options. Statement 6.11 addresses the importance of involving caregivers/parents and discusses the role they play in the assessment and treatment. No set of guidelines can account for every set of individual circumstances on a global scale.

Statement 6.1

We recommend health care professionals working with gender diverse adolescents:

a. **Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.**
b. **Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.**
c. **Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.**
d. **Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.**
e. **Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.**

When assessing and supporting TGD adolescents and their families, care providers/health care professionals (HCPs) need both general as well as gender-specific knowledge and training. Providers who are trained to work with adolescents and families play an important role in navigating aspects of adolescent development and family dynamics when caring for youth and families (Adelson et al., 2012; American Psychological Association, 2015; Hembree et al., 2017). Other chapters in these standards of care describe these criteria for professionals who provide gender care in more detail (see Chapter 5—Assessment for Adults; Chapter 7—Children; or Chapter 13—Surgery and Postoperative Care). Professionals working with adolescents should understand what is and is not known regarding adolescent gender identity development, and how this knowledge base differs from what applies to adults and prepubertal children. Among HCPs, the mental health professional (MHP) has the most appropriate training and dedicated clinical time to conduct an assessment and elucidate treatment priorities and goals when working with transgender youth, including those seeking gender-affirming medical/surgical care. Understanding and managing the dynamics of family members who may share differing perspectives regarding the history and needs of the

young person is an important competency that MHPs are often most prepared to address.

When access to professionals trained in child and adolescent development is not possible, HCPs should make a commitment to obtain training in the areas of family dynamics and adolescent development, including gender identity development. Similarly, considering autistic/neurodivergent transgender youth represent a substantial minority subpopulation of youth served in gender clinics globally, it is important HCPs seek additional training in the field of autism and understand the unique elements of care autistic gender diverse youth may require (Strang, Meagher et al., 2018). If these qualifications are not possible, then consultation and collaboration with a provider who specializes in autism and neurodiversity is advised.

Statement 6.2

We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.

Adolescence is a developmental period that involves physical and psychological changes characterized by individuation and the transition to independence from caregivers (Berenbaum et al., 2015; Steinberg, 2009). It is a period during which young people may explore different aspects of identity, including gender identity.

Adolescents differ regarding the degree to which they explore and commit to aspects of their identity (Meeus et al., 2012). For some adolescents, the pace to achieving consolidation of identity is fast, while for others it is slower. For some adolescents, physical, emotional, and psychological development occur over the same general timeline, while for others, there are certain gaps between these aspects of development. Similarly, there is variation in the timeline for gender identity development (Arnoldussen et al., 2020; Katz-Wise et al., 2017). For some young people, gender identity development is a clear process that starts in early childhood, while for others pubertal changes contribute to a person's experience of themselves as a particular gender (Steensma, Kreukels et al., 2013), and for many others a process may begin well after pubertal changes are completed. Given these variations, there is no one particular pace, process, or outcome that can be predicted for an individual adolescent seeking gender-affirming care.

Therefore, HCPs working with adolescents should promote supportive environments that simultaneously respect an adolescent's affirmed gender identity and also allows the adolescent to openly explore gender needs, including social, medical, and physical gender-affirming interventions should they change or evolve over time.

Statement 6.3

We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

Given the many ways identity may unfold during adolescence, we recommend using a comprehensive biopsychosocial assessment to guide treatment decisions and optimize outcomes. This assessment should aim to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care. As mentioned in Statement 6.1, MHPs have the most appropriate training, experience, and dedicated clinical time required to obtain the information discussed here. The assessment process should be approached collaboratively with the adolescent and their caregiver(s), both separately and together, as described in more detail in Statement 6.11. An assessment should occur prior to any medically necessary medical or surgical intervention under consideration (e.g., puberty blocking medication, gender-affirming hormones, surgeries). See medically necessary statement in Chapter 2—Global Applicability, Statement 2.1; see also Chapter 12—Hormone Therapy and Chapter 13—Surgery and Postoperative Care.

Youth may experience many different gender identity trajectories. Sociocultural definitions and experiences of gender continue to evolve over time, and youth are increasingly presenting with a range of identities and ways of describing their experiences and gender-related needs (Twist & de

Graaf, 2019). For example, some youth will realize they are transgender or more broadly gender diverse and pursue steps to present accordingly. For some youth, obtaining gender-affirming medical treatment is important while for others these steps may not be necessary. For example, a process of exploration over time might not result in the young person self-affirming or embodying a different gender in relation to their assigned sex at birth and would not involve the use of medical interventions (Arnoldussen et al., 2019).

The most robust longitudinal evidence supporting the benefits of gender-affirming medical and surgical treatments in adolescence was obtained in a clinical setting that incorporated a detailed comprehensive diagnostic assessment process over time into its delivery of care protocol (de Vries & Cohen-Kettenis, 2012; de Vries et al., 2014). Given this research and the ongoing evolution of gender diverse experiences in society, a comprehensive diagnostic biopsychosocial assessment during adolescence is both evidence-based and preserves the integrity of the decision-making process. In the absence of a full diagnostic profile, other mental health entities that need to be prioritized and treated may not be detected. There are no studies of the long-term outcomes of gender-related medical treatments for youth who have not undergone a comprehensive assessment. Treatment in this context (e.g., with limited or no assessment) has no empirical support and therefore carries the risk that the decision to start gender-affirming medical interventions may not be in the long-term best interest of the young person at that time.

As delivery of health care and access to specialists varies globally, designing a particular assessment process to adapt existing resources is often necessary. In some cases, a more extended assessment process may be useful, such as for youth with more complex presentations (e.g., complicating mental health histories (Leibowitz & de Vries, 2016)), co-occurring autism spectrum characteristics (Strang, Powers et al., 2018), and/or an absence of experienced childhood gender incongruence (Ristori & Steensma, 2016). Given the unique cultural, financial, and geographical factors that exist for specific populations, providers should design assessment models that are flexible and allow for appropriately timed care for as many young people as possible, so long as the assessment effectively obtains information about the adolescent's strengths, vulnerabilities, diagnostic profile, and individual needs. Psychometrically validated psychosocial and gender measures can also be used to provide additional information.

The multidisciplinary assessment for youth seeking gender-affirming medical/surgical interventions includes the following domains that correspond to the relevant statements:

- **Gender Identity Development:** Statements 6.12.a and 6.12.b elaborate on the factors associated with gender identity development within the specific cultural context when assessing TGD adolescents.
- **Social Development and Support; Intersectionality:** Statements 6.4 and 6.11 elaborate on the importance of assessing gender minority stress, family dynamics, and other aspects contributing to social development and intersectionality.
- **Diagnostic Assessment of Possible Co-Occurring Mental Health and/or Developmental Concerns:** Statement 6.12.d elaborates on the importance of understanding the relationship that exists, if at all, between any co-occurring mental health or developmental concerns and the young person's gender identity/gender diverse expression.
- **Capacity for Decision-Making:** Statement 6.12.c elaborates on the assessment of a young person's emotional maturity and the relevance when an adolescent is considering gender affirming-medical/surgical treatments.

Statement 6.4

We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.

Multiple studies and related expert consensus support the implementation of approaches that promote acceptance and affirmation of gender diverse youth across all settings, including families, schools, health care facilities, and all other organizations and communities with which they

interact (e.g., Pariseau et al., 2019; Russell et al., 2018; Simons et al., 2013; Toomey et al., 2010; Travers et al., 2012). Acceptance and affirmation are accomplished through a range of approaches, actions, and policies we recommend be enacted across the various relationships and settings in which a young person exists and functions. It is important for the family members and community members involved in the adolescent's life to work collaboratively in these efforts unless their involvement is considered harmful to the adolescent. Examples proposed by Pariseau et al. (2019) and others of acceptance and affirmation of gender diversity and contemplation and expression of identity that can be implemented by family, staff, and organizations include:

1. Actions that are supportive of youth drawn to engaging in gender-expansive (e.g., nonconforming) activities and interests;
2. Communications that are supportive when youth express their experiences about their gender and gender exploration;
3. Use of the youth's asserted name/pronouns;
4. Support for youth wearing clothing/uniforms, hairstyles, and items (e.g., jewelry, makeup) they feel affirm their gender;
5. Positive and supportive communication with youth about their gender and gender concerns;
6. Education about gender diversity issues for people in the young person's life (e.g., family members, health care providers, social support networks), as needed, including information about how to advocate for gender diverse youth in community, school, health care, and other settings;
7. Support for gender diverse youth to connect with communities of support (e.g., LGBTQ groups, events, friends);
8. Provision of opportunities to discuss, consider, and explore medical treatment options when indicated;
9. Antibullying policies that are enforced;
10. Inclusion of nonbinary experiences in daily life, reading materials, and curricula (e.g., books, health, and sex education classes, assigned essay topics that move beyond the binary, LGBTQ, and ally groups);
11. Gender inclusive facilities that the youth can readily access without segregation from nongender diverse peers (e.g., bathrooms, locker rooms).

We recommend HCPs work with parents, schools, and other organizations/groups to promote acceptance and affirmation of TGD identities and expressions, whether social or medical interventions are implemented or not as acceptance and affirmation are associated with fewer negative mental health and behavioral symptoms and more positive mental health and behavioral functioning (Day et al., 2015; de Vries et al., 2016; Greytak et al., 2013; Pariseau et al., 2019; Peng et al., 2019; Russell et al., 2018; Simons et al., 2013; Taliaferro et al., 2019; Toomey et al., 2010; Travers et al., 2012). Russell et al. (2018) found mental health improvement increases with more acceptance and affirmation across more settings (e.g., home, school, work, and friends). Rejection by family, peers, and school staff (e.g., intentionally using the name and pronoun the youth does not identify with, not acknowledging affirmed gender identity, bullying, harassment, verbal and physical abuse, poor relationships, rejection for being TGD, eviction) was strongly linked to negative outcomes, such as anxiety, depression, suicidal ideation, suicide attempts, and substance use (Grossman et al., 2005; Klein & Golub; 2016; Pariseau et al., 2019; Peng et al., 2019; Reisner, Greytak et al., 2015; Roberts et al., 2013). It is important to be aware that negative symptoms increase with increased levels of rejection and continue into adulthood (Roberts et al., 2013).

Neutral or indifferent responses to a youth's gender diversity and exploration (e.g., letting a child tell others their chosen name but not using the name, not telling family or friends when the youth wants them to disclose, not advocating for the child about rejecting behavior from school staff or peers, not engaging or participating in other support mechanisms (e.g., with psychotherapists and support groups) have also been found to have negative consequences, such as increased depressive symptoms (Pariseau et al., 2019). For these reasons, it is important not to ignore a youth's gender questioning or delay consideration of the youth's gender-related

care needs. There is particular value in professionals recognizing youth need individualized approaches, support, and consideration of needs around gender expression, identity, and embodiment over time and across domains and relationships. Youth may need help coping with the tension of tolerating others' processing/adjusting to an adolescent's identity exploration and changes (e.g., Kuper, Lindley et al., 2019). It is important professionals collaborate with parents and others as they process their concerns and feelings and educate themselves about gender diversity because such processes may not necessarily reflect rejection or neutrality but may rather represent efforts to develop attitudes and gather information that foster acceptance (e.g., Katz-Wise et al., 2017).

Statement 6.5

We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.

Some health care providers, secular or religious organizations, and rejecting families may undertake efforts to thwart an adolescent's expression of gender diversity or assertion of a gender identity other than the expression and behavior that conforms to the sex assigned at birth. Such efforts at blocking reversible social expression or transition may include choosing not to use the youth's identified name and pronouns or restricting self-expression in clothing and hairstyles (Craig et al., 2017; Green et al., 2020). These disaffirming behaviors typically aim to reinforce views that a young person's gender identity/expression must match the gender associated with the sex assigned at birth or expectations based on the sex assigned at birth. Activities and approaches (sometimes referred to as "treatments") aimed at trying to change a person's gender identity and expression to become more congruent with the sex assigned at birth have been attempted, but these approaches have not resulted in changes in gender identity (Craig et al., 2017; Green et al., 2020). We recommend against such efforts because they have been found to be ineffective and are associated with increases in mental illness and poorer psychological functioning (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020).

Much of the research evaluating "conversion therapy" and "reparative therapy" has investigated the impact of efforts to change gender expression (masculinity or femininity) and has conflated sexual orientation with gender identity (APA, 2009; Burnes et al., 2016; Craig et al., 2017). Some of these efforts have targeted both gender identity and expression (AACAP, 2018). Conversion/reparative therapy has been linked to increased anxiety, depression, suicidal ideation, suicide attempts, and health care avoidance (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020). Although some of these studies have been criticized for their methodologies and conclusions (e.g., D'Angelo et al., 2020), this should not detract from the importance of emphasizing efforts undertaken a priori to change a person's identity are clinically and ethically unsound. We recommend against any type of conversion or attempts to change a person's gender identity because 1) both secular and religion-based efforts to change gender identity/expression have been associated with negative psychological functioning that endures into adulthood (Turban, Beckwith et al., 2020); and 2) larger ethical reasons exist that should underscore respect for gender diverse identities.

It is important to note potential factors driving a young person's gender-related experience and report of gender incongruence, when carried out in the context of supporting an adolescent with self-discovery, is not considered reparative therapy as long as there is no a priori goal to change or promote one particular gender identity or expression (AACAP, 2018; see Statement 6.2). To ensure these explorations are therapeutic, we recommend employing affirmative consideration and supportive tone in discussing what steps have been tried, considered, and planned for a youth's gender expression. These discussion topics may include what felt helpful or affirming, what felt unhelpful or distressing and why. We recommend employing affirmative responses to these steps and discussions, such as those identified in SOC-8 Statement 6.4.

Statement 6.6

We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including review of the benefits and risks.

TGD youth may experience distress related to chest and genital anatomy. Practices such as chest binding, chest padding, genital tucking, and genital packing are reversible, nonmedical interventions that may help alleviate this distress (Callen-Lorde, 2020a, 2020b; Deutsch, 2016a; Olson-Kennedy, Rosenthal et al., 2018; Transcare BC, 2020). It is important to assess the degree of distress related to physical development or anatomy, educate youth about potential nonmedical interventions to address this distress, and discuss the safe use of these interventions.

Chest binding involves compression of the breast tissue to create a flatter appearance of the chest. Studies suggest that up to 87% of trans masculine patients report a history of binding (Jones, 2015; Peitzmeier, 2017). Binding methods may include the use of commercial binders, sports bras, layering of shirts, layering of sports bras, or the use of elastics or other bandages (Peitzmeier, 2017). Currently, most youth report learning about binding practices from online communities composed of peers (Julian, 2019). Providers can play an important role in ensuring youth receive accurate and reliable information about the potential benefits and risks of chest binding. Additionally, providers can counsel patients about safe binding practices and monitor for potential negative health effects. While there are potential negative physical impacts of binding, youth who bind report many benefits, including increased comfort, improved safety, and lower rates of misgendering (Julian, 2019). Common negative health impacts of chest binding in youth include back/chest pain, shortness of breath, and overheating (Julian, 2019). More serious negative health impacts such as skin infections, respiratory infections, and rib fractures are uncommon and have been associated with chest binding in adults (Peitzmeier, 2017). If binding is employed, youth should be advised to use only those methods considered safe for binding—such as binders specifically designed for the gender diverse population—to reduce the risk of serious negative health effects. Methods that are considered unsafe for binding include the use of duct tape, ace wraps, and plastic wrap as these can restrict blood flow, damage skin, and restrict breathing. If youth report negative health impacts from chest binding, these should ideally be addressed by a gender-affirming medical provider with experience working with TGD youth.

Genital tucking is the practice of positioning the penis and testes to reduce the outward appearance of a genital bulge. Methods of tucking include tucking the penis and testes between the legs or tucking the testes inside the inguinal canal and pulling the penis back between the legs. Typically, genitals are held in place by underwear or a gaff, a garment that can be made or purchased. Limited studies are available on the specific risks and benefits of tucking in adults, and none have been carried out in youth. Previous studies have reported tight undergarments are associated with decreased sperm concentration and motility. In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh, 2019) although there are no definitive studies evaluating these adverse outcomes. Further research is needed to determine the specific benefits and risks of tucking in youth.

Statement 6.7

We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.

When discussing the available options of menstrual-suppressing medications with gender diverse youth, providers should engage in shared decision-making, use gender-inclusive language (e.g., asking patients which terms they utilize to refer to their menses, reproductive organs, and genitalia) and perform physical exams in a sensitive, gender-affirmative manner (Bonnington et al., 2020; Krempasky et al., 2020). There is no formal research evaluating how menstrual

suppression may impact gender incongruence and/or dysphoria. However, the use of menstrual suppression can be an initial intervention that allows for further exploration of gender-related goals of care, prioritization of other mental health care, or both, especially for those who experience a worsening of gender dysphoria from unwanted uterine bleeding (see Statement 6.12d; Mehringer & Dowshen, 2019). When testosterone is not used, menstrual suppression can be achieved via a progestin. To exclude any underlying menstrual disorders, it is important to obtain a detailed menstrual history and evaluation prior to implementing menstrual-suppressing therapy (Carswell & Roberts, 2017). As part of the discussion about menstrual-suppressing medications, the need for contraception and information regarding the effectiveness of menstrual-suppressing medications as methods of contraception also need to be addressed (Bonnington et al., 2020). A variety of menstrual suppression options, such as combined estrogen-progestin medications, oral progestins, depot and subdermal progestin, and intrauterine devices (IUDs), should be offered to allow for individualized treatment plans while properly considering availability, cost and insurance coverage, as well as contraindications and side effects (Kanj et al., 2019).

Progestin-only hormonal medication are options, especially in trans masculine or nonbinary youth who are not interested in estrogen-containing medical therapies as well as those at risk for thromboembolic events or who have other contraindications to estrogen therapy (Carswell & Roberts, 2017). Progestin-only hormonal medications include oral progestins, depo-medroxyprogesterone injection, etonogestrel implant, and levonorgestrel IUD (Schwartz et al., 2019). Progestin-only hormonal options vary in terms of efficacy in achieving menstrual suppression and have lower rates of achieving amenorrhea than combined oral contraception (Pradhan & Gomez-Lobo, 2019). A more detailed description of the relevant clinical studies is presented in Chapter 12—Hormone Therapy. HCPs should not make assumptions regarding the individual's preferred method of administration as some trans masculine youth may prefer vaginal rings or IUD implants (Akgul et al., 2019). Although hormonal medications require monitoring for potential mood lability, depressive effects, or both, the benefits and risks of untreated menstrual suppression in the setting of gender dysphoria should be evaluated on an individual basis. Some patients may opt for combined oral contraception that includes different combinations of ethinyl estradiol, with ranging doses, and different generations of progestins (Pradhan & Gomez-Lobo, 2019). Lower dose ethinyl estradiol components of combined oral contraceptive pills are associated with increased breakthrough uterine bleeding. Continuous combined oral contraceptives may be used to allow for continuous menstrual suppression and can be delivered as transdermal or vaginal rings.

The use of gonadotropin releasing hormone (GnRH) analogues may also result in menstrual suppression. However, it is recommended gender diverse youth meet the eligibility criteria (as outlined in Statement 6.12) before this medication is considered solely for this purpose (Carswell & Roberts, 2017; Pradhan & Gomez-Lobo, 2019). Finally, menstrual-suppression medications may be indicated as an adjunctive therapy for breakthrough uterine bleeding that may occur while on exogenous testosterone or as a bridging medication while awaiting menstrual suppression with testosterone therapy. When exogenous testosterone is employed as a gender-affirming hormone, menstrual suppression is typically achieved in the first six months of therapy (Ahmad & Leinung, 2017). However, it is vital adolescents be counseled ovulation and pregnancy can still occur in the setting of amenorrhea (Gomez et al., 2020; Kanj et al., 2019).

Statement 6.8

We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender-related surgery until the transition is made to adult care.

HCPs with expertise in child and adolescent development, as described in Statement 6.1, play an important role in the continuity of care for

young people over the course of their gender-related treatment needs. Supporting adolescents and their families necessitates approaching care using a developmental lens through which understanding a young person's evolving emotional maturity and care needs can take place over time. As gender-affirming treatment pathways differ based on the needs and experiences of individual TGD adolescents, decision-making for these treatments (puberty suppression, estrogens/androgens, gender-affirmation surgeries) can occur at different points in time within a span of several years. Longitudinal research demonstrating the benefits of pubertal suppression and gender-affirming hormone treatment (GAHT) was carried out in a setting where an ongoing clinical relationship between the adolescents/families and the multidisciplinary team was maintained (de Vries et al., 2014).

Clinical settings that offer longer appointment times provide space for adolescents and caregivers to share important psychosocial aspects of emotional well-being (e.g., family dynamics, school, romantic, and sexual experiences) that contextualize individualized gender-affirming treatment needs and decisions as described elsewhere in the chapter. An ongoing clinical relationship can take place across settings, whether that be within a multidisciplinary team or with providers in different locations who collaborate with one another. Given the wide variability in the ability to obtain access to specialized gender care centers, particularly for marginalized groups who experience disparities with access, it is important for the HCP to appreciate the existence of any barriers to care while maintaining flexibility when defining how an ongoing clinical relationship can take place in that specific context.

An ongoing clinical relationship that increases resilience in the youth and provides support to parents/caregivers who may have their own treatment needs may ultimately lead to increased parental acceptance—when needed—which is associated with better mental health outcomes in youth (Ryan, Huebner et al., 2009).

Statement 6.9

We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

TGD adolescents with gender dysphoria/gender incongruence who seek gender-affirming medical and surgical treatments benefit from the involvement of health care professionals (HCPs) from different disciplines. Providing care to TGD adolescents includes addressing 1) diagnostic considerations (see Statements 6.3, 6.12a, and 6.12b) conducted by a specialized gender HCP (as defined in Statement 6.1) whenever possible and necessary; and 2) treatment considerations when prescribing, managing, and monitoring medications for gender-affirming medical and surgical care, requiring the training of the relevant medical/surgical professional. The list of key disciplines includes but is not limited to adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, social work, support staff, and the surgical team.

The evolving evidence has shown a clinical benefit for transgender youth who receive their gender-affirming treatments in multidisciplinary gender clinics (de Vries et al., 2014; Kuper et al., 2020; Tollit et al., 2019). Finally, adolescents seeking gender-affirming care in multidisciplinary clinics are presenting with significant complexity necessitating close collaboration between mental health, medical, and/or surgical professionals (McCallion et al., 2021; Sorbara et al., 2020; Tishelman et al., 2015).

As not all patients and families are in the position or in a location to access multidisciplinary care, the lack of available disciplines should not preclude a young person from accessing needed care in a timely manner. When disciplines are available, particularly in centers with existing multidisciplinary teams, disciplines, or both, it is recommended efforts be made to include the relevant providers when developing a gender care team. However, this does not mean all disciplines are necessary to provide care to a particular youth and family.

If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST) for an adolescent, only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical HCPs and MHPs (American Psychological Association, 2015; Hembree et al., 2017; Telfer et al., 2018). Further assessment results and written opinions may be requested when there is a specific clinical need or when team members are in different locations or choose to write their own summaries. For further information see Chapter 5—Assessment for Adults, Statement 5.5.

Statement 6.10

We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to the initiation of treatment, of the reproductive effects, including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.

While assessing adolescents seeking gender-affirming medical or surgical treatments, HCPs should discuss the specific ways in which the required treatment may affect reproductive capacity. Fertility issues and the specific preservation options are more thoroughly discussed in Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

It is important HCPs understand what fertility preservation options exist so they can relay the information to adolescents. Parents are advised to be involved in this process and should also understand the pros and cons of the different options. HCPs should acknowledge adolescents and parents may have different views around reproductive capacity and may therefore come to different decisions (Quain et al., 2020), which is why HCPs can be helpful in guiding this process.

HCPs should specifically pay attention to the developmental and psychological aspects of fertility preservation and decision-making competency for the individual adolescent. While adolescents may think they have made up their minds concerning their reproductive capacity, the possibility their opinions about having biologically related children in the future might change over time needs to be discussed with an HCP who has sufficient experience, is knowledgeable about adolescent development, and has experience working with parents.

Addressing the long-term consequences on fertility of gender-affirming medical treatments and ensuring transgender adolescents have realistic expectations concerning fertility preservation options or adoption cannot not be addressed with a one-time discussion but should be part of an ongoing conversation. This conversation should occur not only before initiating any medical intervention (puberty suppression, hormones, or surgeries), but also during further treatment and during transition.

Currently, there are only preliminary results from retrospective studies evaluating transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assumptions about what future adult goals an adolescent may have. Research in childhood cancer survivors found participants who acknowledged missed opportunities for fertility preservation reported distress and regret surrounding potential infertility (Armuand et al., 2014; Ellis et al., 2016; Lehmann et al., 2017). Furthermore, individuals with cancer who did not prioritize having biological children before treatment have reported "changing their minds" in survivorship (Armuand et al., 2014).

Given the complexities of the different fertility preservation options and the challenges HCPs may experience discussing fertility with the adolescent and the family (Tishelman et al., 2019), a fertility consultation is an important consideration for every transgender adolescent who pursues medical-affirming treatments unless the local situation is such that a fertility consultation is not covered by insurance or public health care plans, is not available locally, or the individual circumstances make this unpreferable.

Statement 6.11

We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents

involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

When there is an indication an adolescent might benefit from a gender-affirming medical or surgical treatment, involving the parent(s) or primary caregiver(s) in the assessment process is recommended in almost all situations (Edwards-Leeper & Spack, 2012; Rafferty et al., 2018). Exceptions to this might include situations in which an adolescent is in foster care, child protective services, or both, and custody and parent involvement would be impossible, inappropriate, or harmful. Parent and family support of TGD youth is a primary predictor of youth well-being and is protective of the mental health of TGD youth (Gower, Rider, Coleman et al., 2018; Grossman et al., 2019; Lefevor et al., 2019; McConnell et al., 2015; Pariseau et al., 2019; Ryan, 2009; Ryan et al., 2010; Simons et al., 2013; Wilson et al., 2016). Therefore, including parent(s)/caregiver(s) in the assessment process to encourage and facilitate increased parental understanding and support of the adolescent may be one of the most helpful practices available.

Parent(s)/caregiver(s) may provide key information for the clinical team, such as the young person's gender and overall developmental, medical, and mental health history as well as insights into the young person's level of current support, general functioning, and well-being. Concordance or divergence of reports given by the adolescent and their parent(s)/caregiver(s) may be important information for the assessment team and can aid in designing and shaping individualized youth and family supports (De Los Reyes et al., 2019; Katz-Wise et al., 2017). Knowledge of the family context, including resilience factors and challenges, can help providers know where special supports would be needed during the medical treatment process. Engagement of parent(s)/caregiver(s) is also important for educating families about various treatment approaches, ongoing follow-up and care needs, and potential treatment complications. Through psychoeducation regarding clinical gender care options and participation in the assessment process, which may unfold over time, parent(s)/caregiver(s) may better understand their adolescent child's gender-related experience and needs (Andrzejewski et al., 2020; Katz-Wise et al., 2017).

Parent/caregiver concerns or questions regarding the stability of gender-related needs over time and implications of various gender-affirming interventions are common and should not be dismissed. It is appropriate for parent(s)/caregiver(s) to ask these questions, and there are cases in which the parent(s)/caregiver(s)' questions or concerns are particularly helpful in informing treatment decisions and plans. For example, a parent/caregiver report may provide critical context in situations in which a young person experiences very recent or sudden self-awareness of gender diversity and a corresponding gender treatment request, or when there is concern for possible excessive peer and social media influence on a young person's current self-gender concept. Contextualization of the parent/caregiver report is also critical, as the report of a young person's gender history as provided by parent(s)/caregiver(s) may or may not align with the young person's self-report. Importantly, gender histories may be unknown to parent(s)/caregiver(s) because gender may be internal experience for youth, not known by others unless it is discussed. For this reason, an adolescent's report of their gender history and experience is central to the assessment process.

Some parents may present with unsupportive or antagonistic beliefs about TGD identities, clinical gender care, or both (Clark et al., 2020). Such unsupportive perspectives are an important therapeutic target for families. Although challenging parent perspectives may in some cases seem rigid, providers should not assume this is the case. There are many examples of parent(s)/caregiver(s) who, over time with support and psychoeducation, have become increasingly accepting of their TGD child's gender diversity and care needs.

Helping youth and parent(s)/caregiver(s) work together on important gender care decisions is a primary goal. However, in some cases, parent(s)/caregiver(s) may be too rejecting of their adolescent child and their child's gender needs to be part of the clinical evaluation process. In these situations, youth may require the engagement of larger systems of advocacy and support to move

forward with the necessary support and care (Dubin et al., 2020).

Statement 6.12

We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:

Statement 6.12.a

The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.

When working with TGD adolescents, HCPs should realize while a classification may give access to care, pathologizing transgender identities may be experienced as stigmatizing (Beek et al., 2016). Assessments related to gender health and gender diversity have been criticized, and controversies exist around diagnostic systems (Drescher, 2016).

HCPs should assess the overall gender-related history and gender care-related needs of youth. Through this assessment process, HCPs may provide a diagnosis when it is required to get access to transgender-related care.

Gender incongruence and gender dysphoria are the two diagnostic terms used in the World Health Organization's International Classification of Diseases (ICD) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM), respectively. Of these two widely used classification systems, the DSM is for psychiatric classifications only and the ICD contains all diseases and conditions related to physical as well as mental health. The most recent versions of these two systems, the DSM-5 and the ICD-11, reflect a long history of reconceptualizing and de-psychopathologizing gender-related diagnoses (American Psychiatric Association, 2013; World Health Organization, 2019a). Compared with the earlier version, the DSM-5 replaced gender identity disorder with gender dysphoria, acknowledging the distress experienced by some people stemming from the incongruence between experienced gender identity and the sex assigned at birth. In the most recent revision, the DSM-5-TR, no changes in the diagnostic criteria for gender dysphoria are made. However, terminology was adapted into the most appropriate current language (e.g., birth-assigned gender instead of natal-gender and gender-affirming treatment instead of gender reassignment (American Psychiatric Association, 2022). Compared with the ICD 10th edition, the gender incongruence classification was moved from the Mental Health chapter to the Conditions Related to Sexual Health chapter in the ICD-11. When compared with the DSM-5 classification of gender dysphoria, one important reconceptualization is distress is not a required indicator of the ICD-11 classification of gender incongruence (WHO, 2019a). After all, when growing up in a supporting and accepting environment, the distress and impairment criterion, an inherent part of every mental health condition, may not be applicable (Drescher, 2012). As such, the ICD-11 classification of gender incongruence may better capture the fullness of gender diversity experiences and related clinical gender needs.

Criteria for the ICD-11 classification gender incongruence of adolescence or adulthood require a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a need to "transition" to live and be accepted as a person of the experienced gender. For some, this includes hormonal treatment, surgery, or other health care services to enable the individual´s body to align as much as required, and to the extent possible, with the person's experienced gender. Relevant for adolescents is the indicator that a classification cannot be assigned "prior to the onset of puberty." Finally, it is noted "that gender variant behaviour and preferences alone are not a basis for assigning the classification" (WHO, ICD-11, 2019a).

Criteria for the DSM-5 and DSM-5-TR classification of gender dysphoria in adolescence and adulthood denote "a marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration' (criterion A, fulfilled when 2 of 6 subcriteria are manifest; DSM-5, APA, 2013; DSM 5-TR, APA, 2022).

Of note, although a gender-related classification is one of the requirements for receiving medical gender-affirming care, such a classification alone does not indicate a person needs medical-affirming care. The range of youth experiences of gender incongruence necessitates professionals provide a range of treatments or interventions based on the individual's needs. Counseling, gender exploration, mental health assessment and, when needed, treatment with MHPs trained in gender development may all be indicated with or without the implementation of medical-affirming care.

Statement 6.12.b

The experience of gender diversity/incongruence is marked and sustained over time.

Identity exploration and consolidation are experienced by many adolescents (Klimstra et al., 2010; Topolewska-Siedzik & Cieciuch, 2018). Identity exploration during adolescence may include a process of self-discovery around gender and gender identity (Steensma, Kreukels et al., 2013). Little is known about how processes that underlie consolidation of gender identity during adolescence (e.g., the process of commitment to specific identities) may impact a young person's experience(s) or needs over time.

Therefore, the level of reversibility of a gender-affirming medical intervention should be considered along with the sustained duration of a young person's experience of gender incongruence when initiating treatment. Given potential shifts in gender-related experiences and needs during adolescence, it is important to establish the young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones or surgeries. Puberty suppression treatment, which provides more time for younger adolescents to engage their decision-making capacities, also raises important considerations (see Statement 6.12f and Chapter 12—Hormone Therapy) suggesting the importance of a sustained experience of gender incongruence/diversity prior to initiation. However, in this age group of younger adolescents, several years is not always practical nor necessary given the premise of the treatment as a means to buy time while avoiding distress from irreversible pubertal changes. For youth who have experienced a shorter duration of gender incongruence, social transition-related and/or other medical supports (e.g., menstrual suppression/androgen blocking) may also provide some relief as well as furnishing additional information to the clinical team regarding a young person's broad gender care needs (see Statements 6.4, 6.6, and 6.7).

Establishing evidence of persistent gender diversity/incongruence typically requires careful assessment with the young person over time (see Statement 6.3). Whenever possible and when appropriate, the assessment and discernment process should also include the parent(s)/caregiver(s) (see Statement 6.11). Evidence demonstrating gender diversity/incongruence sustained over time can be provided via history obtained directly from the adolescent and parents/caregivers when this information is not documented in the medical records.

The research literature on continuity versus discontinuity of gender-affirming medical care needs/requests is complex and somewhat difficult to interpret. A series of studies conducted over the last several decades, including some with methodological challenges (as noted by Temple Newhook et al., 2018; Winters et al., 2018) suggest the experience of gender incongruence is not consistent for all children as they progress into adolescence. For example, a subset of youth who experienced gender incongruence or who socially transitioned prior to puberty over time can show a reduction in or even full discontinuation of gender incongruence (de Vries et al., 2010; Olson et al., 2022; Ristori & Steensma, 2016; Singh et al., 2021; Wagner et al., 2021). However, there has been less research focused on rates of continuity and discontinuity of gender incongruence and gender-related needs in pubertal and adolescent populations. The data available regarding broad unselected gender-referred pubertal/adolescent cohorts (from the Amsterdam transgender clinic) suggest that, following extended assessments over time, a subset of adolescents with gender incongruence presenting for gender care elect not to pursue gender-affirming medical care

(Arnoldussen et al., 2019; de Vries, Steensma et al., 2011). Importantly, findings from studies of gender incongruent pubertal/adolescent cohorts, in which participants who have undergone comprehensive gender evaluation over time, have shown persistent gender incongruence and gender-related need and have received referrals for medical gender care, suggest low levels of regret regarding gender-related medical care decisions (de Vries et al., 2014; Wiepjes et al., 2018). Critically, these findings of low regret can only currently be applied to youth who have demonstrated sustained gender incongruence and gender-related needs over time as established through a comprehensive and iterative assessment (see Statement 6.3).

Statement 6.12.c

The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.

The process of informed consent includes communication between a patient and their provider regarding the patient's understanding of a potential intervention as well as, ultimately, the patient's decision whether to receive the intervention. In most settings, for minors, the legal guardian is integral to the informed consent process: if a treatment is to be given, the legal guardian (often the parent[s]/caregiver[s]) provides the informed consent to do so. In most settings, assent is a somewhat parallel process in which the minor and the provider communicate about the intervention and the provider assesses the level of understanding and intention.

A necessary step in the informed consent/assent process for considering gender-affirming medical care is a careful discussion with qualified HCPs trained to assess the emotional and cognitive maturity of adolescents. The reversible and irreversible effects of the treatment, as well as fertility preservation options (when applicable), and all potential risks and benefits of the intervention are important components of the discussion. These discussions are required when obtaining informed consent/assent. Assessment of cognitive and emotional maturity is important because it helps the care team understand the adolescent's capacity to be informed.

The skills necessary to assent/consent to any medical intervention or treatment include the ability to 1) comprehend the nature of the treatment; 2) reason about treatment options, including the risks and benefits; 3) appreciate the nature of the decision, including the long-term consequences; and 4) communicate choice (Grootens-Wiegers et al., 2017). In the case of gender- affirming medical treatments, a young person should be well-informed about what the treatment may and may not accomplish, typical timelines for changes to appear (e.g., with gender-affirming hormones), and any implications of stopping the treatment. Gender-diverse youth should fully understand the reversible, partially reversible, and irreversible aspects of a treatment, as well as the limits of what is known about certain treatments (e.g., the impact of pubertal suppression on brain development (Chen and Loshak, 2020)). Gender-diverse youth should also understand, although many gender-diverse youth begin gender- affirming medical care and experience that care as a good fit for them long-term, there is a subset of individuals who over time discover this care is not a fit for them (Wiepjes et al., 2018). Youth should know such shifts are sometimes connected to a change in gender needs over time, and in some cases, a shift in gender identity itself. Given this information, gender diverse youth must be able to reason thoughtfully about treatment options, considering the implications of the choices at hand. Furthermore, as a foundation for providing assent, the gender-diverse young person needs to be able to communicate their choice.

The skills needed to accomplish the tasks required for assent/consent may not emerge at specific ages per se (Grootens-Wiegers et al., 2017). There may be variability in these capacities related to developmental differences and mental health presentations (Shumer & Tishelman, 2015) and dependent on the opportunities a young person has had to practice these skills (Alderson, 2007). Further, assessment of emotional and cognitive maturity must be conducted separately for each gender-related treatment decision (Vrouenraets et al., 2021).

The following questions may be useful to consider in assessing a young person's emotional and

cognitive readiness to assent or consent to a specific gender-affirming treatment:

- Can the young person think carefully into the future and consider the implications of a partially or fully irreversible intervention?
- Does the young person have sufficient self-reflective capacity to consider the possibility that gender-related needs and priorities can develop over time, and gender-related priorities at a certain point in time might change?
- Has the young person, to some extent, thought through the implications of what they might do if their priorities around gender do change in the future?
- Is the young person able to understand and manage the day-to-day short- and long-term aspects of a specific medical treatment (e.g., medication adherence, administration, and necessary medical follow-ups)?

Assessment of emotional and cognitive maturity may be accomplished over time as the care team continues to engage in conversations about the treatment options and affords the young person the opportunity to practice thinking into the future and flexibly consider options and implications. For youth with neurodevelopmental and/or some types of mental health differences, skills for future thinking, planning, big picture thinking, and self-reflection may be less-well developed (Dubbelink & Geurts, 2017). In these cases, a more careful approach to consent and assent may be required, and this may include additional time and structured opportunities for the young person to practice the skills necessary for medical decision-making (Strang, Powers et al., 2018).

For unique situations in which an adolescent minor is consenting for their own treatment without parental permission (see Statement 6.11), extra care must be taken to support the adolescent's informed decision-making. This will typically require greater levels of engagement of and collaboration between the HCPs working with the adolescent to provide the young person appropriate cognitive and emotional support to consider options, weigh benefits and potential challenges/costs, and develop a plan for any needed (and potentially ongoing) supports associated with the treatment.

Statement 6.12.d

The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and/or gender-affirming medical treatments have been addressed.

Evidence indicates TGD adolescents are at increased risk of mental health challenges, often related to family/caregiver rejection, non-affirming community environments, and neurodiversity-related factors (e.g., de Vries et al., 2016; Pariseau et al., 2019; Ryan et al., 2010; Weinhardt et al., 2017). A young person's mental health challenges may impact their conceptualization of their gender development history and gender identity-related needs, the adolescent's capacity to consent, and the ability of the young person to engage in or receive medical treatment. Additionally, like cisgender youth, TGD youth may experience mental health concerns irrespective of the presence of gender dysphoria or gender incongruence. In particular, depression and self-harm may be of specific concern; many studies reveal depression scores and emotional and behavioral problems comparable to those reported in populations referred to mental health clinics (Leibowitz & de Vries, 2016). Higher rates of suicidal ideation, suicide attempts, and self-harm have also been reported (de Graaf et al., 2020). In addition, eating disorders occur more frequently than expected in non-referred populations (Khatchadourian et al., 2013; Ristori et al., 2019; Spack et al., 2012). Importantly, TGD adolescents show high rates of autism spectrum disorder/characteristics (Øien et al., 2018; van der Miesen et al., 2016; see also Statement 6.1d). Other neurodevelopmental presentations and/or mental health challenges may also be present, (e.g., ADHD, intellectual disability, and psychotic disorders (de Vries, Doreleijers et al., 2011; Meijer et al., 2018; Parkes & Hall, 2006).

Of note, many transgender adolescents are well-functioning and experience few if any mental health concerns. For example, socially transitioned pubertal adolescents who receive medical

gender- affirming treatment at specialized gender clinics may experience mental health outcomes equivalent to those of their cisgender peers (e.g., de Vries et al., 2014; van der Miesen et al., 2020). A provider's key task is to assess the direction of the relationships that exist between any mental health challenges and the young person's self-understanding of gender care needs and then prioritize accordingly.

Mental health difficulties may challenge the assessment and treatment of gender-related needs of TGD adolescents in various ways:

1. First, when a TGD adolescent is experiencing acute suicidality, self-harm, eating disorders, or other mental health crises that threaten physical health, safety must be prioritized. According to the local context and existing guidelines, appropriate care should seek to mitigate the threat or crisis so there is sufficient time and stabilization for thoughtful gender-related assessment and decision-making. For example, an actively suicidal adolescent may not be emotionally able to make an informed decision regarding gender-affirming medical/surgical treatment. If indicated, safety-related interventions should not preclude starting gender-affirming care.
2. Second, mental health can also complicate the assessment of gender development and gender identity-related needs. For example, it is critical to differentiate gender incongruence from specific mental health presentations, such as obsessions and compulsions, special interests in autism, rigid thinking, broader identity problems, parent/child interaction difficulties, severe developmental anxieties (e.g., fear of growing up and pubertal changes unrelated to gender identity), trauma, or psychotic thoughts. Mental health challenges that interfere with the clarity of identity development and gender-related decision-making should be prioritized and addressed.
3. Third, decision-making regarding gender-affirming medical treatments that have life-long consequences requires thoughtful, future-oriented thinking by the adolescent, with support from the parents/caregivers, as indicated (see Statement 6.11). To be able to make such an informed decision, an adolescent should be able to understand the issues, express a choice, appreciate and give careful thought regarding the wish for medical-affirming treatment (see Statement 6.12c). Neurodevelopmental differences, such as autistic features or autism spectrum disorder (see Statement 6.1d, e.g., communication differences; a preference for concrete or rigid thinking; differences in self-awareness, future thinking and planning), may challenge the assessment and decision-making process; neurodivergent youth may require extra support, structure, psychoeducation, and time built into the assessment process (Strang, Powers et al., 2018). Other mental health presentations that involve reduced communication and self-advocacy, difficulty engaging in assessment, memory and concentration difficulties, hopelessness, and difficulty engaging in future-oriented thinking may complicate assessment and decision-making. In such cases, extended time is often necessary before any decisions regarding medical-affirming treatment can be made.
4. Finally, while addressing mental health concerns is important during the course of medical treatment, it does not mean all mental health challenges can or should be resolved completely. However, it is important any mental health concerns are addressed sufficiently so that gender -affirming medical treatment can be provided optimally (e.g., medication adherence, attending follow-up medical appointments, and self-care, particularly during a postoperative course).

Statement 6.12.e

The adolescent has been informed of the reproductive effects, including the potential loss of fertility, and available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.

For guidelines regarding the clinical approach, the scientific background, and the rationale, see Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

Statement 6.12.f

The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.

The onset of puberty is a pivotal point for many gender diverse youth. For some, it creates an intensification of their gender incongruence, and for others, pubertal onset may lead to gender fluidity (e.g., a transition from binary to nonbinary gender identity) or even attenuation of a previously affirmed gender identity (Drummond et al., 2008; Steensma et al., 2011, Steensma, Kreukels et al., 2013; Wallien & Cohen-Kettenis, 2008). The use of puberty-blocking medications, such as GnRH analogues, is not recommended until children have achieved a minimum of Tanner stage 2 of puberty because the experience of physical puberty may be critical for further gender identity development for some TGD adolescents (Steensma et al., 2011). Therefore, puberty blockers should not be implemented in prepubertal gender diverse youth (Waal & Cohen-Kettenis, 2006). For some youth, GnRH agonists may be appropriate in late stages or in the post-pubertal period (e.g., Tanner stage 4 or 5), and this should be highly individualized. See Chapter 12—Hormone Therapy for a more comprehensive review of the use of GnRH agonists.

Variations in the timing of pubertal onset is due to multiple factors (e.g., sex assigned at birth, genetics, nutrition, etc.). Tanner staging refers to five stages of pubertal development ranging from prepubertal (Tanner stage 1) to post-pubertal, and adult sexual maturity (Tanner stage 5) (Marshall & Tanner, 1969, 1970). For assigned females at birth, pubertal onset (e.g., gonadarche) is defined by the occurrence of breast budding (Tanner stage 2), and for birth-assigned males, the achievement of a testicular volume of greater than or equal to 4 mL (Roberts & Kaiser, 2020). An experienced medical provider should be relied on to differentiate the onset of puberty from physical changes such as pubic hair and apocrine body odor due to sex steroids produced by the adrenal gland (e.g., adrenarche) as adrenarche does not warrant the use of puberty-blocking medications (Roberts & Kaiser, 2020). Educating parents and families about the difference between adrenarche and gonadarche helps families understand the timing during which shared decision-making about gender-affirming medical therapies should be undertaken with their multidisciplinary team.

The importance of addressing other risks and benefits of pubertal suppression, both hypothetical and actual, cannot be overstated. Evidence supports the existence of surgical implications for transgender girls who proceed with pubertal suppression (van de Grift et al., 2020). Longitudinal data exists to demonstrate improvement in romantic and sexual satisfaction for adolescents receiving puberty suppression, hormone treatment and surgery (Bungener et al., 2020). A study on surgical outcomes of laparoscopic intestinal vaginoplasty (performed because of limited genital tissue after the use of puberty blockers) in transgender women revealed that the majority experienced orgasm after surgery (84%), although a specific correlation between sexual pleasure outcomes and the timing of pubertal suppression initiation was not discussed in the study (Bouman, van der Sluis et al., 2016), nor does the study apply to those who would prefer a different surgical procedure. This underscores the importance of engaging in discussions with families about the future unknowns related to surgical and sexual health outcomes.

Statement 6.12.g

The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, breast growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). To

ensure sufficient time for psychological adaptations to the physical change during an important developmental time for the adolescent, 12 months of hormone treatment is suggested. Depending upon the surgical result required, a period of hormone treatment may need to be longer (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty, breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of hormone therapy on the proposed surgery. In addition, for individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Consideration of ages for gender-affirming medical and surgical treatment for adolescents

Age has a strong, albeit imperfect, correlation with cognitive and psychosocial development and may be a useful objective marker for determining the potential timing of interventions (Ferguson et al., 2021). Higher (i.e., more advanced) ages may be required for treatments with greater irreversibility, complexity, or both. This approach allows for continued cognitive/emotional maturation that may be required for the adolescent to fully consider and consent to increasingly complex treatments (see Statement 6.12c).

A growing body of evidence indicates providing gender-affirming treatment for gender diverse youth who meet criteria leads to positive outcomes (Achille et al., 2020; de Vries et al., 2014; Kuper et al., 2020). There is, however, limited data on the optimal timing of gender-affirming interventions as well as the long-term physical, psychological, and neurodevelopmental outcomes in youth (Chen et al., 2020; Chew et al., 2018; Olson-Kennedy et al., 2016). Currently, the only existing longitudinal studies evaluating gender diverse youth and adult outcomes are based on a specific model (i.e., the Dutch approach) that involved a comprehensive initial assessment with follow-up. In this approach, pubertal suppression was considered at age 12, GAHT at age 16, and surgical interventions after age 18 with exceptions in some cases. It is not clear if deviations from this approach would lead to the same or different outcomes. Longitudinal studies are currently underway to better define outcomes as well as the safety and efficacy of gender-affirming treatments in youth (Olson-Kennedy, Garofalo et al., 2019; Olson-Kennedy, Rosenthal et al., 2019). While the long-term effects of gender-affirming treatments initiated in adolescence are not fully known, the potential negative health consequences of delaying treatment should also be considered (de Vries et al., 2021). As the evidence base regarding outcomes of gender-affirming interventions in youth continues to grow, recommendations on the timing and readiness for these interventions may be updated.

Previous guidelines regarding gender-affirming treatment of adolescents recommended partially reversible GAHT could be initiated at approximately 16 years of age (Coleman et al., 2012; Hembree et al., 2009). More recent guidelines suggest there may be compelling reasons to initiate GAHT prior to the age of 16, although there are limited studies on youth who have initiated hormones prior to 14 years of age (Hembree et al., 2017). A compelling reason for earlier initiation of GAHT, for example, might be to avoid prolonged pubertal suppression, given potential bone health concerns and the psychosocial implications of delaying puberty as described in more detail in Chapter 12—Hormone Therapy (Klink, Caris et al., 2015; Schagen et al., 2020; Vlot et al., 2017; Zhu & Chan, 2017). Puberty is a time of significant brain and cognitive development. The potential neurodevelopmental impact of extended pubertal suppression in gender diverse youth has been specifically identified as an area in need of continued study (Chen et al., 2020). While GnRH analogs have been shown to be safe when used for the treatment of precocious puberty, there are concerns delaying exposure to sex hormones (endogenous or exogenous) at a time of peak bone mineralization may lead to decreased bone mineral density. The potential decrease in bone mineral density as well as the clinical significance of any decrease requires continued study (Klink, Caris et al., 2015; Lee, Finlayson et al.,

2020; Schagen et al., 2020). The potential negative psychosocial implications of not initiating puberty with peers may place additional stress on gender diverse youth, although this has not been explicitly studied. When considering the timing of initiation of gender-affirming hormones, providers should compare the potential physical and psychological benefits and risks of starting treatment with the potential risks and benefits of delaying treatment. This process can also help identify compelling factors that may warrant an individualized approach.

Studies carried out with trans masculine youth have demonstrated chest dysphoria is associated with higher rates of anxiety, depression, and distress and can lead to functional limitations, such as avoiding exercising or bathing (Mehringer et al., 2021; Olson-Kennedy, Warus et al., 2018; Sood et al., 2021). Testosterone unfortunately does little to alleviate this distress, although chest masculinization is an option for some individuals to address this distress long-term. Studies with youth who sought chest masculinization surgery to alleviate chest dysphoria demonstrated good surgical outcomes, satisfaction with results, and minimal regret during the study monitoring period (Marinkovic & Newfield, 2017; Olson-Kennedy, Warus et al., 2018). Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined by a multidisciplinary team experienced in adolescent and gender development (see relevant statements in this chapter). The duration or current use of testosterone therapy should not preclude surgery if otherwise indicated. The needs of some TGD youth may be met by chest masculinization surgery alone. Breast augmentation may be needed by trans feminine youth, although there is less data about this procedure in youth, possibly due to fewer individuals requesting this procedure (Boskey et al., 2019; James, 2016). GAHT, specifically estrogen, can help with development of breast tissue, and it is recommended youth have a minimum of 12 months of hormone therapy, or longer as is surgically indicated, prior to breast augmentation unless hormone therapy is not clinically indicated or is medically contraindicated.

Data are limited on the optimal timing for initiating other gender-affirming surgical treatments in adolescents. This is partly due to the limited access to these treatments, which varies in different geographical locations (Mahfouda et al., 2019). Data indicate rates of gender-affirming surgeries have increased since 2000, and there has been an increase in the number of TGD youth seeking vaginoplasty (Mahfouda et al., 2019; Milrod & Karasic, 2017). A 2017 study of 20 WPATH-affiliated surgeons in the US reported slightly more than half had performed vaginoplasty in minors (Milrod & Karasic, 2017). Limited data are available on the outcomes for youth undergoing vaginoplasty. Small studies have reported improved psychosocial functioning and decreased gender dysphoria in adolescents who have undergone vaginoplasty (Becker et al., 2018; Cohen-Kettenis & van Goozen, 1997; Smith et al.,2001). While the sample sizes are small, these studies suggest there may be a benefit for some adolescents to having these procedures performed before the age of 18. Factors that may support pursuing these procedures for youth under 18 years of age include the increased availability of support from family members, greater ease of managing postoperative care prior to transitioning to tasks of early adulthood (e.g., entering university or the workforce), and safety concerns in public spaces (i.e., to reduce transphobic violence) (Boskey et al., 2018; Boskey et al., 2019; Mahfouda et al., 2019). Given the complexity and irreversibility of these procedures, an assessment of the adolescent's ability to adhere to postsurgical care recommendations and to comprehend the long-term impacts of these procedures on reproductive and sexual function is crucial (Boskey et al., 2019). Given the complexity of phalloplasty, and current high rates of complications in comparison to other gender-affirming surgical treatments, it is not recommended this surgery be considered in youth under 18 at this time (see Chapter 13—Surgery and Postoperative Care).

Additional key factors that should be taken into consideration when discussing the timing of interventions with youth and families are addressed in detail in statements 6.12a-f. For a summary of the criteria/recommendations for medically necessary gender-affirming medical treatment in adolescents, see Appendix D.

CHAPTER 7 Children

These Standards of Care pertain to prepubescent gender diverse children and are based on research, ethical principles, and accumulated expert knowledge. The principles underlying these standards include the following 1) childhood gender diversity is an expected aspect of general human development (Endocrine Society and Pediatric Endocrine Society, 2020; Telfer et al., 2018); 2) childhood gender diversity is not a pathology or mental health disorder (Endocrine Society and Pediatric Endocrine Society, 2020; Oliphant et al., 2018; Telfer et al., 2018); 3) diverse gender expressions in children cannot always be assumed to reflect a transgender identity or gender incongruence (Ehrensaft, 2016; Ehrensaft, 2018; Rael et al., 2019); 4) guidance from mental health professionals (MHPs) with expertise in gender care for children can be helpful in supporting positive adaptation as well as discernment of gender-related needs over time (APA, 2015; Ehrensaft, 2018; Telfer et al., 2018); 5) conversion therapies for gender diversity in children (i.e., any "therapeutic" attempts to compel a gender diverse child through words, actions, or both to identify with, or behave in accordance with, the gender associated with the sex assigned at birth are harmful and we repudiate their use (APA, 2021; Ashley, 2019b, Paré, 2020; SAMHSA, 2015; Telfer et al., 2018; UN Human Rights Council, 2020).

Throughout the text, the term "health care professional" (HCP) is used broadly to refer to professionals working with gender diverse children. Unlike pubescent youth and adults, prepubescent gender diverse children are not eligible to access medical intervention (Pediatric Endocrine Society, 2020); therefore, when professional input is sought, it is most likely to be from an HCP specialized in psychosocial supports and gender development. Thus, this chapter is uniquely focused on developmentally appropriate psychosocial practices, although other HCPs, such as pediatricians and family practice HCPs may also find these standards useful as they engage in professional work with gender diverse children and their families.

This chapter employs the term "gender diverse" given that gender trajectories in prepubescent children cannot be predicted and may evolve over time (Steensma, Kreukels et al., 2013). At the same time, this chapter recognizes some children will remain stable in a gender identity they articulate early in life that is discrepant from the sex assigned at birth (Olson et al., 2022). The term, "gender diverse" includes transgender binary and nonbinary children, as well as gender diverse children who will ultimately not identify as transgender later in life. Terminology is inherently culturally bound and evolves over time. Thus, it is possible terms used here may become outdated and we will find better descriptors.

This chapter describes aspects of medical necessary care intended to promote the well-being and gender-related needs of children (see medically necessary statement in the Global Applicability chapter, Statement 2.1). This chapter advocates everyone employs these standards, to the extent possible. There may be situations or locations in which the recommended resources are not fully available. HCPs/teams lacking resources need to work toward meeting these standards. However, if unavoidable limitations preclude components of these recommendations, this should not hinder providing the best services currently available. In those locations where some but not all recommended services exist, choosing not to implement potentially beneficial care services risks harm to a child (Murchison et al., 2016; Telfer et al., 2018; Riggs et al., 2020). Overall, it is imperative to prioritize a child's best interests.

A vast empirical psychological literature indicates early childhood experiences frequently set the stage for lifelong patterns of risk and/or resilience and contribute to a trajectory of development more or less conducive to well-being and a positive quality of life (Anda et al., 2010; Masten & Cicchetti, 2010; Shonkoff & Garner, 2012). The available research indicates, in general, gender diverse youth are at greater risk for experiencing psychological difficulties (Ristori & Steensma, 2016) than age- matched cisgender peers as a result of encountering destructive experiences, including trauma and maltreatment stemming from gender diversity-related rejection and other harsh, non-accepting interactions (Barrow & Apostle, 2018; Giovanardi et al., 2018; Gower, Rider, Brown et al., 2018; Grossman & D'Augelli, 2006; Hendricks & Testa, 2012; Reisner, Greytak

et al., 2015; Roberts et al., 2014; Tishelman & Neumann-Mascis, 2018). Further, literature indicates prepubescent children who are well accepted in their gender diverse identities are generally well-adjusted (Malpas et al., 2018; Olson et al., 2016). Assessment and treatment of children typically emphasizes an *ecological* approach, recognizing children need to be safe and nurtured in each setting they frequent (Belsky, 1993; Bronfenbrenner, 1979; Kaufman & Tishelman, 2018; Lynch & Cicchetti, 1998; Tishelman et al., 2010; Zielinski & Bradshaw, 2006). Thus, the perspective of this chapter draws on basic psychological literature and knowledge of the unique risks to gender diverse children and emphasizes the integration of an ecological approach to understanding their needs and to facilitating positive mental health in all gender care. This perspective prioritizes fostering well-being and quality of life for a child throughout their development. Additionally, this chapter also embraces the viewpoint, supported by the substantial psychological research cited above, that psychosocial gender-affirming care (Hidalgo et al., 2013) for prepubescent children offers a window of opportunity to promote a trajectory of well-being that will sustain them over time and during the transition to adolescence. This approach potentially can mitigate some of the common mental health risks faced by transgender and gender diverse (TGD) teens, as frequently described in literature (Chen et al., 2021; Edwards-Leeper et al., 2017; Haas et al., 2011; Leibowitz & de Vries, 2016; Reisner, Bradford et al., 2015; Reisner, Greytak et al., 2015).

Developmental research has focused on understanding various aspects of gender development in the earliest years of childhood based on a general population of prepubescent children. This research has typically relied on the assumption that child research participants are cisgender (Olezeski et al., 2020) and has reported gender identity stability is established in the preschool years for the general population of children, most of whom are likely not gender diverse (Kohlberg, 1966; Steensma, Kreukels et al., 2013). Recently, developmental research has demonstrated gender diversity can be observed and identified in young prepubescent children (Fast & Olson, 2018; Olson & Gülgöz, 2018; Robles et al., 2016). Nonetheless, empirical study in this area is limited, and at this time there are no psychometrically sound assessment measures capable of reliably and/or fully ascertaining a prepubescent child's self-understanding of their own gender and/or gender-related needs and preferences (Bloom et al., 2021). Therefore, this chapter emphasizes the importance of a nuanced and individualized clinical approach to gender assessment, consistent with the recommendations from various guidelines and literature (Berg & Edwards-Leeper, 2018; de Vries & Cohen-Kettenis, 2012; Ehrensaft, 2018; Steensma & Wensing-Kruger, 2019). Research and clinical experience have indicated gender diversity in prepubescent children may, for some, be fluid; there are no reliable means of predicting an individual child's gender evolution (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013), and the gender-related needs for a particular child may vary over the course of their childhood.

It is important to understand the meaning of the term "assessment" (sometimes used synonymously with the term "evaluation"). There are multiple contexts for assessment (Krishnamurthy et al., 2004) including rapid assessments that take place during an immediate crisis (e.g., safety assessment when a child may be suicidal) and focused assessments when a family may have a circumscribed question, often in the context of a relatively brief consultation (Berg & Edwards-Leeper, 2018). The term assessment is also often used in reference to "diagnostic assessment," which can also be called an "intake" and is for the purpose of determining whether there is an issue that is diagnosable and/or could benefit from a therapeutic process. This chapter focus on comprehensive assessments, useful for understanding a child and family's needs and goals (APA, 2015; de Vries & Cohen-Kettenis, 2012; Srinath et al., 2019; Steensma & Wensing-Kruger, 2019). This type of psychosocial assessment is not necessary for all gender diverse children, but may be requested for a number of reasons. Assessments may present a useful opportunity to start a process of support for a gender diverse child and their family, with the understanding that gender diverse children benefit when their family dynamics include

Statements of Recommendations

7.1- We recommend health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess a general knowledge of gender diversity across the life span.
7.2- We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.
7.3- We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.
7.4- We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.
7.5- We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.
7.6- We recommend health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning, and language skills.
7.7- We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).
7.8- We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.
7.9- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.
7.10- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age-appropriate psychoeducation about gender development.
7.11- We recommend that health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.
7.12- We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.
7.13- We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.
7.14- We recommend the health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.
7.15- We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

acceptance of their gender diversity and parenting guidance when requested. Comprehensive assessments are appropriate when solicited by a family requesting a full understanding of the child's gender and mental health needs in the context of gender diversity.

In these circumstances, family member mental health issues, family dynamics, and social and cultural contexts, all of which impact a gender diverse child, should be taken into consideration (Barrow & Apostle, 2018; Brown & Mar, 2018; Cohen-Kettenis et al., 2003; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Ristori & Steensma, 2016; Tishelman & Neumann-Mascis, 2018). This is further elaborated upon in the text below.

It is important HCPs working with gender diverse children strive to understand the child and the family's various aspects of identity and experience: racial, ethnic, immigrant/refugee status, religious, geographic, and socio-economic, for example, and be respectful and sensitive to cultural context in clinical interactions (Telfer et al., 2018). Many factors may be relevant to culture and gender, including religious beliefs, gender-related expectations, and the degree to which gender diversity is accepted (Oliphant et al., 2018). Intersections between gender diversity, sociocultural diversity, and minority statuses can be sources of strength, social stress, or both (Brown & Mar, 2018; Oliphant et al., 2018; Riggs & Treharne, 2016).

Each child, family member, and family dynamic is unique and potentially encompasses multiple cultures and belief patterns. Thus, HCPs of all disciplines should avoid stereotyping based on preconceived ideas that may be incorrect or biased (e.g., that a family who belongs to a religious organization that is opposed to appreciating gender diversity will necessarily be unsupportive of their child's gender diversity) (Brown & Mar, 2018). Instead, it is essential to approach each family openly and understand each family member and family pattern as distinct.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 7.1

We recommend the health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess general knowledge of gender diversity across the life span.

HCPs working with gender diverse children should acquire and maintain the necessary training and credentials relevant to the scope of their role as professionals. This includes licensure, certification, or both by appropriate national and/or regional accrediting bodies. We recognize the specifics of credentialing and regulation of professionals vary globally. Importantly, basic licensure, certification, or both may be insufficient in and of itself to ensure competency working with gender diverse children, as HCPs specifically require in-depth training and supervised experience in childhood gender development and gender diversity to provide appropriate care.

Statement 7. 2

We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.

HCPs should receive training and supervised expertise in general child and family mental health across the developmental spectrum from toddlerhood through adolescence, including evidence-based assessment and intervention approaches. Gender diversity is not a mental health disorder; however, as cited above, we know mental health can be adversely impacted for gender diverse children (e.g., through gender minority stress) (Hendricks & Testa, 2012) that may benefit from exploration and support; therefore, mental health expertise is highly recommended. Working with children is a complex endeavor, involving an understanding of a child's developmental needs at various ages, the ability to comprehend the forces impacting a child's well-being both inside and outside the family (Kaufman & Tishelman, 2018), and an ability to fully assess when a child is unhappy or experiencing significant mental health difficulties, related or unrelated to gender. Research has indicated high levels of adverse experiences and trauma in the gender diverse community of children, including susceptibility to rejection or even maltreatment (APA, 2015; Barrow & Apostle, 2018; Giovanardi et al., 2018; Reisner, Greytak et al., 2015; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). HCPs need to be cognizant of the potential for adverse experiences and be able to initiate effective interventions to prevent harm and promote positive well-being.

Statement 7.3

We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.

The experience of gender diversity in autistic children as well as in children with other forms of neurodivergence may present extra clinical complexities (de Vries et al., 2010; Strang, Meagher et al., 2018). For example, autistic children may find it difficult to self-advocate for their gender-related needs and may communicate in highly individualistic ways (Kuvalanka et al., 2018; Strang, Powers et al., 2018). They may have varied interpretations of gender-related experiences given common differences in communication and thinking style. Because of the unique needs of gender diverse neurodivergent children, they may be at high risk for being misunderstood (i.e., for their communications to be misinterpreted). Therefore, professionals providing support to these children can best serve them by receiving training and developing expertise in autism and related neurodevelopmental presentations and/or collaborating with autism specialists (Strang, Meagher et al., 2018). Such training is especially relevant as research has documented

higher rates of autism among gender diverse youth than in the general population (de Vries et al., 2010; Hisle-Gorman et al., 2019; Shumer et al., 2015).

Statement 7.4

We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.

Continuing professional development regarding gender diverse children and families may be acquired through various means, including through readings (journal articles, books, websites associated with gender knowledgeable organizations), attending on-line and in person trainings, and joining peer supervision/consultation groups (Bartholomaeus et al., 2021).

Continuing education includes 1) maintaining up-to-date knowledge of available and relevant research on gender development and gender diversity in prepubescent children and gender diversity across the life span; 2) maintaining current knowledge regarding best practices for assessment, support, and treatment approaches with gender diverse children and families. This is a relatively new area of practice and health care professionals need to adapt as new information emerges through research and other avenues (Bartholomaeus et al., 2021).

Statement 7.5

We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.

A comprehensive assessment, when requested by a family and/or an HCP can be useful for developing intervention recommendations, as needed, to benefit the well-being of the child and other family members. Such an assessment can be beneficial in a variety of situations when a child and/or their family/guardians, in coordination with providers, feel some type of intervention would be helpful. Neither assessments nor interventions should ever be used as a means of covertly or overtly discouraging a child's gender diverse expressions or identity. Instead, with appropriately trained providers, assessment can be an effective means of better understanding how to support a child and their family without privileging any particular gender identity or expression. An assessment can be especially important for some children and their families by collaborating to promote a child's gender health, well-being, and self-fulfillment.

A comprehensive assessment can facilitate the formation of an individualized plan to assist a gender diverse prepubescent children and family members (de Vries & Cohen-Kettenis, 2012; Malpas et al., 2018; Steensma & Wensing-Kruger, 2019; Telfer et al., 2018; Tishelman & Kaufman, 2018). In such an assessment, integrating information from multiple sources is important to 1) best understand the child's gender needs and make recommendations; and 2) identify areas of child, family/caregiver, and community strengths and supports specific to the child's gender status and development as well as risks and concerns for the child, their family/caregivers and environment. Multiple informants for both evaluation and support/intervention planning purposes may include the child, parents/caregivers, extended family members, siblings, school personnel, HCPs, the community, broader cultural and legal contexts and other sources as indicated (Berg & Edwards-Leeper, 2018; Srinath, 2019).

An HCP conducting an assessment of gender diverse children needs to explore gender-related issues but must also take a broad view of the child and the environment, consistent with the ecological model described above (Bronfenbrenner, 1979) to fully understand the factors impacting a child's well-being and areas of gender support and risk (Berg & Edwards-Leeper, 2018; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Tishelman & Neumann-Mascis, 2018). This includes understanding the strengths and challenges experienced by the child/family and that are present in the environment. We advise HCPs conducting an assessment with gender diverse children to consider incorporating multiple assessment domains, depending on the child and the family's needs and circumstances. Although some of the latter listed domains below do not directly address the child's gender (see items 7–12 below), they need to be accounted for in a gender assessment, as indicated by clinical judgment, to understand the complex web of factors

that may be affecting the child's well-being in an integrated fashion, including gender health, consistent with evaluation best practices a (APA, 2015; Berg & Edwards-Leeper, 2018; Malpas et al., 2018) and develop a multi-pronged intervention when needed.

Summarizing from relevant research and clinical expertise, assessment domains often include 1) a child's asserted gender identity and gender expression, currently and historically; 2) evidence of dysphoria, gender incongruence, or both; 3) strengths and challenges related to the child, family, peer and others' beliefs and attitudes about gender diversity, acceptance and support for child; 4) child and family experiences of gender minority stress and rejection, hostility, or both due to the child's gender diversity; 5) level of support related to gender diversity in social contexts (e.g., school, faith community, extended family); 6) evaluation of conflict regarding the child's gender and/or parental/caregiver/sibling concerning behavior related to the child's gender diversity; 7) child mental health, communication and/or cognitive strengths and challenges, neurodivergence, and/or behavioral challenges causing significant functional difficulty; 8) relevant medical and developmental history; 9) areas that may pose risks (e.g., exposure to domestic and/or community violence, any form of child maltreatment; history of trauma; safety and/or victimization with peers or in any other setting; suicidality); 10) co-occurring significant family stressors, such as chronic or terminal illness, homelessness or poverty; 11) parent/caregiver and/or sibling mental health and/or behavioral challenges causing significant functional difficulty; and 12) child's and family's strengths and challenges.

A thorough assessment incorporating multiple forms of information gathering is helpful for understanding the needs, strengths, protective factors, and risks for a specific child and family across environments (e.g., home/school). Methods of information gathering often include 1) interviews with the child, family members and others (e.g., teachers), structured and unstructured; 2) caregiver and child completed standardized measures related to gender; general child well-being; child cognitive and communication skills and developmental disorders/disabilities; support and acceptance by parent/caregiver, sibling, extended family and peers; parental stress; history of childhood adversities; and/or other issues as appropriate (APA, 2020; Berg & Edwards-Leeper, 2018; Kaufman & Tishelman, 2018; Srinath, 2019).

Depending on the family characteristics, the developmental profile of the child, or both, methods of information gathering also may also benefit from including the following 1) child and/or family observation, structured and unstructured; and 2) structured and visually supported assessment techniques (worksheets; self-portraits; family drawings, etc.) (Berg & Edwards-Leeper, 2018).

Statement 7.6

We recommend that health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning and language skills.

Given the complexities of assessing young children who, unlike adults, are in the process of development across a range of domains (cognitive, social, emotional, physiological), it is important to consider the developmental status of a child and gear assessment modalities and interactions to the individualized abilities of the child. This includes tailoring the assessment to a child's developmental stage and abilities (preschoolers, school age, early puberty prior to adolescence), including using language and assessment approaches that prioritize a child's comfort, language skills, and means of self-expression (Berg & Edwards-Leeper, 2018; Srinath, 2019). For example, relevant developmental factors, such as neurocognitive differences (e.g., autism spectrum conditions), and receptive and expressive language skills should be considered in conducting the assessment. Health care professionals may need to consult with specialists for guidance in cases in which they do not possess the specialized skills themselves (Strang et al., 2021).

Statement 7.7

We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).

HCPs conducting an assessment with gender diverse children and families need to account for developmental, emotional, and environmental factors that may constrain a child's, caregiver's, sibling or other's report or influence their belief systems related to gender (Riggs & Bartholomaeus, 2018). As with all child psychological assessments, environmental and family/caregiver reactions (e.g., punishment), and/or cognitive and social factors may influence a child's comfort and/or ability to directly discuss certain factors, including gender identity and related issues (Srinath, 2019). Similarly, family members may feel constrained in freely expressing their concerns and ideas depending on family conflicts or dynamics and/or other influences (e.g., cultural/religious; extended family pressure) (Riggs & Bartholomaeus, 2018).

Statement 7.8

We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.

The goal of psychotherapy should never be aimed at modifying a child's gender identity (APA, 2021; Ashley, 2019b; Paré, 2020; SAMHSA, 2015; UN Human Rights Council, 2020), either covertly or overtly. Not all gender diverse children or their families need input from MHPs as gender diversity is not a mental health disorder (Pediatric Endocrine Society, 2020; Telfer et al., 2018). Nevertheless, it is often appropriate and helpful to seek psychotherapy when there is distress or concerns are expressed by parents to improve psychosocial health and prevent further distress (APA, 2015). Some of the common reasons for considering psychotherapy for a gender diverse child and family include the following 1) A child is demonstrating significant conflicts, confusion, stress or distress about their gender identity or needs a protected space to explore their gender (Ehrensaft, 2018; Spivey and Edwards-Leeper, 2019); 2) A child is experiencing external pressure to express their gender in a way that conflicts with their self-knowledge, desires, and beliefs (APA, 2015); 3) A child is struggling with mental health concerns, related to or independent of their gender (Barrow & Apostle, 2018); 4) A child would benefit from strengthening their resilience in the face of negative environmental responses to their gender identity or presentation (Craig & Auston, 2018; Malpas et al., 2018); 5) A child may be experiencing mental health and/or environmental concerns, including family system problems that can be misinterpreted as gender congruence or incongruence (Berg & Edwards-Leeper, 2018); and 6) A child expresses a desire to meet with an MHP to get gender-related support. In these situations, the psychotherapy will focus on supporting the child with the understanding that the child's parent(s)/caregiver(s) and potentially other family members will be included as necessary (APA, 2015; Ehrensaft, 2018; McLaughlin & Sharp, 2018). Unless contraindicated, it is extremely helpful for parents/guardians to participate in some capacity in the psychotherapy process involving prepubescent children as family factors are often central to a child's well-being. Although relatively unexplored in research involving gender diverse children, it may be important to attend to the relationship between siblings and the gender diverse child (Pariseau et al., 2019; Parker & Davis-McCabe, 2021).

HCPs should employ interventions tailor-made to the individual needs of the child that are designed to 1) foster protective social and emotional coping skills to promote resilience in the face of potential negative reactions to the child's gender identity, expressions, or both (Craig & Austin, 2016; Malpas et al., 2018; Spencer, Berg et al., 2021); 2) collaboratively problem-solve social challenges to reduce gender minority stress (Barrow & Apostle, 2018; Tishelman & Neumann-Mascis, 2018); 3) strengthen environmental supports for the child and/or members of the immediate and extended family (Kaufman & Tishelman, 2018); and 4) provide the child an opportunity to further understand their internal gender experiences (APA, 2015; Barrow& Apostle, 2018; Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). It is helpful for HCPs to develop a relationship with a gender diverse child and family that can endure over time as needed. This enables the child/family to establish a long-term trusting relationship throughout childhood whereby the HCP can offer support and guidance as a child matures and as potentially

different challenges or needs emerge for the child/family (Spencer, Berg et al., 2021; Murchison et al., 2016). In addition to the above and within the limits of available resources, when a child is neurodivergent, an HCP who has the skill set to address both neurodevelopmental differences and gender is most appropriate (Strang et al., 2021).

As outlined in the literature, there are numerous reasons parents/caregivers, siblings, and extended family members of a prepubescent child may find it useful to seek psychotherapy for themselves (Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). As summarized below, some of these common catalysts for seeking such treatment occur when one or more *family members* 1) desire education around gender development (Spivey & Edwards-Leeper, 2019); 2) are experiencing significant confusion or stress about the child's gender identity, expression, or both (Ashley, 2019c; Ehrensaft, 2018); 3) need guidance related to emotional and behavioral concerns regarding the gender diverse child (Barrow & Apostle, 2018; 4) need support to promote affirming environments outside of the home (e.g., school, sports, camps) (Kaufman & Tishelman, 2018); 5) are seeking assistance to make informed decisions about social transition, including how to do so in a way that is optimal for a child's gender development and health (Lev & Wolf-Gould, 2018); 6) are seeking guidance for dealing with condemnation from others, including political entities and accompanying legislation, regarding their support for their gender diverse child (negative reactions directed toward parents/caregivers can sometimes include rejection and/or harassment/abuse from the social environment arising from affirming decisions (Hidalgo & Chen, 2019); 7) are seeking to process their own emotional reactions and needs about their child's gender identity, including grief about their child's gender diversity and/or potential fears or anxieties for their child's current and future well-being (Pullen Sansfaçon et al., 2019); and 8) are emotionally distressed and/or in conflict with other family members regarding the child's gender diversity (as needed, HCPs can provide separate sessions for parents/caregivers, siblings and extended family members for support, guidance, and/or psychoeducation) (McLaughlin & Sharp, 2018; Pullen Sansfaçon et al., 2019; Spivey & Edwards-Leeper, 2019).

Statement 7.9

We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.

Consistent with the ecological model described above and, as appropriate, based on individual/family circumstances, it can be extremely helpful for HCPs to prioritize coordination with important others (e.g., teachers, coaches, religious leaders) in a child's life to promote emotional and physical safety across settings (e.g., school settings, sports and other recreational activities, faith-based involvement) (Kaufman & Tishelman, 2018). Therapeutic and/or support groups are often recommended as a valuable resource for families/caregivers and/or gender diverse children themselves (Coolhart, 2018; Horton et al., 2021; Malpas et al., 2018; Murchison et al., 2016).

Statement 7.10

We recommend HCPs offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age appropriate psycho-education about gender development.

Parents/caregivers and their gender diverse child should have the opportunity to develop knowledge regarding ways in which families/caregivers can best support their child to maximize resilience, self-awareness, and functioning (APA, 2015; Ehrensaft, 2018; Malpas, 2018; Spivey & Edwards-Leeper, 2019). It is neither possible nor is it the role of the HCP to predict with certainty the child's ultimate gender identity; instead, the HCP's task is to provide a safe space for the child's identity to develop and evolve over time without attempts to prioritize any particular developmental trajectory with regard to gender (APA, 2015; Spivey & Edwards-Leeper, 2019). Gender diverse children and early adolescents have different needs and experiences than older adolescents, socially and physiologically, and those differences should be reflected in the individualized approach HCPs

provide to each child/family (Keo-Meir & Ehrensaft, 2018; Spencer, Berg et al., 2021).

Parents/caregivers and their children should also have the opportunity to develop knowledge about gender development and gender literacy through age-appropriate psychoeducation (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy involves understanding the distinctions between sex designated at birth, gender identity, and gender expression, including the ways in which these three factors uniquely come together for a child (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). As a child gains gender literacy, they begin to understand their body parts do not necessarily define their gender identity and/or their gender expression (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy also involves learning to identify messages and experiences related to gender within society. As a child gains gender literacy, they may view their developing gender identity and gender expression more positively, promoting resilience and self-esteem, and diminishing risk of shame in the face of negative messages from the environment. Gaining gender literacy through psychoeducation may also be important for siblings and/or extended family members who are important to the child (Rider, Vencill et al., 2019; Spencer, Berg et al., 2021).

Statement 7.11

We recommend health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender-affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.

As a child matures and approaches puberty, HCPs should prioritize working with children and their parents/caregivers to integrate psychoeducation about puberty, engage in shared decision-making about potential gender-affirming medical interventions, and discuss fertility-related and other reproductive health implications of medical treatments (Nahata, Quinn et al., 2018; Spencer, Berg et al., 2021). Although only limited empirical research exists to evaluate such interventions, expert consensus and developmental psychological literature generally support the notion that open communication with children about their bodies and preparation for physiological changes of puberty, combined with gender-affirming acceptance, will promote resilience and help to foster positive sexuality as a child matures into adolescence (Spencer, Berg et al., 2019). All these discussions may be extended (e.g., starting earlier) to include neurodivergent children, to ensure there is enough time for reflection and understanding, especially as choices regarding future gender- affirming medical care potentially arise (Strang, Jarin et al., 2018). These discussions could include the following topics:

- Review of body parts and their different functions;
- The ways in which a child's body may change over time with and without medical intervention;
- The impact of medical interventions on later sexual functioning and fertility;
- The impact of puberty suppression on potential later medical interventions;
- Acknowledgment of the current lack of clinical data in certain areas related to the impacts of puberty suppression;
- The importance of appropriate sex education prior to puberty.

These discussions should employ developmentally appropriate language and teaching styles, and be geared to the specific needs of each individual child (Spencer, Berg et al., 2021).

Statement 7.12

We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.

Gender social transition refers to a process by which a child is acknowledged by others and has the opportunity to live publicly, either in all situations or in certain situations, in the gender identity they affirm and has no singular set of parameters or actions (Ehrensaft et al., 2018).

Gender social transition has often been conceived in the past as binary—a girl transitions to a boy, a boy to a girl. The concept has expanded to include children who shift to a nonbinary or individually shaped iteration of gender identity (Chew et al., 2020; Clark et al., 2018). Newer research indicates the social transition process may serve a protective function for some prepubescent children and serve to foster positive mental health and well-being (Durwood et al., 2017; Gibson et al., 2021; Olson et al., 2016). Thus, recognition that a child's gender may be fluid and develop over time (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013) is not sufficient justification to negate or deter social transition for a prepubescent child when it would be beneficial. Gender identity evolution may continue even after a partial or complete social transition process has taken place (Ashley, 2019e; Edwards-Leeper et al., 2018; Ehrensaft, 2020; Ehrensaft et al., 2018; Spivey & Edwards-Leeper, 2019). Although empirical data remains limited, existing research has indicated children who are most assertive about their gender diversity are most likely to persist in a diverse gender identity across time, including children who socially transition prior to puberty (Olson et al., 2022; Rae et al., 2019; Steensma, McGuire et al., 2013). Thus, when considering a social transition, we suggest parents/caregivers and HCPs pay particular attention to children who consistently and often persistently articulate a gender identity that does not match the sex designated at birth. This includes those children who may explicitly request or desire a social acknowledgement of the gender that better matches the child's articulated gender identity and/or children who exhibit distress when their gender as they know it is experienced as incongruent with the sex designated at birth (Rae et al., 2019; Steensma, Kreukels et al., 2013).

Although there is a dearth of empirical literature regarding best practices related to the social transition process, clinical literature and expertise provides the following guidance that prioritizes a child's best interests (Ashley, 2019e; Ehrensaft, 2018; Ehrensaft et al, 2018; Murchison et al., 2016; Telfer et al., 2018): 1) social transition should originate from the child and reflect the child's wishes in the process of making the decision to initiate a social transition process; 2) an HCP may assist exploring the advantages/benefits, plus potential challenges of social transition; 3) social transition may best occur in all or in specific contexts/settings only (e.g., school, home); and 4) a child may or may not choose to disclose to others that they have socially transitioned, or may designate, typically with the help of their parents/caregivers, a select group of people with whom they share the information.

In summary, social transition, when it takes place, is likely to best serve a child's well-being when it takes place thoughtfully and individually for each child. A child's social transition (and gender as well) may evolve over time and is not necessarily static, but best reflects the cross-section of the child's established self-knowledge of their present gender identity and desired actions to express that identity (Ehrensaft et al., 2018).

A social transition process can include one or more of a number of different actions consistent with a child's affirmed gender (Ehrensaft et al., 2018), including:

- Name change;
- Pronoun change;
- Change in sex/gender markers (e.g., birth certificate; identification cards; passport; school and medical documentation; etc.);
- Participation in gender-segregated programs (e.g., sports teams; recreational clubs and camps; schools; etc.);
- Bathroom and locker room use;
- Personal expression (e.g., hair style; clothing choice; etc.);
- Communication of affirmed gender to others (e.g., social media; classroom or school announcements; letters to extended families or social contacts; etc.).

Statement 7.13

We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.

It is important children who have engaged in social transition be afforded the same opportunities as other children to continue considering

meanings and expressions of gender throughout their childhood years (Ashley 2019e; Spencer, Berg et al., 2021). Some research has found children may experience gender fluidity or even detransition after an initial social transition. Research has not been conclusive about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition—due to gender evolution, or potentially other reasons (e.g., safety concerns; gender minority stress) (Olson et al., 2022; Steensma, Kreukels et al., 2013). A recent research report indicates in the US, detransition occurs with only a small percentage of youth five years after a binary social transition (Olson et al., 2022); further follow-up of these young people would be helpful. Replication of these findings is important as well since this study was conducted with a limited and self-selected participant pool in the US and thus may not be applicable to all gender diverse children. In summary, we have limited ability to know in advance the ways in which a child's gender identity and expressions may evolve over time and whether or why detransition may take place for some. In addition, not all gender diverse children wish to explore their gender (Telfer et al., 2018). Cisgender children are not expected to undertake this exploration, and therefore attempts to force this with a gender diverse child, if not indicated or welcomed, can be experienced as pathologizing, intrusive and/or cisnormative (Ansara & Hegarty, 2012; Bartholomaeus et al., 2021; Oliphant et al., 2018).

Statement 7.14

We recommend health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.

Social transition in prepubescent children consists of a variety of choices, can occur as a process over time, is individualized based on both a child's wishes and other psychosocial considerations (Ehrensaft, 2018), and is a decision for which possible benefits and challenges should be weighted and discussed.

A social transition may have potential benefits as outlined in clinical literature (e.g., Ehrensaft et al., 2018) and supported by research (Fast & Olson, 2018; Rae et al., 2019). These include facilitating gender congruence while reducing gender dysphoria and enhancing psychosocial adjustment and well-being (Ehrensaft et al., 2018). Studies have indicated socially transitioned gender diverse children largely mirror the mental health characteristics of age matched cisgender siblings and peers (Durwood et al., 2017). These findings differ markedly from the mental health challenges consistently noted in prior research with gender diverse children and adolescents (Barrow & Apostle, 2018) and suggest the impact of social transition may be positive. Additionally, social transition for children typically can only take place with the support and acceptance of parents/caregivers, which has also been demonstrated to facilitate well-being in gender diverse children (Durwood et al., 2021; Malpas et al., 2018; Pariseau et al., 2019), although other forms of support, such as school-based support, have also been identified as important (Durwood et al., 2021; Turban, King et al., 2021). HCPs should discuss the potential benefits of a social transition with children and families in situations in which 1) there is a consistent, stable articulation of a gender identity that is incongruent with the sex assigned at birth (Fast & Olson, 2018). This should be differentiated from gender diverse expressions/behaviors/interests (e.g., playing with toys, expressing oneself through clothing or appearance choices, and/or engaging in activities socially defined and typically associated with the other gender in a binary model of gender) (Ehrensaft, 2018; Ehrensaft et al., 2018); 2) the child is expressing a strong desire or need to transition to the gender they have articulated as being their authentic gender (Ehrensaft et al., 2018; Fast & Olson, 2018; Rae et al., 2019); and 3) the child will be emotionally and physically safe during and following transition (Brown & Mar, 2018). Prejudice and discrimination should be considerations, especially in localities where acceptance of gender diversity is limited or prohibited (Brown & Mar, 2018; Hendricks & Testa, 2012; Turban, King et al., 2021). Of note, there can also be possible risks to a gender diverse child who does not socially transition, including 1) being ostracized or bullied for being perceived as not conforming to prescribed community

gender roles and/or socially expected patterns of behavior; and 2) living with the internal stress or distress that the gender they know themselves to be is incongruent with the gender they are being asked to present to the world.

To promote gender health, the HCP should discuss the potential challenges of a social transition. One concern often expressed relates to fear that a child will preclude considering the possible evolution of their gender identity as they mature or be reluctant to initiate another gender transition even if they no longer feel their social transition matches their current gender identity (Edwards-Leeper et al., 2016; Ristori & Steensma, 2016). Although limited, recent research has found some parents/caregivers of children who have socially transitioned may discuss with their children the option of new gender iterations (for example, reverting to an earlier expression of gender) and are comfortable about this possibility (Olson et al., 2019). Another often identified social transition concern is that a child may suffer negative sequelae if they revert to the former gender identity that matches their sex designated at birth (Chen et al., 2018; Edwards-Leeper et al., 2019; Steensma & Cohen-Kettenis, 2011). From this point of view, parents/caregivers should be aware of the potential developmental effect of a social transition on a child.

HCPs should provide guidance to parents/caregivers and supports to a child when a social gender transition is being considered or taking place by 1) providing consultation, assessment, and gender supports when needed and sought by the parents/caregivers; 2) aiding family members, as needed, to understand the child's desires for a social transition and the family members' own feelings about the child's expressed desires; 3) exploring with, and learning from, the parents/caregivers whether and how they believe a social transition would benefit their child both now and in their ongoing development; 4) providing guidance when parents/caregivers are not in agreement about a social transition and offering the opportunity to work together toward a consistent understanding of their child's gender status and needs; 5) providing guidance about safe and supportive ways to disclose their child's social transition to others and to facilitate their child transitioning in their various social environments (e.g., schools, extended family); 6) facilitating communication, when desired by the child, with peers about gender and social transition as well as fortifying positive peer relationships; 7) providing guidance when social transition may not be socially accepted or safe, either everywhere or in specific situations, or when a child has reservations about initiating a transition despite their wish to do so; there may be multiple reasons for reservations, including fears and anxieties; 8) working collaboratively with family members and MHPs to facilitate a social transition in a way that is optimal for the child's unfolding gender development, overall well-being, and physical and emotional safety; and 9) providing psychoeducation about the many different trajectories the child's gender may take over time, leaving pathways open to future iterations of gender for the child, and emphasizing there is no need to predict an individual child's gender identity in the future (Malpas et al., 2018).

All of these tasks incorporate enhancing the quality of communication between the child and family members and providing an opportunity for the child to be heard and listened to by all family members involved. These relational processes in turn facilitate the parents/caregivers' success in making informed decisions about the advisability and/or parameters of a social transition for their child (Malpas et al., 2018).

One role of HCPs is to provide guidance and support in situations in which children and parents/caregivers wish to proceed with a social transition but conclude that the social environment would not be accepting of those choices, by 1) helping parents/caregivers define and extend safe spaces in which the child can express their authentic gender freely; 2) discussing with parents/caregivers ways to advocate that increase the likelihood of the social environment being supportive in the future, if this is a realistic goal; 3) intervening as needed to help the child/family with any associated distress and/or shame brought about by the continued suppression of authentic gender identity and the need for secrecy; and 4) building both the child's and the family's resilience, instilling the understanding that if the social environment is having difficulty accepting a child's social transition and affirmed gender identity, it is not because of some shortcoming in the child but because of

insufficient gender literacy in the social environment (Ehrensaft et al., 2018).

Statement 7.15

We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

All children have the right to be supported and respected in their gender identities (Human Rights Campaign, 2018; Paré, 2020; SAMHSA, 2015). As noted above, gender diverse children are a particularly vulnerable group (Barrow & Apostle, 2018; Cohen-Kettenis et al., 2003; Giovanardi et al., 2018; Gower, Rider, Coleman et al., 2018; Grossman & D'Augelli, 2007; Hendricks & Testa, 2012; Reisner, Greytak et al., 2015; Ristori & Steensma, 2016; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). The responsibilities of HCPs as advocates encompass acknowledging social determinants of health are critical for marginalized minorities (Barrow & Mar, 2018; Hendricks & Testa, 2012). Advocacy is taken up by all HCPs in the form of child and family support (APA, 2015; Malpas et al., 2018). Some HCPs may be called on to move beyond their individual offices or programs to advocate for gender diverse children in the larger community, often in partnership with stakeholders, including parents/caregivers, allies, and youth (Kaufman & Tishelman, 2018; Lopez et al., 2017; Vanderburgh, 2009). These efforts may be instrumental in enhancing children's gender health and promoting their civil rights (Lopez et al., 2017).

HCP's voices may be essential in schools, in parliamentary bodies, in courts of law, and in the media (Kuvalanka et al., 2019; Lopez et al., 2017; Whyatt-Sames, 2017; Vanderburgh, 2009). In addition, HCPs may have a more generalized advocacy role in acknowledging and addressing the frequent intentional or unintentional negating of the experience of gender diverse children that may be transmitted or communicated by adults, peers, and in media (Rafferty et al., 2018). Professionals who possess the skill sets and find themselves in appropriate situations can provide clear de-pathologizing statements on the needs and rights of gender diverse children and on the damage caused by discriminatory and transphobic rules, laws, and norms (Rafferty et al., 2018).

CHAPTER 8 Nonbinary

Nonbinary is used as an umbrella term referring to individuals who experience their gender as outside of the gender binary. The term nonbinary is predominantly but not exclusively associated with global north contexts and may sometimes be used to describe indigenous and non-Western genders. The term nonbinary includes people whose genders are comprised of more than one gender identity simultaneously or at different times (e.g., bigender), who do not have a gender identity or have a neutral gender identity (e.g., agender or neutrois), have gender identities that encompass or blend elements of other genders (e.g., polygender, demiboy, demigirl), and/or who have a gender that changes over time (e.g., genderfluid) (Kuper et al., 2014; Richards et al., 2016; Richards et al., 2017; Vincent, 2019). Nonbinary people may identify to varying degrees with binary-associated genders, e.g., nonbinary man/woman, or with multiple gender terms, e.g., nonbinary and genderfluid (James et al., 2016; Kuper et al., 2012). Nonbinary also functions as a gender identity in its own right (Vincent, 2020). It is important to acknowledge this is not an exhaustive list, the same identities can have different meanings for different people, and the use of terms can vary over time and by location.

Genderqueer, first used in the 1990s, is an identity category somewhat older than nonbinary—which first emerged in approximately the late 2000s (Nestle et al., 2002; Wilchins, 1995). Genderqueer may sometimes be used synonymously with nonbinary or may communicate a specific consciously politicized dimension to a person's gender. While transgender is used in many cultural contexts as an umbrella term inclusive of nonbinary people, not all nonbinary people consider themselves to be transgender for a range of reasons, including because they consider being transgender to be exclusively within the gender binary or because they do not feel "trans enough" to describe themselves as transgender (Garrison, 2018). Some nonbinary people are unsure or ambivalent about whether they would describe themselves as transgender (Darwin, 2020; Vincent, 2019).

In the context of the English language, nonbinary people may use the pronouns they/them/theirs, or neopronouns which include e/em/eir, ze/zir/hir, er/ers/erself among others (Moser & Devereux, 2019; Vincent, 2018). Some nonbinary people use a combination of pronouns (either deliberately mixing usage, allowing free choice, or changing with social context), or prefer to avoid gendered pronouns entirely, instead using their name. Additionally, some nonbinary people use she/her/hers, or he/him/his, sometimes or exclusively, whilst in some regions in the world descriptive language for nonbinary people does not (yet) exist. In contexts outside of English, a wide range of culturally specific linguistic adaptations and evolutions can be observed (Attig, 2022; Kirey-Sitnikova, 2021; Zimman, 2020). Also of note, some languages use one pronoun that is not associated with sex or gender while others gender all nouns. These variations in language are likely to influence nonbinary people's experience of gender and how they interact with others.

Recent studies suggest nonbinary people comprise roughly 25% to over 50% of the larger transgender population, with samples of youth reporting the highest percentage of nonbinary people (Burgwal et al., 2019; James et al., 2016; Watson, 2020). In recent studies of transgender adults, nonbinary people tend to be younger than transgender men and transgender women and in studies of both youth and adults, nonbinary people are more likely to have been assigned female at birth (AFAB). However, these findings should be interpreted with caution as there are likely a number of complex, sociocultural factors influencing the quality, representativeness, and accuracy of this data (Burgwal et al., 2019; James et al., 2016; Watson, 2020; Wilson & Meyer, 2021) (see also Chapter 3—Population Estimates).

Understanding gender identities and gender expressions as a non-linear spectrum

Nonbinary genders have long been recognized historically and cross-culturally (Herdt, 1994; McNabb, 2017; Vincent & Manzano, 2017). Many gender identity categories are culturally specific and cannot be easily translated from their context, either linguistically or in relation to the Western paradigm of gender. Historical settler colonial interactions with indigenous people with

non-Western genders remain highly relevant as cultural erasure and the intersections of racism and cisnormativity may detrimentally inform the social determinants of health of indigenous gender diverse people. From the 1950s, gender was used to reference the socially constructed categorization of behaviors, activities, appearance, etc. in relation to a binary model of male/man/masculine, and female/woman/feminine within contemporary Western contexts. However, gender now has a wider range of possible meanings, appreciating interrelated yet distinguishable concepts, including gendered biology (sex), gender roles, gender expression, and gender identity (Vincent, 2020). Aspects of gender expression that might traditionally be understood culturally as "masculine", "feminine", or "androgynous" may be legitimately expressed among people of any and all gender identities, whether nonbinary or not. For example, a nonbinary individual presenting in a feminine manner cannot be taken to imply they will necessarily later identify as a woman or access interventions associated with transgender women, such as vaginoplasty. A person's gender nonconformity in relation to cultural expectations should neither be viewed as a cause for concern nor assumed to be indicative of clinical complexity—for example, a nonbinary person assigned male at birth (AMAB) wearing feminine-coded clothing, using she/her pronouns, but keeping a masculine-coded first name.

Modeling gender as a spectrum offers greater nuance than a binary model. However, there remain significant limitations in a linear spectrum model that can lead to uncritical generalizations about gender. For example, while it is intuitive to position the "binary options" (man/male, woman/female) at either end of such a continuum, doing so situates masculinity as oppositional to femininity, failing to accommodate gender neutrality, the expression of masculinity and femininity simultaneously, and genderqueer or non-Western concepts of gender. It is essential HCPs do not view nonbinary genders as "partial" articulations of transgender manhood (in nonbinary people AFAB) or transgender womanhood (in nonbinary people AMAB), or definitively as "somewhere along the spectrum of masculinity/femininity"; some nonbinary individuals consider themselves outside male/female dichotomization altogether. A *non-linear* spectrum indicates differences of gender expression, identity, or needs around gender affirmation between clients should not be compared for the purposes of situating them along a linear spectrum. Additionally, the interpretation of gender expression is subjective and culturally defined, and what may be experienced or viewed as highly feminine by one person may not be viewed as such by another (Vincent, 2020). HCPs benefit from avoiding assumptions about how each client conceptualizes their gender and by being prepared to be led by a given client's personal understanding of gender as it relates to the client's gender identity, expression, and any need for medical care.

The gender development process experienced by all transgender and gender diverse (TGD) people regardless of their relationship to a gender binary appear to share similar themes (e.g., awareness, exploration, meaning making, integration), but the timing, progression, and personal experiences associated with each of these processes vary both within and across groups of transgender and nonbinary people (Kuper, Wright et al., 2018; Kuper, Lindley et al., 2019; Tatum et al., 2020). Sociocultural and intersectional perspectives can be helpful at contextualizing gender development and social transition, including how individual experiences are shaped by the social and cultural context and how they interact with additional domains of identity and personal experience.

The need for access to gender-affirming care

Some nonbinary people seek gender-affirming care to alleviate gender dysphoria or incongruence and increase body satisfaction through medically necessary interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). Some nonbinary people may feel a certain treatment is necessary for them—see also Chapter 5—Assessment of Adults (Beek et al., 2015; Jones et al., 2019; Köhler et al., 2018), whilst others do not (Burgwal & Motmans, 2021; Nieder, Eyssel et al., 2020), and the proportion of nonbinary people who seek gender-affirming care and the specific goals of

that care, remains unclear. It is the role of the health care professional to provide information about existing medical options (and their availability) that might help alleviate gender dysphoria or incongruence and increase body satisfaction without making assumptions about which treatment options may best fit each individual person.

Motivations for accessing (or not accessing) gender-affirming medical interventions, including hormone treatment, surgeries, or both are heterogeneous and potentially complex (Burgwal & Motmans, 2021; Vincent, 2019, 2020) and should be explored collaboratively before making decisions about physical interventions. The need of an individual to access gender-affirming medical procedures cannot be predicted by their gender role, expression, or identity. For example, some transgender women have no need of vaginoplasty, while some nonbinary individuals AMAB may need and benefit from that same intervention. Further, nonbinary people seeking gender-affirming care associated closely with a transition pathway from their assigned sex/gender to the other binarily-recognized category (i.e., estrogen therapy and vaginoplasty for someone AMAB) does not undermine the validity of their nonbinary identity.

While barriers to care remain widespread for many transgender people, nonbinary people appear to experience particularly high rates of difficulty accessing both mental health and gender-affirming medical care (Clark et al., 2018; James, 2016). Many nonbinary people report having experiences with health care professionals who were not affirming of their nonbinary gender, including experiences where health care professionals convey beliefs that their gender is not valid, or they are fundamentally more difficult to provide care for (Valentine, 2016; Vincent, 2020). Nonbinary people may face provider assumptions that they do not need or want gender-affirming treatment (Kcomt et al., 2020; Vincent, 2020) and have described experiencing pressure to present themselves as transgender men or transgender women (within a binary framework of gender) in order to access treatment (Bradford et al., 2019; Taylor et al., 2019). At times, nonbinary people find themselves educating the provider from whom they are seeking services despite the inappropriateness of providers relying primarily on their patients for education (Kcomt et al., 2020). In comparison to transgender men and transgender women, Burgwal and Motmans (2021) found that nonbinary people experienced more fear of prejudice from health care providers, less confidence in the services provided, and greater difficulty knowing where to go to for care. Studies in both Europe and US have shown that nonbinary individuals tend to delay care more often than binary transgender men or transgender women, with fear of insensitive or incompetent treatment being the most cited reason (Burgwal & Motmans, 2021; Grant et al., 2011). Nonbinary people also appear less likely to disclose their gender identity to their health care providers than other transgender people (Kcomt et al., 2020).

The need for an appropriate level of support

Providing gender-affirming care to nonbinary people goes beyond the provision of specific gender-affirming interventions such as hormone therapy or surgery and involves supporting the overall health and development of nonbinary people. Minority stress models have been adapted to conceptualize how the gender-related stressors experienced by transgender people are associated with physical and mental health disparities (Delozier et al., 2020; Testa et al., 2017). Nonbinary people appear to experience minority stressors that are both similar to and unique from those experienced by transgender men and transgender women. Johnson (2020) reported that experiences of invalidation are particularly high among nonbinary people, e.g., statements or actions conveying a belief that nonbinary identities are not "real" or are the result of a "fad" or "phase," and nonbinary people appear less likely than transgender men and transgender women to have their correct pronouns used by others. Similarly, nonbinary people have described feeling "invisible" to others (Conlin, 2019; Taylor, 2018) and one study found that nonbinary youth reported lower levels of self-esteem in comparison to young transgender men and transgender women (Thorne, Witcomb et al., 2019).

While many TGD people report experiences of discrimination, victimization, and interpersonal rejection (James, 2016) including bullying within

samples of youth (Human Rights Campaign, 2018; Witcomb et al., 2019), the prevalence of these experiences may vary across groups and appears influenced by additional intersecting characteristics. For example, Newcomb (2020) found transgender women and nonbinary youth AMAB experienced higher levels of victimization than transgender men and nonbinary youth AFAB, with nonbinary youth AMAB reporting the highest levels of traumatic stress. In a second study, Poquiz (2021) found transgender men and transgender women experienced higher levels of discrimination than nonbinary people. This intersectional complexity is also likely contributing to the variability in findings from studies comparing the physical and mental health of nonbinary and transgender men and transgender women, with some studies indicating more physical and mental health concerns among nonbinary people, some reporting less concerns, and some reporting no difference between groups (Scandurra, 2019).

Given nonbinary identity narratives may be less widely available than more binary-oriented identity narratives, nonbinary people may have less resources available to explore and articulate their gender-related sense of self. For example, this might include access to community spaces and interpersonal relationships where nonbinary identity can be explored, or access to language and concepts that allow more nuanced consideration of nonbinary experiences (Bradford et al., 2018; Fiani & Han, 2019; Galupo et al., 2019). Clinical guidance is now developing to assist providers in adapting gender-affirming therapeutic care to meet these unique experiences of nonbinary people (Matsuno, 2019; Rider, Vencill et al., 2019).

Gender-affirming medical interventions for nonbinary people

In contexts where a particular medical intervention does not have established precedent, it is important that before the intervention is considered, the individual is provided with an overview of the available information, including recognition of potential knowledge limits. It is equally important to undertake and document a comprehensive discussion of the physical changes needed and the potential limitations in achieving those attributes, as well as the implication that any given intervention may or may not enhance an individual's ability to express their gender.

With regards to estrogen therapy for nonbinary people AMAB, it is important to note the possibility of breast growth cannot be avoided (Seal, 2017). Although the extent of growth is highly variable, this should be made clear if a nonbinary person seeks some of the other changes associated with estrogen therapy (such as softening of skin and reduction in facial hair growth) but does not want or is ambivalent about breast growth. Likewise, for nonbinary people AFAB who may wish to access testosterone to acquire some changes but not others, it should be recognized that if facial hair development is needed, genital growth is inevitable (Seal, 2017). The time frame for taking testosterone means these changes are likely also to be accompanied by an irreversible vocal pitch drop, although the extent of each is individual (Vincent, 2019; Ziegler et al., 2018). A vocal pitch drop without the development of body hair is another such challenge. For some nonbinary people, hair removal is a very important part of their gender affirmation (Cocchetti, Ristori, Romani et al., 2020).

If hormonal therapy is discontinued and gonads are retained, many physical changes will revert to pre-hormone therapy status as gonadal hormones once again take effect, including reversal of amenorrhea and body hair development in nonbinary people AFAB and reduction in muscular definition and erectile dysfunction in nonbinary people AMAB. Other changes will be permanent such as "male-pattern" baldness, genital growth, and facial hair growth in nonbinary people AFAB or breast development in nonbinary people AMAB (Hembree et al., 2017). These will require further interventions to reverse, such as electrolysis or mastectomy and are sometimes described as "partially reversible" (Coleman et al., 2012). As the implications of using low-dose hormone therapy are not documented in this patient population, it is important to consider monitoring for cardiovascular risk and bone health if low-dose hormone therapy is used. For more detailed information see Chapter 12—Hormone Therapy.

If neither testosterone nor estrogen expression is needed, inhibition of estrogen and/or testosterone

Statements of Recommendations

8.1- We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their experience of gender.
8.2- We recommend health care professionals consider gender-affirming medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."
8.3- We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment, unless hormone therapy is required to achieve the desired surgical result.
8.4- We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

production is possible. The implications of this with regards to increased cardiovascular risk, reduced bone mineralization, and risk of depression should be discussed and measures taken to mitigate risk (Brett et al., 2007; Vale et al., 2010; Wassersug & Johnson, 2007). For more information see also Chapter 9—Eunuchs and Chapter 12—Hormone Therapy. Exploration of medical and/or social transition independently of each other and options to explore hormones, surgery, or both independently of each other should be available to everyone, whether the person is a transgender man, transgender woman, or a nonbinary person.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 8.1

We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their nonbinary experiences of gender.

An individualized assessment with a nonbinary person starts with an understanding of how they experience their own gender and how this impacts their goals for the care they are seeking. How individuals conceptualize their gender-related experiences are likely to vary across groups and cultures and may incorporate experiences associated with other intersecting aspects of identity (e.g., age, sexuality, race, ethnicity, socioeconomic status, disability status) (Kuper et al., 2014; Subramanian et al., 2016).

HCPs should avoid making a priori assumptions about any client's gender identity, expression, or needs for care. They should also be mindful that a client's nonbinary experience of gender may or may not be relevant to the assessment and treatment-related goals. The extent to which the client's gender is relevant to their treatment goals should determine the level of detail at which their gender identity is explored. For example, when seeking care for a presenting concern wholly unrelated to gender, simply determining the correct name and pronouns may be sufficient (Knutson et al., 2019). When addressing a concern for which current or past hormonal or surgical status is relevant, more detail may be needed, even if the concern is not specifically gender-related.

Clinical settings need to be welcoming, reflective of the diversity of genders, and affirm the experiences of gender of nonbinary people to be culturally competent. Ensuring clinic and provider information (e.g., websites), forms (e.g., intake surveys), and other materials are inclusive of nonbinary identities and experiences conveys that nonbinary people are welcome and recognized (Hagen & Galupo, 2014). Using free text fields for gender identity and pronouns is more inclusive than using a list of response options. Ensuring privacy at the reception desk, setting up alternatives for listing legal names in digital databases (in cultural contexts where this is necessary), installing gender-neutral toilets, and setting up alternatives to calling out the legal name in the waiting room are additional examples of transgender and gender diverse (TGD) cultural competency (Burgwal et al., 2021). In care settings, it is important preferences for names, pronouns, and other gender-related terms are asked and used both initially and on a regular basis as they may vary over time and circumstance.

HCPs are encouraged to adopt an approach that focuses on strengths and resilience.

Increasingly, critiques are emerging regarding HCPs over-focus on gender-related distress as it is also important to consider experiences of increased comfort, joy, and self-fulfilment that can result from self-affirmation and access to care (Ashley, 2019a; Benestad, 2010). In addition to utilizing diagnoses when/where required to facilitate access to care, HCPs are encouraged to collaboratively explore with clients this broader range of potential gender-related experiences and how they may fit with treatment options (Motmans et al., 2019). For all TGD people, resiliency factors such as supportive relationships, participation in communities that include similar others, and identity pride are essential to consider as they are associated with a range of positive health outcomes (Bowling et al., 2019; Budge, 2015; Johns et al., 2018).

Awareness of the limitations that exist in the tools providers have historically used to assess transgender people's experience of dysphoria is important as they may be particularly pronounced for many nonbinary people. Most gender-related measures assume clients experience their gender in a binary way, among other concerns (e.g., Recalled Gender Identity Scale, Utrecht Gender Dysphoria Scale). While several newer measures have been developed in an attempt to better capture the experiences of nonbinary people (McGuire et al., 2018; McGuire et al., 2020), open-ended discussion is likely to provide a deeper and more accurate understanding of each individual's unique experiences of dysphoria and their associated care needs. Similarly, while more recent iterations of diagnostic categories (i.e., "gender dysphoria" in the DSM 5 and "gender incongruence" in ICD-11) were intended to be inclusive of people with nonbinary experiences of gender, they may not adequately capture the full diversity and scope of experiences of gender-related distress, particularly for nonbinary people. In addition to distress associated with aspects of one's physical body and presentation (including features that may be existing or absent), distress may arise from how one experiences their own gender, how one's gender is perceived within social situations, and from experiences of minority stress associated with one's gender (Winters & Ehrbar, 2010). Nonbinary peoples' experiences in each of these areas may or may not be similar to those of transgender men or women.

A person-centered approach for affirming care includes specific discussion of how different interventions may or may not shift the client's comfort with their own experience of gender, and how their gender is perceived by others. Nonbinary people can face challenges in reconciling their personal identities with the limits of the medical treatments available and can also encounter confusion and intolerance from society regarding their gender presentations (Taylor et al., 2019). Emerging research suggests the medical treatment needs of nonbinary people are particularly diverse, with some reporting needs for treatments that have typically been associated with transition trajectories historically associated with transgender men and women and some reporting alternative approaches (e.g., low dose hormone therapy, surgery without hormone therapy), some reporting a lack of interest in medical treatment, and some reporting feeling unsure about their needs (Burgwal & Motmans, 2021; James et al., 2016). Conceptualizing assessment as an ongoing process is particularly important given gender-related experiences and associated needs may shift throughout the lifespan. Given the ongoing evolution in treatment options and knowledge of treatment effects, particularly for nonbinary people, clients will benefit from providers who regularly seek up-to-date knowledge and convey these updates to their clients.

Statement 8.2

We recommend health care professionals consider medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."

Previous requirements for accessing hormonal treatment and surgery, such as "living in a gender role that is congruent with one's gender identity," do not reflect the lived experiences of many TGD people (Coleman et al., 2012). Due to the entrenched nature of the gender binary in most contemporary Western cultures, one can typically only be understood by others as a man or woman within most settings (Butler, 1993). Hence, the visibility and understanding of nonbinary embodiments and expressions is limited. This is due to gendered cues

being almost always understood in reference to a gender binary (Butler, 1993). Presently, it can be difficult for nonbinary people to be reliably recognized as their gender via visual cues associated with their gender expression (e.g., clothing, hair). However, androgyny or gender nonconformity may be communicated by the mixing or combining of cultural markers with traditionally masculine or feminine connotations. Because there is no commonly recognized "nonbinary category" within most contemporary Western, global north cultural contexts, nonbinary visibility often necessitates explicit sharing of one's gender with others or the use of cues that may be interpreted as gender nonconformity (but not necessarily nonbinary).

For these reasons, framing access to medical care in the context of someone experiencing a "social gender transition" where they are "living in a gender role that is congruent with one's gender identity" is not in line with the way many TGD people understand themselves and their personal transition process. For some, "living in a gender role that is congruent with one's gender identity" does not involve changes in name, pronouns, or gender expression even as medical intervention may be necessary. Even if a person is able to live in ways that are congruent with their gender identity, it may be difficult for an outside observer to assess this without learning directly from that person how they understand their own experience in this regard. Expectation of "social gender transition" may be unhelpful when considering eligibility for gender- affirming care, such as hormones and surgery, and rigid expectations of what a "social gender role transition" "should" look like can be a barrier to care for nonbinary people. There is no logical requirement gender-affirming medical interventions can only be done once a person legally changes their name, changes the gender marker on their identity documents, or wears or refrains from wearing particular items of clothing. Nonbinary people may struggle to access recognition of their genders on formal documentation, which may negatively affect their mental health or well-being (Goetz & Arcomano, 2021). TGD people may benefit from specific support in accessing (or retaining) their gender marker of preference. A requirement that someone disclose their gender identity in all circles of their lives (family, work, school, etc.) in order to access medical care may not be consistent with their goals and can place them at risk if it is not safe to do so.

Statement 8.3

We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment unless hormone therapy is required to achieve the desired surgical result.

The trajectory of "hormones before surgery" is an option across a range of surgical interventions. Some nonbinary people will seek gender-affirming surgical treatment to alleviate gender incongruence and increase body satisfaction (Beek et al., 2015; Burgwal & Motmans, 2021; Jones et al., 2019; Koehler et al., 2018), but do not want hormonal treatment or are unable to undergo hormonal therapy due to other medical reasons (Nieder, Eyssel et al., 2020). Currently, it is unknown for which proportion of nonbinary people these options apply.

Perhaps the surgery which has some specific association with nonbinary people (rather than sought by transgender men or undergone by some cisgender women) is mastectomy in nonbinary people AFAB who have not taken testosterone—although testosterone is not a requirement for this type of surgery—and some nonbinary people AFAB may need breast reduction (McTernan et al., 2020). An example of a surgery for which at least a period of hormone therapy may be necessary is metoidioplasty that enhances the enlarged clitoris produced by testosterone therapy. See Chapter 13—Surgery and Postoperative Care for more detail on whether hormone therapy is necessary for various surgeries. Procedures addressing the internal reproductive system include hysterectomy, unilateral or bilateral salpingo-oophorectomy, and vaginectomy. Hormone therapy is not required for any of these procedures, but hormone replacement therapy (either with estrogens, testosterone, or both) is advisable in those individuals undergoing a total gonadectomy to prevent adverse effects on their cardiovascular and musculoskeletal systems (Hembree et al., 2017; Seal, 2017). For phalloplasty, while there is no surgical requirement per se for a minimum period of testosterone

treatment, virilization (or the absence of virilization) of the clitoris and labia minora may impact the choice of surgical technique and influence surgical options. For more information see Chapter 13—Surgery and Postoperative Care.

Nonbinary AMAB clients should be informed commencing estrogen therapy post-surgically with no prior history of estrogen therapy may influence (perhaps adversely) the surgical result (Kanhai, Hage, Asscheman et al., 1999; Kanhai, Hage, Karim et al., 1999). Nonbinary people AMAB requesting a bilateral orchiedectomy do not require estrogen therapy to achieve a better outcome (Hembree et al., 2017). In these contexts, it is good practice to inform clients of the risks and benefits of hormone replacement therapy (estrogens, testosterone, or both) in preventing adverse effects on the cardiovascular and musculoskeletal system as well as alternative treatment options, such as calcium plus vitamin D supplementation to prevent osteoporosis (Hembree et al., 2017; Seal, 2017; Weaver et al., 2016). See also Chapter 9—Eunuchs for those who choose to forgo hormone replacement therapy. In the case of vaginoplasty, individuals should be advised lack of testosterone-blocking therapy may cause postoperative hair growth in the vagina when hair-bearing skin graft and flaps have been used (Giltay & Gooren, 2000).

Additional surgical requests for nonbinary people AMAB include penile-preserving vaginoplasty, vaginoplasty with preservation of the testicle(s), and procedures resulting in an absence of external primary sexual characteristics (i.e., penectomy, scrotectomy, orchiectomy, etc.). The surgeon and individual seeking treatment are advised to engage in discussions so as to understand the individual's goals and expectations as well as the benefits and limitations of the intended (or requested) procedure, to make decisions on an individualized basis and collaborate with other health care providers who are involved (if any).

Statement 8.4.

We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

All nonbinary individuals who seek gender-affirming hormonal therapies should be offered information and guidance about fertility options (Hembree et al., 2017; De Roo et al., 2016; Defreyne, Elaut et al., 2020; Defreyne, van Schuvlenbergh et al., 2020; Nahata et al., 2017; Quinn et al., 2021). It is important to discuss the potential impact of hormone therapy on fertility prior to initiation. This discussion should include fertility preservation options, the extent to which fertility may or may not be regained if hormone therapy is ceased, and the fact that hormone therapy per se is not birth control. For more information see Chapter 16—Reproductive Health.

Recent studies suggest that nonbinary individuals are less likely to access care and make their needs for potential interventions heard (Beek et al., 2015; Taylor et al., 2019). As such, it stands to reason that any gender diverse individual should be offered information on current options and techniques for fertility preservation, ideally prior to commencing hormonal treatment as the quality of the sperm or eggs may be impacted by exposure to hormones (Hamada et al., 2015; Payer et al., 1979). However, this should in no way preclude making inquiries and seeking more information at a later time, as there is evidence that fertility is still possible for individuals taking estrogen and testosterone (Light et al., 2014). A decision by a nonbinary or gender diverse person that fertility preservation or counseling is not needed should not be used as a basis for denying or delaying access to hormonal treatment.

CHAPTER 9 Eunuchs

Among the many people who benefit from gender-affirming medical care, those who identify as eunuchs are among the least visible. The 8th version of the Standards of Care (SOC) includes a discussion of eunuch individuals because of their unique presentation and their need for medically necessary gender-affirming care (see Chapter 2—Global Applicability, Statement 2.1).

Eunuch individuals are those assigned male at birth (AMAB) and wish to eliminate masculine physical features, masculine genitals, or genital functioning. They also include those whose testicles have been surgically removed or rendered nonfunctional by chemical or physical means and who identify as eunuch. This identity-based definition for those who embrace the term eunuch does not include others, such as men who have been treated for advanced prostate cancer and reject the designation of eunuch. We focus here on those who identify as eunuchs as part of the gender diverse umbrella.

As with other gender diverse individuals, eunuchs may also seek castration to better align their bodies with their gender identity. As such, eunuch individuals are gender nonconforming individuals who have needs requiring medically necessary gender-affirming care (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008).

Eunuch individuals identify their gender identities in various ways. Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation. The focus of this chapter is on the treatment and care for those who identify as eunuchs. Health care professionals (HCPs) will encounter eunuchs requesting hormonal interventions, castration, or both to become eunuchs. These individuals may also benefit from a eunuch community because of the identification—with or without actual castration.

While there is a 4000-year history of eunuchs in society, the greatest wealth of information about contemporary eunuch-identified people is found within the large online peer-support community that congregates on sites such as the Eunuch Archive (www.eunuch.org), which was established in 1998. The moderators of this site attempt to maintain both medical and historical accuracy in its discussion forums, although there is certainly misinformation as well. According to the website, as of January 2022, there have been over 130,000 registered members from various parts of the world and frequently over 90% of those reading the site are "guests" rather than members. The website lists over 23,000 threads and nearly 220,000 posts. For example, two threads giving instructions for self-castration by injection of different toxins directly into the testicles have about 2,500 posts each, and each has been read well over one million times. Beginning in 2001, there have been 20 annual international gatherings of the Eunuch Archive community in Minneapolis in addition to many regional gatherings elsewhere. While the topic of castration is of interest to the great majority of people who participate in the discussions, it is a minority of the membership who seriously seek or have undergone castration. Many former Eunuch Archive members have achieved their goals and no longer participate.

Because of misconceptions and prejudice about historic eunuchs, the invisibility of contemporary eunuchs, and the social stigma that affects all gender and sexual minorities, few eunuch individuals come out publicly as eunuch and many will tell no one and will share only with like-minded people in an online community or are known as such only to close family and friends (Wassersug & Lieberman, 2010). The stereotypes of eunuchs are often highly negative (Lieberman 2018), and eunuchs may suffer the same minority stress as other stigmatized groups (Wassersug & Lieberman, 2010). Research into minority stress affecting gender diverse people should therefore include eunuchs.

The current set of recommendations is directed at professionals working with individuals who identify as eunuchs (Johnson & Wassersug, 2016; Vale et al., 2010) requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs). Although not a specific diagnostic category in the ICD or DSM, eunuch is a useful construct as it speaks to the specifics of eunuch experience while also connecting it to the experience of gender incongruence more broadly. Eunuch individuals will present themselves clinically in various ways. They wish for

Statements of Recommendations

9.1- We recommend health care professionals and other users of the Standards of Care 8th guidelines should apply the recommendations in ways that meet the needs of eunuch individuals
9.2- We recommend health care professionals should consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.
9.3- We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.
9.4- We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

a body that is compatible with their eunuch identity—a body that does not have fully functional male genitalia. Some other eunuch individuals feel acute discomfort with their male genitals and need to have them removed to feel comfortable in their bodies (Johnson et al., 2007; Roberts et al., 2008). Others are indifferent to having male external genitalia as long as they are only physically present and do not function to produce androgens and male secondary sexual features (Brett et al., 2007). Hormonal means may be used to suppress the production of androgens, although orchiectomy provides a permanent solution for those not wishing genital functioning (Wibowo et al., 2016). Some eunuch individuals desire lower testosterone levels achieved with orchiectomy, but many will elect some form of hormone replacement to prevent adverse effects associated with hypogonadism. Most who elect hormone therapy choose either a full or partial replacement dose of testosterone. A smaller number elect estrogen.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 9.1.

We recommend health care professionals and other users of the Standards of Care, Version 8 guidelines should apply the recommendations in ways that meet the needs of eunuch individuals.

Eunuch individuals are part of the population of gender diverse people who experience gender incongruence and may also seek gender-affirming care. Like other transgender and gender diverse (TGD) individuals, eunuchs require access to affirming care to gain comfort with their gendered self. Each section of the SOC addresses the needs of diverse individuals, and eunuchs can be included within that group. They may have commonality with some nonbinary individuals in that social transition may not be a desired option, and hormone therapy may not play the same role as it might in a social transition or transition within the binary (Wassersug & Lieberman, 2010).

Like other gender diverse individuals, eunuch individuals may be aware of their identity in childhood or adolescence. Due to the lack of research into the treatment of children who may identify as eunuchs, we refrain from making specific suggestions.

Eunuch individuals may seek medical or surgical care (hormone suppression, orchiectomy, and, in some cases, penectomy) to achieve physical, psychological, or sexual changes (Wassersug & Johnson, 2007). It is important all patients, including both eunuchs and those seeking castration, establish and maintain a relationship with an HCP that is built upon trust and mutual understanding. Given a lack of awareness of eunuchs within the general medical community and the fear among many individuals seeking castration they will not be accepted, many do not receive appropriate primary care and screening tests (Jäggi et al., 2018). Increased awareness and education among medical providers will help address the need to be informed about the need to include eunuchs in discussions of gender diversity (Deutsch, 2016a). It goes without saying that eunuchs require and deserve the same primary care services as the general population. The topic of screening tests for cancers, such as prostate and breast, is an important area for

discussion as the risks of hormone-related cancers are likely different among male-assigned people whose testosterone and estrogen levels are not in the male range. Due to a lack of studies looking at the prevalence and incidence of hormone-related cancers in the eunuch population, there is no evidence to guide how often to screen for hormone-related cancers with prostate exams, PSA measurements, mammograms, etcetera.

The large literature on prostate cancer patients who have been medically or surgically castrated provides information about some of the effects of post-pubertal castration (such as potential osteoporosis, depression, or metabolic syndrome), but voluntary eunuchs may interpret the results very differently from those castrated for medical reasons. Chemical or surgical castration may be experienced as a source of distress to cis men with prostate cancer, while the same treatment may be affirming and a source of comfort for eunuch individuals. Similarly, transmasculine people who have a mastectomy to gain comfort with their bodies experience that surgery differently from ciswomen who undergo mastectomy to treat breast cancer (Koçan & Gürsoy, 2016; van de Grift et al., 2016). The prostate cancer information is well summarized by Wassersug et al. (2021) who provide references that explore the large literature on the subject. Such information on the effects of castration should be made available to those seeking castration.

Following an assessment as per the SOC-8, medical options requested by the patient can be considered and prescribed, if appropriate. These options can be tailored to the individual to create a plan that reflects their specific needs and preferences. The number and type of interventions applied and the order in which these take place may differ from person to person. These options are consistent with both the assessment and surgery chapters of the SOC-8. Treatment options for eunuchs to consider include:

- Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual, or androgynous;
- Orchiectomy to stop testicular production of testosterone;
- Orchiectomy with or without penectomy to alter their body to match their self-image;
- Orchiectomy followed by hormone replacement with testosterone or estrogen.

Per statement 5.6 in Chapter 5—Assessment of Adults, eunuch individuals seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

Statement 9.2.

We recommend health care professionals consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.

The same assessment process recommended in the SOC-8 ought to apply to eunuchs (see Chapter 5—Assessment of Adults). The Eunuch Archive has a large number of posts from individuals finding great difficulty in seeking medical providers who will perform castration surgery. There are a large number of eunuch individuals who have performed self-surgery or have had surgery performed by people who are not credentialed medical providers (Johnson & Irwig, 2014). There are also clinical reports of eunuch individuals who have self-castrated and accounts of patients who have misled medical providers to obtain castration (Hermann & Thorstenson, 2015; Mukhopadhyay & Chowdhury, 2009). There is no doubt when members of this population are denied access to quality medical treatment, they will take actions that may cause them great harm, such as bleeding and infection that may require hospital admission (Hay, 2021; Jackowich et al., 2014; Johnson & Irwig, 2014). Because of these serious problems and harm caused through self-surgery, surgery by unqualified practitioners or the unsupervised use of medications that affect hormones, it is important health care providers create a welcoming environment and consider various treatment options after careful assessment

to avoid the problems that lack of access to treatment and withholding treatment will cause.

When desired, castration can be achieved either chemically or surgically. For some, chemical castration can be an appropriate trial prior to undergoing surgical castration to determine how the individual feels when hypogonadal (Vale et al., 2010). Chemical castration is usually reversible if the medications are discontinued (Wassersug et al., 2021). The most common types of medications used to lower testosterone levels are antiandrogens and estrogen.

The two most commonly used antiandrogens, cyproterone acetate and spironolactone, are oral. Estrogen is sometimes prescribed for prostate cancer patients to lower serum testosterone levels via negative feedback at the hypothalamus and pituitary gland. Estrogens and antiandrogens may not fully suppress testosterone levels into the female or castrate range, and oral estrogens increase the risk of venous thromboembolism. Although not commonly used due to cost, gonadotropin releasing hormone (GnRH) agonists are a very effective method for suppressing the production of sex steroids and fertility (Hembree et al., 2017). When selecting a medication, we advise using those which have been studied in multiple transgender populations (i.e., estrogen, cyproterone acetate, GnRH agonists) rather than medications with little to no peer-reviewed scientific studies (i.e., bicalutamide, rectal progesterone, etc.) (Angus et al., 2021; Butler et al., 2017; Efstathiou et al., 2019; Tosun et al., 2019).

Many eunuch individuals pursue hormone replacement therapy following castration as they do not desire the complete suppression of hormone levels and consequent problems, such as the increased risk of osteoporosis. The two main options for replacement of sex steroids are testosterone and estrogen that may be used in full or partial replacement doses. The majority elect testosterone as they present as male and are not interested in feminization. A minority elect estrogen at a high enough dose to prevent osteoporosis, but low enough avoid most feminization. They may identify as nonbinary, agender, or other (Johnson et al., 2007; Johnson & Wassersug, 2016).

Although studies on hormone replacement therapy in eunuchs are lacking, findings from cisgender men treated for prostate cancer can be informative regarding the effects of hormone therapy. In a randomized controlled trial of 1,694 cisgender men treated for locally advanced or metastatic prostate cancer, one group received a GnRH agonist and the other received transdermal estrogen (Langley et al., 2021). Cisgender men who received the GnRH agonist developed signs and symptoms of both androgen and estrogen deficiency, whereas men who received the estrogen patch only developed androgen-depleting symptoms. Both groups had high rates of sexual side effects (91%), and weight gain was similar among the groups. Compared with cisgender men receiving the GnRH agonist, cisgender men treated with estrogen patches had a higher self-reported quality of life, lower rates of hot flushes (35% vs. 86%), and higher rates of gynecomastia (86% vs. 38%). Metabolically, cisgender men receiving estrogen patches had favorable changes with a lower mean fasting glucose, fasting total cholesterol, systolic and diastolic blood pressure. Conversely, cisgender men receiving the GnRH agonist experienced the opposite effects. Based on this study, eunuchs may consider a low dose of transdermal estrogen therapy to avoid adverse estrogen-depleting effects, which include hot flashes, fatigue, metabolic effects, and loss of bone mineral density (Hembree et al., 2017; Langley et al., 2021). For further information see Chapter 12—Hormone Therapy.

Statement 9.3.

We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.

A frequent topic on the discussion boards of the Eunuch Archive is the difficulty of finding practitioners who are able to understand their needs. Eunuchs and those seeking castration usually are less visible than other gender minorities (Wassersug & Lieberman, 2010). Due to stigma and fear of rejection by the medical community, they may not voluntarily disclose their identity and desires to their medical or mental health providers. In some environments, medical providers may not be aware eunuchs exist and may not even know they have treated eunuch-identified patients.

The SOC section on assessment is applicable to eunuch individuals. Like other gender diverse individuals, those seeking castration can engage in an informed consent process in which qualified providers conduct assessments to ensure individuals are capable of providing informed consent prior to medical interventions and to ensure a mental health problem is not the etiology of the desire. As with other sexual and gender minorities, working with eunuchs requires an understanding that they are a diverse population, and that each person is eunuch in their own way (Johnson et al., 2007). The person seeking services benefits from the professional's accepting stance, open inquiry, suspension of judgment, and flexible expectations, combined with professional competency and expertise.

To provide appropriate treatment, providers must establish trust and respect by creating an inclusive environment for eunuch-identified people. For eunuch-identified individuals, the ideal intake form would ask the assigned sex and identified gender and offer multiple gender options, including "eunuch" and "other." Individuals may identify with more than one option and should be able to select more than one.

HCPs may be involved in the assessment, psychotherapy (if desired), preparation, and follow-up for medical and surgical gender-affirming interventions. They may also provide support for partners and families. Eunuch-identified individuals who want the support of a qualified mental health provider will benefit from a therapist who meets the experience and criteria set out in Chapter 4—Education.

While some individuals seeking or considering castration come to counseling or therapy because they want emotional support or help with decision-making, many come to providers for an assessment in preparation for specific medical interventions (Vale et al., 2010).

Statement 9.4.

We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

Several research studies have contributed to our knowledge of contemporary eunuch-identified people and have explored demographic characteristics and sexuality (Handy et al., 2015; Vale et al., 2013; Wibowo et al., 2012, 2016). Medical and MHPs should assume eunuchs are sexual people capable of sexual activity, pleasure, and relationships, unless they report otherwise (Wibowo et al., 2021). Research has shown there is great diversity among eunuchs regarding the level of desire, type of preferred physical or sexual contact, and nature of preferred relationships (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008). While some enjoy active sex lives with or without romantic relationships, others identify as asexual or aromantic and are relieved by the loss of libido achieved through surgical or chemical castration (Brett et al., 2007). Each person is different, and one's genital status does not determine sexual or romantic attraction (Walton et al., 2016; Yule et al., 2015).

Regardless of the type of chemical suppression or surgery a person has undergone, they may be capable of sexual pleasure and sexual activity. Contrary to popular belief, eunuchs are not necessarily asexual or nonsexual (Aucoin & Wassersug, 2006). Safe sex education is necessary for all people who engage in sexual activity that could involve an exchange of body fluids. See Chapter 17—Sexual Health for information regarding sex education and safe sex options for people with diverse genders and sexualities. In addition, fertility preservation should be discussed when considering medical interventions that might impact the possibilities for future parenthood. For more considerations see Chapter 16—Reproductive Health.

CHAPTER 10 Intersex

The Standards of Care, Version 7 included a chapter on the applicability of the standards to people with physical intersexuality who become gender-dysphoric and/or change their gender because they differ from transgender individuals without intersexuality in phenomenological presentation, life trajectories, prevalence, etiology, and stigma risks. The current chapter provides an update and adds recommendations on the medically necessary clinical approach to the management of individuals with intersexuality in general (see medical necessity statement in Chapter 2—Global Applicability, Statement 2.1). Because a newborn with an atypical sexual differentiation may already present with clinical challenges, including the need for family education and support from early on, the decision-making on gender assignment, subsequent clinical gender management, components of which—especially genital surgery—may be controversial, and a later risk of gender dysphoria development and gender change that is markedly increased (Sandberg & Gardner, 2022).

Terminology

"Intersex" (from Latin, literal translation "between the sexes") is a term grounded in the binary system of sex underlying mammalian (including human) reproduction. In medicine, the term is colloquially applied to individuals with markedly atypical, congenital variations in the reproductive tract. Some variations, often labeled "genital ambiguity," preclude the simple recognition of somatic sex as male or female and, in resource-rich societies, may require a comprehensive physical, endocrine, and genetic work-up, before a sex/gender is "assigned." In recent years "intersex" has also become an identity label adopted by some individuals with intersex conditions and a subset of (non-intersex) individuals with a non-binary gender identity (Tamar-Mattis et al., 2018).

At a 2005 international consensus conference on intersex management, intersex conditions were subsumed under a new standard medical term, "Disorders of Sex Development" (DSD), defined as "congenital conditions in which development of chromosomal, gonadal, or anatomical sex is atypical" (Hughes et al., 2006). DSD covers a much wider range of conditions than those traditionally included under intersexuality and comprises conditions such as Turner syndrome and Klinefelter syndrome, which are much more prevalent. In addition, many affected individuals dislike the term "disorder," viewing it as inherently stigmatizing (Carpenter, 2018; Griffiths, 2018; Johnson et al., 2017; Lin-Su, et al., 2015; Lundberg et al., 2018; Tiryaki et al., 2018). Health care professionals (HCPs) also vary in their acceptance of the term (Miller et al., 2018). The wide-spread alternative reading of DSD as "Differences in Sex Development" can be seen as less pathologizing, but is semantically unsatisfactory as this term does not distinguish the typical genital differences between males and females from atypical sexual differentiation. Other recent attempts to come up with less obviously stigmatizing terms such as "Conditions Affecting Reproductive Development" (CARD; Delimata et al., 2018) or "Variations of/in Sex Characteristics" (VSC; Crocetti, et al., 2021) are also not specific to intersexuality.

Given these definitional issues, in this chapter we are using the term "intersexuality" (or "intersex") to refer to congenital physical manifestations only. This is done for both descriptive clarity and historical continuity. This choice is not meant to indicate an intention on our part to take sides in the ongoing discussion regarding the concept of sex/gender as a bipolar system or as a continuum, which may vary with considerations of context and utility (Meyer-Bahlburg, 2019). In 21st century societies, the concepts of sex and gender are in a process of evolution.

Prevalence

The prevalence of intersex conditions depends on the definition used. Obvious genital atypicality ("ambiguous genitalia") occurs with an estimated frequency ranging from approximately 1:2000—1:4500 people (Hughes et al., 2007). The most inclusive definitions of DSD estimate a prevalence of up to 1.7% (Blackless et al., 2000). Although these numbers are high in aggregate, the individual conditions associated with the intersex variations tend to be much rarer. For instance, androgen insensitivity syndrome (AIS) occurs in approximately 1 in 100,000 46,XY births (Mendoza & Motos, 2013), and classic congenital adrenal

hyperplasia (CAH) in approximately 1 in 15,000 46,XX births (Therrell, 2001). Prevalence figures for individual syndromes may vary dramatically between countries and ethnic groups.

Presentation

The presentation of individuals with intersex traits varies widely. Intersexuality can be recognized during prenatal ultrasound imaging, although most individuals will be identified during genital examinations at birth. In resource-rich societies, such children will undergo extensive medical diagnostic procedures within the first weeks of life. Taking into consideration the specific medical diagnosis, physical and hormonal findings, and information from long-term follow-up studies about gender outcome, joint decision-making between the health-care team and the parents generally leads to the newborn being assigned to the male or female sex/gender. Some individuals with intersexuality come to the attention of specialists only around the age of puberty, for instance, when female-raised adolescents are evaluated for primary amenorrhea.

HCPs assisting individuals with both intersexuality and gender uncertainty need to be aware that the medical context in which such individuals have grown up is typically very different from that of non-intersex TGD people. There are many different syndromes of intersexuality, and each syndrome can vary in its degree of severity. Thus, hormonal and surgical treatment approaches vary accordingly.

Some physical manifestations of intersexuality may require early urgent intervention, as in cases of urinary obstruction or of adrenal crisis in CAH. Most physical variations among individuals with intersexuality neither impair function, at least in the early years, nor risk safety for the individual. Yet, the psychosocial stigma associated with atypical genital appearance often motivates early genital surgery (commonly labeled 'corrective' or 'normalizing') long before the individual reaches the age of consent. This approach is highly controversial because it conflicts with ethical principles supporting a person's autonomy (Carpenter, 2021; Kon, 2015; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). In addition, among the manifestations without immediate safety concerns, some individuals, when older, may opt for a range of medical interventions to optimize function and appearance. The specifics of medical treatments are far beyond the scope of what can be addressed in this chapter, and the interested reader should consult the respective endocrine and surgical literature.

Some intersex conditions are associated with a greater variability in long-term gender identity outcome than others (Dessens et al., 2005). For instance, the incidence of a non-cisgender gender identity in 46,XX individuals with CAH assigned female may be as high as 5–10% (Furtado et al., 2012). The substantial biological component underlying gender identity is a critical factor that must be considered when offering psychosocial, medical, and surgical interventions for individuals with intersex conditions.

There is also ample evidence people with intersexuality and their families may experience psychosocial distress (de Vries et al., 2019; Rosenwohl-Mack et al., 2020; Wolfe-Christensen et al., 2017), in part related to psychosocial stigma (Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg, Reyes-Portillo et al., 2017; Meyer-Bahlburg et al., 2018).

Intersexuality in the psychiatric nomenclature

Since 1980, the American psychiatric nomenclature recognized individuals with intersexuality who meet the criteria for gender identity variants; however, their diagnostic categorization changed with successive DSM editions. For instance, in DSM-III (American Psychiatric Association, 1980), the Axis-I category of "transsexualism" could not be applied to such individuals in adulthood, but such children were labeled "gender identity disorder of childhood," with the medical intersex condition to be specified in Axis III. In DSM-IV-TR (American Psychiatric Association, 2000), individuals with intersexuality were excluded from the Axis-I category of "gender identity disorder" regardless of age and, instead, grouped with other conditions under the category "gender identity disorder not otherwise specified." In DSM-5 (American Psychiatric Association, 2013), which moved away from the multiaxial

Statements of Recommendations

10.1- We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.
10.2- We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.
10.3- We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.
10.4- We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.
10.5- We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.
10.6- We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.
10.7- We suggest health care professionals refer children/individuals with intersexuality and their families to mental-health providers as well as peer and other psychosocial supports as indicated.
10.8- We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.
10.9- We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.
10.10- We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.
10.11- We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.
10.12- We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

system, "gender identity disorder" was re-defined as "gender dysphoria" and applied regardless of age and intersex status, but individuals with intersexuality received the added specification "with a disorder of sex development" (Zucker et al., 2013). The just published text revision of DSM-5 (American Psychiatric Association, 2022) keeps the term gender dysphoria. Note, however, the recent revision of the International Classification of Diseases [ICD-11; World Health Organization, 2019a] has moved "gender incongruence" from the chapter "Mental, Behavioral, or Neurodevelopmental Disorders" to a new chapter "Conditions Related to Sexual Health."

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 10.1

We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.

Intersexuality, a subcategory of DSD, is a complex congenital condition that requires the involvement of experts from various medical and behavioral disciplines (Hughes et al., 2006). Team composition and function can vary depending on team location, local resources, diagnosis, and the needs of the individual with intersexuality and her/his/their family. The ideal team includes pediatric subspecialists in endocrinology, surgery and/or urology, psychology/psychiatry, gynecology, genetics, and, if available, personnel trained in social work, nursing, and medical ethics (Lee et al., 2006). The structure of the team can be in line with 1) the traditional multidisciplinary medical model; 2) the interprofessional model; or 3) the transdisciplinary model. Although these structures can appear similar, they are in fact very different and can exert varying influences on how the team functions (Sandberg & Mazur, 2014). The 2006 Consensus Statement makes no decision about which model is best—multidisciplinary, interdisciplinary, or transdisciplinary—and only states the models "imply different degrees of collaboration and professional

autonomy" (Lee, Nordenström et al., 2016). Since the publication of the Consensus Statement in 2006, such teams have been created both in Europe and in the US. A listing of teams in the US can be found on the DSD-Translational Network (DSD-TRN) website. There are also teams in a number of European countries (Thyen et al., 2018). While there are barriers to the creation of teams as noted by Sandberg and Mazur (2014), multidisciplinary teams help address a number of problems that have undermined the successful care of individuals with an intersex diagnosis and their families, such as the scattered nature of services, the limited or absent communication between professionals, and the resulting fragmented nature of the explanations individuals receive that cause more confusion than clarity.

Most individuals born with intersexuality will be identified at birth or shortly thereafter, while others will be identified at later times in the life cycle, for example at puberty (see Brain et al., 2010, Table 1). When this happens the team approach will be modified based on the diagnosis and the age of the person. In some circumstances, the composition of the team can be expanded to include other specialists as needed.

It has been reported children seen by a multidisciplinary team were significantly more likely to receive nearly the full range of services rather than only those services offered by a single provider (Crerand et al., 2019). Parents who received such care positively endorsed psychosocial services and the team approach and reported receiving more information than those who did not interact with such a team (Crerand et al., 2019).

Statement 10.2

We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.

Results from interviews with medical trainees (Liang et al., 2017; Zelin et al., 2018) and from programmatic self-audits and surveys (DeVita et al., 2018; Khalili et al., 2015) suggest medical training programs are not adequately preparing practitioners to provide competent care to individuals presenting with gender dysphoria and intersexuality. Professional and stakeholder attendees of intersex-specific events have identified ongoing education and collaboration as an important professional development need (Bertalan et al., 2018; Mazur et al., 2007). This may be especially true for adult care providers who may have less clinical guidance or support in assisting those individuals who are transitioning from pediatric to adult care (Crouch & Creighton, 2014).

However, there are few guidelines for training or assessing practitioner competency in managing these topics, and those that are available primarily apply to mental health professionals (MHPs) (Hollenbach et al., 2014), with the exception of a primary care guide (National LGBTQIA + Health Education Center, 2020).

For HCPs wanting to improve their competency, seeking consultation from experts may be an option when formal education or empirical guidelines are otherwise unavailable. Given the relative widespread adoption of multidisciplinary expert teams in the treatment of intersexuality (Pasterski et al., 2010), individuals serving on these teams are well positioned to consult with and educate other health care staff who may not have received adequate training (Hughes et al., 2006). Therefore, it is recommended the training of other professionals be a central component of team development (Auchus et al., 2010) and members of multidisciplinary teams receive training specific to team-based work, including strategies for engaging in interprofessional learning (Bisbey, et al., 2019; Interprofessional Education Collaborative Expert Panel, 2011).

Statement 10.3

We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.

Full disclosure of medical information to families of children with intersex conditions through education and counseling should begin at the time of diagnosis and should be consistent with guidance from multiple international consensus guidelines. One of the most challenging issues presented by a newborn with intersexuality, particularly

when associated with noticeable genital ambiguity, is sex assignment and from the parents' perspective, the gender of rearing (Fisher, Ristori et al., 2016). Given this is a very stressful situation for most parents, it is generally recommended the decisions about sex/gender should be made as quickly as a thorough diagnostic evaluation permits (Houk & Lee, 2010). However, the criteria for sex/gender decisions have changed over time. In the second half of the 20th century, the decisions were biased towards female assignment, because feminizing genital surgery was seen as easier and less side-effect prone than masculinizing surgery. Yet, in certain intersex conditions, for instance 46,XY 5α-RD-2 deficiency, female sex/gender assignment was found to be associated with high rates of later gender dysphoria and gender change (Yang et al., 2010). Therefore, since the International Consensus Conference on Intersex Management in 2005, sex/gender assignment takes into consideration the gradually accumulating data on long-term gender outcome in the diverse conditions of intersexuality.

The practice of disclosure seeks to enable more fully informed decision-making about care. Additionally, while shame and stigma surrounding intersexuality is associated with poorer psychosocial outcomes, open and proactive communication of health information has been proposed as a strategy to reduce those risks (de Vries et al., 2019). Depending on the person's diagnosis and developmental stage, intersex conditions may differentially impact individuals and their health care needs. Intersex-health-related communication must therefore be continuous and tailored to the individual. Research on decision-making in intersex care suggests families are influenced by how clinical teams communicate (Timmermans et al., 2018). In keeping with the SOC, we encourage providers to adopt normalizing, affirming language and attitudes across education and counseling functions. For example, describing genital atypia as a "variation" or "difference" is more affirming than using the terms "birth defect" or "abnormality."

All HCPs involved in an individual's care can provide essential education and information to families. In multidisciplinary teams, the type of education may align with an HCP's area of expertise, for example, a surgeon educating the individual on their anatomy, an endocrinologist teaching the specifics of hormonal development, or an MHP conveying the spectrums of gender and sexual identity. Other HCPs may need to provide comprehensive education. Families should receive information that is pertinent to the individual's specific intersex variation, when known. All HCPs can supplement this information with patient-centered resources available from support groups. People with intersexuality have also been hired as team members to provide education using their lived experience.

Consensus guidelines also recommend families be offered ongoing peer and professional psychosocial support (Hughes et al., 2006) that may involve counseling with a focus on problem-solving and anticipatory guidance (Hughes et al., 2006). For example, families may seek guidance in educating other people—siblings, extended family, and caregivers—about the specific intersex condition of an individual. Other families may need support or mental health care to manage the stress of intersex treatment. Adolescents may benefit from guidance on how to disclose information to peers as well as from support when navigating dating and sex. Providing counseling may also involve guiding families and individuals of all ages through a shared decision-making process around medical or surgical care. Providers may employ decision aids to support this process (Sandberg et al., 2019; Weidler et al., 2019).

Statement 10.4

We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.

Communicating health information is a multi-directional process that includes the transfer of information from providers to patients, from parents to patients, as well as from patients back to their providers (Weidler & Peterson, 2019). While much emphasis has been placed on communicating to parents around issues of diagnosis and surgical decision-making, youth with DSD have reported barriers to engaging with health care providers and may not always turn

to their parents for support (Callens et al., 2021). To prepare individuals to be fully engaged and autonomous in their treatment, it is critical both providers and parents communicate continuously with children/individuals.

Providers must set an expectation as soon as possible for ongoing, open communication between all parties, especially since parents may experience distress due to the uncertainty associated with DSD and may seek quick fixes (Crissman et al., 2011; Roberts et al., 2020). Models of shared decision-making as well as related decisional tools have been developed to support ongoing communication between HCPs and families/individuals (Karkazis et al., 2010; Sandberg et al., 2019; Siminoff & Sandberg, 2015; Weidler et al., 2019). In addition to setting an expectation for dialogue, providers can also set the tone of communication. Providers can help parents and individuals tolerate diagnostic uncertainty while simultaneously providing education on anatomic variations, modeling openness to gender and sexual identity, and welcoming the child's/individual's questions. As they age, children/individuals may have questions or need age-appropriate information on issues of sex, menstruation, fertility, the need for hormone treatment (adrenal/sex), bone health, and cancer risk.

Parents also play a critical role in educating their children and may be the first people to disclose health information to their child (Callens et al., 2021). As part of expectation-setting around communication, providers should prepare parents to educate their child and members of their support system about the intersex diagnosis and treatment history. Some parents report difficulties in knowing how much to disclose to others as well as to their own children (Crissman et al., 2011; Danon & Kramer, 2017). The stress parents experience while raising children with an intersex condition is increased when parents adopt an approach that minimizes disclosure/discussion of their child's diagnosis (Crissman et al., 2011). The level of stress also varies by developmental stage, with parents of adolescents reporting higher rates of stress (Hullman et al., 2011). Therefore, HCPs should assist parents in developing strategies specific to their child's developmental stage that address their psychosocial or cultural concerns and values (Danon & Kramer, 2017; Weidler & Peterson, 2019). Finally, broader research on sexuality and gender variance has found—counter to the associations between shame/stigma and negative health outcomes—supportive family behaviors (including talking with children about their identity and connecting them with peers) predicted greater self-esteem and better health outcomes in individuals (Ryan et al., 2010).

Statement 10.5

We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.

Psychological, social, and cultural constructs all intersect with biological factors to form an individual's gender identity. As a group, individuals with intersexuality show increased rates of gender nonconforming behavior, gender-questioning, and cross-gender wishes in childhood, dependent in part on the discrepancy between the prenatal sex-hormonal milieu in which the fetal brain has differentiated and the sex assigned at birth (Callens et al., 2016; Hines, et al., 2015; Meyer-Bahlburg et al., 2016; Pasterski et al., 2015). Gender identity problems are observed at different rates in individuals with different intersex conditions (de Vries et al., 2007). More recently, some individuals have been documented to develop a nonbinary identity, at least privately (Kreukels et al., 2018). Although the majority of people with intersexuality may not experience gender dysphoria or wishes for gender transition, they may still have feelings of uncertainty and unanswered questions regarding their gender (Kreukels et al., 2018). Questions about gender identity may arise from such factors as genital appearance, pubertal development, and knowledge of items such as the diagnostic term of the medical condition, gonadal status, sex chromosome status, and a history of genital surgery. Therefore, HCPs need to be accessible for clients to discuss such questions and feelings, openly converse about gender diversity, and adopt a less binary approach to gender. HCPs are advised to guide parents as well in supporting their children in exploring gender.

Furthermore, such support should not be confined to the childhood years. Rather, individuals should be given the opportunity to explore their gender identity throughout their lifetime, because different phases may come with new questions regarding gender (for example, puberty/adolescence, childbearing age). Children in general may have questions regarding their gender identity at salient points during their maturation and evolution. When faced with additional stressors, for example, genital ambiguity, genital examinations and procedures, as well as the intersectionality of cultural bias and influences, individuals with intersexuality may need support and should be encouraged to seek educated professional assistance and guidance when needed. Also, HCPs should inquire regularly to determine if their clients with intersexuality need such support. When people experience gender incongruence, gender-affirming interventions may be considered. Procedures that should be applied in such interventions are described in other chapters.

Statement 10.6

We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.

Individuals with intersexuality are reported to experience stigma, feelings of shame, guilt, anger, sadness and depression (Carroll et al., 2020; Joseph et al., 2017; Schützmann et al., 2009). Higher levels of psychological problems are observed in this population than in the general population (Liao & Simmonds, 2014; de Vries et al., 2019). In addition, parental fear of stigmatization and adjustment to their child's diagnosis must not be overlooked by the clinical team. Parents may benefit from supportive counseling to assist them both in managing clinical decision-making (Fleming et al., 2017; Rolston et al., 2015; Timmermans et al., 2019) as well as understanding the impact of clinical decisions on their view of their child (Crissman et al., 2011; Fedele et al., 2010).

Thyen et al. (2005) found repeated genital examinations appear to be correlated with shame, fear and pain and may increase the likelihood of developing post-traumatic stress disorder (PTSD) later in life (Alexander et al., 1997; Money & Lamacz, 1987). Exposure to repeated genital examinations, fear of medical interventions, and parental and physician secrecy about being intersex ultimately undermine the self-empowerment and self-esteem of the person with intersexuality (Meyer-Bahlburg et al., 2018; Thyen et al., 2005; Tishelman et al., 2017; van de Grift, Cohen-Kettenis et al., 2018). For recommendations on how to conduct genital examinations to minimize adverse psychological side effects see Tishelman et al. (2017).

There is an active movement within the intersex community to alleviate stigma and to return human rights and dignity to intersex people rather than viewing them as medical anomalies and curiosities (Yogyakarta Principles, 2007, 2017). Chase (2003) summarizes the major reasons for the intersex advocacy movement and outlines how stigma and emotional trauma are the outcome of ignorance and the perceived need for secrecy. Public awareness of intersex conditions is very limited, and images and histories of individuals with intersexuality are still presented as "abnormalities of nature". We, therefore, advise HCPs to actively educate their colleagues, individuals with intersexuality, their families, and communities, raise public awareness, and increase knowledge about intersexuality. Societal awareness and knowledge regarding intersexuality may help reduce discrimination and stigmatization. Tools and education/information materials may also help individuals with intersexuality disclose their condition, if desired (Ernst et al., 2016).

HCPs should be able to recognize and address stigmatization in their clients (Meyer-Bahlburg et al., 2018) and should encourage people with intersexuality of various ages to connect via support groups. There is a need for developing specific techniques/methods for assisting clients to cope with stigma related to intersex.

Statement 10.7

We suggest health care professionals refer children/individuals with intersexuality and their families to mental health professionals as well as peer and other psychosocial supports as indicated.

For almost all parents, the birth of a child with intersexuality is entirely unexpected and comes as a shock. Their inability to respond immediately to the ubiquitous question, "Is your baby a boy or a girl?", their lack of knowledge about the child's condition, the uncertainty regarding the child's future, and the pervasive intersex stigma are likely to cause distress, sometimes to the level of PTSD and may lead to prolonged anxiety and depression (Pasterski et al., 2014; Roberts et al., 2020; Wisniewski & Sandberg, 2015). This situation may affect parental care and long-term outcome of their child with intersexuality (Schweizer et al., 2017). As these children grow up, they are also at risk of experiencing intersex stigma in its three major forms (enacted, anticipated, internalized) in all spheres of life (Meyer-Bahlburg et al., 2018), along with other potential difficulties such as body image problems, gender-atypical behavior, and gender identity questioning. Many may face the additional challenge presented by the awareness of the incongruence between their assigned gender and biological characteristics such as sexual karyotype, gonads, past and/or current sex-hormonal milieu, and reproductive tract configuration. This situation may also adversely affect the individuals' mental health (Godfrey, 2021; Meyer-Bahlburg, 2022). A recent online study of a very large sample of LGBTQ youth indicated that LGBTQ youth who categorized themselves as having a physical intersex variation had a rate of mental health problems that was higher than the rate in LGBTQ youth without intersexuality (Trevor Project, 2021). As intersex conditions are rare, parents of such children and later the individuals themselves may experience their situation as unique and very difficult for others to understand. Thus, based on clinical experience, there is a consensus among HCPs who are experienced in intersex care, that social support is a crucial component of intersex care, not only through professional support by MHPs (Pasterski et al., 2010), but also, importantly, through support groups of individuals with intersex conditions (Baratz et al., 2014; Cull & Simmonds, 2010; Hughes et al., 2006; Lampalzer et al., 2021). A detailed international listing of DSD and intersex peer support and advocacy groups with their websites has been provided by Lee, Nordenström et al. (2016). Given the heterogeneity of intersex conditions and treatment regimens, an individual with intersexuality may find it most helpful to associate with a support group that includes members with the same or similar condition as that of the individual. It is important HCPs specializing in intersex care also collaborate closely with such support groups so that occasional differences in opinions regarding specific aspects of care can be resolved through detailed discussions. Close contacts between HCPs and support groups also facilitate community-based participatory research that benefits both sides.

Statement 10.8

We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.

While many people with intersexuality have a gender identity in line with their XX or XY karyotype, there is sufficient heterogeneity that HCPs should be able to provide customized approaches. For example, among XX individuals with virilizing CAH, a larger than expected minority have a male gender identity (Dessens et al., 2005). Among XY individuals with partial androgen insensitivity syndrome, gender identity can vary significantly (Babu & Shah, 2021). Furthermore, among XY individuals with 5α-reductase-2 (5α-RD-2) deficiency and with 17-beta-hydroxysteroid dehydrogenase-3 deficiency who are assigned the female sex at birth, a large fraction (56–63% and 39–64%, respectively) change from a typical female gender role to a typical male gender role as they age (Cohen-Kettenis, 2005).

People with intersexuality have a wide range of medical options open to them depending on their gender identity and its alignment with anatomy. These options include puberty suppression medication, hormonal treatment, and surgeries, all customized to the unique circumstances of the individual (Weinand & Safer, 2015; Safer & Tangpricha, 2019) (for further information see Chapter 6—Adolescents and Chapter 12—Hormone Therapy). Specifically, when functional gonads are present, puberty may be temporarily suspended by using gonadotropin-releasing hormone (GnRH) analogues. Such intervention can

facilitate the necessary passage of time needed by the individual to explore gender identity and to actively participate in sex designation, especially for conditions in which sex role change is common (i.e., in female-raised individuals with 5α-RD-2 deficiency; Cocchetti, Ristori, Mazzoli et al., 2020; Fisher, Castellini et al., 2016).

HCPs can counsel individuals and their families directly if the providers have sufficient expertise and can leverage expertise needed to determine both a course of treatment appropriate for the individual and the logistics involved in implementing the chosen therapeutic option.

Statement 10.9

We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.

International human rights organizations have increasingly expressed their concerns that surgeries performed before a child can participate meaningfully in decision-making may endanger the child's human rights to autonomy, self-determination, and an open future (e.g., Human Rights Watch, 2017). Numerous medical and intersex advocacy organizations as well as several countries have joined these international human rights groups in recommending the delay of surgery when medically feasible (Dalke et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). However, it is important to note some anatomic variations, such as obstruction of urinary flow or exposure of pelvic organs, pose an imminent risk to physical health (Mouriquand et al., 2016). Others, such as menstrual obstruction or long-term malignancy risk in undescended testes, have eventual physical consequences. A third group of variations, i.e., variations in the appearance of external genitals or vaginal depth, pose no immediate or long-term physical risk. The above recommendation addresses only those anatomic variations that, if left untreated, have no immediate adverse physical consequences and where delaying surgical treatment poses no physical health risk.

Non-urgent surgical care for individuals with these variations is complex and often contested, particularly when an individual is an infant or a young child and cannot yet participate in the decision-making process. Older people with intersexuality have reported psychosocial and sexual health problems, including depression, anxiety, and sexual and social stigma (de Vries et al., 2019; Rosenwohl-Mack et al., 2020). Some studies have suggested individuals with a specific variation (e.g., 46,XX CAH) agree with surgery being performed before adolescence (Bennecke et al., 2021). Recent studies suggest some adolescents and adults are satisfied with the appearance and function of the genitals after childhood surgery (Rapp et al., 2021). A child's genital difference can also become a source of stress for parents, and there is research that reports a correlation of surgery to create binary genitals with a limited amount of reduction in parental distress (Wolfe-Christensen et al., 2017), although a minority of parents may report decisional regret (Ellens et al., 2017). Consequently, some organizations recommend surgery be offered to very young children (American Urological Association, 2019; Pediatric Endocrine Society, 2020).

This shows the division within the medical field regarding its management guidelines for early genital surgery. The authors of this chapter also did not reach complete consensus. Some intersex specialists consider it potentially harmful to insist on a universal deferral of early genital surgery for genital variations without immediate medical risks. Reasons supporting this view include 1) intersex conditions are highly heterogeneous with respect to type and severity as well as associated gonadal structure, function, and malignancy risk; 2) societies and families vary tremendously in gender norms and intersex stigma potential; 3) early surgery may present certain technical advantages; and 4) a review of surveys of individuals with intersexuality (most of whom had previously undergone genital surgery) show the majority endorse surgery before the age of consent, especially in the case of individuals with 46,XX CAH and less strongly for individuals with XY intersex conditions (Meyer-Bahlburg, 2022). Experts supporting this view call for an individualized approach to

decisions regarding genital surgery and its timing. This approach has been adopted by medical societies with high rates of intersex specialists (Bangalore Krishna et al., 2021; Pediatric Endocrine Society, 2020; Speiser et al., 2018; Stark et al., 2019) and by certain support organizations (CARES Foundation; Krege et al., 2019).

Nonetheless, long-term outcome studies are limited and most studies reporting positive outcomes lack a non-surgical comparison group (Dalke, et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). There is also no evidence surgery protects children with intersex conditions from stigma (Roen, 2019). Adults with intersexuality do experience stigma, depression, and anxiety related to their genitalia, but can also experience stigma whether or not they have surgery (Ediati et al., 2017; Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg et al., 2018). There is also evidence surgeries may lead to significant cosmetic, urinary, and sexual complications extending into adulthood (Gong & Cheng, 2017; National Academies of Sciences, Engineering, and Medicine, 2020). Recent studies suggest some groups of individuals may have particularly negative experiences with gonadectomy, although this risk has to be weighed against that of gonadal malignancy (Duranteau et al., 2020; Rapp et al., 2021). People with intersex conditions are also far more likely than the general population to be transgender, to be gender diverse, or to have gender dysphoria (Almasri et al., 2018; Pasterski et al., 2015). Genital surgeries of young children may therefore irreversibly reinforce a binary sex assignment that is not aligned with the persons' future. These findings, together with human rights perspectives, support the call for the delay in the decision for surgery until the individual can decide for him/her/themselves.

Systematic long-term follow-up studies are urgently needed to compare individuals with the same intersex conditions who differ in the age at surgery or have had no surgery with regard to gender identity, mental health, and general quality of life.

Statement 10.10

We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.

Intersex conditions are rare, and intersex genital and gonadal anatomy are heterogeneous. Surgeries have been associated with a risk of significant long-term complications (e.g., National Academies of Sciences, Engineering, and Medicine, 2020), and most surgical training programs do not prepare trainees to provide this specialized care (Grimstad, Kremen et al., 2021). In recognition of the complexity of surgical care across the lifespan, standards produced by expert and international consensus recommend this care be provided by multidisciplinary teams of experts (Krege et al, 2019; Lee, Nordenström et al., 2016; Pediatric Endocrine Society, 2020). Therefore, we advise surgical care be limited to intersex-specialized, multidisciplinary settings that include surgeons experienced in intersex care.

Statement 10.11

We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.

Individuals with certain intersex conditions may have reproductively functional genitalia but experience infertility due to atypical gonadal development. Others may have functioning gonads with viable germ cells but an inability to achieve natural fertility secondary to incongruent internal or external genitalia (van Batavia & Kolon, 2016). Pubertal suppression, hormonal treatment with sex steroid hormones, and gender affirming surgeries may all have an adverse impact on future fertility. The potential consequences of the treatment and fertility preservation options should therefore be reviewed and discussed.

Individuals with functioning testes should be advised prolonged treatment with estrogen and suppression of testosterone, as studied in TGD people without intersexuality, may cause testicular atrophy and a reduction in sperm count (Mattawanon et al., 2018). Although interruption

of such gender affirming hormonal treatment may improve sperm quality, a complete reversal of semen impairment cannot be guaranteed (Sermondade et al., 2021). The principal fertility preservation option for individuals with functioning testes is cryopreservation of sperm collected through masturbation or vibratory stimulation (de Roo et al., 2016). Although there are no data for success in humans, there is a proposal to offer direct testicular extraction and cryopreservation of immature testicular tissue to adolescents who have not yet undergone spermarche (Mattawanon et al., 2018).

Individuals with functioning ovaries should be advised testosterone therapy usually results in cessation of both menses and ovulation, often within a few months of initiating therapy. There are major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility. In transgender people, one study reported testosterone treatment may be associated with the development of polycystic ovarian morphology (Grynberg et al., 2010). However, other researchers have not found evidence of polycystic ovarian syndrome (PCOS) among transgender men receiving gender affirming hormone therapy based on metabolic (Chan et al., 2018) or histologic parameters (de Roo et al., 2017). Individuals with an intact uterus and functioning ovaries may regain their fertility potential if testosterone therapy is discontinued.

Fertility preservation options in post-pubertal people with intersexuality and functioning ovaries include hormonal stimulation for mature oocyte cryopreservation or ovarian tissue cryopreservation. Alternatively, stimulated oocyte extraction has been reported even for a transgender man continuing testosterone therapy (Greenwald, 2021). Similarly, oocyte cryopreservation after ovarian stimulation has been reported in a transgender boy receiving GnRHa therapy (Rothenberg et al., 2019). It should be noted ovarian stimulation, temporary cessation of GnRHa, testosterone treatment, or both, as well as gynecological procedures, can all be psychologically distressing to individuals, with the stress reaction being influenced by mental health, gender identity, and other medical experience. Applicability of certain interventions may depend on the support of other people in the individual's social network, including potential partners.

Statement 10.12

We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

For people with intersex characteristics, the likelihood of infertility may be recognized in infancy, childhood, adolescence as well as in adulthood, without first engaging in attempts to conceive. For many individuals, a diagnosis of infertility accompanies the intersex diagnosis (Jones, 2019). For some individuals, assisted heterologous fertilization (e.g., oocyte or sperm donation) may be an option. Multiple adoption pathways exist. Some may require commitment and a considerable investment of time. Individuals who are either not interested in engaging in the efforts to achieve fertility previously described or for whom fertility is not possible can benefit from early exposure to the options available for adoption and alternative parenthood. While uterus transplantation has had preliminary success in people with Mullerian agenesis (Richards et al., 2021), there is no protocol to date that avoids exposure of the developing fetus to the risks associated with the medications used to avoid transplant rejection.

CHAPTER 11 Institutional Environments

This chapter addresses care for transgender and gender diverse (TGD) individuals who reside in institutions. By definition, institutions are facilities or establishments in which people live and receive care in a congregate or large group setting, where individuals may or may not have freedom of movement, individual consent, or agency. Carceral facilities (correctional facilities, immigration detention centers, jails, juvenile detention centers) and noncarceral facilities (long-term care facilities, in-patient psychiatric facilities, domiciliaries, hospice/palliative care, assisted living facilities) are residential institutions where health care access for transgender persons may be provided. Much of the evidence in support of proper care of TGD persons comes from carceral settings. However, the recommendations put forth here apply to all institutions that house TGD individuals, both carceral and noncarceral (Porter et al., 2016). All of the recommendations of the Standards of Care apply equally to people living in both types of institutions. People should have access to these medically necessary treatments irrespective of their housing situation within an institution (Brown, 2009). Care for an institutionalized person must consider the individual does not have the access that non-institutionalized persons have to securing care on their own. For that reason, institutionalized persons must be supported in being able to receive the Standards of Care established by the World Professional Association for Transgender Health (WPATH).

TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care (see Chapter 2—Global Applicability, Statement 2.1), which is ranked as their number one concern while incarcerated (Brown, 2014; Emmer et al., 2011). The systemic racial inequities inherent in many carceral environments (Sawyer, 2020), racial disparities in health outcomes (Nowotny et al., 2017), and the overrepresentation of TGD people of color in some facilities (Reisner et al., 2014) punctuate a need for facility leadership to attend to transitional care access issues. Controlled studies show clinically significant health and mental health disparities for justice-involved transgender people compared to matched groups of transgender people who have not been incarcerated or jailed (Brown and Jones, 2015). Too often the agencies, structures, and personnel that provide care are lacking in knowledge, training, and capacity to care for gender diverse people (Clark et al., 2017). Discrimination against TGD residents in palliative care settings, including hospice, is common, and the needs of TGD patients or their surrogates have been ignored in these settings (Stein et al., 2020). This is one reason why lesbian, gay, bisexual and transgender (LGBT)

Statements of Recommendations

11.1- We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8 apply equally to people living in institutions.
11.2- We suggest institutions provide all staff with training on gender diversity.
11.3- We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so without undue delay and in accordance with the SOC-8.
11.4- We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with the SOC-8 when sought by the individual, without undue delay.
11.5- We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.
11.6- We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.
11.7- We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations rather than solely their anatomy or sex assignment at birth.
11.8- We recommend institutional personnel establish housing policies that ensure the safety of TGD residents without segregating or isolating these individuals.
11.9- We recommend institutional personnel allow TGD residents the private use of shower and toilet facilities upon request.

patients may choose to hide their sexual and/or gender identity when they enter a nursing home, despite the fact that prior to their admission to the facility they had been living publicly as a LGBT-identified person (Carroll, 2017; Serafin et al., 2013).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable. The majority of the available literature related to institutions focuses on those who are incarcerated in jails, prisons, or other carceral environments. Literature about other institutional types were also considered and referenced where available. We hope future investigations will address this relative lack of data from noncarceral institutions. The recommendations summarized above are generalizable to a variety of institutional settings that have characteristics in common, including extended periods of stay, loss of or limited agency, and reliance on institutional staff for some or all of the basic necessities of life.

Statement 11.1

We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8, apply equally to TGD people living in institutions.

Just as people living in institutions require and deserve mental and medical health care in general and in specialty areas, we recognize TGD people are in these institutions and thus need care specific to TGD concerns. We recommend the application of the Standards of Care (SOC) to people living in institutions as basic principles of health care and ethics (Beauchamp & Childress, 2019; Pope & Vasquez, 2016). Additionally, numerous courts have long upheld the need to provide TGD-informed care based in the WPATH SOC to people living in institutions as well (e.g., Koselik v. Massachusetts, 2002; Edmo v. Idaho Department of Corrections, 2020). Agencies that provide staffing for long-term, in-home services should also be aware of the applicability of the Standards of Care.

Statement 11.2

We suggest institutions provide all staff with training on gender diversity.

Because TGD care affects a small percentage of the population, it requires specialized training as outlined in this SOC Version 8. While the level of training will vary based on the staff member's role within the institutional setting, all staff will need training in addressing residents appropriately while other clinical staff may need more intensive training and/or consultation. These training recommendations also apply to agencies that supply staffing for in-home, long-term care. Misgendering institutionalized residents, not allowing for gender appropriate clothing, shower facilities, or housing, and not using chosen names communicates a lack of respect for TGD residents who may experience repeated indignities as emotionally traumatic, depressing, and anxiety-producing. By providing all institutional staff with training on gender diversity and basic competence in transgender-related health care issues, these harms can be prevented (Hafford-Letchfield et al., 2017). Surveys indicate individuals working with incarcerated individuals as well as in workers in noncarceral settings like palliative care have significant knowledge gaps (Stein et al., 2020; White et al., 2016). Hafford-Letchfied et al. (2017) showed benefit to training residential long-term care staff when such training began with "recognizing LBGT issues" and existed in "care homes". If the assigned health care providers lack the expertise to assess and/or treat gender diverse persons under their charge, outside consultation should be sought from professionals with expertise in the provision of gender-affirming health care (Brömdal et al., 2019; Sevelius and Jenness, 2017).

Statement 11.3

We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so

without undue delay and in accordance with the SOC-8.

TGD persons may be admitted to institutions in need of evaluation for gender-affirming hormonal care or may develop this need after they have resided in an institutional setting for varying degrees of time. It is not uncommon for TGD persons to be denied access to hormonal care for months or years after making such needs known or to be undertreated and poorly monitored, delaying the necessary titration of medications for safety and efficacy (Keohane, 2018; Kosilek v. Massachusetts, 2002; Monroe v. Baldwin et al., 2019). This can result in significant negative mental health outcomes to include depression, anxiety, suicidality, and surgical self-treatment risks (Brown, 2010). As with all medically necessary health care, access to gender-affirming hormone therapies should be provided in a timely fashion when indicated for a TGD resident, in both carceral and noncarceral institutional environments. Medical professionals shall appropriately titrate hormones based on laboratory results and clinical outcomes to ensure results are within the range of recommended standards within the field of endocrinology. Such labs shall be taken at a frequency so as not to delay appropriate titration.

TGD elderly people living in long-term care facilities have unique needs (Boyd, 2019; Caroll, 2017; Porter, 2016). When elderly individuals request hormonal treatment, while physicians should assess pre-existing conditions, rarely do such conditions absolutely contraindicate administering hormones in this population (Ettner, 2013). People with gender incongruence in institutions may also have coexisting mental health conditions (Brown and Jones, 2015; Cole et al., 1997). These conditions should be evaluated and treated appropriately as part of the overall assessment. Persons receiving hormones must be closely medically monitored to avoid potential drug interactions and polypharmacy (Hembree et al., 2017).

TGD persons who enter an institution on an appropriate regimen of gender-affirming hormone therapy should be continued on the same or similar therapies and monitored according to the SOC Version 8. A "freeze frame" approach is inappropriate and dangerous (Kosilek v. Massachusetts, 2002). A "freeze frame" approach is the outmoded practice of denying hormones to people who are not already on them or keeping TGD persons on the same dose of hormones throughout their institutionalization that they were receiving upon admission, even if that dose was an initiation (low) dose. TGD persons who are deemed appropriate for de novo gender-affirming hormone therapy should be started on such therapy just as they would be outside of an institution (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009). The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a significant likelihood of negative outcomes (Brown, 2010; Sundstrom and Fields v. Frank, 2011), such as surgical self-treatment by autocastration, depressed mood, increased gender dysphoria, and/or suicidality (Brown, 2010; Maruri, 2011).

If an individual in an institution does receive gender-affirming hormones and/or surgeries, decisions regarding housing in sex-segregated facilities may need to be reassessed for the safety and well-being of the TGD person (Ministry of Justice [UK], 2016).

Statement 11.4

We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with SOC-8, when sought by the individual, without undue delay.

TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009; Edmo v. Idaho Department of Corrections, 2020). The consequences of denial or lack of access to gender- affirming surgeries for residents of institutions who cannot access such care outside of their institutions may be serious, including substantial worsening of gender dysphoria symptoms, depression, anxiety, suicidality, and the possibility of surgical self-treatment

(e.g., autocastration or autopenectomy; Brown, 2010; Edmo v. Idaho Department of Corrections, 2020; Maruri, 2011). It is not uncommon for residents of institutions to be denied access to evaluation for gender-affirming surgery as well as denial of the treatment itself, even when medically necessary (Kosilek v. Massachusetts/Dennehy, 2012; Edmo v. Idaho Department of Corrections, 2020). The denial of medically necessary evaluations for and the provision of gender-affirming surgical treatments and necessary aftercare is inappropriate and inconsistent with these Standards of Care.

Statement 11.5

We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.

Gender expression refers to people having hairstyles, grooming products, clothing, names, and pronouns associated with their gender identity in their culture and/or community (American Psychological Association, 2015; Hembree et al., 2017). Gender expression is the norm among most people within a culture or a community. Social transition is the process of TGD persons beginning and continuing to express their gender identity in ways that are authentic and socially perceptible. Often, social transition involves behavior and public presentation differing from what is usually expected for people assigned a given legal gender marker at birth. A gender marker is the legal label for a person's sex that is typically assigned or designated at birth on official documents (American Psychological Association, 2015). This is most commonly recorded as male or female but also intersex or "X" in some nations and jurisdictions. TGD individuals need the same rights to gender expression afforded cisgender people living both outside and inside institutional settings. Staff acceptance of social transition also sets a tone of respect and affirmation that may enhance respect and affirmation with others residing in the institution, thereby increasing safety and reducing some aspects of gender incongruence.

Research indicates social transition and congruent gender expression have a significant beneficial effect on the mental health of TGD people (Bockting & Coleman, 2007; Boedecker, 2018; Devor, 2004; Glynn et al., 2016; Russell et al., 2018). To allow for expressing gender identity, these recommendations include being allowed to wear gender congruent clothing and hairstyles, to obtain and use gender-appropriate hygiene and grooming products, to be addressed by a chosen name or legal last name (even if unable to change the assigned name legally yet), and to be addressed by a pronoun consistent with one's identity. These elements of gender expression and social transition, individually or collectively as indicated by the individual's needs, reduce gender dysphoria/incongruence, depression, anxiety, self-harm ideation and behavior, suicidal ideation and attempts (Russell et al., 2018). Furthermore, these elements of congruent gender expression enhance well-being and functioning (Glynn et al., 2016).

Statement 11.6

We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.

Given that an increasing percentage of people openly identify as gender diverse, there is a need to develop and implement practices and policies that meet the needs of these people irrespective of where they live (McCauley et al., 2017). For example, institutions should utilize medical and administrative records systems for their residents that track gender markers consistent with gender identity and not solely sex assigned at birth. In developing these recommendations, there was recognition that gender expansiveness can challenge some institutional norms where TGD people live. However, all institutions have the responsibility to provide for the safety and well-being of all persons living therein (Australia, 2015; Corrective Services New South Wales, 2015; Edmo v. Idaho Department of Corrections, 2020; Kosilek v. Massachusetts, 2002; NCCHC, 2015). Sevelius and colleagues (2020) demonstrated correct pronoun usage is gender-affirming for

transgender women and correlates with positive mental health and HIV-related health outcomes. If a resident of an institution has legally changed names, the institutional records should be changed to reflect those changes.

Statement 11.7

We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations, rather than solely their anatomy or sex assignment at birth.

The separation of people based on sex assigned at birth, a policy almost universally implemented in institutional settings (Brown and McDuffie, 2009; Routh et al., 2017), can create an inherently dangerous environment (Ledesma & Ford, 2020). Gender diverse people are extremely vulnerable to stigmatization, victimization, neglect, violence, and sexual abuse (Banbury, 2004; Beck, 2014; Jenness and Fenstermaker, 2016; Malkin & DeJong, 2018; Oparah, 2012; Stein et al., 2020). This systemic sex-segregated rigidity often fails to keep TGD people safe and may impede access to gender-affirming health care (Stohr, 2015). As a result, institutions should follow procedures that routinely evaluate the housing needs and preferences of TGD inmates (e.g., Federal Bureau of Prisons, 2016). Likewise, the Prison Rape Elimination Act specifically cites TGD individuals as a vulnerable population and directs prisons nationwide in the US to consider the housing preferences of these inmates (Bureau of Justice Assistance, 2017).

Statement 11.8

We recommend institutional personnel establish housing policies that ensure the safety of transgender and gender diverse residents without segregating or isolating these individuals.

Assigning placement for a TGD resident solely on the basis of their genital anatomy or sex assigned at birth is misguided and places people at risk for physical and/or psychological harm (Scott, 2013; Simopoulos & Khin, 2014; Yona & Katri, 2020). It is well established within carceral settings, transgender individuals are far more likely than other prisoners to be sexually harassed, assaulted, or both (James et al., 2016; Jenness & Fenstermaker, 2016; Malkin & DeJong, 2019). While placement decisions need to address security concerns, shared decision-making that includes the input of the individual should be made on a case-by-case basis (Federal Bureau of Prisons, 2016; Jenness and Smyth, 2011). Some transgender women prefer to reside in a male facility while others feel safer in a female facility. Given the range of gender identities, expression and transition status is so heterogeneous among gender diverse people, keeping residents safe requires flexible decision-making processes (Yona & Katri, 2020). One of the fears older LBGT individuals have living in long-term care is mistreatment by roommates (Jablonski et al., 2013). Consequently, housing in nursing homes and assisted living facilities should consider assigning rooms to elders based on their self-identified gender without regard to birth assignment or surgical history and in collaboration with the TGD patient.

Solitary confinement, sometimes referred to as administrative segregation in carceral facilities, refers to physical isolation of individuals during which they are confined in their cells for approximately twenty-three hours each day. The use of isolation is employed in some carceral facilities as a disciplinary measure as well as a means of protecting prisoners who are considered a risk to themselves or others or who are at risk of sexual assault by other inmates. However, isolating prisoners for safety concerns, if necessary, should be brief, as isolation can cause severe psychological harm and gross disturbances of functioning (Ahalt et al., 2017; Scharff Smith, 2006). National prison standards organizations as well as The United Nations consider isolation longer than 15 days to be torture (NCCHC, 2016; United Nations, 2015).

Statement 11.9

We recommend institutional personnel allow transgender and gender diverse residents the private use of shower and toilet facilities, upon request.

The necessity and importance of privacy is universal irrespective of gender identity. TGD

individuals report avoiding public restrooms, limiting the amount they eat and drink so as not to have to use a public facility, often leading to urinary tract infections and kidney-related problems (James et al., 2016). TGD individuals in institutions are often deprived of privacy in bathroom and shower use, which can result in psychological harm and/or physical and sexual abuse (Bartels and Lynch, 2017; Brown, 2014; Cook-Daniels, 2016; Mann, 2006). Similarly, in carceral environments, pat downs, strip searches and body cavity searches should be conducted by staff members of the same sex with the understanding this may not be possible in extreme emergencies. The incidental viewing of searches by other employees should be avoided (Bureau of Justice Assistance, 2017). Private use of shower and toilet facilities for incarcerated transgender people is also required by some laws, including for instance the United States' federal Prison Rape Elimination Act in the US.

The population of aging/older TGD persons who need to be served by institutions is increasing (Carroll, 2017; Witten & Eyler, 2016). Many long-term care and other facilities catering to the needs of the aging need to take into consideration the needs of their non-cisgender residents (Ettner, 2016; Ettner & Wiley, 2016). Surveys of HCPs working with elders in hospice and palliative care settings as well as other long-term care facilities report patients who identify as TGD often do not get their basic needs met, are discriminated against in their medical care access, or are physically and/or emotionally abused (Stein et al., 2020) A survey of retirement and residential care providers in Australia found little experience with or understanding of the issues facing this population. Indeed, many elderly TGD residents admitted to concealing their gender identity, bowing to the fear of insensitive treatment or frank discrimination (Cartwright et al., 2012; Cook-Daniels, 2016; Grant et al., 2012; Horner et al., 2012; Orel & Fruhauf, 2015).

CHAPTER 12 Hormone Therapy

Transgender and gender diverse (TGD) persons may require medically necessary gender-affirming hormone therapy (GAHT) to achieve changes consistent with their embodiment goals, gender identity, or both (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). This chapter describes hormone therapy recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to initiation of hormone therapy for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Ever since the first World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) was published in 1979 and in subsequent updates of the SOC, including SOC version 7, GAHT has been accepted as medically necessary (Coleman et al., 2012). WPATH endorsed the Endocrine Society's guidelines for GAHT for TGD persons in 2009 and 2017 (Hembree et al., 2009; Hembree et al., 2017). The European Society for Sexual Medicine has also published a position statement on hormone management in adolescent and adult TGD people (T'Sjoen et al., 2020). When provided under medical supervision, GAHT in adults is safe (Tangpricha & den Heijer, 2017; Safer & Tangpricha, 2019). However, there are some potential long-term risks, and careful monitoring and screening are required to reduce adverse events (Hembree et al., 2017; Rosenthal, 2021).

In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017). Health care professionals (HCPs) can use serum testosterone and/or estradiol levels to monitor most sex steroid treatments. However, conjugated estrogens or synthetic estrogen use cannot be monitored. The assumption that the estrone/estradiol ratio should be monitored was not supported in a recent cohort study as there was no relationship between estrone concentration and change in body fat or breast development seen in a European cohort of 212 adult transgender women during a 1-year follow-up of hormone treatment (Tebbens et al., 2021). This study demonstrated higher estrone concentrations or higher estrone/estradiol ratios are not associated with antagonistic effects on feminization (fat percentage and breast development) (Tebbens et al., 2021). Thus, monitoring of the estrone to estradiol ratio is not supported by the current published evidence. Previously used conjugated estrogens have been abandoned in favor of bioidentical estrogens. Even if several studies have shown a significantly greater risk of thromboembolic and cardiovascular complications with the use of oral conjugated estrogens compared with oral estradiol in postmenopausal women, no randomized controlled trials have taken place, either in postmenopausal women or in transgender people undergoing estrogen treatment (Smith et al., 2014).

The approach to GAHT differs and depends on the developmental stage of the individual at the time of initiation of hormone therapy as well as their treatment goals. Hormone therapy is not recommended for children who have not begun endogenous puberty. In eligible youth (as per Chapter 6—Adolescents) who have reached the early stages of puberty, the focus is usually to delay further pubertal progression with gonadotropin releasing hormone agonists (GnRHas) until an appropriate time when GAHT can be introduced. In these cases, pubertal suppression is considered medically necessary. Eligible adults may initiate GAHT if they fulfill the criteria as per Chapter 5—Assessment for Adults. In addition, health care providers should discuss fertility goals and fertility preservation procedures prior to initiating GAHT. See Chapter 16—Reproductive Health.

GAHT with feminine embodiment goals typically consists of estrogen and an androgen-lowering medication (Hembree et al., 2017). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence the potential benefits of progesterone administration outweigh the potential risks (Iwamoto, T'Sjoen et al., 2019). Masculinizing GAHT typically consists of testosterone. Both WPATH and the Endocrine Society recommend monitoring levels of sex

hormones. While GAHT is customized to meet the individual needs of the TGD person, typically hormone levels are maintained at a concentration sufficient to support good bone health and are not supraphysiologic (Hembree et al., 2017; Rosen et al., 2019).

Statements of Recommendations

12.1- We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents after they first exhibit physical changes of puberty (Tanner stage 2).
12.2- We recommend health care professionals use gonadotropin releasing hormone (GnRH) agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated.
12.3- We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are either not available or are cost prohibitive.
12.4- We suggest health care professionals prescribe GnRH agonists for suppression of sex steroids without concomitant sex steroid hormone replacement in eligible* transgender and gender diverse adolescents seeking such intervention and who are well into or have completed pubertal development (past Tanner stage 3) but are either unsure about or do not want to begin sex steroid hormone therapy.
12.5- We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment for eligible* transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent.
12.6- We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at levels appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.
12.7- We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.
12.8- We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care required for transgender and gender diverse adolescents.
12.9- We recommend health care professionals institute regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.
12.10- We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about the options available for fertility preservation prior to initiating puberty suppression and prior to treating with hormone therapy.
12.11- We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment for transgender and gender diverse people.
12.12- We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of the physical changes induced by sex hormonal treatment.
12.13- We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment.
12.14- We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age > 45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended.
12.15- We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as a component of gender-affirming hormonal treatment.
12.16- We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gender diverse people with testes who are taking estrogen as part of a hormonal treatment plan if the individual's goal is to approximate circulating sex hormone concentrations in cisgender women.
12.17- We recommend health care professionals monitor hematocrit (or hemoglobin) in transgender and gender diverse people treated with testosterone.
12.18- We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery.
12.19- We suggest health care professionals counsel transgender and gender diverse people about the various options available for gender-affirmation surgery unless surgery is not indicated or is medically contraindicated.
12.20- We recommend health care professionals initiate and continue gender-affirming hormone therapy for eligible* transgender and gender diverse people who require this treatment due to demonstrated improvement in psychosocial functioning and quality of life.
12.21- We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

** For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents and Appendix D.*

In most cases, GAHT is maintained throughout life. It is not known if doses of GAHT should be reduced in older TGD people. Discontinuation of hormone therapy may result in bone loss in TGD individuals and will definitely do so in individuals whose gonads have been removed (Wiepjes et al., 2020). Routine primary care should also be performed (see Chapter 15—Primary Care). Epidemiology studies have reported an increased incidence of cardiovascular disease and venous thromboembolism (VTE) in TGD people receiving estrogen, most notably in older people and with different preparations of GAHT (Irwig, 2018; Maraka et al., 2017). TGD individuals treated with testosterone may also have increased adverse cardiovascular risks and events, such as increased myocardial infarction, blood pressure, decreased HDL-cholesterol, and excess weight (Alzahrani et al., 2019; Irwig, 2018; Kyinn et al., 2021). Health care professionals (HCPs) should discuss lifestyle and pharmacologic therapy with patients who are at the highest risk of developing cardiovascular disease (see Chapter 15—Primary Care). Polycythemia is another disorder that may present in TGD people taking testosterone (Antun et al., 2020). Therefore, it is important to continuously monitor for the development of conditions that can be exacerbated by GAHT throughout life (Hembree et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Gender-Affirming Hormone Therapy in Youth

The following sections will discuss hormone therapy in TGD youth. Depending on the developmental stage of the youth, this hormone therapy generally comprises two phases, namely pubertal suppression followed by the addition of GAHT. During the first phase, pubertal development is halted to allow the youth to explore their gender identity and embodiment goals to prepare for the next phase, which may include GAHT. This section will discuss the recommendations for the use of gonadotropin releasing hormone agonists (GnRHas) as well as alternate approaches to pubertal suppression and will be followed by recommendations for GAHT. Sections that are applicable to youth and adults will follow in the next section.

Statement 12.1

We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents only after they first exhibit physical changes of puberty (Tanner stage 2).

In general, the goal of GnRHa administration in TGD adolescents is to prevent further development of the endogenous secondary sex characteristics corresponding to the sex designated at birth. Since this treatment is fully reversible, it is regarded as an extended time for adolescents to explore their gender identity by means of an early social transition (Ashley, 2019e). Treatment with GnRHas also has therapeutic benefit since it often results in a vast reduction in the level of distress stemming from physical changes that occur when endogenous puberty begins (Rosenthal, 2014; Turban, King et al., 2020).

For those prepubertal TGD children who have been persistent in their gender identity, any amount of permanent development of secondary sex characteristics could result in significant distress. While one might consider use of a GnRHa to prevent initiation of puberty in such individuals who remain at Tanner Stage 1, this use of GnRHa has not been recommended (Hembree et al., 2017). When a child reaches an age where pubertal development would normally begin (typically from 7-8 to 13 years for those with ovaries and from 9 to 14 years for those with testes), it would be appropriate to screen the child more frequently, perhaps at 4-month intervals, for signs of pubertal development (breast budding or testicular volume > 4 cc). Given the typical tempo of pubertal development (3.5–4 years for completion), it would be very unlikely for permanent pubertal changes to develop if one is only in puberty for 4 months or less. Thus, with frequent follow-up, the initiation of puberty can easily be detected before there are irreversible physical changes, and GnRHa can be started at that time with great efficacy. Of note, following initiation of a GnRHa, there is typically

a regression of one Tanner stage. Thus, if there is only Tanner stage 2 breast development, it typically fully regresses to the prepubertal Tanner stage 1; the same is typically true with Tanner stage 2 testes (often not even discernable to the patient and is not associated with development of secondary sex characteristics).

Given GnRHas work through GnRH receptor desensitization, if there's no uptick in endogenous GnRH stimulation of the pituitary (the first biochemical sign of puberty), there's no need for GnRH receptor desensitization. In addition, because of the wide variability in the timing of the start of puberty (as noted above), it is hard to justify using a GnRHa that might have some unknown risk if there's no physiological benefit before pubertal onset. Using a GnRHa with a child at Tanner stage 1 would only be indicated in cases of constitutional delay in growth and puberty, likely alongside the start of GAHT.

However, the use of a GnRHa could be considered in a child who, due to a constitutional delay in growth and puberty, starts GAHT while still in Tanner Stage 1. Initiating GAHT may activate the hypothalamic-pituitary gonadal axis in the beginning but may also mask the effects on the body of this activation. To avoid body changes with the potential to exacerbate an individual's gender incongruence, the GnRHa can be started as an adjunctive therapy to the GAHT shortly after the initiation of the GAHT to provide for pubertal development of the identified phenotype.

In addition, the suppression of the development of secondary sex characteristics is most effective when sex hormonal treatment is initiated in early to mid-puberty when compared with the initiation of sex hormonal treatment after puberty is completed (Bangalore-Krisha et al., 2019). Correspondingly, for adolescents who have already completed endogenous puberty and are considering starting GAHT, GnRHas can be used to inhibit physical functions, such as menses or erections, and can serve as a bridge until the adolescent, guardian(s) (if the adolescent is not able to consent independently), and treatment team reach a decision (Bangalore-Krishna et al., 2019; Rosenthal, 2021).

The onset of puberty occurs through reactivation of the hypothalamic-pituitary-gonadal axis. Clinical assessment of the stages of puberty is based on physical features that reflect that reactivation. In individuals with functioning ovaries, Tanner stage 2 is characterized by the budding of the mammary gland. The development of the mammary gland occurs from exposure to estrogen produced by the ovaries. In individuals with functioning testes, Tanner stage 2 is characterized by an increase in testicular volume (typically greater than 4 ml). The growth of the testes is mediated through the gonadotropins luteinizing hormone (LH) and follicle stimulating hormone (FSH). In the later stages, the testes produce enough testosterone to induce masculinization of the body.

Statement 12.2

We recommend health care professionals use GnRH agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated. For supporting text, see Statement 12.4.

Statement 12.3

We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are not available or are cost prohibitive. For supporting text, see Statement 12.4.

Statement 12.4.

We suggest health care professionals prescribe GnRH agonists to suppress sex steroids without concomitant sex steroid hormone replacement in eligible transgender and gender diverse adolescents seeking such intervention who are well into or have completed pubertal development (past Tanner stage 3) but are unsure about or do not wish to begin sex steroid hormone therapy.

GnRHas reduce gonadotrophin and sex steroid concentrations in TGD adolescents and thus halt the further development of secondary sex characteristics (Schagen et al., 2016). Their use is generally safe with the development of hypertension being the only short-term adverse event reported in the literature (Delemarre-van de Waal & Cohen-Kettenis, 2006; Klink, Bokenkamp et al., 2015). GnRHas prevent the pituitary gland from

secreting LH and FSH (Gava et al., 2020). When the gonadotropins decrease, the gonad is no longer stimulated to produce sex hormones (estrogens or androgens), and the sex hormone levels in the blood decrease to prepubertal levels. GnRHa treatment leads to partial regression of the initial stages of the already developed secondary sex characteristics (Bangalore et al., 2019). TGD adolescents with functioning ovaries will experience diminished growth of breast tissue, and if treatment is started at Tanner stage 2, the breast tissue may disappear completely (Shumer et al., 2016). Menarche can be prevented or discontinued following the administration of GnRHas in adolescents with a uterus. In TGD adolescents with functioning testes, testicular volume will regress to a lower volume.

When GnRHa treatment is started in adolescents at the later phases of pubertal development, some physical changes of pubertal development, such as late-stage breast development in TGD adolescents with functioning ovaries and a lower voice and growth of facial hair in TGD adolescents with functioning testes, will not regress completely, although any further progression will be stopped (Delemarre-van de Waal & Cohen-Kettenis, 2006). GnRHas have been used since 1981 for the treatment of central precocious puberty (Comite et al., 1981; Laron et al., 1981), and their benefits are well established (please also see the statements in Chapter 6—Adolescents). The use of GnRHas in individuals with central precocious puberty is regarded as both safe and effective, with no known long-term adverse effects (Carel et al., 2009). However, the use of GnRHas in TGD adolescents is considered off-label because they were not initially developed for this purpose. Nonetheless, data from adolescents prescribed GnRHas in a similar dose and fashion demonstrate effectiveness in delaying the onset of puberty although the long-term effects on bone mass have not been well established (Klink, Caris et al., 2015). Although long-term data are more limited in TGD adolescents than in adolescents with precocious puberty, data collection specifically in this population are ongoing (Klaver et al., 2020; Lee, Finlayson et al., 2020; Millington et al., 2020; Olson-Kennedy, Garofalo et al., 2019).

We recognize even though GnRHas are a medically necessary treatment, they may not be available for eligible adolescents because it is not covered by health insurance plans in some countries or may be cost-prohibitive. Therefore, other approaches should be considered in these cases, such as oral or injectable progestin formulations. In addition, for adolescents older than 14 years, there are currently no data to inform HCPs whether GnRHas can be administered as monotherapy (and for what duration) without posing a significant risk to skeletal health. This is because the skeleton will not have any exposure to adequate levels of sex steroid hormones (Rosenthal, 2021).

A prolonged hypogonadal state in adolescence, whether due to medical conditions such as hypergonadotropic hypogonadism, iatrogenic causes such as GnRHa monotherapy or physiological conditions such as conditional delay of growth and development, is often associated with an increased risk of poor bone health later in life (Bertelloni et al., 1998; Finkelstein et al., 1996). However, bone mass accrual is a multifactorial process that involves a complex interplay between endocrine, genetic, and lifestyle factors (Anai et al., 2001). When deciding on the duration of GnRHa monotherapy, all contributing factors should be considered, including factors such as pretreatment bone mass, bone age, and pubertal stage from an endocrine perspective and height gain, as well as psychosocial factors such as mental maturity and developmental stage relative to one's adolescent cohort and the adolescent's individual treatment goals (Rosenthal, 2021). For these reasons, a multidisciplinary team and an ongoing clinical relationship with the adolescent and the family should be maintained when initiating GnRHa treatment (see Statements 6.8, 6.9, and 6.12 in Chapter 6—Adolescents). The clinical course of the treatment, e.g., the development of bone mass during GnRHa treatment and the adolescent's response to treatment, can help to determine the length of GnRHa monotherapy.

Statement 12.5

We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment in eligible*

transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent. For supporting text, see Statement 12.6.

Statement 12.6

We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at a level appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.

Sex steroid hormone therapy generally comprises two treatment regimens, depending on the timing of the GnRHa treatment. When GnRHa treatment is started in the early stages of endogenous pubertal development, puberty corresponding with gender identity or embodiment goals is induced with doses of sex steroid hormones similar to those used in peripubertal hypogonadal adolescents. In this context, adult doses of sex steroid hormones are typically reached over approximately a 2-year period (Chantrapanichkul et al., 2021). When GnRHa treatment is started in late- or postpubertal transgender adolescents, sex steroid hormones can be given at a higher starting dose and increased more rapidly until a maintenance dose is achieved, resembling treatment protocols used in transgender adults (Hembree et al., 2017). An additional advantage of GnRHa treatment is sex steroid hormones do not have to be administered in supraphysiological doses, which would otherwise be needed to suppress endogenous sex steroid production (Safer & Tangpricha, 2019). For TGD individuals with functioning testes, GnRHa treatment (or another testosterone-blocking medication) should be continued until such time as the TGD adolescent/young adult ultimately undergoes gonadectomy, if this surgical procedure is pursued as a medically necessary part of their gender-affirming care. Once adult levels of testosterone are reached in TGD individuals with functioning ovaries who have been initially suppressed with GnRHa's, testosterone alone at physiological doses is typically sufficient to lower ovarian estrogen secretion, and GnRHas can be discontinued as discussed below (Hembree et al., 2017). For TGD adolescents with functioning ovaries who are new to care, GAHT can be accomplished with physiological doses of testosterone alone without the need for concomitant GnRHa administration (Hembree et al., 2017).

Gender-affirming sex steroid hormone therapy induces the development of secondary sex characteristics of the gender identity. Also, the rate of bone mineralization, which decreases during treatment with GnRHa's, rapidly recovers (Klink, Caris et al., 2015). During GnRHa treatment in early-pubertal TGD adolescents, the bone epiphyseal plates are still unfused (Kvist et al., 2020; Schagen et al., 2020). Following the initiation of sex steroid hormone treatment, a growth spurt can occur, and bone maturation continues (Vlot et al., 2017). In postpubertal TGD adolescents, sex steroid hormone treatment will not affect height since the epiphyseal plates have fused, and bone maturation is complete (Vlot et al., 2017).

In TGD adolescents with functioning testes, the use of 17-ß-estradiol for pubertal induction is preferred over that of synthetic estrogens, such as the more thrombogenic ethinyl estradiol (see Appendix D (Asscheman et al., 2015). It is still necessary to either continue GnRHa's to suppress endogenous testosterone production or transition to another medication that suppresses endogenous testosterone production (Rosenthal et al., 2016). Breast development and a female-typical fat distribution are among a number of physical changes that occur in response to estrogen treatment. See Appendix C—Table 1.

For TGD adolescents seeking masculinizing treatment, androgens are available as injectable preparations, transdermal formulations, and subcutaneous pellets. For pubertal induction, the use of testosterone-ester injection is generally recommended by most experts initially because of cost, availability, and experience (Shumer et al., 2016). It is advised to continue GnRHas at least until a maintenance level of testosterone is reached. In response to androgen treatment, virilization of the body occurs, including a lowering of the voice, more muscular development particularly in the upper body, growth of facial and body hair, and clitoral enlargement (Rosenthal et al., 2016). See Appendix C—Table 1.

In almost all situations, parental/caregiver consent should be obtained. Exceptions to this recommendation, in particular when caregiver or parental involvement is determined to be harmful to the adolescent, are described in more detail in Chapter 6—Adolescents (see Statement 6.11) where the rationale for involving parents/caregivers in the consent process is also described.

Statement 12.7

We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.

Menstrual suppression is a treatment option commonly needed by TGD individuals who experience distress related to menses or the anticipation of menarche. Statement 6.7 in Chapter 6—Adolescents describes this in more detail. To achieve amenorrhea, menstrual suppression can be initiated as a solo option before initiating testosterone or alongside testosterone therapy (Carswell & Roberts, 2017). Some youth, who are not ready for testosterone therapy or are not yet at an appropriate pubertal/developmental stage to begin such treatment, will benefit from the induction of amenorrhea (Olson-Kennedy, Rosenthal et al., 2018). Adolescents who experience an exacerbation of dysphoria related to the onset of puberty may elect to be treated with GnRHas for pubertal suppression (also see the Adolescents chapter).

Progestogens may be effective in adolescents whose goal is solely menstrual suppression. Continuous administration of progestin-only oral pills (including the contraceptive and noncontraceptive options), medroxyprogesterone injections, or levonorgestrel intrauterine device can be used for induction of amenorrhea (Pradhan & Gomez-Lobo, 2019). TGD individuals with functioning ovaries who start testosterone therapy may have 1–5 menstrual cycles before amenorrhea is achieved (Taub et al., 2020). Once amenorrhea is achieved, some TGD individuals with functioning ovaries may also choose to continue progestin treatment for birth control if relevant to their sexual practices.

TGD individuals with functioning ovaries and a uterus should be counseled about the potential for breakthrough menstrual bleeding in the first few months after initiating menstrual suppression. With GnRHa therapy, breakthrough bleeding may occur 2–3 weeks after initiation of the medication. For individuals seeking contraception or for those who continue to experience menstrual bleeding on progestin therapy, an estrogen combination with progestin may be considered for the maintenance of amenorrhea, yet they should be counseled on the possible side effect of breast development (Schwartz et al., 2019).

Statement 12.8

We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care of transgender and gender diverse adolescents.

As with the care of adolescents, we suggest where possible a multidisciplinary expert team of medical and mental health professionals (MHPs) be assembled to manage this treatment. In adolescents who pursue GAHT (given this is a partly irreversible treatment), we suggest initiating treatment using a schedule of gradually increasing doses after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and has established the individual possesses the mental capacity to give informed consent (Hembree et al., 2017). Specific aspects concerning the assessment of adolescents and the involvement of their caregivers and a multidisciplinary team are described in more detail in Chapter 6—Adolescents.

If possible, TGD adolescents should have access to experts in pediatric transgender health from multiple disciplines including primary care, endocrinology, fertility, mental health, voice, social work, spiritual support, and surgery (Chen, Hidalgo et al., 2016; Eisenberg et al., 2020; Keo-Meier & Ehrensaft, 2018). Individual providers are encouraged to form collaborative working relationships with providers from other disciplines to facilitate referrals as needed for the individual youth and their family (Tishelman et al., 2015). However, the lack of available

experts and resources should not constitute a barrier to care (Rider, McMorris et al., 2019). Helpful support for adolescents includes access to accurate, culturally informed information related to gender and sexual identities, transition options, the impact of family support, and connections to others with similar experiences and with TGD adults through online and in person support groups for adolescents and their family members (Rider, McMorris et al., 2019).

Many TGD adolescents have been found to experience mental health disparities and initial mental health screening (e.g., PHQ-2, GAD) can be employed as indicated (Rider, McMorris et al., 2019). Providers should keep in mind being transgender or questioning one's gender does not constitute pathology or a disorder. Therefore, individuals should not be referred for mental health treatment exclusively on the basis of a transgender identity. HCPs and MHPs who treat these youths and make referrals should, at a minimum, be familiar with the impact of trauma, gender dysphoria, and gender minority stressors on any potential mental health symptomatology, such as disordered eating, suicidal ideation, social anxiety. These health care providers should also be knowledgeable about the level of readiness of inpatient mental health services in their region to provide competent, gender-affirming care to TGD youth (Barrow & Apostle, 2018; Kuper, Wright et al., 2018; Kuper, Mathews et al., 2019; Tishelman & Neumann-Mascis, 2018). Statements 6.3, 6.4, and 6.12d in Chapter 6—Adolescents address this in more detail. Because parents of these youth commonly experience high levels of anxiety immediately after learning their youth is TGD, and their response to their child predicts that child's long-term physical and mental health outcomes, appropriate referrals for mental health support of the parents can be of great utility (Coolhart et al., 2017; Pullen Sansfaçon et al., 2015; Taliaferro et al., 2019).

Statement 12.9

We recommend health care professionals organize regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until a stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.

Sex steroid hormone therapy is associated with a broad array of physical and psychological changes (Irwig, 2017; Tangpricha & den Heijer, 2017) (see Appendix C—Table 1). After sex steroid hormone therapy has been initiated, the HCP should regularly assess the progress and response of the individual to the treatment (also see Chapter 6—Adolescents). This evaluation should assess the presence of any physical changes as well as the impact of treatment on gender dysphoria (if present) and psychological well-being (see Appendix C—Table 1). Clinical visits provide important opportunities for HCPs to educate patients about the typical time course required for physical changes to manifest and encourage realistic expectations. During the first year of hormone therapy, sex steroid hormone doses are often increased. A major factor guiding the dose is the serum level of the corresponding sex steroid hormone. In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017).

In addition to assessing the positive changes associated with sex steroid hormone therapy, the HCP should regularly assess whether the treatment has caused any adverse effects (see Appendix C—Table 2). Examples of adverse signs and symptoms include androgenic acne or bothersome sexual dysfunction (Braun et al., 2021; Kerckhof et al., 2019). GAHT also has the potential to adversely influence several laboratory tests. For example, spironolactone may cause hyperkalemia, although it is an uncommon and transient phenomenon (Millington et al., 2019). Testosterone increases the red blood cell count (hematocrit), which may occasionally cause erythrocytosis (Antun et al., 2020) (see Statement 12.17) (Hembree et al., 2017). Both estrogen and testosterone can alter lipid parameters, such as high-density protein lipoprotein (HDL) cholesterol and triglycerides (Maraka et al., 2017). See Appendix C—Tables 3 and 4.

The frequency of clinical evaluations should be individualized and guided by the individual's response to treatment. We suggest clinical assessments be performed approximately every 3 months during the first year of hormone therapy in patients who are stable and are not experiencing significant adverse effects (Appendix C—Table 5). We suggest rather than recommend testing be carried out every 3 months in the first year to allow some flexibility on the timing of these tests as there is no strong evidence or evidence from published studies supporting specific testing intervals. If an individual does experience an adverse effect, more frequent laboratory testing and/or clinical visits are often needed. Given the potential harm associated with sex hormone levels that exceed expected ranges in humans, we strongly recommend regular testing be performed as a standard practice when initiating GAHT in TGD individuals. Once a person has reached a stable adult dose of sex steroid hormone with no significant adverse effects, the frequency of clinic visits can be reduced to one to two per year (Hembree et al., 2017).

Statement 12.10

We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about options for fertility preservation prior to initiating puberty suppression and prior to administering hormone therapy.

Pubertal suppression and hormone treatment with sex steroid hormones may have potential adverse effects on a person's future fertility (Cheng et al., 2019) (see also Chapter 6—Adolescents and Chapter 16—Reproductive Health). Although some TGD people may not have given much thought to their future reproductive potential at the time of their initial assessment to begin medical therapy, the potential implications of the treatment and fertility preservation options should be reviewed by the hormone prescriber and discussed with the person seeking these therapies (Ethics Committee of the American Society for Reproductive Medicine et al., 2015; De Roo et al., 2016).

Individuals with testes should be advised prolonged treatment with estrogen often causes testicular atrophy and a reduction in sperm count and other semen parameters (Adeleye et al., 2018). Nonetheless, there are major gaps in knowledge, and findings regarding the fertility of trans feminine people who take estrogen and antiandrogens are inconsistent (Cheng et al., 2019). In one study, heterogeneity in testicular histology was evident whether patients discontinued or continued therapy prior to orchiectomies (Schneider et al., 2015). For example, the discontinuation of estrogen and antiandrogens for six weeks resulted in complete spermatogenesis in 45% of individuals with the remainder showing meiotic arrest or spermatogonial arrest (Schneider et al., 2015). However, serum testosterone levels confirmed to be within female reference ranges leads to complete suppression of spermatogenesis in most transgender women (Vereecke et al., 2020). The principal fertility preservation option for patients with functioning testes is sperm cryopreservation, also known as sperm banking (Mattawanon et al., 2018). For prepubertal patients, suppression of puberty with GnRHs pauses the maturation of sperm (Finlayson et al., 2016).

Individuals with functioning ovaries should be advised testosterone therapy usually results in the cessation of menses and ovulation, often within a few months of initiation (Taub et al., 2020). There are also major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility of TGD patients (Eisenberg et al., 2020; Stuyver et al., 2020). One study found testosterone treatment may be associated with polycystic ovarian morphology, whereas other studies reported no metabolic (Chan et al., 2018) or histologic (De Roo et al., 2017; Grynberg et al., 2010) evidence of polycystic ovary syndrome (PCOS) following treatment with testosterone, and some studies have found a pre-existing higher prevalence of PCOS in transgender patients with ovaries (Baba, 2007; Gezer et al., 2021). TGD patients with an intact uterus and ovaries often regain their fertility potential if testosterone therapy is discontinued (Light et al., 2014). Indeed, a live birth after assisted reproductive technology has been reported following hormone-stimulated egg retrieval from a TGD

individual who did not discontinue testosterone therapy (Greenwald et al., 2021; Safer and Tangpricha, 2019). Other fertility preservation options for TGD patients with ovaries are oocyte cryopreservation and embryo cryopreservation with sperm from a partner or donor. The above options require hormonal stimulation for egg retrieval and the use of assisted reproductive technology.

For early pubertal transgender youth, suppression of puberty with GnRHa's pauses the maturation of germ cells, although a recent report noted ovarian stimulation of a TGD adolescent treated with a GnRHa's in early puberty (and continued during ovarian stimulation) resulted in a small number of mature oocytes that were cryopreserved (Rothenberg et al., 2019). Treating an TGD adolescent with functioning testes in the early stages of puberty with a GnRHa not only pauses maturation of germ cells but will also maintains the penis in a prepubertal size. This will likely impact surgical considerations if that person eventually undergoes a penile-inversion vaginoplasty as there will be less penile tissue to work with. In these cases, there is an increased likelihood a vaginoplasty will require a more complex surgical procedure, e.g., intestinal vaginoplasty (Dy et al., 2021; van de Grift et al., 2020). Such considerations should be included in any discussions with patients and families considering use of pubertal blockers in early pubertal adolescents with functioning testes.

Statement 12.11

We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment in transgender and gender diverse people.

TGD people seeking masculinization must be informed about the possibilities, consequences, limitations, and risks associated with testosterone treatment. Testosterone therapy is contraindicated during pregnancy or while attempting to become pregnant given its potential iatrogenic effects on the fetus. Relative contraindications to testosterone therapy include severe hypertension, sleep apnea, and polycythemia since these conditions can be exacerbated by testosterone. Monitoring blood pressure and lipid profiles should be performed before and after the onset of testosterone therapy. The increase in blood pressure typically occurs within 2 to 4 months following the initiation of testosterone therapy (Banks et al., 2021). Patients who develop hypercholesterolemia and/or hypertriglyceridemia may require treatment with dietary modifications, medication, or both.

TGD people seeking feminizing treatment with a history of thromboembolic events, such as deep vein thrombosis and pulmonary embolism, should undergo evaluation and treatment prior to the initiation of hormone therapy. This is because estrogen therapy is strongly associated with an increased risk of thromboembolism, a potentially life-threatening complication. In addition, risk factors that can increase the risk of thromboembolic conditions, such as smoking, obesity, and sedentary lifestyle, should be modified. In patients with nonmodifiable risk factors, such as a known history of thrombophilia, a past history of thrombosis, or a strong family history of thromboembolism, treatment with transdermal estrogen concomitant with anticoagulants may decrease the risk of thromboembolism. However, there are limited data to guide treatment decisions. The presence of a disease at baseline such as a hormone sensitive cancer, coronary artery disease, cerebrovascular disease, hyperprolactinemia, hypertriglyceridemia, and cholelithiasis should be evaluated prior to the initiation of gender-affirming hormone therapy as relative risks may be shifted in association with exogenous hormone treatment (Hembree et al., 2017).

Statement 12.12

We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of physical changes induced by sex hormone treatment.

The effects of testosterone treatment are multiple and may include the appearance of increased body and facial hair, male pattern baldness, increased muscle mass and strength, decreased fat mass, deepening of the voice, interruption of

menses (if still present), increased prevalence and severity of acne, clitoral enlargement, and increased sexual desire (Defreyne, Elaut et al., 2020; Fisher, Castellini et al., 2016; Giltay & Gooren, 2000; T'Sjoen et al., 2019; Yeung et al., 2020). Other testosterone-associated changes include increased lean body mass, skin oiliness, (de Blok et al., 2020; Hembree et al., 2017; Kuper, Mathews et al., 2019; Taliaferro et al., 2019; Tishelman & Neumann-Mascis, 2018) (see Appendix C—Table 1).

Estrogen treatment induces breast development. However, fewer than 20% of individuals reach Tanner breast stages 4–5 after 2 years of treatment (de Blok et al., 2021). Additional changes include decreases in testicular volume, lean body mass, skin oiliness, sexual desire, spontaneous erections, facial hair, and body hair along with increased subcutaneous body fat) (see Appendix C—Table 1). In adult patients, estrogen does not alter a person's voice or height (Iwamoto, Defreyne et al., 2019; Wiepjes et al., 2019).

The time course and extent of physical changes vary among individuals and are related to factors such as genetics, age of initiation, and overall state of health (Deutsch, Bhakri et al., 2015; van Dijk et al., 2019). Knowledge of the extent and timing of sex hormone–induced changes, if available, may prevent the potential harm and expense of unnecessary treatment changes, dosage increases, and premature surgical procedures (Dekker et al., 2016).

Statement 12.13

We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment. For supporting text, see Statement 12.15.

Statement 12.14

We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age >45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended. For supporting text, see Statement 12.15).

Statement 12.15

We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as part of a gender- affirming hormonal treatment.

Determining the safest and most efficacious estrogen compound and route of administration for TGD people is an important topic. The recommended estrogen-based regimens are presented in Appendix C—Table 4. The Amsterdam Medical Center (AMC) first reported 45 events of VTE occurring in 816 transgender women, notably an expected incidence ratio of VTE 20-fold higher than that reported in a reference population (van Kesteren et al., 1997). Following this report, the AMC clinic recommended the use of transdermal estradiol for transgender women older than 40 years of age, which subsequently lowered the incidence of VTE (Nota et al., 2019; Toorians et al., 2003). Other studies suggested ethinyl estradiol is associated with a higher risk of blood clotting due to an increased resistance to the anticoagulating effects of activated protein C (APC) and elevated concentrations of the clotting factors protein C and protein S (Toorians et al., 2013). Other studies published within the past 15 years from other clinics reported transgender women taking other forms of estrogen had lower rates of VTE than transgender women taking ethinyl estradiol (Asscheman et al., 2013). Furthermore, a 2019 systematic review concluded ethinyl estradiol administration was associated with the highest risk of VTE in transgender women, while an association between progesterone use and VTE was also identified (Goldstein et al., 2019).

The 2017 Endocrine Society guidelines did not recommend conjugated equine estrogens (CEEs) as a treatment option because blood levels of conjugated estrogens cannot be measured in transgender women making it difficult to prevent supraphysiologic dosing of estrogen and thereby increasing the potential risk of VTE (Hembree et al., 2017). A retrospective study from the UK examined the risks of oral CEE versus oral estradiol valerate versus oral ethinyl estradiol and found up to a 7-fold increase in the percentage of transgender women in the oral CEE group

who developed VTE compared with transgender women using other forms of estrogen (Seal et al., 2012). In a nested, case-control study, over 80,000 cisgender women aged 40–79 who developed a VTE were matched to approximately 390,000 cisgender women without VTE; the results showed oral estradiol use had a lower risk of VTE than conjugated estrogens, and transdermal estrogen was not associated with an increased risk of VTE (Vinogradova et al., 2019).

A systematic review evaluated several formulations of estrogen and identified a retrospective and a cross-sectional study that made head-to-head comparisons of the risks associated with different formulations (Wierckx, Mueller et al., 2012; Wierckx et al., 2013). No identified studies evaluating the risk of different formulations of estrogen employed a prospective interventional design. The retrospective study examined 214 transgender women taking transdermal estradiol (17β-estradiol gel 1.5 mg/d or estradiol patch 50 mcg/d) or a daily intake of oral estrogens (estradiol 2 mg/d, estriol 2 mg/d, ethinyl estradiol 50 mcg/day, or ethinyl estradiol 30–50 mcg in an oral contraceptive) (Wierckx et al., 2013). Within a 10-year observation period, 5% of the cohort developed a VTE, 1.4% (3 of 214) experienced a myocardial infarction (MI), and 2.3% (5 of 214) a transient ischemic attack or cerebrovascular accident (TIA/CVA). The prevalence of VTE, MI and TIA/CVA was increased following the initiation of estrogen therapy. However, the authors did not report differences between regimens of estrogen in terms of these endpoints.

The same group of investigators conducted a cross-sectional study that examined 50 transgender women (mean age 43 10) taking oral estrogen (estradiol valerate 2 mg/d, estriol 2 mg/d or ethinyl estradiol 50–120 mcg/day) or using transdermal estradiol (17β-estradiol 1.5 mg/day or estradiol 50 mcg/day) over a follow-up duration of 9.2 years (Wierckx, Mueller et al., 2012). Twelve percent (n = 6) developed either a VTE, MI, or a TIA/CVA. Two of the participants were taking conjugated estrogen 0.625 mg/d (one person in combination with cyproterone acetate), 2 participants were taking ethinyl estradiol 20–50 mcg/d, 1 was taking cyproterone acetate 50 mg/d, while the estrogen regimen used by the sixth participant was not defined. None of the subjects taking oral estradiol or transdermal estradiol developed a VTE, MI, or TIA/CVA.

One prospective study examined the route of estrogen administration in 53 transgender women in a multicenter study carried out throughout Europe. Transgender women younger than 45 years of age (n = 40) received estradiol valerate 4 mg/d in combination with cyproterone acetate (CPA) 50 mg/d and transgender women older than 45 years of age (n = 13) received transdermal 17β-estradiol, also with CPA. No VTE, MI, or TIA/CVA was reported after a 1-year follow-up in either the oral or transdermal estrogen group. An additional retrospective study from Vienna found no occurrences of VTE among 162 transgender women using transdermal estradiol who were followed for a mean of 5 years (Ott et al., 2010).

We are strongly confident in our recommendation against the use of ethinyl estradiol based on historical data from the Amsterdam clinic demonstrating a reduction in the incidence of VTE after discontinuing the use of ethinyl estradiol and the recent systematic review demonstrating an increased risk of VTE in transgender women taking ethinyl estradiol (Weinand & Safer, 2015). We are confident in our recommendation against the use of CEE based on the 2012 study by Seal et al. demonstrating an increased risk of VTE in transgender women taking CEE compared with other formulations of estrogen and with data from cisgender women on hormone replacement therapy (Canonico et al., 2007; Seal et al., 2012). Prospective and retrospective studies in transgender women have reported occurrences of VTE/MI/CVA only in those taking CEE or ethinyl estradiol. Since estradiol is inexpensive, more widely available, and appears safer than CEE in limited studies, the committee recommends against using CEE when estradiol is an available treatment option. The quality of studies may be limited to prospective, cohort or cross-sectional study designs; however, the stronger level of recommendation is based on the consistent evidence supporting the association between the use of ethinyl estradiol and CEE and a greater risk of VTE/MI/CVA in transgender women.

We are also confident in our recommendation for the administration of transdermal preparations of estrogen in older transgender women

(age > 45 years) or those with a previous history of VTE. The confidence in our recommendation is based on the decreased incidence of VTE reported from the Amsterdam clinic when transgender women are switched to using transdermal preparations after age 40 (van Kesteren et al., 1997). Furthermore, the prospective, multicenter cohort study ENIGI found no incidence of VTE/MI/CVA in transgender women who are routinely switched to transdermal estrogen at age 45 (Dekker et al., 2016). In addition, a study by Ott et al. demonstrated no incidence of VTE in 162 transgender women treated with estradiol patches (Ott et al., 2010).

With the exception of cyproterone acetate (note this is not approved for use in the US because of concerns of potential hepatotoxicity), the use of progestins in hormone therapy regimens remains controversial. To date, there have been no quality studies evaluating the role of progesterones in hormone therapy for transgender patients.

We are aware some practitioners who prescribe progestins, including micronized progesterone, are under the impression there may be improvements in breast and/or areolar development, mood, libido, and overall shape for those seeking it along with other benefits yet to be demonstrated (Deutsch, 2016a; Wierckx, van Caenegem et al., 2014). However, these improvements remain anecdotal, and there are no quality data to support such progestin use. An attempted systematic review we commissioned for this version of the SOC failed to identify enough data to make a recommendation in favor of any progestins. Instead, existing data suggest harm is associated with extended progestin exposure (Safer, 2021).

For cisgender women who have a uterus, progestins in combination with estrogens are necessary to avoid the endometrial cancer risk associated with the administration of unopposed estrogen. For cisgender women who do not have a uterus, progestins are not used. The best data for the concerns related to progestin use come from comparisons between the above two cisgender populations, which we acknowledge is not necessarily generalizable to this population. Although not definitive of a class effect for all progestins, medroxyprogesterone added to combined equine estrogens is associated with greater breast cancer and cardiac risks (Chlebowski 2020; Manson, 2013). It is important to note data from the Women's Health Initiative (WHI) studies may not be generalizable to transgender populations. Compared with the cisgender women in the studies, transgender populations seeking hormone therapy tend to be younger, do not use equine estrogen, and hormone therapy in these cases address current mental health and quality of life and not solely risk prevention (Deutsch, 2016a).

Potential adverse effects of progestins include weight gain, depression, and lipid changes. Micronized progesterone may be better tolerated and may have a more favorable impact on the lipid profile than medroxyprogesterone (Fitzpatrick et al., 2000). When paired with estrogens for transgender women, the progestin cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas—none of which are seen when estrogens are paired with GnRH agonists or spironolactone (Bisson, 2018; Borghei-Razavi, 2014; Defreyne, Nota et al., 2017; Sofer et al., 2020).

Thus, data to date do not include quality evidence supporting a benefit of progestin therapy for transgender women. However, the literature does suggest a potential harm of some progestins, at least in the setting of multi-year exposure. If, after a discussion of the risks and benefits of progesterone treatment, there is a collaborative decision to begin a trial of progesterone therapy, the prescriber should evaluate the patient within a year to review the patient's response to this treatment.

Statement 12.16

We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gendered diverse people with testes taking estrogen as part of a hormonal treatment plan if their individual goal is to approximate levels of circulating sex hormone in cisgender women.

Most gender clinics in the US and Europe prescribe estrogen combined with a testosterone-lowering medication (Mamoojee et al., 2017) (see Appendix C—Table 5). In the

US, spironolactone is the most commonly prescribed testosterone-lowering medication, while GnRHas are commonly used in the UK, and cyproterone acetate are most often prescribed in the rest of Europe (Angus et al., 2021; Kuijpers et al., 2021). The rationale for adding a testosterone-lowering medication is two-fold 1) to lower testosterone levels to within the reference range of cisgender women; and 2) to reduce the amount of estrogen needed to achieve adequate physical effects. Each testosterone-lowering medication has a different side effect profile. Spironolactone is an antihypertensive and potassium-sparing diuretic, and thus may lead to hyperkalemia, increased frequency of urination, and a reduction in blood pressure (Lin et al., 2021). Cyproterone acetate has been associated with the development of meningioma and hyperprolactinemia (Nota et al., 2018). GnRHa's, while very effective in lowering testosterone levels, can result in osteoporosis if doses of estrogen given concurrently are insufficient (Klink, Caris et al., 2015).

One systematic review identified one study that reported findings from a head-to-head comparison of the testosterone-lowering medications cyproterone acetate and leuprolide (Gava et al., 2016). Two studies compared a group of transgender women taking estrogen plus testosterone-lowering medications with a group who received only estrogen. The systematic review did not provide sufficient evidence to suggest any of the three testosterone-lowering medications had a better safety profile in terms of improved outcomes in bone health, testosterone levels, potassium levels, or in the incidence of hyperprolactinemia or meningiomas (Wilson et al., 2020). Therefore, no recommendation can be given. The review did report spironolactone-based regimens were associated with a 45% increase in prolactin levels, whereas cyproterone-based regimens increased prolactin levels by more than 100%. However, the clinical significance of elevated prolactin levels is not clear because the rates of prolactinomas were not significantly elevated in either the spironolactone- or CPA-treated groups (Wilson et al., 2020). One retrospective, cohort study from a single center in the US reported no clinically significant increases in prolactin levels in 100 transgender women treated with estrogen plus spironolactone (Bisson et al., 2018). A retrospective study from the Netherlands of 2,555 transgender women taking primarily CPA with various formulations of estrogen reported an increased standardized incidence ratio of meningiomas in patients who used cyproterone acetate after gonadectomy for many years when compared with the general Dutch population (Nota et al., 2018). Furthermore, in a shorter study in Belgium, 107 transgender women had transient elevations in prolactin levels following treatment with cyproterone acetate, which declined to normal after discontinuation (Defreyne, Nota et al., 2017). A recent publication, not included in the systematic review, examined 126 transgender women taking spironolactone, GnRHas, or cyproterone and concluded cyproterone was associated with higher prolactin levels and a worse lipid profile than spironolactone or GnRHas (Sofer et al., 2020). After balancing the costs and accessibility of measuring prolactin levels against the clinical significance of an elevated level, a decision was made not to make a recommendation for or against monitoring prolactin levels at this time. HCPs should therefore make individualized clinical decisions about the necessity to measure prolactin levels based on the type of hormone regimen and/or the presence of symptoms of hyperprolactinemia or a pituitary tumor (e.g., galactorrhea, visual field changes).

Cyproterone has also been linked to meningiomas. Nine cases of meningioma have been reported in the literature among transgender women primarily taking cyproterone acetate (Mancini et al., 2018). This increased risk has also been identified in cisgender populations. In 2020, the European Medicines Agency published a report recommending cyproterone products with daily doses of 10 mg or more should be restricted because of the risk of developing meningioma (European Medicines Agency, 2020). Most likely this association is a specific effect of cyproterone acetate and has not been extrapolated to include other testosterone-lowering drugs. In the US, where cyproterone acetate is not available, the North American Association of Central Cancer Registries (NAACCRs) database did not identify an increased risk of brain tumors (not specific to

meningiomas) among transgender women (Nash et al., 2018). Furthermore, there was not an increase in the hazard ratio of brain tumors in the Kaiser cohort of 2,791 transgender women compared with cisgender controls (Silverberg et al., 2017). No long-term studies have reported on the risk of meningiomas and prolactinomas in transgender women taking GnRHas.

Our strong recommendation for the use of testosterone-lowering medications as part of a hormone regimen for transgender individuals with testes is based on the global practice of using these medications in addition to estrogen therapies as well as the relatively minimal risk associated with these therapies. However, we are not able to make a recommendation favoring one testosterone-lowering medication over another at this time. The published data thus far raises some concerns about the risk of meningiomas with the prolonged use (>2 years) and higher doses (>10mg daily) of cyproterone acetate (Nota et al., 2018; Ter Wengel et al., 2016; Weill et al., 2021).

Bicalutamide is an antiandrogen that has been used in the treatment of prostate cancer. It competitively binds to the androgen receptor to block the binding of androgens. Data on the use of bicalutamide in trans feminine populations is very sparse and safety data is lacking. One small study looked at the use of bicalutamide 50 mg daily as a puberty blocker in 23 trans feminine adolescents who could not obtain treatment with a GnRH analogue (Neyman et al., 2019). All adolescents experienced breast development which is also commonly seen in men with prostate cancer who are treated with bicalutamide. Although rare, fulminant hepatotoxicity resulting in death has been described with bicalutamide (O'Bryant et al., 2008). Given that bicalutamide has not been adequately studied in trans feminine populations, we do not recommend its routine use.

The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The Food & Drug Administration (FDA) approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. Data on the use of 5α-reductase inhibitors in trans feminine populations is very sparse (Irwig, 2021). It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We therefore do not recommend their routine use in trans feminine populations. Finasteride may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. Nonetheless, treatment with a 5α-reductase inhibitor may impair clitoral growth and the development of facial and body hair in trans masculine individuals. Studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in transgender populations.

Statement 12.17

We recommend health care professionals monitor hematocrit (or hemoglobin) levels in transgender and gender diverse people treated with testosterone.

There are good quality data suggesting a rise in hematocrit (or hemoglobin) is associated with TGD persons treated with testosterone (Defreyne et al., 2018). The testosterone regimens in the systematic review included testosterone esters ranging from the equivalent of 25–250 mg SC/IM weekly, testosterone undecanoate 1000 mg every 12 weeks, or testosterone gel 50 mg applied daily to the skin (Defreyne et al., 2018; Gava et al., 2018; Giltay et al., 2000; Meriggiola et al., 2008; Pelusi et al., 2014; T'Sjoen et al., 2005; Wierckx, van Caenegem et al., 2014; Wierckx, van de Peer et al., 2014). The expected rise should be consistent with reference ranges in cisgender males.

Statement 12.18

We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery. For supporting text, see Statement 12.19.

Statement 12.19

We suggest health care professionals counsel eligible* transgender and gender diverse people about the various options for gender-affirmation surgery unless surgery is either not indicated or is medically contraindicated.

Despite the absence of evidence, perioperative clinical standards for gender-affirmation surgeries have included cessation of hormone therapy for 1–4 weeks before and after surgery, most commonly genital surgeries (Hembree et al., 2009). Such practice was meant to mitigate the risk of VTE associated with exogenous estrogen administration (Hembree et al., 2009). Estrogen and testosterone could then be resumed at some point postoperatively.

After careful examination, investigators have found no perioperative increase in the rate of VTE among transgender individuals undergoing surgery, while being maintained on sex steroid treatment throughout when compared with that among patients whose sex steroid treatment was discontinued preoperatively (Gaither et al., 2018; Hembree et al., 2009; Kozato et al., 2021; Prince & Safer, 2020). Sex steroid treatment is especially important after gonadectomy to avoid the sequelae of hypogonadism, the risk of developing osteoporosis, and for the maintenance of mental health and quality of life (Fisher, Castellini et al., 2016; Rosen et al., 2019). Thus, hormone providers and surgeons should educate patients about the necessity for continuous exogenous hormone therapy after gonadectomy.

To be able to educate patients and serve as clinical advocates, HCPs should be knowledgeable about the risks and benefits of gender-affirmation surgeries and should also be cognizant of the performance measures and surgical outcomes of the surgeons to whom they might refer patients (Beek, Kreukels et al., 2015; Colebunders et al., 2017; Wiepjes et al., 2018). In general, most medically necessary surgeries can be thought of as involving three regions: the face, chest/breasts, and genitalia (internal and external). Additional medically necessary procedures include body contouring and voice surgery. See medical necessity statement in Chapter 2—Global Applicability, Statement 2.1).

Multiple procedures are available for facial gender-affirming surgeries including, but not limited to chondrolanryngoplasty, rhinoplasty, contouring or augmentation of the jaw, chin, and forehead, facelift, hair removal and hair transplantation (see Chapter 13—Surgery and Postoperative Care). Procedures available for chest/breast surgery include breast augmentation, double mastectomy with nipple grafts, periareolar mastectomy, and liposuction. The most common gender-affirmation surgery for TGD individuals with endogenous breast development is masculinizing chest surgery (mastectomy) (Horbach et al., 2015; Kailas et al., 2017).

Internal genital surgery procedures include but are not limited to orchiectomy, hysterectomy, salpingo-oophorectomy, vaginoplasty, and colpectomy/vaginectomy (Horbach et al., 2015; Jiang et al., 2018). The inner lining in vaginoplasty is typically constructed from penile skin, skin grafts, a combination of both, or a bowel segment. Removal of the uterus/ovaries can be performed individually or all at once (hysterectomy, salpingo-oophorectomy, and colpectomy). If colpectomy is performed, a hysterectomy must also be performed. The ovaries may remain in situ, upon patient request. A potential benefit of leaving one or both ovaries is fertility preservation, while the downside is the potential for the development of ovarian pathology, including cancer (De Roo et al., 2017).

External genital surgery procedures include but are not limited to vulvoplasty, metoidioplasty, and phalloplasty (Djordjevic et al., 2008; Frey et al., 2016). Hair removal is generally necessary before performing external genital procedures (Marks et al., 2019). Vulvoplasty can include the creation of the mons, labia, clitoris, and urethral opening. Urethral lengthening is an option for both metoidioplasty and phalloplasty, but is associated with a greatly increased complication rate (Schechter & Safa, 2018). Wound care and physical therapy are necessary for managing wounds resulting from the donor sites for phalloplasty (van Caenegem, Verhaeghe et al., 2013). Pelvic physical therapy can also be an important adjunct intervention after surgery for managing voiding and sexual function (Jiang et al., 2019). Dialogue, mutual understanding, and clear communication in a common language between patients, HCPs, and surgeons will contribute to well-considered decisions about the available surgical procedures.

Statement 12.20

We recommend health care professionals initiate and continue gender-affirming hormone

therapy for eligible* transgender and gender diverse people who wish this treatment due to demonstrated improvement in psychosocial functioning and quality of life. For supporting text, see Statement 12.21.

Statement 12.21

We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

Several mental health disparities have been documented in the transgender population including depression, suicidality, anxiety, decreased self-esteem, and post-traumatic stress disorder (Arcelus et al., 2016; Becerra-Culqui et al, 2018; Bouman et al., 2017; Eisenberg et al., 2017; Heylens, Elaut et al., 2014; Witcomb et al., 2018). The gender minority stress model provides evidence of several mediators and moderators of these disparities (Hendricks & Testa, 2012; Meyer, 2003). Mediators and moderators of mental health disparities unique to transgender people include experiences of discrimination, victimization, misgendering, family rejection, and internalized transphobia (Hendricks & Testa, 2012). Factors that have a positive effect on mental health include family acceptance, supportive social and romantic relationships, transgender community connectedness, protection by affirming and inclusive policies, policies of affirmation and inclusion, possession of updated legal name/gender documentation, and achievement of physical gender transition based on individualized embodiment goals (Bauer et al., 2015; Bockting et al., 2013; Bouman et al., 2016; Davey et al., 2014; de Vries et al., 2014; Du Bois et al., 2018; Gower, Rider, Brown et al., 2018; Hendricks & Testa, 2012; Keo-Meier et al., 2015; Meier et al., 2013; Pflum et al., 2015; Ryan et al., 2010; Smith et al., 2018).

Hormone therapy has been found to positively impact the mental health and quality of life of TGD youth and adults who embark on this treatment (Aldridge et al., 2020; Allen et al., 2019; Bauer et al., 2015; Nobili et al., 2018; Russell et al., 2018; Ryan, 2009). In many cases, hormone therapy is considered a lifesaving intervention (Allen et al., 2019; Grossman & D'Augelli, 2006; Moody et al., 2015). Several studies have found associations between the initiation of hormone therapy and improved mental health in youth and adults (Aldridge et al., 2020; Costa et al., 2016; de Vries et al., 2014; Kuper et al., 2020; Nguyen et al., 2018; White Hughto & Reisner, 2016), including improvements in quality of life (Gorin-Lazard et al., 2012; Gorin-Lazard et al., 2013; Murad et al., 2010; Newfield et al., 2006; Nobili et al., 2018; White Hughto & Reisner, 2016), a reduction in anxiety and depression (Aldridge et al., 2020; Colizzi et al., 2014; Davis & Meier, 2014; de Vries, Steensma et al., 2011; Gómez-Gil et al., 2012; Rowniak et al., 2019), decreased stress, and decreased paranoia (Keo-Meier & Fitzgerald, 2017). A prospective, controlled trial using the Minnesota Multiphasic Personality Inventory-2 (MMPI-2) demonstrated significant improvement in multiple domains of psychological functioning in transgender men after only 3 months of testosterone treatment (Keo-Meier et al., 2015). Although there are higher rates of autism symptoms in the transgender population, these symptoms have not been found to increase after the initiation of hormone therapy (Nobili et al., 2020).

As a reduction in depressive symptoms may correlate with a decrease in the risk of suicide, withholding hormone therapy based on the presence of depression or suicidality may cause harm (Keo-Meier et al., 2015; Levy et al., 2003). Turban, King et al. (2020) found a decrease in the odds of lifetime suicidal ideation in adolescents who required pubertal suppression and had access to this treatment compared with those with a similar desire with no such access (Turban, King et al., 2020). A recent systematic review found pubertal suppression in TGD adolescents was associated with an improved social life, decreased suicidality in adulthood, improved psychological functioning and quality of life (Rew et al., 2020). Because evidence suggests hormone therapy is directly linked to decreased symptoms of depression and anxiety, the practice of withholding hormone therapy until these symptoms are treated with traditional psychiatry is considered to have iatrogenic effects

(Keo-Meier et al., 2015). If psychiatric treatment is indicated, it can be started or adjusted concurrently without discontinuing hormone therapy.

**For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents as well as Appendix D.*

CHAPTER 13 Surgery and Postoperative Care

Medically necessary gender-affirmation surgery (GAS) refers to a constellation of procedures designed to align a person's body with their gender identity (see Chapter 2—Global Applicability for medical necessity, Statement 2.1). This chapter describes surgery and postoperative care recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to surgery for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Recognizing the diverse and heterogeneous community of individuals who identify as transgender and gender diverse (TGD), gender-affirming surgical interventions may be categorized along a spectrum of procedures for individuals assigned male at birth (AMAB) and assigned female at birth (AFAB).

In appropriately selected TGD individuals, the current literature supports the benefits of GAS. While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis (Canner et al., 2018; Gaither et al., 2018; Morrison et al., 2016). In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective (Agarwal et al., 2018; Frederick et al., 2017; Top & Balta, 2017; van de Grift, Elaut et al., 2017; van de Grift et al., 2016), retrospective (Bertrand et al., 2017; Claes et al., 2018; Esmonde et al., 2019; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Poudrier et al., 2019; Wolter et al., 2015; Wolter et al., 2018), and cross-sectional cohort studies (Olson-Kennedy, Warus et al., 2018; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; van de Grift, Elfering et al., 2018). The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective (Weigert et al., 2013; Zavlin et al., 2018), 1 retrospective cohort (Fakin et al., 2019), and 3 cross-sectional cohort studies (Kanhai et al., 2000; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018). All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective (Buncamper et al., 2017; Cardoso da Silva et al., 2016; Kanhai, 2016; Manero Vazquez et al., 2018; Papadopulos, Zavlin et al., 2017; Tavakkoli Tabassi et al., 2015; Wei et al., 2018; Zavlin et al., 2018), 15 retrospective cohort (Bouman, van der Sluis et al., 2016; Buncamper et al., 2015; Hess et al., 2016; Jiang et al., 2018; LeBreton et al., 2017; Manrique et al., 2018; Massie et al., 2018; Morrison et al., 2015; Papadopulos, Lelle et al., 2017; Raigosa et al., 2015; Salgado et al., 2018; Seyed-Forootan et al., 2018; Sigurjonsson et al., 2017; Simonsen et al., 2016; Thalaivirithan et al., 2018), and 3 cross-sectional cohort studies have recently been reported (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018).

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident

Statements of Recommendations

13.1- We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:
13.1.a- Training and documented supervision in gender-affirming procedures;
13.1.b- Maintenance of an active practice in gender-affirming surgical procedures;
13.1.c- Knowledge about gender diverse identities and expressions;
13.1.d- Continuing education in the field of gender-affirmation surgery
13.1.e- Tracking of surgical outcomes.
13.2- We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.
13.3- We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.
13.4- We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.
13.5- We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity).
13.6- We suggest health care professionals consider gender-affirming genital procedures for eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).
13.7- We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.
13.8- We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.
13.9- We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.
13.10- We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.
13.11- We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

** For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescents chapters and Appendix D.*

when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort (Garaffa et al., 2010; Stojanovic et al., 2017; Vukadinovic et al., 2014), 6 retrospective cohort (Cohanzad, 2016; Garcia et al., 2014; Simonsen et al., 2016; van de Grift, Pigot et al., 2017; van der Sluis et al., 2017; Zhang et al., 2015), and 4 cross-sectional studies (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; Wierckx, Van Caenegem et al., 2011), which reviewed the risks and benefits of these procedures.

In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort (Morrison et al., 2020), 5 retrospective cohort (Bellinga et al., 2017; Capitán et al., 2014; Noureai et al., 2007; Raffaini et al., 2016; Simon et al., 2022), and 2 cross-sectional studies (Ainsworth & Spiegel, 2010; van de Grift, Elaut

et al., 2018). All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial GAS significantly improves both mid- and long-term quality of life (Morrison et al., 2020). The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended.

Additional procedures and/or interventions such as hair removal (prior to facial and/or genital surgery) may be required as part of the preoperative process. See Chapter 15—Primary Care. Furthermore, consultation with pelvic floor physical therapy may be important (or required) both before and after surgery.

Representative surgical interventions include (for complete list, see appendix E and the end of this chapter):

AMAB: facial feminization surgery (including chondrolaryngoplasty/vocal cord surgery), gender-affirming breast surgery, body contouring procedures, orchiectomy, vagino/vulvoplasty (with/without depth), aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

AFAB: facial masculinization surgery, gender-affirming chest surgery, hysterectomy/oophorectomy, metoidioplasty (including placement of testicular prosthesis), phalloplasty (including placement of testicular/penile prostheses), body contouring procedures, aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

It is important surgeons understand the indication(s) and the timing for GAS. This is especially important when caring for adolescents (see Chapter 6—Adolescents).

It is important the surgeon and the patient participate in a shared decision-making approach that includes 1) a multidisciplinary approach; 2) an understanding of the patient's goals and expectations; 3) a discussion regarding the surgical options and associated risks and benefits; and 4) an informed plan for aftercare (see Chapter 5—Assessment for Adults). These recommendations are designed to facilitate an individualized approach to care.

Appropriate aftercare is essential for optimizing outcomes (Buncamper et al., 2015; Lawrence, 2003), and it is important patients are informed about postoperative needs (including local wound care, activity restrictions, time off from work or school, etc.). In addition, it is important the surgeon is available to provide and facilitate postoperative care, refer to specialty services, or both as needed. This may include the need for ongoing support (i.e., both from the caregiver as well as the primary care provider, mental health professionals (MHPs), or both), as well as the need for routine primary care (i.e., breast/chest cancer screening, urologic/gynecologic care, etc.).

With the increase both in public interest and in the number of gender-affirming surgical procedures (Canner et al., 2018; Ross, 2017; Shen et al., 2019), additional training, tracking of outcomes, and continuing medical education for surgeons are necessary (Schechter et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 13.1

We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:

a. **Training and documented supervision in gender-affirming procedures;**
b. **Maintenance of an active practice in gender-affirming surgical procedures;**
c. **Knowledge about gender diverse identities and expressions;**
d. **Continuing education in the field of gender-affirmation surgery;**
e. **Tracking of surgical outcomes.**

Surgeons offering GAS may have a variety of surgical specialty training and backgrounds. The most common surgical specialties include plastic surgery, urology, gynecology, otolaryngology and oro-maxillofacial surgery (Jazayeri et al., 2021). Consistent with other surgical domains, we recommend only surgeons who are certified or eligible to be certified by their respective national professional boards offer GAS. Furthermore, it is recommended surgeons offering care for TGD people have received documented training in gender-affirming procedures and principles of gender-affirming care (Schechter et al., 2017; Schechter & Schechter, 2019). The latter includes, but is not limited, to knowledge about gender diverse identities and expressions, and how those affect patient goals, expectations, and outcomes. It is important surgeons offering GAS be familiar with the available procedures and can provide informed consent. If surgeons do not offer a requested procedure, they may offer a referral for a second opinion. Surgeons offering GAS are expected to participate in continuing education activities in the field of GAS (i.e., meetings, conferences, seminars, etc.) to maintain current knowledge. We further recommend surgical outcomes be tracked and communicated to the patients as part of the informed consent (Schechter et al., 2017).

In addition, hospitals, institutions, and physician offices that offer GAS need to be knowledgeable regarding cultural competencies (i.e., language, terminology, etc.). This may require ongoing and regular staff education.

Statement 13.2

We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.

Prior to breast augmentation or mastectomy, individuals need to be informed about and assessed for breast cancer risk factors, including genetic mutations (i.e., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery (Brown, Lourenco et al., 2021; Brown & Jones, 2015; Colebunders et al., 2014; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Breast cancer screening balances the identification of cancer with the selection of appropriate imaging, tests, and procedures. Currently, evidence-based screening guidelines specific for TGD individuals do not exist (Salibian et al., 2021), however, recent guidelines have been proposed by the American College of Radiology (Brown, Lourenco et al., 2021). Because the risk of cancer in individuals seeking gender-affirming breast augmentation or mastectomy is similar to that in the general population (even in the setting of hormone use), existing cancer screening guidelines need to be followed (Brown & Jones, 2015; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Professionals need to be familiar with updates to these guidelines as they are subject to change. Individuals who undergo gender-affirming surgery of the chest should have ongoing breast cancer surveillance, which should be overseen by their primary care providers.

Statement 13.3

We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.

Details about the timing, technique, and duration of the aftercare requirements are shared with patients in the preoperative period such that appropriate planning may be undertaken. This includes a discussion regarding the anticipated staging of surgical procedures (and associated travel requirements). Given the small number of surgeons who specialize in GAS, it is common for patients to travel for their procedures. Prior to surgery, surgeons should provide patients with a postoperative follow-up schedule. The surgeon should discuss the duration of the patient's travel dates, the anticipated inpatient versus outpatient stay, and the potential need for flexibility in travel arrangements (especially if complications occur). Given the complexity and cost of travel and lodging, changes in the care plan should be shared with the patient as early as possible. Surgeons should facilitate continuity of care with a local provider upon returning home.

Aftercare and postsurgical follow-up are important. Gender-affirming surgical procedures

often have specific aftercare requirements, such as postsurgery resources (stable, safe housing; resources for travel and follow-up care), instructions in health-positive habits (e.g., personal hygiene, healthy living, prevention of urinary tract infections (UTIs) and sexually-transmitted infections (STIs) (Wierckx, Van Caenegem et al., 2011)), postsurgery precautions or limitations on activities of daily life (e.g., bathing, physical activity, exercise, nutritional guidance, resumption of sexual activity) (Capitán et al., 2020), postsurgery resumption of medications (i.e., anticoagulants, hormones, etc.), and detailed postsurgery self-care activities (e.g., postvaginoplasty dilation and douching regimens, activation of a penile prosthesis, strategies to optimize postphalloplasty urination, recommendations for hair transplant care) (Capitán et al., 2017; Falcone et al., 2018; Garcia, 2018; Hoebeke et al., 2005). Some aspects of postsurgery self-care activities may be introduced prior to surgery and are reinforced after surgery (Falcone et al., 2018). As issues such as wound disruptions, difficulty with dilation, and UTIs may occur (Dy et al., 2019), the follow-up period provides an opportunity to intervene, mitigate, and prevent complications (Buncamper et al., 2016; Garcia, 2021).

Statement 13.4

We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.

Infertility is often a consequence of both gender-affirming hormone therapy (temporary) and GAS (permanent), and fertility preservation is discussed prior to medical interventions, surgical interventions, or both (Defreyne, van Schuylenbergh et al., 2020; Jahromi et al., 2021; Jones et al., 2021). Surgical interventions that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these interventions and on an ongoing basis thereafter (Hembree et al., 2017).

For specific recommendations regarding reproductive options, see Chapter 16—Reproductive Health.

Statement 13.5

We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity). For supporting text, see Statement 13.6.

Statement 13.6

We suggest health care professionals consider gender-affirming genital procedures in eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result unless hormone therapy is either not desired or is medically contraindicated).

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). Depending upon the surgical result required, a period of hormone treatment may be required (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty) or preferred for psychological reasons, anatomical reasons, or both (breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of this on the proposed surgery.

For individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Statement 13.7

We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.

Substantial evidence (i.e., observational studies (Monstrey et al., 2001; Stojanovic et al., 2017), literature reviews and expert opinions (Esteva de Antonio et al., 2013; Frey et al., 2017; Hadj-Moussa et al., 2019; Pan & Honig, 2018), established guidelines (Byne et al., 2018; Chen, Fuqua et al., 2016; Hembree et al., 2017; Karasic & Fraser, 2018; Klein, Paradise et al., 2018; Weissler et al., 2018), and a thematic content analysis (Gerritse et al., 2018), support the importance of a multidisciplinary (i.e., medical, mental health, and surgery) approach to transgender health care.

A multidisciplinary approach is especially important in managing mental health issues if these are experienced by a TGD person undergoing GAS (de Freitas et al., 2020; Dhejne et al., 2016; van der Miesen et al., 2016). In addition, primary care providers and medical specialists can help support decisions regarding the timing of surgery, surgical outcomes and expectations, perioperative hormone management, and optimization of medical conditions (Elamin et al., 2010; Hembree et al., 2017).

For specific recommendations regarding presurgical assessment in adolescents, see Chapter 6—Adolescents.

Statement 13.8

We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.

Gender identities may present along a spectrum, and the expression of a person's identity may vary quite widely amongst individuals (Beek et al., 2015; Koehler et al., 2018). While the overall goal of a particular procedure usually includes reduction of gender dysphoria (van de Grift, Elaut et al., 2017) or achieving gender congruence, gender diverse presentations may lead to individually customized surgical requests some may consider "non-standard" (Beek et al., 2015; Bizic et al., 2018). Individually customized surgical requests can be defined as 1) a procedure that alters an individual's gender expression without necessarily aiming to express an alternative, binary gender; 2) the "non-standard" combination of well-established procedures; or 3) both.

This is designed to help counsel and inform the patient as well as to ensure their goals can be achieved. The patient and their surgeon need to work together to ensure the patient's expectations are realistic and achievable, and the proposed interventions are safe and technically feasible. The patient and their surgical team need to engage in a shared decision-making process (Cavanaugh et al., 2016). This informed consent process needs to address the irreversibility of some procedures, the newer nature of some procedures, and the limited information available about the long-term outcomes of some procedures.

Statement 13.9

We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.

Postoperative complications following metoidioplasty/phalloplasty comprise the urinary tract and sexual function (Kang et al., 2019; Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019). Reported urethral complications (related to urethral lengthening) include urethral strictures 35–58%, urethral fistulae 15–70% (Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019), diverticulae, mucocele due to vaginal remnant, and hair growth within the neourethra (Berli et al., 2021; Veerman et al., 2020). Complications related to sexual function include limited to absent tactile and/or erogenous sensation, difficulties with orgasm function, and complications with penile prosthetics (Kang et al., 2019; Santucci, 2018). Penile prosthesis-related complications are estimated to involve infection (incidence 8–12%),

malfunction, urethral erosion, skin extrusion, and dislocation of its bone fixation (Falcone et al., 2018; Kang et al., 2019; Morrison et al., 2016). Although most urethral and prosthetic complications occur in the immediate and intermediate postoperative period, complications can occur at any time. Early detection may reduce morbidity (e.g., urethral strictures resulting in fistulae, pending erosion of a penile prosthetic leading to infection and requiring total explant) (Blecher et al., 2019).

Routine follow-up to assess for early evidence of urethral stricture (or other urinary issues) includes bladder ultrasound measurement of postvoid residual volume (to screen for and stage neourethral stricture), fluoroscopic urethrography (to identify and stage neourethral strictures, fistulae, and diverticulae), and cystourethroscopy to examine the urethra and bladder. TGD men may also have routine urologic issues that need not be related to gender transition (urinary calculi, hematuria, and genitourinary malignancies; fertility preservation) (Sterling & Garcia, 2020a, 2020b).

Statement 13.10

We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.

Vaginoplasty is a safe procedure (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). While complications may occur, most are self-limited or can be treated with minor interventions (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). Minor complications include issues such as the formation of granulation tissue, intravaginal hair growth, delayed wound healing or wound disruption (or both), aesthetic concerns, and introital stenosis (Ferrando, 2020; Kloer et al., 2021). While these complications are usually self-limited, they may impact patient well-being after surgery. Additionally, these issues may go either undiagnosed or may be misdiagnosed if patients are not able to access care provided by professionals with expertise in the field of transgender health. We recommend patients be followed by their primary surgeon in person and at regular intervals—for example at two weeks, three months, six months, and one year after surgery—although more follow-up may be indicated for some individuals.

Additional gynecologic care is conducted throughout the TGD person's lifetime and can be managed in many settings. A speculum exam to check for granulation tissue, hair, and lesions can be performed by the primary care provider, gynecologist, or GAS surgeon and may be necessary outside of the immediate postoperative period (Grimstad, McLaren et al., 2021; Suchak et al., 2015; van der Sluis et al., 2020). After confirmation by laboratory testing, UTIs, STIs, and other fluctuations in the vaginal microbiome may be treated following relevant guidelines formulated for cisgender populations (Hooton, 2012; Sherrard et al., 2018). Manual prostate checks are performed based on relevant guidelines formulated for cisgender populations via the vaginal canal, as the prostate is located on the anterior wall of the vagina (Carter et al., 2013).

Other complications include issues such as stenosis of the neovaginal canal, rectovaginal fistulae, and inflammation (intestinal vaginoplasty) (Bustos et al., 2021). These require a combination of nonsurgical and surgical treatment with consultation and possible referral back to the primary surgeon with other surgical consultants (i.e., colorectal surgeon), if required. In addition, as pelvic floor dysfunction may affect 30–40% of patients both prior to and following vaginoplasty, the availability of pelvic floor physical therapists is an important adjunct in the postoperative period (Jiang et al., 2019).

Statement 13.11

We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

The percentage of individuals who regret their GAS is very low (between 0.3% and 3.8%) (De Cuypere & Vercruysse, 2009; Defreyne, Motmans et al., 2017; Hadj-Moussa et al., 2019; Hadj-Moussa, Agarwal et al., 2018; Hadj-Moussa, Ohl et al., 2018; Landén et al., 1998; Narayan et al., 2021; van de Grift, Elaut et al., 2018; Wiepjes et al., 2018). The highest incidence of

regret was reported at a time when surgical techniques were less refined, the role of multidisciplinary care was less established, and the *Standards of Care* did not exist or were not widely known (Landén et al., 1998). Regret can be temporarily or permanent and may be classified as (Narayan et al., 2021) social regret (caused by difficulties in familial, religious, social, or professional life), medical regret (due to long-term medical complications, disappointment in surgical results or inadequate preoperative decision-making), and true gender-related regret (mostly based on patient experienced misdiagnosis, insufficient exploration of gender identity, or both). This classification is in accordance with previously discussed positive and negative predictive factors (De Cuypere & Vercruysse, 2009; Gils & Brewaeys, 2007; Pfäfflin & Junge, 1998).

A multidisciplinary team can help identify the etiology of regret as well as the temporal stability of the surgical request (Narayan et al., 2021). Following this evaluation and in consideration of the individual's circumstances, medical and/or surgical interventions with the intent of either continuing transition or performing surgical procedures to return anatomy to that of the sex assigned at birth may be indicated. For further information see Chapter 5—Assessment of Adults.

**For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescent chapters and Appendix D*

GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

CHAPTER 14 Voice and Communication

Human beings engage in communication practices not only to exchange ideas about the outside world, but also to present themselves as sociocultural beings and to negotiate forms of address, referral and treatment by others that allow them to feel safe and respected (Azul et al., 2022). The human voice is widely regarded as one of the key modalities that contributes to the communication of gender as one of the dimensions of human diversity. However, other aspects and ways of communicating (e.g., articulation, word choice, gesture, listener perceptions and attributions) need to be considered as well (Azul, 2015; Azul & Hancock, 2020). Throughout this chapter "voice and communication" is used as a phrase encompassing the meaning-making practices in which each of the participants of a social encounter engage according to their own needs, wishes, identifications, and capacities.

While a binary understanding of gender has dominated the research literature in this area, the approach recommended in this chapter implies a broadly inclusive view of gender identification (e.g., trans feminine, trans masculine, gender fluid, nonbinary, genderqueer, agender) and the understanding that gender does not exist in isolation, but intersects with other aspects of human diversity (e.g., First Nation status, ethnicity/race, sexuality, dis/ability, faith/religion/spirituality). The recommendations in this chapter apply to all transgender and gender diverse (TGD) people who are seeking professional voice and communication support, including children, adolescents, younger and older adults, and people who wish to transition or detransition, irrespective of their intervention choices.

Not every TGD person experiences challenges with or wants professional support for their voice and communication, but those who do often encounter barriers in accessing care. Although the percentages vary by country and TGD subpopulation, the statistics support the concern TGD people are not able to access voice and communication services when and how they desire (Eyssel et al., 2017; James et al., 2016; Oğuz et al., 2021; Södersten et al., 2015; Veale et al., 2019). In these studies, the percentage of TGD people wishing to receive voice and communication training or voice surgery is generally higher than the percentage of people who have undergone these interventions. With few exceptions, access to voice training is usually greater than access to voice surgery. Groups of TGD people who are further marginalized in their societies, such as TGD people of marginalized race/ethnicity, experience discrimination and limited access to care at even greater rates (James et al., 2016; Xavier et al., 2005).

Cost, not knowing where to access services, and services not being available are amongst the most common barriers cited by research participants. According to studies in the US (Hancock & Downs, 2021; Kennedy & Thibeault, 2020), Turkey (Oğuz et al., 2021), and Aotearoa/New Zealand (Veale et al., 2019), lack of accurate information about options for voice and communication services among TGD people is a significant and ubiquitous barrier to care. Notably, in Sweden, all TGD people are offered support for their voice and communication when a diagnosis of gender incongruence is made (Södersten et al., 2015). Additionally, cultural responsiveness of providers is only slowly improving (Hancock & Haskin, 2015; Jakomin et al., 2020; Matthews et al., 2020; Sawyer et al., 2014). Hancock and Downs (2021) have conducted preliminary work to identify specific barriers to voice and communication services and develop effective means for eliminating them.

This chapter is intended to provide guidance for health care professionals (HCPs) to support and foster well-being in all TGD people who are experiencing challenges or distress regarding their own voice and communication practices and/or regarding responses and attributions they receive from others (Azul et al., 2022).

A number of different approaches TGD people can use to modify their voice and communication, either individually or in combination include self-initiated change, which may be supported by resources TGD people use to guide their voice use and communication practice; behavioral change supported by voice and communication specialists (hereafter referred to as "voice and communication training"); and change as a result of androgen hormonal treatment and/or laryngeal surgery. The currently existing research evidence

does not include self-initiated change, but is focused on the latter three approaches.

A "voice and communication specialist" is someone who has knowledge regarding the ongoing and dynamic agency of speaker and listener practices, relevant professional interventions including behavioral, hormonal, and surgical, and relevant processes related to biophysiology, sociocultural meaning-making, and external material forces (Azul & Hancock, 2020). This specialist is capable of conducting appropriate assessments to inform the TGD person's choice and support the exploration of goals and intervention options by providing guidance in a culturally responsive, person-centered approach. This specialist has knowledge and skills in behavioral voice and communication intervention approaches.

Practices amenable to behavioral change include: speaking and singing voice, mindfulness, relaxation, respiration, pitch and pitch range, voice quality, resonance/timbre, loudness, projection, facial expression, gesture, posture, movement, introducing self to others, describing identifications and requesting culturally responsive treatment and forms of address by others, assertive and resilient responses to misattributions, practicing implementation of voice use and communication practices with different people and in different everyday settings (e.g., Hancock & Siegfriedt, 2020; Mills & Stoneham, 2017).

Voice and communication services are offered as part of a complete and coordinated approach to health, including support for medical, psychological, and social needs (Södersten et al., 2015); however, there are no prerequisites (e.g., hormone use, pursuit of surgeries, or duration living in a gender role). The overall purposes of voice and communication support for TGD people are:

- To educate clients about the factors that influence functional voice and communication practices and the communication of the speaker's identity (speaker, listener, professional practices, external material, biophysiological, and sociocultural factors);
- To enable clients to communicate their sense of sociocultural belonging (e.g., in terms of gender) in everyday encounters in a manner that matches the client's desired self-presentation and to develop, maintain and habituate voices, vocal qualities, and communication practices that support the clients' goals in a manner that does not harm the voice production mechanism;
- To provide training in functional voice production for clients who present with restrictions of voice function (e.g., as a result of overextending their voice production mechanism);
- To support clients with developing the capacity to assertively negotiate desired forms of address and referral from others (e.g., names, pronouns, titles) and to respond to misattributions in a skillful manner that contributes to increasing and maintaining the client's well-being;
- To support clients to develop the problem-solving skills needed to manage anxiety, stress, and dysphoria in collaboration with mental health providers; and to navigate barriers to practice or real-life use of one's preferred voice and communication.
- To provide, or refer clients to, supportive resources that facilitate developing voice and communication skills, vocal awareness, and well-being.
- To refer clients to, or collaborate with, other specialists such as mental health practitioners, laryngeal surgeons, and endocrinologists, who may be more equipped to meet the specific needs of that client. This may be especially relevant in cases where clients face unique challenges due to multiple barriers to their health and well-being or when the client wishes to pursue laryngeal surgery or hormone therapy.

Two types of laryngeal surgeries are relevant for TGD populations: those for raising voice pitch (e.g., glottoplasty with retro-displacement of the anterior commissure, cricothyroid approximation (CTA), feminization laryngoplasty, laser-assisted voice adjustment (LAVA)) (Anderson, 2007; Anderson, 2014; Brown, 2000; Casado, 2017; Geneid, 2015; Gross, 1999; Kelly et al., 2018; Kanagalingam, 2005; Kim, 2017; Kim, 2020; Kocak, 2010; Kunachak, 2000; Mastronikolis, 2013; Mastronikolis et al., 2013; Matai, 2003; Meister,

Statements of Recommendations

14.1- We recommend voice and communication specialists assess current and desired vocal and communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.
14.2- We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.
14.3- We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.
14.4- We recommend health care professionals consider working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.
14.5- We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

2017; Mora, 2018; Neumann, 2004; Nuyen et al., 2022; Orloff, 2006; Pickuth, 2000; Remacle, 2011; Thomas & MacMillan, 2013; Tschan, 2016; Van Borsel, 2008; Wagner, 2003; Wendler, 1990; Yang, 2002) and for lowering voice pitch (e.g., thyroplasty type III, vocal fold injection augmentation) (Bultynck et al, 2020; Isshiki et al., 1983; Kojima, et al. 2008; Webb et al., 2021). Reported acoustic benefits of pitch-raising surgery include increased voice pitch (average frequency (f_o)) and increased Min f_o(the lowest frequency in physiological voice range). TGD people's self-rating ratings show general satisfaction with voice postsurgery, although individuals who are interested in more comprehensive changes to vocal self-presentation may need to engage in behavioral interventions with a voice and communication specialist in addition to laryngeal surgery (Brown, Chang et al. 2021; Kelly et al., 2018; Nuyen et al., 2022). Potential harms of pitch-raising surgery can be assessed and addressed in voice training by a voice and communication specialist. Reported harms of pitch-raising surgery include voice problems such as dysphonia, weak voice, restricted speaking voice range especially upper range (lowered Max f_o, in the physiological voice range), hoarseness, vocal instability, and lowering of frequency values over time (Kelly et al., 2018; Song & Jiang, 2017), although the rate of these outcomes is inconsistent.

Research on pitch-lowering surgeries is limited. However, studies including eight TGD people who elected to undergo thyroplasty type III after continued dissatisfaction with hormonal treatment (Bultynck et al., 2020) and one person who received injection augmentation after testosterone therapy and voice training (Webb et al., 2020), reported statistically significant lowering of fundamental frequency, perceived as pitch.

Estrogen treatment in TGD people has not been associated with measurable voice changes (Mészáros et al., 2005), while testosterone treatment in TGD people has been found to result in both desired and undesired changes in gender- and function-related aspects of voice production (Azul, 2015; Azul et al., 2017, 2018, 2020; Azul & Neuschaefer-Rube, 2019; Cosyns et al., 2014; Damrose, 2008; Deuster, Di Vicenzo et al., 2016; Deuster, Matulat et al. 2016; Hancock et al., 2017; Irwig et al., 2017; Nygren et al., 2016; Van Borsel et al., 2000; Yanagi et al., 2015; Ziegler et al., 2018). Desired changes associated with testosterone treatment include lowered voice pitch, increased male attributions to voice, and increased satisfaction with voice. Reported dissatisfaction with testosterone treatment include lack of or insufficient lowering of voice pitch, dysphonia, weak voice, restricted singing pitch range, and vocal instability. These areas can be assessed and addressed in voice training by a voice and communication specialist.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 14.1.

We recommend voice and communication specialists assess current and desired vocal and

communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.

Voice and communication specialists may assess satisfaction with the presentation of sociocultural positionings in communicative encounters, including gender and other intersecting identifications, taking into consideration that these may or may not be static over time; attributions received from others, and how these relate to the individual's identifications, wishes, and well-being; ratings of voice and speech naturalness; and voice and communication function in relation to vocal demands. Assessments may vary in nature (e.g., client-reported outcome measures, perceptual, acoustic, aerodynamic, endoscopic) according to their purpose (Davies et al., 2015; Leyns et al., 2021; Oates & Dacakis, 1983). For example, laryngeal visualization is used when individuals present with a concomitant voice problem, (e.g., muscle tension dysphonia) (Palmer et al., 2011) or experience voice difficulties, which may or may not be secondary to medical gender-affirming interventions of androgen therapy or laryngeal surgery (Azul et al., 2017).

Voice and communication specialists inform intervention-seeking TGD people who are dissatisfied with their voice and communication about available interventions that support TGD people with their voice, communication, and well-being. The nature of each option, including potential outcomes and permanence, is presented objectively to provide the TGD person respect and autonomy in decision-making. Appropriate intervention plans are individualized and feasible and should be inclusive of any professional services available. Goals may evolve over the course of the support period as the TGD person explores modifications to voice and communication, assesses their satisfaction with achieved change and refines their goals.

Statement 14.2.

We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.

Academic and licensing credentials of voice and communication specialists (e.g., speech-language pathologists, speech therapists, singing voice teachers, voice coaches) vary by location but typically do not specify criteria for working with specific populations. Standard curricula in formal education for these professions often do not include specific or adequate training for working with TGD populations (Jakomin et al., 2020; Matthews et al., 2020). General knowledge and skills related to the vocal mechanism and interpersonal communication are foundational but insufficient for conducting culturally responsive, person-centered care for TGD people that is effective, efficient, inclusive, and accessible (Hancock, 2017; Russell & Abrams, 2019).

Professionals in this area should receive comprehensive education that invites them to develop self-awareness, cultural humility, and cultural responsiveness in order to be respectful of and attentive to gender diversity and other aspects of a client's identifications that can take a variety of forms and imply a range of different support needs (Azul, 2015; Azul et al., 2022). Client preferences for use of names, formal forms of address, gender entry, and pronouns need to be respected in all communication with and about the client (including medical records, reports, emails). Education also needs to inform the setting up of a training space or clinic and administrative practices that are designed to be welcoming to TGD people and allow TGD people to feel safe and respected when raising concerns or issues with the voice and communication support team.

Voice and communication specialists working with TGD people will need working knowledge of applicable intervention principles, mechanisms, and effectiveness, competence in teaching and modeling voice and communication modification skills, and a basic understanding of transgender health, including hormonal and surgical treatments and trans-specific psychosocial issues. Education needs to include methodologies and practices that have been developed within TGD communities and shown to be effective and should ideally be presented by or in collaboration with TGD people with lived experience of voice and communication support.

Statement 14.3.

We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.

A voice and communication specialist is well positioned to provide information and guidance to the TGD person expressing dissatisfaction with their voice or communication when available. There is evidence voice and communication specialists provide support in such a way that a client's satisfaction with voice and communication can be achieved, thereby reducing gender dysphoria and improving communication-related quality of life (Azul, 2016; Block, 2017; Deuster, Di Vincenzo et al., 2016; Hancock, 2017; Hancock et al., 2011; Hardy et al., 2013; Kelly et al., 2018; McNamara, 2007; McNeill et al., 2008; Owen & Hancock, 2010; Pasricha et al., 2008; Söderpalm et al., 2004; Watt et al., 2018).

There is empirical evidence that behavioral voice support for TGD AMAB people is effective with regard to achieving the targeted voice changes (Oates, 2019). Seven studies prior to 2020 provide empirical evidence for the effectiveness of voice training, although it is somewhat weak (Carew et al., 2007; Dacakis, 2000; Gelfer & Tice, 2013; Hancock et al., 2011;Hancock & Garabedian, 2013; McNeill et al., 2008; Mészáros et al., 2005). Voice training methods across these seven studies were similar and indicated voice training can be effective at increasing average fundamental frequency (average pitch), fundamental frequency range (pitch range), satisfaction with voice, self-perception and listener perception of vocal femininity, voice-related quality of life, and social and vocational participation. Weaknesses of the identified studies include lack of randomized controlled trials evaluating voice training, small sample sizes, inadequate long-term follow-up, and lack of control of confounding variables. In 2021, another systematic review of the effects of behavioral speech training for AMAB people reached similar conclusions (Leyns et al., 2021).

Until recently, there was almost no research exploring the effectiveness of voice training with TGD AFAB people. There is, however, some promising, although weak evidence of effectiveness from a case study (Buckley et al., 2020) and one uncontrolled prospective study of group voice training (Mills et al., 2019).

Statement 14.4.

We recommend health care professionals working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.

This statement does not intend to require TGD people receive presurgical voice training. Rather, it is recommended that every available support be offered to provide individualized informational counseling critical to person-centered care. The recommendation is for the TGD person's consideration to be informed as necessary by individualized informational counseling based on voice assessment, trial voice training, and discussion of expected voice outcomes and risks of surgery with a voice and communication specialist.

For most types of laryngeal surgery, voice training is recommended both prior to surgery to ensure preparation of the vocal mechanism for the surgical intervention and postsurgery to ensure a return to functional voice production (Branski et al., 2006; Park et al., 2021). For pitch-raising surgery in particular, another reason a trial of voice training is recommended is because there are indications certain measures improve with training but not with pitch-raising surgery (e.g., factors relevant to intonation and naturalness, such as maximum *f0* pitch in speech range; Kelly et al., 2018).

The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient, particularly with regard to comparing outcomes with and without other interventions (i.e., testosterone) (Bultynck et al., 2020). There are more techniques and studies of pitch-raising surgeries, but the quality of the evidence is still low. Outcomes from pitch-raising surgeries have been compared to outcomes from having no surgery (Anderson, 2007, 2014; Brown et al., 2000;

Geneid et al., 2015; Gross, 1999; Kim, 2017; Kocak et al., 2010; Kunachak et al., 2000; Matai et al., 2003; Meister et al., 2017; Neumann & Welzel, 2004; Orloff et al., 2006; Pickuth et al., 2000; Remacle et al., 2011; Thomas & Macmillan, 2013; Tschan et al., 2016; Van Borsel et al., 2008; Yang et al., 2002), another type of surgical technique (Mora, 2018), voice training alone (Kanagalingam, 2005; Mastronikolis, 2013; Wagner, 2003) and surgery in conjunction with voice training (Casado, 2017; Kelly et al., 2018).

In the 11 studies reporting whether participants had voice training prior to pitch-raising surgery, most participants had prior voice training, but remained dissatisfied with voice and sought surgical intervention. Thus, most studies of surgical outcomes reflect the combined effects of voice training and surgical intervention. Attributes predicting which clients will pursue surgery after training are unknown.

Statement 14.5.

We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

The research on the effects of androgen treatment on voice and communication of TGD people points to diverse and unpredictable effects on individual clients. While a number of studies have revealed effects on voice that matched TGD people's expectations and wishes, there is high quality evidence demonstrating TGD people are not always satisfied with the vocal outcomes of testosterone therapy, and many experience difficulties such as inadequate pitch lowering, compromised voice quality, vocal loudness, vocal endurance, pitch range, and flexibility (Azul, 2015, 2016, 2017, 2018; Cosyns et al., 2014; Nygren et al., 2016; Ziegler et al., 2018). A recent meta-analysis of 19 studies examining the effects of at least 1 year of testosterone therapy estimated 21% of participants did not achieve cisgender male normative frequencies, 21% of participants reported incomplete voice-gender congruence and voice problems, and 16% were not completely satisfied with their voice (Ziegler, 2018).

For people who wish to be treated with androgens, accurate informational counseling prior to commencing treatment should enable the development of realistic expectations to avoid disappointment regarding the permanent impact of hormone treatment on voice and communication. In addition, TGD people who do not have access to or do not wish to be treated with testosterone, but want to change their voice and those who are dissatisfied with the outcomes of testosterone treatment can be advised by a voice and communication specialist of alternative and additional support options (e.g., behavioral voice and communication training; pitch-lowering surgery).

CHAPTER 15 Primary Care

Primary care is the broadest of health care disciplines and is defined as the "provision of integrated, accessible health care services by health care professionals who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community." (Institute of Medicine, 1996).

Primary care providers (PCPs) encompass a wide range of health care professionals (HCPs) who deliver this care, including general and family medical practitioners, nurse practitioners, advanced practice nurses, physician associates/assistants, and internists. PCPs are represented by a variety of educational backgrounds, training, and specialties. Given the type of degree and the nature of the specialty, the scope of practice varies, and not all providers may be trained or qualified to directly provide the full breadth of transgender health care, such as mental health, genital/pelvic care, or postoperative care, following gender-affirming procedures. Physicians and other providers receive little education in transgender and gender-diverse (TGD) health at any time during their training (Dubin et al., 2018), and thus most skills are currently acquired in practice, either informally or through brief continuing education opportunities, see also Chapter 4—Education. However, if providers are competent to deliver similar care for cisgender patients, they should develop competency in caring for TGD patients. The competencies outlined below are all to be understood as being within the provider's scope of licensure and practice. However, all PCPs should be able to manage the comprehensive health of TGD patients either directly or by appropriate referral to other HCPs, including other specialists, for evaluation and treatment. There is no evidence competency in caring for TGD patients can only be achieved through a formal or certification process. In explicitly stating recommended competencies, however, PCP's and TGD persons across all settings can share a standard set of expectations of the knowledge, skills, and cultural competence required for the care of TGD persons.

Due to the unique medical, surgical, and social conditions faced by TGD people, PCPs need distinct competencies in the care of TGD persons, apart from what is expected of all PCP's who may otherwise care for a diverse population that includes ethnic, racial, or sexual minorities. Professional bodies from a range of generalist disciplines have issued position statements and guidelines specific to the care of TGD people (American College of Obstetricians and Gynecology, 2021; Italian Society of Gender, Identity and Health (SIGIS); the Italian Society of Andrology and Sexual Medicine (SIAMS); the Italian Society of Endocrinology (SIE), 2021; Polish Sexological Society, 2021; the Southern African HIV Clinicians' Society, 2021). Wylie et al. (2016) state "For the most part, the general health and well-being of transgender people should be attended to within the primary care setting, without differentiation from services offered to cisgender (non-transgender) people for physical, psychological, and sexual health issues. Specific care for gender transition is also possible in primary care." There are many examples of these services being provided safely and effectively outside of specialist care in diverse cities such as Toronto and Vancouver in Canada, New York and Boston in the US, and in Sydney, Australia, (Radix & Eisfeld, 2014; Reisner, Radix et al., 2016; Spanos et al., 2021).

Hormone therapy

Whether TGD patients receive medically necessary gender-affirming hormone therapy (GAHT) from a specialist, e.g., an endocrinologist, or a PCP may depend on the availability of knowledgeable and welcoming providers and country-level factors, such as health care regulations and health services funding (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). In much of the world, specialty services for TGD people are partly or wholly unavailable, which reinforces the need for all health providers to undertake

training in the provision of gender-affirming care. In some countries, PCPs may be required to refer TGD patients to specialist services (e.g., gender identity clinics) resulting in unacceptable delays to access GAHT (Royal College of General Practitioners, 2019).

Hormone-related therapy encompasses a range of interventions, such as puberty suppression and hormone initiation or hormone maintenance. With training, gender-affirming hormone therapy can be managed by most PCPs. Regardless of whether they serve as the primary hormone prescriber, all PCPs should be familiar with the medications, suggested monitoring, and potential side effects associated with GAHT (see Chapter 12—Hormone Therapy). PCPs should be able to make appropriate referrals to appropriate providers for all transition-related services they do not themselves provide.

This chapter supports the argument GAHT can be prescribed by PCPs or other non-specialists—"Considering barriers to health care access and the importance of GAHT to this population, it is imperative that PCPs are able and willing to provide GAHT for TGD patients." (Shires, 2017).

PCPs are commonly called upon to provide care for a broad range of conditions and needs, including those with which they may have had limited or no prior experience. Often this involves accessing commonly used and readily available reference sources, such as professional society guidelines or obtaining a subscription to online knowledge bases. PCPs are advised to use a similar approach when asked to provide basic GAHT care by using the Standards of Care as well as other readily accessed resources (Cheung et al., 2019; Hembree et al., 2017; Oliphant et al., 2018; T'Sjoen et al., 2020). It should be noted most of the commonly used medications in gender-affirming regimens are familiar to everyday primary care practice, including, but not limited to, testosterone, estradiol, progesterone and other progestagens, and spironolactone.

Mental health

PCPs should be able and willing to assess and provide mental health support for TGD people and GAHT that can alleviate gender dysphoria and allow gender expression. At the very least, they should be aware of these needs and consult additional specialty support if needed.

Preventive care

General practitioners are versed to provide comprehensive primary and secondary cancer prevention as a part of routine primary care. Evidence-based cancer prevention guidelines vary globally due to differences in national guidelines and levels of access to screening modalities at the local level. To date, research on the long-term impact of GAHT on cancer risk is limited (Blondeel et al., 2016; Braun et al., 2017). We have insufficient evidence to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018). However, cancer screening should commence, in general, according to local guidelines. Several modifications are discussed in detail, below, depending on the type and duration of hormone use, surgical intervention, or both. In caring for transgender patients, the PCP should maintain an updated record of which organs are present in TGD patients so that appropriate, routine screening can be offered.

This organ inventory should be updated based on the surgical history or any development that has occurred due to taking gender-affirming hormones. Not all PCP's provide care across the lifespan. However, if providers routinely care for children, adolescents, or elder cisgender persons, they should develop competency in transgender care that is applicable to these age groups. If they are unable to do so, then PCPs should be able to make appropriate referrals to other HCPs who care for these populations.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

15.1- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines.
15.2- We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods.
15.3- We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.
15.4- We recommend health care professionals counsel transgender and gender diverse people about their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.
15.5- We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.
15.6- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration the length of time of hormone use, dosing, current age, and the age at which hormones were initiated.
15.7- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.
15.8- We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.
15.9- We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.
15.10- We recommend health care professionals offer cervical cancer screening to transgender and gender diverse people who currently have or previously had a cervix following local guidelines for cisgender women.
15.11- We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.
15.12- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors to assess the optimal age and necessity for osteoporosis screening.
15.13- We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.
15.14- We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Statement 15.1

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people, that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines. For supporting text, see Statement 15.3.

Statement 15.2

We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods. For supporting text, see Statement 15.3.

Statement 15.3

We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.

Cardiovascular disease (CVD) and stroke are the leading causes of mortality worldwide (World Health Organization, 2018). Extensive data among racial, ethnic, and sexual minorities in multiple settings demonstrate significant disparities in the prevalence of CVD and its risk factors as well as in the outcomes to medical interventions. Structural factors such as access to care, socioeconomic status, and allostatic load related to minority stress contribute to these disparities (Flentje et al., 2020; Havranek et al., 2015; Streed et al., 2021). TGD people often experience social, economic, and discriminatory conditions similar to other minority populations with known increased cardiovascular risk (Carpenter et al., 2020; James et al., 2016; Reisner, Radix et al., 2016). TGD persons of racial, ethnic, and sexual

minorities have been shown to experience increased impact related to intersectional stress. Conversely, access to gender-affirming care, including GAHT, may buffer against the elevation of CVD risk due to the improvement in quality of life and reduction in gender dysphoria and incongruence (Defreyne et al., 2019; Martinez et al., 2018). PCPs can significantly improve TGD health through screening and prevention of CVD and its associated risk conditions—such as tobacco use, diabetes mellitus, hypertension, dyslipidemia, and obesity.

The few, primarily US based, studies evaluating the prevalence of CVD, stroke, or CVD risk in TGD persons independent of GAHT indicate an elevated CV risk, including high rates of undiagnosed and untreated CV risk factors with inadequate CV prevention when compared with cisgender populations (Denby et al., 2021; Malhotra et al., 2022; Nokoff et al., 2018). In one population-based study, TGD people had greater odds of discrimination, psychological distress, and adverse childhood experience, and these were associated with increased odds of having a cardiovascular condition (Poteat et al., 2021).

In US studies that are based on data from the Behavioral Risk Factor Surveillance System, both transgender men and transgender women show a higher prevalence of myocardial infarction (MI), stroke, or any CVD compared with cisgender men, cisgender women or both. Results vary based on the adjustment of data for additional variables, including race, income, or cardiovascular risk factors (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Gender nonbinary persons also have higher odds of CVD (Downing & Przedworski, 2018). Data on hormone use was not collected in these studies, which are also limited by the use of self-reported health histories. In the US, TGD individuals presenting for GAHT may have higher rates of undiagnosed and untreated CVD risk factors compared with the cisgender population (Denby et al., 2021), although this may not be applicable globally.

A large 2018 case control study from several US centers that used 10:1 cisgender matched controls found no statistically significant difference in rates of MI or stroke between transgender women and cisgender men, and no difference in rates of MI, stroke, or venous thromboembolism (VTE) between transgender men and cisgender men or women. There was a statistically significant hazard ratio of 1.9 for VTE among transgender women when compared with cisgender men. A subcohort of transgender women who initiated GAHT during (versus prior to) the 6-year study window did show an increased risk of stroke. Increases in rates of VTE in the overall cohort of transgender women and in rates of stroke in the initiation subcohort of transgender women demonstrated calculated numbers-needed-to-harm (not reported in the paper) between 71-123 (Getahun et al., 2018). Other studies have demonstrated no increase in CV events or stroke among transgender men undergoing testosterone therapy, although studies are limited by their small sample size, relatively short follow-up, and the younger age of the sample population (Martinez et al., 2020; Nota et al., 2019).

European and US studies in transgender women who have accessed feminizing GAHT increasingly indicate a higher risk of CVD, stroke, or both, compared with cisgender women and, in some studies, cisgender men (Getahun et al., 2018; Nota et al., 2019; Wierckx et al., 2013). Many of these studies had significant limitations, such as variably adjusting for CV-related risk factors, small sample sizes—especially involving older transgender women—and variable duration and types of GAHT (Connelly et al., 2019; Defreyne et al., 2019, Martinez et al., 2020). Furthermore, the overall increased risk was small. In many of these studies, the majority of transgender women who experienced cardiac events or stroke were over 50 years old, had one or more CVD risk factors, and were taking a variety of hormone regimens, including, but not limited, to ethinyl estradiol, a synthetic estrogen that confers significant elevations in thrombotic risk and is not recommended for use in feminizing regimens (Gooren et al., 2014; Martinez et al., 2020). Current limited evidence suggests estrogen-based GAHT is associated with an increased risk of myocardial infarction and stroke, but whether this small risk is a result of GAHT or an effect of pre-existing CV risk is unclear. There are no known studies that specifically address CVD and

related conditions in nonbinary individuals, individuals who use subphysiologic doses of gender-affirming hormones, or in adults previously treated with puberty suppression.

PCPs can best address CVD risk during GAHT by assessing TGD people for CVD and modifiable CVD risk factors, such as diabetes mellitus, hypertension, hyperlipidemia, obesity, and smoking, as well as by addressing the impact of minority stress on cardiovascular risk (Streed et al., 2021). In addition, PCPs can mitigate transgender cardiovascular health disparities by providing a timely diagnosis and treatment of risk conditions and by tailoring their management in a way that supports ongoing gender-affirming interventions.

Risk assessment guidelines vary based on the national or international context and scientific affiliation of guideline developers. CVD prevention guidelines also vary in terms of the nature and frequency of the risk assessment for otherwise healthy adults under age 40 (Arnett et al., 2019; Piepoli et al., 2020; Précoma et al., 2019; Streed et al., 2021; WHO, 2007). Over age 40, when cardiovascular risk increases, guidelines clearly recommend scheduled risk assessments using a calculated prediction of ten-year total CVD risk based on risk prediction equations from large population samples. Examples of risk calculators include SCORE (recommended by the European Guidelines on CVD Prevention), Pooled Cohort Studies Equations (2013 AHA ACC Guideline on the Assessment of CVD risk), Framingham Risk scores, and the World Health Organization (WHO) Risk Prediction Charts. The WHO charts were developed based on information from the countries in each WHO subregion. In many low resource settings, facilities are not available to measure cholesterol or serum glucose, and alternative predication charts are available without these measures.

Of note, all current cardiovascular risk calculators are gendered, using sex as a significant risk variable. There is currently insufficient data on cardiovascular risk interventions across the lifespan in TGD persons with medical and surgical interventions to adjust these predictive equations. Nonetheless, it is clear both sex assigned at birth and medical transition can affect the parameters used to calculate cardiovascular risk (Connelly et al., 2019; Defreyne et al., 2019; Maraka et al., 2017; Martinez et al., 2020). Providers can take a variety of approaches to using cardiovascular risk calculators in TGD persons, including employing the risk calculator for the sex assigned at birth, affirmed gender, or a weighted average of the two, taking into consideration total lifetime exposure to GAHT. Although data are lacking, using the affirmed gender for transgender adults with a history of pubertal-age GAHT initiations is likely to be most appropriate. Patients with a history of submaximal GAHT use or prolonged periods of time postgonadectomy without hormone replacement before roughly age 50 may require an even more nuanced approach. Providers should be aware of the characteristics and limitations of the risk calculator in use and should engage patients in shared decision-making regarding these specific considerations.

There are currently no studies comparing the prevalence of dyslipidemia between transgender and cisgender samples, while controlling for hormone use. As noted previously, data in other populations demonstrate the presence of psychosocial stress during childhood and remote adulthood favor adiposity and abnormal lipid metabolism. Both testosterone- and estrogen-based GAHT affect lipid metabolism, although evidence is limited by the variety of hormone regimens and additional variables (Connelly et al., 2019; Defreyne et al., 2019; Deutsch, Glidden et al., 2015; Maraka et al., 2017; Martinez et al., 2020;). On balance, estrogen tends to increase high-density lipoprotein (HDL) cholesterol and triglycerides with variable effects on low density lipoprotein (LDL) cholesterol, while testosterone variably affects triglycerides, decreases HDL cholesterol and increases LDL cholesterol. The method of administration may also affect this pattern, particularly in relation to oral versus transdermal estrogen and their impact on triglycerides (Maraka et al., 2017). In general, the effect sizes of these differences are minimal, and the overall impact on cardio- and cerebrovascular outcomes is unclear. There are no studies examining hormone effects in TGD people with pre-existing dyslipidemia with hormone use starting over age 50, or investigating effects beyond 2-5 years of therapy.

Studies comparing the prevalence of hypertension between TGD and cisgender samples that controlled for hormone use are lacking. Data in other populations demonstrate chronic and acute psychosocial stress, including experiences of discrimination can mediate hypertension (Din-Dzietham et al., 2004; Spruill, 2010). In US studies that were based on the Behavioral Risk Factor Surveillance System, a large national US health survey, there were no differences in reported hypertension between transgender men or women compared with cisgender samples (Alzahrani et al., 2019; Nokoff et al., 2018).

Studies of testosterone—and estrogen-based GAHT have shown inconsistent effects on systolic and diastolic blood pressure. A retrospective study of the effects of estrogen- and testosterone-based GAHT regimens on blood pressure found a slight reduction in systolic blood pressure with the initiation of estrogen-based regimens; while there was a slight elevation (4 mm Hg) in mean systolic blood pressure on long term follow-up of testosterone-based regimens, this difference was at the margin of statistical significance and of limited clinical relevance (Banks et al., 2021). A systematic review concluded, given the limited quality of the studies, there is insufficient data to reach conclusions on the effects of gender-affirming hormone therapy on blood pressure (Connelly et al., 2021). Spironolactone, often used as an androgen blocker in feminizing GAHT, is a potassium sparing diuretic and may increase potassium when used in conjunction with ACE inhibitors or angiotensin receptor blocker medications, as well as salt substitutes. There are no studies examining hormone effects in TGD people with pre-existing hypertension with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. Transgender persons receiving GAHT should undergo any additional blood pressure screening or monitoring indicated by WPATH guidelines for GAHT.

There are limited data comparing the prevalence of diabetes mellitus between TGD and cisgender samples independent of hormone use. Recent data from the STRONG cohort study (Islam et al., 2021) found the prevalence and incidence of type 2 diabetes was more common in the trans feminine cohort compared with cisgender females but not cisgender male controls. No significant differences in the prevalence or incidence of type 2 diabetes were observed in the trans masculine cohort and in TGD persons overall after starting hormone therapy. However, the mean follow-up for both cohorts was 2.8 and 3.1 years, respectively (Islam et al., 2021). Data in other populations, including sexual minorities, indicates chronic and acute psychosocial stress can mediate the development and control of type 2 diabetes (Beach et al., 2018; Kelly & Mubarak, 2015).

US studies based on the Behavioral Risk Factor Surveillance System found no differences in reported diabetes between transgender men, transgender women and nonbinary persons compared with cisgender persons (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Several small studies have shown a higher-than-expected prevalence of polycystic ovarian syndrome or hyperandrogenemia among transgender men (Feldman et al., 2016), conditions associated with insulin resistance and diabetes risk. While studies of both testosterone- and estrogen-based GAHT show varying effects on weight/body fat, glucose metabolism, and insulin resistance (Defreyne et al., 2019), most do not demonstrate any increase in prediabetes or diabetes (Chan et al., 2018; Connelly et al., 2019). There are no studies examining hormone effects in TGD people with pre-existing diabetes, with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. There are currently no studies specifically addressing diabetes in adults previously treated with puberty suppression.

While intermediate-outcome studies of the effects of GAHT on blood pressure and lipids are helpful for hypothesis generation and for studying etiology, future studies should focus on cardiovascular outcomes of interest, with a specific focus on individual predictors such as age, route and dose of hormones used, and total lifetime exposure to GAHT. Interpretation of data should always consider whether cisgender controls were of the same natal sex or identified gender.

Statement 15.4

We recommend health care professionals counsel transgender and gender diverse people about

their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.

Tobacco use is a leading contributor to cardiovascular disease, pulmonary disease, and cancer worldwide (World Health Organization, 2020). TGD persons have a higher prevalence of tobacco use compared with cisgender individuals, which varies across the gender spectrum (Azagba et al., 2019; Buchting et al., 2017). This pattern is consistent with other populations experiencing minority stress (Gordon et al., 2021). PCPs can promote protective factors against tobacco use, including reducing exposure to personal or structural discrimination, having gender-affirming identification, and having health insurance (Kidd et al., 2018; Shires & Jafee, 2016).

The health risks of tobacco use affect TGD persons disproportionately, primarily due to decreased access to culturally competent, affordable screening, and treatment of tobacco-related diseases (Shires & Jafee, 2016). Smoking may further increase cardiovascular and VTE risk for TGD individuals taking feminizing GAHT (Hontscharuk, Alba, Manno et al., 2021). Smoking also doubles or triples the risk of general surgery complications, such as wound healing, scarring, and infection (Yoong et al., 2020) and increases these risks for those accessing gender-affirming surgeries. Data in cisgender populations show quitting smoking prior to surgery and maintaining abstinence for six weeks postoperatively significantly reduces complications (Yoong et al., 2020).

There are currently few studies of smoking cessation programs specifically focused on TGD persons (Berger & Mooney-Somers, 2017). However, limited evidence suggests PCPs can enhance smoking cessation efforts by addressing the effects of minority stress (Gamarel et al., 2015) and incorporating gender-affirming interventions, such as GAHT (Myers & Safer, 2016).

HCPs should take into consideration the significant barriers people habituated to nicotine encounter when attempting cessation. Nicotine replacement therapy and/or other cessation adjuncts should be made available, with an emphasis on individual preferences and a recognition of underlying behavioral health factors that contribute to continued nicotine use. Decision-making regarding approaches to GAHT or surgery should include consideration of the "first do no harm" principle of medical practice, with the realities of an individual patient's abilities and needs.

Statement 15.5

We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.

Aging presents specific social, physical, and mental health challenges for TGD persons. While the literature on aging and transgender elders is limited, many older TGD adults have experienced a lifetime of stigma, discrimination, and repression of identified gender (Fabbre & Gaveras, 2020; Witten, 2017). This experience affects TGD elders' interactions with health care systems (Fredriksen-Goldsen et al., 2014; Kattari & Hasche, 2016; Walker et al., 2017). Transgender elders are more likely than cisgender LGB peers to report poor physical health, even when controlling for socio-demographic factors (Fredriksen-Goldsen 2011; Fredriksen-Goldsen et al., 2014). Reduced access to culturally competent care and the sequelae of minority stress often result in delayed care, potentially exacerbating chronic conditions common with aging (Bakko & Kattari, 2021; Fredriksen-Goldsen et al., 2014).

Although there are few studies on gender-affirming medical interventions among TGD elders, evidence suggests older adults experience a significantly higher quality of life with medical transition even when compared with younger TGD adults (Cai et al., 2019). Although age itself is not an absolute contraindication or limitation to gender-affirming medical or surgical interventions, TGD elders may not be aware of the current range of social, medical or surgical options available that can help them meet their individual needs (Hardacker et al., 2019; Houlberg, 2019).

While studies on mental health among TGD elders are limited, those over age fifty experience significantly higher rates of depressive symptoms and perceived stress compared with cisgender LGB and heterosexual older adults (Fredriksen-Goldsen 2011, Fredriksen-

Goldsen et al., 2014). Risk factors specific to TGD elders include gender- and age-related discrimination, general stress, identity concealment, victimization, and internalized stigma, while social support and community belonging appear protective (Fredriksen-Goldsen et al., 2014; Hoy-Ellis & Fredriksen-Goldsen, 2017; White Hughto & Reisner, 2018). PCPs can assist patients by encouraging spirituality, self-acceptance and self-advocacy, and an active healthy lifestyle, all of which are associated with resilience and successful aging (McFadden et al., 2013; Witten, 2014).

TGD elders often face social isolation, loss of support systems, and disconnection from close friends and children (Fredriksen-Goldsen 2011; Witten, 2017). The most common aging concerns among TGD persons are losing the ability to care for themselves followed by having to go into a nursing home or assisted living facility (Henry et al., 2020). While long-term care settings offer the helpful needed assistance, they also have the potential for physical or emotional abuse, for denial of GAHT and routine care, for being "outed," and being prevented from living and dressing according to one's affirmed gender (Auldridge et al., 2012; Pang et al., 2019; Porter et al., 2016). TGD elders identify senior housing, transportation, social events, support groups as being the most needed services (Auldridge et al., 2012; Witten, 2014).

Despite barriers, most TGD persons engage in successful aging strengthened by self-acceptance, caring relationships, and advocacy (Fredriksen-Goldsen 2011; Witten, 2014). PCPs should address core health issues facing TGD elders, including mental health, gender-affirming medical interventions, social support, and end of life/long-term care.

Beyond the independent impact of factors such as minority stress and social determinants of health in later years, data are lacking on specific health issues facing transgender people who use GAHT later in life, individuals who began GAHT at a younger age, and those seeking to continue or begin GAHT in their sixth, seventh, eighth, or later decades. With an increasing proportion of transgender people beginning GAHT at younger ages, including some who begin at the time of puberty, studies to examine the impact of decades of such treatment on long-term health are ever more important.

Statement 15.6

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration length of time of hormone use, dosing, current age, and the age at which hormones were initiated.

TGD individuals taking estrogen-based GAHT will develop breasts, and therefore warrant consideration for breast cancer screening. Exogenous estrogen may be one of multiple factors that contribute to breast cancer risk in cisgender people. Two cohort studies have been published evaluating breast cancer prevalence among transgender women in the Netherlands (Gooren et al., 2013) and the US (Brown & Jones, 2015). Both were retrospective cohorts of clinical samples using a diagnosis of breast cancer as the outcome of interest and cisgender controls as a comparison group. Neither study involved prospective screening for breast cancer, and both had significant methodological limitations. Numerous guidelines have been published (Deutsch, 2016a) recommending some combination of "age plus length of estrogen exposure" as the determinant of need to commence screening. These recommendations are based on expert consensus only and are evidentiarily weak.

BRCA1 and 2 mutations increase the risk of breast cancer, however the role sex hormone exposure plays, if any, in this increased risk is unclear (Rebbeck et al., 2005) The degree of increase in risk, if any, from gender-affirming estrogen therapy is unknown. Patients with a known BRCA1 mutation should be counseled about the unknowns and shared decision-making with informed consent should occur between the patient and provider, recognizing the numerous benefits of GAHT.

Breast cancer screening among transgender women should also take into consideration the likelihood that a transgender woman's breasts may be denser on mammography. Dense breasts, a history of injecting breasts with fillers such as silicone, and breast implants may complicate the interpretation of mammographic findings (Sonnenblick et al., 2018). Therefore, special

techniques should be used accordingly. People who have injected particles such as silicone or other fillers for breast augmentation may also develop complications, such as sclerosing lipogranulomas, which obscure normal tissue on mammography or ultrasound.

Statement 15.7

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.

For TGD people assigned female at birth and who developed breasts via natal puberty, there are theoretical concerns about whether direct exposure to testosterone and exposure to aromatized estrogen resulting from testosterone therapy are risk factors for the development of breast cancer. Limited retrospective data has not demonstrated increased risk for breast cancer among transgender men (Gooren et al., 2013; Grynberg et al., 2010), however prospective and comparison data are lacking. Most people in this group will have some breast tissue remaining, and therefore it is important for providers to be aware breast cancer risk is not zero in this population. The timing and approach to breast cancer screening in this group who have had chest surgery is currently not established, and, similar to cisgender men with significant family history or BRCA gene mutation, screening via MRI or ultrasound may be appropriate. Because the utility and performance of these approaches have not been studied and because self- and HCP-led chest/breast screening exams are not recommended in cisgender women due to potential harms of both false-positive results and over-detection (detection of a cancer which would have regressed on its own with no need for intervention), any approach to screening in this group should occur in the context of shared decision-making between patients and providers regarding the potential harms, benefits, and unknowns of these approaches.

Statement 15.8

We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.

Current consensus guidelines do not recommend routine ovarian cancer screening for cisgender women. Case reports of ovarian cancer among transgender men have been reported (Dizon et al., 2006; Hage et al., 2000). There is currently no evidence testosterone therapy leads to an increased risk of ovarian cancer, although long-term prospective studies are lacking (Joint et al., 2018).

Statement 15.9

We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.

TGD people with ovaries who are taking testosterone-based GAHT are often in an oligo- or anovulatory state, or otherwise experience shifts in luteal phase function and progesterone production. This condition combined with the possible increased estrogen exposure from aromatization of exogenous testosterone raises the concern for excessive or unopposed endometrial estrogen exposure, although the clinical significance is unknown. Histologic studies of the endometrium in TGD people taking testosterone have found atrophy rather than hyperplasia (Grimstad et al., 2018; Grynberg et al., 2010; Perrone et al., 2009). In a large cohort of trans masculine people who underwent a hysterectomy with oophorectomy, benign ovarian histopathology was noted in all cases (n = 85) (Grimstad et al., 2020). While prospective outcome data are lacking, there is insufficient evidence at this time to support a recommendation transgender men undergo routine hysterectomy or oophorectomy solely to prevent endometrial or ovarian cancer. Certainly, unexplained signs/symptoms of endometrial or ovarian cancer should be evaluated appropriately.

Statement 15.10

We recommend health care professionals offer cervical cancer screening to transgender and

gender diverse people who currently have or previously had a cervix, following local guidelines for cisgender women.

Individuals with a cervix should undergo routine cervical cancer screening and prevention according to age-based regional practices and guidelines. This includes vaccination against the human papilloma virus (HPV) and screening according to local guidelines, including cytologic, high-HPV co-testing if available. It is important HCPs be mindful of performing pelvic speculum examinations in a manner that minimizes pain and distress for transgender masculine people.

TGD people with a cervix are less likely to have had conventional cervical cancer screening, either because the exam can cause worsening of dysphoria and/or because general practitioners and patients are misinformed about the need for this screening (Agenor et al., 2016; Potter et al., 2015). In addition, testosterone therapy can result in atrophic changes of the genital tract, and the duration of testosterone use has been associated with a greater likelihood of obtaining an inadequate sample for cytologic screening of cervical cancer (Peitzmeier et al., 2014). Alternatives to speculum exams and cervical cytology, such as provider- or self-collected high-risk HPV swabs, may be of particular benefit for screening people with a cervix. Research underway in the US is investigating the use of self-collected vaginal high-risk HPV testing among transgender masculine populations. HPV swabs were found to be highly acceptable among transgender men with a sensitivity to high-risk HPV of 71.4% (negative predictive value of 94.7%) and a specificity of 98.2% (Reisner et al., 2018). Further study is needed to evaluate the harms of HPV primary screening in transgender men in terms of the potential increased harms associated with invasive examinations and colposcopies.

Statement 15.11

We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.

Human immunodeficiency virus (HIV) prevalence is disproportionately high in TGD populations. A recent large metanalysis found a global odds ratio for HIV infection of sixty-six for trans feminine individuals and 6.8 for trans masculine individuals (Stutterheim et al., 2021). PCPs have unique opportunities to provide crucial education and implement prevention strategies, especially related to decreasing HIV burden among TGD people. Mistrust of health care providers due to past experiences of discrimination and transphobia impacts HIV prevention and disrupts the linkage to care efforts (Sevelius et al., 2016). Stigma, lack of adequate training, and innate power hierarchies within medical establishments, all contribute to ambivalence and uncertainty among HCPs when caring for TGD people (Poteat et al., 2013). Finally, a lack of inclusiveness and gender-affirming practices in the health care setting may lead to TGD people feeling unsafe discussing sensitive topics, such as HIV diagnosis and avoiding care out of fear (Bauer et al., 2014; Gibson et al., 2016; Seelman et al., 2017).

HCPs should be aware of this broader context within which many TGD people are seeking care for either gender-affirming hormones, HIV pre-exposure chemoprophylaxis/treatment (PrEP), or both. There may be various misconceptions about the safety of taking gender-affirming hormones concurrently with antiretroviral therapy for HIV chemoprophylaxis or treatment.

Direct study of antiretroviral/gender-affirming hormone therapy (ART/GAHT) interactions has been limited. A subanalysis of transgender women and trans feminine persons in the multinational iPrEx trial found poor effectiveness in this group in the intention-to-treat analysis, although effectiveness was similar to that in cisgender gay men among those transgender participants who adhered to the medication as prescribed, suggesting that uptake and adherence to PrEP remain challenging in this population. Two studies of the effects of GAHT on tenofovir diphosphate (Grant et al., 2021) and tenofovir diphosphate and emtricitabine (Shieh et al., 2019) found the significantly lowered ART drug levels were unlikely to be of clinical significance. Overall, data on the interactions between hormonal contraceptives and antiretrovirals are reassuring in terms of the impact of hormones on ART (Nanda

et al., 2017). Because estradiol is partially metabolized by cytochrome P450 (CYP) 3A4 and 1A2 enzymes, potential drug interactions with other medications that induce or inhibit these pathways, such as non-nucleoside reverse transcriptase inhibitors (NNRTIs, e.g., efavirenz (EFV) and nevirapine (NVP)), may exist (Badowski et al., 2021). However, the preferred first-line ART regimens in most countries include integrase inhibitors, which have minimal to no drug interactions with gender-affirming hormones and can be used safely (Badowski, 2021; Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021). If concerns exist about potential interactions, HCPs should monitor blood hormone levels as needed. Therefore, TGD people living with HIV and taking antiretroviral medications should be counseled that taking antiretrovirals alongside GAHT is safe.

Statement 15.12

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors, to assess the optimal age and necessity for osteoporosis screening. For supporting text, see Statement 15.13.

Statement 15.13

We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.

Estrogen and testosterone both support bone formation and turnover. Decreased sex hormone levels are associated with a greater risk of osteoporosis in older age (Almeida et al., 2017). TGD individuals may receive medical and/or surgical interventions that have the potential to influence bone health, such as sex hormone treatment, androgen blockade, and gonadectomy. Therefore, a detailed medical history, including past and present use of hormones along with gonadal surgeries, is necessary to establish the need for osteoporosis screening.

Several observational studies have compared bone mineral density (BMD) of TGD adults before and after gender-affirming hormone therapy along with in TGD individuals compared with sex-at-birth matched cisgender controls.

Low BMD may exist before the initiation of hormones. One study showed a lower mean areal BMD at the femoral neck, total hip, and spine in transgender women than in age-matched cisgender male controls (Van Caenegem, Taes et al., 2013). Another study revealed a high prevalence of low BMD scores among TGD youth before starting puberty blockers (Lee, Finlayson et al., 2020). The authors of both studies concluded low rates of physical activity may be an important contributor to these findings.

Acceleration of bone loss can occur after gonadectomy if hormones are stopped or if hormones levels are suboptimal. In one study, thirty percent of transgender women who had undergone gonadectomy had low bone mass, and this correlated with lower 17-ß estradiol levels and adherence to GAHT (Motta et al., 2020).

Investigation of the effects of GAHT on BMD have revealed TGD women receiving estrogen therapy show improvements in BMD. A systematic review and meta-analysis on the impact of sex hormones on bone health of transgender individuals included 9 eligible studies in transgender women (n = 392) and 8 eligible studies in transgender men (n = 247) published between 2008 and 2015. The meta-analysis revealed transgender women showed a statistically significant increase in lumbar spine BMD (but not femoral neck BMD) compared with baseline measures. Among transgender men, there were no statistically significant changes in the lumbar spine, femoral neck, and total hip BMD at 12 and 24 months after starting testosterone compared with baseline measures (Singh-Ospina et al., 2017). Since the publication of this study, the European Network for Investigation of Gender Incongruence (ENIGI) study, a multicenter prospective observational study (Belgium, Norway, Italy, and the Netherlands) published results on BMD outcomes for 231 transgender women and 199 transgender men one year after initiating GAH (Wiepjes et al., 2017). Transgender women had an increase in BMD of the lumbar spine, total hip and

femoral neck, and increased BMD of the total hip occurred in transgender men. One study reported no fractures in transgender individuals at 12 months following initiation of hormones in 53 transgender men and 53 transgender women (Wierckx, van Caenegem et al., 2014). No studies suggest GAHT should be an indication for enhanced osteoporosis screening. Rather, gaps in GAHT in those who have undergone prior gonadectomy would be a consideration for such screening.

Clinical practice guidelines include recommendations for osteoporosis screening in TGD individuals (Deutsch, 2016a; Hembree et al., 2017; Rosen et al., 2019). For TGD people, both the International Society for Clinical Densitometry and the Endocrine Society suggest consideration of baseline BMD screening before initiation of hormones. Further recommendations for BMD screening are based on several factors including sex reported at birth and age along with the presence of traditional risk factors for osteoporosis, such as prior fracture, high risk medication use, conditions associated with bone loss, and low body weight (Rosen et al., 2019). Specifically, the ISCD guidelines state BMD testing is indicated for TGD individuals if they have a history of gonadectomy or therapy that lowers endogenous gonadal steroid levels prior to the initiation of GAHT, hypogonadism with no plan to take GAHT or known indications for BMD testing (Rosen et al., 2019). However, the evidentiary basis for these recommendations is weak.

The recommended screening modality for osteoporosis is dual energy x-ray absorptiometry (DXA) of the lumbar spine, total hip, and femoral neck (Kanis, 1994). However in many low- and middle-income countries, BMD tests using DXA are not available, and routine DXA-based screening is conducted in few countries, the US being an exception.

PCPs should discuss ways to optimize bone health with TGD people. In addition, PCPs should provide information about the importance of nutrition and exercise on maintaining bone health. TGD individuals with (or at risk) for osteoporosis should be informed about the benefits of weight bearing exercise along with strength and resistance exercises in limiting bone loss (Benedetti et al., 2018). Nutrition is integral to bone health. Nutritional deficiencies, including insufficient calcium intake and low vitamin D, can result in low bone mineralization. Vitamin D and calcium supplementation have been shown to reduce hip as well as total fracture incidence (Weaver et al., 2016). Although relevant to all populations, this discussion is pertinent as a high prevalence of hypovitaminosis D has been observed in TGD populations (Motta et al., 2020; Van Caenegem, Taes et al., 2013).

Statement 15.14

We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Hair removal is necessary both for the elimination of facial hair (Marks et al., 2019) as well as in preparation for certain gender-affirming surgeries (GAS) such as vaginoplasty, phalloplasty, and metoidioplasty (Zhang et al., 2016). Preoperative permanent hair removal is required for any skin area that will either be brought into contact with urine (e.g., used to construct a neourethra) or be moved to reside within a partially closed cavity within the body (e.g., used to line the neovagina) (Zhang et al., 2016). Hair removal techniques used in gender-affirming care are electrolysis hair removal (EHR) and laser hair removal (LHR) (Fernandez et al., 2013). EHR is currently the only US Food and Drug Administration–approved method of permanent hair removal, whereas LHR is approved for permanent hair reduction (Thoreson et al., 2020).

EHR involves the use of an electric current with a very fine probe that is manually inserted sequentially into individual hair follicles (Martin et al., 2018). Since this method uses direct mechanical destruction of the blood supply to the hair, it can be used on all hair colors and skin types (Martin et al., 2018). EHR is time consuming and costly as it requires each hair follicle to be treated individually, but is effective for permanent hair removal. For genital permanent hair removal prior to GAS, this treatment needs to be performed by a practitioner competent in genital hair removal as this method differs

from that of the face and body. EHR is more painful than LHR, with possible side effects of erythema, crusting, and swelling (Harris et al., 2014). Postinflammatory hyperpigmentation is a risk for dark-skinned individuals (Richards & Meharg, 1995). Pain can be controlled with topical local anesthetic and cooling techniques, and tolerance to EHR does develop to some degree with many persons able to tolerate longer sessions (Richards & Meharg, 1995).

LHR uses laser energy to target hair follicles. It is beneficial for larger surface areas. The mechanism is photo-thermolysis, whereby light from a laser selectively targets melanin in the hair shaft (Gao et al., 2018). This energy is converted to heat, which damages the follicles within the skin that produce hairs and results in the destruction of hair growth. Further treatments are needed to achieve best results and are typically spaced six weeks apart to allow for hair cycling (Zhang et al., 2016). Because LHR targets melanin, results may be limited for those with grey, blonde, or red hair.

There are specific considerations for using LHR in dark-skinned individuals (Fitzpatrick skin types IV to VI) (Fayne et al., 2018)). The higher melanin content of the epidermis can compete with the target chromophore of the light or laser, which is the melanin in the hair shaft of the hair follicle. For selective thermolysis to occur, heat diffuses from the hair shaft to the follicular stem cells to cause damage. In darker skin types, rather than reaching the target melanin in the hair shaft, light is absorbed in the epidermis where it is then converted to heat. This may result in poorer clinical outcomes and a higher rate of thermally induced adverse effects, such as hypo- or hyperpigmentation, blistering, and crust formation (Fayne et al., 2018). The selection of laser wavelength is critical in reducing this risk, with longer wavelength recommended to minimize the absorption of light in epidermal melanin and thus maximize efficacy and minimize adverse effects in patients with dark skin (Zhang et al., 2016). Side effects from LHR can include the feeling of sunburnt after treatment, as well as inflammation, redness, hyperpigmentation, and swelling. Flashing lights have been known to induce seizures in susceptible patients, so patients should be screened for this risk. Pain and discomfort during the procedure can also represent a significant barrier, and PCPs should be prepared to prescribe topical or systemic analgesics, such as a eutectic mixture of local anesthetics (EMLA) or a low dose systemic opioid. For genital GAS, some have recommended a 3-month wait after the last planned hair removal treatment before proceeding with surgery to confirm that no further hair regrowth will occur (Zhang et al., 2016).

CHAPTER 16 Reproductive Health

All humans, including transgender individuals, have the reproductive right to decide whether or not to have children (United Nations Population Fund, 2014). Medically necessary gender-affirming hormonal treatments (GAHTs) and surgical interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1) that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Hembree et al., 2017; Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these treatments and to continue these conversations on an ongoing basis thereafter (Hembree et al., 2017). Established FP options, such as embryo, oocyte, and sperm cryopreservation, may be available for postpubertal transgender individuals (Nahata et al., 2019). Research protocols for ovarian and testicular tissue cryopreservation have also been developed and studied (Borgström et al., 2020; Nahata et al., 2019; Rodriguez-Wallberg, et al., 2019). Whereas the use of embryos, mature oocytes, and sperm have all proven to be efficacious when employed within clinical treatments, cryopreserved gonadal tissues would require either future retransplantation aimed at obtaining fully functional gametes or the application of laboratory methods for culture, which are still under development in basic science research settings. Of note, recent American Society for Reproductive Medicine guidelines have lifted the experimental label on ovarian tissue cryopreservation, but evidence remains limited in prepubertal children (Practice Committee of the American Society for Reproductive Medicine, 2019).

Individualized care should be provided in the context of each person's parenthood goals. Some research suggests transgender and gender diverse (TGD) people may be less likely to desire genetically related children or children at all when compared with cisgender peers (Defreyne, van Schuylenbergh et al., 2020; Russell et al., 2016; von Doussa et al., 2015). Yet, several other studies have shown many TGD individuals 1) desire genetically related children; 2) regret missed opportunities for FP; and 3) are willing to delay or interrupt hormone therapy to preserve fertility and/or conceive (Armuand, Dhejne et al., 2017; Auer et al., 2018; De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Tornello & Bos, 2017).

Many barriers to FP have been reported, such as cost (which is exacerbated when insurance coverage is lacking), urgency to start treatment, inability to make future-oriented decisions, inadequate provider knowledge/provider biases that affect offering FP, and difficulties accessing FP (Baram et al., 2019; Defreyne, van Schuylenbergh et al., 2020). Additionally, transgender individuals may have worsening dysphoria due to various steps in the FP process that are inseparably connected with the gender assigned at birth (Armuand, Dhejne, et al., 2017; Baram et al., 2019). When available, a multidisciplinary team approach, where both medical and mental health providers collaborate with gender-affirming fertility specialists, can help overcome some of these barriers (Tishelman et al., 2019). TGD individuals should be educated about the distinction between fertility (utilizing one's own gametes/reproductive tissues) and pregnancy. In addition to fertility considerations, efforts to ensure equitable high-quality care for all forms of family planning and building throughout the full reproductive continuum must be maintained. This includes procreative options such as perinatal care, pregnancy, delivery, and postpartum care, as well as family planning and contraceptive options to prevent unplanned pregnancies, and pregnancy termination if sanctioned (Bonnington et al., 2020; Cipres et al., 2017; Krempasky et al., 2020; Light et al., 2018; Moseson, Fix et al., 2020). TGD people who wish to carry a pregnancy should undergo standard of care preconception care and prenatal counseling and should receive counseling about breast/chest feeding in environments supportive of people with diverse gender identities and experiences (MacDonald et al., 2016; Obedin-Maliver & Makadon, 2016).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and

Statements of Recommendations

16.1- We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:
16.1.a- Known effects of hormone therapies/surgery on future fertility;
16.1.b- Potential effects of therapies that are not well studied and are of unknown reversibility;
16.1.c- Fertility preservation (FP) options (both established and experimental);
16.1.d- Psychosocial implications of infertility.
16.2- We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.
16.3- We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.
16.4- We recommend health care professionals counsel pre- or early-pubertal transgender and gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.
16.5- We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care, prenatal counseling regarding use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.
16.6. We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.
16.7. We recommend providers who offer pregnancy termination services ensure procedural options are gender-affirming and serve transgender people and those of diverse genders.

harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 16.1

We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:

a. **Known effects of hormone therapies/surgeries on future fertility;**
b. **Potential effects of therapies that are not well studied and are of unknown reversibility;**
c. **Fertility preservation (FP) options (both established and experimental;**
d. **Psychosocial implications of infertility.**

TGD individuals assigned female at birth

GAHT may negatively impact future reproductive capacity (Hembree et al., 2017). Based on current evidence in transgender men and gender diverse people assigned female at birth, these risks are as follows:

Gonadotropin-releasing hormone agonists (GnRHas) may be used for pubertal suppression to prevent further pubertal progression until adolescents are ready for masculinizing treatment. GnRHas may also be used for menstrual suppression. GnRHas impact the maturation of gametes but do not cause permanent damage to gonadal function. Thus, if GnRHas are discontinued, oocyte maturation would be expected to resume.

There are few studies detailing the effects of testosterone therapy on reproductive function in transgender men (Moravek et al., 2020). Restoration of normal ovarian function with oocyte maturation after testosterone interruption has been demonstrated in transgender men who have achieved natural conception. A retrospective study on oocyte cryopreservation showed no differences in the total number of oocytes retrieved or in the number of mature oocytes between transgender men and age- and BMI-matched cisgender women (Adeleye et al., 2018, 2019). The first results have recently been published evaluating live birth rates after controlled ovarian stimulation in transgender men compared with cisgender women (Leung et al., 2019). Testosterone was discontinued prior to ovarian stimulation. Overall, the results concerning the influence of testosterone on reproductive organs and their function appear to be reassuring. However, there have been no prospective studies to date evaluating the effect of long-term hormone therapy on fertility (i.e., started in adolescence) or in those treated with GnRHas in early puberty followed by testosterone therapy. It is important to take into consideration that required medications and procedures for cryopreserving oocytes (a

pelvic examination, vaginal ultrasound monitoring, and oocyte retrievals) may lead to increasing gender dysphoria in transgender men (Armuand, Dhejne et al., 2017).

Surgical interventions among transgender men will have obvious implications for reproductive capacity. If patients desire a hysterectomy, the option should be offered of preserving the ovaries to retain the possibility of having a genetically related child. Alternatively, if the ovaries are removed either separately or concurrently with the hysterectomy, egg freezing should be offered prior to surgery and/or ovarian tissue cryopreservation can be done at the time of oophorectomy. Although this procedure is no longer considered experimental, many transgender men may desire *in vitro* maturation of primordial follicles, which is still investigational. Studies evaluating oocyte function have shown oocytes isolated from transgender men with testosterone exposure at the time of oophorectomy can be matured *in vitro* to develop normal metaphase II meiotic spindle structure (De Roo et al., 2017; Lierman et al., 2017).

TGD individuals assigned male at birth

Based on current evidence in transgender women and gender diverse people assigned male at birth (AMAB), the influence of medical treatment is as follows:

GnRHas inhibit spermatogenesis. Data suggest discontinuation of treatment results in a re-initiation of spermatogenesis, although this may take at least 3 months and most likely longer (Bertelloni et al., 2000). Furthermore, the psychological burden of re-exposure to testosterone should be considered.

Anti-androgens and estrogens result in an impaired sperm production (de Nie et al., 2020; Jindarak et al., 2018; Kent et al., 2018). Spermatogenesis might resume after discontinuation of prolonged treatment with anti-androgens and estrogens, but data are limited (Adeleye et al., 2019; Alford et al., 2020; Schneider et al., 2017). Testicular volumes diminish under the influence of gender-affirming hormone treatment (Matoso et al., 2018). Semen quality in transgender women may also be negatively affected by specific life-style factors, such as a low frequency of masturbation, wearing the genitals tight against the body (e.g., with use of tight undergarments for tucking) (Jung & Schuppe, 2007; Mieusset et al., 1985, 1987; Rodriguez-Wallberg, Häljestig et al., 2021).

Statement 16.2

We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.

Research shows many transgender adults desire biological children (De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Wierckx, Van Caenegem et al., 2012), yet FP rates remain widely variable, particularly in youth (< 5%–40%) (Brik et al., 2019; Chen et al., 2017; Chiniara et al., 2019; Nahata et al., 2017; Segev-Becker et al., 2020). In a recent survey, many youth acknowledged their feelings about having a biological child might change in the future (Strang, Jarin et al., 2018). Non-elective sterilization is a violation of human rights (Ethics Committee of the American Society for Reproductive Medicine, 2015; Equality and Human Rights Commission, 2021; Meyer III et al., 2001) and due to advances in social attitudes, fertility medicine, and affirmative transgender health care, opportunities for biological parenthood during transition should be supported for transgender people. Due to the influence clinical opinion may have on transgender or nonbinary people's FP and on parenting decisions, FP options should be explored by health care providers alongside options such as fostering, adoption, coparenting, and other parenting alternatives (Bartholomaeus & Riggs, 2019). Transgender patients who have been offered this type of discussion and have been given the choice to undergo procedures for FP have reported the experience to be an overall positive one (Armuand, Dhejne et al., 2017; De Sutter et al., 2002; James-Abra et al., 2015).

In other patient populations, fertility referrals and formal fertility programs have been shown to increase FP rates and improve patient satisfaction (Kelvin et al., 2016; Klosky, Anderson et al., 2017; Klosky, Wang et al., 2017;

Shnorhavorian et al., 2012) Physician attitudes have been investigated, and recent studies indicate both an awareness and a desire to provide fertility-related information to children and their families (Armuand et al., 2020). However, barriers have also been identified, including lack of knowledge, comfort, and resources (Armuand, Nilsson et al., 2017; Frederick et al., 2018). Thus, the need for appropriate training of health care providers has been highlighted, with emphasis placed on fertility counseling and offering FP options to all at-risk individuals in an unbiased way (Armuand, Nilsson et al., 2017). Parents' recommendations have also been shown to significantly influence FP rates in adolescent and young adult males with cancer (Klosky, Flynn et al., 2017). While there are clear clinical differences in these populations, these findings can help inform best practices for fertility counseling and FP referrals for transgender individuals.

Statement 16.3

We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.

Cryopreservation of sperm and oocytes are established FP techniques and can be offered to pubertal, late pubertal, and adult birth assigned males and birth assigned females, respectively, preferably prior to the initiation of GAHT (Hembree et al., 2017; Practice Committee of the American Society for Reproductive Medicine, 2019). Cryopreservation of embryos can be offered to adult (post-pubertal) TGD people who wish to have a child and have an available partner. The future use of cryopreserved gametes is also dependent on the gametes and reproductive organs of the future partner (Fischer, 2021; Maxwell et al., 2017)

Although semen parameters have been shown to be compromised when FP is performed after initiation of GAH medication (Adeleye et al., 2019), one small study showed when the treatment was discontinued, semen parameters were comparable to those in TGD patients who had never undergone GAH treatment. With regard to ovarian stimulation, oocyte vitrification yield and subsequent use of the oocytes in in-vitro fertilization (IVF), there is no reason to anticipate a different outcome in assisted reproductive technology (ART) treatments for TGD patients than that obtained in cisgender patients undergoing ART—other than individual confounding factors related to (in)fertility—when gametes are banked prior to any medical treatment (Adeleye et al., 2019). The use of oocytes in ART treatment resulted in similarly successful outcomes in TGD compared with controlled, matched cisgender patients (Adeleye et al., 2019; Leung et al., 2019; Maxwell et al., 2017).

Although these are established options, few pubertal, late pubertal or adult TGD people undergo FP (Nahata et al., 2017), and many experience challenges while undergoing FP interventions. Not only is access and cost of these methods a barrier (particularly in regions without insurance coverage), but these procedures are often physically and emotionally uncomfortable, and many express concerns about postponing the transitioning process (Chen et al., 2017; De Sutter et al., 2002; Nahata et al., 2017; Wierckx, Stuyver et al., 2012). Especially for the birth assigned females, the invasiveness of endovaginal ultrasound follow-up of the ovarian stimulation and oocyte retrieval procedures (and associated psychological distress) have been cited as a barrier (Armuand, Dhejne et al., 2017; Chen et al., 2017). There is also the concern young adults going through transitioning may not have a clear vision of parenting and are therefore likely to decline the opportunity to use FP at that time—while as adults, they may have different opinions about parenthood (Cauffman & Steinberg, 2000). The reduction of gender dysphoria during transitioning could also influence the decision-making process surrounding FP (Nahata et al., 2017). Based on research showing TGD youths' fertility perspectives may change over time (Nahata et al., 2019; Strang, Jarin et al., 2018), FP options should be discussed on an ongoing basis.

Statement 16.4

We recommend health care professionals counsel pre- or early-pubertal transgender and

gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.

For prepubertal and early-pubertal children, FP options are limited to the storage of gonadal tissue. Although this option is available for TGD children in the same way that it is available for cisgender prepubertal and early-pubertal oncological patients, there is no literature describing the utilization of this approach in the transgender population. Ovarian tissue autotransplantation has resulted in over 130 live births in cisgender women. Most of these patients conceived naturally without ART (Donnez & Dolmans, 2015; Jadoul et al., 2017), and the majority stored their ovarian tissue either as adults or during puberty. Although the recent American Society for Reproductive Medicine guideline has lifted the experimental label from ovarian tissue cryopreservation (Practice Committee of the American Society for Reproductive Medicine, 2019), there are very few case reports describing a successful pregnancy in a woman following the transplantation of ovarian tissue cryopreserved before puberty. Demeestere et al. (2015) and Rodriguez-Wallberg, Milenkovic et al. (2021) described cases of successful pregnancies following transplantation of tissue procured at the age of 14, and recently Matthews et al. (2018) described the case of a girl diagnosed with thalassemia who had ovarian tissue stored at the age of 9 and transplantation 14 years late. She subsequently conceived through IVF and delivered a healthy baby.

Currently, the only future clinical application for storing ovarian tissue is autotransplantation, which might be undesirable in a transgender man (due to the potentially undesirable effects of estrogen). A laboratory procedure that would make it possible to mature oocytes *in vitro* starting with ovarian tissue would be the ideal future application of stored ovarian tissue for transgender people, but this technique is currently only being investigated and optimized in basic science research settings (Ladanyi et al., 2017; Oktay et al., 2010).

Prepubertal procurement of testicular tissue has been documented as a low-risk procedure (Borgström et al., 2020; Ming et al., 2018). Some authors have also described this approach as a theoretical option in transgender people (De Roo et al., 2016; Martinez et al., 2017; Nahata, Curci et al., 2018). However, there are no reports in the literature describing the clinical or investigational utilization of this FP option for TGD patients. Moreover, the viability of the clinical application of autotransplantation of testicular tissue remains unknown in humans, and *in vitro* maturation techniques are still in the realm of basic science research. Thus, specialists currently consider this technique experimental (Picton et al., 2015). The possibility of storing gonadal tissue should be discussed prior to any genital surgery that would result in sterilization, although the probability of being able to use this tissue must be clearly addressed.

Statement 16.5

We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care and prenatal counseling regarding the use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.

Most transgender men and gender diverse people (AFAB) retain their uterus and ovaries and thus can conceive and carry a pregnancy even after long-term testosterone use (Light et al., 2014). Many transgender men desire children (Light et al., 2018; Wierckx, van Caenegem et al., 2012) and are willing to carry a pregnancy (Moseson, Fix, Hastings et al., 2021; Moseson, Fix, Ragosta et al., 2021). ART has expanded the opportunity for many transgender men to conceive and fulfill their family planning wishes (De Roo et al., 2017; Ellis et al., 2015; Maxwell et al., 2017). Some transgender men report psychological isolation, dysphoria related to the gravid uterus and chest changes, and depression (Charter, 2018; Ellis et al., 2015; Hoffkling et al., 2017; Obedin-Maliver & Makadon, 2016). Conversely, other studies have reported some positive experiences during pregnancy as well (Fischer, 2021; Light et al., 2014). Mental health providers should be involved to provide support, and counseling should be

provided addressing when to stop and when to resume gender-affirming hormones, what options are available for the mode of delivery and for chest/breast feeding (Hoffkling et al., 2017). Finally, system-level and interpersonal-level interventions should be implemented to ensure person-centered reproductive health care for all people (Hahn et al., 2019; Hoffkling et al., 2017; Moseson, Zazanis et al., 2020; Snowden et al., 2018).

Given the potential harmful effects of testosterone on the developing embryo, discontinuing testosterone or masculinizing hormone therapy prior to conception and during the entire pregnancy is recommended. However, the optimal time for both the discontinuation of testosterone prior to pregnancy and its resumption after pregnancy is unknown. Since stopping gender-affirming hormones may cause distress and exacerbate dysphoria in transgender men, when and how to stop this therapy should be discussed during prenatal counseling (Hahn et al., 2019). Because information about the duration of testosterone exposure and the risk of teratogenicity is lacking, testosterone use should be discontinued prior to attempting pregnancy and before stopping contraception. Moreover, there is limited information regarding health outcomes of infants born to transgender men. Small case series attempting to evaluate this question have revealed no adverse physical or psychosocial differences between infants born to transgender men and infants in the general population (Chiland et al., 2013).

Chest/Breast feeding

In the limited studies evaluating lactation and chest/breast feeding, the majority of transgender men and TGD individuals AFAB who chose to chest/breast feed postpartum were successful, with research suggesting induction of lactation is in part dependent on preconception counseling and experienced lactation nursing support (MacDonald et al., 2016; Wolfe-Roubatis & Spatz, 2015). Specifically, transgender men and TGD people who use testosterone should be informed 1) although quantities are small, testosterone does pass through chest/breast milk; and 2) the impact on the developing neonate/child is unknown, and therefore gender-affirming testosterone use is not recommended during lactation but may be resumed after discontinuation of chest/breast feeding (Glaser et al., 2009). Transgender men and other TGD individuals AFAB should be made aware some patients who carry a pregnancy may experience undesired chest growth and/or lactation even after chest reconstruction and should therefore be supported if they desire to suppress lactation (MacDonald et al., 2016).

There is limited information concerning lactation in transgender women as well as other TGD AMAB but many also express the desire to chest/breast feed. While there is a case report of a transgender woman successfully lactating and chest/breast feeding her infant after hormonal support using a combination of estrogen, progesterone, domperidone, and breast pumping (Reisman & Goldstein, 2018), the nutritional and immunological profile of chest/breast milk under these conditions has not been studied. Therefore, patients need to be informed about the risks and benefits of this approach to child feeding (Reisman & Goldstein, 2018).

Statement 16.6

We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.

Many TGD individuals may retain reproductive capacity, and they (if they retain a uterus, ovaries, and tubes) or their sexual partners (for sperm producing individuals) may experience unplanned pregnancies (James et al., 2016; Light et al., 2014; Moseson, Fix et al., 2020). Therefore, intentional family planning counseling, including contraception and abortion conducted in gender-expansive ways is needed (Klein, Berry-Bibee et al., 2018; Obedin-Maliver, 2015; Stroumsa & Wu, 2018). TGD people AFAB may not use contraception due to an erroneous assumption that testosterone is a reliable form of contraception (Abern & Maguire, 2018; Ingraham et al., 2018; Jones, Wood et al., 2017; Potter et al., 2015). However, based on current understanding, testosterone should not be considered a reliable form of contraception because of its incomplete suppression of the hypothalamic-pituitary-adrenal axis (Krempasky et al., 2020). Furthermore, pregnancies have occurred while individuals are amenorrheic due

to testosterone use, which may outlast active periods of administration (Light et al., 2014). Pregnancy can also occur in TGD people after long-term testosterone use (at least up to 10 years), although the effect on oocytes and baseline fertility is still unknown (Light et al., 2014).

TGD people AFAB may use a variety of contraceptive methods (Abern & Maguire, 2018; Bentsianov et al., 2018; Bonnington et al., 2020; Chrisler et al., 2016; Cipres et al., 2017; Jones, Wood et al., 2017; Krempasky et al., 2020; Light et al., 2018).These methods may be used explicitly for pregnancy prevention, menstrual suppression, abnormal bleeding, or other gynecological needs (Bonnington et al., 2020; Chrisler et al., 2016; Krempasky et al., 2020; Schwartz et al., 2019). Contraceptive research gaps within this population are profound. No studies have examined how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or non-hormonal and barrier contraceptive methods (e.g., internal and external condoms, non-hormonal intrauterine devices, diaphragms, sponges, etc.).

Gender diverse individuals who currently have a penis and testicles may engage in sexual activity with individuals who have a uterus, ovaries, and tubes of any gender. Gender diverse people who have a penis and testicles can produce sperm even while on gender-affirming hormones (i.e., estrogen), and although semen parameters are diminished among those who are currently using or who have previously used gender-affirming hormones, azoospermia is not complete and sperm activity is not totally suppressed (Adeleye et al., 2019; Jindarak et al., 2018; Kent et al., 2018). Therefore, contraception needs to be considered if pregnancy is to be avoided in penis-in-vagina sexual activity between a person with a uterus, ovaries, and tubes and one with a penis and testicles, irrespective of the use of gender-affirming hormones by either partner. Currently, contraceptive methods available for use by the sperm-producing partner are primarily mechanical barriers (i.e., external condoms, internal condoms), permanent sterilization (i.e., vasectomy), and gender-affirming surgery (e.g., orchiectomy, which also results in sterilization). Contraceptive counseling that considers sperm producing, egg producing, and gestating partners (as relevant) is recommended.

Statement 16.7

We recommend providers who offer pregnancy termination services ensure procedural approaches are gender-affirming and serve transgender people and those of diverse genders.

Unplanned pregnancies and abortions have been reported among TGD individuals with a uterus (Abern & Maguire, 2018; Light et al., 2014; Light et al., 2018; Moseson, Fix et al., 2020) and documented through surveys of abortion-providing facilities (Jones et al., 2020). However, the population-based epidemiology of abortion provision and the experiences and preferences of TGD individuals AFAB undergoing abortion still represents a critical gap in research (Fix et al., 2020; Moseson, Fix et al., 2020; Moseson, Lunn et al., 2020). Nonetheless, given that pregnancy capacity exists among many TGD people and pregnancies may not always be planned or desired, access to safe, legal, and gender-affirming pregnancy medical and surgical termination services is necessary.

CHAPTER 17 Sexual Health

Sexual health has a profound impact on physical and psychological well-being, regardless of one's sex, gender, or sexual orientation. However, stigma about sex, gender and sexual orientation influences individual's opportunities to live out their sexuality and to receive appropriate sexual health care. Specifically, in most societies, cisnormativity and heteronormativity lead to the assumption that all people are cisgender and heterosexual (Bauer et al., 2009), and that this combination is superior to all other genders and sexual orientations (Nieder, Güldenring et al., 2020; Rider, Vencill et al., 2019). Hetero-cisnormativity negates the complexity of gender, sexual orientation, and sexuality and disregards diversity and fluidity. This is all the more important since sexual identities, orientations, and practices of transgender and gender diverse (TGD) people are characterized by an enormous diversity (Galupo et al., 2016; Jessen et al., 2021; Thurston & Allan, 2018; T'Sjoen et al., 2020). Likewise, a strong cross-cultural tendency toward allonormativity—the assumption that all people experience sexual attraction or interest in sexual activity—negates the diverse experiences of TGD people, especially those who locate themselves on the asexual spectrum (McInroy et al., 2021; Mollet, 2021; Rothblum et al., 2020).

The World Health Organization (WHO, 2010) emphasizes sexual health depends on respect for the sexual rights of all people, including the right to express diverse sexualities and to be treated respectfully, safely, and with freedom from discrimination and violence. Sexual health discourses have focused on agency and body autonomy, which include consent, sexual pleasure, sexual satisfaction, partnerships, and family life (Cornwall & Jolly, 2006; Lindley et al., 2021). In light of this, the WHO defines sexual health as "a state of physical, emotional, mental, and social well-being in relation to sexuality and not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled" (WHO, 2006, p. 5). This includes individuals on the asexual spectrum, who may not experience sexual attraction to others but may still choose to be sexual at times (e.g., via self-stimulation) and/or experience interest in forming and building romantic relationships (de Oliveira et al., 2021).

Scientific attention to the sexual experiences and behaviors of TGD people has grown in recent years (Gieles et al., 2022; Holmberg et al., 2019; Klein & Gorzalka, 2009; Kloer et al., 2021; Mattawanon et al., 2021; Stephenson et al., 2017; Tirapegui et al., 2020; Thurston & Allan, 2018). This expansion within the literature reflects a sex-positive framework (Harden, 2014), a framework that recognizes both the positive aspects such as sexual pleasure (Laan et al., 2021) and potential risks associated with sexuality (Goldhammer et al., 2022; Mujugira et al., 2021). Studies of TGD people's sexuality, however, often lack validated measures, an appropriate control group, or a prospective design (Holmberg et al., 2019). Additionally, most focus exclusively on sexual functioning (Kennis et al., 2022), and thus neglecting sexual satisfaction and broader operationalizations of sexual pleasure beyond functioning. The effects of current TGD-related medical treatments on sexuality are heterogeneous (Özer et al., 2022; T'Sjoen et al., 2020), and there has been little research on the sexuality of TGD adolescents (Bungener et al., 2017; Maheux et al., 2021; Ristori et al., 2021; Stübler & Becker-Hebly, 2019; Warwick et al., 2022). While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date there is insufficient research on the effectiveness of such interventions. Focusing on the promotion of sexual health, the World Association for Sexual Health (WAS) asserts the importance of sexual pleasure and considers self-determination, consent, safety, privacy, confidence, and the ability to communicate and negotiate sexual relations as major facilitators (Kismödi et al., 2017). WAS asserts sexual pleasure is integral to sexual rights and human rights (Kismödi et al., 2017). To contribute to

Statements of Recommendations

17.1- We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills needed to address sexual health issues (relevant to their care provision).
17.2- We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.
17.3- We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.
17.4- We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.
17.5- We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectations of the transgender and gender diverse individual and assess their level of understanding of possible changes.
17.6.-We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.
17.7- We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.
17.8- We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

the sexual health of TGD people, health care professionals (HCPs) need both transgender-related expertise and sensitivity (Nieder, Güldenring et al., 2020). With the goal of improving sexual health care for TGD people to an ethically-sound, evidence-based and high-quality level, HCPs must provide their health services with the same care (i.e., with transgender-related expertise), respect (i.e., with transgender-related sensitivity), and investment in sexual pleasure and sexual satisfaction as they provide for cisgender people (Holmberg et al., 2019).

In many societies, nonconforming gender expressions can elicit strong (emotional) reactions, including in HCPs. Thus, when initiating a health-related contact or establishing a therapeutic relationship, a nonjudgmental, open and welcoming manner is most likely ensured when HCPs reflect on their emotional, cognitive, and interactional reactions to the person (Nieder, Güldenring et al., 2020). In addition, transgender-related expertise refers to identifying the impact the TGD person's intersectional identities and experiences of marginalization and stigma may have had on their whole self (Rider, Vencill et al., 2019). To adequately address the specific physical, psychological, and social conditions of TGD people, HCPs must be aware these conditions are generally overlooked due to hetero-cis-normativity, lack of knowledge, and lack of skills (Rees et al., 2021). It is also important to consider cultural norms in relation to sexuality. For example, in some African cultures, the idea of sex as taboo restricts the number of acceptable terms to be used when taking a sexual history (Netshandama et al., 2017). Culturally respectful language can facilitate talking openly about one's sexual history and reduce ambiguity or shame (Duby et al., 2016). In addition, HCPs must be sensitive to the history of (mis)use of sexual identity and orientation as a gatekeeping function to exclude transgender people from gender-affirming health care (Nieder & Richter-Appelt, 2011; Richards et al., 2014). The following recommendations aim to improve sexual health care for TGD people.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 17.1

We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills to address sexual health issues (relevant to their care provision).

It is important HCPs addressing the sexual health of TGD people be familiar with commonly used terminology (see Chapter 1—Terminology) and invite those seeking care to explain terms with which the provider may not be familiar. In this context, it is also important HCPs (are

prepared to) take a sexual history and offer treatment (according to their competencies) in a gender-affirming way with a sex-positive approach (Centers for Disease Control, 2020; Tomson et al., 2021). However, HCP's should apply greater importance to the terminology that the TGD person uses for their own body over more traditionally accepted or used medical terminology (Wesp, 2016). When talking about sexual practices, it is advisable to focus on body parts (e.g., "Do you have sex with people with a penis, people with a vagina, or both?"; ACON, 2022) and what role they play in their sexuality (e.g., "During Sex, do any parts of your body enter your partners body, such as their genitals, anus, or mouth?"; ACON, 2022).

Statement 17.2

We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.

To achieve gender-affirming care, it is crucial HCPs providing transition-related medical interventions be sufficiently informed about the possible effects on sexual function, pleasure, and satisfaction (T'Sjoen et al., 2020). Since clinical data indicate that TGD people score significantly lower in sexual pleasure compared to cisgender individuals, this is even more important (Gieles et al., 2022). If the HCP cannot provide information about the effects of their treatment on sexual function, pleasure, and satisfaction, they are at least expected to refer the individual to someone qualified to do so. If the sexuality-related effects of their treatment are unknown, HCPs should inform their patients accordingly. As introduced above, the sexuality of TGD people often challenges heteronormative views. Nevertheless, there is a large amount of literature (e.g., Bauer, 2018; Laube et al., 2020; Hamm & Nieder, 2021; Stephenson et al., 2017) highlighting the spectrum character of sexuality that does not fit into expectations of what male and female sexuality entails (neither cis- nor transgender), let alone that of gender diverse people (e.g., nonbinary, agender, genderqueer). Thus, these aspects should be carefully considered by HCPs as cisnormativity, heteronormativity, and transition-related medical interventions, all have a strong impact on sexual health.

Sexual pleasure has been well documented as a factor in improving sexual, mental, and physical health outcomes (Anderson, 2013). Next to sexual function, HCPs providing sexual health care must address sexual pleasure and satisfaction as a key factor within sexual health. Historically sexual health care has been disease focused, and this is particularly true for research and clinical practice in working with TGD patients. Although competent sexual health care regarding HIV and STIs is necessary, integration of valuing sexual pleasure of TGD patients is also necessary. Calls for integrating sexual pleasure as a focal point in STI prevention education and interventions rest on the understanding that pleasure is a motivator of behavior (Philpott et al., 2006). TGD people are concerned about their sexual pleasure and need HCPs who are knowledgeable about the diversity of sexual practices and anatomical functioning particular to TGD health care.

Statement 17.3

We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.

When appropriate and relevant to clinical concerns, inclusion of a sexual and/or romantic partner(s) in sexual health care decision-making can increase TGD patients' sexual well-being and satisfaction outcomes (Kleinplatz, 2012). TGD people may choose a range of transition-related medical interventions, and these interventions may have mixed results in shifting experiences of anatomical dysphoria (Bauer & Hammond, 2015). When discussing the impact of medical interventions on sexual functioning, pleasure, and satisfaction, inclusion of partner(s) can increase knowledge of potential changes and encourage communication between partners (Dierckx et al., 2019). Because the process of transitioning is often not a completely solitary endeavor, the inclusion of sexual and/or romantic partners in transition-related health care can facilitate the process of "co-transitioning" (Lindley et al., 2020;

Siboni et al., 2022; Theron & Collier, 2013) and can also support sexual growth and adjustment both in the individual as well as in the relationship. Social and psychological barriers to sexual functioning and pleasure, including experiences of gender dysphoria, stigmatization, lack of sexual and relationship role models, and limited skills, can have negative impacts on overall sexual health (Kerckhof et al., 2019). Supportive, gender-affirming sexual communication between partners improves sexual satisfaction outcomes for TGD people (Stephenson et al., 2017; Wierckx, Elaut et al., 2011).

Inclusion of sexual and/or romantic partners offers an additional opportunity to set realistic expectations, disseminate helpful and accurate information, and facilitate gender-affirming positive communication related to sexual health. Ultimately, however, it is important to recognize individual choices related to gender health and transition are the patients to make, not a partner's decision. It is important the inclusion of partners in sexual health-related care occur only when appropriate and as desired by patients. Contraindications might include interpersonal dynamics that are abusive or violent, in which case patient safety overrides partner involvement. Finally, it is critical HCPs treat all people in an affirming and inclusive manner, including sexual and romantic partners. This means, for example, monitoring and addressing assumptions and potential biases about the gender or sexual orientation of a patient's partner(s) or a patient's relationship structure.

Statement 17.4

We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.

The TGD community is disproportionately impacted by stigma, discrimination, and violence (de Vries et al., 2020; European Union Agency for Fundamental Rights, 2020; McLachlan, 2019). These experiences are often traumatic in nature (Burnes et al., 2016; Mizock & Lewis, 2008) and can create barriers to sexual health, functioning, and pleasure (Bauer & Hammond, 2015). For example, stigmatizing narratives about transgender sexualities can increase dysphoria and sexual shame, increasing potential avoidance of the sexual communication needed for safety and optimizing pleasure (Stephenson et al., 2017). Research demonstrates stigma, a history of sexual violence, and body image concerns can negatively impact sexual self-esteem and agency, for example the ability to assert what is pleasurable or to negotiate condom use (Clements-Nolle et al., 2008; Dharma et al., 2019). Additionally, gender dysphoria can be exacerbated by past trauma experiences and ongoing trauma-related symptoms (Giovanardi et al., 2018). It may be difficult for some TGD individuals to engage sexually using the genitals with which they were born, and they may choose to avoid such stimulation altogether, disrupting arousal and/or orgasmic processes (Anzani et al., 2021; Bauer & Hammond, 2015; Iantaffi & Bockting, 2011) or result in complex feelings about orgasm (Chadwick et al., 2019). HCPs providing gender-affirming counseling and interventions must be knowledgeable about the spectrum of sexual orientations and identities (including asexual identities and practices) to avoid assumptions based in heteronormative, cisnormative, allonormative modes of behavior or satisfaction while also affirming the potential impacts of stigma and trauma on sexual health and pleasure (Nieder, Güldenring et al., 2020). Some level of disconnect or dissociation may at times be present, particularly in the case of acute trauma symptoms (Colizzi et al., 2015). It is important HCPs be aware of these potential impacts on sexual health, functioning, pleasure, and satisfaction, so they may refer patients as needed to trauma-informed sexual counselors, mental health providers, or both, who may be of further assistance and may also normalize and validate TGD patients exploring multiple diverse pathways of healing and accessing sexual pleasure.

Statement 17.5

We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectation of the transgender and gender diverse individual, and assess their level of understanding of possible changes.

Transition-related care can affect sexual function, pleasure, and satisfaction, both in positive and negative ways (Holmberg et al., 2018; Kerckhof et al., 2019; Thurston & Allan, 2018; Tirapegui et al., 2020). On the positive side, gender-affirming care can help TGD people improve their sexual functioning and increase their sexual pleasure and satisfaction (Kloer et al., 2021; Özer et al., 2022; T'Sjoen et al., 2020). On the negative side, however, data indicate problematic sexual health outcomes due to hormonal and surgical treatments (Holmberg et al., 2018; Kerckhof et al., 2019, Stephenson et al., 2017; Weyers et al., 2009). Transition-related hormones may affect mood, sexual desire, the ability to have an erection and ejaculation, and genital tissue health, which in turn can impact sexual function, pleasure and sexual self-expression (Defreyne, Elaut et al., 2020; Garcia & Zaliznyak, 2020; Kerckhof et al., 2019; Klein & Gorzalka, 2009; Wierckx, Elaut et al., 2014). TGD people who wish to use their original genital anatomy for penetrative sex may benefit from medications that address sexual health side effects of hormone therapy, such as erectile dysfunction, medications for TGD persons taking estrogen or antiandrogens, and topical estrogen and/or moisturizers for TGD persons experiencing vaginal atrophy or dryness due to testosterone therapy.

Sexual desire, arousal, and function may also be affected by the use of psychotropic drugs (Montejo et al., 2015). As some TGD people are prescribed medication to treat depression (Heylens, Elaut et al., 2014), anxiety (Millet et al., 2017) or other mental health concerns (Dhejne et al., 2016), their potential side effects on sexual health should be considered.

Many gender-affirming surgeries can have significant effects on erogenous sensation, sexual desire and arousal as well as sexual function and pleasure. The impact of these changes for patients may be mixed (Holmberg et al., 2018). Chest surgeries (breast reduction, mastectomy, and breast augmentation) and body contouring surgeries, for example, may offer desired changes in form and appearance thereby reducing psychological distress that can disrupt sexual functioning but may adversely affect erogenous sensation (Bekeny et al., 2020; Claes et al., 2018; Rochlin et al., 2020). Genital surgeries in particular can potentially affect sexual function and pleasure in adverse ways, although they are likely to be experienced positively as the patient's body becomes more aligned with their gender, potentially opening new avenues for sexual pleasure and satisfaction (Hess et al., 2018; Holmberg et al., 2018; Kerckhof et al., 2019).

There are numerous examples of this in the extant literature:

- Surgery may result in a decrease, a total loss, or a possible increase in erogenous stimulation and/or experienced sensation compared with the patient's presurgery anatomy (Garcia, 2018; Sigurjónsson et al., 2017).
- A particular surgical option may be associated with specific limitations to sexual function that may manifest immediately, in the future, or at both timepoints, and which patients should consider before finalizing their choice when considering different surgical options (Frey et al., 2016; Garcia, 2018; Isaacson et al., 2017).
- Postsurgical complications can adversely affect sexual function by either decreasing the quality of sexual function (e.g., discomfort or pain with sexual activity) or by precluding satisfactory intercourse (Kerckhof et al., 2019; Schardein et al., 2019).

In general, satisfaction with any medical treatment is heavily influenced by the patient's expectations (Padilla et al., 2019). Furthermore, when patients have unrealistic expectations before treatment, they are much more likely to be dissatisfied with the outcome, their care, and with their HCP (Padilla et al., 2019). Therefore, it is important to both provide patients with adequate information about their treatment options and to understand and consider what is important to the patient with regard to outcomes (Garcia, 2021). Finally, it is important the HCP ensure patients understand the potential adverse effects of a treatment on their sexual function and pleasure so that a well-informed decision can be made. This is relevant for both meeting the standard of informed consent (i.e.,

discussion and understanding) and for providing an opportunity to offer further clarification to patients and, if desired, to their partners (Glaser et al., 2020).

Statement 17.6

We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.

The WHO (2015) recommends HCPs implement brief sexuality-related communication in primary care for all adolescents and adults. Therefore, TGD persons who are sexually active or considering sexual activity may benefit from sexuality-related communication or counseling for the purpose of HIV/STI prevention. These conversations are particularly important as TGD persons are disproportionately impacted by human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs) relative to cisgender persons (Baral et al., 2013; Becasen et al., 2018; Poteat et al., 2016). However, few data are available for non-HIV STIs, such as chlamydia, gonorrhea, syphilis, viral hepatitis, and herpes simplex virus (Tomson et al., 2021). The United Nations Joint Programme on HIV/AIDS estimates transgender women are 12 times more likely than other adults to be living with HIV (UNAIDS, 2019). A meta-analysis estimated a pooled global HIV prevalence of 19% among transgender women who have sex with men (Baral et al., 2013). HIV/STI risk is concentrated among TGD subgroups at the confluence of multiple biological, psychological, interpersonal, and structural vulnerabilities. In particular, transfeminine persons who have sex with cisgender men, belong to minoritized racial/ethnic groups, live in poverty, and engage in survival sex work are at elevated HIV/STI risk (Becasen et al., 2018; Poteat et al., 2015; Poteat et al., 2016). Less is known about HIV/STI risk among transgender men or gender diverse persons AFAB. Small studies in high-income countries indicate a laboratory-confirmed HIV prevalence of 0-4% among transmasculine people (Becasen et al., 2018; Reisner & Murchison, 2016). Almost no research has been conducted with transmasculine people who have sex with cisgender men in high-HIV-prevalence countries. Despite limited epidemiologic data, transmasculine persons who have sex with cisgender men frequently report HIV/STI risk related to receptive vaginal and/or anal sex (Golub et al., 2019; Reisner et al., 2019; Scheim et al., 2017) and may be more susceptible to HIV acquisition from vaginal intercourse than (pre-menopausal) cisgender women due to hormone-related vaginal atrophy.

HCPs will need to supplement general guidelines by developing the knowledge and skills needed for discussing sexual health issues with TGD people, such as the use of gender-affirming language (see Statement 17.1 in this chapter). It is critical HCPs avoid assumptions about HIV/STI risk based solely on a patient's gender identity or anatomy. For example, many transgender people are not sexually active, and TGD persons may use prosthetics or toys for sex. To provide appropriate prevention counseling, HCPs should inquire about the specific sexual activities TGD people engage in, and the body parts (or prosthetics) involved in those activities (ACON, 2022). Well-prepared HCPs (including, but not limited to mental health providers) may also engage in in-depth counseling with their patients to address the underlying drivers of HIV/STI risk (see Statement 17.3 in this chapter).

In all cases, HCPs should be sensitive to the collective and individual histories of TGD people (e.g., stereotypes and stigma about trans sexualities and gender dysphoria) and should explain to patients the reasons for sexuality-related inquiries and the voluntary nature of such inquiries. In discussing HIV/STI prevention, HCPs should refer to the full range of prevention options including barrier methods, post-exposure prophylaxis, pre-exposure prophylaxis, and HIV treatment to prevent onwards transmission (WHO, 2021). Trans-specific considerations for pre-exposure prophylaxis are addressed in Statement 17.8.

Statement 17.7

We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.

Like cisgender patients, TGD adolescents and adults should be offered screening for HIV/STIs in accordance with existing guidelines and based on their individual risk of HIV/STI acquisition, considering anatomy and behavior rather than gender identity alone. Where local or national guidelines are unavailable, WHO (2019a) offers global recommendations; more frequent screening is recommended for transgender people who have sex with cisgender men as a key population affected by HIV.

Gender-affirming genital surgeries and surgical techniques have implications for STI risks and screening needs, as outlined in recent guidelines from the US Centers for Disease Control (Workowski et al., 2021). For instance, transfeminine persons who have had penile inversion vaginoplasty using only penile and scrotal skin to line the vaginal canal are likely at lower risk of urogenital Chlamydia trachomatis *(C. trachomatis)* and Neisseria gonorrhoeae *(N. gonorrhoeae)*, but newer surgical techniques that employ buccal or urethral mucosa or peritoneum flaps could in theory increase susceptibility to bacterial STIs relative to the use of penile/scrotal skin alone (Van Gerwen et al., 2021). Routine STI screening of the neovagina (if exposed) is recommended for all transfeminine persons who have had vaginoplasty (Workowski et al., 2021). For transmasculine persons who have had metoidioplasty with urethral lengthening, but not vaginectomy, testing for bacterial urogenital STIs should include a cervical swab because infections may not be detected in urine (Workowski et al., 2021).

Further, it is important for HCPs to offer testing at multiple anatomical sites as STIs in transgender patients are often extragenital (Hiransuthikul et al., 2019; Pitasi et al., 2019). Consistent with WHO (2020) recommendations, self-collection of samples for STI testing should be offered as an option, particularly if patients are uncomfortable or unwilling to undergo provider-collected sampling due to gender dysphoria, trauma histories, or both. Where relevant, integration of HIV/STI testing with regular serology used to monitor hormone therapy may better facilitate access to care (Reisner, Radix et al., 2016; Scheim & Travers, 2017).

Statement 17.8

We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

For TGD adolescents and adults at substantial risk of HIV infection (generally defined as an ongoing serodiscordant relationship or condomless sex outside of a mutually monogamous relationship with a known HIV-negative partner; WHO, 2017), pre-exposure prophylaxis (PrEP) is an important HIV prevention option (Golub et al., 2019; Sevelius et al., 2016; WHO, 2021). To encourage uptake of PrEP, in 2021 the US Centers for Disease Control recommended all sexually active adolescents and adults be informed about PrEP and offered it if requested (CDC, 2021). For treatment among people living with HIV, transgender-specific guidelines are available in some settings (e.g., Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019).

For both HIV prevention and treatment, there are antiretroviral dosing and administration considerations specific to TGD persons. For oral PrEP, only daily dosing is currently recommended for TGD persons as studies demonstrating the effectiveness of event-driven PrEP with emtricitabine/tenofovir disoproxil fumarate (TDF) have been limited to cisgender men (WHO, 2019c). In addition, while emtricitabine/tenofovir alafenamide (TAF) is a new oral PrEP option, as of early 2022 it is not recommended for people at risk of HIV acquisition through receptive vaginal sex due to a lack of evidence (CDC, 2021). Finally, long-acting injectable formulations of both PrEP and HIV treatment are increasingly available (e.g., cabotegravir for PrEP), and while they are recommended for all patients who might benefit from injectable options, indicated injection sites (i.e., the gluteal muscle) may be unsuitable for individuals who have used soft tissue fillers (Rael et al., 2020).

There is little evidence supporting the occurrence of drug-drug interactions between gender-affirming hormones and PrEP medications. A few small studies, primarily relying on self-reported PrEP use, have shown reduced PrEP drug concentrations in transgender women undergoing hormone therapy, although

concentrations remained in the protective range (Yager & Anderson, 2020). A subsequent drug-drug interaction study using directly observed PrEP therapy failed to detect an impact of hormone therapy on PrEP drug concentrations in transgender women and found transgender women and men taking hormone therapy achieved high levels of protection against HIV infection (Grant et al., 2020). Most importantly, for many TGD people, no impact of PrEP on hormone concentrations has been detected. With regard to HIV treatment, specific antiretroviral medications may impact hormone concentrations; however, these can be managed by selecting alternative agents, monitoring and adjusting hormone dosing, or both (Cirrincione et al., 2020) as detailed in guidelines from the US Department of Health and Human Services (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019). Nevertheless, concerns about drug-drug interactions, particularly interactions that may limit hormone concentrations, represent a barrier to the implementation and adherence to antiretroviral therapy for HIV prevention or treatment (Radix et al., 2020; Sevelius et al., 2016). Therefore, it is advisable for HCPs to proactively address such concerns with those who are candidates for PrEP or HIV treatment. Integration of PrEP or HIV treatment with hormone therapy may further reduce barriers to implementation and adherence (Reisner, Radix et al., 2016). Integration may be achieved through colocation or through coordination with an HIV specialist if the primary care provider does not have the necessary expertise. Some TGD persons may benefit from standalone PrEP or sexual health services that provide greater privacy and flexibility, and thus differentiated service delivery models are needed (Wilson et al., 2021).

CHAPTER 18 Mental Health

This chapter is intended to provide guidance to health care professionals (HCPs) and mental health professionals (MHPs) who offer mental health care to transgender and gender diverse (TGD) adults. It is not meant to be a substitute for chapters on the assessment or evaluation of people for hormonal or surgical interventions. Many TGD people will not require therapy or other forms of mental health care as part of their transition, while others may benefit from the support of mental health providers and systems (Dhejne et al., 2016).

Some studies have shown a higher prevalence of depression (Witcomb et al., 2018), anxiety (Bouman et al., 2017), and suicidality (Arcelus et al., 2016; Bränström & Pachankis, 2022; Davey et al., 2016; Dhejne, 2011; Herman et al., 2019) among TGD people (Jones et al., 2019; Thorne, Witcomb et al., 2019) than in the general population, particularly in those requiring medically necessary gender-affirming medical treatment (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). However, transgender identity is not a mental illness, and these elevated rates have been linked to complex trauma, societal stigma, violence, and discrimination (Nuttbrock et al., 2014; Peterson et al., 2021). In addition, psychiatric symptoms lessen with appropriate gender-affirming medical and surgical care (Aldridge et al., 2020; Almazan and Keuroghlian; 2021; Bauer et al., 2015; Grannis et al., 2021) and with interventions that lessen discrimination and minority stress (Bauer et al., 2015; Heylens, Verroken et al., 2014; McDowell et al., 2020).

Mental health treatment needs to be provided by staff and implemented through the use of systems that respect patient autonomy and recognize gender diversity. MHPs working with transgender people should use active listening as a method to encourage exploration in individuals who are uncertain about their gender identity. Rather than impose their own narratives or preconceptions, MHPs should assist their clients in determining their own paths. While many transgender people require medical or surgical interventions or seek mental health care, others do not (Margulies et al., 2021). Therefore, findings from research involving clinical populations should not be extrapolated to the entire transgender population.

Addressing mental illness and substance use disorders is important but should not be a barrier to transition-related care. Rather, these interventions to address mental health and substance use disorders can facilitate successful outcomes from

Statements of Recommendations

18.1- We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.
18.2- We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.
18.3- We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact that mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.
18.4- We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender- affirmation surgery.
18.5- We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.
18.6- We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.
18.7- We recommend health care professionals ensure if transgender and gender diverse people need in-patient or residential mental health, substance abuse or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.
18.8- We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.
18.9- We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.
18.10- We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

transition-related care, which can improve quality of life (Nobili et al., 2018).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 18.1

We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.

Because patients generally are assumed to be capable of providing consent for care, whether the presence of cognitive impairment, psychosis, or other mental illness impairs the ability to give informed consent is subject to individual examination (Applebaum, 2007). Informed consent is central to the provision of health care. The health care provider must educate the patient about the risks, benefits, and alternatives to any care that is offered so the patient can make an informed, voluntary choice (Berg et al., 2001). Both the primary care provider or endocrinologist prescribing hormones and the surgeon performing surgery must obtain informed consent. Similarly, MHPs obtain informed consent for mental health treatment and may consult on a patient's capacity to give informed consent when this is in question. Psychiatric illness and substance use disorders, in particular cognitive impairment and psychosis, may impair an individual's ability to understand the risks and benefits of the treatment (Hostiuc et al., 2018). Conversely, a patient may also have significant mental illness, yet still be able to understand the risks and benefits of a particular treatment (Carpenter et al., 2000). Multidisciplinary communication is important in challenging cases, and expert consultation should be utilized as needed (Karasic & Fraser, 2018). For many patients, difficulty understanding the risks and benefits of a particular treatment can be overcome with time and careful explanation. For some patients, treatment of the underlying condition that is interfering with the capacity to give informed consent—for example treating an underlying psychosis—will allow the patient to gain the capacity to consent to the required treatment. However, mental health symptoms such as anxiety or depressive symptoms that do not affect the capacity to give consent should not be a barrier for gender-affirming medical treatment, particularly as this treatment has been found to reduce mental health symptomatology (Aldridge et al., 2020).

Statement 18.2

We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.

The inability to adequately participate in perioperative care due to mental illness or substance use should not be viewed as an obstacle to needed transition care, but should be seen as an indication mental health care and social support be provided (Karasic, 2020). Mental illness and substance use disorders may impair the ability of the patient to participate in perioperative care (Barnhill, 2014). Visits to health care providers, wound care, and other aftercare procedures (e.g., dilation after vaginoplasty) may be necessary for a good outcome. A patient with a substance use disorder might have difficulty keeping necessary appointments to the primary care provider and the surgeon. A patient with psychosis or severe depression might neglect their wound or not be attentive to infection or signs of dehiscence (Lee, Marsh et al., 2016). Active mental illness is associated with a greater need for further acute medical and surgical care after the initial surgery (Wimalawansa et al., 2014).

In these cases, treatment of the mental illness or substance use disorder may assist in achieving successful outcomes. Arranging more support for the patient from family and friends or a home health care worker may help the patient participate sufficiently in perioperative care for surgery to proceed. The benefits of mental health treatments that may delay surgery should be weighed against the risks of delaying surgery and should

include an assessment of the impact on the patients' mental health delays may cause in addressing gender dysphoria (Byne et al., 2018).

Statement 18.3

We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.

Gender-affirming surgical procedures vary in terms of their impact on the patient. Some procedures require a greater ability to follow preoperative planning as well as engage in peri- and postoperative care to achieve the best outcomes (Tollinche et al., 2018). Mental health symptoms can influence a patient's ability to participate in the planning and perioperative care necessary for any surgical procedure (Paredes et al., 2020). The mental health assessment can provide an opportunity to develop strategies to address the potential negative impact mental health symptoms may have on outcomes and to plan support for the patient's ability to participate in the planning and care. Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health (Owen-Smith et al., 2018; van de Grift, Elaut et al., 2017). These benefits are weighed against the risks of each procedure when the patient and provider are deciding whether to proceed with the treatment. HCPs can assist TGD people in reviewing preplanning and perioperative care instructions for each surgical procedure (Karasic, 2020). Provider and patient can collaboratively determine the necessary support or resources needed to assist with keeping appointments for perioperative care, obtaining necessary supplies, addressing financial issues, and handling other preoperative coordination and planning. In addition, issues surrounding appearance-related and functional expectations, including the impact of these various factors on gender dysphoria, can be explored.

Statement 18.4

We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender-affirmation surgery.

Regardless of specialty, all HCPs have a responsibility to support patients in accessing medically necessary care. When HCPs are working with TGD people as they prepare for gender-affirming surgical procedures, they should assess the levels of psychosocial and practical support required (Deutsch, 2016b). Assessment is the first step in recognizing where additional support may be needed and enhancing the ability to work collaboratively with the individual to successfully navigate the pre-, peri-, and postsurgical periods (Tollinche et al., 2018). In the perioperative period, it is important to help patients optimize functioning, secure stable housing, when possible, build social and family supports by assessing their unique situation, plan ways of responding to medical complications, navigate the potential impact on work/income, and overcome additional hurdles some patients may encounter, such as coping with electrolysis and tobacco cessation (Berli et al., 2017). In a complex medical system, not all patients will be able to independently navigate the procedures required to obtain care, and HCPs and peer navigators can support patients through this process (Deutsch, 2016a).

Statement 18.5

We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.

Transgender populations have higher rates of tobacco and nicotine use (Kidd et al., 2018). However, many are unaware of the well-documented smoking-associated health risks (Bryant et al., 2014). Tobacco consumption increases the risk of developing health problems (e.g., thrombosis) in individuals receiving gender-affirming hormone treatment, particularly estrogens (Chipkin & Kim, 2017).

Tobacco use has been associated with worse outcomes in plastic surgery, including overall complications, tissue necrosis, and the need for surgical revision (Coon et al., 2013). Smoking also increases the risk for postoperative infection (Kaoutzanis et al., 2019). Tobacco use has been shown to affect

the healing process following any surgery, including gender-related surgeries (e.g., chest reconstructive surgery, genital surgery) (Pluvy, Garrido et al., 2015). Tobacco users have a higher risk of cutaneous necrosis, delayed wound healing, and scarring disorders due to hypoxia and tissue ischemia (Pluvy, Panouilleres et al., 2015). In view of this, surgeons recommend stopping the use of tobacco/nicotine prior to gender-affirmation surgery and abstaining from smoking up to several weeks postoperatively until the wound has completely healed (Matei & Danino, 2015). Despite the risks, cessation may be difficult. Tobacco smoking and nicotine use is addictive and is also used as a coping mechanism (Matei et al., 2015). HCPs who see patients longitudinally before surgery, including mental health and primary care providers, should address the use of tobacco/nicotine with individuals in their care, and either assist TGD people in accessing smoking cessation programs or provide treatment directly (e.g., varenicline or bupropion).

Statement 18.6

We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.

TGD people entering inpatient psychiatric, substance use treatment, or medical units should be maintained on their current hormone regimens. There is an absence of evidence supporting routine cessation of hormones prior to medical or psychiatric admissions. Rarely, a newly admitted patient may be diagnosed with a medical complication necessitating suspension of hormone treatment, for example an acute venous thromboembolism (Deutsch, 2016a). There is no strong evidence for routinely stopping hormone treatment prior to surgery, and the risks and benefits for each individual patient should be assessed before doing so (Boskey et al., 2018).

Hormone treatment has been shown to improve quality of life and to decrease depression and anxiety (Aldridge et al., 2020; Nguyen et al., 2018; Nobili et al., 2018; Owen-Smith et al., 2018, Rowniak et al., 2019). Access to gender-affirming medical treatment is associated with a substantial reduction in the risk of suicide attempt (Bauer et al., 2015). Halting a patient's regularly prescribed hormones denies the patient of these salutary effects, and therefore may be counter to the goals of hospitalization.

Some providers may be unaware of the low risk of harm and the high potential benefit of continuing transition-related treatment in the inpatient setting. A study of US and Canadian medical schools revealed that students received an average of 5 hours of LGBT-related course content over their entire four years of education (Obedin-Maliver et al., 2011). According to a survey of Emergency Medicine physicians, who are often responsible for making quick decisions about medications as patients are being admitted, while 88% reported caring for transgender patients, only 17.5% had received any formal training about this population (Chisolm-Straker et al., 2018). As education about transgender topics increases, more providers will become aware of the importance of maintaining transgender patients on their hormone regimens during hospitalization.

Statement 18.7

We recommend health care professionals ensure if transgender and gender diverse people need inpatient or residential mental health, substance abuse, or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.

Many TGD patients encounter discrimination in a wide range of health settings, including hospitals, mental health treatment settings, and drug treatment programs (Grant et al., 2011). When health systems fail to accommodate TGD individuals, they reinforce the longstanding societal exclusion many have experienced (Karasic, 2016). Experiences of discrimination in health settings lead to avoidance of needed health care due to anticipated discrimination (Kcomt et al., 2020).

The experience of discrimination experienced by TGD individuals is predictive of suicidal ideation (Rood et al., 2015; Williams et al., 2021). Gender minority stress associated with rejection and nonaffirmation has also been associated with suicidality (Testa et al., 2017). Denial of access to gender appropriate bathrooms has been

associated with increased suicidality (Seelman, 2016). However, the use of chosen names for TGD people has been associated with lower depression and suicidality (Russell et al., 2018). Structural as well as internalized transphobia must be addressed to reduce the incidence of suicide attempts in TGD people (Brumer et al., 2015). To successfully provide care, health settings must minimize the harm done to patients because of transphobia by respecting and accommodating TGD identities.

Statement 18.8

We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.

While minority stress and the direct effects of discriminatory societal discrimination can be harmful to the mental health of TGD people, strong social support can help lessen this harm (Trujillo et al., 2017). TGD children often internalize rejection from family and peers as well as the transphobia that surrounds them (Amodeo et al., 2015). Furthermore, exposure to transphobic abuse may be impactful across a person's lifespan and may be particularly acute during the adolescent years (Nuttbrock et al., 2010).

The development of affirming social support is protective of mental health. Social support can act as a buffer against the adverse mental health consequences of violence, stigma, and discrimination (Bockting et al., 2013), can assist in navigating health systems (Jackson Levin et al., 2020), and can contribute to psychological resilience in TGD people (Bariola et al., 2015; Başar and Öz, 2016). Diverse sources of social support, especially LGBTQ+peers and family, have been found to be associated with better mental health outcomes, well-being, and quality of life (Bariola et al., 2015; Başar et al., 2016; Kuper, Adams et al., 2018; Puckett et al., 2019). Social support has been proposed to facilitate the development of coping mechanisms and lead to positive emotional experiences throughout the transition process (Budge et al., 2013).

HCPs can support patients in developing social support systems that allow them to be recognized and accepted as their authentic identity and help them cope with symptoms of gender dysphoria. Interpersonal problems and lack of social support have been associated with a greater incidence of mental health difficulties in TGD people (Bouman, Davey et al., 2016; Davey et al., 2015) and have been shown to be an outcome predictor of gender-affirming medical treatment (Aldridge et al., 2020). Therefore, HCPs should encourage, support, and empower TGD people to develop and maintain social support systems. These experiences can foster the development of interpersonal skills and help with coping with societal discrimination, potentially reducing suicidality and improving mental health (Pflum et al., 2015).

Statement 18.9

We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.

Psychotherapy has a long history of being used in clinical work with TGD people (Fraser, 2009b). The aims, requirements, methods and principles of psychotherapy have been an evolving component of the Standards of Care from the initial versions (Fraser, 2009a). At present, psychotherapeutic assistance and counseling with adult TGD people may be sought to address common psychological concerns related to coping with gender dysphoria and may also help some individuals with the coming-out process (Hunt, 2014). Psychological interventions, including psychotherapy, offer effective tools and provide context for the individual, such as exploring gender identity and its expression, enhancing self-acceptance and hope, and improving resilience in hostile and disabling environments (Matsuno and Israel, 2018). Psychotherapy is an established alternative therapeutic approach for addressing mental health symptoms that may be revealed during the initial assessment or later during the follow-up for gender-affirming medical interventions. Recent research shows, although mental health symptoms are reduced following gender-affirming medical treatment, levels of anxiety remain high (Aldridge et al., 2020) suggesting psychological therapy can play a role in helping

individuals suffering from anxiety symptoms following gender-affirming treatment.

In recent years, the uses and potential benefits of specific psychotherapeutic modalities have been reported (Austin et al., 2017; Budge, 2013; Budge et al., 2021; Embaye, 2006; Fraser, 2009b; Heck et al., 2015). Specific models of psychotherapy have been proposed for adult transgender and nonbinary individuals (Matsuno & Israel, 2018). However, more empiric data is needed on the comparative benefits of different psychotherapeutic models (Catelan et al., 2017). Psychotherapy can be experienced by transgender persons as a fearful as well as a beneficial experience (Applegarth & Nuttall, 2016) and presents challenges to the therapist and to alliance formation when it is associated with gatekeeping for medical interventions (Budge, 2015).

Experience suggests many transgender and nonbinary individuals decide to undergo gender-affirming medical treatment with little or no use of psychotherapy (Spanos et al., 2021). Although various modalities of psychotherapy may be beneficial for different reasons before, during, and after gender-affirming medical treatments and varying rates of desire for psychotherapy have been reported during different stages of transition (Mayer et al., 2019), a requirement for psychotherapy for initiating gender-affirming medical procedures has not been shown to be beneficial and may be a harmful barrier to care for those who do not need this type of treatment or who lack access to it.

Statement 18.10

We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

The use of "reparative" or "conversion" therapy or gender identity "change" efforts is opposed by many major medical and mental health organizations across the world, including the World Psychiatric Association, Pan American Health Organization, American Psychiatric and American Psychological Associations, Royal College of Psychiatrists, and British Psychological Society. Many states in the US have instituted bans on practicing conversion therapy with minors. Gender identity change efforts refers to interventions by MHPs or others that attempt to change gender identity or expression to be more in line with those typically associated with the person's sex assigned at birth (American Psychological Association, 2021).

Advocates of "conversion therapy" have suggested it could potentially allow a person to fit better into their social world. They also point out some clients specifically ask for help changing their gender identities or expressions and therapists should be allowed to help clients achieve their goals. However, "conversion therapy" has not been shown to be effective (APA, 2009; Przeworski et al., 2020). In addition, there are numerous potential harms. In retrospective studies, a history of having undergone conversion therapy is linked to increased levels of depression, substance abuse, suicidal thoughts, and suicide attempts, as well as lower educational attainment and less weekly income (Ryan et al., 2020; Salway et al., 2020; Turban, Beckwith et al., 2020). In 2021, the American Psychological Association resolutions states that "scientific evidence and clinical experience indicate that GICEs [gender identity change efforts] put individuals at significant risk of harm" (APA, 2021).

While there are barriers to ending gender identity "change" efforts, education about the lack of benefit and the potential harm of these practices may lead to fewer providers offering "conversion therapy" and fewer individuals and families choosing this option.

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Conflict of Interest

Conflict of interests were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential.

Ethical Approval

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Appendix A METHODOLOGY

1. Introduction

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Evidence-based research provides the basis for sound clinical practice guidelines and recommendations but must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

The SOC-8 revision committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers and stakeholders with diverse perspectives and geographic representation. All committee members completed conflict of interest declarations.*

A guideline methodologist assisted with the planning and development of questions, and an independent team undertook systematic reviews that were used to inform some of the statements for recommendations. Additional input to the guidelines was provided by an international advisory committee, legal experts, and feedback received during a public comment period. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus of the final recommendations was attained using a Delphi process that included all members of the Standards of Care Revision committee and required that recommendation statements were approved by 75% of members. Supportive and explanatory text of the evidence for the statements were written by chapter members. Drafts of the chapters were reviewed by the Chair and the Co-Chairs of the SOC Revision Committee to ensure the format was consistent, evidence was properly provided, and recommendations were consistent across chapters. An independent team checked the references used in the SOC-8 before the guidelines were fully edited by a single professional. A detailed overview of the SOC-8 Methodology is described below.

2. Difference between the methodology of the SOC-8 and previous editions

The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are:

- The involvement of a larger group of professionals from around the globe;
- A transparent selection process to develop the guidelines steering committee as well as to select chapter leads and members;
- The inclusion of diverse stakeholders in the development of the SOC-8
- Management of conflicts of interest
- The use of a Delphi process to reach agreement on the recommendations among SOC-8 committee members
- The involvement of an independent body from a reputable university to help develop the methodology and undertake independent systematic literature reviews where possible
- Recommendations were graded as either "recommend" or "suggest" based upon the strength of the recommendations.
- The involvement of an independent group of clinical academics to review citations.
- The involvement of international organizations working with the transgender and gender diverse (TGD) community, members of WPATH and other professional organizations as well as the general public who provided feedback through a public comment period regarding the whole SOC-8.

3. Overview of SOC-8 development Process

The steps for updating the Standards of Care are summarized below:

1. Establishing Guideline Steering Committee including Chair, and Co-Chairs (July 19, 2017)
2. Determining chapters (scope of guidelines)
3. Selecting Chapter Members based upon expertise (March 2018)
4. Selecting the Evidence Review Team: John Hopkins University (May 2018)
5. Refining topics included in the SOC-8 and review questions for systematic reviews
6. Conducting systematic reviews (March 2019)
7. Drafting the recommendation statements
8. Voting on the recommendation statements using a Delphi process (September 2019–February 2022)
9. Grading of the recommendations statements
10. Writing the text supporting the statements
11. Independently validating the references used in the supportive text
12. Finalizing a draft SOC-8 (December 1, 2021)
13. Feedback on the statements by International Advisory Committee
14. Feedback on the entire draft of the SOC-8 during a public comment period (November 2021–January 2022)
15. Revision of Final Draft based on comments (January 2022- May 2022)
16. Approval of final Draft by Chair and Co-Chairs (June 10, 2022)
17. Approval by the WPATH Board of Directors
18. Publication of the SOC-8
19. Dissemination and translation of the SOC-8

3.1. Establishment of Guideline Steering Committee

The WPATH Guideline Steering Committee oversaw the guideline development process for all chapters of the Standards of Care. Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board from WPATH members applying for these positions. Job descriptions were developed for the positions of Co-Chairs, Chapter Leads, Chapter Members and Stakeholder. WPATH members were eligible to apply by completing an application form and submitting their CV. The Board of WPATH voted for the position of co-chair (one member of the board did not participate in view of conflict of interest). The chairs and co-chairs selected the chapter leads and members (as well as stakeholders) based on the application form and CVs.

The Guideline Steering Committee for Standards of Care 8th Version are:

- Eli Coleman, PhD (Chair) Professor, Director and Academic Chair, Institute for Sexual and Gender Health, Department of Family Medicine and Community Health, University of Minnesota Medical School (USA)
- Asa Radix, MD, PhD, MPH (Co-chair) Senior Director, Research and Education Callen-Lorde Community Health Center Clinical Associate Professor of Medicine New York University, USA
- Jon Arcelus, MD, PhD (Co-chair) Professor of Mental Health and Well-being Honorary Consultant in Transgender Health University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

3.2. Determination of topics for chapters

The Guideline Steering Committee determined the chapters for inclusion in the Standards of Care by reviewing the literature and by reviewing the previous edition of the SOC. The chapters in the Standards of Care 8th Version:

1. Terminology
2. Global Applicability
3. Population estimates
4. Education*
5. Assessment of Adults
6. Adolescent
7. Children
8. Nonbinary
9. Eunuch
10. Intersex
11. Institutional environments
12. Hormone Therapy
13. Surgery and Postoperative Care
14. Voice and communication
15. Primary care
16. Reproductive Health
17. Sexual Health
18. Mental Health

* The Education Chapter was originally intended to cover both education and ethics. A decision was made to create a separate committee to write a chapter on ethics. In the course of writing the chapter, it was later determined topic of ethics was best placed external to the SOC8 and required further in-depth examination of ethical considerations relevant to transgender health.

3.3. Selection of chapter members

A call for applications to be part of the SOC-8 review committee (chapter lead or member) was sent to the WPATH membership. The Chairs of the Guideline Steering Committee appointed the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members were required to be WPATH Full Members in good standing and content experts in transgender health, including in at least one chapter topic. Chapter Leads reported to the Guideline Steering Committee and were responsible for coordinating the participation of Chapter Members. Chapter members reported directly to the Chapter Lead.

Each chapter also included stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that included a transgender child, sibling, partner, parent, etc. Stakeholders were not required to be full members of WPATH.

The Chapter Members were expected to:

- Participate in the development refinement of review questions
- Read and provide comments on all materials from the Evidence Review Team
- Critically review draft documents, including the draft evidence report
- Review and assess evidence and draft recommendations
- Participate in the Delphi consensus process
- Develop the text to back up the recommendation statements
- Grade each statement to describe the strength of the recommendation
- Review and address the comments from the Chairs during the whole process
- Develop the content of the chapters
- Review comments from public comments and assist in the development of a revision of guidelines
- Provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members was provided, as needed. Training content included formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation state-

ments, grading the evidence and the recommendations, and information about the guideline development program and process.

A total of 26 chapter-leads were appointed (some chapters required co-leads), 77 chapter members and 16 stakeholders. A total of 127 were selected. During the SOC process, 8 people left, due to personal or work-related issues. Therefore, there were 119 final authors of the SOC-8.

3.4. Selection of the evidence review team

The WPATH Board issued a request for applications to become the Evidence Review Team. For Standards of Care 8th Version the WPATH Board engaged the Evidence Review Team at Johns Hopkins University under the leadership of Karen Robinson.

- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

Dr Robinson also guided the steering committee in the development of the SOC-8 by providing advice and training in the development of PICO questions, statements, and the Delphi process as well as undertaking a very rigorous systematic literature review where direct evidence was available.

Conflict of interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team were asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, are personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

3.5. Refinement of topics and review of questions

The Evidence Review Team abstracted the recommendation statements from the prior version of the Standards of Care. With input from the Evidence Review Team, the Guideline Steering Committee and Chapter Leads determined:

- Recommendation statements that needed to be updated
- New areas requiring recommendation statements

3.6. Conduct the systematic reviews

Chapter Members developed questions to help develop recommendation statements. For the questions eligible for systematic review, the Evidence Review Team drafted review questions, specifying the Population, Interventions, Comparisons, and Outcomes (PICO elements). The Evidence Review Team undertook the systematic reviews. The Evidence Review Team presented evidence tables and other results of the systematic reviews to the members of the relevant chapter for feedback.

Protocol

A separate detailed systematic review protocol was developed for each review question or topic, as appropriate. Each protocol was registered on PROSPERO.

Literature search

The Evidence Review Team developed a search strategy appropriate for each research question including MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team searched additional databases as deemed appropriate for the research question. The search strategy included MeSH and text terms and was not limited by language of publication or date.

The Evidence Review Team hand searched the reference lists of all included articles and recent, relevant systematic reviews. The Evidence Review Team searched ClinicalTrials.gov for any additional relevant studies.

Searches were updated during the peer review process.

The literature included in the systematic review was mostly based on quantitative studies conducted in Europe, the US or Australia. We acknowledge a bias towards perspectives from the global north that does not pay sufficient attention to the diversity of lived experiences and perspectives within transgender and gender diverse (TGD) communities across the world. This imbalance of visibility in the literature points to a research and practice gap that needs to be addressed by researchers and practitioners in the future in order to do justice to the support needs of all TGD people independent of gender identification.

Study selection

The Evidence Review Team, with input from the Chapter Workgroup Leads, defined the eligibility criteria for each research question *a priori*.

Two reviewers from the Evidence Review Team independently screened titles and abstracts and full-text articles for eligibility. To be excluded, both reviewers needed to agree that the study met at least one exclusion criteria. Reviewers resolved differences regarding eligibility through discussion.

Data extraction

The Evidence Review Team used standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer abstracted the data, and a second reviewer confirmed the abstracted data.

Assessment of risk of bias

Two reviewers from the Evidence Review Team independently assessed the risk of bias for each included study. For

randomized controlled trials, the Cochrane Risk of Bias Tool was used. For observational studies, the Risk of Bias in Non-Randomized Studies—of Interventions (ROBINS-I) tool was used. Where deemed appropriate, existing recent systematic reviews were considered and evaluated using ROBIS.

Data synthesis and analysis

The Evidence Review Team created evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups reviewed and provided comments on the evidence tables.

Grading of the evidence

The Evidence Review Team assigned evidence grades using the GRADE methodology. The strength of the evidence was obtained using predefined critical outcomes for each question and by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

3.7. Drafting of the Recommendation Statements

Chapter Leads and Members drafted recommendation statements. The statements were crafted to be feasible, actionable, and measurable.

Evidence-based recommendation statements were based on the results of the systematic, and background literature reviews plus consensus-based expert opinions.

The Chair and Co-Chairs and Chapter Leads reviewed and approved all recommendation statements for clarity and consistency in wording. During this review and throughout the process any overlap between chapters was also addressed.

Many chapters had to work closely together to ensure consistency of their recommendations. For example, as there are now separate chapters for childhood and adolescence, to ensure consistency between both chapters, some authors were part of both chapters. For a similar reason, when applicable, a workgroup collaborated with other Chapter Workgroups on topics shared between the chapters (i.e., Assessment of Children, Assessment of Adults, Hormone Therapy, Surgery and Postoperative Care and Reproductive Health).

3.8. Approval of the recommendations using the Delphi process

Formal consensus for all statements was obtained using the Delphi process (a structured solicitation of expert judgements in three rounds). For a recommendation to be approved, a minimum of 75% of the voters had to approve the statement. A minimum of 65% of the SOC-8 members had to take part in the Delphi process for each statement. People who did not approve the statement had to provide information as to the reasons for their disapproval, so the statement could be modified (or removed) according to this feedback. Once modified, the statement was put through the Delphi process again. If after 3 rounds the statement was not approved, the statement was removed from the SOC. Every member of the SOC voted for each statement. There was a response rate between (74.79% and 94.96%) for the statements.

3.9. Grading criteria for statements

Once the statements passed the Delphi process, chapter members graded each statement using a process adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. This a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations (Guyatt et al., 2011). The statements were graded based on factors such as:

- The balance of potential benefits and harms
- Confidence in that balance or quality of evidence
- Values and preferences of providers and patients
- Resource use and feasibility

The statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
  - the evidence is of high quality
  - estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice)
  - there are few downsides of therapy/intervention/strategy
  - there is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
- Weak recommendations ("we suggest") are for those interventions/therapy/strategies where:
  - there are weaknesses in the evidence base
  - there is a degree of doubt about the size of the effect that can be expected in practice
  - there is a need to balance the potential upsides and downsides of interventions/therapy/strategies
  - there are likely to be varying degrees of acceptance among providers and patients or those for whom the recommendation applies.

3.10. Writing of the text supporting the statements

Following the grading of the statements, the Chapter Workgroups wrote the text providing the rationale or reasoning for the recommendation. This included providing the available evidence, providing details about potential benefits and harms, describing uncertainties, and information about implementation of the recommendation, including expected barriers or challenges among others. References use APA-7 style, to support the information in the text. Links to resources are also provided, as appropriate. The text, including whether a recommendation has been described as strong or weak, was reviewed and approved by the Chair and Co-Chairs.

3.11. External validation of references used to support the statements

A group of independent clinical academics working in the field of transgender health reviewed the references used in every chapter in order to validate that the references were appropriately used to support the text. Any queries regarding the references were sent back to the chapters for review.

3.12. Finalizing a draft SOC-8

A final SOC-8 draft was made available for comments.

3.13. Distribute Standards of Care for review by international advisors

The statements of the recommendations of Standards of Care 8th were circulated among the broader Standards of Care Revision Committee and the WPATH International Advisory Group, which included the Asia Pacific Transgender Network (APTN), the Global Action for Transgender Equality (GATE), the International Lesbian, Gay, Bisexual, Transgender, Intersex Association (ILGA), and Transgender Europe (TGEU).

3.14. Public comment period

The revised draft version of the Standards of Care document was posted online for comment from the public, including WPATH members, on the WPATH website. A 6-week period was allocated for comments. A total of 1,279 people made comments on the draft with a total of 2,688 comments.

3.15. Revision of final draft based on comments

The Chapter Leads and Guideline Steering Committee considered the feedback and made any necessary revisions. All public comments were read and, where appropriate, integrated into the background text.

As part of this process, 3 new Delphi statements were developed and 2 were modified enough to require a new vote by the SOC-8 committee. This meant a new Delphi process was initiated in January 2022. The results of this Delphi process were accepted by the chapters, and the new statements were added or modified accordingly. The new supportive text was added.

All the new versions of the chapters were reviewed again by the Chair and Co-Chairs and changes or modifications were suggested. Finally, once the Chairs and the Chapter Members were satisfied with the draft, the chapter was finalized.

All new references were double checked by an independent member.

3.16. Approval of final draft by Chair and Co-Chairs

Modifications were reviewed by the Chairs and were accepted by them.

3.17. Approval by the WPATH Board of Directors

The final document was presented to the WPATH Board of Directors for approval and it was approved on the 20th of June 2022.

3.18. Publication of the SOC-8 and dissemination of the Standards of Care

The Standards of Care was disseminated in a number of venues and in a number of formats including publication in the International Journal of Transgender Health (the official scientific journal of WPATH).

4. Plan to Update

A new edition of the SOC (SOC-9) will be developed in the future, when new evidence and/or significant changes in the field necessitating a new edition is substantial.

*The development of SOC-8 was a complex process at a time of COVID-19 and political uncertainties in many parts of the world. Members of the SOC-8 worked on the SOC-8 on top of their day-to-day job, and most of the meetings took place out of their working time and during their weekends via Zoom. There were very few face-to-face meetings, most of them linked to WPATH, USPATH or EPATH conferences. Committee members of the SOC-8 were not paid as part of this process.

Appendix B GLOSSARY

CISGENDER refers to people whose current gender identity corresponds to the sex they were assigned at birth.
DETRANSITION is a term sometimes used to describe an individual's retransition to the gender stereotypically associated with their sex assigned at birth.
EUNUCH refers to an individual assigned male at birth whose testicles have been surgically removed or rendered non-functional and who identifies as a eunuch. This differs from the standard medical definition by excluding those who do not identify as eunuch.
EUNUCH-IDENTIFIED: An individual who feels their true self is best expressed by the term eunuch. Eunuch-identified individuals generally desire to have their reproductive organs surgically removed or rendered non-functional.
GENDER: Depending on the context, gender may reference gender identity, gender expression, and/or social gender role, including understandings and expectations culturally tied to people who were assigned male or female at birth. Gender identities other than those of men and women (who can be either cisgender or transgender) include transgender, nonbinary, genderqueer, gender neutral, agender, gender fluid, and "third" gender, among others; many other genders are recognized around the world.
GENDER-AFFIRMATION refers to being recognized or affirmed in a person's gender identity. It is usually conceptualized as having social, psychological, medical, and legal dimensions. Gender affirmation is used as a term in lieu of transition (as in medical gender-affirmation) or can be used as an adjective (as in gender-affirming care).
GENDER-AFFIRMATION SURGERY (GAS) is used to describe surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity.
GENDER BINARY refers to the idea there are two and only two genders, men and women; the expectation that everyone must be one or the other; and that all men are males, and all women are females.
GENDER DIVERSE is a term used to describe people with gender identities and/or expressions that are different from social and cultural expectations attributed to their sex assigned at birth. This may include, among many other culturally diverse identities, people who identify as nonbinary, gender expansive, gender nonconforming, and others who do not identify as cisgender.
GENDER DYSPHORIA describes a state of distress or discomfort that may be experienced because a person's gender identity differs from that which is physically and/or socially attributed to their sex assigned at birth. Gender Dysphoria is also a diagnostic term in the DSM-5 denoting an incongruence between the sex assigned at birth and experienced gender accompanied by distress. Not all transgender and gender diverse people experience gender dysphoria.
GENDER EXPANSIVE is an adjective often used to describe people who identify or express themselves in ways that broaden the socially and culturally defined behaviors or beliefs associated with a particular sex. Gender creative is also sometimes used. The term gender variant was used in the past and is disappearing from professional usage because of negative connotations now associated with it.
GENDER EXPRESSION refers to how a person enacts or expresses their gender in everyday life and within the context of their culture and society. Expression of gender through physical appearance may include dress, hairstyle, accessories, cosmetics, hormonal and surgical interventions as well as mannerisms, speech, behavioral patterns, and names. A person's gender expression may or may not conform to a person's gender identity.
GENDER IDENTITY refers to a person's deeply felt, internal, intrinsic sense of their own gender.
GENDER INCONGRUENCE is a diagnostic term used in the ICD-11 that describes a person's marked and persistent experience of an incompatibility between that person's gender identity and the gender expected of them based on their birth-assigned sex.
INTERSEX refers to people born with sex or reproductive characteristics that do not fit binary definitions of female or male.
MISGENDER/MISGENDERING refers to when language is used that does not correctly reflect the gender with which a person identifies. This may be a pronoun (he/him/his, she/her/hers, they/them/theirs) or a form of address (sir, Mr.).
NONBINARY refers to those with gender identities outside the gender binary. People with nonbinary gender identities may identify as partially a man and partially a woman or identify as sometimes a man and sometimes a woman, or identify as a gender other than a man or a woman, or as not having a gender at all. Nonbinary people may use the pronouns they/them/theirs instead of he/him/his or she/her/hers. Some nonbinary people consider themselves to be transgender or trans; some do not because they consider transgender to be part of the gender binary. The shorthand NB or "enby" is sometimes used as a descriptor for nonbinary. Examples of nonbinary gender identities are genderqueer, gender diverse, genderfluid, demigender, bigender, and agender.
RETRANSITION refers to second or subsequent gender transition whether by social, medical, or legal means. A retransition may be from one binary or nonbinary gender to another binary or nonbinary gender. People may retransition more than once. Retransition may occur for many reasons, including evolving gender identities, health concerns, family/societal concerns, and financial issues.
SEX ASSIGNED AT BIRTH refers to a person's status as male, female, or intersex based on physical characteristics. Sex is usually assigned at birth based on appearance of the external genitalia. AFAB is an abbreviation for "assigned female at birth." AMAB is an abbreviation for "assigned male at birth."
SEXUAL ORIENTATION refers to a person's sexual identity, attractions, and behaviors in relation to people on the basis of their gender(s) and or sex characteristics and those of their partners. Sexual orientation and gender identity are distinct terms.
TRANSGENDER or trans are umbrella terms used to describe people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth. These words should always be used as adjectives (as in "trans people") and never as nouns (as in "transgenders") and never as verbs (as in "transgendered").

TRANSGENDER MEN or **TRANS MEN** or **MEN OF TRANS EXPERIENCE** are people who have gender identities as men and who were assigned female at birth. They may or may not have undergone any transition. FTM or Female-to-Male are older terms that are falling out of use.
TRANSGENDER WOMEN or **TRANS WOMEN** or **WOMEN OF TRANS EXPERIENCE** are people who have gender identities as women and who were assigned male at birth. They may or may not have undergone any transition. MTF or Male-to-Female are older terms that are falling out of use.
TRANSITION refers to the process whereby people usually change from the gender expression associated with their assigned sex at birth to another gender expression that better matches their gender identity. People may transition socially by using methods such as changing their name, pronoun, clothing, hair styles, and/or the ways that they move and speak. Transitioning may or may not involve hormones and/or surgeries to alter the physical body. Transition can be used to describe the process of changing one's gender expression from any gender to a different gender. People may transition more than once in their lifetimes.
TRANSPHOBIA refers to negative attitudes, beliefs, and actions concerning transgender and gender diverse people as a group. Transphobia may be enacted in discriminatory policies and practices on a structural level or in very specific and personal ways. Transphobia can also be internalized, when transgender and gender diverse people accept and reflect such prejudice about themselves or other transgender and gender diverse people. While transphobia sometimes may be a result of unintentional ignorance rather than direct hostility, its effects are never benign. Some people use the term anti-transgender bias in place of transphobia.

Appendix C GENDER-AFFIRMING HORMONAL TREATMENTS

Table 1. Expected time course of physical changes in response to gender-affirming hormone therapy

Testosterone Based Regimen		
Effect	**Onset**	**Maximum**
Skin Oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	6–12 months	>5 years
Scalp hair loss	6–12 months	>5 years
Increased muscle mass/ strength	6–12 months	2–5 years
Fat redistribution	1–6 months	2–5 years
Cessation of menses	1–6 months	1–2 years
Clitoral enlargement	1–6 months	1–2 years
Vaginal atrophy	1–6 months	1–2 years
Deepening of voice	1–6 months	1–2 years
Estrogen and testosterone-lowering based regimens		
Effect	**Onset**	**Maximum**
Redistribution of body fat	3–6 months	2–5 years
Decrease in muscle mass and strength	3–6 months	1–2 years
Softening of skin/ decreased oiliness	3–6 months	Unknown
Decreased sexual desire	1–3 months	Unknown
Decreased spontaneous erections	1–3 months	3–6 months
Decreased sperm production	Unknown	2 years
Breast growth	3–6 months	2–5 years
Decreased testicular volume	3–6 months	Variable
Decreased terminal hair growth	6–12 months	> 3 years
Increased scalp hair	Variable	Variable
Voice changes	None	

Adapted from Hembree et al., 2017.

Table 2. Risks associated with gender affirming hormone therapy (bolded items are clinically significant) (Updated from SOC-7)

RISK LEVEL	Estrogen-based regimens	Testosterone-based regimens
Likely increased risk	**Venous Thromboembolism**	**Polycythemia**
	Infertility	**Infertility**
	Hyperkalemia[s]	Acne
	Hypertrigyceridemia	Androgenic Alopecia
	Weight Gain	Hypertension
		Sleep Apnea
		Weight Gain
		Decreased HDL Cholesterol and increased LDL Cholesterol
Likely increased risk with presence of additional risk factors	Cardiovascular Disease Cerebrovascular Disease Meningioma[c] Polyuria/Dehydration[s] Cholelithiasis	Cardiovascular Disease Hypertriglyceridemia
Possible increased risk	Hypertension Erectile Dysfunction	
Possible increased risk with presence of additional risk factors	Type 2 Diabetes Low Bone Mass/ Osteoporosis Hyperprolactinemia	Type 2 Diabetes Cardiovascular Disease
No increased risk or inconclusive	Breast and Prostate Cancer	Low Bone Mass/ Osteoporosis Breast, Cervical, Ovarian, Uterine Cancer

[c]cyproterone-based regimen
[s]spironolactone-based regimen

Table 3. Gender-Affirming Hormone Regimens In Transgender And Gender Diverse Youth (Adapted from the Endocrine Society Guidelines; Hembree et al., 2017)

Induction of female puberty (estrogen-based regimen) with oral 17ß-estradiol
Initiate at 5µg/kg/d and increase every 6 months by 5 µg/kg/d up to 20 µg/kg/d according to estradiol levels
Adult dose = 2-6 mg/day
In postpubertal TGD adolescents, the dose of 17ß-estradiol can be increased more rapidly:
1 mg/d for 6 months followed by 2 mg/d and up according to estradiol levels
Induction of female puberty (estrogen-based regimen) with transdermal 17ß-estradiol
Initial dose 6.25-12.5 µg/24 h (cutting 24 g patch to ¼ then ½)
Titrate up by every 6 months by 12.5 µg/24 h according to estradiol levels
Adult dose = 50-200 µg/24 hours
For alternatives once at adult dose (Table 4)
Induction of male puberty (testosterone-based regimen) with testosterone esters
25 mg/m²/2 weeks (or alternatively half this dose weekly)
Increase by 25 mg/m²/2 weeks every 6 months until adult dose and target testosterone levels are achieved. See alternatives for testosterones (Table 4)

Table 4. Hormone regimens in transgender and gender diverse adults*

Estrogen-based regimen (Transfeminine)	
Estrogen	
Oral or sublingual	
Estradiol	2.0-6.0 mg/day
Transdermal	
Estradiol transdermal patch	0.025-0.2 mg/day
Estradiol gel various	‡ daily to skin
Parenteral	
Estradiol valerate or cypionate	5-30 mg IM every 2 weeks 2-10 IM every week
Anti-Androgens	
Spironolactone	100–300 mg/day
Cyproterone acetate	10 mg/day**
GnRH agonist	3.75–7.50 mg SQ/IM monthly
GnRH agonist depot formulation	11.25/22.5 mg SQ/IM 3/6 monthly
‡ Amount applied varies to formulation and strength	
Testosterone-Based Regimen (Transmasculine)	
Transgender males	
Testosterone	
Parenteral	
Testosterone enanthate/ cypionate	50–100 IM/SQ weekly or 100–200 IM every 2 weeks
Testosterone undecanoate	1000 mg IM every 12 weeks or 750 mg IM every 10 weeks
Transdermal testosterone	
Testosterone gel	50-100 mg/day
Testosterone transdermal patch	2.5–7.5 mg/day

Doses are titrated up or down until sex steroid hormone levels are in the therapeutic range. Hormone regimens do not reflect all formulations that are available in all pharmacies throughout the world. Hormone regimens may have to be adapted to what is available in local pharmacies.
**Kuijpers et al (2021).

Table 5. Hormone monitoring of transgender and gender diverse people receiving gender-affirming hormone therapy (Adapted from the Endocrine Society Guidelines)

Transgender male or trans masculine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and 1 to 2 times per year thereafter to monitor for appropriate physical changes in response to testosterone.
2. Measure serum total testosterone every 3 months (with dose changes) until levels are at goal
   a. For parenteral testosterone, the serum total testosterone should be measured midway between injections. The target level is 400-700 ng/dL. Alternatively, measure peak and trough peaks to ensure levels remain in the range of reference men.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before injection. If the level is < 400 ng/dL, adjust the dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 week of daily application (at least 2 hours after application of product).
3. Measure hematocrit or hemoglobin concentrations at baseline and approximately 3 months (with dose changes) for the first year and then one to two times a year.

Transgender Female or trans feminine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and one to two times per year thereafter to monitor for appropriate physical changes in response to estrogen.
   a. Serum testosterone levels should be less than 50 ng/dL.
   b. Serum estradiol should be in the range of 100-200 pg/mL.
2. For individuals receiving spironolactone, serum electrolytes, in particular potassium, and kidney function, in particular creatinine, should be monitored.
3. Follow primary care screening per primary care chapter recommendations

Appendix D SUMMARY CRITERIA FOR HORMONAL AND SURGICAL TREATMENTS FOR ADULTS AND ADOLESCENTS

The SOC-8 guidelines are intended to be flexible in order to meet the diverse health care needs of TGD people globally. While adaptable, they offer consensus-based standards derived from the best available scientific evidence for promoting optimal health care and guiding the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender affirming interventions are clinical guidelines; individual health care professionals and programs, in consultation with the TGD person, may modify them. Clinical departures from the SOC may occur due to a TGD person's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, discussed with the TGD person, and documented. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve. This summary criteria needs to be read in conjunction with the relevant chapters (see Adult Assessment and Adolescent chapters).

SUMMARY CRITERIA FOR ADULTS

Related to the assessment process

- Health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment should liaise with professionals from different disciplines within the field of trans health for consultation and referral, if required*
- If written documentation or a letter is required to recommend gender affirming medical and surgical treatment (GAMST), only one letter of assessment from a health care professional who has competencies in the assessment of transgender and gender diverse people is needed.

Criteria for hormones

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
d. Other possible causes of apparent gender incongruence have been identified and excluded;
e. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
f. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

Criteria for surgery

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
d. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
e. Other possible causes of apparent gender incongruence have been identified and excluded;
f. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
g. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).*

*These were graded as suggested criteria

SUMMARY CRITERIA FOR ADOLESCENTS

Related to the assessment process

- A comprehensive biopsychosocial assessment including relevant mental health and medical professionals;
- Involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible;
- If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical and mental health professionals (MHPs).

Puberty blocking agents

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Hormonal treatments

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Surgery

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. At least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

Appendix E GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF MICHAEL K. LAIDLAW, M.D.

Confidential Redacted Copy

Redactions are pursuant to this Court's Protective Order in this case.

I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. The information provided regarding my professional background are detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

4. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland disorders. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

5. I have been retained by Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment.

6. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

7. I have testified as an expert witness either at trial or in deposition in the following in the past four years:

a. 2022 Testified in Court. *August Dekker, et at. V Simone Marstiller, et al.*, Case No. 4:22-cv-00325 (N.D. Fla.). Report October 2, 2022.

b. 2022 Testified at Deposition. *C.P., by and through his parents, Patricia Pritchard and Nolle Pritchard, and Patricia Pritchard v. Blue Cross Blue Shield of Illnois*, Case No. 3:20-cv-06145 (W.D. Wash.)

c. 2021 Testified in Court and Deposition. *Juliana Paoli v. Joseph Hudson, et al.,* Case No. VCU279126 (CA Superior, Tulare County)

8. A list of my publications is contained in my curriculum vitae, which is attached as Attachment A.

9. I am being compensated at an hourly rate of $450 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. I am being compensated at an hourly rate of $650 for testimony at depositions or trial. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

10. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the treatment of gender dysphoria, including for minors and adults; and (4) my review of the various declarations submitted by Plaintiffs.

11. I was provided with and reviewed the following case-specific materials: The Florida Medicaid's "Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria"; the expert declaration of Johanna Olson-Kennedy; the expert declaration of Loren Schechter; the expert declaration of Dan H. Karasic; the expert declaration of Armand H. Matheny Antommaria; the declaration of Brit Rothstein; the declaration of August Dekker; the declaration of Jane Doe; the declaration of Jade Ladue; files from Florida Medicaid.

12. In my professional opinion, treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution. Except in the case of a fatal injury or disease, the minor will become an adult and present to the adult physician. The adult

physician must be able to have a thorough understanding of any condition which alters the biological development of children and, in the case of the endocrinologist, be knowledgeable about the long term effects of hormones on the human body, particularly when the hormones are being used in ways that alter development.

13. The following expresses my expert opinion regarding minors and adults who present with a disparity between their biological sex and internal feeling about their gender, specifically with regard to the use of social transition, medications which block normal pubertal development, the applications of hormones of the opposite sex, and surgical procedures that alter the genitalia and/or breasts for those individuals.

I. Background

A. Endocrine Disorders

14. Before discussing gender dysphoria and gender affirmative therapy from the perspective of an endocrinologist, it is helpful to discuss the background of endocrine diseases. This background demonstrates the difference in gender dysphoria, which is a psychological diagnosis, and other conditions treated by endocrinologists, which are physical diagnoses.

15. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided into three main types: those that involve hormone excess,

those that involve hormone deficiency, and those that involve structural abnormalities of the glands such as cancers.

16. It is important for the endocrinologist to determine the cause of hormone gland excess or deficiency in order to devise an appropriate treatment plan. The plan will generally be to help bring the hormones back into balance and thus bring the patient back to health.

17. To give an example of hormone excess, hyperthyroidism is a term which means overactivity of the thyroid gland. In this condition excess thyroid hormone is produced by the thyroid gland. This results in various physical and psychological changes for the afflicted patient. Examples of physical changes can include tachycardia or fast heart rate, hand tremors, and weight loss. Examples of psychological symptoms include anxiety, panic attacks, and sometimes even psychosis.

18. An endocrinologist can recognize thyroid hormone excess in part by signs and symptoms, but can also confirm the diagnosis with laboratory testing that shows the thyroid hormones to be out of balance. Once this is determined and the degree of excess is known, then treatments can be given to bring these levels back into balance to benefit the patient's health and to prevent other disease effects caused by excess hormone.

19. To give another example, consider a deficiency of insulin. Insulin is a hormone which regulates blood glucose levels. If there is damage to the pancreas such that insulin levels are very low, then blood glucose levels will rise. If the glucose levels rise to a certain abnormally high level, then this is considered diabetes. In the case of type 1 diabetes, insulin levels are abnormally low and therefore blood glucose levels are abnormally high leading to a variety of signs and symptoms. For example, the patient may have extreme thirst, frequent urination, muscle wasting, and weight loss. They may often experience lethargy and weakness.

20. In this case laboratory tests of glucose and insulin levels can confirm the diagnosis. Once diabetes is confirmed, the patient is then treated with insulin to help restore glucose balance in the body and prevent long-term complications of diabetes.

21. To give an example of a structural abnormality, a patient may have a lump on the thyroid gland in the neck. This may be further examined by an imaging test such as an ultrasound. A needle biopsy can be performed so that the cells can be examined under a microscope. A trained medical professional such as a pathologist can then examine the cells to determine if they are benign or cancerous. In the case of a thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

22. Noteworthy in the preceding three examples is that all three disease conditions are diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging test of an organ, an examination of cells under a microscope, or all three may be employed in the diagnosis of endocrine disease.

B. Gender Dysphoria is a Psychological Diagnosis

23. Gender dysphoria, on the other hand, is not an endocrine diagnosis, it is in fact a psychological diagnosis. It is diagnosed purely by psychological methods of behavioral observation and questioning.

24. Likewise what is termed gender identity is a psychological concept. It has no correlate in the human body. In the letter to the editor I wrote with my colleagues, discussed above, we wrote in our critique of the Endocrine Society Guidelines that "There are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" (Laidlaw et al., 2019).

25. For example, one cannot do imaging of the human brain to find the gender identity. Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, genetic testing, or other biological markers that can identify the gender identity. There is no known gene that maps to gender identity or to gender dysphoria. In other words, there is no objective physical measure to identify either gender identity or gender dysphoria.

26. This is in contrast to all other endocrine disorders which have a measurable physical change in either hormone levels or gland structure which can be confirmed by physical testing. Therefore, gender dysphoria is a purely psychological phenomenon and not an endocrine disorder. But as my colleagues and I wrote in our letter to the editor, it becomes an endocrine condition through gender affirmative therapy: "Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDCS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy" (Laidlaw et al. 2019).

27. As a practicing endocrinologist and scientist, I have made a study of GD and its treatment for two reasons: 1) I want to be sure that my colleagues and I understand the science before we treat any patients with GD; and 2) I am concerned that the medical society that claims to speak for me and other endocrinologists has abandoned scientific principles in endorsing treatments for GD that have questionable scientific support. The opinions expressed in this report are the result of my own experience, studies, education, and review of the scientific literature related to GD.

C. Gender Dysphoria and Desistance

28. GD is a persistent state of distress that stems from the feeling that one's gender identity does not align with their physical sex (American Psychiatric Association, 2013). It has been a relatively rare condition in children and adolescents. However there have been very significant increases in referrals for this condition noted around the globe.

29. For example, in the UK, "The number of referrals to GIDS [Gender Identity Development Service] has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519" (Bell v Tavistock Judgment, 2020). There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

30. The French National Academy of Medicine wrote recently: "Parents addressing their children's questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence" (SEGM, 2022).

31. In "a study of the Finnish gender identity service, '75% of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria' (Kaltiala-Heino, 2015). In fact,

'68% had their first contact with psychiatric services due to other reasons than gender identity issues.' The same study also showed that 26% percent had an autistic spectrum disorder and that a disproportionate number of females (87%) were presenting to the gender clinics compared to the past" (Laidlaw in gdworkinggroup.org, 2018).

32. Desistance is a term indicating that the child, adolescent, or adult who initially presented with gender incongruence has come to experience a realignment of their internal sense of gender and their physical body. "Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric" (Laidlaw et al., 2019; Ristori & Steensma, 2016).

33. Because there is no physical marker to diagnose gender identity, and because it is not possible to predict which child or adolescent will desist, it is not possible to know which young person will remain transgender identified as adults. Also, because the rate of desistance is so high, gender affirmative therapy will necessarily cause serious and irreversible harm to many children and adolescents who would naturally outgrow the condition if not affirmed.

34. Dr. Olson-Kennedy states that "[t]he studies pertaining to desistance upon which the GAPMS Memo relies pertain to prepubertal youth, not adolescents. In fact, contrary to the GAPMS Memo's assertion, studies show that if gender

dysphoria is present in adolescence, it usually persists (DeVries, et al., 2011)." (Oslon-Kennedy decl, p. 22).

35. Dr. Olson-Kennedy confuses prepubertal (a medical term) with preadolescence (a psychological designation). Puberty which pertains to the phsyical development of the reproductive tract, breasts and associated secondary sex characterestics can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved children aged twelve and under. For example table 1 in Ristori and Steensma 2016 shows multiple studies involving children. For the three most recent - Singh (2012), Wallien & Cohen-Kettenis (2008), and Drummond et al. (2008) - these involved age ranges from 3 to nearly 13 years old.[1] The desistance rate varied from 61 to 88%. Since the upper age was twelve (or slightly higher), this would include children in the age range of 8-12 years old many of whom were going through puberty based on their age and were therefore not Tanner stage 1 (pre-pubertal).[2] Therefore Dr. Olson-Kennedy's statement that

1 "This study provided information on the natural histories of 25 girls with gender identity disorder (GID). Standardized assessment data in childhood (mean age, 8.88 years; range, 3-12 years)" (Drummond et al., 2008).
"The mean age of the participating gender-referred children was 10.47 years (SD = 1.27; range, 8.11–12.77)" (Wallien et al., 2009).
" Standardized assessment data in childhood (mean age, 7.49 years; range, 3–12 years) and at follow-up (mean age, 20.58 years; range, 13–39 years) were used to evaluate gender identity and sexual orientation outcome. At follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria." (Singh, 2012).

2 To my knowledge the desistance literature does not examine Tanner stages of puberty as part of their studies. However one can infer based on the ages that many children had at least begun puberty (Tanner stage 2) or were at a more advanced stage of puberty.

"[t]he studies pertaining to desistance upon which the GAPMS Memo relies pertain to prepubertal youth" is incorrect.

D. Biological Sex in Contrast to Gender Identity

36. A recognition and understanding of biological sex is critical to my practice as an endocrinologist because the endocrine physiology of men and women, boys and girls, differ.

37. Biological sex is the objective physical condition of having organs and body parts which correspond to a binary sex. There are only two physical sexes, male and female. The male is identified as having organs and tissues such as the penis, testicles and scrotum. The female sex is identified by having organs and tissues such as the labia, vagina, uterus, and ovaries. Biological sex is easily identified by physical observation such that adults and even young children can identify the biological sex of a newborn baby.

38. This is in contrast to gender identity, which does not exist in any physical sense. It is a subjective identification known only once a patient makes it known. It cannot be identified by any physical means, cannot be confirmed by any outside observer, and can change over time.

39. It is also noteworthy that the physical organs described above as representing biological sex have a physical genetic correlate. In other words, it is a

well-established scientific fact that two X chromosomes identify the cells correlating to a female person, and an X and a Y chromosome correlate to a male person.

40. Sex is clearly identified in 99.98% of cases by chromosomal analysis (Sax, 2002). Sex is also clearly recognized at birth in 99.98% of cases (Id.). Therefore, sex is a clear provable objective reality that can be identified through advanced testing such as karyotyping, or simple genital identification at birth by any layperson. The other 0.02% of cases have some disorder of sexual development (DSD). DSDs do not represent an additional sex or sexes, but simply a disorder on the way to binary sex development (Chan et al., 2021).

E. Human Sexual Development

1. Embryologic development

41. Another confirmation that there are only two biological sexes comes from what is known about embryologic development and fertilization. The biologic development of the human person begins with a gamete from a female termed an ovum or egg and a gamete from a biological male which is termed sperm. The fertilization of the egg by the sperm begins the process of human biological development. The cells of the fertilized ovum then multiply and the person undergoes the incredible changes of embryologic development.

42. It is noteworthy that the male sperm comes from the biological male and the female egg comes from the biological female. There is no other third or

fourth or fifth type of gamete that exists to begin the development of the human person. This is consistent with the binary nature of human sex (Alberts et al., 2002).

43. The sex binary of the human embryo is further developed between roughly weeks 8 to 12 of human development. There are two primitive structures present within the developing embryo called the Wolffian duct and Mullerian ducts (Larsen et al., 2003). The Wolffian ducts develop into substructures of the genitalia including the vas deferens and epididymis which belong exclusively to the male sex. For the female, the Mullerian ducts go on to form the uterus, fallopian tubes, cervix and upper one third of the vagina which belong exclusively to the female sex (Id.)

44. Significantly once the male structures are developed from Wolffian ducts, the Mullerian ducts are obliterated. This means that throughout the rest of embryological development the Mullerian ducts will not form into biological female structures. Likewise, in the female, the Wolffian ducts are destroyed by week 12 and will not form male structures at any point in the future (Id.).

45. Thus we can see in very early development that the sex binary is imprinted physically not only in the chromosomes, but also on the very organs that the body produces. Additionally, the potential to develop organs of the opposite sex is eliminated. Thus, in the human being there are only two physical tracts that one may progress along, the one being male and the other being female (Wilson and Bruno, 2022).

2. Pubertal Development

46. As mentioned previously, at the time of birth an infant's sex is easily identified through observation of the genitalia. Corresponding internal structures could also be confirmed through imaging if needed.

47. In early childhood, some low level of sex hormones are produced by the sex glands. The male testes produce testosterone. The female ovaries produce primarily the hormone estrogen. These sex glands remain quiescent for the most part, producing low levels of sex hormones until the time of pubertal development.

48. Puberty is a time of development of the sex organs, body, brain and mind. There are well known changes in physical characteristics of the male such as growth of facial hair, deepening of the voice, and increasing size of the testicles and penis. Importantly the testicles will develop sperm under the influence of testosterone and become capable of ejaculation. Because of these changes, the male will become capable of fertilizing an egg. The inability to produce sperm sufficient to fertilize an egg is termed infertility.

49. For the female, pubertal development includes changes such as breast development, widening of the pelvis, and menstruation. The female will also begin the process of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs from the ovary. Once the eggs are released in a manner in which they can become fertilized by human sperm then the female is termed fertile.

The inability to release ovum that can be fertilized is infertility (Kuohong and Hornstein, 2021).

3. Tanner stages of development

50. From a medical perspective it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development.

Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system which will allow the stage of puberty to be known.

51. Tanner stages are divided into five. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

52. Awareness of the Tanner stage of the developing adolescent is also useful to assess for maturation of sex organ development leading to fertility. For girls, the first menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). The first appearance of sperm (spermarche) will typically be Tanner stages 4 (Id.).

If puberty is blocked or disrupted before reaching these critical stages, the sex glands will be locked in a premature state and incapable of fertility.

4. Biological Sex Cannot Be Changed

53. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

54. Furthermore, as noted earlier, several of the sex specific structures (such as the epidymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to resuscitate these ducts and continue development of opposite sex structures.

55. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

56. In fact, as I will discuss, gender affirming therapy actually leads to infertility and potential sterilization.

F. Iatrogenic Harms

57. The term iatrogenic is used in medicine to describe harms or newly created medical conditions that are the result of medications, surgeries, or even psychological treatments. In this section I will discuss the iatrogenic harms of "gender affirmative treatment," for females. Each of the four interventions which I will describe (social transition, blocking normal puberty, opposite sex hormones, and surgery) lead to iatrogenic harms to the patient. These harms will be described in detail below. I speak of these harms because it is important to understand that once a patient begins GAT it is more likely the patient will continue on to surgery (de Vries et al., 2014). Thus, GAT interrupts the natural desistence process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist, because if I did not understand these harms, I could not advise patients of the risks associated with GAT.

G. Gender Affirmative Therapy

58. The approaches to gender dysphoria in minors may be divided into three main types. (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal sense of gender with their physical sex. Another would be

to "watch and wait" and allow time and maturity to help the young person align sex and gender through natural desistance. The third option, which is the focus of that which follows, is referred to as gender affirmative therapy.

59. Gender affirmative therapy (GAT) of adults and minors consists of psychosocial, medical, and surgical interventions that attempt to psychologically and medically alter the patient so that they come to believe they may become similar to the physical sex which aligns with their gender identity (but not their biological sex) and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

60. The application of this medical therapy to minors[3] is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suffers from a lack of a quality evidence-base, poorly performed studies, and ongoing unethical human experimentation.

3. "[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age.1 Additionally, *Bright Futures* guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age,2 dividing the group into early (ages 11–14 years), middle (ages 15–17 years), and late (ages 18–21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988,3 which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in the case of a child with special health care needs.
Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life" (Hardin, 2017).

1. Social transition

61. The first stage of gender affirmative therapy is termed social transition. Social transition is a psychological intervention. The child may be encouraged to adopt the type of clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a culture. For example, in the United States a boy might wear his hair long and wear dresses in order to socially transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

62. Social transition of the child has been noted by expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex.

63. From an endocrine point of view, it is understandable that a child having the outward appearance of the opposite sex, would believe that he or she is destined to go through puberty of the opposite sex as they have only a poor understanding of the internal structures of the body, the function of the sex glands, the role of the sex glands in fertility and so forth.

64. Therefore, it would be quite frightening for a boy who believes he is a girl to be turning into a man with all of the adult features that accompany manhood. Vice versa, the girl who has become convinced that she is a boy will be frightened by the physical changes brought on by womanhood.

65. In fact, it would appear that in the minds of the children and adolescents that they are anticipating a sort of disease state in the future by the hormone changes that will occur as a normal and natural part of human development. Until relatively recently in human history, it has not been possible to interfere with puberty through pharmaceutical means.

2. Medications which Block Pubertal Development

a. Background

66. A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications (PB) that act directly on the pituitary to cause the endocrine condition known as hypogonadotropic hypogonadism (HH).

67. In order to understand what is occurring in this process, it is helpful to be aware of normal hormone function during pubertal development.

There is a small pea-sized gland in the brain called the pituitary. It is sometimes referred to as the "master gland" as it controls the function of several other glands. One key function for our purposes is the control of the sex glands. There are two specific hormones produced by the pituitary referred to as luteinizing hormone (LH) and follicle stimulating hormone (FSH). These are responsible for sex hormone

production and fertility. The LH and FSH act as signals to tell the sex glands begin or continue their function.

68. In the adult male, the production of LH will cause adult levels of testosterone to be produced by the testicles. In the adult female, the production of LH will cause adult levels of estrogen to be produced by the ovaries.

69. In early childhood, prior to the beginning of puberty, the pituitary function with respect to the sex glands is quiescent. However, during pubertal development LH will signal the testicle to increase testosterone production and this carries the boy through the stages of pubertal development into manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen production and carries the girl through the stages of development into womanhood.

70. Hypogonadotropic hypogonadism is a medical condition in which the pituitary does not send the hormonal signals (LH and FSH) to the sex glands. Therefore the sex glands are unable to make their sex specific hormones of testosterone or estrogen.

71. If this condition occurs during puberty, the effect will be to stop pubertal development. This is a disease state which is diagnosed and treated by the endocrinologist.

72. Medications such as GnRH anologues (sometimes called puberty blockers) act on the pituitary gland to lower the pituitary release of LH and FSH

levels dramatically. The result is a blockage of the signaling of the pituitary to the testicles or ovaries and therefore underproduction of the sex hormones. This will stop normal menstrual function for the female and halt further pubertal development. For the male this will halt further pubertal development. If the male had already reached spermarche, then production of new sperm will stop.

b. GnRH Agonist Medication Effects Vary by Use Case

73. There are a variety of uses for GnRH agonists. The use and outcome can be very different for different applications.

74. For example, the initial development of the medication called Lupron was for the treatment of prostate cancer. The idea being that blocking pituitary hormones will block the adult male's release of testosterone from the testicles. Since testosterone will promote the growth of prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent the growth and spread of prostate cancer. This is a labeled use of the medication. In other words, there is FDA approval for this use.

75. Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is activated at an abnormally young age, say age four, to begin pubertal development. In order to halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. Here the action of the medication on the

pituitary will disrupt the signaling to the sex glands, stop early sex hormone production, and therefore stop abnormal pubertal development.

76. Then, at a more normal time of pubertal development, say age 11, the medication is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland function and timing of puberty. This is a labeled use for a GnRH agonist medication.

77. What about the use of GnRH anologue medications such as Lupron in gender affirmative therapy? In these cases, we have physiologically normal children who are just beginning puberty or are somewhere in the process of pubertal development. They have healthy pituitary glands and sex organs. However, a puberty blocking medication is administered to stop normal pubertal development.

78. In this case the condition of hypogonadotropic hypogonadism described above (a medical disease) is induced by medication and is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH anologue medications have not been FDA approved for this use. The use of GnRH anolgue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case.

c. Hypogonadotropic Hypogonadism

i. Description and Diagnosis

79. As described above, hypogonadotropic hypogonadism is a condition in which the pituitary fails to send signals to the gonads thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

80. As an endocrinologist I frequently evaluate patients to ascertain if they have the condition of hypogonadotropic hypogonadism. This is done by a laboratory evaluation. If the patient has this condition, I then determine the cause and the proper treatment.

81. The primary hormone of the pituitary which is abnormal in this condition is called luteinizing hormone or LH. In order to diagnose the condition, a laboratory test with reference ranges based on the person's sex and age is used to evaluate the blood sample.

82. For example, figure 1 shows the normal laboratory reference range for LH over the course of a month in an adult pre-menopausal female (0.5-76.3 mIU/mL) (Quest LH, 2023). A very low level of LH (red) with low estrogen levels indicates hypogonadotropic hypogonadism[4].

4 Levels will be similarly low for adolescents, though the normal reference range is different.

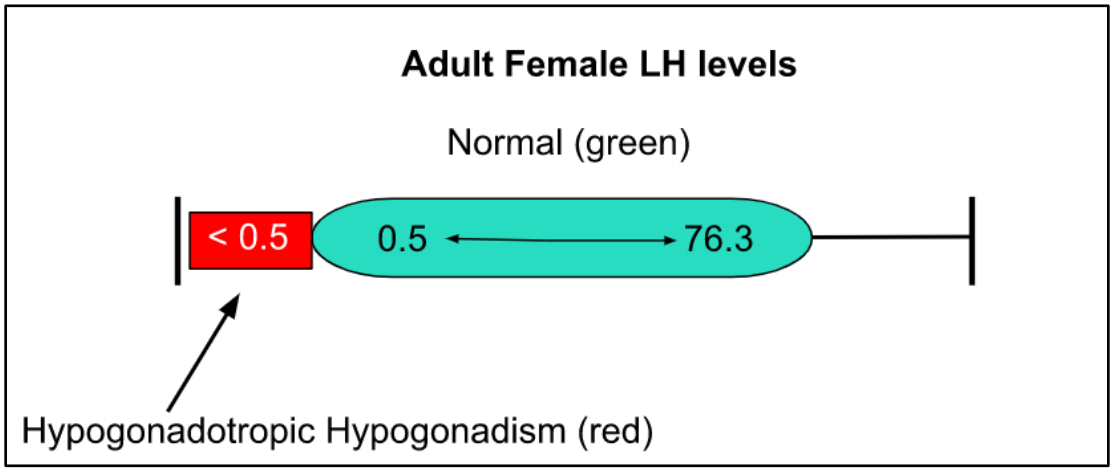

Figure 1.

83. As one can see, in hypogonadotropic hypogonadism the level of LH is below the reference range. In the female, this causes the cessation of estrogen production, and in the male it causes cessation of testosterone production. In adolescents of either sex, this will stop further pubertal development. For females in mid-puberty or beyond, this condition will also stop normal menstrual cycles and ovulation. For the male in mid-puberty or beyond, it will cause the cessation of normal sperm production.

84. As an endocrinologist, I would confirm the condition of hypogonadotropic hypogonadism based on laboratory results and then treat this medical condition.

85. What occurs to pituitary hormones and the sex hormones[5] when administering a GnRH analogue medication such as Lupron? The effect is identical

5 The primary sex hormones being estrogen for females and testosterone for males.

to figure 1. Over time, the result of the medication is to cause very low LH levels (red) leading to low sex hormone levels thereby medically inducing the condition of hypogonadotropic hypogonadism.

86. In gender affirmative therapy, the medical condition of hypogonadotropic hypogonadism is being deliberately created by the use of medications called GnRH analogues, one of which is called Lupron.

ii. Confidential [redacted]

87. Confidential [redacted]

88. Confidential [redacted]

Confidential [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Table 1

89. Confidential [redacted]

Confidential

90. Confidential

Confidential

91. Confidential

6 The implant is continuously effective for one year. If one were to remove the implant after one year it can take 6-18 months or longer for HH to resolve. It's also possible that HH will not resolve.

Confidential [redacted]

c. Adverse Health Consequences of Blocking Normal Puberty

i. Infertility

92. Confidential [redacted]

Confidential [redacted]

93. Dr. Antommaria writes that "The [Endocrine Society] guideline recommends that informed consent for pubertal blockers and gender-affirming hormones include a discussion of the implications for fertility and options for fertility preservation (Antommaria decl, p.23). However, even though procedures to preserve fertility are available, studies show that less than 5% of adolescents receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental. These experimental

forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child" (Laidlaw, Cretella, et al., 2019).

94. Confidential [redacted]

95. Dr. Antommaria states that "Florida Medicaid provides coverage for the use of puberty blockers to treat central precocious puberty, but now prohibits coverage for the use of puberty blockers to treat gender dysphoria, even though the use of puberty blockers to treat both conditions has comparable risks and is supported by comparable types of evidence" (Antommaria decl, p. 24). These statements fail to recognize the very different effects of PB medication in early childhood versus during adolescence.

96. Giving puberty blockers to a four year old with central precocious puberty will obviously not impair fertility, as the four year old has not yet become fertile. The child will at a later time have the puberty blocker discontinued and then normal pubertal development can proceed. Therefore when they are no longer taking the medication, they will gain natural fertility.

97. Confidential [redacted]

Confidential [redacted]

ii. Sexual Dysfunction

98. Confidential [redacted]

Confidential

99. Confidential

iii. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

100. Puberty is a time of rapid bone development. This time period is critical in attaining what we call peak bone density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019).

101. Confidential

7 Jazz's age is somewhere in the mid-teens during this episode.

Confidential [redacted]

102. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. In my practice I order and interpret DEXA scans for this purpose.

103. The Z-score of a DEXA scan is used to compare a patient's bone density to the same population based on age and sex. For example a person who has a bone density similar to the average of the population would be at the 50th percentile. Those who have greater relative bone density would be above the 50th percentile. Those who have lower bone density would have a Z score below the 50th percentile.

104. Puberty blockers used in adolescence to cause HH will inhibit the normal accrual of bone density. This can be evaluated by DEXA scan. In a study in the UK, 44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months (Carmichael, 2021).

105. Figure 2 shows the Z-scores of the average age matched population percentile which is 50%. It shows the average baseline (before puberty blockers) Z-score percentile for the study participants. It also shows the bone density percentile at 12, 24, and 36 months. One can see that the average baseline z score was about

32% compared to peers of similar age and sex. At 12 months this had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers and remained at this low level.

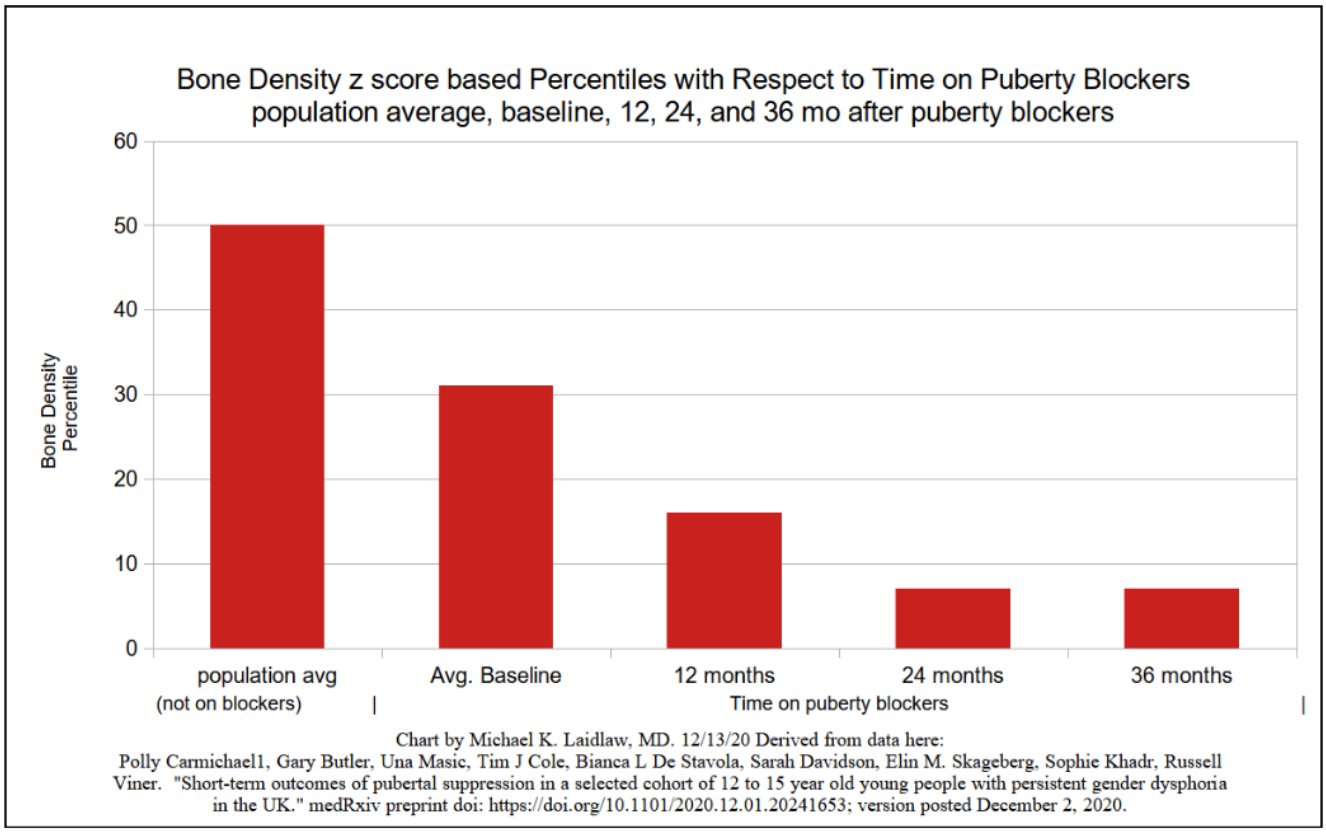

Figure 2

106. [redacted]

107. Confidential [redacted]

108. Confidential [redacted]

109. [redacted]

8 "This" refers to cardiovascular disease: "Diagnosis and treatment of amenorrheic states is of increasing clinical importance because lifetime menstrual irregularities are known to be predictive of subsequent CVD in women."

[redacted]

iv. [redacted]

110. [redacted]

[redacted]

d. The Effect of Puberty Blockers on Desistance

111. As stated earlier a very high proportion of minors diagnosed with gender dysphoria will eventually desist or come to accept their physical sex. Puberty blockers have been shown to dramatically alter natural desistance.

112. In a Dutch study that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study, the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in

sterilization. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries[9].

3. Opposite Sex Hormones

113. The third stage of gender affirmative therapy involves using hormones of the opposite sex (also called cross sex hormones) at high doses to attempt to create secondary sex characteristics in the person's body.

a. Testosterone

114. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule 3 controlled substance by the DEA: "Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence" (DEA, 2022). A licensed physician with a valid DEA registration is required to prescribe testosterone.

115. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood, sexual function, libido, and bone density. Prescription testosterone is given to correct the abnormally low levels and bring them back into balance. The dose of testosterone must be carefully considered and monitored to avoid excess levels in the male as

9 The surgeries were consequential in another important way. One person who had a vaginoplasty died of post-surgical complications of necrotizing fasciitis which is a rapidly progressive and very severe infection of the soft tissues beneath the skin and which has a high mortality (Id.).

there are a number of serious concerns when prescribing testosterone. The use of high dose testosterone in females is experimental.

116. Regarding the potential for abuse, the labeling reads "Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication...Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions...Abuse and misuse of testosterone are seen in male and female adults and adolescents...There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice." (Actavis Pharma, 2018)

117. Adverse events with respect to the nervous system include: "Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia." (Actavis Pharm, 2018)

118. With regard to ultimate height, "[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth" (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been.

119. With respect to the cardiovascular system of men using ordinary doses, "Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men" (Actavis Pharma, 2018). No clinical safety trials have been performed for women or adolescent girls to my knowledge.

120. "There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the lef] and pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using testosterone products, such as testosterone cypionate" (Actavis Pharma, 2018).

121. A very recently published study of adverse drug reactions (ADRs) as part of gender affirming hormone therapies in France states that "[o]ur data show a previously unreported, non-negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years… In transgender men taking testosterone enanthate, all reported ADRs were cardiovascular events, with pulmonary embolism in 50% of cases" (Yelehe et al., 2022).

122. There are also serious concerns regarding liver dysfunction: "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis

[generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications" (Actavis Pharma, 2018).

123. In GAT, what is termed "cross sex hormones" is the use of hormones of the opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these hormones are administered. When hormone levels climb above normal levels they are termed supraphysiologic.

i. Hyperandrogenism

124. Hyperandrogenism is a medical condition of elevated blood androgens such as testosterone. As an endocrinologist I frequently evaluate patients to determine if they have the condition of hyperandrogenism. Hyperandrogenism in the female or male is harmful and can lead to various maladies.

125. In order to diagnose hyperandrogenism, a laboratory blood test of testosterone is done. In hyperandrogenism, one will find testosterone levels elevated above the reference range.

126. For example for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).[10] However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

10 For females aged 11-17 the reference range is <= 40 and below this age group, the range is even lower.

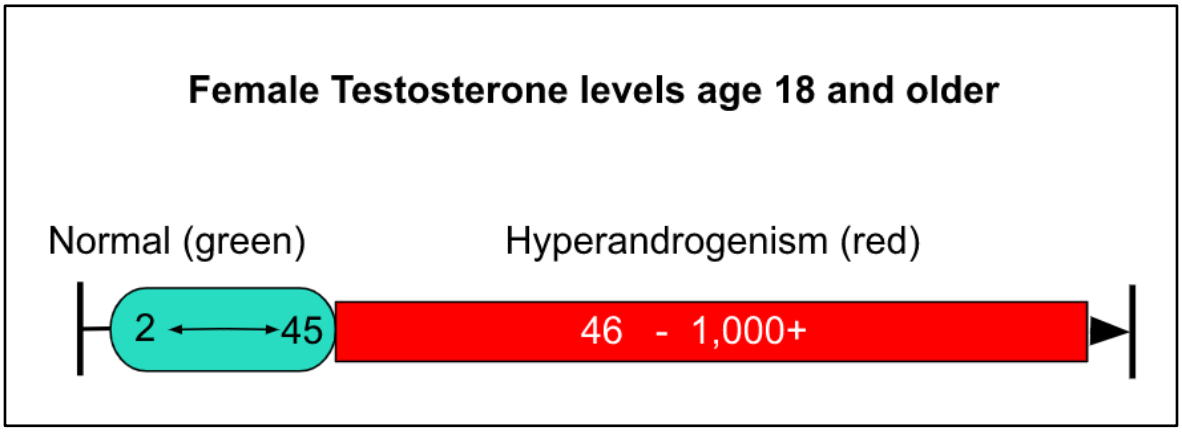

Figure 3

127. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL.

128. I frequently diagnose and treat the hyperandrogen condition called polycystic ovarian syndrome (PCOS). These patients have elevated testosterone levels. These levels are mildly to moderately elevated and may range from 50-150. Hyperandrogenism found in PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

129. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause severely elevated testosterone levels in the 300-1000 range. Once the cause of a hyperandrogen condition is identified, treatments may be put in place to help bring the testosterone levels down to the normal reference range.

130. Recommendations from the Endocrine Society's clinical guidelines related to GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL[11] which is on the same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A simple calculation shows this level for the adult may be anywhere from 6 to 100 times higher than native female testosterone levels. In doing so they are inducing severe hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

131. The following chart shows testosterone levels in the normal adult female range (blue), PCOS (graycrine tumors, and gender affirmative therapy as part of female to male (FtM) transition (figure 4).

11 In the Endocrine Society's Guidelines there is no grading of evidence for the rationale of using such high supraphysiologic doses of opposite sex hormones for the female or male. There seems to be an underlying assumption that because the person believes to be the opposite sex then they acquire the sex specific laboratory ranges of the opposite sex. "The root cause of this flaw in thinking about diagnostic ranges was exemplified in a response letter by Rosenthal et al claiming that gender identity determines the ideal physiologic range of cross-sex hormone levels (5). Thus, a psychological construct, the 'gender identity', is imagined to affect physical reality and change a person's sex-specific laboratory reference ranges. This is clearly not the case, otherwise there would be no serious complications of high-dose androgen treatment in transgender males" (Laidlaw et al., 2021).

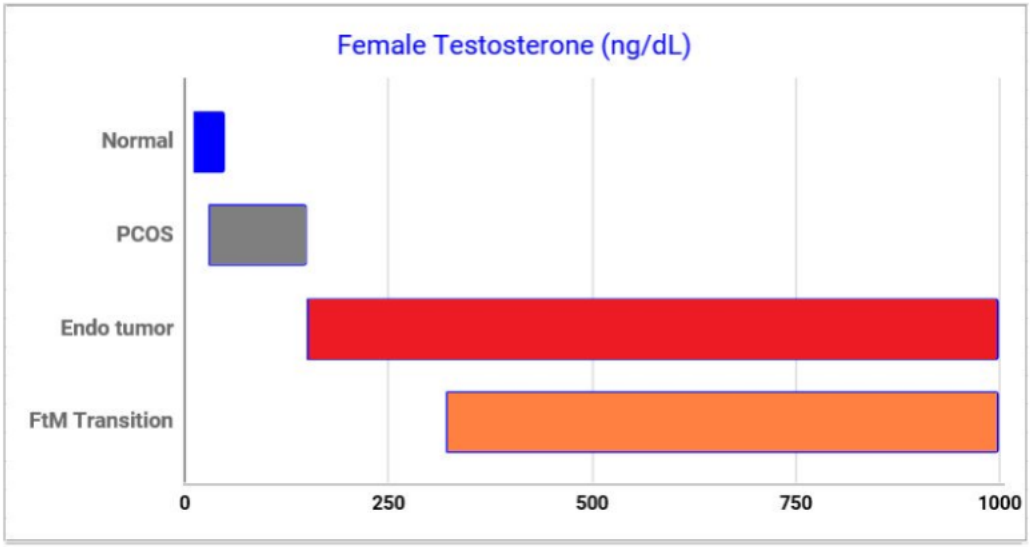

Image by Michael K Laidlaw. MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations of the Endocrine Society/WPATH are to bring levels into the 300-1000 range which is 6-100 times higher than normal endogenous adult female levels.

Figure 4.

ii. Confidential [redacted]

132. Confidential [redacted]

133. Confidential [redacted]

12 See II.B. Medical Concerns Regarding Brit Rothstein

Confidential [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 2

134. Confidential [redacted]

135. Confidential [redacted]

136. Confidential [redacted]

13 See II.D. Medical Concerns Regarding August Dekker
14See II.A. Medical Concerns Regarding K.F.

iii. Medical Problems Related to Hyperandrogenism

137. With respect to cardiovascular risk "Studies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone" (Laidlaw et al.,2021; Alzahrani et al., 2019). I would expect Brit Rothstein and August Dekker to be at increased risk of cardiovascular disease due to hyperandrogenism.

138. Permanent physical effects of testosterone therapy involve irreversible changes to the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen, back and other areas is known as hirsutism. Should the female eventually regret her decision to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the scalp may also occur. I would expect these changes to occur to the plaintiffs taking testosterone to induce hyperandrogenism. Common sense suggests that changes of voice and hair growth could be psychologically troubling should a patient decide to detranstition and attempt to reintegrate into society as female.

139. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina (Hembree, 2017). The breasts have been shown to have an increase in fibrous breast tissue and a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high dose testosterone include ovarian and breast cancer

(Hembree, 2017). I would expect some or all of these effects and risks to occur to the plaintiffs taking testosterone to induce hyperandrogenism.

140. According to research anabolic steroid abuse[15] has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with AAS [anabolic androgenic steroids, i.e. testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states" (Hall, 2005). Moreover, "[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms" (Hall, 2005).

141. Confidential [redacted]

15Anabolic steroid abuse involves the deliberate creation of hyperandrogenism in the body as a result of high doses of testosterone or other androgens.

Confidential

iv. Erythrocytosis as a Result of Hyperandrogenism

142. I regularly monitor patients who are receiving testosterone to evaluate for erythrocytosis. Erythrocytosis is a condition of high red blood cell counts. Prolonged hyperandrogenism such as occurs with the use of testosterone at supraphysiologic levels can cause erythrocytosis.

143. Males and females have different reference ranges for red blood cells (measured as hematocrit). For example the normal range of hematocrit for females over age 18 is 35.0-45.0% and males 38.5-50.0% (Quest Hematocrit, 2023). Levels above this range signify erythrocytosis (see figure 5).

16 See II.A. Medical Concerns Regarding K.F.
17 See II.B. Medical Concerns Regarding Brit Rothstein

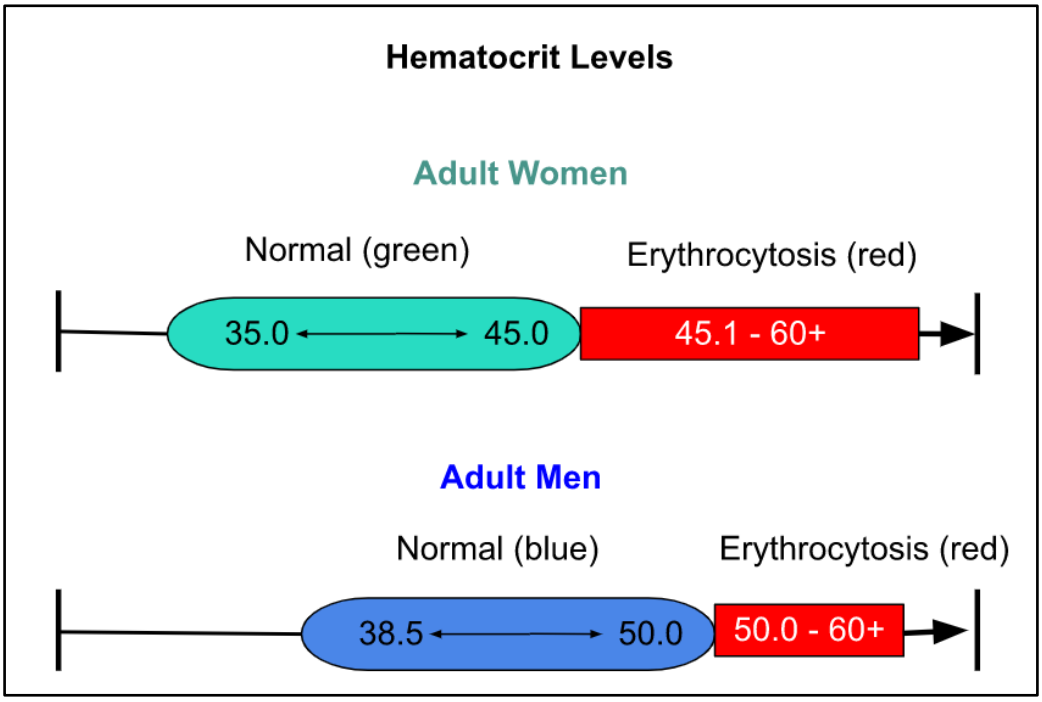

Figure 5.

144. As one can see, there is an overlap in the ranges of males and females such that levels between 45.1 and 50 are considered normal for the male. However for the female these levels are considered erythroctotic. Levels above 50 for the male are considered erythrocytosis and for the female severe erythrocytosis.

145. The Madsen study was a "20-year follow-up study in [1,073] adult trans men who started testosterone therapy and had monitoring of hematocrit at our center" (Madsen, 2021). In this study, 24% of trans men had hematocrit levels 50% at some time which would be considered severe erythrocytosis. Unfortunately, they did not examine the hematocrit range of 45-50. However one would presume that this would occur in at least the same percentage or higher as those who had developed severe erythrocytosis.

146. Any level of erythrocytosis in young women has been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

147. Confidential [redacted]

148. Confidential [redacted]

Confidential [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 3

Confidential [redacted]

b. Estrogen

149. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient's age. Another labeled use of estrogen is to treat menopausal symptoms. The use of estrogen to treat pediatric age males is experimental.

i. Hyperestrogenism

150. Hyperestogenemia is a condition of elevated blood estrogens such as estradiol. I regularly evaluate patients for hyperestrogenemia in my practice. Hyperestrogenemia in the male is harmful and can lead to various maladies.

151. In order to diagnose hyperestrogenemia, a laboratory blood test of estrogen is performed. In hyperestrogenemia, one will find estrogen levels elevated above the reference range.

152. For example, in an adult male the normal estrogen reference range is 60-190 pg/mL (Quest Estrogen, 2023). Levels above this range are consistent with hyperestrogenemia. See figure 6.

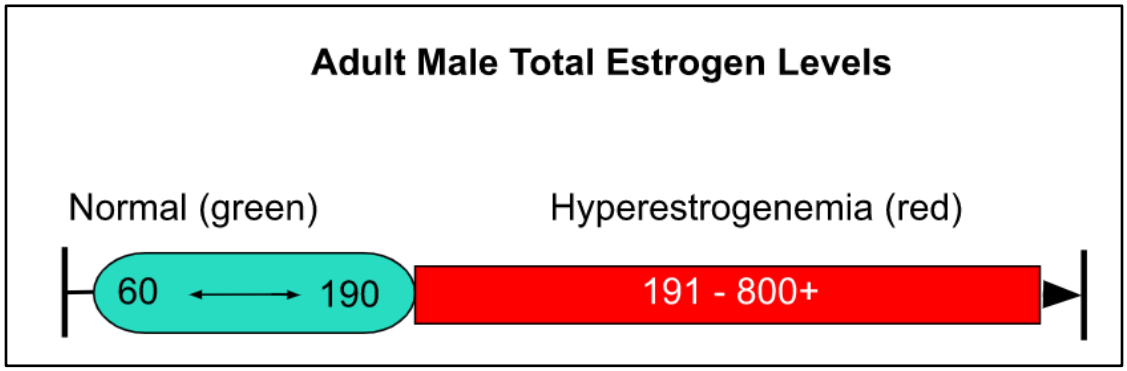

Figure 6.

153. There are medical conditions which can result in hyperestrogenemia. For example, "[t]he concentration of estrogen in cirrhotic patients is thought to increase by fourfold compared to individuals without cirrhosis" (Pagadala, 2023). Certain rare tumors for example of the adrenal gland can result in estrogen levels 3 to 10 fold higher than normal (Cavlan, 2010).

154. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. Endocrine Society guidelines recommend raising estradiol levels to 2 to 43 times above the normal range.[18] The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. I evaluate and treat patients with gynceomastia. I have prescribed medication and have referred patients for surgery for this condition.

18 Estradiol is a type of estrogen. Endocrine Society Guidelines recommend raising estradiol levels to 100-200 pg/mL (Hembree, 2017). The normal adult male estradiol range is 7.7-42.6 pg/mL (Labcorp Estadiol, 2023).

155. Other changes of secondary sex characteristics may develop because of hyperestrogenemia such as softening of the skin and changes in fat deposition and muscle development.

156. Long-term consequences of hyperestrogenemia include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also "[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism[19] over 5 fold" (Irwig, 2018).

157. Breast cancer is a relatively uncommon problem of the male. However the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel et al., 2019).

158. Sexual dysfunction, including decreased sexual desire and decreased spontaneous erections, is another adverse effect of hyperestrogenemia (Hembree, 2017).

159. Confidential [redacted]

19 Venous thromboembolism is a blood clot that develops in a deep vein and "can cause serious illness, disability, and in some cases, death" (CDC, 2022).

4. Surgeries

160. The fourth stage of gender affirmative therapy is surgical alterations of the body of various kinds in an attempt to somehow mimic features of the opposite sex.

161. As an endocrinologist, I refer patients for surgeries for endocrine conditions. I have to be aware of the indications for surgery, the risks and benefits of surgery, and long term comorbidities that may arise from surgeries.

162. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

163. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases an unhealthy body part is surgically removed in order to restore health.

164. In some cases a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

165. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot de novo create new organs. If a person's kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

166. There are a variety of gender affirming surgeries for females. These may include mastectomies, metoidioplasty, and phalloplasty.

a. Mastectomy

167. Mastectomies are the surgical removal of the breasts. The procedure is used in GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent loss of the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to widening and thickening due to the stresses of breathing and arm movement. Other potential complications include the loss of normal nipple sensation and difficulties with wound healing (American Cancer Society, 2022).

168. It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery, 2022).

169. Another important consideration is that compared to the removal of an unhealthy gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and there is no organic disease process such as a cancer warranting their removal. The future woman who later desists is left with regret about what happened to her at an age before she could provide true informed consent. Functioning breasts cannot be created by a surgeon and restored to a patient in case of regret. She is left with permanent injury and loss of function with respect to her breasts.

b. GAT Surgeries on the Male

170. GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina which is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

171. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

c. GAT Surgeries of the Female Pelvis and Genitalia

172. Other types of surgery for females include those of the genitalia and reproductive tract. For example, the ovaries, uterus, fallopian tubes, cervix and the vagina may be surgically removed. Removal of the ovaries results in sterilization.

173. Importantly, removing female body parts does not produce a male. Rather, the female has had sex specific organs permanently destroyed with no hope of replacement, while remaining biologically female.

174. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which allow for erection, therefore erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

175. Complications may include urinary stricture, problems with blood supply to the transplanted roll of tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the

clitoris (Mayo Clinic, Masculinizing Surgery, 2022). A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4% (Wang, 2022).

H. Life Threatening Physical Medical Conditions Versus Suicidal Ideation

176. Any child or adolescent who has suicidal ideation or has attempted suicide should receive immediate, appropriate psychiatric care. Psychologists and psychiatrists are trained in the recognition and treatment of suicidal ideation and prevention of suicide. A child or adolescent with gender dysphoria who also has suicidal ideation should not be treated any differently. They require compassionate care and a full psychological evaluation of comorbidities such as depression, anxiety, and self-harming behaviors.

177. However, suicidal ideation or attempts are categorically different than other life-threatening situations, such as a rapidly expanding brain tumor or a severe infection. In these situations, a medication or a surgery is used to stop the progression of an organic physical condition. In contrast, the danger to the self with suicidal ideation relates to a condition of the mind.

178. Gender affirmative therapy does not treat any life-threatening physical condition. In fact, it creates a number of new medical conditions as described above. It is also not an appropriate treatment for suicidal ideation. Neither puberty blocking

medications, nor testosterone, nor estrogen have been FDA approved for suicide prevention. Moreover, as noted above, the hormone imbalances generated by the medications used in GAT actually increase psychological conditions that lead to suicidal ideation and completed suicide.

I. Informed Consent

179. Any person who is to take a medication, undergo a surgical procedure, or have a psychological intervention should understand the risks and benefits before proceeding. A discussion of these risks and benefits should be provided by medical professionals and then the person of sufficient intellectual capacity and maturity can consent to the treatment.

180. Naturally difficulties arise when a minor is involved in the process of medical decision-making. Their intellect, emotions, and judgment are not fully developed and they are not capable of fully appreciating permanent, life altering changes such as described above. Therefore, they cannot provide informed consent. They may sometimes "assent" to a procedure or medication with a parent or guardian making the final decision.

181. With respect to GAT, in my opinion, it is not possible for the parent or guardian to make a true informed consent decision for the child because of the poor quality of evidence of benefit, the known risks of harm, and the many unknown long-term risks of harm which could only truly be known after years and decades of

gender affirmative therapy. A parent or guardian cannot consent to dubious treatments which result in irreversible changes to their child's body, infertility, sexual dysfunction, and in many cases eventual sterilization.

182. Because this age group is still undergoing brain development and they are immature with respect to intellect, emotion, judgment, and self-control, in my professional opinion there is a significant chance a young person may later regret the irreversible bodily changes that result from hormones or from removing an organ or organs that will no longer function and cannot be replaced.

183. I would also note that adolescents are more prone to high-risk behavior and less likely to fathom the risks and consequences of these decisions (Steinberg, 2008).

J. The WPATH and The Endocrine Society

184. According to their declarations, the experts Dr. Johanna Olson-Kennedy, Dr. Loren Schechter, and Dr. Dan H. Karasic are members of WPATH. Dr. Schechter was "co-lead author of the surgical and postoperative care chapter" for SOC 8 (Schechter decl, p 4). Dr. Karasic was a lead author of the Mental Health chapter for SOC 8 (Karasic decl, p. 3).

185. WPATH's Standards of Care 7 were produced over a decade ago in 2011. They were prepared within their advocacy organization and are purported to be a "professional consensus about the psychiatric, psychological, medical, and

surgical management of gender dysphoria" (WPATH, 2022). However, the "professional consensus" exists only within the confines of its organization. Furthermore, their Standards of Care 7, unlike the Endocrine Society's guidelines, do not have a grading system for either the strength of their recommendations or the quality of the evidence presented.

186. While the Endocrine Society has issued "Endocrine Treatment of Gender-Dysphoric / Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," these are only "guidelines." The Endocrine Society's guidelines (ESG) specifically state that their "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care" (Hembree at al, 2017, p. 3895).

187. With respect to the makeup of authors of the ESG, nine out of ten authors were members of WPATH or worked on WPATH's scientific committees. Seven of those nine had at some time been in WPATH leadership including the WPATH presidency and board of directors (File: WPATH - Endocrine Society 2017 guidelines.pdf).

188. In the Endocrine Society's guidelines, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence". "The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating

children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies" (Laidlaw et al., 2019).

189. Unlike some other recommendations for adolescent GAT, the Endocrine Society's guidelines do not include any grading of the quality of evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for adolescent mastectomy or other surgeries.

190. Endocrinologists W. Malone and P. Hruz and colleagues have written critically of the Endocrine Society's (ES) guidelines: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence (5), and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological well-being (6). Lastly, the claim of relative safety of these interventions ignores the growing body of evidence of adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret" (Malone et al., 2021).

191. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines"

(McCartney et al., 2022). They wrote "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) They relate that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). Therefore we can conclude that with regard to the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence not all recommendations were "based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries". Furthermore, these ESG 2017 were highly subject to conflicts of interest. As related earlier, nine out of the 10 authors were members or worked on the scientific committees of the advocacy group WPATH. Additionally, the ESG 2017 document was endorsed by WPATH. The "Enhancing Trustworthiness" article recommends the opposite composition of authors for guidelines: "A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]" (McCartney et al., 2022).

192. WPATH Standards of Care 8 (SOC 8) were just published Sep. 6, 2022 (Coleman et al., 2022) . In a correction to the SOC 8, all guidelines for minimum age of surgery were removed, meaning a minor of any age could be referred for any of the GAT surgeries listed previously (Correction IJTH, 2022). All guidelines for minimum age of oppposite sex hormones were also removed.

193. The correction reads: "On page S258, the following text was removed: 'The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above.

– Hormonal treatment: 14 years
– Chest masculinization: 15 years
– Breast augmentation, Facial Surgery: 16 years
– Metoidioplasty, Orchiectomy, Vaginoplasty,
– Hysterectomy, Fronto-orbital remodeling: 17 years
– Phalloplasty: 18 years'" (WPATH SOC 8 Correction, p. S261).

194. Of great concern is that the minimum age recommendations were retracted, it appears, in contradiction to the recommendation of their own expert consensus:

"On page S66, the following text was removed:
'Age recommendations for irreversible surgical procedures were determined by a review of existing literature and the expert consensus of mental health providers, medical providers, and surgeons highly experienced in providing care to TGD adolescents.'" (WPATH SOC 8 Correction, p. S260).

195. Additionally, a chapter regarding eunuchs was inserted into SOC 8 that gives recommendations for how to induce hypogonadism in men who have the

eunuch "gender identity"[20] by either orchiectomy [testicle removal] or chemical castration such as with GnRH analogues (Coleman et al., 2022)[21].

196. The SOC8 also used an aberrant form of the GRADE approach for systematic reviews that removed the grading of quality of evidence (which should be categorized as very low, low, moderate, and high quality).[22] Instead any recommendation of "recommend" is automatically assigned as high quality of evidence. SOC 8 also failed to provide evidence profile tables which should include "an explicit judgment of each factor that determines the quality of evidence for each outcome" (Guyatt et al., 2021).

20 The notion that there is a "eunuch gender identity" further invalidates the gender identity as a serious biological property of human beings: "Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation" (Coleman et al., 2022, p. S88).

21 "Treatment options for eunuchs to consider include:
• Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual,
or androgynous;
• Orchiectomy [testicle removal] to stop testicular production
of testosterone;
• Orchiectomy with or without penectomy to
alter their body to match their self-image;
• Orchiectomy followed by hormone replacement with testosterone or estrogen. " (Id.)

22 From SOC 8 "The [recommendation] statements were classified as:
• Strong recommendations ("we recommend") are for
those interventions/therapy/strategies where:
• the evidence is of high quality" (Id., p. S250).

197. Such a modification of GRADE is explicitly recommended against in the referenced GRADE document[23] and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based.

198. For at least the reasons above, in my professional opinion WPATH SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

K. Harms of off-label treatments in GAT

199. Dr. Antommaria makes a faulty comparison between migraine headaches and gender dysphoria (Antommaria decl, p. 7). First, migraine headaches are a neurological condition with a potential vascular component and not a condition of the mind, nor found as a psychological diagnosis in the DSM-5. Second the treament of migraine headaches with a medication such as sumitriptan or similar are labled indications for the condition unlike GnRH agonists and opposite sex hormones in GAT (FDA.gov sumitriptan). Third, the side effects of medications like sumitriptan do not alter or block normal human development such as the case with puberty blocking medication, or cause permanent alterations of the body such as

23From the GRADE guidelines: "Some organizations have used modified versions of the GRADE approach. We recommend against such modifications because the elements of the GRADE process are interlinked because modifications may confuse some users of evidence summaries and guidelines, and because such changes compromise the goal of a single system with which clinicians, policy makers, and patients can become familiar" (Guyatt et al., 2011).

with sex hormones, or lead to the permanent loss of healthy functioning organs such as occurs with surgeries which alter sex as a part of GAT.

200. Dr. Olson-Kennedy also draws a faulty comparison when she compares the off-label use of antibiotics or anti-histamines to blocking normal puberty, administering high-dose opposite sex hormones, or the permanent removal of healthy organs as part of GAT (Olson-Kennedy decl, p. 38). The health consequences are categorically different and the lifelong potential for permanent injury are extremely high in GAT.

L. The Lack of Evidence of Effectiveness of GAT

201. There is much additional evidence that questions the long-term benefits of opposite sex hormones and gender reassignment surgery and in fact suggests serious harms.

1. Sweden's Long-term study of 30 years of data by Dhejne

202. The most comprehensive study of its kind is from Sweden in 2011. The authors examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides

and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden.

2. The Branstrom and Pachankis Retraction

203. Other published studies of GAT have been shown to have serious errors. For example, a major correction was issued by the American Journal of Psychiatry. The authors and editors of a 2020 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors including myself led to a reanalysis of the data and a corrected conclusion stating that in fact the data showed no improvement in mental health for transgender identified individuals after surgical treatment nor was there improvement with opposite sex hormones ("Correction", 2020; Van Mol et al., 2020).

204. The initial reports of this study claimed that the authors found treatment benefits with surgery, and this was shared widely in the media. For example, ABC News posted an article titled "Transgender surgery linked with better long-term mental health, study shows" (Weitzer, 2019). An NBC news/Reuters headline reads "Sex-reassignment surgery yields long-term mental health benefits, study finds" (Reuters, 2019).

205. However, after twelve authors from around the world including our team investigated the study in detail, a number of serious errors were exposed leading to a retraction (Kalin, 2020; Anckarsäter et al., 2020).

206. In our letter to the editor which I co-wrote with former Chairman of Psychiatry at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the original Branstrom report when compared to the previous body of knowledge yielded from the Swedish Dhejne study. We wrote that "[t]he study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion" (Van Mol, Laidlaw, et al., 2020).

207. In another letter, Professor Mikael Landen writes that "the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes" (Landen, 2020).

208. In another letter to the editor, psychiatrist David Curtis noted that "[t]he study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has

any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery" (Curtis, 2020).

209. In yet another critical letter, Dr. Agnes Wold states that "[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria" (Wold, 2020).

3. Flawed studies based on the problematic 2015 US Transgender Survey

210. A 2021 study by Almazan and Keurghlian attempted to address mental health outcomes in relation to surgery as a part of GAT (Almazan & Keurghlian, 2021). This was not a randomized controlled study nor a prospective observational study. Rather the study relied upon the 2015 US Transgender Survey (USTS), which has been severely criticized for its serious limitations and weaknesses.

211. D'Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation" (Turban, 2020). They write in their critique of the USTS that it is "a convenience

sampling, a methodology which generates low-quality, unreliable data." (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample...Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status." They also state that "[s]tigmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress" (D'Angelo et al., 2021).

4. Mastectomy Surgery for Minors

212. Any serious look at long-term effects at surgical treatment would follow subjects out at least ten years. For example, an article was published recently examining patients who had mild calcium disorders due to a gland called the parathyroid. They compared a group of patients who had surgical removal of the parathyroid to a control group who had not. They examined data ten years after surgery was completed and concluded that parathyroid surgery in this group "did not appear to reduce morbidity or mortality" in that patient group (Pretorius, 2022).

213. To my knowledge there exists no comparable studies of minors with gender dysphoria comparing those who had mastectomy surgery to a control group who had not. There are also no known studies of minors followed for 10 years or more to determine the long-term risks and benefits of mastectomy for gender dysphoria.

214. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. For example, there is a study titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). The study authors conclude that "[c]hest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults." However, there are a number of problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors state "is not yet validated." (*Id*., p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

215. There exists another poorly designed study which suffers from similar methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years (Mehringer, 2021). The follow up time after surgery was only 19 months and no data is provided or analyzed about key psychiatric information such as comorbid psychological illnesses, self-harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

216. Information returned from the study surveys were all qualitative and included responses such as "[My chest dysphoria] made me feel like shit, honestly. It made me suicidal. I would have breakdowns". Another respondent stated, "I've been suicidal quite a few times over just looking at myself in the mirror and seeing [my chest]. That's not something that I should have been born with" (Mehringer, 2021). The omission of psychiatric data is a major flaw in the study and also irresponsible given the obviously dangerous psychological states that some of these young people were in.

217. Since such a high proportion of subjects were using testosterone (83%), some of the responses could be attributed to adverse effects of testosterone. For example, as related earlier, high dose testosterone can manifest in irritability and

aggressiveness. One study subject responded, “I get tingly and stuff and it kind of makes me want to punch something" (Mehringer, 2022).

218. The testosterone labeling also indicates nausea and depression as adverse reactions which are described by another study subject “There’s a feeling of hopelessness, of desperation, of—almost makes me feel physically sick" (Actavis Pharma, Inc., 2018; Mehringer, 2022).

219. The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit: "These findings...underscore the importance of insurance coverage not being restricted by age" (Mehrniger, 2021). This also appears to be part of the aim of the flawed Olson-Kennedy study which stated “changes in clinical practice and in insurance plans’ requirements for youth with gender dysphoria who are seeking surgery seem essential” (Olson-Kennedy, 2018). So these two studies, rather than being a thorough examination of the psychological and physical risks and benefits of mastectomy surgery over the long-term appear instead to exist, at least in part, to validate the need for insurance companies to insure the costs of these dubious procedures for minors.

5. Centers for Medicare and Medicaid Services

220. The Centers for Medicare and Medicaid Services ("CMS") has found "inconclusive" clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: "The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population."

221. Dr. Schecter states: "The result of CMS's review of the evidence is not applicable to other population groups" (Schecter decl, p. 39). However it does not make the converse true as Dr. Schecter seems to imply. In other words, the CMS review does not therefore mean that there is conclusive evidence of benefit and lack of harm for the under 65 population. On the contrary, evidence of benefit is lacking and the risks and harms due to GAT are very high as I have described.

6. Nations and States Question and Reverse Course on GAT

222. Also noteworthy is that other nations are questioning and reversing course regarding gender affirmative therapy. For example in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers in GAT, they concluded that "there is real uncertainty over the short and long-term consequences of the treatment with

very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment" (*Bell v. Tavistock* Judgment, 2020).

223. The case was appealed and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments. In its conclusion the appeals court stated that "[c]linicians will inevitably take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed by the advantages and disadvantages of the proposed course of treatment and in the light of evolving research and understanding of the implications and long-term consequences of such treatment. Great care is needed to ensure that the necessary consents are properly obtained " (*Bell v. Tavistock* Appeal, Judgment, 2021).

224. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write, "As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive,

exploratory approach with gender-questioning patients should not be considered conversion therapy" (Griffin et al., 2021).

225. In 2020, Finland recognized that "[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited," and recommended prioritizing psychotherapy for gender dysphoria and mental health comorbidities over medical gender affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, "[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors".

226. In 2021, Sweden's largest adolescent gender clinic announced that it would no longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical trials (SEGM, 2021). "In December 2019, the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years. These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to assess the risk / benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments" (Gauffen and Norgren, 2021).

227. Dr Hilary Cass "was appointed by NHS England and NHS Improvement to chair the Independent Review of Gender Identity Services for children and young people in late 2020" (The Cass Review website, 2022). In her interim report dated February 2022, it states that "[e]vidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally" (Cass, 2022).

M. Assessment of the patient with gender dysphoria

228. In light of the very serious medical concerns and potential harms of gender affirmative therapy, there are several criteria that I believe would be important to fulfill before applying the GAT model to a patient.

a. Minors should be evaluated to determine if they will follow the natural pattern of desistance which 50 to 98% of pediatric age children will follow[24].

b. Patients, parents and guardians should be made aware of other options for treatment of gender dysphoria including active psychosocial treatment or watching and waiting with support in order to help with natural desistance.

c. The patient should be provided an assessment by a qualified psychologist or psychiatrist who does not follow the WPATH GAT model. If

24 From the DSM-5: "Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary…In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%" (American Psychiatric Association, 2013).

underlying psychological conditions are diagnosed then these should be adequately evaluated and treated before proceeding to hormones and surgery.

d. If a medicalized approach with hormones such as testosterone or medications to stop menstruation is being considered then a clear description of the risks and benefits needs to be conveyed to the patient and if a minor also the parent or guardian. It needs to be verified that they fully understand these risks.

e. If surgical procedures such as mastectomy, hysterectomy, ovariectomy, orchiectomy, or vaginoplasty are being considered then clear descriptions of the risks and benefits need to be conveyed to the patient, and if a minor, the parent or guardian.

229. However, even if a minor and their parents or guardian are made fully aware of the risks and benefits of hormones and surgeries, in my opinion, the minor does not have adequate maturity and judgment to make permanent changes to their body that may result in infertility/sterility and the permanent loss of organs such as breasts whose functions will not be fully utilized (such as breastfeeding) until adulthood.

II. Medical Concerns Regarding Plaintiffs

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25 "Studies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone" (Laidlaw et al.,2021; Alzahrani et al., 2019).

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26 The ESG state that "the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/ gender incongruent in adolescence " (Hembree, 2017.)

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27 The ESG state that "social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence" (Hembree, 2017).

28 With respect to estrogen, the ESG state that it is essential that "the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment" (Id.).

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III. Conclusion

306. The gender affirmative therapy model suffers from serious deficiencies in logic and lacks scientific foundation. The deep error hidden in this model is that one cannot in fact change sex. One cannot acquire the deep characteristics of

29 There are serious concerns regarding liver dysfunction with testosterone: "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications" (Actavis Pharma, 2018).

biological sex in order to gain the complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

307. Children and adolescents are of such immature minds that they are likely to believe that it is possible. In fact they may come to believe that their inherent, biologically necessary puberty is "terrifying" or needs to be stopped. Social transition serves to convince the child or adolescent that they can be the opposite sex. Puberty blockers sustain this state of mind by retaining a childlike state with respect to the genitalia and body habitus. High dose opposite sex hormones then cause medical conditions such as hirsutism and irreversible damage to the vocal cords in females and gynecomastia in males. These conditions serve to convince the young person that they are going through puberty of the opposite sex when in fact they are not developing sexually and are infertile.

308. There are known risks for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist. The

two adult plaintiffs and the two plaintiffs' children have comorbidities which make GAT particularly dangerous.

309. WPATH's newly released SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

310. For the reasons set forth above, in my professional opinion as an endocrinologist, no child or adolescent should receive puberty blockers to block normal puberty, nor should they receive supraphysiologic doses of opposite sex hormones to attempt to alter secondary sex characteristics, nor should they have surgeries to remove or alter the breasts, genitalia or reproductive tracts as part of GAT. The child cannot consent or assent to these procedures. The parent or guardian also cannot consent to the life altering changes resulting from GAT. There exists insufficient evidence of benefit for adults, but serious concerns for risk of harm.

311. Finally, the June 2022 AHCA GAPMS report states: "Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety" (FL Medicaid GAPMS, 2022). I strongly agree with that statement.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 17th day of February, 2023.

/s/ Michael K. Laidlaw

Michael K. Laidlaw, M.D.

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Attachment A

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EMPLOYMENT

2006-Present	Michael K Laidlaw, MD Inc. Private Practice – Endocrinology, Diabetes, and Metabolism. Rocklin, CA

EDUCATION

2004-2006	Endocrinology and Metabolism Fellowship - Los Angeles County/University of Southern California Keck School of Medicine
2001-2004	Internal Medicine Residency - Los Angeles County/University of Southern California Keck School of Medicine
1997-2001	University of Southern California Keck School of Medicine Doctor of Medicine Degree May 2001
1990-1997	San Jose State University Bachelor of Science Degree in Biology with a concentration in Molecular Biology, Cum Laude

LICENSURE

California Medical License – Physician and Surgeon: # A81060: Nov 6, 2002. Exp 5/31/2024.

PROFESSIONAL AFFILIATIONS

Endocrine Society 2006-2022
American Board of Internal Medicine - Endocrinology, Diabetes, and Metabolism – 2006
American Board of Internal Medicine - Internal Medicine - 2005
National Board of Physicians and Surgeons - Endocrinology, Diabetes, & Metabolism 2018-2024
National Board of Physicians and Surgeons - Internal Medicine 2018-2024

HONORS AND RECOGNITION

2010	Endocrine Society Harold Vigersky Practicing Physician Travel Award
2004-2005	Vice President - Joint Council of Interns and Residents
2002-2004	Council Member – Joint Council of Interns and Residents
1996, 1997	Dean's Scholar, San Jose State University
1995	Golden Key National Honor Society

RESEARCH AND PUBLICATIONS

2021	Publication – Michael K Laidlaw, Andre Van Mol, Quentin Van Meter, Jeffrey E Hansen. Letter to the Editor from M Laidlaw et al.: "Erythrocytosis in a Large Cohort of Trans Men Using Testosterone: A Long-Term Follow-Up Study on Prevalence, Determinants, and Exposure Years." The Journal of Clinical Endocrinology & Metabolism, Volume 106, Issue 12, December 2021, Pages e5275–e5276, https://doi.org/10.1210/clinem/dgab514
2020	Publication – Van Mol A, Laidlaw MK, Grossman M, McHugh P. "Correction: Transgender Surgery Provides No Mental Health Benefit." Public Discourse, 13 Sep 2020. https://www.thepublicdiscourse.com/2020/09/71296/
2020	Publication – VanMol A, Laidlaw MK, Grossman M, McHugh P.. "Gender-affirmation surgery conclusion lacks evidence (letter)". Am J Psychiatry 2020; 177:765–766.
2020	Publication – Laidlaw MK. "The Pediatric Endocrine Society's Statement on Puberty Blockers Isn't Just Deceptive. It's Dangerous." Public Discourse. 13 Jan 2020. https://www.thepublicdiscourse.com/2020/01/59422/
2019	Speech to the U.K. House of Lords – Laidlaw MK. "Medical Harms Associated with the Hormonal and Surgical Therapy of Child and Adolescent Gender Dysphoria". Parliament, London, U.K. 15 May 2019.
2019	Publication – Laidlaw MK, Cretella M, Donovan K. "The Right to Best Care for Children Does Not Include the Right to Medical Transition". The American Journal of Bioethics. Volume 19. Published online 20 Feb 2019. 75-77. https://doi.org/10.1080/15265161.2018.1557288
2018	Publication – Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, Pages 686–687, https://doi.org/10.1210/jc.2018-01925 (first published on-line 11/2018)
2018	Publication – Laidlaw MK. "The Gender Identity Phantom". gdworkinggroup.org, 24 Oct 2018. http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom/
2018	Publication – Laidlaw MK. "Gender Dysphoria and Children: An Endocrinologist's Evaluation of 'I am Jazz'". Public Discourse, 5 Apr 2018. https://www.thepublicdiscourse.com/2018/04/21220/
2013	Abstract – Poster presentation Jun 2013. Endocrine Society Annual Meeting. A 12 Step Program for the Treatment of Type 2 Diabetes and Obesity.
2011	Abstract – Poster presentation Nov 2011. Journal of Diabetes Science and Technology. A Video Game Teaching Tool for the Prevention of Type 2 Diabetes and Obesity in Children and Young Adults.
2011	Abstract – Journal of Diabetes Science and Technology. A Web-Based Clinical Software Tool to Assist in Meeting Diabetes Guidelines and Documenting Patient Encounters.
2008	Abstract - Accepted to Endocrine Society Annual Meeting 2008. Hypercalcemia with an elevated 1,25 dihydroxy-Vitamin D level and low PTH due to granulomatous disease.

2005-2006	Clinical Research - University of Southern California – Utility of Thyroid Ultrasound in the Detection of Thyroid Cancer. Study involving the use of color flow/power doppler ultrasound and ultrasound guided biopsy to detect the recurrence of thyroid cancer in patients with total thyroidectomies.
2005	Certification - Certification in Diagnostic Thyroid Ultrasound and Biopsy – AACE 2005
2003	Certification - Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research. University of Southern California. 29 Sep 2003 - 29 Sep 2006
2002-2005	Clinical Research - University of Southern California - Determining the Role of Magnesium in Osteoporosis. Study involved collecting and analyzing patient data related to patient characteristics, laboratory results, bone mineral density exams, nutrition analysis, and genetic analysis in order to determine a link between magnesium deficiency and osteoporosis.
1996	Research Assistant - San Jose State University - Role of the suprachiasmatic nucleus pacemaker in antelope ground squirrels.
1995-1996	Research Assistant - San Jose State University/NASA. Acoustic tolerance test and paste diet study for space shuttle rats.

EXPERT WITNESS WORK AND AMICUS BRIEFS

2022	Expert Witness Report – Laidlaw MK. C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and PATRICIA PRITCHARD, Plaintiff, vs. BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendants. Case No. 3:20-cv-06145-RJB
2022	Expert Witness Report – Laidlaw MK. DISTRICT COURT OF TRAVIS COUNTY, TEXAS 459th JUDICIAL DISTRICT. PFLAG, INC., ET AL., Plaintiffs, v. GREG ABBOTT, ET AL., Defendants. NO. D-1-GN-22-002569. 3 July 2022.
2022	Expert Witness Report #2 – Laidlaw MK. United States District Court for the District of Arizona. DH and John Doe, Plaintiffs, vs. Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity, Defendant. Case No. 4:20-cv-00335-SHR. 24 Jun 2022. (Sealed under Protective Order).
2022	Expert Witness Report – Laidlaw MK. United States District Court for the Middle District of Alabama Northern Division. REV. PAUL A. EKNES-TUCKER, et al., Plaintiffs, v. KAY IVEY, in her official capacity as Governor of Alabama, et al., Defendants. Civil Action No. 2:22-cv-184-LCB. 2 May 2022.
2021	Brief of Amicus Curiae – Bursch, John J., McCaleb, Gary S., Van Meter, Quentin L., Laidlaw, Michael K., Van Mol, Andre, Hansen, Jeffrey E. Brief of Amicus Curiae. United States Court of Appeals for the Eight Circuit. DYLAN BRANDT, et al., Plaintiffs-Appellees v. LESLIE RUTLEDGE, in her official capacity as the Arkansas Attorney General, et. al. Defendants-Appellants. 23 Nov 2021.
2020	Expert Witness – JULIANA PAOLI v. JOSEPH HUDSON et al. heard in THE SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF TULARE. CASE NO. 279126. 2021.
2021	Brief of Amicus Curiae – Bursch, John J., McCaleb, Gary S., Grossman, Miriam, Van Meter, Quentin L., Laidlaw, Michael K., Van Mol, Andre, Hansen, Jeffrey E.

Brief of Amicus Curiae. United States Court of Appeals for the Eleventh Circuit. DREW ADAMS, Plaintiffs-Appellee v. SCHOOL BOARD OF ST. JOHNS COUNTY, FLORIDA, et. al. Defendants-Appellant. 26 Oct 2021.

2020 Expert Witness Affidavit 1 & 2 – Laidlaw MK. Supreme Court of British Columbia. File No. S2011599, Vancouver Registry. Between A.M. Plaintiff and Dr. F and Daniel McKee Defendants. 11/23/20 & 11/25/20.

2020 Brief of Amicus Curiae – Wenger, Randal L., McCaleb, Gary S., Grossman, Miriam, Laidlaw, Michael K., McCaleb, Gary S., Van Meter, Quentin L., Van Mol, Andre. Brief of Amicus Curiae. United States Court of Appeals for the Ninth Circuit. LINDSAY HECOX and JANE DOE, with her next friends Jean Doe and John Doe, Plaintiffs-Appellees v. BRADLEY LITTLE, in his official capacity as Governor of the State of Idaho, et. al. Defendant-Appellant. 19 Nov 2020

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2018 Brief of Amicus Curiae – Alliance Defending Freedom, Campbell, James A., Grossman, Miriam, Laidlaw, Michael K., McCaleb, Gary S., Van Meter, Quentin L., Van Mol, Andre. Brief of Amicus Curiae. United States Court of Appeals for the Eleventh Circuit. Drew Adams, Plaintiff-Appellee, v. School Board of St. Johns County, Florida, Defendant-Appellant. 12/27/2018.

PERSONAL

Languages: Conversational Spanish, French
Tutor: Biochemistry, computer science, High School mentor
Computers: Ruby, Rails, Javascript, C++, C, Java, and HTML programming

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF KRISTOPHER KALIEBE, M.D.

Introduction

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been asked by the defendants to discuss my membership in professional associations, and the relevant guidelines and policies concerning gender dysphoria in those associations. I have been asked to provide a review of the evidence base for treatments of gender dysphoria. I also have been asked to opine on the influence of activism and suppression of open inquiry which has distorted academic dialogue and made published research and expert recommendations untrustworthy with regard to gender dysphoria.

2. This report is entirely my own work product, and no one was consulted for this this report.

3. If called to testify in this matter, I will testify truthfully based on my personal experience and knowledge.

4. I am being compensated at an hourly rate of $400 per hour for my time preparing this declaration. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Here I provide a summary of my major points:

a. While historical reports of gender dysphoria exist, it has been rare until the last two decades.

b. There is no consensus in the field regarding the treatment of gender dysphoria, nor is there an evidence-base sufficient to lead to any confident recommendations.

c. Multiple reviews of the evidence base regarding treatment of gender dysphoria indicate that the evidence for affirmative treatment is low-quality.

d. Small numbers of advocate physicians within medical organizations have been able to leverage moralized claims and low quality evidence in order to promote affirmative care for gender dysphoria.

e. Significant evidence points to a spread of ideology combined with technologically induced contagion effects leading the recent increase in gender dysphoria.

f. As American medical professional organizations have already endorsed the concept of affirmative care as evidence-based and ethical, they are no longer neutral with regards to the science and have instead entered into advocacy roles.

g. Much of the slogans and assumptions associated with affirmative care for gender dysphoria are conjecture, opinion or misinformation presenting as established fact.

h. Due to the highly politicized and ideological nature of the issue of gender dysphoria, there is limited rigorous scholarly dialogue within American professional medical organizations and medical journals.

Background

6. I am an associate professor at the University of South Florida in Tampa Florida. I am Board Certified in Psychiatry, Child and Adolescent Psychiatry and Forensic Psychiatry. My clinical work has been primarily in University based clinics, Federally Qualified Health Centers and juvenile corrections.

7. I was awarded my medical degree in 1999, and subsequently completed general psychiatry, child and adolescent psychiatry and forensic psychiatry training. This training includes education in human biology, human sexuality, development, brain functioning, normal development and psychopathology. Gender dysphoria and gender dysphoria treatment were part of my professional training.

8. From 2005 to 2016 I was Assistant Professor at Louisiana State University Health Science Center – New Orleans. I was the program director of the LSU Child Psychiatry Fellowship for 2 years. Since 2016 I have been Associate Professor at the University of South Florida where my clinical roles which mainly include working with juvenile corrections, supporting primary care physicians through the Florida Medicaid Psychiatric Medication hotline and in a university child and adolescent psychiatry clinic. I cover at Tampa General Hospital and recently added an adult psychiatry resident clinic to my schedule. I also practice forensic psychiatry including child and adult cases, both within criminal and civil court.

9. As a supervising physician at the University of South Florida's Silver Child Development Center my role is to function as a clinical supervisor and instructor. Child psychiatry residents and general psychiatry residents serve as the primary patient evaluators and clinicians. I evaluate new patients directly, and after see patients directly as needed. I oversee the resident's work products and function as the physician of record. Within this clinic I evaluate and treat patients with gender dysphoria.

10. In addition to these direct clinical experiences, part of my scope of duties within the Silver Child Development Center is training residents regarding the treatment of patients, including patients with gender dysphoria.

11. Within the juvenile justice system I also evaluate and treat patients with gender dysphoria. I further have been consulted to provide a second opinion and coordinate care regarding a patient with gender dysphoria in the Louisiana juvenile correctional system.

12. In addition to direct clinical care, I am routinely consulted by colleagues. Within my work at the Florida Medicaid Psychiatric Hotline I have collaborated in the care of patients with gender dysphoria. My colleague consultation includes providing my opinion regarding would a youth be competent to consent as requested by an endocrinologist regarding a youth considering puberty blockers on

a path toward sex hormone treatment and potential surgeries. I have been consulted regarding psychotherapeutic approaches to young adult patients who detransitioned.

13. I have extensive teaching experience including medical students, general psychiatry residents, child and adolescent psychiatry fellows and forensic psychiatry fellows. I have years of extensive positive feedback from medical students and psychiatrist residents.

14. My approach to the practice of medicine includes utilizing and appreciating the amazing progress modern medicine has made. I practice and support conventional medicine, I have strongly advocated for the expansion of Federally Qualified Health Centers, along with improved collaboration of mental health with primary care (Kaliebe 2016, Kaliebe 2017).

15. My support of, and attempts to improve conventional medicine, is balanced by a healthy degree of caution. The history of medicine is filled with examples of the harms which can come with unproven, unnecessary, aggressive or counterproductive interventions. As such, I've presented twice at the Preventing Overdiagnosis conference.

16. I am involved with Integrative Medicine, focused mainly on the role of mind-body medicine, mindfulness, nutrition and exercise, along with how modern medicine has adopted approaches which underemphasize and at times neglect the basics of health. Another academic interest of mine is the tradeoffs and stress of

moving to primarily electronics based communications, especially on young people. (Kaliebe 2002, Gerwin 2018) I have a longstanding interest in how technology and the media intersect with society and culture, including the impacts of social media, recent increases in tribalism and the spread of misinformation.

17. With Paul Weigle, I co-edited the Child and Adolescent Psychiatric Clinics of North America *Youth Internet Habits and Mental Health* edition in 2018 with 16 chapters by invited experts on digital and mental health related issues. (Kaliebe 2018)

18. I am a member of the American Academy of Psychiatry and the American Psychiatric Association. I have been most active within the American Academy of Child and Adolescent Psychiatry (AACAP). I was awarded status as a Distinguished Fellow at AACAP in 2016. I first presented regarding the media at the 2004 AACAP annual conference, and have now presented at the annual conference 25 times. I served as co-chair of the Media Committee from 2013-2021. I served as the Liaison from AACAP to the American Academy of Pediatrics from 2016-2022. I was an author on their practice guidelines for telepsychiatry. I have also served AACAP in the state affiliates, for the Louisiana Council for Child Psychiatry I was secretary / treasurer for 4 years and served as president for 2 years.

19. I have a longstanding interest in psychotherapy. I have additional training in Cognitive Behavioral Therapy and trauma-focused therapies. I have been

providing psychotherapy and teaching psychotherapy to psychiatry trainees throughout my career. I currently routinely supervise psychiatry residents regarding psychotherapy with the USF residency program. I created and taught a Cognitive Behavioral Therapy practicum for LSU residents from 2007 to 2016. I was a member of the Association for Behavioral and Cognitive Therapies from 2004 to 2016.

20. I have been on the Best Doctors list annually since 2007.

21. I also practice and teach forensic psychiatry and have testified in deposition or trial in the following cases over the past four years:

a. Civil Testimony, retained by the defense:

i. In the Interest of RW, LL, AP Minor Children January 28, 2020 Circuit Court of the 13th judicial circuit, Juvenile Division, Judge Lisa Campbell, Tampa FL

b. Civil Testimony, court appointed:

i. February 28, 2020, Jeffrey Spivey, petitioner/father and Teresa Spivey N/K/A Teresa Cartwright, respondent/mother Case No.: 2016 DR0471's, Circuit Court of the 12th judicial circuit in and for Manatee County Florida. Judge Kevin Bruning

c. Civil Testimony, court appointed:

i. Re: The Marriage of Robyn Cohen McCarthy and John McCarthy November 1, 2019 11th Judicial Circuit, Family Division, Dade County, Judge Jason Dimitris, Miami FL

d. Criminal Testimony, retained by the defense:

i. The State of Florida v. Bill Paul Marquardt December 19, 2019 5th Judicial Circuit, Sumner County, Florida, Judge William Hallman III, Bushnell Florida

ii. The State of Florida v. Bill Paul Marquardt August 24, 2022 5th Judicial Circuit, Sumner County, Florida, Judge Mary P. Hatcher Bushnell Florida

e. Civil Depositions, retained by the defense:

i. Z.M.L., a minor, through her parents and guardians, -vs- D.R. Horton, Inc., a foreign corporation authorized to do business in Florida, United States District Court, Middle Division of Florida, Tampa, May 6, 2021

ii. THE ESTATE of JEAN LINDOR, deceased minor, by and through the Personal Representative of the Estate, JAMES LACROIX and NOUSE ANDREE LACROIX, individually, Plaintiffs, v. BOS TRANSPORT, LLC, a Florida Limited Liability Company, and ORESTES ZAMORA FLEITES, individually, December 5th, 2022

f. Civil Depositions, retained by the plaintiff:

i. Carlton Collins, individually, and on behalf of his minor son, Connor Samuel Collins v. David R. Wallace, Sr., M.D. Louisiana's 14th judicial district, Civil Suit: 2019 – 4128 – D, March 4th, 2022

g. Criminal Deposition, retained by the defense:

i. State of Florida v. Justin Mitchell Pennell, 2020CF000159FAXWS, 6th Judicial Circuit of the State of Florida in and for Pasco County, March 11, 2022Since 2016

22. A list of my publications is attached to this report as Exhibit "A".

The abrupt rise in transgender and non-binary identification

23. The discussion regarding transgender care is in the context of an unexplained and remarkable rise in patients reporting gender dysphoria. During my medical school experience and 3 residencies, I never encountered a patient reporting symptoms of gender dysphoria. For eleven years, from 2005 to 2016, I had a busy psychiatry clinic with about 80% minors and 20% adult patients without a single patient expressing gender dysphoria.

24. During those eleven years, none of the hundreds of medical students or residents I supervised presented cases to me describing patients with gender dysphoria. None of my social work or psychologist colleagues ever asked for consultation or advice regarding how to clinically approach patients with gender dysphoria. Within the last year, on a single day, I have treated three adolescent patients diagnosed with gender dysphoria.

25. My experience is consistent with statistics indicating an abrupt rise in gender dysphoria and presentations to medical clinics for related services. When a new patient population emerges, it creates challenges for physicians to respond. In medicine, typically when such an abrupt change in patient populations occur, the subsequent scholarly literature would typically discuss and debate underlying causes of this phenomenon.

26. Never before has there been large cohorts of individuals seeking medical services to alter their secondary sex characteristics. There had been decades of extremely rare treatment which was at the time acknowledged as compassionate but experimental care. Yet the current patients expressing gender dysphoria represent primarily a new and distinct patient population, not a population which has historically existed.

27. As a psychiatrist, I have encountered many patients who are uncomfortable with their bodies. This discomfort and dissatisfaction is often comingled with anxiety and depression, along with various diagnoses which involve bodily discomfort including eating disorders or Body Dysmorphic Disorder.

28. I have observed bodily discomfort more often in females, and especially as girls enter puberty, which is consistent with the epidemiological literature. Puberty introduces significant challenges and risks to females as they receive more attention from males, including adult males, along with increased competition from peers. Puberty now comes much younger than for our ancestors, creating a greater mismatch between brain and body maturity.

29. While the exact number is unknown it can be said that the incidence of gender dysphoria in youth was previously rare. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders published in 2013 rated in adults at 2-14 per 100000 (American Psychiatric Association p454).

Referrals at the Tavistock clinic in England increased over 50 fold in just a decade from 2009 to 2019. (Tavistock & Portman, NAHS Foundation Trust, 2020).

30. Similar increases have been reported across much of the economically advanced countries in the world, many showing over 1000% rise in gender dysphoria over the last decades (Marianowicz-Szczygiel 2022). This phenomenon requires some explanation and any complex phenomenon likely has a multifactorial line of causation. Yet multiple lines of evidence point to direct social influences and online and social media contagion as a major contributors to this increase in gender dysphoria. Biological factors causing the increase of gender dysphoria, such as endocrine disrupting chemicals, are plausible but have not been explored in the scholarly literature.

31. The involvement of social spread is supported by Lisa Littman's work (Littman 2018). It is supported by the timing of the massive increase in gender dysphoria coinciding with the rise in social media and associated "influencers". It is supported by the largest rise in gender dysphoria occurring in vulnerable adolescent females. This is precisely the same population most susceptible to online contagions such as "functional" rapid onset tics disorders, suicidal behavior, non-suicidal self-harm and increase self-reported Dissociative Identity Disorder.

32. The influence of culture, medical theories and ideology on symptom production is long-standing and well known. Shorter detailed numerous examples

of how culture intersects with psychiatric illness from the Victorian to modern era (Shorter 1993). For a discussion of how psychopathology can spread among psychiatric disorders, see Horesh et al's recent article (Horesh 2022).

33. Humans evolved as a sexually dimorphic, ultra-social and cultural species. Culture has co-mingled with our evolution, because unlike other animals, learning from others enables our very survival. Humans acquire a considerable portion of our behaviors and viewpoints "by tapping into a large body of non-genetic information that has been filtered and accumulated over generations. This process, termed cumulative cultural evolution, creates a storehouse in the form of strategies, attentional biases, motivations, tastes, and cognitive heuristics that are necessary for us to accomplish even the basics of survival". (p 210 Henrich 2021).

34. Thus humans can't explain the rationale for much of our routines, habits and customs because they have been shaped over time, some for thousands of year, some more recently. This raises the possibility there is time tested wisdom in many of our cultural adaptations. Cumulative culture constantly changes, but the recent rate of change has been exponentially faster due to the explosion of technologies. The modern world is thus experiencing perhaps the largest generation gap in history. Today's children and adolescents are exposed to so much more than out grandparents.

35. In ancient evolutionary environments, copying others aided survival via the transmission of acquired knowledge about what areas are safe, how to make shelters or weapons, what berries or mushrooms are safe to eat, and what type of social behavior is acceptable within a group. Humans' brains are particularly adapted with exceptional abilities to notice and copy the behavior of others.

36. Transmission of culture occurs in part via humans naturally mimicking what we observe in others. Yet these same instincts that develop helpful behavioral norms also enable social contagions that co-mingle with mental and behavioral disorders. Long-standing scholarly consensus exists confirming that direct social contagion not only affects health such as cardiac disease (Christakis. 2013), but interacts with technology enabled spread of mental health problems. (Haltigan 2023)

37. This can be seen in relation to suicide contagion (Yıldız,2019), non-suicidal self-injury (Jarvi, 2013), contagion related to eating disorders such as anorexia (Allison 2014). Since the Covid 19 pandemic, there has been an explosive increase of young people displaying features of Dissociative Identity Disorder and movements similar to those seen in Tic Disorders such as Tourette's (Pringsheim 2021). A google scholar review shows a dozen articles linking rapid onset tic disorders to social media. Similar to other examples of social contagion, these sudden onset tic presentations tend to be comorbid with pre-existing mental illnesses and adolescent girls show themselves to be the most susceptible.

38. The phenomenon labeled Mass Social Media Induced Illness (Giedinghagen, 2022) shows us that at scale, users of social media can develop technology facilitated psychosomatic illness. Psychiatrists have seen an abrupt rise in patients presenting with a self-diagnosis (Rettew 2022).

39. Consistent with all this evidence, the spread of beliefs about gender identity, such that all individuals should consider and question their gender identity, appears quite plausibly capable of significantly increasing the incidence of gender dysphoria. This is especially true as traditional sources of knowledge about the world such as families, school, local culture and religion have been replaced by what children observe on electronic screens. Youth even form complex reciprocal relationships with their avatars (Szolin 2023).

40. In their February 25, 2022 press release "Medicine and gender transidentity in children and adolescents" the French National Academy of Medicine notes "Whatever the mechanisms involved in the adolescent – overuse of social networks, greater social acceptability, or example in the entourage - this epidemic-like phenomenon results in the appearance of cases or even clusters in the immediate surroundings". It continues "The vigilance of parents in response to their children's questions on transidentity or their malaise, underlining the addictive character of excessive consultation of social networks which is both harmful to the psychological development of young people and responsible, for a very important part, of the

growing sense of gender incongruence." Thus the French National Academy of Medicine has concluded that the "epidemic-like" rise in gender dysphoria is tied to social media.

41. Psychiatrists also believe social media has significantly contributed to the rise in gender dysphoria. Yet most child and adolescent psychiatrists admit to me they will not speak publicly on this subject due to how sensitive the topic is, and also fears of hostilities from activists along with condemnation and retribution from others within their universities or organizations.

42. My personal conversations align with recent polling. While I was on stage presenting at the October 2022 American Academy of Child and Adolescent Psychiatry annual conference, as part of the presentation, the audience was anonymously polled on a number of topics. When polled: *How often do you see teens who seem to be influenced by social media in regards to their sexual and/or gender identity?* 80 of 97 (82%) indicated social media was an influence s*omewhat often* or *very often*. To my knowledge, this is the first data confirming that the vast majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in gender dysphoria.

43. A similar poll was conducted at the January 18, 2023, meeting of the Child & Adolescent Psychiatry Society of Greater Washington, all attendees were physician members. For the question *How often do you see teens who seem to be*

influenced by social media in regards to their sexual and/or gender identity? Of the 34 respondents, 47% indicated *Occasionally* and 35% indicated *Often*. So again 82% of these child and adolescent psychiatrists reported they see their patients gender identity is influenced by social media.

44. It is plausible and probable that ideological and social factors underlie the increase in gender dysphoria. This does not rule out other factors. Concern, open discussion and scholarly exploration of this data does not constitute bias, discrimination or transphobia. This area requires thoughtful analysis and further study.

Review of the Evidence Base for Treatments of Gender Dysphoria

45. Neither Gender dysphoria (GD) itself, nor what is the best psychotherapeutic or medical approach is well understood. My review of the research concludes that the evidence base for gender dysphoria treatments is mixed and generally low quality. Below I provide detail to this assessment.

46. The administration of sex hormones and performing of surgeries are medical interventions with substantial risks, and as these interventions target otherwise healthy tissue, a high degree of evidence is expected before such a life altering intervention. Until recently cross sex hormone and surgeries for gender dysphoria have been exceedingly rare, thus there exists nominal long term data. It is especially challenging to evaluate this evidence base due to changing definitions and

epidemiology. It is my opinion that insufficient data is available to make confident proclamation regarding the risks and benefits of treatments of gender dysphoria.

47. I have reviewed Drs. Brignardello-Peterson and Wiercioch's 2022 *Effects of gender affirming therapies in people with gender dysphoria: Evaluation of the best available evidence*. This report was compiled for the Florida Agency for Health Care Administration. This report utilized GRADE: Grading of recommendations, assessment, development, and evaluations. This is the most widely used method for appraising studies to be included in systematic reviews and guidelines. (Goldet 2013). Their review revealed that the quality of evidence supporting treatments is generally low. The conclusions rendered fit the data and are logically sound.

48. Drs. Brignardello-Peterson and Wiercioch's review is consistent with the Endocrine Society's own grading in their 2017 Clinical Practice Guidelines. The Endocrine Society also utilizes the GRADE system (Hembree 2017). In fact, the Endocrine Society 2017 Clinical Practice Guidelines only grade as moderate or high quality recommendations for assessment or education. All recommendations regarding treatment are graded as supported by very low-quality or low quality evidence.

49. Similar to the state of Florida, countries across the globe have responded to concerns about medical practice for gender dysphoria by conducting

reviews. After the reviews, each country changed their approach. Many of these countries, due in part to their smaller and better organized medical systems, have offered more comprehensive and structured treatment regimens for gender dysphoria. In addition, these treatment options in Nordic countries have been in place longer than they have been typically more available in the United States.

50. In Sweden, the National Board of Health and Welfare (NBHW) was commissioned by the Swedish government to update guidelines via its *Care of Children and Adolescents with Gender Dysphoria*. After this systematic review was published in 2022 by the Swedish Agency for Health Technology Assessment and Assessment of Social Services, Sweden's NBHW recommended a move away from cross sex hormones. The authors conclude that risks currently outweighs the possible benefits and most patients will need psychotherapy and supports rather than medical care. The Swedish National Board of Health and Welfare reported the 3 main factors:

a. A lack of reliable scientific evidence concerning the safety and efficacy of treatments.

b. Increasing concerns about de-transition.

c. Uncertainty brought about by the extreme rise in those seeking care, especially females.

51. They further conclude that "Evidence for non-binary gender identity is lacking." and the evidence is limited for adults. They further report "Gender dysphoria rather than gender identity should determine access to care". The authors conclude the "For adolescent with gender incongruence NBHW deems that the risks of puberty suppressing treatment with GnRH -analogues and gender affirming hormonal treatment currently outweighs the possible benefits. Treatment should be offered only in exceptional cases."

52. Sweden has made these changes within a context of longstanding access to care for gender dysphoria and much of the available data regarding longer term outcomes. A 2011 article reviewed sex-reassigned patients in Sweden from 1973 to 2003 and showed increased risk for suicide attempts and inpatient psychiatric care. (Dhejne 2011). A recent article, initially published claiming positive mental health results, after Letters to the Editors, caused a correction (Bränström 2020). This article reviewed patients diagnosed with gender incongruence between 2005 and 2015. The reanalysis and multiple Letters to the Editor in the end led even the authors to conclude that the methodological shortcomings preclude any statement on the suitability of surgery in persons seeking treatment for gender noncongruence. The peer review issues exemplified by these events will be discussed later in this report.

53. Finland is another Nordic country with an organized medical system and longstanding availability of care for gender dysphoria. Finland's recent Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) *Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors* concluded "The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders." The authors further report cross sex identification "even in extreme cases, generally disappears during puberty. In some cases it persists or intensifies."

54. The authors state "A lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options." They conclude: "In light of available evidence, gender reassignment of minors is an experimental practice. Based on studies examining gender identity in minors, hormonal interventions may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no

irreversible treatment should be initiated. Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported."

55. In their 2021 Position statement, *Recognizing and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence*, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) provides an overview of Gender Dysphoria and highlights the importance of respecting an individual's gender identity.

56. This position statement indicates that "Comprehensive Assessment is critical." "Evidence and professional opinion is divided whether an affirmative approach should be taken in relation to treatment of transgender children or whether other options are more appropriate." They further reflect that "There is a paucity of quality evidence on the outcomes of those presenting with Gender Dysphoria."

57. The 2022 press release of the French National Academy of Medicine, *Medicine and gender transidentity in children and adolescents*, reporting that on the epidemic like increase and that "This primarily social problem is based, in part, on a questioning of an excessively dichotomous vision of gender identity by some young people." "Therefore, faced with a request for care for this reason, it is essential to provide, first of all, a medical and psychological support to these children or adolescents, but also to their parents, especially since there is no test to distinguish a "structural" gender dysphoria from transient dysphoria in adolescence.

Moreover, the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to "detransition". It is therefore advisable to extend as much as possible the psychological support phase."

58. They further report "However, a great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause."

59. Similarly, The National Health Service of England commissioned the Cass Review to evaluate the safety and effectiveness of gender dysphoria care. The systematic review commissioned in the UK found the evidence for puberty blockers and cross-sex hormones to be of "very low certainty."

60. "The key limitation to identifying the effectiveness and safety of gender-affirming hormones for children and adolescents with gender dysphoria is the lack of reliable comparative studies. All the studies included in the evidence review are uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using modified GRADE. A fundamental limitation of all the uncontrolled studies included in this review is that any changes in scores from baseline to follow-up could be attributed to a regression-to-the-mean. " The authors further noted that the studies have relatively short follow-up and studies with a longer follow-up are needed to determine the long-

term effect of gender-affirming hormones for children and adolescents with gender dysphoria.

61. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose reports themselves to have a "mission is to promote evidence-based care, education, research, public policy, and respect in transgender health." WPATH has created their Stands of Care (SOC) documents which shares some features equivalent to what a medical organization would call a clinical practice guideline. These documents are referred to as the Standards of Care (SOC), the 2011 edition as SOC -7 and the 2022 version as SOC-8. The authors of SOC-8 state: "The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment."

62. Due to its recent release, a thorough systematic review of WPATH SOC-8 is not available. Dahlen et al provided a systematic review and quality assessment of international clinical practice guidelines for gender minority/trans people which included the review of WPATH SOC-7. They note that WPATH SOC7 "contains no list of key recommendations nor auditable quality standards." Among the principal findings was that WPATH SOC 7 cannot be considered 'gold

standard'. The WPATH review scored poorly on editorial independence, applicability, and rigor of development. The review scored better on scope, stakeholder involvement and clarity of presentation. The reviewers noted that WPATH and other international clinical practice guidelines tended to prioritize stakeholder involvement rather than methodological rigor.

63. Among the implications were that "Clinicians should be made aware that gender minority/trans health CPGs outside of HIV-related topics are linked to a weak evidence base" and that "Organizations producing guidelines and aspiring to higher-level quality could use more robust methods, handling of competing interests and quality assessment."

64. The Mayo Clinic Proceedings article, *Clinical Practice Guidelines: a Primer on Development and Dissemination*, (Murad 2017) highlights that "trustworthy clinical practice guidelines require a systematic review to select the best available evidence and should explicitly evaluate the quality of evidence". The authors' criteria for trustworthy guidelines include:

a. "Be based on explicit and transparent process that minimizes distortions, biases and conflicts of interest"

b. "Provide a clear explanation of the logical relationships between alternative care options and health outcomes"

c. "Provide ratings of the quality of evidence and the strength of the recommendations"

65. Despite the well-known methodological weakness to SOC 7, WPATHS created SOC 8 in a similar manner, again disregarding the conventions expected to create a trustworthy clinical practice guideline.

66. While SOC 8 is a large document and it is beyond the scope of this report to review completely, I must note 4 major concerns as a mental health professional.

a. SOC 8 makes no analysis of privileging gender affirmation over body affirmation. For clinicians and psychotherapist these trade-offs are fundamental concerns.

b. SOC 8 suggests consumer-driven medical and surgical interventions and deems these medically necessary without adequate supporting evidence.

c. SOC 8 normalizes self-mutilation via inclusion of "Eunichs" as just another non-binary category without any suggestion that these individual require mental health assessment prior to any consideration of chemical or surgical procedures.

d. SOC 8 downplays concerns related to de-transitioning.

67. Four final thoughts regarding the limited evidence for treatments for gender dysphoria. Firstly, advocates of gender affirming treatments point to short-term improvements observed in some studies. It is possible that much of these improvements are placebo effects. Placebo effects are positive changes based on expectations. Placebo effects are routinely seen in other treatments, such as pills for depression. Vulnerable youth expressing gender dysphoria may be especially susceptible to believe in remedies celebrated by online influencers or advocate physicians. The enthusiastic claims of effectiveness of gender affirming treatments in the press, by medical societies and expressed by advocates at high prestige institutions, would be expected to enhance placebo effects (Clayton 2022). This creation of false expectations has significant potential to cause harm.

68. The second concern is many proponents of early transition of youth with gender dysphoria point to what is known as the "Dutch Protocol". Yet a recent reviews display that while some call published reports regarding results of the Dutch Protocol reliable research, this "research", is in fact severely flawed (Biggs 2022). This is because the Dutch protocol selected out patients to assure only the most successful outcomes. The clinicians flipped the questionnaire, leaving it unclear if gender dysphoria was resolved. Lastly, concomitant psychotherapy confounds whether effects were from psychotherapy or the hormones and surgeries. Added to this, is that clinics in the United States do not follow the rigor of the

original studies, and as such the result are unlikely to be generalizable (Abbruzzese 2022).

69. The third problem regards Informed Consent. It is a concern of clinicians, as I have been asked about it by colleagues. It is curious that there has been minimal dialogue exploring the unanswered questions related to informed consent in medical journals. These matters are disputed in other journals (Latham 2022, Levine 2022). Medical organizations have come out strongly for affirmative care, supporting the opinion that minors have the emotional and cognitive development to be responsible for whatever consequence their teenage selves make. Yet when the question was mandatory life in prison in Miller V. Alabama, The American Academy of Child and Adolescent Psychiatry (with the American Medical Association) Amicus Curiae (2012. P2-3) claims: "Scientists have found that adolescents as a group, even at later stages of adolescence, are more likely than adults to engage in risky, impulsive, and sensation-seeking behavior. This is, in part, because they overvalue short-term benefits and rewards, and are less capable of controlling their impulses making them susceptible to acting in a reflexive rather than a planned voluntary manner. Adolescents are also more emotionally volatile and susceptible to stress and peer influences. In short, the average adolescent cannot be expected to act with the same control or foresight as a mature adult." It is thus my opinion that The American Academy of Child and Adolescent Psychiatry is so

politicized it cannot keep track of its own claims in Amicus Briefs which contradict each other. Unless this organization is willing to backpedal on its well substantiated and well documented arguments in the Miller v Alabama case, how can it basically argue the opposite when it comes to consent for irreversible treatment within the context of low quality evidence and significant risk of harm?

70. The fourth concern is most grave. A recent article in the New England Journal of Medicine tracked 315 youths undergoing 2 years of gender affirming hormones (Chen 2023). Within 315 hormone treated youth there were 2 completed suicides. Curiously, this remarkably high suicide rate is not explored in the article. By comparison, a recent review tracked the Gender Identity Development Service in England, Wales and Northern Ireland from 2010 to 2020 (Biggs 2022). This found 4 completed suicides of 15032 transgender patients over 10 years. As Gender Identity Development Service in these locations were overwhelmed with patients, only a small fraction were receiving gender affirming hormones. If these are compared the American hormone treatment group, it would be akin to a waitlist control. Thus the most recent research shows a much higher than expected rate of suicide in the condition of affirmative hormone treatment.

Lack of consensus regarding treatment of gender dysphoria

71. With rapidly growing cohorts of patients expressing novel symptoms clusters in an new area of medicine where a limited evidence base exist, differences

of opinion regarding clinical care for gender dysphoria are expected. It would be remarkable if there was uniformity of opinion. Furthermore, gender care is politicized, and opinions tend to cluster in a manner consistent with an influence of political ideology (Regnerus 2022).

72. Within this context of low quality evidence and divergent opinions, there are bound to be calls for reasonable clinical safeguards. There are also serious reservations regarding the effectiveness and concerns about the risks from affirmative treatment for Gender Dysphoria (Clayton 2022, Biggs 2022).

73. Much of the push for affirmative treatment for gender dysphoria treatment has come from professional organizations such as the Endocrine Society, American Academy of Pediatrics and the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry. Medical professional organizations are large bureaucracies which serve many functions. They are important components of our medical system and usually provide great services for the profession and the public.

74. Just as other parts of society, professional medical organizations are susceptible to tribal influences and politicization. Their influence and credibility can be misused in a harmful manner. I have directly observed, that over the last decade, but particularly the last 5 years these organizations have prioritized a politicized and narrow vision of social justice advocacy. While this has arisen from

good intentions, it has contributed to the creation and spread of misinformation regarding treatment of gender dysphoria. I will explain how this occurred.

75. I have directly observed that within these organizations, the members most enthusiastic about a certain type of medicine self-selected into "special interest groups" or committees. For instance, the psychopharmacology committee is filled with supporters of using psychopharmacology and the psychotherapy committee is populated by members enthusiastic about psychotherapy. Committees on gender and sexuality have been no exception. By participating in a committee, a small group of people can establish themselves as content experts within their organization.

76. Using committees as content experts usually works well, as it did during my eight years as co-chair within AACAP's media committee. ACCAP leadership utilized our input to make decisions about policy statements, clinical recommendations, public education or relevant legislation.

77. Over the recent years that gender clinics started to spread across America, gender medicine enthusiasts self-selected into these clinics and also into gender relevant committees. Most physicians are wary of the very concept that it can be beneficial to give cross sex hormones to still developing minors. Thus those who venture into medicalized gender care are already a select few who bring to this work certain viewpoints and aspirations. Just as with the psychopharmacology or

psychotherapy committee members, gender committee members have strong personal and professional investment in the success of their favored type of treatment. This created a well-intentioned but homogenous group of gender medicine supporters.

78. Without the knowledge of most members of a professional organization, as few as the dozen members in a committee can steer these organization's leadership to advocate for treatments or policy positions. Once medical organizations have come out with policy statements, clinical practice guidelines and press releases advocating strongly for a position, they have difficulty accepting they may have misstated evidence, advocated for unwise policy or otherwise caused harm.

79. For example, the highly influential 2018 Policy Statement from the American Academy of Pediatrics (AAP) (Rafferty 2018) contained many citation errors, overstatements and unfortunately mischaracterized the longstanding and well-regarded clinical approach of watchful waiting (Cantor 2020). This policy statement has been particularly detrimental to the scholarly exchange of ideas related to gender dysphoria treatments, as it used the prestige and trustworthiness of the AAP to privilege the concept of affirmative care and denigrate other treatment. It also increased momentum to enshrine social transition and access to

medical treatments in minors, whether or not these are prudent or evidence based approaches.

80. Medical and psychiatric journals editors are surely aware of their affiliated professional organization's policy statements and political advocacy. Since the Endocrine Society, American Academy of Pediatrics, American Psychiatric Association and American Academy of Child and Adolescent Psychiatry have been all openly involved in political advocacy in support of gender affirming care, in reality their journal are no longer are scientifically neutral. This politicization is reflected in the editors' actions as medical and psychiatric journals have recently attempted to consolidate favorable opinion toward gender affirming treatments for gender dysphoria rather than promoting open scholarly debate.

81. This is not just my theory, Michael Norko, the editor of the Journal of the American Academy of Psychiatry and the Law emailed to me in June 2022: "The Journal is an instrument of AAPL, and it is my responsibility as Editor to lead it in a direction that supports the efforts and goals of the parent organization."

82. Not surprisingly, skeptical voices have been difficult to find within any of the journals of the Endocrine Society, American Academy of Pediatrics, American Psychiatric Association or American Academy of Child and Adolescent Psychiatry. In fact, I have not found a single skeptical or even ideologically balanced article in any of these journals. Journal editors have a wide discretion to

choose what topics are covered in their journals by choosing what articles are sent for review, commentaries, clinical perspective, vetting Letters to the Editor guiding what is included in the book review column and setting policies.

83. The medical journal I follow most closely, The Journal of the American Academy of Child and Adolescent Psychiatry has only published articles seeking conformity of thought with gender ideology and affirmative care, and has not allowed actual scholarly dialogue to be voiced. Please see the commentaries (Dixon 20202), clinical perspectives (Turban 2017, Turban 2018), and book reviews (Suto 2021, Chilton 2021, Kim 2021).

84. The 2017 Turban article provided the perspectives of transgender and gender nonconforming youth and reading that viewpoint can certainly be valuable for clinicians. Yet most striking was the youth's ideological assertions, misunderstanding of the evidence and pleas for their physicians to believe suppositions such as ""Sexuality and gender are two different things. TOTALLY separate." and "Puberty blockers and cross-sex hormones can save my life." It also contained a pressure to join the movement: "Let me know that you are on my team." These youth somehow have gotten the impression there is no doubt regarding the safety and efficacy of hormones and surgery. They also have the belief that changing society is the solution to their mental health challenges: "If I am depressed or anxious, it's likely not because I have issues with my gender identity,

but because everyone else does." More striking was that that authors expressed agreement with the youths' ideology. The authors conclude: "Likely due to a combination of minority stress and dysphoria related to being 'trapped in the wrong body,' these young people are disproportionately burdened by depression, anxiety, and suicide attempts." The evidence actually points to youth who are depressed, anxious and suicidal are more like express gender dysphoria (Kaltiala 2020).

85. The Journal of the American Academy of Child and Adolescent Psychiatry even published a Commentary filled with misinformation which pressured researchers to adopt progressive gender theories to "become allies" (Dixon 2022). It is curious but revealing that the participants seemed uninterested in core unanswered questions such as why individuals experience themselves as nonbinary or transgender. Conversely, the youth and authors used the commentary to push researchers to adopt ideology and allyship. These pressures on scholars are antithetical to the scientific method and have been a corrupting force in much recent research and academic dialogue regarding sex and gender. This politicized, low quality scholarship has minimal credibility and is a prime example of how medical journals have prioritized advocacy and ideology over trustworthy science. With two child and adolescent psychiatric colleagues, in response to Dixon et al, we wrote a Letter to the Editor of the Journal of the American Academy of Child and

Adolescent Psychiatry. The journal editor refused to even send this letter out for review.

86. Not only are the articles one sided, the peer review process regarding gender medicine within medical journals has become dysfunctional. Many recent examples show how prominent medical journals ignore significant weakness in methods, allow erroneous conclusions and overstatement of the strength of the evidence when articles support affirmative care or related concepts (Bigg 2020, Deangelo 2021, Kalin 2020, Giovanelli R. 2022). As mentioned earlier, the Journal of the American Psychiatric Association published a study with an erroneous positive conclusion regarding gender surgeries in Sweden, prompting a flurry of letters to the editors and later revision (Bränström 2020).

87. In 2018 Lisa Littman published an article which revealed aspects of the rapid spread of gender dysphoria in adolescents. After this research was peer reviewed and published, the journal PLOS ONE had a re-editing of the publication with a commentary added. This showed a disregard for the typical rules of scientific discourse, and should be noted was not a corrections, as there was no finding of error, misconduct or faulty methods. As confirmed by the PLOS ONE re-review, Dr. Littman's research methods were unremarkable and comparable to other mental health research, and this was not a correction as claimed by activists. Various journals also published articles deriding Dr. Littman's work and she was personally

harassed by activists. Brown University also did not make any effort to defend her Dr. Littman from attacks on her freedom to pursue science. This antagonism of Dr. Littman was not about her methods, but rather that her data indicated that Gender Dysphoria was spreading in a pattern consistent with social influence. Dr. Littman's other heresy was revealing how many parents perceive the gender affirming approach is dysfunctional. (Littman 2018)

88. Similar dynamics are in place even in newsletters. A colleague related a difficult experience with editors of the American Academy of Psychiatry and the Law Newsletter. The editors would not permit him to describe in his article the actual problematic behaviors of youth who declared themselves to be transgender on his inpatient unit. This silencing of actual clinical situations undermine the exchange of ideas on how to best provide clinical care.

89. Thankfully, journals outside of medicine have not allied themselves to one viewpoint and are willing to embrace open scholarly dialogue (Abbruzzesse 2023, D' Angelo 2021).

The breakdown of scholarly dialogue

90. Open inquiry is the ability to ask questions and share ideas without risk of censure. It is fundamental to medical research and scientific progress. Within medicine the ability for constructive disagreement and the expression of divergent

opinions has withered with regards to questions of biological sex, gender and gender medicine.

91. Political and social pressures are not new to this line of research and clinical care and do not come from only one political pole or fraction of society. Yet especially within the last decade, academia, including academic medicine has become more tribal, moralizing and more likely to attempt to silence divergent opinions (Bindewald 2021).

92. I witnessed these dynamics personally at the American Psychiatric Association 2022 annual conference. At the Clinical Perspective *The Management of Adolescent Onset Transgender Identity: Should "Best Practices" Change* on May 24th 2022, the was a preamble. In a procedure I've never before seen at a conference, the representatives from American Psychiatric Association who were monitoring the event were asked by leadership to read a statement prior to presentation indicating the content of the presentation clashed with official proclamations of the organization. During this Clinical Perspectives four speakers presented convincing data and opined that they questioned the evidence based and logic supporting current affirmative psychotherapy and medicalized practice regarding the treatment of transgender youth. Most of the audience respectfully sat while enjoying the thoughtful presentation. Yet a small crowd in the audience was disruptive. There were many interruptions of the presentation by a member of the

crowd who repeatedly provided his input. During the question-and-answer session, a series "questions" were rather hostile ad-hominem statements towards the presenters. Only a tiny fraction of the questions actually responded to any of the evidence or viewpoints presented. I have never previously observed any comparable unprofessional behavior or hostility toward presenters in any medical or psychiatric conference.

93. Similarly, in 2018 Lisa Littman, MD presented her research data at American Academy of Child and Adolescent Psychiatry conference and received personal enmity which caused a colleague to remark he has never seen a presenter at a conference treated with such hostility. I did not attend live but later watched the presentation online and also heard the many demeaning and unprofessional comments directed toward Dr. Littman.

94. Members of APA and AACAP who attend meetings and observe scholars being condemned will certainly think twice before voicing their concerns. This polarization and moralization can create a "spiral of silence": an appearance of agreement because a small moralizing group dominates the discussion (Noelle-Neumann 1974). This is consistent with my experience as I have been told by a range of child psychiatrists, from very senior AACAP "life members" to residents in training that they are unwilling to openly express their viewpoint, but they do not see data or logic supporting gender affirming treatments.

95. The 2022 American Academy of Child and Adolescent Psychiatry conference featured at least 6 presentations related to gender dysphoria or transgender patients, none presenting new research. Yet a research Symposium was rejected which was to include a prominent international researcher, Dr. Littman, a clinician experienced in treating gender dysphoria and was to feature detransitioners. The AACAP program committee co-chair James McGough later indicated via a May 28th 2022 email this highly unusual rejection was in part due to "concerns" about the methods employed in several of the presentations and that detransitioners would be involved. It defies logic that the only time methods are an issue is when the results of the research raises questions about affirmative care. Furthermore, I am aware of a number of presentations which have been accepted with the condition of making a small adjustment. The detransitioners as discussants could have easily been replaced as their only role would be to ask questions after the research is presented.

96. Dr. McGough indicates he took these concerns seriously. He referred concerned parties to "Aron Janssen co-chair the AACAP committee charged with taking the lead on trans issues." Dr. McGough also noted that "Aron is also on the program committee". A program committee member "taking the lead on trans issues" would give Dr. Janssen significant power to support or suppress presentations. I have seen Dr. Janssen present twice and spoken with him. Though

we disagree, he is a thoughtful person and means well. Yet those concerned with free exchange of scholarly ideas should notice the words he chose in his 2021 "Perspectives" article (Janssen 2021) whereas he characterized legislative and political endeavors to limit medical care as "malicious changes" that "provide fodder to perpetuate discrimination, fear and exclusion." He specifically states: "It is our ethical responsibility to respond to this assault".

97. Dr. Janssen characterizes those arguing against gender affirmative care as making "an effort to oppress". This all makes clear he does not want open rigorous scholarly exchange that would raise substantial questions about the ethics and efficacy of gender affirming care. It is further my assessment that across medical organizations and medical journals those who are "taking the lead on trans issues" share Dr. Janssen perspective.

98. For those not familiar with the proceedings of medical conferences, research symposiums are eagerly sought out by the medical societies. The same program chair has commented to me personally that research symposiums are by far the easiest type of presentation to be accepted. For this same conference I also submitted, with two other physicians, for a Special Interest Group presentation which was to feature data on de-transitioning. This proposal obviously provided data which raised questions about affirmative care, it was also not accepted.

99. Despite unclear evidence and significant disagreement among psychiatrists regarding the treatment of gender dysphoria, medical professional organizations have enthusiastically conducted a public campaign to portray these treatments as evidence based. The organizations' political activism has important ramifications and creates a false impression that gender affirming treatment rests on strong and settled science. Two recent press releases provide examples. The September 28th 2022 American Academy of Pediatrics (AAP) press release regarding the State of Oklahoma condemnation of any limits on gender affirming health care. Defending scope of practice is typical for medical associations. Yet the press release frames these limits as discrimination based on gender identity, a moralized characterization of restrictions on care.

100. American Academy of Pediatrics' opposition to Oklahoma's limits on moral grounds (discrimination) fails to acknowledge ethical concerns regarding treatment of children with gender dysphoria including large scale potentially irreversible damage to minors. This is an example of two competing moral frameworks which both express valid concerns. As such, a more appropriate perspective from a medical organization would be a call for reasoned dialogue to evaluate the moral claims on each side, examine the logic and data behind these moral frameworks and treatments. It is not immoral to seek to find more cautious ways to care for and support those with gender dysphoria, or to seek a higher level

of evidence before allowing minors to make permanent decisions regarding altering their bodies.

101. Curiously, the AAP statement invokes parental rights, but without clarifying if the AAP supports the very likely majority, who do not want hormonal or surgical treatment for their child's gender dysphoria. This AAP statement misses an opportunity to show respect for those who disagree, which is an indication of how politicized the AAP organization has become.

102. The American Academy of Child and Adolescent Psychiatry (AACAP) made a number of similar statements regarding limits on care such as the March 1, 2022 statement which characterized actions in Texas as "attacks" which endanger young people. The statement curiously claims "Gender affirming care is informed by long-standing standards of care and by evidence-based clinical studies". How longstanding are we talking about, because gender dysphoria was previously so rare I went over 20 years from medical school through over the first decade of my career without a single patient reporting gender dysphoria. The first gender clinic in the United States just opened in 2007. It is reasonable for AACAP to defend scope of practice, oppose criminalization of physicians and call out inappropriate use of child protective services. Yet a medical professional organization overstating evidence and using divisive rhetoric reveals serious ideological and political influence which undermines it's own legitimacy.

103. Even more revealing is the American Academy of Child and Adolescent Psychiatry's (AACAP) March 18th, 2022 press release reveals their leadership's strident position by remarking on an education bill, outside psychiatrists' area of expertise. AACAP's statement used politicized derogatory phrasing by calling Florida's legislation the "Don't Say Gay or Trans" bill. The press release quotes the current president of AACAP who demonizes supporters of the bill as unconscionable and implies these supporters "target and harm" LGBTQ+ youth". The American Academy of Child and Adolescent Psychiatry's leadership moralizes the debate, uses polarizing language and does not engage in forthright discussion which must include skepticism, not just affirmation.

104. It should be noted the national organization offered my regional AACAP branch (in the Tampa area) the opportunity to sign on to "BRIEF OF AMICI CURIAE AMERICAN ACADEMY OF PEDIATRICS AND ADDITIONAL NATIONAL AND STATE MEDICAL AND MENTAL HEALTH ORGANIZATIONS IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION". The Tampa regional organization refused to sign on.

105. While I have little direct experience with the Endocrine Society, my assessment is that many endocrinologists, and perhaps most, also believe their professional organization is also too strongly influenced by activist physicians.

Similar to AACAP and AAP, they take a polarized position and misstate the strength of the evidence regarding gender affirming care. In particular, the April 20th 2022 press release "Endocrine Society Opposes Florida Department of Health Policy on Gender Dysphoria Treatment for Children and Adolescents" reveals overstatements of the strength of evidence and the false appearance of consensus in the medical community. This statement mischaracterizes puberty delaying medication as a "safe, reversible and conservative approach." This statement claims that attempts to restrict care are based on politics, rather than acknowledging legitimate concerns. It is interesting that they cite the Endocrine Society's own clinical practice guidelines. As noted previously, the Endocrine Society's own guidelines themselves graded the supporting evidence as low or very low quality for their clinical recommendations.

106. These organizations portrayal of affirmative treatments for gender dysphoria as both effective and virtuous has had a chilling effect on scholarly dialogue regarding gender dysphoria in the medical community. This framework brands those who disagree regarding the evidence base as morally inferior and biased. Through mechanisms I will describe below, moralization has been counter-productive to developing trustworthy science and has contributed to the spread of misinformation regarding treatment approaches to gender dysphoria.

107. Prudent physicians generally avoid being part of a partisan and moralized debate, and do not want to be harassed by gender activists (Evans 2021). When anonymously polled, as cited above, physicians are free to provide their actual opinion and show their skepticism. Supporters of affirmative care could survey physicians to specifically test their hypothesis of broad based support. Why have they not conducted such a survey?

108. As mentioned earlier, the highly politicized dialogue regarding the issue of transgender care (Evans 2021) mirrors a larger phenomenon within the academic community. On many complex and divisive issues within academia, there has been a push from the progressive left demanding conformity of opinion with a narrow, highly moralized viewpoints (Bindewald 2021). The example of gender dysphoria shows that academic medicine has not been immune to this same phenomenon.

109. Pressures to make affirmative therapies the only treatment for gender dysphoria essentially push all parties involved to adopt a simple clear framework for gender dysphoria treatment. Yet simple and clear does not represent the reality or the evidence base. All- or-nothing rhetoric can be an effective technique to rally support around a cause. Yet the treatment of gender dysphoria has complex ethical, legal, social and clinical trade-offs.

110. This moralized framing of affirmative treatments for gender dysphoria encourages a cognitive shortcut known as attribution substitution. Attribution substitution is the process whereby a simple, related moral judgement is substituted for various conceptually complex decisions. This common cognitive bias causes humans to intuitively believe viewpoints which appear virtuous, especially ideas which seem widely held within their social group. Affirmative care does sound compassionate and supportive, and these minor semantic can have a surprising influence.

111. For comparison, the Covid-19 pandemic provided a clear parallel of how moralizing medical issues can lead to misinformation and poor decision making. Individuals' tribal associations were shown to often influence their viewpoint of lockdowns, masks and vaccines more than data. (Kerr 2021, Jiang 2021). Call for conformity meant that dissenting physicians, even academic titans like John Ioannidis, Jay Bhattacharya, and Scott Atlas were treated badly both online and within the medical community. These pressures against voicing skepticism distorted the professional dialogue. Respectful conflict of opinion and impersonal rigorous exchange would have likely reduced harms, such as education loss and mental health deterioration associated with prolonged American school closures during the pandemic (Dooley 2022).

112. Ideological homogeneity and group identity are risk factors for developing irrational beliefs and spreading misinformation. (Su 2022, Sun 2022, Macy 2018). This directly relates to attitudes about transgenderism and gender dysphoria treatments where ideological dogma has distorted scientific exploration. Those who dare to question the dogma are treated as heretics.

113. These dynamics are understandable. Many times within psychiatry and medicine we as practitioners face enormous suffering. Gender non-conforming patients do at times face harassment and discrimination. Patients expressing gender dysphoria have high rates of depression, anxiety and self-harm. All physicians and mental health professionals want to help. Those who started gender clinics hoped to relieve suffering. Yet in medicine false hope can cause suffering.

114. All humans, including physicians, tend to find arguments in favor of conclusions we want to believe, and this bias in known as motivated reasoning (Peters 2020). Supporters of gender affirming treatment want to believe they have found an ethical and evidence based solution. This motivated reasoning explains the strong divergence between the enthusiastic support for gender affirming treatments and the relatively weak evidence base.

115. Once a group, such as a gender committee, endorses a statement of belief, such as “gender affirmative care is life-saving”, the other psychiatrists in their professional organization who have not reviewed the facts tend not to question

it. Psychiatrists face a rapidly expanding evidence base across disorders, and we depend on specialization to lead us toward progress in our varied patient populations.

116. Especially if the "experts" assert a strong moral claim regarding a clinical approach, other members would assume it is based on strong evidence. This creates a group process whereas the leadership responds to show support and loyalty, and others tend to follow. Support of this moral claim becomes a marker of virtue and raises status within the group. Those who are skeptical tend to self-censor (a Spiral of Silence) rather than taking a risk of being called unethical. These dynamics, especially leaderships' endorsement, make opinions appear like facts within the group. Members of this group they never hear counter arguments or disconfirming data and become ever more confident.

117. Within such moralized environments education and intelligence offer limited protection from irrational beliefs. In fact, sophisticated language skills enable virtuosity in creating and promoting false narratives. These dynamics have happened many times before in medicine and it is my assessment this has occurred again with regards to affirmative treatments of gender dysphoria.

118. Contrary to popular belief, humans' emotional programing drives much of our cognitive processes. That is, we tend to create beliefs that go along with what we feel, rather than the other way around. This usually works well, but also causes

serious problems. In cognitive therapy it is known as "emotional reasoning". Emotional reasoning helps explain opinion cascades, partisanship and group-think.

119. Our highly social nature and limited rationality demand that, in medicine and science, we create conditions which foster trustworthy data and minimize the creation and spread of misinformation. Recently, as shown, medical organizations and journals have prioritized advocacy, putting them at risk for producing and officially sanctifying misinformation.

120. A prescription for open exchange and deliberate consideration regarding gender dysphoria treatments should aspire to:

a. Solicit a diversity of perspectives.

b. Discuss the argument, rather than the person making the argument.

c. Clarify the methods, source of data and its limitations.

d. Use precise language rather than broad ideologies.

e. Discuss potential sources of bias, including those related to group affiliation.

f. Quickly acknowledge and correct mistakes.

121. This framework would depersonalize the search for truth and esteem empirical dialogue. Yet conflict is required to help us create a trustworthy scholarly dialogue regarding gender dysphoria. This has not occurred and as such claim that there is an evidence base supporting gender affirming treatments is not credible.

122. Complex ethical issues regarding treatment of gender dysphoria deserve attention. Yet pressures to accept affirmation treatment as being the most virtuous and only effective approach discourages good faith scholarly dialogue. Furthermore, the characterization of those who oppose gender affirming care as transphobic or hateful has been used to justify silencing scholars whose data or logic does not support the gender affirming approach. This occurred with Lisa Littman. Former sex researchers have left the field due to the harassment and intellectual bullying they had received (Soh 2021).

123. Thus we are in the curious situation where in private, but not in public, most psychiatrists will acknowledge their doubts regarding affirmative care. My personal interactions with many thoughtful well regarded psychiatrists display a full range of views. Most child and adolescent psychiatrists consider automatic affirmation inappropriate, even though many are willing to use affirmative approaches selectively. (Evans 2021). Most psychiatrists are willing to admit we don't have enough research to really know how to proceed.

124. Within medicine and academia we need to create space to allow input from those who hold the opinion that logic and the evidence base do not support medical interventions for gender dysphoria. We require a frank discussion of the moral issues involved, including moral hazards associated with medical treatments

for gender dysphoria. Currently, I see no evidence any of this scholarly dialogue happening.

125. Beyond hormones and surgeries, thus the costs and benefits of gender self-identification have not gone through academic inquiry with open rigorous academic review. Social affirmation can be considered a psychosocial treatment, and the recent push for adoption of social affirmation is an attempt at a grand social experiment. This is most concerning as it pertains to children. Statements of physician advocates and medical organizations are used to justify social affirmation, yet social affirmation of children seems more driven by ideology than thoughtful reflection. Throughout human history societies have grouped children by biological sex rather than gender identity. In fact, children naturally group themselves by biological sex (Maccoby 1998). Grouping children by biological sex requires tradeoffs but works well. As it has been standard practice throughout the world there has never been the need for literature to defend this practice. Yet abandoning this convention for the experiment of childhood gender self-identification appears imprudent on many grounds, not least of which is that it will likely be psychologically destabilizing for children and adolescents.

126. Social affirmation for children is portrayed as ethical, but to what degree it is ethical depends on how it will affect children's lives. No substantial evidence guides this movement to rewire a basic element of society. There is a

longstanding forensic psychiatric literature showing that children are suggestible (Ceci 2000). It is easy to see the widespread suggestions of the existence of multiple genders and each child should declare their gender will increase confusion and cross sex identification. This should be expected to increase the incidence of, and persistence of, gender dysphoria. It is thus reasonable to expect social affirmation can cause harm, especially for emotionally vulnerable and neurocognitively impaired youth.

127. Social affirmation of children's and adolescents' self-declared gender requires more research and discussion before the risks and benefits are fully explored(Zucker 2020). Until more is known, and more rigorous scholarly dialogue takes place, society and academic medicine should avoid pushing such a large scale social experiment.

Psychotherapy

128. Patients presenting with gender dysphoria have real symptoms, typically with other comorbid mental health disorders. These patients require validation and support. I recommend their mental health treatment start with psychosocial supports and psychotherapy (Schwartz 2021). In psychiatry, we typically refer to other providers such as social workers, psychologists and licensed clinical therapists who tend to provide the bulk of psychotherapy. Despite this, as

noted in my background, I have extensive experience with psychotherapy, and additional training beyond the majority of psychiatrists.

129. Quality psychotherapy includes the process of exploring patient life history, emotions, coping style and thought patterns. This includes validating how patients feel, but it also includes teaching patients to not be guided solely by their feelings. Psychotherapy involves getting patients to recognize their own thought patterns, disturbed emotions, and, when appropriate, includes challenging irrational, self-defeating and harmful beliefs.

130. There is not an evidence base to support strictly "affirmative" psychotherapy for gender dysphoria, where therapists actively agree with a patient's self-assessment. Automatically agreeing with patient viewpoints is a radical departure from traditional mental health treatments and psychotherapy. Psychiatrists do not "affirm" hopelessness in depression, delusions in schizophrenia or distorted body image in anorexia or body dysmorphic disorder. The similarities between body dysmorphic disorder and gender dysphoria, and the contrast in how they are approached, provide significant evidence of how ideological and political forces have influenced medical practice (Kohls 2022).

131. Is it, for example, sensible, compassionate or good medical practice to, for instance, soon after a sexual assault, to automatically agree with a teen's new

self-assigned gender label? What about when a 9 year old girl spontaneously says "I feel like I am a boy", do we immediately ask what boy name to call her(him)?

132. In psychotherapy with a patient with gender dysphoria, the therapist would not advise a patient to change a gender identity, but also should not "agree" that a patient is the opposite sex. It is surely reasonable and compassionate for a psychotherapist to prefer a patient no longer to suffer with gender dysphoria. It would be inappropriate for a mental health professional to prefer gender dysphoria to continue. Yet the false binary of affirmative psychotherapy versus conversion therapy for gender dysphoria is being used to push therapists from any consideration that acceptance of one's biological sex or resolution of gender dysphoria is a positive event.

133. This categorizing of quality psychotherapy as conversion therapy is a serious misunderstanding of the complexities of ethical and effective psychotherapy (Schwartz 2021, D' Angelo 2021). The term "conversion therapy" is often misused by the supporters of affirmative care as an attempt to devalue and pathologize approaches other than purely affirming a patient's gender self-identification (Griffin 2021, Evans 2020). The only conversation therapy which has ever been researched is the attempt to change, or convert, sexual orientation.

134. Sexual orientation, with rare exception, appears to arise from in utero or early life biological factors. Thus conversion therapy for sexual orientation is

ineffective, hostile and pathologizing to same sex attracted individuals. Decades ago conversation therapy was rejected by modern medicine and mental health. Conversion therapy is a historical reality within the United States, but accusations of conversation therapy have been used as a technique to change the discussion from a question of nuanced mental health care to all-or-nothing thinking regarding affirmation. During my entire career I have never once encountered a single mental health professional that has practiced conversion therapy for sexual orientation. Nor has a single patient ever described to me that they endured conversion therapy.

135. Gender identity is distinct from sexual orientation. Gender identity is often described as fluid, and as this implies, often changes over time, particularly in young people. This gender fluidity is also why it is inappropriate to affirm a declared gender identity in a child. Psychotherapists need space to ask questions about gender identity. Exploring gender identity is not conversion therapy.

136. Time-tested and widely effective psychotherapy approaches include supportive therapy or cognitive behavioral therapy. Cognitive behavioral therapy has proven effective for virtually every mental health condition it has been researched for, including the full range of anxiety disorders, depressive and mood disorders, disturbed anger, sleep disturbance and trauma reactions including Post Traumatic Stress Disorder. Due to the high levels of comorbidity of psychiatric disorders in patients with gender dysphoria, cognitive behavioral therapy could be

extremely helpful as the same approach and techniques have proven effective with so many problems including anxiety, depression and in reducing self-harm.

137. Any psychotherapy should aim to help individuals gain a deeper understanding of themselves, develop coping skills and provide a neutral, unbiased process. Beyond standard psychotherapies, more specific and nuanced approaches for gender dysphoria exist, such as Exploratory Therapy (https://genderexploratory.com/). This "talking therapy" allows time for exploration of mental health concerns without pushing an ideological or political agenda.

138. Advocates of affirmative treatment dismissal of other approaches can be especially harmful in the cases of gender dysphoria presenting in the context of severe pre-existing psychiatric illness. Psychotherapy could led to the resolution of these comorbid illnesses. I can provide three examples.

139. Trauma: There is longstanding psychiatric literature showing that exposure to sexual trauma can lead to changes in gender expression (Cosentino 1993), and this has also been revealed by recent research on detransitioners. (Littman 2021). A recent review on Dissociative Identity Disorder and co-occurring Gender Dysphoria showed frequent childhood sexual abuse (Soldati 2022).

140. A core feature of Post-Traumatic Stress Disorder (PTSD) is avoidance. Repeatedly patients have described to me their physical and emotional distress when they are exposed to trauma reminders. Thus, they frequently have difficulty engaging in psychotherapy for PTSD. Even if they participate, they often actively avoid discussing their trauma. This is unfortunate as trauma focused therapies such as Trauma Focused Cognitive Behavioral Therapy have an excellent evidence base.

141. The massive rise in expressions of gender dysphoria has been most pronounced in adolescent females. This is a population where assessment for, and treatment of trauma, should be a top priority. Furthermore, based on the link between sexual abuse and gender dysphoria seen in detransitioners, assessment and treatment of trauma symptoms should be prioritized. It is possible that for many patients the delivery of trauma based psychotherapy may cause the desistence of gender dysphoria, which in some cases could be considered a co-occurring disorder related to the trauma.

142. Another feature which links gender dysphoria to trauma is the well-known phenomenon of traumatized individuals feeling "cut off" or disconnected from their bodies (Van der Kolk, 1994). Van der Kolk and other prominent PTSD experts recommend mind-body techniques and experiential moving meditations such as yoga to help the body process trauma. These techniques help ground people in the physical world, mindfully experience their bodies and increase positive

physical sensations. While only small studies exist, yoga is being used with success in many settings including prisons and substance abuse facilities. Yoga and other somatic therapies should be studied as a component of comprehensive treatment for gender dysphoria.

Autism

143. Autism Spectrum Disorders are neurodevelopment disorders. People with Autism Spectrum Disorder by definition have problems with social communication and interaction along with restricted or repetitive behaviors or interests. People with Autism Spectrum Disorders are consistently shown to be at increased risk for developing gender dysphoria (Cooper 2022). One review found gender dysphoria to be over 4 times as likely in patients with Autism Spectrum Disorders (Hisle-Gorman et al., 2019). Another review found compared to typically developing control, autistic adults who endorsed the wish to be the opposite sex were found to have more mental health challenges, bullying, suicidal ideation and worse quality of life. They also had worse autism symptoms and more co-morbid disorders than autistic adults who did not report the wish to be the opposite sex.

144. Autistic people experiencing gender dysphoria are a complex patient cohort. There is limited evidence of how best to help and support this specific populations. Due to the neurocognitive limitations in patients with Autism Spectrum Disorders they may be more suggestible. Autistic patients struggle

socially and often spend large amounts of time online. Due to their rigid and obsessive thought patterns, if they develop gender dysphoria they can become fixated and preoccupied with receiving hormonal or surgical procedures, whether or not they understand the risks. Patients with Autism Spectrum Disorder can be incredibly insistent, single minded and determined. They also may have limited insight and minimal ability to anticipate the negative consequences of obtaining the object of their obsessions. Until more is known about the specific outcome related to this vulnerable population, caution with any clinical approach is warranted. Again, special psychotherapy approaches would likely be helpful in this population, but as of yet none have been studied.

Borderline Personality Disorder

145. Personality Disorders are enduring patterns of inner experience and behavior which deviates from expected and causes distress and impairment in functioning. The epidemiology of personality disorders in individuals with gender dysphoria is unknown and estimates vary (Furlong 2022). Many estimates have the population extremely increased, such as 50% of adults, but others show smaller increases. One review of emergency room visits of transgender patients diagnosed personality disorders at 4%, versus matched community sample of 1%. The hospitalized sample was at 5% versus 2% in controls (Lam 2021). Little scholarly

guidance exists regarding specific approaches related to the various personality disorders with comorbid gender dysphoria.

146. In Borderline Personality Disorder there is, by definition, an unstable sense of self, and this leads to frequent personality changes. This typically means sudden shifts in employment, relationship, sexual identity, frequent moves and changes in types of friends. Patients with Borderline Personality Disorder often have early life trauma and find many social environments invalidating. Patients with Borderline Personality Disorder have high levels of emotional dysregulation, self-harm and substance use. This population is extremely difficult to treat.

147. With an unstable sense of self being a feature of the disorder, this patient population seems an especially poor candidate for affirming treatments, especially irreversible treatments. There are two psychotherapeutic approaches which have shown significant success, the most established is Dialectical Behavioral Therapy (Gillespie 2022), but Mentalization Base Therapy (Vogt 2019) also has significant evidence as a successful approach.

148. Especially for a young person developing signs of Borderline Personality Disorder, starting these proven approaches as early as possible is their best chance of avoiding a life course which is full of emptiness, struggle and suffering. Again, in this patient population, a focus on gender affirming treatments as the solution to this constellation of serious mental health problems is extremely

problematic, and appears likely to cause harm if it delays access to evidenced based treatments.

Conclusion

149. It is scientific and medical consensus that patients with gender dysphoria typically also have a mix of anxiety, depression, self-harm, personality disorders, neurodevelopmental disorders and trauma related symptoms. Yet these mental health problems generally pre-date or co-occur with the development of gender dysphoria.

150. There is not a scientific or medical consensus that comorbid mental health disorders are due to "untreated" gender dysphoria. This claim does not match the data. These co-occurring mental health problems pre-date and are, for the most part, not caused by the gender dysphoria.

151. As reported in the Finnish review (PALKO / COHERE Finland 2020): "A lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment." The Finnish experience shows that "treating" the gender dysphoria with affirmative medications and surgeries does not resolve the patients' mental health disorders (Kaltiala 2020).

152. Claims of medical necessity for hormones and surgeries for minors can be refuted by the fact that all cohorts of previous children and adolescent throughout human history have never "needed" these procedures. The burden of proof is on those who proposed hormones and surgeries for minors to conduct long term studies and show these practices to be safe and effective. These are currently experimental approaches which seem highly intertwined with ideology. As detransitioners become more visible and relate their stories, it is clear that this ideology has distorted the practice of medicine, leading to harm.

153. The medical system has a long history of spurts of overdiagnosis and overtreatment. Many of our interventions such as frontal lobotomies were celebrated at the time. Eventually society sees the harm, pushes back and the medical profession eventually reforms.

154. Harmful and unnecessary interventions are especially likely to occur when patient desires are combined with financial incentives and the best of intentions. The American opiate epidemic was ushered in by "expert" physicians who proposed physicians need more compassion because "pain is the 5th vital sign" (Mandell 2016, Adams 2016). Too much compassion can cause harm.

155. Psychiatrist Anna Lembke, in her 2016 *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* discusses how susceptible to manipulations physicians can be. "Doctors are by and large

pleasers. They make it through the complex maze of schooling all the way to medical school by figuring out early what people want and providing it." (Lembke 2016 P 104) In this way, physicians tend to go along with patient narratives and over-treat.

156. Conditions resting on entirely subjective assessments like level of pain or gender identity have the most potential for harmful overtreatment. In both cases, patients can easily find out what symptoms to report to obtain the treatment they desire. In the current political climate, physicians feel the pressure to not be assailed as a "gatekeepers", even when logic and data tell them outside social pressures should not distort medical care.

157. Dr. Lembke discusses the modern phenomenon of illness as identity: "Illness identities offer a chance for community." "The adoption of illness identities is driven by the breakdown of traditional social roles. Illness provides a way to define the self in a rapidly changing and increasingly fragmented world. Furthermore, ill persons today are lionized as heroes because they fight a battle against overwhelming physical forces. In a world where the struggle for basic survival (food, clothing, shelter) has become largely irrelevant for most Americans, the ill person is among the last great warriors." (Lemke 2016 P 98)

158. What Lembke points out is critical to the debate regarding gender dysphoria treatments. Community is so important for all of us, but especially

adolescents. There is significant evidence that a lack of socialization, and social struggles are factors which put adolescents at risk for gender dysphoria.

159. Depression and anxiety in adolescents often relate to social struggles and these generally predate the emergence of gender dysphoria. Autism is primarily a social disorder. Many child psychiatrists have expressed to me their experience that patients expressing a transgender or non-binary orientation have tended to struggle socially prior to declaring this orientation.

160. Sweden, England and Finland have all reviewed the evidence and pressed pause. These are countries with medical systems that have better tracking, more organized care and compassionate attitudes toward gender non-conforming persons. As the Finish review stated (PALKO / COHERE Finland 2020): "The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders."

161. After reviews, all countries concluded that restricting care and emphasizing psychotherapy rather than hormones and surgery is the compassionate course. Affirmative treatments are not, in fact, medically necessary. This is true when it comes to the most grave concern of all, suicide. Based on long term data in Sweden, Gender Affirming treatment have not been shown to be life-saving. We do not have convening data that affirmative treatments reduce suicidality, and based

on recent data, we should be especially concerned that it could increase it(Chen 2023).

162. When claims are made that there exists a scientific and medical consensus supporting gender affirming care for gender dysphoria, this rests on the assertions of a small group of physicians who are already personally invested in this type of care. Those already providing hormones and surgeries have extremely powerful reasons to want to believe affirmative care is effective, and thus they are biased. I know psychiatrists involved in this type of care and they are smart, compassionate physicians. I have no doubt they have received significant positive feedback from patients and families. This is consistent with multiple studies showing short term benefit in mood and social dysphoria from affirming treatment.

163. Yet when the enthusiasm for affirming procedures is this celebratory, it is also clear that the detransitioners and other patients with less optimal outcomes will not return to these affirmative providers. We need controlled studies because gender clinics staff's personal experience is thus potentially biased toward the good responders they continue to see, without clear tracking of the rest. Short term positives responses can also be explained by placebo effects, especially under the current conditions where most gender clinics offer multidisciplinary teams providing support and therapy along with hormones and medical procedures.

164. For these many reasons the "gender experts" are not neutral observers. This is why long term controlled studies are needed. Just over two decades ago a previous group of "experts" minimized the risks of opiates when they proposed pain as the 5th vital sign. This turned out to be a large scale social disaster instigated in large part by the medical community. When aligned with economic and ideological forces, a small group of physicians can wield disproportionate influence. The modern medical system does make serious mistakes at scale. We should be taking a cautious approach and encouraging rigorous open scholarly dialogue where physicians who doubt the merits of affirmative gender care can speak freely without being attacked as immoral.

165. Gender roles will always exist, as humans are a sexually dimorphic species. Gender roles are not problems to be solved, but we do need to acknowledge the trade-offs. Much of the ideological and political activism is a reaction against a perception that gender roles are too rigid or stifling. Many young people want more ability to express themselves as they please, and it is agreed that we need to create space for all in our society. Yet the recent overall rise in depression, anxiety and self-harm supports that we are not meeting the needs of our youth. Yet in the debate regarding treatments for gender dysphoria, the medical system should still apply rules of evidence and proceed with caution.

I declare, pursuant to 28 U.S.C. s. 1746, under penalty of perjury that the foregoing is true and correct. Executed this 17th day of February, 2023.

Kristopher E. Kaliebe, M.D.

Attachment "A"

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Medicine and gender transidentity in children and adolescents, Press release of the French National Academy of Medicine February 25, 2022 https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en

Recognizing and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence. August 2021, Position statement 103, Royal Australian and New Zealand College of Psychiatrists https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria

Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors, 2020 https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474

Rafferty J; COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH; COMMITTEE ON ADOLESCENCE; SECTION ON LESBIAN, GAY, BISEXUAL, AND TRANSGENDER HEALTH AND WELLNESS. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Pediatrics. 2018 Oct;142(4):e20182162. doi: 10.1542/peds.2018-2162. Epub 2018 Sep 17. PMID: 30224363.

Press Releases

Retrieved February 6, 2023

https://www.aacap.org/AACAP/zLatest_News/Floridas_Dont_Say_Gay_or_Trans_Law_Stigmatizes_LGBTQ_Youth_Families.aspx

https://www.aacap.org/AACAP/zLatest_News/AACAP_Statement_Opposing_Actions_in_Texas.aspx

https://www.aap.org/en/news-room/news-releases/aap/2022/statement-from-the-american-academy-of-pediatrics-and-the-oklahoma-chapter-of-the-american-academy-of-pediatrics-on-gender-affirming-care/

https://www.endocrine.org/news-and-advocacy/news-room/2022/endocrine-society-opposes-florida-department-of-health-policy-on-gender-dysphoria-treatment

Kristopher Kaliebe, M.D.

Publications

Kaliebe, Kristopher and Adrian Sondheimer. "The media: Relationships to psychiatry and children." *Academic Psychiatry* 26.3 (2002): 205-215.

Kaliebe, Kristopher "Rules of thumb: three simple ideas for overcoming the complex problem of childhood obesity." *Journal of the American Academy of Child & Adolescent Psychiatry* 53.4 (2014): 385-387.

Kaliebe, Kristopher. "Dr Kaliebe Replies", Journal of the American Academy of Child & Adolescent Psychiatry, (2014) 53:10 1134.

Kaliebe, Kristopher "The Future of Psychiatric Collaboration in Federally Qualified Health Centers." *Psychiatric Services* (2016): appi-ps.

Kaliebe, Kristopher, and Josh Sanderson. "A Proposal for Postmodern Stress Disorder." The American journal of medicine 129.7 (2016): e79.

Osofsky, Howard J., Anthony Speier, Tonya Cross Hansel, John H. Wells II, **Kristopher E. Kaliebe**, and Nicole J. Savage. "Collaborative Health Care and Emerging Trends in a Community-Based Psychiatry Residency Model." *Academic Psychiatry* (2016): 1-8.

Yeh, Y. Y. and **K. Kaliebe**. "Impact of Nutrition on Neurocognition." *Southern medical journal* 109.8 (2016): 454.

K. Kaliebe Expanding Our Reach: Integrating Child and Adolescent Psychiatry Into Primary Care at Federally Qualified Health Centers. J Am Acad Child Adolesc Psychiatry. 56.11 (2017)

Kiss, R. and **Kaliebe, K**., Stress and Inflammation: New Perspectives on Major Depressive Disorder. JAACAP Connect, p.22. Winter 2020

Tamburello, A., Penn, J., Negron-Muñoz, R., & **Kaliebe, K**. (2023). Prescribing Psychotropic Medications for Justice-Involved Juveniles. Journal of Correctional Health Care.

Books, Textbook Chapters:

Weigle, P., **Kaliebe, K**., Dalope, K., Asamoah, T., & Shafi, R. M. A. (2021). 18 Digital Media Use in Transitional-Age Youth: Challenges and Opportunities. Transition-Age Youth Mental Health Care: Bridging the Gap Between Pediatric and Adult Psychiatric Care, 357.

Invited Publications

"Telepsychiatry in Juvenile Justice Settings", **K Kaliebe**, J Heneghan, T Kim, Child and Adolescent Clinics of North America, 20 (2011) 113-123

American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Telepsychiatry and AACAP Committee on Quality Issues. Clinical Update: Telepsychiatry With Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2017 Oct; 56(10):875-893. Epub 2017 Jul 25. PMID: 28942810.

Kaliebe, Kristopher and Paul Weigle. "Child Psychiatry in the Age of the Internet." (2017). Child and Adolescent Psychiatric Clinics of North America, April 2018Volume 27, Issue 2, Pages xiii–xv

Gerwin, Roslyn L., **Kristopher Kaliebe,** and Monica Daigle. "The Interplay Between Digital Media Use and Development." Child and Adolescent Psychiatric Clinics 27.2 (2018): 345-355.

CURRICULUM VITAE

Kristopher Edward Kaliebe, MD

Associate Professor
University of South Florida, Morsani College of Medicine, Tampa Florida

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Tampa FL 33613
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kkaliebe@usf.edu

Citizenship

United States

Education

Graduate/Medical: St. George's University
School of Medicine, Grenada, West Indies
Medical Doctor — January 1995- June 1999

Undergraduate: Columbia College,
Columbia University
New York, NY,
Bachelor of Arts, Biochemistry — September 1988-May 1992

Postgraduate Training

Clinical Fellowships:
Fellow, Forensic Psychiatry (PGY6)
Louisiana State University Medical Center
1542 Tulane Ave., New Orleans, LA 70112 — July 2004 to June 2005

Fellow, Child and Adolescent Psychiatry (PGY 4-5)
Louisiana State University Medical Center
1542 Tulane Ave., New Orleans, LA 70112 — July 2002 to June 2004

Chief Resident in Child and Adolescent Psychiatry

- Acted as liaison between Child Psychiatry Fellows and Administration
- Coordinated with Program Director lecture and rotation schedules

July 2003 to June 2004

Residency:

Resident, Psychiatry (PGY 2-3)
University of Medicine and Dentistry-
New Jersey Medical School
185 S Orange Ave, Newark, NJ 07103 July 2000- June 2002

Internship: (PGY 1)
University of Medicine and Dentistry-
New Jersey Medical School
185 S Orange Ave, Newark, NJ 07103 July 1999- June 2000

Diplomate, American Board of Psychiatry and Neurology:

- Board Certification in General Psychiatry, awarded 2004, active
- Specialty Board Certification Child and Adolescent Psychiatry, awarded 2005, active
- Specialty Board Certification Forensic Psychiatry, awarded 2007, active

Awards, Honors, Honorary Society Memberships:

Department of Veterans Affairs Special Contribution Award for Clinical Service in Psychiatry
February 22, 2002

Outstanding Resident Award, Presented at the American Academy of Child and Adolescent Psychiatry, Miami, Florida,
October 17, 2003

Inducted into Berkeley Preparatory School Athletic Hall of Fame, Tampa, Florida,
November 7, 2003

Fellow, Louisiana State University Academy for the Advancement of Educational scholarship
October 2007 – 2016

Best Doctors, Louisiana in the subspecialty of Child and Adolescent Psychiatry
Awarded 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016

Best Doctors, in Tampa Florida
2017, 2018, 2019, 2020, 2021, 2022

Awarded status as a Distinguished Fellow of the American Academy of Child and Adolescent Psychiatry

July 6, 2016

Appointments:

Associate Professor, University of South Florida Medical School, Department of Psychiatry. September 2016 to present

- Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF General Psychiatry Residents and Child and Adolescent Psychiatry fellows who performed assessment, consultation, and treatment.

Tampa General Hospital Psychiatrist on Duty September 2016 to present

Manage the night, weekend and holiday clinical responsibilities of Tampa General Hospital including the over 1000 bed hospital and a 24-hour emergency room. Usually done in partnership with a psychiatric resident from the University of South Florida.

Facility Psychiatrist. Tampa Residential Facility September 2016 to present

- Performed psychiatric evaluations and treatment in Florida's juvenile correctional system. Tampa Residential Facility is the most intensive level of mental health and substance abuse treatment, subcontracted to Truecore Solutions.

Facility Psychiatrist. Les Peters Academy Residential Facility

May 2017 to present

- Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted to Truecore Solutions.

Staff Psychiatrist, Orleans Parish Justice System March 2018 to July 2018

- Performed telepsychiatric evaluations and treatment in Orleans Parish Prison correctional system, subcontracted to Correct Care Solutions.

Facility Psychiatrist. Charles Britt Academy Residential Facility

November 2019 to July 2022

•Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted by Sequel.

Facility Psychiatrist. Columbus Youth Academy Residential Facility

June 2020 to present

•Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted by Sequel.

Louisiana State University Health Science Center Assistant Professor of Clinical Psychiatry July 2005 to June 2017

Louisiana State University Health Science Center Associate Professor of Clinical Psychiatry July 2016 - 2017

Mental Health Medical Director, St. Charles Community Health Center, Luling, Louisiana July 2005 to 2016

- Evaluated and treated a primarily Medicaid and underserved population of adult, child and adolescent patients in a Federally Qualified Health Care Center.

Coordinator for Child and Adolescent Integrated Mental and Behavioral Health Services, Louisiana Mental and Behavioral Health Capacity Project
September 2012 to July 2017

- Performed assessment, consultation, training, prevention, and education services to Federally Qualified Health Centers and community clinics in Coastal Louisiana.
- Evaluated and treat both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist, Back-up coverage, Louisiana Juvenile Justice System July 2016 to September 2022

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system, subcontracted to Wellpath (formerly Correct Care Solutions).
- Back up on call coverage for on-site psychiatrists
- As needed evaluated and treated remote video conferencing equipment (telehealth).

Staff Psychiatrist, Louisiana Juvenile Justice System July 2010 to July 2016

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system, subcontracted to Correct Care Solutions.
- Evaluated and treated both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist on Duty October 2011 to July 2016
Children Hospital, Calhoun Campus. New Orleans, Louisiana

- Facilitated development of protocols and supervision regarding the training of Medical Students, General Psychiatry Residents and Child and Adolescent Psychiatric Fellows who utilize the Calhoun unit as primary training site for Child Psychiatry.
- Manage night and weekend clinical responsibilities for Children's Hospital emergency room and Inpatient Psychiatric Unit, including individually assessing all inpatients each weekend.

Staff Psychiatrist, Louisiana State University Juvenile Justice Program
July 2005 to August 2010

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system at Bridge City Center for Youth and Jetson Center for Youth.
- Evaluated and treated both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist, Florida Parish Juvenile Detention Center,
July 2007 to August 2010

- Performed psychiatric evaluations and treatment using remote video conferencing equipment (telehealth).

Medical Officer on Duty July 2002 to July 2005
New Orleans Adolescent Hospital. New Orleans, Louisiana

- Managed clinical responsibilities of Crisis Intervention Services, a 24-hour emergency mental health response team serving families, children and adolescents from the Southeast Louisiana region.
- Managed two psychiatric inpatient units including a twenty bed adolescent and ten bed children's unit after hours on call.
- On call physician for Crisis Respite, a short term residential facility for children and adolescents located on hospital grounds.

Psychiatrist on Duty September 2003 to July 2005
New Orleans Veterans Administration Medical Center, New Orleans, Louisiana

- Managed clinical psychiatric responsibilities of a 450 bed hospital
- Managed clinical psychiatric responsibilities of a 27 bed inpatient psychiatric unit
- Managed clinical psychiatric responsibilities of 24-hour emergency room

Psychiatrist on Duty September 2001 to June 2002
New Jersey Medical Center Veterans Administration

- East Orange Medical Center, East Orange, NJ

Managed clinical psychiatric responsibilities of 24 hour emergency room along with a 295 bed hospital, 30 Nursing Home and 30 Domiciliary beds.

- Lyons Hospital, Lyons, NJ

Managed clinical psychiatric responsibilities of 356 bed hospital.

Teaching, Lecture

Undergraduate Medical Student

BMS6920.002, BMS6920.001 University of South Florida: Created five session elective: "Mind Body Medicine" Developed as part of University of South Florida medical school elective curriculum from 2017-current. Offered for up to 12 students as a credited elective including study guide, organizing readings, and experiential class learning.
2017 to present

At Louisiana State University Health Science Center New Orleans:

4 one-hour lectures instructing all Medical Students (MS2) in Child and Adolescent mental health during Psychiatry Basic Science block

February 2004 to February 2016

LSU Physical therapy
Annual 2 two-hour lectures on a range of mental health topics annually

2012 to 2016

LSU Public Health
Annual 2 hour lecture on psychopharmacology to incoming Masters Level students in Public Health

2012 to 2016

Graduate Medical Teaching

MEL 8602 C65 M: Child and Adolescent Psychiatry

Child and Adolescent Psychiatry Resident Teaching:

Arranged and co-instructed Forensics Lecture Series, bi-annually 10 lecture hours and 4 hours of individual lectures.

2016 to present.

Teach various topics within residency training. 1 lecture per year.

2016 to present.

University of South Florida General Psychiatry Residency:

Co-Produced elective track for 2 residents per year within University of South Florida Psychiatry Residency. Supervision of Integrative Psychiatry residents within the University of South Florida's Integrative Psychiatry Track, biweekly sessions utilizing curriculum from the Andrew Weil Center for Integrative Medicine**.**

July 2020- present

Forensic Psychiatry Resident Teaching:

Teach child and corrections related forensic topics within residency training. 4 lectures per year.

2018 to present.

LSUHSC New Orleans, General Psychiatry Resident Teaching

- Created and taught one hour weekly (44 weeks per year) Cognitive Behavioral Therapy practicum for PGY 3 residents

2007 to 2016

- One hour lecture on evolution and mood disorder each year for PGY3 residents
  2010 to 2016

LSUHSC New Orleans Child and Adolescent Psychiatry Resident Teaching

- One-hour didactic lectures on psychopharmacology for 8 weeks and cognitive behavior therapy for 4 weeks bi-annually
  2008-2016
- Organized and taught majority of the year-long bi-weekly one hour didactic program entitled Special Topics including a wide range of topics including development, forensic psychiatry, evolution, anthropology, nutrition, effects of technology, electronic media, sleep, exercise and physical activity, wellness and systems of care.
  2008 to 2016

LSU- Kenner Family Practice Residency:
Once yearly didactic lectures for 1 to 2 hours for Kenner Family Practice Residents
2009 to 2016

Created one session Mini-Course: "Optimizing Neurocognition through Nutrition." Developed and co-facilitated a module as part of Goldring Center for Culinary Medicine curriculum for medical students and other trainees with Annie Yeh, MD). Offered as a 1 credit elective for Tulane medical students including study guide, organizing readings, online webinar to be viewed prior to class, case studies during class and test.
2014

At Louisiana State University Health Science Center New Orleans: Core Clinical Psychiatry Rotation Lecture, 1 hour lecture presented to MS3 students every six weeks to 3rd year medical students covering Child Psychiatry Basics.
October 2003 to June 2005

At University of Medicine and Dentistry- New Jersey Medical School, Department of Psychiatry
• Lecture: "The Media and Psychiatry" for General Psychiatry Residents, created as part of the Culture and Psychiatry Seminar
August 2001 and 2002

Teaching, Supervisory

At University of South Florida, Tampa Florida:

Medical Student supervision

University of South Florida - 2017 to present
MEL 8109 L69 M

BCC 7154 002 M Psychiatry / Neurology Clerkship. Medical Students rotation through clinic one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic

Psychiatry Elective, 2 to 4 week Medical Student rotation through Child and Adolescent Psychiatry Silver Center Resident Clinic

Graduate Medical Education Supervision

Child and Adolescent Psychiatry Residency

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF Child and Adolescent Psychiatry residents who performed assessment, consultation, and treatment.

September 2016 to June 2021

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry correctional psychiatry with USF Child and Adolescent Psychiatry residents who observe clinical care in juvenile correctional facilities.

September 2016 to present

General Psychiatry Residency:

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF General Psychiatry Residents who performed assessment, consultation, and treatment.

September 2016 to present

Forensic Psychiatry Resident Teaching

Supervision of forensic psychiatry trainees within the University of South Florida forensic psychiatry training program**.** This includes review of resident competency evaluations along with co-evaluation of criminal defendants as individual cases arise.

2018 to present

At Louisiana State University Health Science Center New Orleans

LSU- Kenner Family Practice Residency:

- One month, once weekly half day mental health rotation at St Charles Community Health Center for all Kenner Family Practice Residents

  2008 to 2016

Clerkship/Residency Directorship:

Child and Adolescent Psychiatry Fellowship Training Director, Louisiana State University Medical Center. Oversaw and supervised resident physician training Managed administrative, evaluation and scheduling issues within the training program Collaborated with Louisiana State University psychiatric faculty to develop policies and procedures at various clinical site.

July 2010 to September 2012

Teaching Awards:

Association for Academic Psychiatry Honorary Fellow

October 2001- October 2002

Louisiana State University Child and Adolescent Psychiatry Department Outstanding Teacher Award for the 2006-2007 academic year

Louisiana State University Child and Adolescent Psychiatry Department Outstanding Teacher Award for the 2015-2016 academic year

Peer to Peer: Institutional Grand Rounds

"The Minds, They are a Changin' – An Overview and Update on MDMA and Psilocybin Grand Rounds University of South Florida Psychiatry Department, Tampa Florida

January 28 2022

"3 Simple Rules for Overcoming Obesity" University of South Florida Endocrinology Department, Tampa Florida

November 9, 2021

"A hard pill to swallow: psychotropic medications in foster care", University of South Florida, Department of Public Health, Tampa Florida

November 3, 2017

"Rules of Thumb: The importance of heuristic and cognitive biases in pediatric physical and mental health" Grand Rounds Children's Hospital, New Orleans

July 30, 2014,

Grand Rounds, Louisiana State University Department of Psychiatry, "Rules of Thumb, lifestyle interventions for mental health professionals." New Orleans, Louisiana

January 23, 2014

"Just say No, the Case against Stimulant Medication" Grand Rounds Children's Hospital, New Orleans, Louisiana

May 19th, 2010

"Violence: Neurobiology, Risk Assessment and Beyond", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana

August 9, 2012

"Is ADHD a Nutritional Disorder", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana

July 28, 2011

"Just say No, the Case Against Stimulant Medication", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana

July 29th, 2010

Grand Rounds Department of Psychiatry, Louisiana State University School of Medicine, New Orleans, Louisiana "The Application of Darwinian Principles to Child Custody Evaluations", New Orleans, Louisiana

May 26th, 2005

"Attention Deficit Hyperactivity Disorder" Grand Rounds Department of Pediatrics, Louisiana State University School of Medicine, New Orleans, Louisiana

May 25th, 2005

"The Media, Our New Social World, How Should Pediatricians Respond?" Grand Rounds, Louisiana State University School of Medicine, Children's Hospital, New Orleans, Louisiana

June 2nd, 2004

"Attention Deficit Disorder" for Louisiana State University Health Science Center Juvenile Corrections Program Continuing Medical Education Presentation via telemedicine New Orleans, Louisiana

March 16th, 2004

"The Media, Relationships to Children and Psychiatry", Grand Rounds, Department of Psychiatry, Louisiana State University School of Medicine, New Orleans, Louisiana

June 4th, 2003

"The Media, Relationships to Children and Psychiatry", Grand Rounds, New Orleans Adolescent Hospital, New Orleans, Louisiana

March 28th 2003

Lectures by Invitation

"The Media, Relationships to Children and Psychiatry" Grand Rounds, University of West Virginia, Charleston, West Virginia, Department of Psychiatry and Behavioral Science

April 10th 2003

"The Media and Child and Adolescent Psychiatry –An Evolving Relationship" Chair and Presenter, Media Theatre, Annual Conference of the American Academy of Child and Adolescent Psychiatry

October 21st, 2004

"The Media, Our New Social World, How Should Health Care Professionals Respond?" Continuing Medical Education Presentation Snowshoe Mountain Retreat, Snowshoe Mountain, West Virginia

September 19th, 2004

"The Application of Darwinian Principles to Child Custody Evaluations" Grand Rounds Department of Psychiatry, University of South Florida, Tampa, Florida

October 31st, 2005

"The Evaluation and Treatment of Traumatized Children and Adolescents with ADHD" Web Cast Presentation and Grand Rounds sponsored by the National Center for Child Traumatic Stress Network's Rural Consortium, New Orleans, Louisiana

January 25th, 2007

"Behavioral Disorder or Traumatized Child?" Louisiana Federation of Families for Children's Mental Health, Children's Mental Health Conference, Houma Louisiana

May 9th, 2008

"Behavioral Disorder or Traumatized Child?" Grand Rounds Tulane University Department of Child Psychiatry, New Orleans, Louisiana

March 13th, 2009

"Brother's Little Helper: The Simpsons Satirizes Stimulant Medication as a Response to Childhood Behavior Problems" Media Theatre, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York Kristopher Kaliebe MD, K. Dalope, MD

October 30, 2010

"Violence Risk Assessment" Louisiana Psychiatric Medical Association Annual Meeting, New Orleans, LA

March 2, 2013,

"Telepsychiatry in Juvenile Justice Settings" part of "Telepsychiatry: Challenges and Successes Across Settings." Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Orlando FL

October 22, 2013

"What are they Missing, When Electronic Media Displaces Sleep, Academics and Exercise" part of **"**Identifying and Treating Internet-Related Mental Health Problems: An Evidence-Based Approach" Clinical Perspectives. Annual meeting of the American Academy of Child and Adolescent Psychiatry, Toronto, Canada

October 24, 2014

"The Implications of the Pharmacological Treatment of Children" Michigan Drug Court Annual Conference, Lansing, Michigan

March 12, 2014

"Three rules to prevent and treat ADHD symptoms" as part of the Louisiana ADHD Symposium, organized by the Louisiana Department of Health and Hospitals ADHD Task Force, Baton Rouge, Louisiana

December 9, 2014

"Non-Pharmaceutical Interventions for ADHD", Invited Professorship: St George's University School of Medicine Complementary and Alternative Medicine Selective, St George's, Grenada, West Indies

August 28 – Sept. 3rd, 2014

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, San Diego, California

October 30, 2014

"The Management of Childhood Obesity" and "Disordered Eating in Children and Adolescents" Oregon Psychiatric Medical Association Conference, Portland, Oregon

February 27 and 28, 2015

"Rules of Thumb: 3 Simple Rules to Optimize Physical and Mental Health" National Alliance for the Mentally Ill Louisiana Annual Conference, New Orleans, Louisiana

April 17, 2015

"ADHD overdiagnosis in Louisiana, a child and adolescent psychiatrist's perspective" Preventing Overdiagnosis Conference, National Institutes of Health (NIH), Bethesda Maryland

September 2, 2015

"An alternative to diagnosis-based practice in pediatric mental health" Preventing Overdiagnosis Conference: National Institutes of Health NIH Bethesda Maryland

September 2, 2015

"Shell Shocked: Growing up in the Murder Capital of America". Discussant for Media Theatre, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Holly Peek, MD, Kristopher Kaliebe, MD San Antonio, Texas

October 29, 2015

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter,

Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, San Antonio, Texas

October 31, 2015

"What are they (we) Missing? When Electronic Media Displaces Sleep, Academics, and Exercise" Grand Rounds University of South Florida Psychiatry Department, Tampa Florida

November 12th, 2015

ADHD overdiagnosis in Louisiana, a child and adolescent psychiatrist's perspective, Louisiana Psychological Association, New Orleans, LA

May 20, 2016

"Rules of Thumb: 3 Simple Rules to Optimize Physical and Mental Health" Crohns and Colitis Association of America Regional Conference, New Orleans, LA,

June 12, 2016

"Evaluating and Assuring the Effective and Safe Use of Psychotropic Medications in Children" Webinar: National Council of Juvenile and Family Court Judges, with Judge Constance Cohen; Janie Huddleston and Dr. Joy Osofsky, Ph.D.

June 24, 2016,

"Psychotropic Medications 101: What Judges Need to Know for Effective Decision Making" Florida Child Protection Summit, with Melinda Sczepanski, Orlando FL

September 9, 2016

"Communicating With the Media and the Public as Child and Adolescent Psychiatrists Around Disaster and Highly Traumatic Events." Workshop, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Media Training Workshop, New York, New York

October 27, 2016

"Evolutionary Biology is a Basic Science for Child and Adolescent Psychiatry" Special Interest Group, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York

October 28, 2016

"Is War Ever Really Over? War-Affected Youth From Home to Host ountry", Discussant, Clinical Perspectives. Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York

October 28, 2016

"Psychotropic Medications 101: The pertinent essentials for all involved in the child welfare system" Florida Child Protection Summit, with Melinda Sczepanski, Orlando, Florida

August 30, 2017

"Safe Use of Psychotropic Medications in Children." 2017 Safe Babies Court Teams Cross Sites Meeting, Fort Lauderdale, Florida

August 17, 2017

"Health Promotion in Pediatric Mental Health" Discussant, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC

October 23, 2017

"New Technologies, New Laws, New Childhood" as part of "Clinical Guidelines for Navigating Media Use" Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC

October 24, 2017

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC

October 26, 2017

"The Business of News, the Role of Child and Adolescent Psychiatrists in the Media, and Risk Communication." Member Services Forum, Annual meeting of the American Academy of Child and Adolescent Psychiatry: Washington, DC

October 27, 2017

"Caught in the net: a child psychiatrist's guide for navigating the internet age.", Workshop, International Association for Child and Adolescent Psychiatry and Allied Professions, Prague, Czechoslovakia

July 27, 2018

Chair, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, "Caught in the Net: How Digital Media Shapes Mental Illnesses in Youth and How Psychiatrists Should Respond." Seattle, Washington

October 24, 2018

"Self-Care in the Child Welfare System" YMCA/Safe Children Coalition Conference, with Catarlyn Glenn, Sarasota Florida

April 18, 2019

"Psychotropic Medications 101: The pertinent essentials for all involved in the child welfare system" Florida Child Protection Summit, with Catarlyn Glenn, Orlando Florida

December 17, 2019

"Caught in the Net: How Digital Media Interacts with Mental Illness in Children and Adolescents", Annual Conference of the Florida Psychiatric Society, Tampa, Florida

September 21, 2019

"Effective Strategies for Higher Education and Beyond" Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Mastering Information Flow for Transitional-Age Youth (TAY): as part of "Promoting Digital Citizenship in Transitional-Aged Youth (TAY) and College Students", Chicago, IL
October 19, 2019

"Caught in the Net: How Digital Media Interacts with Mental Illness", virtually presented at the Andrew Weil Center for Integrative Medicine, Tucson, Arizona
April 1, 2020

"A deeper dive into child and adolescent psychopharmacology for families and professionals involved in the child welfare system" Florida Child Protection Summit, with Catarlyn Glenn. Orlando, FL
September 3, 2020

"Screenagers: Next Chapter – How Online Behaviors Affect Depression and Anxiety Disorders in Adolescents", Media Theater (virtual) Annual meeting of the American Academy of Child and Adolescent Psychiatry
October 19, 2020.

"Helping Child Psychiatrists Navigate the Internet Age", "Career Focus: Setup Your Own Telepsychiatry Practice", "COVID-19 Related Psychiatric Issues"
Oasis Child and Adolescent Psychiatry Conference, Charleston, SC
May 17, 2021

"Conversation about health information, COVID, news, and related topics", discussant and breakout group leader, Digital Media and Mental Health Research Virtual Retreat
May 24th 2021

"The Social Dilemma: Helping Families Navigate the Pull, Pulse, and Power of Social Media", Media Theater, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual
October 29, 2021

"Appealing Applications for Adolescent Mental Health: Social Media's Transformation During the COVID-19 Pandemic", Discussant, Clinical Perspective, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual
October 25, 2021

"Angry Young Men, Common Threads in Different Types of Extremist Groups" as part of Political Extremism & Hate Group Recruitment of Adolescents", Clinical Perspective, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual
October 26, 2021

"Angry Young Men: Boys and Adolescent Males with Disruptive and Aggressive Behavior", "Nutritional Child Psychiatry" Oasis Child and Adolescent Psychiatry Conference, Charleston, SC

May 1st / 2nd, 2022

"Sexts, Lies & Videogames: Adolescent Boys, the Internet, & Mental Health" Chair and presenter on violence and young men: Clinical Perspective, Annual Meeting of the American Academy of Psychiatry Annual Meeting, New Orleans, LA

May 25, 2022

Clinical Activities or Innovation

Licensure:

Louisiana State Medical License, expires December 31st, 2022
Florida Medical License, expires January 31st, 2024

Federal DEA Controlled Substances License 12/31/2023
Louisiana license for Controlled Dangerous Substances expires 10/1/2022
Certification: ECFMG Certificate 0-573-532-9

Forensic Training:

Florida Forensic Examiner Training completed through the University of South Florida Department of Mental Health Law and Policy

August 15-17, 2019

Certifications in Psychotherapy:

Basic Practicum in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY

July 13, 2003

Advanced Practicum in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY

July 20, 2003

Associate Fellowship in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY,

July 15, 2005

Accelerated Resolution Therapy, Basic Training

April 1-3, 2017

Accelerated Resolution Therapy, Enhanced Training

Sept 31, October 1, 2018

Accelerated Resolution Therapy, Advanced Training
October 2,3, 2018

American Association of Medical Colleges Medical Education Research Certificate
October 13th, 2010

Scholarly Activity

Funded block grants

Co-investigator on the Mental and Behavioral Health Capacity Project from September 2012 to June 2017

Unfunded research

Supervisor mentoring Medical Students:

University of South Florida IRB: Faculty Advisor Co Investigator May 2021

What is the impact of coronavirus confinement on Japanese college students' mental health? Ivana Radosavljevic STUDY002335

University of South Florida IRB: Faculty Advisor Co Investigator May 2021
Changes in college aged students' metabolic health due to Covid-19 confinement Matthew Udine, STUDY002341

PI as student supervisor, STUDY004118, IRB approved as Exempt Status, Palliative Care Patients' Attitudes & Openness to Psilocybin assisted Psychotherapy for Treatment of Existential Distress, Julia Wang

Journal Publications:

Peer Reviewed

Kaliebe, Kristopher and Adrian Sondheimer. "The media: Relationships to psychiatry and children." *Academic Psychiatry* 26.3 (2002): 205-215.

Kaliebe, Kristopher "Rules of thumb: three simple ideas for overcoming the complex problem of childhood obesity." *Journal of the American Academy of Child & Adolescent Psychiatry* 53.4 (2014): 385-387.

Kaliebe, Kristopher. "Dr Kaliebe Replies", Journal of the American Academy of Child & Adolescent Psychiatry, (2014) 53:10 1134.

Kaliebe, Kristopher "The Future of Psychiatric Collaboration in Federally Qualified Health Centers." *Psychiatric Services* (2016): appi-ps.

Kaliebe, Kristopher, and Josh Sanderson. "A Proposal for Postmodern Stress Disorder." The American journal of medicine 129.7 (2016): e79.

Osofsky, Howard J., Anthony Speier, Tonya Cross Hansel, John H. Wells II, **Kristopher E. Kaliebe**, and Nicole J. Savage. "Collaborative Health Care and Emerging Trends in a Community-Based Psychiatry Residency Model." *Academic Psychiatry* (2016): 1-8.

Yeh, Y. Y. and **K. Kaliebe**. "Impact of Nutrition on Neurocognition." *Southern medical journal* 109.8 (2016): 454.

K. Kaliebe Expanding Our Reach: Integrating Child and Adolescent Psychiatry Into Primary Care at Federally Qualified Health Centers. J Am Acad Child Adolesc Psychiatry. 56.11 (2017)

Kass, R. and **Kaliebe, K**., Stress and Inflammation: New Perspectives on Major Depressive Disorder. JAACAP Connect, p.22. Winter 2020

Case Reports, Technical Notes, Letters

Books, Textbook Chapters:

Weigle, P., Kaliebe, K., Dalope, K., Asamoah, T., & Shafi, R. M. A. (2021). 18 Digital Media Use in Transitional-Age Youth: Challenges and Opportunities. Transition-Age Youth Mental Health Care: Bridging the Gap Between Pediatric and Adult Psychiatric Care, 357.

Papers in Press:

Accepted for publication: Prescribing Psychotropic Medications for Justice-Involved Juveniles, Journal of Correctional Health Care, A Tamburello, J Penn, R Negron-Muñoz, **K Kaliebe**

Invited Publications

"Telepsychiatry in Juvenile Justice Settings", **K Kaliebe**, J Heneghan, T Kim, Child and Adolescent Clinics of North America, 20 (2011) 113-123

American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Telepsychiatry and AACAP Committee on Quality Issues. Clinical Update: Telepsychiatry With Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2017 Oct; 56(10):875-893. Epub 2017 Jul 25. PMID: 28942810.

Kaliebe, Kristopher and Paul Weigle. "Child Psychiatry in the Age of the Internet." (2017). Child and Adolescent Psychiatric Clinics of North America, April 2018Volume 27, Issue 2, Pages xiii–xv

Gerwin, Roslyn L., **Kristopher Kaliebe,** and Monica Daigle. "The Interplay Between Digital Media Use and Development." Child and Adolescent Psychiatric Clinics 27.2 (2018): 345-355.

Other Research and Creative Achievements:

Poster Presentations:

"Collaborative Child and Adolescent Psychiatry within Primary Care Clinics in Coastal Louisiana" Poster, Annual meeting of the American Academy of Child and Adolescent Psychiatry, **Kristopher Kaliebe MD**, Joy Osofsky, PhD; Howard Osofsky, MD, PhD; Lucy King, BA; Tonya Hansel, PhD, San Antonio, TX

October 29, 2015

"Benefits of Integrating Young Child Psychiatric Services Into Primary Care Clinics in Underserved Communities" Poster, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, NY Joy Osofsky, PhD; Howard Osofsky, MD, PhD; Lucy King, BA; Tonya Hansel, PhD, **Kristopher Kaliebe MD**

October 28, 2016

"Integrating child and adolescent psychiatry into community based primary care networks", Poster, International Association for Child and Adolescent Psychiatry and Allied Professions, Prague, Czechoslovakia **Kristopher Kaliebe MD**

July 25, 2018

" The Prevalence of the Adverse Childhood Experiences (ACE) in Florida Youth Referred to the Department of Juvenile Justice" Poster, Annual meeting of the American Academy of Psychiatry and the Law, Greg Iannuzzi, MD, Mark Greenwald, PhD**, Kristopher Kaliebe MD**

October 25, 2018

Other articles:

"LSU's *Breakfast Club* emphasizes education and recruitment into Child and Adolescent Psychiatry", American Academy of Child and Adolescent Psychiatry News,

January 2004

"Trix are for Kids!", American Academy of Child and Adolescent Psychiatry News,

May, 2013

Expanded Psychiatric Care Can Transform Federally Qualified Health Centers, American Psychiatric Association News,

..... Published online June 17, 2016

News Stories on Suicide, Fictional Content may Increase Risk for Contagion, Hansa Bhargava and **Kristopher Kaliebe**, American Academy of Pediatrics News, *Mastering the Media Column*,

Published online July 10, 2019

Webinars and creation of enduring materials:

Rules for Optimal Health, Webinar, University of South Florida Quality Parenting Initiative, Florida's Center for Child Welfare Information and Training Resources for Child Welfare Professionals, released
..... December 11, 2017

Florida's Center for Child Welfare Information and Training Resources, webinars series on pediatric mental health for child welfare professionals and caregivers, Kristopher Kaliebe with Catarolyn Johnson;
..... June 1, 8, 15, 22 and 29, 2020

"Don't just sit there- Adapt and Optimize in a post Covid world" University of South Florida Global Health Conversation Series, presented virtually
September 22, 2020

Service

Membership in Professional Organizations:

Member, American Academy of Child and Adolescent Psychiatry (AACAP),
2000 to present

AACAP Media Committee member
2003 –2021

C0-Chair, AACAP Media Committee
2013-2021

Media Committee Liaison to the Complementary and Integrative Medicine Committee of the AACAP
2012 to 2019

Liaison to the Committee on Communications and Media of the American Academy of Pediatrics, from American Academy of Child and Adolescent Psychiatry (AACAP)
2015 to present

Member Association for Behavioral and Cognitive Therapies
2004 – 2016

Member American Academy of Psychiatry and the Law
2004 to present

Member Zero to Three

2017 to 2021

Member Louisiana Council for Child Psychiatry (LCCP)
2003 to 2016

Louisiana Council for Child Psychiatry (LCCP)

Secretary-Treasurer
March 2010-March 2014

President
March 2014- June 2016

Member, American Psychiatric Association
2000 - 2012 , 2021 to present

LSUHSC Psychiatry Interest Group Faculty advisor
2008 to 2012

University of South Florida Medical School Integrative Medicine Student Interest Group faculty advisor
January 2020 to present

University of South Florida Medical School Mindfulness and Meditation in Medicine Group faculty advisor
January 2022 to present

University of South Florida Interdisciplinary (university wide) Psychedelics Interest Group faculty advisor
March 2022 to present

Editorial Posts and Activities:
Journal editorships, Reviewer

LSUHSC Institutional Review Board alternate reviewer 2008-2012

Safety Committee Member, Accelerated Resolution Therapy for Treatment of Complicated Grief in Senior Adults, University of South Florida
2017-19

Expert reviewer for *Adolescent Psychiatry* Thematic Special Issue: Coming of Age Online: Challenges of Treating the Internet Generation: (2), 4, 2014

Expert reviewer for *Academic Psychiatry* Media Column June 2018

Expert Reviewer for *Pediatrics* January 2021

Expert reviewer for *Academic Psychiatry* Media Column March 2022

Expert Reviewer for *Harvard Review of Psychiatry* May 2021

Co-editor: Kaliebe, Kristopher, and Paul Weigle. Youth Internet Habits and Mental Health, An Issue of Child and Adolescent Psychiatric Clinics of North America, E-Book. Vol. 27. No. 2. Elsevier Health Sciences. 2018

Member, Planning Committee for the Digital Media and Mental Health Research Retreat hosted by the nonprofit Children and Screens.
May 24th, 25th 2021.

Revised: October 2022

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.

Case No. 4:22-cv-00325-RH-MAF

REBUTTAL EXPERT REPORT OF QUENTIN VAN METER, M.D.

I, Quentin Van Meter, M.D., declare that the facts contained herein are true and correct to the best of my knowledge and belief, and that the opinions expressed herein represent my own.

Introduction

1. I have been asked by counsel for the Defendants to respond to the expert report of Dr. Johanna Olson-Kennedy.

2. I received my B.A. in Science from the College of William and Mary and my M.D. from the Medical College of Virginia, Virginia Commonwealth University. I am currently a pediatric endocrinologist in private practice in Atlanta, Georgia. I am the President of Van Meter Pediatric Endocrinology, P.C. I am on the clinical faculties of Emory University School of Medicine and Morehouse College of Medicine, in the role of adjunct Associate Professor of Pediatrics. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Georgia since 1991. I have been previously licensed to practice medicine in California, Louisiana, and Maryland.

3. I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his

Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children, adolescents, and adults, but I am focusing this report on working with children and adolescents.

4. The bases for my opinions expressed in this report are my review of Dr. Olson-Kennedy's report dated February 16, 2023, my professional experience as a pediatric endocrinologist, and my knowledge of the pertinent scientific literature, including those publications listed in the attached bibliography.

5. A list of my publications is included in my curriculum vitae, which is attached as Exhibit "A" hereto.

6. Over the past four years, I have testified at trial and/or deposition in the following cases:

- 2019: Multiple Plaintiffs v. State of Ohio Bureau of Records, Columbus, Ohio, deposed.
- 2020: Loughman v. Loughman, Harris County, Texas, deposed, court testimony.
- 2021: Spahr v. Spahr, St Louis County, Missouri, court testimony.
- 2021: Laura Cauthen v. James Cauthen, Cobb County, Georgia, court testimony.

7. I am being compensated at an hourly rate for actual time devoted, at the rate of $350 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

Response to Dr. Olson-Kennedy

8. In paragraph 1 on page 8 of her report, Dr. Olson-Kennedy wrongly states that gender identity "has a strong biological basis." To the contrary, there is no biologic basis for gender identity.[1] Genetic markers have been evaluated but there is no statistical significance between genomic sequences in trans-identified individuals compared to the sequences of non-trans humans of the same sex.[2,3] MRI studies on human adults do not show an identifiable female or male brain.[4] A study purporting to show a female configuration of the brain in trans female patients was marred by the small sample size and inability to reproduce the findings[5] and the differences reported can be explained by neuroplasticity.[6]

9. The term gender has crept into the vernacular as a replacement for the word sex. Gender originally was a linguistic term describing nouns as either masculine or feminine in a number of languages. It was actually John Money who introduced the term gender identity as the internal sexed self in 1955.[6] This contradicts this statement in paragraph 1 of Dr. Olson-Kennedy's opinion, suggesting that it was coined by Robert J. Stoller some 9 years later. Dr. Olson-Kennedy states that gender identity and gender are the same, when that is not the case if sex and gender are used interchangeably.

10. Contrary to the suggestion in paragraph 8 of the report, there is absolutely no spectrum to biologic sex. Sex is binary. Individuals with disorders of sexual differentiation are not a third sex.[8] Mosaicism can occur in varying degrees, but the patient remains either male or female, not both. In my clinical

experience over 42 years of practice, none of my hundreds of DSD patients have experienced any gender identity confusion. The same Endocrine Society whose guidelines say "biologic sex" is a term that should not be used subsequently published a statement that biologic sex is a necessary determinant of human propensity for disease, and that it is necessary to understand the response to therapeutic interventions.[9]

11. In paragraph 10 on page 12 of her report, Dr. Olson-Kennedy refers to the World Professional Association of Transgender Health's (WPATH's) Standards of Care version 8 (SOC 8). However, "SOC 8" are not indeed standards of care, by definition, since there is clearly no consensus of opinion For example, Drs. Kenneth Zucker and Paul McHugh are internationally recognized experts in the field of human sexuality and yet their contrary viewpoints were not discussed or included in "SOC 8".

12. As Dr. Olson-Kennedy notes in paragraphs 11 and 12, the WPATH "SOC 7" served as the template for the recommendations of the Endocrine Society, the Pediatric Endocrine Society, the UCSF guidelines and the position statement of the American Academy of Pediatrics. However, she fails to note that all of the recommendations were essentially the product of authors in leadshipe positions within WPATH. The recommendations are not uniformly supported by members of those other organizations. The American Academy of Pediatrics' 67,000 members were not consulted. The Endocrine Society sent their standards out for comment to membership before approval, but they did not

acknowledge the input or make any changes based on our objections. The Pediatric Endocrine Society requested input from membership with a warning that suggestions like those we made to the Endocrine Society would not be considered. The leadership of the American Academy of Pediatrics called to question the wisdom of that organization's 2018 policy statement.[10]

13. The vast amount of publications which exist, including the DSM-V[1] and the Handbook of Human Sexuality published by the American Psychological Association indicate gender identity is fluid and can change.[11] There are over 11 published studies which clearly prove that desistance occurs in children who have been allowed to proceed uninterrupted through natural puberty ranging 50-98 percent of the time.[1,12,13,14,15,16,17,18,19,20,21] In-depth mental health evaluation of the patient, the family, and those in close contact with the patient and subsequent counseling to resolve pathology is truly beneficial and most often effective.[22]

14. In paragraph 14 on pages 13-14 of her report, Dr. Olson-Kennedy incorrectly suggests that my report attached to the GAPMS determination somehow endorsed what she calls "conversion," "redirection," and "corrective" therapy. Nowhere in my report do I state that I endorse conversion or redirection therapy. Those are her terms, not mine. Instead, I outline the use of extensive in-depth evaluation of the mental health of the patient, parents, and siblings and assessment of the adverse childhood events to which the patient was exposed. The term conversion therapy is used pejoratively to suggest that allowing the patient to examine their underlying mental health issues is somehow converting

a male or female patient, when recommended counseling is indeed just addressing the mental health morbidities to facilitate healing the patient.

15. In paragraph 16 of her report, Dr. Olson-Kennedy expands on a topic never mentioned by me and refers to "people like me" who advocate "redirection" therapy. But my report never mentions "redirection" therapy. She refers to my statement on the recommended use of counseling as unethical and ineffective. In doing so, she refuses to acknowledge the consequential body of literature in peer-reviewed journals which shows the beneficial outcomes that result from counseling.[22,23,24,25,26] She also stands against her own referenced documents (Endocrine Society Guidelines and WPATH SOC 7) which state that first and foremost, mental health evaluations and counseling must be done before any social, medical, or surgical interventions are considered. The American Academy of Pediatrics' policy statement does clearly state that any kind of counseling is unethical, but it came under fire for that.[27,28]

16. In paragraph 17 on pages 15-16 of her report, Dr. Olson-Kennedy's version of wait-and-see suggests that once puberty starts, medical intervention follows immediately, whereas wait-and-see has been used by others to describe waiting until *completion* of puberty at the age of consent, since by that time the vast majority of patients have desisted.

17. In paragraphs 18, 19, and 20 on pages 16-18 of her report, Dr. Olson-Kennedyattempts to make her treatment plans sound compassionate and other treatment plans sound barbaric. She is wrong in stating that there is no goal to

affirm any specific outcome. Why would anyone socially transition a child if their goal were not to follow on with medical, and then surgical transition. The director of the transgender clinic in Columbus, Ohio stated, under oath, that she was unaware of any patients who dropped out from that pathway.[29] Dr. Olson-Kennedy's statement that there is no data to support the automaticity of the intervention cascade is true because there is no transparency of full data from any of the transgender care centers. Her theory that social affirmation in pre-pubertal patients does not lead to medical and surgical interventions during puberty is false.[13]

18. Dr. Olson-Kennedy's claim in paragraph 21 on page 18 of her report that treatment is individualized is not substantiated by data from each transgender center, again with a complete lack of transparency.

19. Dr. Olson-Kennedy refuses to recognize that patients with gender dysphoria have undercurrent mental health issues. Patients referred to me with the diagnosis of gender dysphoria have undercurrent depression and/or anxiety that historically preceded the gender dysphoria. The published literature suggests that a conservative estimate for undercurrent mental health issues is 70%. Data are hard to extract because there is no uniformity or transparency to the protocols used in the transgender clinics in the United States. The recent published data from the NIH study clearly point that out. Each of the four study centers had different consent forms and the study design was an observation of the response to interventions at four independent sites.[30] This was the explanation used to

explain why there was no central uniform design or accountability to an Institutional Review Board (IRB).

20. GnRH super-agonists (puberty blockers) interrupt signaling to the gonads and thereby suppress the innate gonadal steroid production. The "Dutch protocol" (cited in paragraph 24 on page 20 of Dr. Olson-Kennedy's report) started pubertal suppression in Tanner stage III (average age 14 years), but never before age 12 (which is the average age of onset of menstruation in females). This intervention is suggested to be used as a "pause" at the very onset of puberty (stage II) by the Endocrine Society Guidelines.[13] However, the pause in U.S. transgender clinics is often for as little as a month.[31] Delayed puberty is a reason why adolescents seek endocrine consultation because of the social consequences that surround delay. It is the most common reason we see adolescent boys for evaluation of short stature.

21. In paragraph 24 on page 20 of her report, Dr. Olson-Kennedy refers to the use of GnRH super-agonist therapy in the FDA-approved indication for precocious puberty and cites the safety data and the reversible nature of such treatment. That is comparing apples to oranges. Stopping puberty in the adolescent age range and then overlapping cross-sex hormones in supraphysiologic dosing is a completely different circumstance. It is an open-ended experiment involving minors with no competent oversight or control. The release of data from Australian and European centers has shown no diminution of gender dysphoria and worsening of mental health, causing their governments

to intervene and stop such therapy[32,33,34,35,36,37,38]. As for using age as a criteria for any intervention, the most recent version of guidelines from WPATH ("SOC 8") eliminates use of age as a determinant of when to intervene socially, medically or surgically.[39]

22. As to paragraphs 25-32 on pages 21-24 of Dr. Olson-Kennedy's report, the "growing body of evidence" of purported benefits of pubertal suppression in regard to the mental health of the adolescents comes from studies of what is called convenience sampling. This describes using survey data obtained by advertising through advocacy sites such as the Trevor Project or the U.S. Transgender Survey to anyone with an interest in the survey subject matter. This inherently biases the nature of the survey participants. People who experienced significant regret or who died as a result of their efforts to transition are not likely to respond. Those who do respond provide answers that cannot be verified. These data bases show potential correlation at best, but prove no direct causation.[40] Unlike blocking precocious puberty, blocking puberty during the adolescent time frame causes irreversible loss of calcium accretion to the skeleton and affects the development of the brain and the gonads.[41] Without knowing if these latter two issues are reversible if the patient chooses to cease suppression of puberty later on, continued use is, once again, an uncontrolled experiment involving minors who cannot ethically consent. The "dark places of despair" she describes are just buried deeper as a result of the false sense of security. The frontal lobe of the teen brain is unable to see the folly of short term gains that

result in long-term losses.[38] Blocking puberty does indeed change the landscape: it leads the patients to cross-sex hormones 100% of the time in the Dutch transgender clinics.[43] The N.I.C.E. review highlighted a clear lack of scientific proof of any benefit from suppressing natural puberty during adolescence, and the UK banned the general use of puberty blockers due to documented worsening of mental health.[44]

23. Beginning with paragraph 32 on page 24 of her report, Dr. Olson-Kennedy discusses cross-sex hormones. Cross-sex hormones are indeed used to transform the appearance of the body to look like the opposite sex. Again, the fact that 100% of children who have puberty blocked also go on the cross-sex hormones points out clearly that the "case-by-case" assessment is really not that at all. The adolescent cannot really consent to a process that induces life-long medical morbidity, including sterilization. The only full population study that has been published indicated that medical intervention did not reduce mental health morbidity after extended periods of time.[45] It is clearly not surprising that there is initial euphoria in females treated with testosterone. There is an increase in physical and emotional energy and a sense of reaching a goal as the physical changes begin to occur. But those who detransition are left with these subsequently unwanted and irreversible physical changes. What starts out as euphoric energy can easily turn into extreme anxiety. The clear risk of cancers, strokes, and heart disease among other pathologies, not to mention infertility, is

widely known. An adolescent minor cannot fully understand or consent to the long-term problems caused by seeking short term "gains."

24. The study referenced in paragraph 39 of Dr. Olson-Kennedy's report included two years of data and is flawed by the death of three patients by suicide.[30] Any independent review board would have halted the study in its tracks with such serious adverse events as death of study participants, especially with a study population already suffering from depression and anxiety. It is also flawed because regret and detransition is known to occur much later than two years after interventions begin. The only truly valid data from long-term studies comes from the two population studies which showed no improvement in mental health over the long run.[45,46]

25. Dr. Olson-Kennedy's opinions about surgical intervention in paragraphs 44 to 46 on pages 28-29 of her report are belied the Branstrom and Djheine studies, which clearly demonstrated that when followed for long-enough periods of time, surgical intervention did not improve mental health.[45,46,47]

26. The "SOC 8" referenced in paragraph 47 on page 30 of her report clearly states that its recommendations are merely guidelines. They are not true standards of care in the legal sense.

27. In paragraph 48 on page 32 of her report, Dr. Olson-Kennedy states that gender-affirming medical interventions are recognized as "medically necessary" by many major medical organizations. However, the guidelines were written by special interest groups within medical organizations, mostly members

of WPATH (8 of the 9 authors of the 2017 revision), reflecting the opinion of WPATH and not the whole of the membership of those organizations. Contrary opinions are suppressed or ignored.[11] Good science involves evolution of thought which considers all data, not just selected, affirming data.

28. In paragraph 40 on page 27 of her report, Dr. Olson-Kennedy simply dismisses the influence of social media. In my experience, patients were convinced they had gender dysphoria because of the online influence to which they were exposed. A Google search that I performed identified 482,000,000 entries on the subject. Troubled adolescents, struggling for acceptance by peers or for some sense of celebrity have existed forever, but social media now presents them with a one-size-fits-all solution which offers acceptance and celebrity instantly. Before the advent of social media, transgender teens turned to parental support and counseling, which resolved their gender identity confusion 60-98% of the time.[22]

29. At least half of my patients were recruited by transgender or non-binary individuals. There is no published data because, once again, there is no transparency about data collection protocols in the transgender centers in the U.S. The studies Dr. Olson-Kennedy cites to "prove" a biologic basis are limited by small numbers and no ability to prove causation.

30. In paragraph 52 on page 32 of Dr. Olson-Kennedy's report, the actual data reported by Zucker, collected before any exposure to medical or social

interventions, showed desistance if the patients were followed through completion of puberty.[22]

31. In paragraph 54 on pages 33-34 of her report, Dr. Olson-Kennedy attempts to draw a distinction between Gender Identity Disorder and Gender Dysphoria to discredit certain studies cited in the GAPMS report. Like Gender Dysphoria, Gender Identity Disorder was based on mental health morbidity as a key part of the diagnostic criteria. Failing to recognize this, Dr. Olson-Kennedy wrongly suggests that these patients did not suffer from gender dysphoria. The name change was just that—a name change.

32. In paragraphs 57 on pages 34-35 and paragraph 64 on page 38 of Dr. Olson-Kennedy's report, she mentions a subset of patients who do not present until adolescence, but then turns around in paragraph 58 and denies that Dr. Lisa Littman's cohort of studied patients could possibly exist and be called, instead, adolescent-onset patients. In fact, upwards of 80% of children presenting with gender incongruence are female (compared to 30% ten years ago) and that of those, the majority are teenagers with no history of gender incongruence in young childhood. Although she dismisses Littman's 2019 study[48,49], the data that Littman collected was not retracted in the accepted revision of her article—the conclusions were the same, but the terminology was revised.

33. In paragraph 65 on page 39 of her report, Dr. Olson-Kennedy explains that the increased incidence of gender incongruence is due to the increased social acceptance from reduction of social stigma. The overwhelming

increase in the number of patients presenting to Tavistock is what caused the NHS to take a deeper look at what caused the rise, and lessening social stigma was clearly shown not to be the cause.[50] What makes data collection nearly impossible in the U.S. is the utter lack of transparency about what goes on behind closed doors. The magnitude of increase in incidence can only be truly ascertained by opening the files of the transgender treatment centers at which time data can be obtained by independent monitors.

34. In paragraph 70 on page 42 of her report, Dr. Olson-Kennedy recognizes the need for longitudinal studies, which have been called for by the original and revised version of the Endocrine Society Guidelines.[13] More importantly, such studies should be rigorous and have a control group. She incorrectly assumes that any random controlled trial is blinded, which clearly is not possible or necessary. She expresses dismay about the probable dropout potential, but does not mention the high dropout rates in the Dutch protocol study which is the foundation upon which transgender clinic protocols are ostensibly built.[51] There has been recent criticism by one of the authors or the Dutch protocol that what he gleaned from having a glimpse inside the U.S. clinics was that his protocol was not actually being followed.[52] Dismissing the need for a randomized control group based on the theory that patients in the control arm will die from suicide is insupportable, since there is published evidence that counseling alone is highly effective in resolving gender dysphoria.[22] It is also obvious that no IRB would even consider allowing a treatment arm in a study that

would include reported complications such as sterility and decreased sexual function, let alone increased risk of heart disease, stroke, and cancer.[53]

35. In response to paragraphs 87-89 on pages 49-50 of Dr. Olson-Kennedy's report, evidence-based medicine is practiced when all sides of a medical issue are researched, and the results graded independently. Evidence-based medicine supports standards of care. It is abused when only some evidence is used, and especially when that evidence is indirect opposition to existing evidence and subsequently published evidence. The GRADE system interprets data to determine the degree to which the recommendations are evidence-based medical practices. The Endocrine Society Guidelines in both iterations failed miserably. SOC7 failed the evidence-based test entirely.[54]

36. Dr. Olson-Kennedy's discussion in paragraphs 91 to 93 on pages 50-51 of her report regarding off-label use of medication compares apples to oranges. There are medications which are used off label because of published studies showing benefit and clear lack of harm, but there is no desire for the manufacturer to apply for FDA approval due to the complexity and cost of doing so, especially when there is no future compensatory return on investment. Puberty blockers were studied for safety and efficacy and their ability to prevent progression of secondary sex characteristics and stall bone maturation in patients with precocious puberty. The drugs passed muster in their ability to do such and were therefore approved by the FDA, with a proviso that the study patients be followed longitudinally indefinitely to monitor for any signals of harm. One such signal

was announced recently and has been added to the product insert of puberty blocking medications used for treatment of precocious puberty.[55] The manufacturers of puberty blockers have not engaged in clinical research studies about the safety and efficacy of puberty blockers in gender incongruent children and adolescents despite the fact that they would profit if these drugs were FDA-approved for such.

37. In response to paragraph 96 on pages 53-54 of Dr. Olson-Kennedy's report, it is a bit self-serving that WPATH recommends multidisciplinary staffing for transgender clinics, all of whom follow its recommended guidelines. It is clear from the history of the Tavistock Clinic that if you do not follow the WPATH protocol or if you call out the harm the WPATH protocol generates, you are not considered to be a part of "the team."[56]

38. In response to paragraphs 99 to 100 on pages 54-55 of Dr. Olson-Kennedy's report, the "growing body of evidence" of purported benefits of pubertal suppression in regard to the mental health of the adolescents comes from studies of convenience sampling involving the retrospective memories of those who chose to answer the surveys. These data bases have been used repeatedly by the authors who cherry pick the recalled memories of participants in an attempt to prove a point. The surveys failed to verify the mental health status of the participants at any point in time by independent examination. They show no direct causation.[57,58,59,60,61] Heretofore, no reputable editor would accept such studies for publication in peer-reviewed journals.

39. Paragraphs 104 to 105 on pages 56-57 of Dr. Olson-Kennedy's report provide another case of apples vs. oranges: the studies of young people with precocious puberty show full recovery of function after two years off therapy. Dr. Olson-Kennedy mentions not using the puberty blockers for longer than two years, thereby admitting the relentless continuum of puberty blockers followed by cross-sex hormones in the U.S. gender clinics—once again proving the pause theory to be mythical. The precocious puberty patients are not in adolescence, which is when calcium accretion is critical.

40. In response to paragraph 108 on page 59 of Dr. Olson-Kennedy's report, supraphysiologic levels of hormones are always prone to cause severe side effects, regardless of whether the patient is experiencing gender dysphoria or not. That proves that they are never appropriate.

41. In response to paragraph 112 on page 60 of her report, Dr. Olson-Kennedy completely ignores the phenomenal published experience of Kenneth Zucker's behavioral interventions because they do not fit the narrative reflected in her report. In fact, desistance has been documented with behavioral health interventions in Canada and Europe since the 1980s. [1,12,13,14,15,16,17,18,19,20,21]

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed this 10th day of March 2023.

/s/ Quentin Van Meter

Quentin Van Meter, M.D.

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38. https://www.engage.england.nhs.uk/specialised-commissioning/gender-dysphoria-services/user_uploads/b1937-ii-interim-service-specification-for-specialist-gender-dysphoria-services-for-children-and-young-people-22.pdf
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42. Paul W. Hruz, Lawrence S. Mayer, and Paul R. McHugh, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," *The New Atlantis*, Number 52, Spring 2017, pp. 3-36
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Exhibit A

QUENTIN L. VAN METER, M.D. **updated 5 March, 2023**
1800 Howell Mill Road NW, Suite 475
Atlanta, Georgia 30318 **(678) 961-2100**

PERSONAL

Home Address:	26 Paces West Drive NW, Atlanta GA 30327
Home Phone:	(404) 963-5618
Date of Birth:	September 13, 1947
Place of Birth:	Laramie, Wyoming
Citizenship:	USA

EDUCATION:

Undergraduate:	College of William & Mary, 1969 B.S. – 1969
Medical School:	Medical College of Virginia, 1973 M.D. – 1973

CLINICAL TRAINING:

Institution:	The University of California, San Francisco
Hospital:	Naval Regional Medical Center, Oakland
Position:	Pediatric Intern – 1973 – 1974 Pediatric Resident – 1974 – 1976
Institution:	Johns Hopkins University
Hospital:	Johns Hopkins Hospital
Position:	Fellow, Pediatric Endocrinology 1978 – 1980 Fellowship Program Director: Claude Migeon, M.D.
Current Position:	Pediatric Endocrinologist Van Meter Pediatric Endocrinology, P.C. 1800 Howell Mill Road, Suite 475 Atlanta, Georgia 30318

PROFESSIONAL CERTIFICATION & SOCIETIES:

Diplomate, National Board of Medical Examiners, 1974

American Board of Pediatrics, certified in general pediatrics, 1978, sub-board certified in Pediatric Endocrinology, 1983

Fellow:	American Academy of Pediatrics, Georgia Chapter 1975 -present President, Uniformed Services West Chapter, 1987 – 1990 District VIII member, AAP Committee on Awards for Excellence in Research, 1990-1994 Editor, The Georgia Pediatrician, 1994 – 1998
	Chairman, Georgia Chapter Legislative Committee, 1996 – 2006
Fellow:	The American College of Pediatricians, 2007 – present Member of the Board of Directors, 2008- present Immediate Past President
Member:	Pediatric Endocrine Society, 1989 – present
Member:	American Diabetes Association Professional Section, 1988 – present
Member:	Endocrine Society, 1994-present
Member:	Southern Pediatric Endocrine Society, 1992 – Present
Member:	American Association of Clinical Endocrinologists, 2005 – 2022
Licensure:	Georgia, #34734

FACULTY POSITIONS:

Institution:	Morehouse School of Medicine
Position:	Associate Clinical Professor, Pediatrics, 2004 – present
Institution:	Emory University School of Medicine
Position:	Adjunct Associate Professor, Pediatrics, 1991 – 2020
Institution:	University of California, San Francisco
Position:	Associate Clinical Professor, Pediatrics, 1989 – 1991
Institution:	University of California, San Diego, School of Medicine
Position:	Assistant Clinical Professor, Pediatrics, 1980 – 1986
Institution:	LSU School of Medicine, Clinical Instructor, Pediatrics, 1977 – 1978

MILITARY SERVICE:

Commission:	Medical Corps, United States Navy, August 1971
Rank:	Captain, retired
Duty Stations:	Health Professional Scholarship Student, 1971 – 1974
	Intern and Resident, Pediatrics, Naval Regional Medical Center, Oakland, 1973 – 1976
	Staff Pediatrician, Naval Regional Medical Center, Oakland, 1976

Staff Pediatrician, Naval Regional Medical Center,
New Orleans, 1976 – 1978

Full time out-service fellow in Pediatric Endocrinology,
Johns Hopkins Hospital, 1978 – 1980

Staff Pediatric Endocrinologist, Naval Hospital San Diego,
1980 – 1986

Chairman and Director, Residency Training, Department of Pediatrics
Naval Hospital Oakland, 1986 – 1991

OTHER PROFESSIONAL ACTIVITIES:

Consultant, Pediatric Endocrinology,
Nellis Air Force Base Hospital, Las Vegas, Nevada
1981 – 1991

Consultant, Pediatric Endocrinology,
Naval Hospital Lemoore, CA
1986 – 1991

Consultant, Pediatric Endocrinology,
Letterman Army Medical Center, Presidio of San Francisco, CA
1990 – 1991

Consulting Endocrinologist,
Columbus Regional Medical Center, Columbus, GA
1991 – 1994

Pediatrician and Pediatric Endocrinologist, partner
Fayette Medical Clinic
Peachtree City, Georgia 30269
September 1991 – October 2003

Speaker's Bureau
Novo Nordisk
Eton Pharamceuticals
AAP Eqipp course on Growth- development committee- 2012

PUBLICATIONS: (Articles in Peer Reviewed Journals)

Riddick, JR, Flora R., Van Meter, QL:
"Computerized Preparation of Two-Way Analysis of Variance Control Charts for Clinical Chemistry," Clinical Chemistry, 18:250, March 1972.

Van Meter, QL, Gareis FJ, Hayes, JW, Wilson, CB:
"Galactorrhea in a 12 Year Old Boy with Chromophobe Adenoma," J. Pediatrics 90:756, May 1977.

Plotnick, LP, Van Meter, QL, Kowarski, AA, "Human Growth Hormone Treatment of Children with Growth Failure and Normal Growth Hormone Levels by Immunoassay: Lack of Correlation with Somatomedin Generation: Pediatrics 71:324, March 1983.

Brawley, RW, Van Meter, QL, "Mebendazole Ascaris Migration," W.J. Med, 145:514015, October 1986.

Van Meter, QL, "The Role of the Primary Care Physician in Caring for Patients with Type-1 Diabetes," Comp Ther 1998; 24(2):93–101

Midyett LK, Rogol AD, Van Meter QL, Frane J, and Bright GM, "Recombinant Insulin-Like Growth factor (IGF)-I Treatment in Short Children with Low IGF-I Levels: First-Year Results from a Randomized Clinical Trial," J Clin Endocrinol Metab, 2010;95:611–619.

Laidlaw MK, Van Meter QL, Hruz PW, Von Mol A, and Malone WJ, Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," J CLin Endo Metab 2019;104: 1-2.

Van Meter QL, Bringing Transparency to the Treatment of Transgender Persons, Issues in Law and Medicine 2019:34;147-152.

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ABSTRACTS/LETTERS:

Van Meter,Q L, & Lee, PA: "Evaluation of Puberty in Male and Female Patients with Noonan Syndrome," Pediatric Research 14:485, 1980.

Van Meter, QL, et al: "Characterization of Pituitary Function in Double Bolus GnRH Infusion as a Diagnostic Tool," Pediatric Research 32:111, 1984.

Van Meter, QL, Felix, SD, Lin, FL: "Evaluation of the Pituitary-Adrenal Axis in Patients Treated with nasal Beclomethasone," (Presented at the 1991 Annual Meeting of the Endocrine Society and the 6th Annual Naval Academic Research Competition, Bethesda, MD, 17 May, 1991).

Rogol AD Midyett LK Van Meter Q, Frane J, Baily J, and Bright GM, Recombinant Human IGF-1 for Children with Primary IGF-1 Deficiency (IGFD): Safety Data from Ongoing Clinical Trials (presented at the PAS 2007, Toronto).

Van Meter Q, Midyett LK, Deeb L et al, Prevalence of primary IGFD among untreated children with short stature in a prospective, multicenter study (Poster POO715) ICE Rio de Janeiro, Brazil 2008.

G.M. Bright[1], W.V.Moore[2], J.Nguyen[3], G. Kletter[4], B. S. Miller[5], Q. L. Van Meter[6], E. Humphriss[1], J.A. Moore[7] and J.L. Cleland[1] Results of a Phase 1b Study of a new long-acting human growth hormone (VRS-317) in pediatric growth hormone deficiency (PGHD). PAS 2014 May 2014

Van Meter Q, Welstead B and Low J, Characteristics of a Population of Obese Children and Adolescents: Suggesting a New Paradigm, presented at ESPE meeting, Dublin 2014.

Wayne V. Moore[1], Patricia Y. Fechner[2], Huong Jil Nguyen[3], Quentin L. Van Meter[4], John S. Fuqua[5] , Bradley S. Miller[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], Safety and Efficacy of Somavaratan (VRS-317), a Long-Acting rhGH, in Children with Growth Hormone Deficiency (GHD): 3-Year Update of the VERTICAL & VISTA Trials, presented at the 2017 Endocrine Society meeting in Orlando FL

Bradley S. Miller[1], Wayne V. Moore[2], Patricia Y. Fechner[3], Huong Jil Nguyen[4], Quentin L. Van Meter[5], John S. Fuqua[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], 3-Year Update of the Phase 2a and Long-term Safety Studies (VERTICAL and VISTA) of Somavaratan (VRS-317), a Long-acting rhGH for the Treatment of Pediatric Growth Hormone Deficiency, presented at the 2017 IMPE meeting in Washington D.C.

ADDITIONAL PRESENTATIONS/LECTURES:

Pediatrics Update, CME Associates, San Diego – Orlando Annual Conferences: Lectures on Pediatric Endocrine Subjects – 1986 – 2001. Course Moderator, 1997, 1998, 1999, 2000, 2001

Endocrine and Gastroenterology Update, CME Associates, Maui HI Nov 2001, Lecturer and Course Moderator

Lecture on Panhypopitutarism, Pharmacia Conference, Nashville TN April 2002.

Family Medicine Review Course, Orlando, FL, 1992 – 2001

Pediatric Grand Rounds, Tanner Medical Center, October 1997

Pediatric Grand Rounds, Hughes Spaulding Children's Hospital, September, 2003

Pediatrics in the Park, Fall CME meeting for the Georgia Chapter of the American Academy of Pediatrics, November 2003

Pediatric Grand Rounds, Columbus Regional Medical Center, January 2004

Frontiers in Pediatrics CME Course, sponsored by the Atlanta Children's Health Network, Atlanta, March 2004.

Pediatric Grand Rounds, Eggleston Children's Hospital, May 2004.

Sue Schley Matthews Pediatric Conference, Columbus Regional Medical Center, September 2004

56th Annual Scientific Assembly and Exhibition of the Georgia Academy of Family Physicians, Nov 2004

Program Co-Chairman: Southern Pediatric Endocrine Society Annual meeting, Nov 2004, November 2014

Presentations on Diabetes, Growth Failure, and Thyroid Disease to the Postgraduate Pediatric Nurse Practitioner Program, Georgia State University, Nov 2005, June 2006, May 2007

Issues in Medicine, US Medical Congress Conference and Exhibition, Las Vegas, meeting planner and speaker, June, 2006

CME Presentations for the Georgia Chapter of the American Academy of Pediatrics Spring and Fall Meetings 2004-present

Pediatric Grand Rounds, Columbus Regional Medical Center, Columbus, GA, 2011-present

Human Growth Foundation Regional CME Conference, Atlanta GA March 2013, February 2014 Columbus Georgia

International Federation of Therapeutic Counseling Choice: Transgender Medicine, IFTCC Launch, October 15, 2018 London, Third International Congress, October 25 2018 Budapest.

Southern Pediatric Endocrine Society, Orlando FL, Feb 2019

Matthew Bulfin Conference, Indianapolis IN April 2019

CMDA annual conference, Ridgecrest NC, May 2019

Support 4 Family conference, London, UK June 2019

Audio Digest Pediatrics - ① v. 41, no. 4; ② v. 41, no. 20; ③ v. 43, no. 17

Audio Digest Family Practice - ① v. 42, no. 5; ② v. 44, no. 11; ③ v. 44, no. 44; ④ v. 45, no 15

Audio Digest Otolaryngology - ① v. 32, no. 14

CURRENT HOSPITAL APPOINTMENTS:

Eggleston/Scottish Rite Children's Hospitals, active staff, Pediatric Endocrinology

PAST AND CURRENT CLINICAL RESEARCH:

2006	Sanofi-Aventis HMR1964D/3001	study completed 2007
2006	Tercica MS301-	study completed 2008
2007	Tercica MS310-	study completed 2008
2007	Tercica MS306-	study completed 2010
2007	Tercica MS316-	study completed 2012
2008	EMD Serono 28358	study completed 2009
2012	Versartis 12VR2	study completed 2014
2012	Debiopharm 8206-CPP-301	study started July 2012
2013	Versartis 13 VR3	study started Dec 2013
2014	Novo-Nordisk Elipse	study started 2014
2015	Versartis 14 VR4	study completed 2017
2017	Mannkind MKC-TI-155	study completed 2019
2018	Abbvie M16-904	study started 2018
2019	Novo-Nordisk Real-4	study started 2019
2019	Lilly 18B-MC-ITSB	study started 2019
2021	Pfizer PROGRES	study started 2021

2021	Lumos OragrowtH210	study started July 2021
2022	Novo-Nordisk Real-8	study started July 2022

LEGAL EXPERT WITNESS:

2017	North Carolina Legislature- transgender bathroom bill
2018	Jessica Siefert transgender case, Cincinnati, OH
2018	Alberta, Canada school system transgender case
2018	Decatur GA School Board transgender case
2019	British Columbia transgender case
2019	Gavin Grimm transgender case, Gloucester County, VA
2019	Rowe vs Isle of Wight School Board, UK
2019	Younger transgender case, Dallas, TX
2020	Alabama State House and Senate committee hearings
2020	Pennsylvania State House Health Subcommittee hearings
2020	Iowa State House committee hearing
2020	California State House committee hearing
2020	Harris County TX custody case
2021	Missouri State House committee hearing
2021	NAACP *v* State of Arkansas
2022	Seifert Civil Suit affidavit
2022	development of Florida GAPMS
2022	testimony before Florida State Medical Board
2023	testimony before Idaho legislative hearing
2023	testimony prepared for Kansas state legislative hearing

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

EXPERT REPORT OF SOPHIE SCOTT, PH.D.

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my curriculum vitae, which includes a list of my publications, is attached as Exhibit A to this report.

2. I have testified as an expert witness in the following cases, at trial or in deposition in the last four years: Bell v Mrs A vs Tavistock and Portman Trust, Case No: CO/60/2020, December 2020.

3. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

4. The opinions expressed in this report are based on my training and experience as a neuroscientist, my reading and my assessment of the relevant neuroscientific literature on brain development, and the potential effects of gonadotropin-releasing hormone (GnRH) agonists (the most common form of what are often called puberty blockers) on the developing brain.

5. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

Introduction

6. I am the Director of University College London's (UCL's) Institute of Cognitive Neuroscience. I have published over 130 peer reviewed scientific papers, including papers in Nature, Science, and the Proceedings of the Academy of Natural Sciences. I am a fellow of the Academy of Medical Sciences, and of the British Academy. Since my PhD was awarded in 1994, I have been working in cognitive neuroscience, a scientific field that examines the relationships between human behaviour to the human brain, and how these can be affected by age, disease and individual differences. *See* Attached Curriculum Vitae.

7. As a neuroscientist I am very familiar with the existence of variations of sexual preference, and the existence of variations in gender identity. I think that the anecdotal evidence we have suggests that transition may, for some younger people, be an effective treatment for gender dysphoria, and that the medical approaches taken to achieve this may therefore be appropriate. Thus is it entirely possible that the use of puberty blockers is appropriate in some exceptional cases of gender dysphoria in prepubescent and adolescent individuals. My concern is that we do not yet have enough evidence about the best ways to identify the individuals for whom they are appropriate: we have not identified any biological markers or other characteristics to identify individuals for whom GnRH antagonists might provide effective; we do not have any reliable studies that show which young gender dysphoric individuals will remain gender dysphoric after adolescence; and we thus do not yet know who might benefit from

this highly medicalised and largely non-reversible treatment. I am also very concerned that the implications of the effects of puberty blockers on the developing brain and body are not well understood. In both of these areas much more research is needed.

8. All cultures recognise the onset of adolescence as the start of the entry into the adult world: it is a journey into that world, and a journey that takes place over several years. In 2005 the US supreme court, influenced partly by this emerging neuroscience research, increased the minimum age for capital punishment to be the same as that for voting and serving on juries. Around the world, many such limitations on the responsibility for teenagers for their own actions are in place – alongside laws which mean that teenagers could not engaging in risky behaviours that could place them or others at risk or having to live with long terms consequences (e.g. ages for driving, drinking alcohol, age of consent, getting a tattoo). Much of this reflects a lay understanding of what neuroscience is now confirming – there is variation from child to child, but teenage brains on the whole are structurally and functionally different from adult brains, and this affects both their engaging with risky behaviour, and their understanding of the implications of risky behaviour.

9. The human brain is formed of approximately 89 billion brain cells, or neurones, most of which are grown during gestation (Bayer et al. 1993; Rakic 1995). Following birth, there is a further period of extended brain development. Directly after birth, the brain grows rapidly, quadrupling in size

between birth and age 6, when it is roughly 90% the size of an adult brain. However the pattern of growth is underpinned by some complex changes that are occurring. These are:

- Synaptic pruning
- Myelination of different brain networks
- Differential growth of specific functional and anatomical areas.

10. Before I go into this in detail it's important to note that brain cells, or neurones, are formed of a cell body, with a long projection (an axon) and branch-like shorter projections (dendrites) from the cell body or from the far end of the axon. The axons can be thought of as ways the neurone can connect to more distant neurones, while the dendrites connect to nearby neurones. These connections are called synapses. Changes in the brain – associated with learning and development - occur largely through the connections between neurones, which can be through the strengthening of existing connections, or through the development of new dendritic connections. The axons are coated in a slim fatty sheath, called myelin: this enables the electrical discharges that enable transfer of information in the brain to be propagated rapidly along the length of the axon. Myelination is a process that increases the speed and efficiently of neural function. Neurones are highly organised in the brain, with the cell bodies forming structure layers on the surface of the brain (the cortex), as well as in sub cortical nuclei of cell bodies: the axons form tracts of connections between cortical areas, to and from sub cortical areas, and between the two hemispheres of the brain.

These tracts look white, due to the fatty myelin sheaths: this leads to the name 'white matter' for these tracts or connective networks. In contrast, the unmyelinated neuronal cell bodies look grey, hence the term 'grey matter'.

11. At birth and in early infancy, many dendritic connections exist and are created between neurones: this is known as *synaptic exuberance*. In the early years of life these are rapidly pruned, at first quickly, then more slowly. During adolescence a more adult profile of synaptic connections starts to appear: this appears most slowly in prefrontal fields compared to sensory and is still not established fully at age 18yrs (Huttenlocher and Dabholkar, 1997). The relationship between synaptic exuberance and pruning and their implications for the developing brain and experience are still being explored, but in terms of brain connectivity, the adult pattern is not yet established at 18: development continues into the early 20s.

12. Myelination in the human brain begins in visual brain areas a couple of months before birth and continues in other sensory brain areas over the first year. This process continues in other cortical and subcortical systems into the middle of the third decade. This has been expressly linked to the development of cognitive skills in children and adolescents, as myelination greatly improves the speed of condition of neurones, and hence their efficiency. Myelination proceeds in a roughly caudal to rostral direction in the brain, which means form back to front. This means that it is frontal and prefrontal fields that are those continuing to be myelinated into the mid 20s: this has been confirmed by more recent studies

looking at fractional anisotopy in the brain (Lebel et al., 2008). At 18yrs old, the connections to the frontal lobes are not myelinated like a mature adult brain, and this is likely to affect frontal lobe functions.

13. Throughout childhood, the brain grows and changes: this involves a non-linear pattern of change in the proportion of white and grey matter, which may partly involve changes in myelination (see above) and also the loss of cells through cell death (Sowell et al. 2004). A recent study looking at this pattern into adolescence found that "First, we found evidence for continued development of both intracranial volume (ICV) and whole brain volume (WBV) through adolescence, albeit following distinct trajectories. Second, our results indicate that CGMV is at its highest in childhood, decreasing steadily through the second decade with deceleration in the third decade, while CWMV increases until mid-to-late adolescence before decelerating" (Mills et al, 2016). This indicates that considerable changes are still happening in the structure of the adolescent brain. In terms of specific brain areas, while the cortex continues to thin through adolescence, the decreases are most marked in the parietal lobes and least marked (or growth is seen) in temporal and prefrontal fields (Tamnes et al, 2017).

Implications

14. The pattern of maturation of the brain in adolescence suggests a particular issue with frontal lobe functions – the frontal and temporal lobes are showing a different pattern of change (in terms of movement towards adult profiles) compared to more caudal fields, and the frontal lobes are the last to be

fully myelinated. The frontal lobes are associated with complex cognitive control processes, so called 'meta-cognitive processes' that enable us to plan our behaviour, control our responses, to be able to adapt our behaviour to different contexts and requirements, and to anticipate the implications and consequences of behaviour. The absence of mature frontal lobe connectivity and functions has been linked to increased impulsivity and risk-taking in adolescence, and to their greater susceptibility to peer opinions and behaviour (Blakemore and Robbins, Nature Neuroscience, 2012). Functional imaging studies – addressing how brains function under different task requirement – have shown that while adults recruit frontal lobe networks during decision making tasks, teenagers are more likely to recruit 'limbic networks" i.e. sub cortical networks linked more to emotional processing and reward processing: the implication is that the differential integrity of frontal lobe connectivity leads to teenagers making different, more risky decisions than adults, and relying on different brain networks to do so. This is backed up by behavioural studies showing that when decision making is 'hot' (i.e. more emotional), under 18yr olds make less rational decisions than when the responses are being made in a colder, less emotional context.

15. Puberty blockers (specifically, gonadotrophin-releasing hormone agonists) work by preventing the release of gonadotrophin-releasing hormone from the hypothalamus. Gonadotrophin releasing hormones have many effects, including stimulating the gonads (testes and ovaries) to produce testosterone and oestrogen. In childhood, the level of Gonadotrophin releasing hormones is very

low, but an increase in this prompts the onset of puberty, with the release of testosterone and oestrogen; these in turn have masculinising or feminising effects on the bodies and the brain. As puberty is associated with very marked changes in the structure of the brain (as outlined above) the use of puberty blockers may have serious consequences for the development of the human brain. We know from studies on sheep (Nuruddin et al, 2013) that treatment around the onset of puberty with gonadotrophin-releasing hormone agonists is associated with significant differences in the size of the amygdala (found to be larger in treated animals) and this was linked to some differences in emotional reactions. The male treated sheep showed greater approach responses and more risk taking behaviours, while the treated female sheep showed higher levels of anxiety and greater avoidance behaviour (Wojniusz et al, 2011). A behavioural study of natal girls who were treated for precocious (early) puberty with Gonadotrophin releasing hormone agonists (Wojniusz 2016) found that they also showed significant greater emotional reactivity on one of the tests used, relative to the control group. The treated girls also showed significantly lower heart rates than the untreated control group. In a commentary on this article (Hayes, 2017) it was pointed out that there were also notably lower scores on IQ measures and sub scales in the group of girls who were treated with Gonadotrophin releasing hormone agonists. He points out that “their reassuring statement in the abstract that girls undergoing GnRHa treatment for CPP and controls “showed very similar scores with regard to cognitive performance” and their conclusion that

"GnRHa treated girls do not differ in their cognitive functioning ... from the same age peers" (Wojniusz et al., 2016) may be overly optimistic. These statements minimize the fairly substantial difference found in IQ scores" (Hayes, 2017). Hayes also points to an older study that found a significant drop in IQ associated with taking triptorelin acetate to treat precocious puberty (Mul et al, 2001). Note that in all of these cases, in humans and other mammals, we cannot say if the results are due to direct effects of the Gonadotrophin releasing hormones on the brain, heart and behaviour, or if they are secondary to this (e.g. due to the altered levels of testosterone or oestrogen, or changes in the heart rate itself). All the papers I can find suggest that we need much more data on the long-term brain effects of Gonadotrophin releasing hormones when administered around puberty, the effects this can have on behaviour, and the extent to which any of this is altered if the treatment with Gonadotrophin releasing hormones is stopped.

16. I am very concerned that the current treatment regime is exposing young people to significant risk of harm. The greater susceptibility to peer pressure in those under 18 may make them especially vulnerable to risk taking, and this may well be enhanced by social media, where actions can be encouraged without any responsibility for outcomes. We need more research to be able to determine the potential for puberty blockers to be effective in alleviating some aspects of gender dysphoria, and to be able to differentiate those who might be helped by this treatment from those who will not. Furthermore, given the risks of puberty blocking treatment, and the fact that these will have irreversible, lifelong

effects, it is very possible for an adolescent to be unable to fully grasp the implications of puberty-blocking treatment, even if the risks are well explained. All the evidence we have suggests that the complex, emotionally charged decisions required to engage with this treatment are not yet acquired as a skill at this age, both in terms of brain maturation and in terms of behaviour.

I declare, pursuant to 28 USC § 1746, under penalty of perjury that the foregoing is true and correct. Executed on February 16th, 2023.

/s/ Sophie Scott
Sophie Scott, Ph.D.

Exhibit "A"

PROF SOPHIE KERTTU SCOTT CBE, FMEDSCI, FBA

Date of Birth: 16-11-1966
Address: Institute of Cognitive Neuroscience, UCL, 17 Queen Square, London, WC1N 3AR
email: sophie.scott@ucl.ac.uk

CURRENT POSITION

2019 – Director, Institute of Cognitive Neuroscience, University College London

EDUCATION/QUALIFICATIONS

1994 University College London, PhD in Cognitive Science
1990 Polytechnic of Central London, BSc (Hons) 2:1, Psychology

PROFESSIONAL HISTORY

1993-1998 MRC Applied Psychology Unit, Cambridge, Senior Scientific Officer
1998-2001 Research Fellow, Institute of Cognitive Neuroscience, UCL.
2001-2005 Wellcome Career Development Fellow, Dept. Psychology, UCL
2004 - Group Leader, Speech Communication Lab
2006- Professor of Cognitive Neuroscience, UCL
2005-2016 Wellcome Trust Senior Fellow, Institute of Cognitive Neuroscience
2013-2019Deputy Director, Institute of Cognitive Neuroscience, UCL
2019 – Director, Institute of Cognitive Neuroscience, University College London
I took maternity leave between June 2006-June 2007.

PRIZES AND RECOGNITION

2022 Awarded an Honorary degree by the University of Westminster
2021 awarded the Michael Faraday prize by the Royal Society
2020 appointed Commander of the Most Excellent Order of the British Empire for services to Neuroscience
2019 Royal Literature Society "Reading Matters" prize, for "The Neuromantics", my podcast with poet and writer Dr Will Eaves
2017 presented the Royal Institution Christmas Lectures
2017 Royal Society Summer Science Exhibition, "What's in a Voice?"
2016 elected as a Fellow of the British Academy
2016-2018 UCL TEDx License holder

2015 spoke at the annual TED conference, Vancouver (talk has been viewed over 4.4 million times on TED.com).
2015 gave Prize Lecture at the Physiology Society meeting, Cardiff.
2014 included in Who's Who
2013 won UCL Provosts' Award for Public Engagement (grade 8 and above category).
2012 Royal Society Summer Science Exhibition, "LOL: Science and Art of Laughter"
2012 Elected as Fellow of the Academy of Medical Sciences
2003 Royal Society Summer Science Exhibition, "Science of Speaking"

SUPERVISION OF GRADUATE STUDENTS

Since 2002, 14 PhD students supervised at UCL, and 35 MSc students at UCL, 2 at City University and one at the University of Reading

EDITORIAL WORK

2015 – associate editor for *The Psychologist* (British Psychological Society monthly journal).
2009 – 2014 Editorial Board of *Cognitive Neuroscience*
2010 – 2013 Section Editor, Language, *Neuropsychologia*
2008 – 2015 Associate Editor of *Brain and Language*
2004 –2009 Associate Editor of the *Quarterly Journal of Experimental Psychology*

MANAGEMENT AND FACILITATION

2020 - PALS Director for EDI
2015 – member, PALS Academic Careers and Diversity Committee
2015-2019– chair of ICN Public Activities Committee
2014 – 2019 deputizing for Prof Neil Burgess (ICN Director) at Faculty of Brain Sciences' Faculty Executive Committee meetings
2004 – representing the Speech Communication Group at the ICN Group Leader's committee

JUDGING AND COMMITTEES

2022 - member of ILCB advisory board
2019- Chair of Board of Trustees, Told By An Idiot theatre company (https://www.toldbyanidiot.org/about/)
2017- 2022 member of the Royal Society Dorothy Hodgkin Fellowship Committee
2015- associate Editor of the Psychologist and Digest Policy Advisory Committee, British Psychological Society

2015 Judge, Comment Awards
2015, 2018 Judge, Philip Leverhulme Prize
2014 Judge, Wellcome science writing prize
2013- Trustee, Jericho House theatre company (registered charity number 1131984)

EXTERNAL EXAMINING

2009-2012 External Examiner, BSc Psychology, University of Sussex
2009-2013 External Examiner, MSc Cognitive Neuroscience, University of York
2015-2019 External Examiner, BSc Psychology, University of Reading

TEACHING

2011-2014 Course convener, "Theories and Paradigms in Cognitive Neuroscience" UCL MSc in Cognitive Neuroscience.
2015- Module Convener, "Science Communication for Cognitive Neuroscientists" UCL MSc/MRes in Cognitive Neuroscience.
2023- Module Convener, "Power, Inclusion, Exclusion and Working with local communities".

GRANTS

Wellcome Trust Hub award development funding, for 'Talking Funny', £13000 over 18 months
Wellcome Trust Public engagement award, for "What's in a Voice" exhibit at the Royal Society Summer Science Exhibition, £20,000 over 12 months.
Wellcome Trust People Award for public engagement activities: for LOL event at the Royal Society, awarded 2012, amount £19,000 over 12 months.
Wellcome Trust Senior Fellowship, awarded April 2010 "Neurobiology of speech communication - cognition, plasticity, and social interactions" total amount awarded £1,184, 506, over 60 months.
Wellcome Trust Senior Fellowship, awarded May 2004 'the Neurobiology of Speech Perception – Cognitive and Clinical Links'. Total amount awarded £800,270, over 60 months.
Wellcome Trust RCDF grant, from April 2001-April 2005, 'the Neurobiology of speech perception'. Total amount awarded £358,376, over 48 months.
Marie Curie Incoming Scientist Fellowship, awarded November 2004, sponsoring Narly Golestani, £100,914 over 24 months.
ESRC grant awarded for new post doctoral researchers, sponsoring Charlotte Jacquemot, awarded May 2004, £30,919 awarded over 12 months.
ESRC grant awarded for new post doctoral researchers, sponsoring Patti Adank, awarded May 2005, £31,591 awarded over 12 months

ESRC +3 studentship award, awarded May 2004 (supervising Carolyn McGettigan)
British Academy meetings award, for the John Morton Festschrift, £2000
Experimental Psychology Society research seminar award, for the John Morton Festschrift, £3000
British Association for the Advancement of Science award for Key events in National Science and Engineering Week, 2008, £1000

ACADEMIC SUPERVISION

2001 -2004 Supervised Charvy Narain, the research assistant on my Wellcome RCDF award. Charvy was awarded a PhD in 2003 and took a job as an editor at Nature Neuroscience: she is now a Scientific Outreach Manager at the University of Oxford.
2002 -2006 supervised Disa Sauter, a research student in the Dept. Psychology at UCL. Disa passed her PhD viva without corrections in December 2006, and currently holds her a lecturer position at the University of Amsterdam..
2004 -2005 Supervised Dr. Charlotte Jacquemot, a post-doctoral fellow. Charlotte has been awarded a permanent CNRS position in France, which she began in 2006
2004 - 2012 supervised Carolyn McGettigan, a research student in the Dept of Human Communication Sciences. Carolyn passed her PhD viva without corrections in March 2008, was employed as a post-doctoral fellow on my Wellcome SRF grant until 2012 when she left to take up a lectureship at RHUL. She is now a Professor at UCL.
2005 -2006 supervised Dr. Patti Adank, a post-doctoral fellow. Patti is now a Professor at UCL.
2005 -2008 Supervised Dr Frank Eisner as a post-doctoral fellow on my Wellcome SRF award. Since January 2009, Frank held post-doc position at the Max-Planck-Institute for Psycholinguistics in Nijmegen, and is now a researcher at the Centre for Cognition of the Donders Institute for Brain, Cognition and Behaviour.
2005 -2007 Supervised Dr. Jonas Obleser as a post-doctoral fellow on my Wellcome SRF award. Since April 2007, Jonas has held a Junior Staff Scientist position at the Max Planck Institute for Human Cognitive and Brain Sciences, Leipzig, Germany, where ran his own research group: he is now a Professor at the Department of Psychology, University of Lübeck.
2005-2007 supervised Dr. Narly Golestani, a post-doctoral fellow, who now heads the Brain and Language Lab at the Cognitive Science Hub of the

University of Vienna, Austria, and at the Department of Psychology at the University of Geneva, Switzerland.2008 -2009 – supervised Nicholas Abreu, who has a Fulbright Scholarship to work in the UK for a year. Nicholas started medical school at Harvard in September 2009.
2009 - 2013 Dr Zarinah Agnew appointed as a post-doctoral fellow on my Wellcome SRF grant. Zarinah now works at UCSF as a post-doc in John Houde's lab.
2010 -2015 supervised Pradheep Shanmugalingam as an ESRC funded PhD student. Pradheep is now training in simultaneous translation.
2012 - 2015 supervising Kyle Jasmin as a PhD student on the UCL/NIH program (NIH supervisor Alex Martin). Kyle joined my lab as a post-doctoral fellow and then was awarded a a Leverhulme research fellowship at Birkbeck: he is now a lecturer at Royal Holloway UL.
2012 -2013 Nadine Lavan joined my lab as an RA for 12 months. Nadine left to take up a PhD place at RHUL: she now holds a Wellcome Fellowship at QMUL.
2013 - Supervising Sophie Meekings as an ESRC funded PhD student. Sophie was awarded a BA fellowship at Newcastle University, and was awarded a Dorothy Hodgkin fellowship in 2021, held at University of York.
2013 - Supervising Sinead Chen as a PhD student funded by a grant from the Taiwanese Government. Sinead now works for a policy think tank in Taiwan.
2013 -2015 Samuel Evans joined my lab as a post-doc on my Wellcome SRF grant. Now a lecturer at the University of Westminster
2013 – 2014 Dana Boebinger joined my lab as an RA. Dana left in August 2014 to start a PhD at Harvard, she is now a post do at the University of Rochester.
2015 – 2016 César Lima joined my lab as a senior post-doctoral fellow on my Wellcome SRF grant. César Lima is Assistant Professor of Psychology at Iscte - University Institute of Lisbon since 2017.
2017- Qing Cai joined my lab as a PhD student with funding from the Chinese government from 2018.
2017- Alexis Deighton McIntyre joined my lab as a PhD student with a UCL Graduate School studentship. In October 2021 she joined the MRC CBU as a postdoctoral researcher.
2018-Addison Billings joined my lab as a PhD student
2019 - Efe Caswell Niven joined my lab as a PhD student

SCIENTIFIC PUBLICATIONS-*REFEREED ARTICLES*

1. Scott, SK, Jasmin, K (2022) Rostro-caudal networks for sound processing in the primate brain, Frontiers in Neuroscience, 16, 1076374, 10.3389/fnins.2022.1076374
2. Scott, SK, Cai, CQ, Billing, A (2022) Robert Provine: the critical human importance of laughter, connections and contagion. Philosophical Transactions of the Royal Society B-Biological Sciences, 377(1863) 20210178 10.1098/rstb.2021.0178
3. Scott, SK (2022) Why public engagement is important for neuroscientists. Nature Reviews Neuroscience, 23(8):453-4.
4. MacIntyre, AD, Scott, SK (2022) Listeners are sensitive to the speech breathing time series: Evidence from a gap detection task. Cognition, 225, 105171 10.1016/j.cognition.2022.105171
5. Conde, T, Correia, AI, Roberto, MS, Scott, SK, Lima, CF, Pinheiro, AP (2022) The time course of emotional authenticity detection in nonverbal vocalizations, Cortex, 151:116-132.
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7. Billing, ADN, Scott, SK (2022) Possible limitations of perceptual studies for informing production networks-The case of laughter. Cortex, 148: : 218-221.
8. MacIntyre, AD, Cai, CQ, Scott, SK (2022) Pushing the envelope: Evaluating speech rhythm with different envelope extraction techniques, Journal of the Acoustical Society of America. 151(3):2002:2026.
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11. Pinheiro, AP, Anikin, A, Conde, T, Sarzedas, J, Chen, S, Scott, SK, Lima, CF (2021) Emotional authenticity modulates affective and social trait inferences from voices. Philosophical Transactions of the Royal Society B-Biological Sciences 376: 20200402.
12. Billing ADN, Cooper RJ, Scott SK (2021) Pre-SMA activation and the perception of contagiousness and authenticity in laughter sounds, Cortex, 143: 57-68.
13. Scott SK (2021) The neural control of volitional vocal production-from speech to identity, from social meaning to song. Philos Trans R Soc Lond B Biol Sci, 377(1841):20200395.

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15. Cosme G, Rosa PJ, Lima CF, Tavares V, Scott S, Chen S, Wilcockson TDW, Crawford TJ, Prata D (2021). Pupil dilation reflects the authenticity of received nonverbal vocalizations. Scientific Reports. 11:3733.
16. Meekings S, Scott SK. (in press) Error in the Superior Temporal Gyrus? A Systematic Review and Activation Likelihood Estimation Meta-Analysis of Speech Production Studies. Journal of Cognitive Neuroscience.
17. Cai Q, Chen S, White SJ, Scott SK (2019). Modulation of humor ratings of bad jokes by other people's laughter. Current Biology. 29(14):R677-R678
18. Scott SK (2019) From speech and talkers to the social world: The neural processing of human spoken language. *Science*. Oct 4;366(6461):58-62.
19. Jasmin K, Lima CF, Scott SK (2019) Understanding rostral-caudal auditory cortex contributions to auditory perception. Nature Reviews Neuroscience, 20(7):425-434
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT DECLARATION OF
PATRICK W. LAPPERT, M.D.

I, Patrick Lappert, M.D., pursuant to 28 USC 1746, declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge.

2. I have been retained by counsel for the defendants in the above captioned lawsuit to provide an expert opinion concerning the nature of gender surgery. That opinion will be based primarily in my own experience as a physician and surgeon. It will also be based in an evaluation of the scientific publications that Plaintiffs have provided to the court in support of their complaint. It will additionally include an examination the world literature on the subject, as well as an examination of the massive public controversies that have led to near complete reversal of public health policy in multiple European states who have turned away from the social, medical, and surgical transitioning of minors.

3. I am a retired plastic surgeon, as well as a retired senior medical officer in the United States Navy. I have been a physician for 40 years. I completed my undergraduate education at the University of California, Santa Barbara. While there I had significant experience in university level research having been invited to be an undergraduate research assistant, working in the laboratory of Dr. Philip C. Laris. It gave me experience in the evaluation of research publications. We were involved in the collaborative work of elucidating the electrodynamic and stoichiometric quantification of the sodium and potassium pump, located in every living cell. I

completed my undergraduate degree in four years, and went directly to medical school.

4. I completed my preliminary medical training while on active duty in the US Navy. I attended the Uniformed Services University of the Health Sciences, F. Edward Hebert School of Medicine, graduating as Doctor of Medicine in 1983.

5. I completed a surgical internship at the Oakland Naval Hospital, followed by Aerospace Medicine/ Flight Surgeon Training at the Naval Aerospace Medical Institute, Naval Air Station Pensacola.

6. I then served for 2 1/2 years with a deploying, front-line Marine Corps fighter squadron, serving in the dual functions of medical department head, and squadron Radar Intercept Officer flying in the F-4 Phantom. I was deployed to Asia and the Western Pacific. I provided medical care to squadron personnel while deployed in Japan, Korea, and the Philippines.

7. I completed my General Surgery residency at the Oakland Naval Hospital- University of California, Davis/ East Bay Consortium. Following residency, I was retained there as a staff surgeon, and was responsible for the training of surgical residents. I was awarded the inaugural "Resident's Choice" award given to the attending surgeon deemed most effective by the residents in training, and presented by Claude Organ, MD, past President, American College of Surgeons.

8. I trained in Plastic and Reconstructive Surgery at the University of Tennessee, Memphis, graduating in 1994. During that training I traveled to Peru and provided craniofacial surgical care for indigent Peruvian children. This included the publication of a case report of surgical management of a very late post traumatic ectopic frontal sinus mucocele.

9. I received Board Certification in General Surgery from the American Board of Surgery in 1992. I received Board Certification in Plastic and Reconstructive Surgery in 1997 from the American Board of Plastic Surgery. I re-certified in Plastic and Reconstructive Surgery in 2008.

10. I served as a staff plastic surgeon at Naval Hospital Portsmouth, Virginia. 1994-2002. I became Department Chairman in 1998, and served in that office until my retirement. We had 5 staff plastic surgeons, and 10 Enlisted and civilian members. I established the Wound Care Center, providing specialized wound care services to a global catchment area. For example, our department was responsible for the limb and pelvic reconstruction of some of the sailors wounded when the USS Cole was attacked while at anchor at Aden in Yemen. I also established and chaired the multi-disciplinary Cleft Palate, Craniofacial Board. We provided comprehensive services for congenital pediatric deformities to a global catchment area.

11. Following selection to the rank of Captain, USN, I was selected to serve as Specialty Leader, Plastic and Reconstructive Surgery for the office of the Surgeon General, USN. In addition to being responsible for the selection and training of surgical residents, I was also responsible for Navy Medical Department policy concerning coverage for services, and medical evaluation and evacuation policy. I was responsible for the resolution of issues concerning what conditions constitute a requirement for immediate care in military hospitals, what may be purchased from civilian medical organizations and provided to eligible members on a delayed (elective) basis, and what is to be considered cosmetic surgery and therefore not an obligation of the government. I served in that position until my retirement. While serving as Department Chairman, I co-authored a textbook chapter on the management of combat injuries with the Chairman of Plastic Surgery at Harvard University, Dr. Eloff Ericksson. During that time I also published the first case report in the world literature detailing the use of endoscopic technique for reduction and plate fixation of a fronto-facial fracture.

12. I retired from the Navy after 24 years of continuous active duty. I was invited to join a surgical group in Scottsbluff Nebraska, primarily to provide comprehensive reconstructive surgery for women suffering breast cancer. I also provided reconstructive services to a very large regional catchment served by the Level II trauma center at Regional West Medical Center (RWMC). I established and

chaired the Cleft Palate/ Craniofacial multi-specialty clinic at RWMC. I also established comprehensive wound care services for the many rural community hospitals in the western prairie including Nebraska, Eastern Wyoming, southwest South Dakota and northeast Colorado.

13. For reasons pertaining to the education of our six children, I moved my practice to Northern Alabama in 2005. I have been a solo practitioner here for the last 17 years. I was brought here by a local hospital that wanted to offer comprehensive breast reconstruction to women affected by breast cancer. I also started a comprehensive wound care center. I have also had a very active practice in aesthetic/ cosmetic surgery. I maintained my own surgical suite for in-office facial rejuvenation procedures as well as minimally invasive body contouring procedures. I was an early adopter of advanced techniques in autologous fat grafting for facial re-contouring as well as for the resolution of radiation burn wounds of the skin. I continued to serve in the training of medical students in my office practice.

14. Although I maintain a practice in wound consultation, skin care, and laser services, I retired from my surgical practice in 2020, after having practiced as a plastic and reconstructive surgeon for 30 years. I was an Active Member in good standing of the American Society of Plastic Surgery for all but the last two years in practice. With only two years remaining in my practice, I elected to forgo a third certification by the American Board of Plastic Surgery. The certification was no

longer necessary for maintaining my hospital credentials, and I saw it as an unjustifiable expense for a solo practitioner planning retirement. When my board certification lapsed, my membership in the American Society of Plastic Surgery lapsed as a result.

15. As can be gleaned from this summary, I have a meaningful breadth of experience, not only in the advanced surgical care of trauma, cancer, head/ neck disease, as well as cranial and facial birth defects. Many of those procedures require the use of the most advanced sensate, microvascular flaps, including composite and pre-fabricated flaps. These are all the same techniques employed by today's gender surgeons. As regards surgery of the breast, I co-authored a ground-breaking article regarding pre-operative plastic surgical planning in the care of women suffering from breast cancer. It is among the most frequently cited papers in the field of breast reconstruction.[1]

16. Since 2014 I have made a concerted effort to examine the medical literature as it pertains to the care of self-identified transgender persons including children and adults. I have had an eight year long running discussion on these issues with Family Practitioners, Pediatricians, Pediatric and Adult Psychologists and

[1] Toth, B.A. and Lappert, P. (1991) Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Pre-Operative Planning. Plastic and Reconstructive Surgery, 87, 1048-1053. http://dx.doi.org/10.1097/00006534-199106000-00006

Psychiatrists, Pediatric Endocrinologists, as well as PhDs who specialize in the evaluation of the validity of scientific publications. During that time I have made many public presentations to teachers, counselors, pastors, and administrators on the subject of transgender, and the medical-scientific evidence that informs that care.

17. I have offered testimony, both written and in person on this issue to state legislators, state health benefits management agencies, as well as to State Attorneys General.

18. I have also had experience in making judgments concerning distinctions between reconstructive surgery and cosmetic surgery. I gained this experience while serving in senior leadership for a government medical care system in which I had no financial stake. I have no financial interests in the matter in question, and the professional opinion that I offer is not influenced by my sources of income nor by my position in any organization that financially benefits from medical services that are discussed in this opinion.

19. My peer-reviewed publications include: Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep; 102(3):553-4; Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87 (6): 1048-53; Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8; Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development

of an ectopic frontal sinus mucocele after pediatric cranial trauma. J Craniofacial Surg. 1995;6(4):327–331; Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov; 98(6): 1125; Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. Plastic and Reconstructive Surgery 1998; 102(5): 1642-5. I have also published the following medical textbooks: Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000.

20. Over the past four years, I have testified at trial and/or deposition in the following cases: *Brandt v. Rutlege*, Case No. 4:21-CV-00450-JM (E.D. Ark.) and *Kadel v. Folwell*, Case No. 1:19CV272 (M.D.N.C.). I have also submitted an expert report in *Siefert v. Hamilton County Job and Family Services,* Case No. 1:17-CV-511 (S.D.Ohio).

21. For my services as an expert witness, I am being compensated at an hourly rate of $400 for preparation of my written testimony as well for deposition and hearing. Additionally my travel expenses will be reimbursed. My compensation is not dependent upon the substance of my opinion nor upon the outcome of the litigation.

22. If called to testify in this matter I will do so truthfully, and to the best of my ability.

23. The Plaintiffs make the claim that "gender affirmation care" including "gender affirming (or confirming) surgery" should be paid for by the State of Florida because such care has scientifically proven efficacy, and safety. Furthermore they claim that there is such an abundance of scientific support for these treatments that they must be understood to be the standard of care, and that there is no controversy in the matter. As shall be seen in this report, the claims made by the plaintiffs are not supported in the science. This will be seen in the examination of those scientific documents which they cite in support of what will be seen to be experimental treatments on children.

24. In recent years professional medical societies have been making a concerted effort to strengthen the scientific basis upon which their particular specialties stand. This effort is commonly given the name "evidence based medicine". It is a systematic effort to categorize the quality of prognostic and therapeutic studies so that physicians reading these publications can distinguish what is vague and speculative from what is a matter of high likelihood, or grave certainty. Tools for making such distinctions have been developed that categorize clinical or experimental findings on the basis of how that data was obtained, the reliability of the test instruments used, the variability of the results, the sample size, and the

likelihood of bias among other factors. For the purposes of this response, I will use the tool developed by the American Society of Plastic Surgery[2]. For prognostic studies, the categorization of evidence is divided into Levels I- V, with Level I being the most rigorous and having the highest likelihood of scientific certainty, and Level V having the least rigor, and having very little certainty. Here are the definitions of those levels according to the American Society of Plastic Surgery:

Level I: High quality prospective cohorts study with adequate power or systematic review of these studies.

Level II: Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT (randomized control study), or systematic review of these studies.

Level III: Case- control study or systematic review of these studies.

Level IV: Case series

Level V: Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles".

25. For therapeutic studies, the ASPS categorization is similar, but with a few helpful distinctions:

[2] The Levels of Evidence and their role in Evidence-Based Medicine Patricia B. Burns, MPH,1 Rod J. Rohrich, MD,2 and Kevin C. Chung, MD, MS3 Plast Reconstr Surg. 2011 Jul; 128(1): 305–310. http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html.

Level	Type of Evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence intervals)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual Cohort study (including low quality RCT, e.g. <80% follow-up)
2C	"Outcomes" research; Ecological studies
3A	Systematic review (with homogeneity) of case-control studies
3B	Individual Case-control study
4	Case series (and poor quality cohort and case-control study
5	Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"

26. These distinctions are very important to physicians who seek to understand the weight of the evidence presented in support of a change in therapeutic care. Sometimes such scientific findings can be so compelling regarding an issue, that professional societies will publish clinical guidelines that strongly suggest conformity to a new treatment plan based in that evidence. Occasionally the evidence will be of such certainty, on a matter that is so grave, that professional

societies and even public law will assert that there exists a standard of care based in this evidence that if ignored has a high probability of injury or harm to the patient. That is what is implied when the phrase "standard of care" is used.

27. To that end, the ASPS document provides a grading system for Practice Recommendations that helps in the decision making. It is a synthesis of the breadth of scientific data that addresses the issue in question. In the case of Grade A there is an accompanying "Strong recommendation", versus Grade D where the evidence is so lacking in empirical value that the proposed treatment can only be offered as an option if at all, depending upon the strength of existing or alternative treatments, and the particular issues of a particular patient.

28. To summarize, it can be said that Level-V evidence is anecdotal, and in the world of surgery it is typified by the phrase "expert opinion". Such evidence is not to be dismissed since it is the known starting point for much meaningful research and discovery. A surgeon with great experience and unassailable credentials will observe something peculiar. He will form a hypothesis about its cause or treatment. Hopefully he will publish his single case report, and share his thoughts with the wider surgical community. Perhaps one of his residents will start a hunt for other cases. Perhaps surgeons who read his paper will report similar cases. Eventually it might lead the surgeon to apply his new principal to a series of cases. The series may already be there in his own case files. If he publishes his series of cases, that would

constitute an improvement to Level-IV evidence. Even then, it would be considered "poor" evidence because it suffers from the fact that it is a small collection of cases, from a single surgeon, and perhaps no one has yet replicated his observations. Additionally it may suffer from "selection bias" (as when the patient decides if he will receive long term follow up), lack of proper controls (which help us to separate out what is the result of our treatment, and what is within the range of normal variation in the population), inadequate study duration (if you claim a long term improvement in survival, you have to follow the patients long-term).

29. An example from the history of surgery will serve to illustrate how Level-IV and V evidence, when widely encouraged and applied through expert opinion, can result in grave missteps. For over 100 years, ulcer disease of the stomach was considered a surgical problem. This very debilitating disease did not appear to be manageable through medical means. Laboratory study of the stomach had already demonstrated that acid production in the stomach is regulated by particular nerves. That finding suggested that if those nerves are cut, acid production will decline, and the ulcer will heal. It was also determined that the surgery must include some form of "drainage procedure" because cutting the nerves would also impair the muscular contracture of the stomach. Through the course of the decades many of the greatest surgeons gave their names to the elegant techniques for selectively cutting the nerves, or draining the stomach in ways that hopefully would

not result in a "gastric cripple" (an all too common outcome). Long hospitalizations, and many months spent accommodating to the reordering of their digestive tract was expected. There is a syndrome of bad effects from these surgeries that most people adapt to but some never do. Nonetheless, untreated peptic ulcer disease was often deadly, either from peritoneal sepsis, or bleeding to death. Because of the gravity of ulcer disease, it was ethically sound to risk "post gastrectomy syndrome" if it meant saving a life.[3] By the 1980s, level II and I studies had demonstrated that peptic ulcer disease is actually a bacterial infection that can be treated with antibiotics and an acid-reducing medication. This had been very seriously suspected for at least 30 years. However, poorly designed studies published by the greatest academic surgeons of the day had utterly suppressed the bacterial explanation in favor of the surgical solution. A very well-reasoned 2014 paper by Seselja and Strasser[4] shows the heuristic pitfalls that can result in unintended harms to patients when surgical decision making is driven by expert opinions that aren't well supported by quality scientific evidence.

30. Generations of surgeons will follow what is taught to them by the academic surgeons. These are esteemed mentors who are responsible for training the

[3] History and evolution of peptic ulcer surgery; John B.BlalockJr.MD1; The American Journal of Surgery Volume 141, Issue 3, March 1981, Pages 317-322

[4] Dunja Šešelja 1, Christian Straßer; Heuristic reevaluation of the bacterial hypothesis of peptic ulcer disease in the 1950s; Acta Biotheor 2014 Dec;62(4):429-54.

next generation of surgeons. That is how it has always been. However today, medical science has advanced in crucial ways through the application of the "science of science". We understand better now how to examine the evidence. We are less likely to make needless errors of judgement because we are better able to analyze the data particularly with regard to its reliability. This is indispensable when studying biological systems that, in every measurable trait, demonstrate great variability. It is particularly essential when examining and caring for the human person, because you have the added dimension of their subjective interior life.

31. In the professional literature that supports gender-affirmation care, the word "transgender" is defined on the basis of a subjective conflict within the patient's internal sense of themselves. It affirms this interior subjective division on the basis of an idea that sex is somehow "assigned" at birth, rather than scientifically discovered through tissue sampling, in utero ultrasound, or simple inspection at birth. In 99.98% of cases, simple inspection correctly detects the sex of the subject. Furthermore, this test can be administered by untrained personnel. His use of the term "assigned" implies that there can be errors of "assignment". Such an assertion demands not only that we examine the result, but we must also look at the consistency of the data. It is well understood that consistency of the data is one of the hallmarks of good evidence. Any test that can be correct 99.98% of the time regardless of who administers the test is perhaps unequaled in scientific medicine.

32. Gender, on the other hand, as it relates to sex, is a very different matter. While there are some aspects of gender that are more fixedly related to the sex, there are large areas of gender that are learned within the milieu of the local culture, and find their origins in family life. There is no objective, repeatable test, with known error rates, that can be used to detect "gender". Gender, as the term is used in the world of medicine and surgery is not objectively measurable. Such traits as hair length, occupation, preference for violent sport, clothing selection, among others, may have vague gender associations, but are so variable from culture to culture as to be useless for our purposes. This is because "gender" is one of the many expressions of the interior life of the person. It is a mercurial thing because it is not entirely fixed to that part of the patient that is a reliable object for examination and treatment. That difficulty with diagnosis and prognosis is further complicated by the fact that variability in gender presentation doesn't just occur within any particular human grouping, it is also known to vary within the span of the life of a single patient.((Zucker, K. J. (2018). The myth of persistence: response to "A critical commentary on follow-up studies and 'desistance 'theories about transgender and gender nonconforming children" by Temple Newhook et al. International Journal of Transgenderism, 19(2), 231–245. Published online May 29, 2018. http://doi.org/10.1080/15532739.2018.1468293)

33. The claim is made that hormone therapy and gender confirmation surgeries can help alleviate gender dysphoria, and that these treatments have been shown to be an effective treatment for gender dysphoria. In support of this claim, a further claim will be made that there is a prevailing consensus of the medical community that these treatments are medically necessary, and are safe and effective treatments for gender dysphoria. We will examine the efficacy, and safety by examining the papers offered in support of these claims. We will examine the world literature more broadly in order to evaluate the claim of a "prevailing consensus". The claim of consensus insists on an absence of important controversy surrounding the use of social, medical, and surgical gender affirmation, particularly with regard to the young. That examination will show that there are startling and permanent differences in outcomes between "affirmation-care" as proposed by the plaintiffs, and the historically proven approach that begins in proven psychological care, and results in resolution nearly 90% of the time.

34. In virtually every instant when the claim of the efficacy and safety of gender-affirmation is made, the WPATH "Standards of Care" will be cited in support. This document is the product of the World Professional Association of Transgender Health. It has had 8 iterations. This document has been, and continues to be produced through a process of consensus-seeking within working committees of experts. As we have seen in our discussion about the grading of scientific

evidence, expert opinion is the most rudimentary level of evidence. It is the starting point of scientific investigation, not the end. As any medical subject is investigated over time, the expert opinion becomes better supported by well developed and monitored scientific processes. In short, expert consensus is only as valuable as the scientific evidence that can be reviewed and evaluated which supports the opinion. If the evidence hasn't progressed very far beyond the category of expert opinion, then we are speaking about evidence that is neither sufficiently developed so as to drive either clinical decision making, nor fiduciary decision making when public or invested resources are involved.

35. It will be recalled that the use of the words "standards of care" imply that a particular treatment or clinical principle, if not employed, would have an unacceptable probability of harm to the patient. The term "standard of care" addresses issues of duty, negligence, harm, and causation. It is a legal term that is applied when evaluating the malpractice of medicine. In its Introduction to the WPATH standards, the authors acknowledge that their document is meant to be a guideline only, and subject to individual and local adaptation, and that it is not binding in any way. On page 2 of v.7 in bold face it states "The Standards of Care are flexible clinical guidelines". This calls into question the motivation for the use of the phrase "standards of care" in all of its publications and statements.

36. If the WPATH document is actually a collection of clinical guidelines, then we must examine how such guidelines are developed. In the International Journal of Quality in Healthcare (2016) Kredo et al.[5] offer a helpful examination of that process. They point out that in the past they were just consensus statements offered by experts in the field. They were "'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." With the push toward evidence based medicine, it was realized that guidelines required more scientific rigor, so in 2011 the definition was changed to, "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'". In order to have real value, clinical practice guidelines must therefore do two things: Use high quality scientific data to evaluate risks, and beneficial results while presenting alternative approaches for the practitioner and patient to consider.

37. With respect to the particular questions at issue in this case, "high quality scientific data to evaluate risks, and results while presenting alternative approaches for the practitioner and patient to consider", should be evidenced in the complaint, and its supporting documents.

[5] Guide to clinical practice guidelines: the current state of play; Kredo et al. Int J Qual Health Care. 2016 Feb; 28(1): 122–128.Published online 2016 Jan 21. doi: 10.1093/intqhc/mzv115

38. Among the scientific publications frequently cited in support of the efficacy and safety of hormonal treatment of transgender persons is a paper by Hembree et al.[6] which is itself a clinical practice guideline promulgated by the Endocrine Society (hereafter ES). Since this paper is a product of the Endocrine Society, it must be understood by reconstructive surgeons given that the referral path of children into the surgical treatment arm is universally through the prior evaluation by an endocrinologist. This guideline was produced in order to update an earlier guideline from 2009. It was produced using GRADE consensus methodology, and is the product of 9 experts who formed the committee. The GRADE methodology cautions its users that "inconsistency of result across multiple studies", "indirectness of evidence", "imprecision in measurement", and "publication bias" are to be watched for in its application; essentially that doctors must watch out for sloppy measurement, and bias in the working group. The scientific evidence used to support the Endocrine Society's special treatment guidelines for gender dysphoric/ gender incongruent persons appears to be of low to very low quality, since the clinical recommendations were so equivocal. It was published in 2017 and includes the statement:

[6] Wylie C Hembree, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

"guidelines cannot guarantee any specific outcome, nor do they establish a standard of care": "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." P. 3895.

39. As was discussed earlier, this language of uncertainty when included in a clinical practice guideline is what we would expect with low quality evidence. This is what the ASPS would call a Grade D result that rests on level IV-V evidence, and is therefore not useful in directing clinical decision making. This consensus process described by Hembree et al. would likely appear very similar to the decision making that drove peptic ulcer surgery in opposition to evidence that it is a bacterial disease. Academic physicians of the highest calibre were making recommendations to their fellow practitioners, as they are now, based upon anecdotal experience and low level evidence.

40. Just 2 years later, in 2019, the ES , along with an international panel of endocrinology societies, concluded "**the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD** [Hypoactive sexual desire disorder]," and that "There are **insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition,** or

for disease prevention." Also, "The **safety of long-term testosterone therapy has not been established."**[7]

41. It is somewhat alarming to note that these findings are entirely consistent with a consensus statement from 5 years earlier in 2014 (8). In the span of just 5 years, the Endocrine Society consensus has swung from "no other indication for androgen in women" to something akin to, "it is crucial that androgens be given to women who are gender dysphoric", and then back to "no other indication for androgen". This kind of consensus oscillation is what you would expect when there is such scant scientific basis for the decision making.

42. Leading experts in the nascent field of "gender-affirmation surgery" will cite the ES guidelines as the "criteria for initiation of surgical treatment", and that such surgery is "often necessary and effective". Additional citation of other specialty consensus statements, developed by similar methodology, includes the American Pediatric Society, and the American Psychiatric Association. These

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[7] Endocrine SocietySusan R Davis, et al, Global Consensus Position Statement on the Use of Testosterone Therapy for Women, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 10, October 2019, Pages 4660–4666, https://doi.org/10.1210/jc.2019-01603.

(8)- Margaret E. Wierman, et al. Androgen Therapy in Women: A Reappraisal: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 99, Issue 10, 1 October 2014, Pages 3489–3510, https://doi.org/10.1210/jc.2014-2260

consensus statements are also important for reconstructive surgeons to be familiar with since it is in these areas of practice that the initial diagnosis of gender dysphoria is made, a diagnosis which constitutes the foundation for referral to surgery. The surgeon must understand the strength of the scientific support of the diagnosis given that in some instances breast surgery, and in all instances genital surgery is an irreversible mutilation of the child resulting in permanent losses to essential human functions.

43. Surgeries that are used in gender-affirmation care are described by plaintiffs experts as being "reconstructive". They include surgeries of the face, the chest, and the genitals. It is crucial to understand the meaning of the term reconstructive surgery, and contrast it with the term "aesthetic surgery". It is precisely this distinction that distinguishes medical necessity, which in turn is the basis for evaluating claims of obligation on the part of the State or any other 3rd party payor, to pay for these procedures. This is an area where I have some experience, having served the office of the Surgeon General, USN as specialty leader for reconstructive surgery. Making determinations of coverage for any agency is essentially about rightly answering this as the first question: "Is this reconstructive, or is this cosmetic?"

44. Reconstructive surgery is the restoration of form and function for a person who has suffered a loss through genetic, in utero developmental accident,

trauma, infection, or surgery for infectious events or cancer. It begins with the most comprehensive knowledge available concerning the nature and function of the injured part, and seeks to optimize function as the primary goal, while seeking to restore the natural form. Both form and function are understood objectively, and both have subjective effects. Restoration of form and function in a combat injured leg has measurable effects on mobility, range of motion, strength, and capacity for work. Subjectively, the impact is profound as well, but it is not the central purpose of the operation.

45. In contrast, aesthetic surgery begins in the subjective life of the patient. The patient presents seeking an opinion concerning the aesthetics of a particular feature, such as the nose. They will express a dislike of the feature. Their hope is that by modifying its appearance, they will improve their interior subjective life. What the patient is seeking is a normal human objective: to improve the aesthetics of things, for ourselves and for the people around us. When the surgeon is planning and performing the operation on the nose, there is great objective precision; however, all of it is placed in the service of the subjective life of the patient. It is of no use for the surgeon to impress himself with a technically perfect result if the patient loathes it. The surgeon additionally has the grave duty of managing the risk for the patient and weighing it against the potential benefit. The patient must not be submitted for a surgery which entails a significant risk of loss if the surgery is being

performed only to achieve an aesthetic outcome. If there is a certainty of loss, then there is a certainty of error. To give a young woman a perfect nose, and in the process destroy her ability to breath through it would be a terrible error of surgical decision making. It is axiomatic in plastic surgery that we are to avoid a predictable sacrificing of function in the pursuit of cosmetic improvement.

46. All of the world's literature in the area of gender affirmation medicine and surgery begins in the subjective life of the patient. In the past the associated diagnostic terms directed us to consider the subtle processes at work in the mind of the patient that cause obsessive thinking, and compulsive behaviors that center on how the world views their sexed appearance. More recently the condition has been "de-pathologised" and now the preferred term of "gender dysphoria" has come into use. This new language has hidden away virtually all of the issues of the interior emotional life of the patient, and left us only with the vaguest descriptions of the patient's condition: "dysphoria", "unhappy". Simple though the term is, it is still entirely in the subjective life of the patient. There is nothing found in the term "gender dysphoria" that points to a lost or otherwise damaged body structure in need of reconstruction. No functional or physical loss is described or even suggested by the term "gender dysphoria". It is a fundamental characteristic of a cosmetic surgery patient that the presenting complaints are only subjective, and in the course of the complete evaluation of the patient, no functional or structural defect is found.

47. A further reason for the crucial importance of clarity in separating what is reconstructive from what is cosmetic is the part that this distinction plays in surgical planning, and informed consent processes. Planning for a reconstructive operation includes an assessment of the size and severity of the wound, or the dimensions and tissue types of the missing part. This determination guides the selection of tissue from other body areas that can be employed in the reconstruction. At the same time the surgeon must understand the scope of the harm that will be caused by harvesting that tissue to complete the reconstruction. That harm is given the name "donor defect", and it forms an important part in the risk/ benefit calculation. For example if I were to reconstruct a man's jaw that was shot away in combat, one of my first options would be to use a portion of bone from the leg. I can transpose that bone to the face, attach the blood supply, then cut and form the bone segment to replace what was lost. One of the important considerations is to prevent loss of function of the leg (donor defect). The operation is in part designed around that consideration because we seek to limit (entirely if possible) the magnitude of the functional loss caused by the donor defect. The only reason that we accept any loss at all is because of the grave nature of the original wound. We accept some small degree of loss if by doing the operation we restore the functions lost in the wounding event. Furthermore, whatever function is lost because of the donor defect is considered a complication had there been any way to avoid it.

48. In contrast cosmetic surgeries, because they begin with an otherwise fully intact person, they do not begin with any assessment of any loss from any of the wounding processes described above. The only measurable findings in cosmetic surgery are those of aesthetic proportion, and which being aesthetic find their importance in the subjective life of the observer. In the case of the cosmetic operation, any functional loss caused by surgery is considered an avoidable complication since the surgery neither anticipates nor yields any functional improvement except in the subjective life of the patient. This is why measures of success in cosmetic surgery are always made using subjective "quality of life" questionnaires.

49. As we examine the particular surgeries used in gender affirmation we will see that there is a very troubling abandonment of these first principles of reconstructive surgery. The first troubling example is "chest masculinization" surgery in female to male presentation patients. This surgery actually begins with the known expectation that the surgery will produce a loss of two essential human functions, namely: sexual arousal, and breast feeding. Both functions are permanently and irretrievably lost, and that loss is one of the expected results or the surgery. This step is then followed by the cosmetic shaping of the chest through the use of liposuctioning in an effort to further masculinize the appearance of the chest. This surgery is now being routinely performed on minor girls, and version 8 of the

WPATH "standards of care", which is presented as authoritative by proponents of gender affirmation, actually recommends mastectomy in girls as young as 15 years of age. This surgery does not involve the restoration of form and function, and is therefore not reconstructive. It is an operation that begins in the subjective life of the patient and aims at a result that also resides entirely within the subjective life of the patient. It is thus by definition an aesthetic (cosmetic) surgery. Because it includes the 100% likelihood of a massive functional loss, it must be considered unsupportable as a matter of policy.

50. Similarly, genital surgery procedures cannot be considered reconstructive because they do not meet the definition of reconstructive surgery. They begin with an obsessive concern or anxiety in the subjective life of an otherwise normal, healthy person. They involve the planned destruction of an essential human function, and they are not restoring a form that is missing due to trauma, genetic accident, in utero event, or disease. The surgery seeks to create counterfeit structures that never could have existed in the patient, except as an artifact of surgery. I have done many reconstructive surgeries involving the entire genital area in patients with military injuries and infectious illnesses. If the injury is so devastating as to require a counterfeit structure, and that is all that can be offered, then there is no question as to how the surgeon must proceed. In contrast, gender affirmation surgery only produces counterfeit structures that are created to serve the

subjective life of the patient. Because these surgeries are cosmetic, and because they are 100% certain to produce grave functional losses, they must not be supported as a matter of public policy, and never be paid for using public funds.

51. In spite of these clear distinctions between reconstructive and cosmetic surgery, proponents of gender affirmation surgery will claim that such procedures are medically necessary. This language of medical necessity is found in the WPATH "standards of care". It should be remembered that the WPATH standard of medical necessity is not supported in reliable scientific evidence, but only on rudimentary, low level, expert opinion/ consensus statement data, which is no support at all. The use of the term "medical necessity" is language that is used by medical insurance programs, both private and public to establish insurance coverage in the case of particular procedures. Benefits of insurance programs can vary from policy to policy, but when the term "medically necessary" is used, it implies that failure to cover the care is likely to cause harm to the beneficiary. For this reason, insurance programs, including state Medicaid programs routinely examine the efficacy of treatments in the management of medical conditions, and develop policies of coverage or exclusion if benefit has not been demonstrated, or if a less hazardous or less expensive process of care can be offered to the beneficiary.

52. There are circumstances in which the exact same surgery may be considered reconstructive in one patient, but cosmetic in another. It is important to

be familiar with this problem since advocates of gender affirmation surgery will use the similarity as the basis for claiming that it should be a covered benefit, and that failure to include surgery in the insurance coverage is evidence of legal prejudice against a particular class of patients. For example, the claim will be made that removal of breast tissue from a female seeking to present as a male is the same as removing breast tissue from a male who suffers from the condition of gynecomastia (female breast tissue on a male chest). Or they will offer the analogy that mastectomy (complete removal of the breast) in a healthy female who seeks to present as male is the same as prophylactic mastectomy in a female who has inherited a high lifetime risk of breast cancer. Both females are at present healthy, both females get mastectomy. Gender affirmation advocates will ask, why one is a covered benefit, and the other excluded?

53. One of the essential mechanisms that third-party payors (including state Medicaid agencies) have for distinguishing reconstructive surgery from cosmetic surgery is found in the laboratory examination of tissue removed during surgery. This tissue examination by the pathology department is required by insurance programs in order to confirm that the operation performed was reconstructive (covered benefit) and not cosmetic (excluded from coverage). Two operations may be outwardly identical even while one is reconstructive and the other cosmetic. An excellent example is breast reduction surgery. This surgery may be reconstructive

if it is performed on patients who suffer from chronic neck, back, and shoulder pain caused by the orthopedic effects of their heavy breasts. The same, technically identical operation, might be done for purely cosmetic reasons. In the case of reconstruction, the patient has an objectively diagnosable condition that causes lost time from work, frequent covered visits to physical therapy, or to pain clinics, chiropractors and radiologists. There is abundant actuarial data, based upon the highest levels of scientific support, that a breast reduction of sufficient weight (based upon the anthropometric measurement of the patient) has a very high probability of resolving the chronic pain. High quality medical literature that addresses this issue, and its importance to insurance plans, is typically very precise in its data gathering and actuarial interpretation.[8] However, pain cannot really be measured. Pain is reported by the patient. Nonetheless, health insurance plans are able to distinguish cosmetic breast lift from reconstructive breast reduction based upon the measured and reported weights of the breast tissue that is submitted to pathology during surgery. An objective, repeatable medical test, with known error rates is used to confirm the diagnosis, ensure correct care for the patient, and separate cosmetic

[8] Accuracy of Predicted Resection Weights in Breast Reduction Surgery: Kung, Theodore A. MD;
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surgery from reconstructive surgery in the interest of preserving medical resources and preventing fraud.

54. No such process exists in the case of mastectomy for chest masculinization of self-identified transgender females seeking to present as males. There is no physical, biochemical, hormonal or tissue pathology, that can be demonstrated to localize the patient's condition in her healthy breasts. It is the young woman's subjective sense of revulsion when she looks at herself that has caused her to believe that mastectomy might make her feel better.

55. In spite of this glaring lack of objective, scientifically validated methodologies for making the diagnosis, or for proving benefit of care, advocates for gender affirmation care will cite many papers, published in peer reviewed professional journals, that claim sufficient improvement in the subjective life of the patient that lifelong morbidity and suicide are avoided. Close examination of this literature will show the very low quality of evidence that is offered, even after many years of affirmation care. Before reviewing the literature supporting gender affirmation, we must understand what it means when an article is reported as "peer reviewed".

56. Peer review is the very important process by which highly educated and trained experts review scientific medical papers for publication. They are examined in order to ensure that the corpus of medical literature is protected from imprecise,

substantively erroneous, or conceptually flawed publications. It is an essential part of the historic, magisterial process in medicine. In fact, it is so much a part of the life-long learning process of doctors that any reputable training program will have a robust "journal club" in which doctors at every level of training take turns at publicly "peer reviewing" an article and leading a lively discussion of its value. A good doctor is constantly peer reviewing. It is an essential element of good medical care because it keeps the doctor in contact with the finest practitioner in their particular field, and thus improving care.

57. Establishing that an article is peer-reviewed is a basic and essential practice. You might read a medical paper with level-III evidence of high quality, or a paper that is level-V evidence of low or questionable quality, both of which undergo peer review, and are published. The level-III will likely drive decision making, and possibly a recommendation as high as "standard of care", while the poor-evidence paper suggests research, or perhaps the consideration of an alternative approach, if that approach does not put the patient in any significant risk. Papers that have very low-quality evidence, such as single case reports, or case collections by a single practitioner, or collected from several practitioners at a single medical center, will be published by peer reviewed medical journals. These papers are not offered to guide clinical decision making. They are offered in the service of advancing the understand of complex problems, and suggesting areas of research

that might lead to higher quality evidence, and thus to future improvements in the quality of care. So, the label "peer reviewed" says absolutely nothing about the value of the evidence for either clinical decision making, or larger issues of practice guidelines, and policies of medical coverage or exclusion by healthcare agencies like state Medicaid programs.

58. A 2019 publication by Miller et al.[9] is typical of a single-surgeon, case collection paper published in a peer reviewed medical journal. It reports a collection of cases that claims to show complete satisfaction on the part of the patients (that 100% would do it again). Upon examination of Dr. Miller's paper we see that it is a report of a single surgeon, and is a retrospective review of his cases. It begins with a chart review of only 34 patients, only 12 of whom responded to the quality-of-life questionnaire. This means 74% of the study patients dropped out (patient self-selection bias, with dropout rate greater than 20% being unacceptably high for publication in most journals). All of the data is based in subjective reporting by the patients, rather than objective findings such as substance abuse rates, psychiatric hospitalization rates, suicide attempt etc.. Published reports which use purely subjective evaluations such as satisfaction surveys, or quality of life surveys etc. are characteristic of the cosmetic surgery literature, not the reconstructive surgery

[9] Miller, TJ, et al. Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes, 21 JPRAS Open 63-74 (2019)

literature. He reports that "every patient surveyed at 1 year" reported that "their life had changed for the better". This statement is again reporting only subjective data, this time following a meaninglessly short follow-up of a very small group that has been biased by self-selection. The overall study is little better from the standpoint of the duration of the study because the final follow-up was only 4 to 7 years. This paper presents level-IV and level-V (low to very low quality) evidence, and is possibly useful in suggesting further research, particularly since the author is a subject matter expert. It is not useful for clinical decision making. Neither can it be presented as evidence for anything more than a cautiously worded practice guideline (as in the ES guideline concerning the use of cross-sex hormones presented above), and certainly can never be used in support of a "standard of care".

59. A 2006 paper by Newfield et al.[10] is an example of a paper that was published in a peer reviewed journal, and perhaps ought not to have been. This paper asserts that mastectomy and chest masculinization in transgender biological females "increases self-esteem and improves body image" while providing the patient with "some security and safety for those who remove their shirts in public areas such as gyms or beaches". This assertion is made by the authors in the paper's preamble, and is an assertion frequently quoted when the paper is cited in evidence to support

[10] Newfield, N, et al., Female to-Male Transgender Quality of Life, 15 Quality of Life Research 1447- 1457 (2006)

gender affirmation surgery. In reading the entirety of the paper one finds that it does not demonstrate this claim at all. The assertion is a personal editorial opinion expressed by the authors in support of transgender surgery. The assertion is never verified in the objective data on post-surgical patients.

60. The paper is a report of an anonymous survey. It claims to provide meaningful information about the effect of female to male transitioning medicine and surgery without even verifying that the subjects who responded to the survey have in fact undergone medical and surgical gender transition. Subjects were recruited **"via online promotion and printed materials, including flyers and postcards that were distributed to San Francisco Bay Area community centers, cafes, stores, and health clinics that serve the transgender community."** In terms of self-selection bias (patient determines who is followed by the study) it is hard to imagine a more problematic patient selection process. The researchers even admit that they were unable to determine how many surveys may have been submitted multiple times by the same study respondent. They write: "Although this procedure *helped* (italics mine)prevent duplicate submissions by the same participant, we could not employ more sophisticated computerized systems due to administrative and financial constraints".

61. All of the demographic information contained in the study was self-reported but not verified, including age, sex, health status, history of hormonal

therapy, and history of gender surgery. The study uses a quality-of-life survey with 36 questions in 8 areas of interest, producing only self-reported subjective information. Even the claim of simple benefit is poorly support, as is reflected in the conclusion to the paper. The authors write, **"The 376 US FTM transgender participants analyzed in this sample had diminished mental-health related QOL compared with the general US population, as measured by the SF36v2. These findings are consistent when compared against specific age and sex norms."** This statement demonstrates the lack of value in the study. The study participants demonstrated a quality of life that is statistically significantly lower than the age/ sex comparison cohort, and the authors can only speculate as to the cause. There is no way to tell if treatment helped, had no effect, or harmed the patients because there was no information available about the anonymous subjects. This is because the anonymous test subjects hadn't received pre-treatment evaluation using the same or comparable test instrument. This study which is frequently offered in support of the claim of efficacy is of the lowest evidentiary value, may be useful for suggesting future research, but is of no value in directing clinical decision making, or meaningful allocation of public resources in the service of public health.

62. Another peer reviewed article, presently cited in filings by advocates in cases pending before federal courts, is from 2013 by Weigert et al.[11] which makes the claim that there is a statistically significant improvement in "psychosocial well-being" following cosmetic breast augmentation in biological males who are presenting as women. This paper is very simple to analyze and classify as not helpful in clinical-therapeutic decision making, or for establishing coverage/ exclusion criteria for public health agencies. At the bottom of the published article is written, "Clinical question/level of evidence: Therapeutic, IV." As was discussed above, this paper is at the same alarmingly low level, because it is a single-center sampling of a small cohort of patients, and relies on subjective, self-reporting through questionnaire, over a short study duration. Patient collection was made between 2008- 2012. The paper was published in 2013. If the peer review process followed the usual timeline, it is likely that there are a significant number of patients in the study who were followed for less than a year. The authors, in the abstract are only able to report the pre-surgery, and the 4th month post-surgery as assured time points. This is remarkably short follow up even for a cosmetic breast augmentation study group. The article is perhaps useful in suggesting inquiry into why their cohort

[11] Weiger, R, Frison,E., Sessiecq, Q., et al.; Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male to Female Transexuals. Plastic and Reoncstructive Surgery, 132(6), 1421-1429. doi:10.1097/01.prs.0000434415.70711.49 (2013)

reported no improvement in physical well-being, given the known association between emotional health and physical health. There is nothing in the article to support even a guardedly worded clinical guideline suggestion.

63. Another citation in legal claims presently before federal courts and offered in support of gender surgery is another peer-reviewed study by Horbach et al. published in 2015.[12] This is a review of transgender surgical literature published between 1995 and encompassing nearly 20 years. It yielded 26 papers that satisfied the search criteria, and includes 1,461 patients. The paper claims that "transgender women (biological males presenting as women) who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale of one to ten". In the conclusion of the paper the authors write, "

"Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. QoL was only reported in one study. Comparison between techniques was difficult due to the lack of standardization."

64. Of the merely 26 studies out of a sampling that spanned 20 years, only one paper was found to have used a standardized metric, one that only measures subjective, patient reported information, and the rest could not even be compared to each other. The authors write,

[12] Horbach, SER, Bouman, M, Smit, JM et al.Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques ; J Sex Med2015 Jun;12(6):1499-512. doi: 10.1111/jsm.12868.55.

"The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools, and follow-up. Standardized protocols and prospective study designs are mandatory for correct interpretation and comparability of data."

65. This result is startlingly reminiscent of a paper offered by Tolstrup et al. published in 2020 (&&). It is a comprehensive literature review on the subject of breast surgery in transgender patients, including both male to female, and female to male presentation. It is a scoping review that yielded 849 papers of which 47 papers met the inclusion criteria based upon title, abstract, and full text. In the study results, the authors report that,

"The summary of outcome domains and classifications showed that there are large variations in outcome evaluation between studies. Although several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes." The authors then conclude by explaining that "Evaluation of outcomes in gender-confirming chest surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies."

66. **Tolstrup's review of the literature[13] show us that the general level of evidence for the efficacy of gender affirmation breast surgery is in the category of "early experimental" evidence.** None of the articles examined rates of psychiatric hospitalization, substance abuse, self-harm behaviors, or suicide. This tells us that the most compelling reason offered for performing these surgeries

[13] Tolstrup A[1], Zetner D[1], Rosenberg J[1] Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review. **Aesthetic Plastic Surgery**, 29 Oct 2019, 44(1):219-228 DOI: 10.1007/s00266-019-01523-1

(psychological distress and suicide risk) isn't even evaluated by the researchers, and can support no claims of efficacy in the world transgender surgery literature.

67. Professionally speaking, these are very disappointing findings from the comprehensive examination of the transgender surgery literature. To have a surgical sub-specialty working diligently, and guided by professionals at the highest levels of academic expertise, that has only produced case-series reports, retrospective case collections, and fruitless 20 year literature reviews, and still only have level-IV and V evidence to show for its work is alarming. It shows that the sub-specialty has not developed uniform descriptive language, standardized reporting nor test instruments that might raise the value of expert opinion to a level that could make reliable recommendations that might help in surgical decision making, rightly inform the consent process, or guide decision making by officials entrusted with the care of public and private medical resources. It would cause me to make a sober review of the medical and surgical principles that are guiding this work.

The Question of Consent in Gender-Affirmation

68. It is firmly established in high quality research[14] (that persons with gender dysphoria have a greater than 30% likelihood of being on the autism

[14] Kaltiala-Heino R, Sumia M, Työläjärvi M, Lindberg N. Two Years of Gender identity service for Minors: overrepresentation of natal girls with severe problems in adolescent development.

spectrum, and a nearly 40% probability of a diagnosis of depression or major anxiety disorder. The proponents of gender surgery will rightly point to the high probability of self-harming behavior, including suicide attempts and completed suicide among self-identified transgender persons.

69. However, as is known by all surgeons, it is considered imprudent to obtain consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm, or to suicidal ideation. These psychological disturbances are known to impair the patient's capacity for understanding the information they are hearing from the surgeon, interpreting that information, and reasoning from that information. If those capacities are impaired by psychological disturbances sufficient to consider suicide, then meaningful consent is not actually possible. Certainly in the case of conditions that constitute a threat to life and limb in a patient with decreased competence, consent may be obtained with the assistance of family, guardian, or in particularly urgent cases a group of professionals who agree on the grave necessity to proceed with surgery.

70. The problem however is that none of the surgeries, on the list of commonly performed gender affirmation surgeries, can be described as emergency operations performed to save the life of the patient. They are all elective because

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Child and Adolescent Psychiatry and Mental Health (2015) 9:9.)

they are scheduled when convenient and after the patient is deemed fully ready. Furthermore, an ever-growing percentage of patients submitted for gender surgeries are minors who by definition are not competent to consent. The claim is made that these surgeries are in fact "lifesaving". This is a claim that is not supported in high quality scientific evidence. In fact, high quality evidence, which I will present below, shows that while self-harm and suicide rates are improved in the very short term for some sub-groupings of patients, in the long-term these problems remain if not worsen.

71. Documents like the WPATH v.8 speak of the need to have these psychological disturbances "well-controlled" prior to surgery. This must be taken to mean that self-harming or suicidal thoughts must be well controlled before one can proceed with surgery. If that is the case, then the main reason for the consenting the child for surgery has been successfully treated medically, and the patient no longer requires the surgery. That would be very felicitous news to the child's parents.

72. What is more troubling is that the co-morbid conditions of autism spectrum disorder, clinical depression, and major anxiety disorder are never examined as the possible causes of the gender identity disturbance. These are conditions that, if treated, might improve or even resolve the gender problem. To the contrary, these serious problems are viewed as mere impediments to gender surgery that must be "reasonably well-controlled" so that surgery may proceed. This is

consistent with the regnant WPATH model that there is a single explanation that the child's condition is caused by a disconnection between biological reality and subjective identity which has an as-yet undiscovered cause, and has only a single solution: the social, medical, and surgical affirmation of the child's gender discordance.

73. Such a single cause/ single solution assumption would seem to be unlikely, given the massive range and the recent complete reversal in the demographics of transgenderism. What used to be a condition that was nearly exclusively found in little boys, and resolved nearly 90% of the time[15], is now predominantly a condition affecting young women, and at a rate that has risen between 4000 and 5000% in the course of the last decade.

74. The claim is often made that gender affirmation surgery is not cosmetic, because it is based in a "medical diagnosis" that can be found listed in the Diagnostic and Statistical Manual. This is a document produced by the American Psychiatric Association. It is essentially a dictionary of terminologies recommended in descriptions of psychiatric conditions. This publication used to include the terms "body dysmorphic disorder", and "gender identity disorder" among others used to describe self-identified transgender person. Changes to the language found in the

[15] Irreversible Damage: The Transgender Craze Seducing Our Daughters; Abigail Shreier, (2020)

DSM are based upon expert consensus methodologies described above, which are the lowest form of scientific evidence. The consensus in not obtained by polling the membership of the Society, but within a small group of provider- advocates. Conditions that were once in the category of paraphillias are now considered normal and not listed. It is in this committee that the decision was made to "depathologize" gender discordance. The difficulty is that without a medical diagnosis, you cannot generate billing for medical services. This is why the term "gender dysphoria" was chosen. No high quality scientific evidence was presented and reviewed by the committee in making the changes.

75. This methodology by the DSM committee has made the document essentially useless in making either a diagnosis, establishing principles of care, or estimating likely resolution of psychiatric medical problems. This appears to be why the National Institute of Mental Health, which has been the original source of funding for the DSM publicly its support for the DSM project just weeks before the present iteration was published in 2013. The fact that gender affirmation physicians and surgeons cite the DSM as a source document for diagnostic criteria is further proof that the condition exists in the subjective life of the patient, and therefore surgery performed to address the subjective condition is by definition cosmetic surgery.

76. Diagnostic and pre-operative selection for of patients for surgery is through a process that begins in psychology, continues with psychological support, and concludes with certification by psychological services that the patient is ready for surgical modification. At no point is there described any medical diagnostic process of history-taking, physical examination, laboratory evaluation, or radiographic examination that is used to confirm a surgical diagnosis. The entire process is in psychological services which is operating on the premise that the anxious child has made a correct diagnosis. The indication for surgery begins in the subjective life of the patient. Surgery is offered to the patient with the assurance that it is likely to improve the subjective life of the patient, and is therefore by definition cosmetic surgery.

On the Safety of Gender Affirmation Surgery

77. A discussion of surgical safety must include anticipated losses which are either expected, or even remotely possible. In order to examine the comparable issues in transgender versus reconstructive surgery our effort is simplified by comparing identical operations. I will describe two operations which use the identical techniques, and even the same tissue source so that we can better compare gender affirmation surgery, with actual reconstructive surgery.

78. On several occasions I have performed the reconstructive operation called "Sensate radial-forearm microvascular free flap hypopharyngeal

reconstruction". I performed this surgery in order to reconstruct the tongue and throat of patients who had suffered a grievous wound of the mouth and throat when he underwent removal of an aggressive cancer. The defects caused by that wounding needed to be replaced with thin, pliant, abrasion and fluid resistant tissue. It needed to provide the patient with sensation in the reconstructed area so that they can feel the food and liquids in their mouth, and manipulate the food so as to swallow it. We selected an area of skin on the inside of the forearm that has regular and robust blood flow, is thin and durable, and has an easily dissected sensory nerve that can be attached to the nerves in the wound. The forearm flap satisfied all the requirements. An operation of this complexity, duration, and technical requirements has many issues, big and small, that can diminish or destroy the result.

79. The throat reconstruction operation is in almost every way identical to the second most commonly performed female to male (FtM) gender affirmation surgery of the genital. It is called the "Sensate radial forearm microvascular free flap phalloplasty". In that operation, the identical flap is raised and transferred. It too must be resistant to abrasion, be water tight, pliant, sensate, and of correct volume. Through a process of incision, plication and suturing, a tubular phallus is constructed within which is a skin lined tube which will serve as the urethra. The suture closures in both flaps is where most things go wrong because the skin edges that define the suture line can lose their blood supply to varying degrees. In the phalloplasty, when

this happens, the patient suffers from delayed healing, urine leakage, varying degrees tissue death, and scarring. All of those problems can happen with either the throat flap, or the phallus flap. When the phallus flap fails, the patient suffers due to varying degrees of tissue loss, chronic urinary leakage, or urinary obstruction due to scarring that can cause kidney injury if left un-treated. When the throat flap fails, bacteria laden saliva will leak into the neck where it can cause fulminant infections, or erode into a major artery and cause the patient to bleed to death in a matter of moments. A singularly terrible event.

80. In the case of the throat operation, if the removal of the cancer had not been performed, there was a known and significant probability that the cancer would have eroded into the tissues of the neck and caused a fulminant infection, or eroded into a large blood vessel, as described above. In contrast, if the phallus flap operation, had not been performed, the patient would have remained fully functional in every human capacity, though suffering from an inner subjective disturbance called gender dysphoria, which has not yet been adequately treated.

81. Both operations involve the use of a highly complex surgical techniques to remedy a wound. In the case of the cancer operation the wound was the result of a cancer that would have ended in a terrible death. In the case of the phallus operation the surgeon is creating multiple physical wounds in a healthy child (castration, loss of pelvic organs of reproduction, de-gloving injury of the forearm, skin graft donor

site injury), with their associated risks of complications. The surgery is performed in attempt to remedy a subjective, patient-reported sense of their identity.

82. Clearly the pre-operative condition of the cancer patient is far more grievous than the condition of the young person who is suffering from gender dysphoria. The cancer patient would likely be more than willing to endure significant loss, such as voice, or teeth, or the sense of smell. And yet, if I were discussing surgical risk pre-operatively with my patient who has the throat cancer, and told him that there was a certainty that in the course of the operation he would lose all of his reproductive organs, he would be justified in asking why he was being subjected to such an unsafe operation. The patient wouldn't be even slightly interested in any further discussion of operative risks. The question of safety addresses itself to the question of potential losses caused by surgery. Transgender surgery of the genital apparatus predictably causes grievous loss that dwarfs such complications as infection, local tissue loss, urinary leakage or scarring. Such surgery can justly be considered universally unsafe in all cases, and particularly grievous when visited upon the young.

83. One of the peer reviewed article presented in support of masculinizing chest surgery, and found in numerous expert opinions submitted in pending federal

cases. It is a 2017 paper, published in the peer reviewed journal JAMA Pediatrics[16]. it claims to support the conclusion that "surgical intervention (mastectomy, or chest masculinization) positively affected both minors and adults". This paper is perhaps the most alarming of all the citations presently offered and deserves a detailed examination.

84. The principle author, Dr. Olson-Kennedy is also an academic expert in her capacity as Associate Professor of Clinical Pediatrics, Keck School of Medicine of USC, and Medical Director of The Center for Transyouth Health and Development in Los Angeles. She holds professional membership in The Society for Pediatric Research, the World Professional Association for Transgender Health(WPATH), and the Society for Adolescent Health and Medicine. If any gender affirmation expert would be in a position to offer high quality, evidence-based publications, it would certainly be Dr. Olson -Kennedy.

85. In their summary of findings, the authors report that "chest dysphoria" is common among "trans males" (natal females seeking to present as males), and that the dysphoria is decreased by surgery. They claim that regret for surgery is "rare". It is a retrospective review of children treated at a single center. The article

[16] Olson-Kennedy,J., Warus, . et al. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts; JAMA Pediatr2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440.

reports breast removal surgery on at least one girl aged 13 years. The average age was 19. Children were entered into the study through recruitment from among patients visiting the clinic, and by telephone over a six-month period. The authors found that patients recruited from among visitors to the clinic (convenience sampling) yielded an abundance of non-operated patients, so they were forced to reach out to all the known post-surgical patients by phone. 26% of the clinic's post-surgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. A 26% drop-out rate is never questioned by the authors. Were they lost to follow up because of dissatisfaction, psychiatric hospitalization, or suicide? This problem is called "self-selection bias", and is evidence of careless study design. Of the remaining 74% of patients, only 72% of them (only 53% of the study patients) completed the survey. This is a second example of self-selection bias. Why would some post-surgical patients who had been successfully contacted, not complete the survey? The authors do not ask the question.

86. In the study, dysphoria was measured using "a novel measure" (an unproven test instrument) which was a series of subjective questions about happiness. Among the designers of this novel test instrument were some of the adolescent patients themselves. Their flawed methodology included the use of an entirely unvalidated test instrument, with no known error rates, or proven predictive

power, **that was in part designed by the minors and young adults who were the subject of the study.** Furthermore, the post-surgical patients were given the survey at varying time intervals post-surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post surgery were included in their flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable claim given that long term, longitudinal population studies show that there is a dramatic rise in post-surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around year 7 post surgery (Dhejne cited below). Surely Dr. Olson-Kennedy is familiar with the international literature on transgender outcomes?

87. Having promised in the introduction to her paper that "chest dysphoria" is reduced by surgery, at the conclusion they confess the fact that the study design and execution produced very low-quality data that is not useful for patient selection, or prediction of outcomes. They even confess that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for performing the operation: mitigation of depression and suicide. The authors write:

"An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings.

Finally, the Chest Dysphoria Scale is not yet validated, and may not represent distress or correlate with validated measures of quality of life, depression, anxiety, or functioning."

88. This paper is a typical example of a publications which are used to support transgender medicine and surgery, written by board certified transgender expert physicians who practice in our nation's largest pediatric gender clinics, and was published in peer-reviewed medical journals. The article is essentially useless in making any clinical decisions regarding who should be offered surgery, what the likelihood is that they will benefit from it, or the likelihood that they will regret their decision. Most importantly, it cannot even vaguely estimate if the risk of hospitalization, incarceration, or suicide will be reduced. For the same reason that the paper is not useful in clinical decision making, it is likewise not meaningful in decision-making by persons responsible the just management of public and private medical resources.

On the Experimental Nature of Transgender Surgery

89. One of the important usages of the term "experimental" in the world of medical care is in the domain of insurance services, both public and private. Leadership in these agencies is charged with the responsibility of managing medical resources in a way that both preserves resources, while at the same time applying those resources to the patient as correctly as medical science and their own actuarial information will allow. Whenever a novel therapy is proposed for a given condition,

insurance services will examine the medical and actuarial data to see if the proposed therapy is likely to yield a result that serves those two purposes (health of the patient, and financial soundness of the insurance process). Typically, in the early years of a new treatment there is resistance on the part of the payors because early on (as discussed in detail above) all that the proponents are able to present is low-level scientific papers that present anecdotal case collections without controls, or multiple studies that can not be compared due to methodological variation or are methodologically questionable due to unvalidated test instruments. History has shown, and the fact remains, that good surgery demands good evidence, particularly when permanent damage to the client is a possible result.

90. Nonetheless, if the insurance agency reviewer see evidence that a new approach may be helpful, they prudently insist that therapies of known value be tried to their reasonable limit first , and that they be found to have failed in solving the patient's condition. Only the will consideration be given to the new treatment.

91. This dynamic process between the patient, the physicians, and the insurance industry has many problems, but good, well validated scientific evidence is not one of those problems. In fact well validated science is typically the best remedy for those problems. Sometime the good science is from the doctors, and sometimes the good science comes from the actuaries. In both cases the patient benefits.

92. From the perspective of the case in question, this sense of the term "experimental surgery" may be the most important. How did the affirmation care scientific model and its associated social, medical and surgical treatments enter into the mainstream of the medical community? Did it follow this same process of gradual acceptance in both the medical and insurance communities through a process of steadily improving evidence levels? Was it used on a careful trial basis after having exhausted treatment by established methods? The answer is that it did so, but only in part.

93. The historically validated treatment model for what is today called gender dysphoria is what is called "watchful waiting". On hearing the name one is tempted to think of this as a resignation to inaction. It is not. It is a psychotherapeutic process that is rooted first in an examination of the cognitive processes of the child, and seeing how the child has responded to the reality of their life. For this reason, in order to be effective, it must include family therapy. The goal is to keep the anxious and confused child in loving contact with reality, while seeking to understand and remedy the subjective dynamic that is provoking the condition of distress. It is essentially the same process used in helping persons who suffer other obsessive-compulsive issues, like eating disorders. Psychological research, having high level evidence, has shown that over the course of time this approach results in over 80%

resolution of the cross-sex self-identification during adolescence, and nearly 92% by young adulthood.(Zucker et al.).

94. This watchful-waiting approach is likely the reason why gender discordance used to be a rare diagnosis. The vast majority of people with the condition resolved the issues, and went on to live their lives without the need for life-long medications, without destructive surgeries, without the loss of their sexual faculties, and without the loss of fertility. What has happened, however, is that the dynamic between patient, physician, and insurance services has been severely disrupted.

95. The science based medical and actuarial management of this condition has been separated from the evidence, and now rests entirely on the opinions of academic experts who have managed to influence the decision makers in their favor. In large part, they have accomplished this by never speaking about watchful waiting except to dismiss it as folly. This process of silence and dismissal is exactly what ulcer surgeons did to the proponents of the scientifically correct infection model of ulcer disease.

96. Silence and dismissal about watchful waiting is not the only reason for the 5,000% increase in the diagnosis of transgender over the past decade. Surgeons who were seeking to achieve the best results for their transgender patients came to realize that most of the difficulty with good cosmetic results was that young men

seeking to present as women tend to appear too masculine, and young women seeking to present as men tend to appear too feminine. They reasoned that if their masculine or feminine development had been arrested early, they would achieve better results. It was reasonable, in light of their treatment model, to think that a better cosmetic result would mean a better resolution of the gender incongruence. Thus the idea was born that the earlier the child was transitioned, the better the cosmetic surgical result, and thus the better psychological result, which is the goal.

97. This theoretical improvement in outcomes for transgender persons through early transition was certainly an idea worth investigating. Because the lifelong effects of the approach might include some really bad outcomes for the children, and because the actual outcomes were unknown at the time, it would have been prudent, and scientifically consistent to categorize this from the above described insurance industry perspective, as experimental. It would have required that the patients exhaust the fully established and proven treatment model of watchful waiting. If that treatment failed to resolve the issue, then on a trial basis, and supervised under very strenuous human experimentation oversight, the affirmation model could be tried.

98. In order for any highly supervised experimental approach to pass ethical standards in human experimentation there would have to have been a previously established diagnostic and patient selection process of very high

specificity. If the proven and established method of watchful waiting is yielding 92% resolution, then what the ethically minded surgeon is really supposed to be doing is trying to find that 8% of children who would have failed watchful waiting, and select them out for surgery earlier in their life. Then studying the result on a very long-term and comprehensive basis, he would have been able to provide high-value evidence that his hypothesis about the successful early management of transgenderism is a safe and valid option for his patient. This was not done. Instead, the routine social and medical transitioning of children began, which includes puberty blockade, and cross-sex hormones in children and youth.

99. Instead of seeking the historically small cohort of children who would have carried the condition into adulthood and treating them, physicians and surgeons are treating all of those children now. Instead of seeking the scientific methodology with which to make a correct diagnosis so as to increase the likelihood that you are operating on the right person, the transgender treatment model is essentially turning all affected children into "the right person". By the time the youth or young adult person arrives in the surgeon's office the process has been locked into place.

100. It would seem that the best course of action for those who serve the insurance industry, including state Medicaid, is to return this process to the time tested dynamic model of patient, physician, and insurance plan discussed above.

Because the affirmation model rests upon such low-quality evidence, it seems justifiable to suspend financial support until such time as testing and patient selection processes are improved to acceptable levels of reliability. Given the serious, lifelong consequences of mis-diagnosis, and the misapplication of surgery, levels of patient selection reliability would have to be quite high.

101. A review of the European literature on this topic is instructful. The American literature used in support of the claim of benefit is of low reliability. We make this assertion based on the fact that to date all scientific citations offered in support of gender affirmation medicine and surgery is that they report studies of short duration. Follow up durations of less than 3 years are common. Some, as we have seen are as short as 4 months. This fact helps us to understand why proponents of the affirmation model are enthusiastic. Medical services in a number of European countries utilize centralized medical databases which employ uniform language, and report care over the life of the citizen.

102. The Swedish medical establishment maintains an excellent and centralized data base of all episodes of care for beneficiaries. It uses uniform language, and captures treatment events at all levels, from school clinics, to psychiatric hospitals, to prison infirmaries, to public clinics. The database can be analyzed for such things as emergency room visits, drug addiction treatment, hospitalization for suicide, psychiatric admissions for self-harming event etc.

103. In 2011, Dhejne et al.[17] published a population based, longitudinal cohort study of that database that sought to examine the lifetime hazard ratio of such things as substance abuse, incarceration for violent behavior, psychiatric hospitalization, and completed suicide. This is level-III evidence of high order given the methodology employed and the proven reliability of the database. It examined persons who have fully completed the gender affirmation process and compares them to age and sex matched controls in the Swedish population. It did not use anonymous surveys, or other faulty convenience sampling. It found the post-transition patients by finding the associated episodes of care, such as when hormone therapy prescriptions began, or admission for gender surgery occurred. The data set spans 30 years. What it shows is that fully transitioned subjects showed a relative risk of suicide roughly equal to the age/ sex matched controls, but the effect appears to last for just a few years. The trend line for death from any cause begins a sharp drop at approximately 10 years and continues to drop massively over the subsequent 15 years. When the researchers looked at the aggregate life-time relative risk of suicide, persons who fully transitioned were over 19 times more likely to have killed themselves when compared to age and sex matched controls. If you only look at the subgroup of biological females who transitioned to male-presentation, the risk of

[17] Dhejne,C., Lichtenstein, P., et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden; PLoS One2011 Feb 22;6(2):e16885. doi: 10.1371/journal.pone.0016885.

suicide is 40 times higher than the control group. Results such as these, because they are obtained using tested and reliable methodology, are able to help meaningfully in clinical and administrative decision making, and in several European countries it has.

104. Over the past several years, the medical systems in Great Britain, Sweden, Finland, and France[18][19][20] have stepped away from early medical and surgical transitioning of the young. The Tavistock-Portman Institute in London, which was the sole provider of these services to children in Great Britain was closed

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[18] **NHS Amendments to service specifications for Gender Identity Development Service** (GIDS) for children and adolescents, **effective 01 Dec 2020**. https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf

[19] **Sweden's Karolinska Hospital** (affectingAstrid Lindgren Children's Hospital's pediatric gender services) issues a **policy change effective April 1, 2021**:

- "…hormonal treatments (*i.e., puberty blocking and cross-sex hormones, see above*) will not be initiated in gender dysphoric patients under the age of 16."
- "For patients between ages 16 and 18, it is hereby decided that treatment may only occur within the clinical trial settings approved by the EPM (*Ethical Review Agency/Swedish Institutional Review Board*)."
- "These changes shall not affect the continued psychological and psychiatric care within BUP (*Public Child and Adolescent Psychiatry*) for patients under 18 years of age." "The patient must receive comprehensive information about potential risks of the treatment…"
- Cited UK High Court Decision, NHS policy change in light of it, and that in "2019, the SBU (*Swedish Agency for Health Technology Assessment and Assessment of Social Services*) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years."[19]
- "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis."

Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf
Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf

[20] **Finland rejects routine "affirmation" pathway for minors with GD. From Finnish Health Authority, *Council for Choices in Health Care in Finland (COHERE Finland)* 2020:**

recently following the public declaration by a review committee that the Institute was "unsafe for children". Similarly, the Karolinska Institute in Stockholm reversed its policy by suspending the medical and surgical transitioning of the young in favor or psychological support and treatment. Similar changes in treatment guidelines for self-identified transgender youth have been published in Finland, and are currently being developed in Italy.

105. Based upon these developments in Europe, it is very troubling to read assessments or declarations by leaders in the field of transgender surgery which assert that these treatments are mainstream and beyond controversy, or that they are part of a core curriculum of surgical training, or that an oral board examiner might fail a candidate surgeon if their answers reveal a reticence to join the mainstream as defined by gender affirmation advocates. The world literature demonstrates emphatically that early medical and surgical transitioning is in fact so controversial that medical leadership in multiple countries has put a stop to it.

106. In summary, transgender surgery is based in a treatment model of affirmation that lacks scientific support based in quality evidence. The scientific support offered by the leaders in the field is entirely composed of small studies, single provider /single center studies that are lacking in control cohorts, and are often rendered uninterpretable due to haphazard case-collections such as the solicitation of study participants without methodology to confirm that the patient is a treatment

subject. All of the studies cited in expert filings by gender affirmation practitioners have short follow-up, and most studies suffer from massive self-selection bias and high drop-out rates. The studies often employ untested assessment methodologies, and all of the literature cited by experts report only subjective data, which is typical of papers that address outcomes in cosmetic surgery.

107. Transgender surgery is, by definition, cosmetic surgery. The move towards surgery begins in the subjective life of the patient, is conducted with the aim of improving the subjective life of the patient, and outcomes are measured in subjective terms based in satisfaction surveys. Transgender surgery violates fundamental principle of cosmetic surgery, because it predictably destroys essential functions of the human person. It is not reconstructive surgery because the patient is physically healthy before the surgery, and has no definable deficit that can be objectively characterized to be the cause of the presenting complaint. There is no objective test to confirm the diagnosis of transgender, and no way to correctly select patients for surgery from among the young. The enterprise of gender affirmation medicine and surgery is based entirely in a consensus of expert opinion of low reliability because it is supported by unreliable scientific evidence.

I declare, pursuant to 28 USC § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 16th day of February, 2023.

/s/ Patrick W. Lappert
Dr. Patrick W. Lappert, M.D.

Curriculum Vitae- Patrick W. Lappert, MD

Education and Training :

— Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. Research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump.

— M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md.

— General Surgery Residency at the Naval Hospital Oakland/ UC Davis East Bay Consortium, 1987-1991

— Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991.

— Plastic Surgery Residency at the University of Tennessee- Memphis, 1992-1994.

Board Certifications in Medicine :

— Board Certified in Surgery — American Board of Surgery, 1992-2002

— Board Certified in Plastic Surgery — American Board of Plastic Surgery, 1997-2018

Medical Staff Appointments :

— Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992

— Associate Professor of Surgery, UC Davis-East Bay, 1991-1992.

— Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, VA 1994-2002

— Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, VA 1996-2002.

— Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002

— Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, VA 1996-20002

— Founding Director, Wound Care Center, Naval Hospital Portsmouth, VA 1995-2002.

— Staff Plastic Surgeon in Nebraska, and Alabama.

U.S.N. Surgeon General Service:

— Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002

Faculty Appointments:

— Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002

Military Service :

— Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978

— Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983 .

— Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985

— Flight Surgeon, Marine Fighter/ Attack Squadron-451

— Radar Intercept Officer in the Marine F-4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor.

— Deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines.

— Service in the US Navy for 24 years

— Service in the US Marine Corp. for 3 years.

— Retired with the rank of Captain, USN in 2002

Military Awards:

— Navy Commendation Medal - For service with Marine Fighter/Attack Squadron - 451

— Meritorious Unit Citation- 3rd award

— Humanitarian Service Medal - For service in the aftermath of the Loma Prieta earthquake.

Publications - Peer Reviewed Medical Journals :

— Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep;102(3):553-4

— Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87: 1048-53

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— Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. P!astic and Reconstructive Surgery 1998;102(5):1642-5.

Publications - Medical Textbooks:

— Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000

Operations and Clinical Experience - Consultations and Discussions : As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.

Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

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*Cosponsoring Associations: American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society–appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments—appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

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Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. (***J Clin Endocrinol Metab*** **102: 3869–3903, 2017)**

Summary of Recommendations

1.0 Evaluation of youth and adults

1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)

1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

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1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 |⊕⊕◯◯)

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 |⊕⊕⊕◯)

2.0 Treatment of adolescents

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 |⊕⊕◯◯)

2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 |⊕⊕◯◯)

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 |⊕⊕◯◯)

2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 |⊕⊕◯◯).

2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕◯◯◯)

2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. (2 |⊕⊕◯◯)

3.0 Hormonal therapy for transgender adults

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 |⊕⊕⊕◯)

3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. (1 |⊕⊕⊕◯)

3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 |⊕⊕◯◯)

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕◯◯◯)

4.0 Adverse outcome prevention and long-term care

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 |⊕⊕◯◯)

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 |⊕⊕◯◯)

4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 |⊕⊕◯◯)

4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 |⊕⊕◯◯)

4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 |⊕⊕◯◯)

4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 |⊕◯◯◯)

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

5.0 Surgery for sex reassignment and gender confirmation

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 ⊕⊕◯◯)

5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)

5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)

5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 ⊕◯◯◯)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 ⊕⊕◯◯).

5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 ⊕◯◯◯)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of "gender dysphoria/gender incongruence." It also reviews the development of "gender identity" and summarizes its natural development. The section on clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking gender-confirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕◯◯◯ denotes very low–quality evidence; ⊕⊕◯◯, low quality; ⊕⊕⊕◯, moderate quality; and ⊕⊕⊕⊕, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the

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values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these "Ungraded Good Practice Statement." Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-of-interest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society's Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline's development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [*e.g.*, stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers' bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are "trapped" in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote "The Transsexual Phenomenon" (4), it was Hirschfeld who coined the term "transsexual" in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through "something in between" to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (*e.g.*, Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (*e.g.*, the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in *CYP21A2* reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24–26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity *per se* (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

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Table 1. Definitions of Terms Used in This Guideline

Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (*e.g.*, a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.
Cisgender: This means not transgender. An alternative way to describe individuals who are not transgender is "non-transgender people."
Gender-affirming (hormone) treatment: See "gender reassignment"
Gender dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced "gender identity disorder" with "gender dysphoria" and changed the criteria for diagnosis.
Gender expression: This refers to external manifestations of gender, expressed through one's name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.
Gender identity/experienced gender: This refers to one's internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is not visible to others.
Gender identity disorder: This is the term used for GD/gender incongruence in previous versions of DSM (see "gender dysphoria"). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using "gender incongruence of childhood."
Gender incongruence: This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity–related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment.
Gender variance: See "gender incongruence"
Gender reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.
Gender-reassignment surgery (gender-confirming/gender-affirming surgery): These terms refer only to the surgical part of gender-confirming/gender-affirming treatment.
Gender role: This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.
Sex designated at birth: This refers to sex assigned at birth, usually based on genital anatomy.
Sex: This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.
Sexual orientation: This term describes an individual's enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.
Transgender: This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.
Transgender male (also: trans man, female-to-male, transgender male): This refers to individuals assigned female at birth but who identify and live as men.
Transgender woman (also: trans woman, male-to female, transgender female): This refers to individuals assigned male at birth but who identify and live as women.
Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.
Transsexual: This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens *et al.* (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development.

Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormone-prescribing clinicians should examine the psychosocial impact of the potential changes on people's lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43–51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender
   4. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:
   1. The condition exists with a disorder of sex development.
   2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (*e.g.*, penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Reference: American Psychiatric Association (14).

of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)

1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:
1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
2. The transsexual identity has been present persistently for at least 2 y.
3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

1. Persistent, well-documented gender dysphoria/gender incongruence
2. The capacity to make a fully informed decision and to consent for treatment
3. The age of majority in a given country (if younger, follow the criteria for adolescents)
4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

1. A qualified MHP has confirmed that:
   - the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
   - gender dysphoria worsened with the onset of puberty,
   - any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
   - the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
2. And the adolescent:
   - has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
   - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
   - agrees with the indication for GnRH agonist treatment,
   - has confirmed that puberty has started in the adolescent (Tanner stage ≥G2/B2),
   - has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

1. A qualified MHP has confirmed:
   - the persistence of gender dysphoria,
   - any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
   - the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
2. And the adolescent:
   - has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
   - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
   - agrees with the indication for sex hormone treatment,
   - has confirmed that there are no medical contraindications to sex hormone treatment.

Reproduced from World Professional Association for Transgender Health (16).

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reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of gender-affirming treatment, or be affected by hormone use.

Values and preferences

The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 |⊕⊕◯◯)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gender-variant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 |⊕⊕⊕◯)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after

cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin treatment. However, sperm numbers when partners of these patients conceive are far below the "normal range" (70, 71).

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. *In vitro* spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74–77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before gender-affirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 |⊕⊕◯◯)

2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 |⊕⊕◯◯)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult

barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87).

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document early pubertal changes.

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 ⊕⊕◯◯)

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider long-acting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

The description of Tanner stages for breast development:
1. Prepubertal
2. Breast and papilla elevated as small mound; areolar diameter increased
3. Breast and areola enlarged, no contour separation
4. Areola and papilla form secondary mound
5. Mature; nipple projects, areola part of general breast contour

For penis and testes:
1. Prepubertal, testicular volume <4 mL
2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
3. Penis longer, testes larger (8–12 mL)
4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
5. Penis adult size; testicular volume > 15 ml

Adapted from Lawrence (56).

precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after "gender-reassignment surgery" (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and gender-reassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first long-term follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD z scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD z scores and of bone mineral apparent density z scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (±1.9) years for 1.3 years (0.5 to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (±1.4) years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age 16.4 (±2.3) years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD z scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog–treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D–deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog–treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/gender-incongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single cross-sectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109–112). These compounds are usually safe, but some side effects have been reported (113–115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dual-energy X-ray absorptiometry scans.

2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 |⊕⊕◯◯)

2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕◯◯◯)

2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 |⊕⊕◯◯)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3–6 mo
Anthropometry: height, weight, sitting height, blood pressure, Tanner stages
Every 6–12 mo
Laboratory: LH, FSH, E2/T, 25OH vitamin D
Every 1–2 y
Bone density using DXA
Bone age on X-ray of the left hand (if clinically indicated)

Adapted from Hembree *et al.* (118).

Abbreviations: DXA, dual-energy X-ray absorptiometry; E2, estradiol; FSH, follicle stimulating hormone; LH, luteinizing hormone; T, testosterone;

Table 8. Protocol Induction of Puberty

Induction of female puberty with oral 17β-estradiol, increasing the dose every 6 mo:
- 5 μg/kg/d
- 10 μg/kg/d
- 15 μg/kg/d
- 20 μg/kg/d
- Adult dose = 2–6 mg/d
- *In postpubertal transgender female adolescents, the dose of 17β-estradiol can be increased more rapidly:*
  - 1 mg/d for 6 mo
  - 2 mg/d

Induction of female puberty with transdermal 17β-estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d):
- 6.25–12.5 μg/24 h (cut 25-μg patch into quarters, then halves)
- 25 μg/24 h
- 37.5 μg/24 h
- Adult dose = 50–200 μg/24 h
- *For alternatives once at adult dose, see Table 11.*
- *Adjust maintenance dose to mimic physiological estradiol levels (see Table 15).*

Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC):
- 25 mg/m^2/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk)
- 50 mg/m^2/2 wk
- 75 mg/m^2/2 wk
- 100 mg/m^2/2 wk
- Adult dose = 100–200 mg every 2 wk
- *In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly:*
  - 75 mg/2 wk for 6 mo
  - 125 mg/2 wk
- *For alternatives once at adult dose, see Table 11.*
- *Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).*

Adapted from Hembree *et al.* (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3–6 mo
- •Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 mo
- •In transgender males: hemoglobin/hematocrit, lipids, testosterone, 25OH vitamin D
- •In transgender females: prolactin, estradiol, 25OH vitamin D

Every 1–2 y
- •BMD using DXA
- •Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached).
For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree *et al.* (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

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for 6 to 7 years before initiating sex hormones (*e.g.*, if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (*e.g.*, human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17β-estradiol may be an alternative for oral 17β-estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for Transgender Adults

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce

the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for transgender individuals. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being (129, 130).

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 ⊕⊕⊕◯)

3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). (1 ⊕⊕⊕◯)

3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 ⊕⊕◯◯)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1–5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 "Adverse Outcome Prevention and Long-Term Care") and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen
Very high risk of adverse outcomes:
•Thromboembolic disease
Moderate risk of adverse outcomes:
•Macroprolactinoma
•Breast cancer
•Coronary artery disease
•Cerebrovascular disease
•Cholelithiasis
•Hypertriglyceridemia
Transgender male: testosterone
Very high risk of adverse outcomes:
•Erythrocytosis (hematocrit > 50%)
Moderate risk of adverse outcomes:
•Severe liver dysfunction (transaminases > threefold upper limit of normal)
•Coronary artery disease
•Cerebrovascular disease
•Hypertension
•Breast or uterine cancer

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Table 11. Hormone Regimens in Transgender Persons

Transgender females[a]	
Estrogen	
Oral	
Estradiol	2.0–6.0 mg/d
Transdermal	
Estradiol transdermal patch (New patch placed every 3–5 d)	0.025–0.2 mg/d
Parenteral	
Estradiol valerate or cypionate	5–30 mg IM every 2 wk 2–10 mg IM every week
Anti-androgens	
Spironolactone	100–300 mg/d
Cyproterone acetate[b]	25–50 mg/d
GnRH agonist	3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly
Transgender males	
Testosterone	
Parenteral testosterone	
Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
Testosterone undecanoate[c]	1000 mg every 12 wk
Transdermal testosterone	
Testosterone gel 1.6%[d]	50–100 mg/d
Testosterone transdermal patch	2.5–7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously.

[a]Estrogens used with or without antiandrogens or GnRH agonist.

[b]Not available in the United States.

[c]One thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

[d]Avoid cutaneous transfer to other individuals.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132–134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5α-Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich *et al.* (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17β-estradiol, or transdermal 17β-estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the "first pass effect" than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual

estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

Our recommendation to maintain levels of gender-affirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (*e.g.*, male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidence-based protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and antiandrogen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12. Masculinizing Effects in Transgender Males

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6–12 mo	4–5 y
Scalp hair loss	6–12 mo	—[a]
Increased muscle mass/strength	6–12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	—[b]
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

[a] Prevention and treatment as recommended for biological men.

[b] Menorrhagia requires diagnosis and treatment by a gynecologist.

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Table 13. Feminizing Effects in Transgender Females

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y[a]
Scalp hair	Variable	—[b]
Voice changes	None	—[c]

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157).

[a]Complete removal of male sexual hair requires electrolysis or laser treatment or both.

[b]Familial scalp hair loss may occur if estrogens are stopped.

[c]Treatment by speech pathologists for voice training is most effective.

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (*e.g.*, breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone–induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and Long-Term Care

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 l⊕⊕○○)

Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:[a]
   a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
3. Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
4. Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
6. Ovariectomy can be considered after completion of hormone transition.
7. Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

[a]Adapted from Lapauw *et al.* (154) and Ott *et al.* (159).

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering gender-affirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 l⊕⊕○○)

Evidence

Estrogen therapy can increase the growth of pituitary lactrotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
2. Measure serum testosterone and estradiol every 3 mo.
   a. Serum testosterone levels should be <50 ng/dL.
   b. Serum estradiol should not exceed the peak physiologic range: 100–200 pg/mL.
3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).
5. Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

This table presents strong recommendations and does not include lower level recommendations.

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4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 l⊕⊕○○)

Evidence

Transgender males

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176–179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at ≥24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 l⊕⊕○○)

Evidence

Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pretreatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than −2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (*e.g.*, when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be

reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. (2 ⊕⊕◯◯)

4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 ⊕◯◯◯)

Evidence

Studies have reported a few cases of breast cancer in transgender females (197–200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1 30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren *et al.* (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210–214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a gender-affirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and

provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other gender-conforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the "threshold of 18 should not be seen as an indication in itself for active intervention." If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologuous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

1. Persistent, well-documented gender dysphoria
2. Legal age of majority in the given country
3. Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)
4. Successful continuous full-time living in the new gender role for 12 mo
5. If significant medical or mental health concerns are present, they must be well controlled
6. Demonstrable knowledge of all practical aspects of surgery (*e.g.*, cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular (239–241).

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (*e.g.*, a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 ⊕⊕◯◯)

5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)

5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)

5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 ⊕◯◯◯)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 ⊕⊕◯◯).

5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 ⊕◯◯◯)

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259–261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of

causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have gender-affirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BAKCGROUND AND QUALIFICATIONS

3. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide an expert opinion on gender identity; the treatment and diagnosis of gender dysphoria; the *Florida Medicaid Generally Accepted*

Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments; and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics.

A. Qualifications and Experience

4. I am a Double Board Certified Physician in Pediatrics and Adolescent Medicine. I specialize in the care of transgender youth and gender diverse children. I am a recognized expert in this field.

5. The information provided regarding my professional background, experiences, publications, and presentations is further detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

6. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange County, California, and from 2000 to 2003, I was a Fellow in adolescent medicine at the Children's Hospital of Los Angeles.

7. I have been a licensed physician in California since 2000. I am currently the Medical Director of the Center for Transyouth Health and Development, in the Division of Adolescent Medicine at the Children's Hospital in Los Angeles, California. The Center is the largest clinic in the United States for transgender youth and provides gender diverse youth with both medical and mental health services, including consultation for families with gender diverse children and routine use of medications to suppress puberty in peri-pubertal youth (i.e., youth at the onset of puberty), gender-affirming hormone use for masculinization and feminization, as well as surgical referrals. Under my direction, the Center conducts rigorous research aimed at understanding the experience of gender diversity and gender dysphoria from childhood through early adulthood.

8. Over the course of my work with this population during the past 16 years, I have provided services for approximately 1000 young people and their families, and currently have an active panel of around 650 patients of varying ages, up to 25 years old.

9. I have been awarded research grants to examine the impact of early interventions including puberty-delaying medication (commonly known as puberty blockers) and gender-affirming hormones on the physiological and

psychosocial development of gender diverse and transgender youth. I have lectured extensively, across the United States and internationally on the treatment and care of gender diverse children and transgender adolescents, the subjects including pubertal suppression, gender-affirming hormone therapy, transitioning teens and the adolescent experience, age considerations in administering hormones, and the needs, risks, and outcomes of hormonal treatments. I have published numerous articles and chapters, both peer reviewed, and non-peer reviewed, on transgender health-related issues.

10. I am currently the principal investigator on a multisite National Institutes of Health grant to continue, for an additional 5 years, an ongoing study examining the impact of gender-affirming medical care for transgender youth on physiologic and psychological health and well-being. The first five years have already been completed. This is the first study of its kind in the U.S. to determine longitudinal outcomes among this population of vulnerable youth. The study to date has yielded approximately 26 manuscripts.

11. I am an Associate Professor at the Keck School of Medicine at the University of Southern California and attending physician at Children's Hospital of Los Angeles. I have been a member of the World Professional Association for Transgender Health (WPATH) since 2010, and a Board Member of the U.S.

Professional Association for Transgender Health (USPATH) since 2017. I was recently appointed to the Executive Board of the USPATH. I am also a member of the Society for Adolescent Health and Medicine and the American Academy of Pediatrics. In addition, I am a member of the LGBT Special Interest Group of the Society for Adolescent Health and Development.

12. I am the 2014 Recognition Awardee for the Southern California Regional Chapter of the Society for Adolescent Health and Medicine.

13. In 2019, I was invited by the University of Bristol as a Benjamin Meaker visiting professor, the purpose of which is to bring distinguished researchers from overseas to Bristol in order to enhance the research activity of the university.

B. Previous Testimony

14. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Fain v. Crouch*, No. 3:20-cv-00740 (S.D. W.Va.); *Kadel v. Folwell*, Case No. 1:19-cv-00272-LCB-LPA (M.D.N.C.); *Miller v. Purdue* (Colorado); *In the interest of JA.D.Y. and JU.D.Y., Children*, Case No. DF-15-09887 (255th Jud. District Ct., Dallas Cty., Tex.); and *Paul E. v. Courtney F.*, No. FC2010-051045 (Superior Ct., Maricopa Cty., Ariz.).

C. Compensation

15. I am being compensated for my work on this matter at a rate of $200.00 per hour for preparation of declarations and expert reports, as well as any pre-deposition and/or pre-trial preparation and any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

D. Bases for Opinions

16. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. *See* **Exhibit A**. It documents my education, training, research, and years of experience in this field and includes a list of publications.

17. I have also reviewed the materials listed in the attached bibliography. *See* **Exhibit B**. The sources cited therein are authoritative, scientific peer-reviewed publications. I generally rely on these materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration.

18. In addition, I have reviewed the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care

Administration (AHCA) in June 2022, along with its attachments, including the "assessments" of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics. I may rely on these documents, as well as those cited in my curriculum vitae and the attached bibliography, as additional support for my opinions.

19. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

EXPERT OPINIONS

A. Gender Identity

1. The term gender identity was originally coined in 1964 by American psychiatrist Robert J. Stoller, a noted psychoanalyst who studied sexual orientation, gender identity, and differences in sexual development.[1] Gender identity is a distinct characteristic and is defined as one's internal sense of being male or female (or rarely, both or neither). It has a strong biological basis. Every person has a gender identity.

2. The concept of gender identity is contemporaneously understood both colloquially and within the domain of science and medicine to denote someone's gender. It is a concept well-understood and accepted in medicine and science. Indeed, gender identity information is commonly collected and reported on within the context of scientific research.[2]

3. The term cisgender refers to a person whose gender identity matches their sex assigned at birth. The term transgender refers to a person whose gender identity does not match their sex assigned at birth.

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[1] Stoller, R.J. (1964). A Contribution to the Study of Gender Identity, *The International journal of psycho-analysis*, 45, 220–226.

[2] Clayton JA, Tannenbaum C. (2016). Reporting Sex, Gender, or Both in Clinical Research? *JAMA*. 316(18): 1863–1864.

4. Historically, "gender" was equated with a person's sex assigned at birth, which refers to the sex assigned to a person when they are born, generally based on external genitalia. However, a more contemporary understanding of gender shows that one's gender identity may differ from one's sex assigned at birth.

5. While both gender identity and sex are often assumed and treated as binary and oppositional, they are more accurately experienced as along a spectrum. For example, there are multiple sex characteristics, such as genitalia, chromosomal makeup, hormones, and variations in brain structure and function. For some of these characteristics there is significant variance as reflected by the dozens of intersex mechanisms and varying gender identities. Additionally, not all sex characteristics, including gender identity, are always in alignment. Accordingly, the Endocrine Society Guidelines state that, "As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided."[3]

[3] Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 102(11): 3869–3903.

6. As early as 1966 it has been understood that gender identity cannot be changed.[4] Efforts to do so have been shown to be unsuccessful and harmful.

B. Gender Dysphoria and its Treatment

7. Gender Dysphoria (GD) is a serious medical condition characterized by distress due to a mismatch between assigned birth sex and a person's internal sense of their gender. GD was formerly categorized as Gender Identity Disorder (GID) but the condition was renamed in May 2013, with the release of the American Psychiatric Association (APA)'s fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).[5] In announcing this change, the APA explained that in addition to the name change, the criteria for the diagnosis were revised "to better characterize the experiences of affected children, adolescents, and adults."[6] The APA further stressed that "gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition."[7]

[4] Benjamin, H. (1966). The Transsexual Phenomenon. New York: The Julian Press, Inc. Publishers.

[5] A text revision to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition was published in 2022 ("DSM-5-TR").

[6] DSM-5.

[7] *Id.*

8. On May 25, 2019, the World Health Assembly approved International Classification of Diseases (ICD) version 11 that had been published by the World Health Organization in 2018.[8] In this newest version of the ICD, all trans-related diagnostic codes were removed from the chapter "Mental and Behavioral Disorders," and the code "Gender incongruence" was included in a new chapter "Conditions related to sexual health." These codes replaced the outdated "Gender Identity Disorder of childhood" (F64.2), "Gender Identity Disorder not otherwise specified" (F64.9), "transsexualism" (F64.0), and "Dual-role transvestism" (F64.1), which perpetuated the idea that patients seeking and undergoing medical interventions for a medical condition are mentally ill.[9]

9. For a person to be diagnosed with GD, there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign to the individual, present for at least six months. In children, the desire to be of the other gender must be present and verbalized.[10] The

[8] World Health Organization. (2018). Gender Incongruence. In International Classification of Diseases, 11th Revision.

[9] Suess Schwend A. (2020). Trans health care from a depathologization and human rights perspective. *Public health reviews*, *41*, 3.

[10] Notably, the DSM-IV included a separate diagnosis for GID in children, which required the child to display a number of behaviors stereotypical of the non-natal gender. That diagnosis, and its list of behavioral requirements, have been deleted from the DSM-5 and replaced by updated and more precise diagnostic criteria.

condition must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

10. The World Professional Association of Transgender Health (WPATH) has clear recommendations for the health of transsexual, transgender, and gender non-conforming people in what is now the Standards of Care version 8 (SOC 8).[11] The SOC are based on the best available science and expert professional consensus. Importantly, SOC 8 is based on the best available science and expert professional consensus in transgender health; its recommendation statements were developed based on data derived from independent systematic literature reviews, background reviews, and expert opinions; and its grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability of these. SOC 8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as treatment for gender dysphoria, based on an individual patient's needs.

11. The WPATH SOC have been endorsed and cited as authoritative by most major medical associations in the United States, including the American

[11] Coleman, et al. (2022) (SOC 8).

Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the Pediatric Endocrine Society, the American College of Physicians, and the American Academy of Family Physicians, among others.

12. The UCSF Center for Excellence in Transgender Care as well as the Endocrine Society have both published comprehensive guidelines for the care of transgender and non-binary individuals that are largely consistent with the WPATH SOC.[12]

13. The GAPMS Memo and some its attached "assessments" discuss a number of approaches to care, though they fail to properly describe them and to discuss their limitations.

14. One of the approaches discussed by Dr. Van Meter is **"reparative" or "corrective"** therapy. *See* Attachment E to GAPMS Memo, at 6 ("Van Meter"). "Conversion" or "reparative" therapy refers to the practice of attempting to change an individual's sexual orientation and attractions from members of the same sex to those of the opposite sex. A similar model of therapy

[12] Deutsch, M.B. (ed.). (2016). Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2d ed.). San Francisco, CA: UCSF Center of Excellence for Transgender Health, https://transcare.ucsf.edu/guidelines (UCSF Guidelines); Hembree, et al. (2017) (Endocrine Society Guidelines).

for individuals with a transgender identity or experience has historically been an approach promoted by some individuals, notwithstanding its ineffectiveness and harmful effects. Accordingly, 20 states and the District of Columbia have banned reparative therapy for youth, and major medical organizations have issued statements deeming the practice to be unethical.[13]

15. A Williams Institute report published in 2019 estimates that just under 700,000 LGBT individuals in the United States have undergone "conversion therapy" at some point in their lifetime, about half of those during adolescence.[14] Because some psychiatrists and sexologists working in the 1960's and 70's perpetuated the idea that being transgender was likely the result of a pathological early childhood experience, many professionals and lay community members continue to believe that gender is malleable. Tactics have ranged from simple redirection, thought pattern alteration or hypnosis to aversion techniques including induction of vomiting, nausea, paralysis or electric shock, have been employed in order to change the expression, behavior, and assertion of one's

[13] Movement Advancement Proj., *Conversion "Therapy" Laws,* https://www.lgbtmap.org/equality-maps/conversion_therapy (last updated Jan. 30, 2023).

[14] Mallory, C., Brown, T. N.T., Conron, K.J. (2019). Conversion Therapy and LGBT Youth: Update. Los Angeles, CA: The Williams Institute, UCLA School of Law.

authentic gender.[15] However, multiple studies show that gender identity has a strong biological basis and cannot be changed. As such, reparative therapy is both ineffective and harmful for transgender and gender diverse youth.

16. **"Redirection"** – Under this approach, advocated by people like Dr. Van Meter, a mental health therapist would encourage caregivers to use positive reinforcement to try to "redirect" children toward behavior that is more typical of their birth-designated sex or less gender specific. Underlying this approach is the assumption that a child's gender identity is malleable through social interventions. The goal of redirection is thus to eliminate gender-diverse desires and expressions over time, and to try to prevent the transgender child from being transgender. This approach is not recommended because negative reinforcement (e.g., shaming the child for gender diverse expression) has substantial negative mental and social health consequences.[16] It also ignores that gender identity is innate and cannot be changed.

17. **Wait-and-see** – The wait-and-see approach (also called watchful waiting) involves waiting to see if the child's gender identity will change as the

[15] *Id.*

[16] Turban, J.L., & Ehrensaft, D. (2018). Research Review: Gender identity in youth: treatment paradigms and controversies. *Journal of child psychology and psychiatry, and allied disciplines*, *59*(12), 1228–1243; Ehrensaft, D. (2017). Gender nonconforming youth: current perspectives. *Adolescent health, medicine and therapeutics*, *8*, 57–67.

child gets older. This approach typically recommends that caregivers prohibit a prepubertal social transition but may allow cross-gender play and clothing within the home or support both masculine and feminine activities as the child explores their interests in other social settings. The wait-and-see approach assumes that gender is binary and becomes fixed at a certain age; it pathologizes gender diversity and fluidity. It is distinguished from following the child's lead, an affirming approach that allows the child to present in the gender role that feels correct and moves at a pace that is largely directed by the child. This approach ignores evidence that young children thrive when given permission to live in the gender that is most authentic to them and are at risk for symptomatic behaviors if prevented from doing so.[17]

18. **Affirmation** – The affirmative approach considers no gender identity outcome: transgender, cisgender, or otherwise, to be preferable.[18] It permits a child to explore gender development and self-definition within a safe setting. A fundamental concept of this approach is that gender diversity is not a mental illness. The gender-affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about

[17] Ehrensaft (2017).

[18] Turban and Ehrensaft (2018).

their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Under this model, a child's self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Support is not characterized by "encouraging" children or youth to be transgender or not, but rather by allowing children who express a desire to undergo a social transition (which may include changing names, pronouns, clothing, hairstyles, etc.) to do so. **For children who have not yet reached puberty, medical intervention is unnecessary and unwarranted.** After the onset of puberty, medical interventions such as puberty blockers, and later hormones and surgery, may be appropriate.

19. While some argue that gender affirmation leads a child or adolescent down a path of inevitable transgender identity, no such evidence exists, either in the scientific or the clinical setting. To the contrary, studies show that gender identification does not meaningfully differ before and after social transition.[19]

[19] Rae, J. R., Gülgöz, S., Durwood, L., DeMeules, M., Lowe, R., Lindquist, G., & Olson, K. R. (2019). Predicting early-childhood gender transitions. *Psychological Science*, 30(5), 669-681.

20. Under both the "wait and see" and affirmative care models, as understood in the scientific literature, medical care is recommended following the onset of puberty.[20]

21. The most effective treatment for adolescents and adults with GD, in terms of both their mental and medical health, contemplates an individualized approach. Medical and surgical treatment interventions are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family, if the patient is a minor. These medical decisions are made by the care team in conjunction with the patient and, if the patient is a minor, the patient's family, and consider the patient's social situation, level of gender dysphoria, developmental stage, existing medical conditions, and other relevant factors. Sometimes treatment begins with puberty delaying medications (also referred to as puberty blockers), later followed by gender-affirming hormones. Most youth, and certainly all adults, accessing treatment are already well into or have completed puberty.

[20] Ehrensaft (2017).

1) Puberty Blockers

22. The beginning signs of puberty in transgender youth (the development of breast buds in assigned birth females and increased testicular volume in assigned birth males) is often a painful and sometimes traumatic experience that brings increased body dysphoria and the potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality.

23. Puberty suppression, which involves the administration of gonadotrophin-releasing hormone analogues (GnRHa), essentially pauses puberty, thereby allowing the young person the opportunity to explore gender without having to experience the anxiety and distress associated with developing the undesired secondary sexual characteristics. In addition, for parents/guardians who are uneducated about gender diversity and/or who have only recently become aware of their child's transgender identity, puberty blockers provide additional time and opportunity to integrate this new information into their own experience and to develop skills to support their child. Puberty suppression also has the benefit of potentially rendering obsolete some gender-affirming surgeries down the line, such as male chest reconstruction, tracheal shave, facial

feminization, and vocal cord alteration, which otherwise would be required to correct the initial "incorrect" puberty.

24. Puberty suppression has been used safely for decades in children with other medical conditions, including precocious puberty, and is a reversible intervention.[21] If the medication is discontinued, the young person continues their endogenous puberty. The "Dutch protocol," developed from a study conducted in the Netherlands and published in 2006, calls for the commencement of puberty blockers for appropriately diagnosed and assessed gender dysphoric youth as early as 12 years of age.[22] Both the Endocrine Society and the WPATH's SOC, however, recommend initiation of puberty suppression at the earliest stages of puberty (usually, Tanner 2) (assuming someone has engaged in services before or around this time), regardless of chronological age, in order to avoid the stress and trauma associated with developing secondary sex characteristics of the natal sex.

[21] Mul, D. & Hughes, I. (2008). The use of GnRH agonists in precocious puberty. *European journal of endocrinology / European Federation of Endocrine Societies*. 159 Suppl 1. S3-8.

[22] de Vries, A.L.C., McGuire, J. K., Steensma, T. D., Wagenaar, E. C. F., Doreleijers, T. A. H., & Cohen-Kettenis, P. T. (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*, *134*(4), 696-704; Biggs M. (2022). The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence. *Journal of sex & marital therapy*, 1–21.

25. A growing body of evidence, including peer-reviewed cross-sectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in youth with GD on psychological functioning including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning.[23]

26. The initial follow-up studies evaluating the use of puberty suppression in relation to psychological well-being in adolescents with GD came from the Netherlands and demonstrated that behavioral and emotional problems and depressive symptoms decreased and general functioning significantly improved during treatment.[24]

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[23] See for example: de Vries, A.L., Steensma, T.D., Doreleijers, T.A., & Cohen-Kettenis, P.T. (2011). Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study. *The Journal of Sexual Medicine*, 8(8), 2276-2283; Turban, J.L., King, D., Carswell, J.M., & Keuroghlian, A.S. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, 145(2):e20191725; van der Miesen, A.I., Steensma, T.D., de Vries, A.L., *et al*. (2020). Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers. *Journal of Adolescent Health*, 66(6), 699-704; Achille, C., Taggart, T., Eaton, N.R., *et al*. (2020). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. *International Journal of Pediatric Endocrinology*, 2020(8), 1-5; and Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. *The journal of sexual medicine*, *12*(11), 2206–2214..

[24] de Vries, et al. (2011); de Vries, et al. (2014).

27. A study from the United Kingdom demonstrated that psychological support and puberty suppression were associated with improved global psychosocial functioning in adolescents with gender dysphoria with a combination of psychological support and puberty suppression, attributing to a greater improvement than psychological support only.[25]

28. A more recent cross-sectional study from the Dutch team demonstrated that transgender youth undergoing pubertal suppression had better psychological functioning than those youth who had not yet begun puberty blockade.[26]

29. Achille et al. demonstrated a positive effect of puberty blockade on mental health in a small, prospective investigation. The study characterized a treatment cohort over progressive interventions moving from puberty blockade to GAH treatment.[27]

30. Overall, this growing body of evidence is consistent with and supports clinical experience demonstrating a significant positive effect of puberty blockade in youth with gender dysphoria.

[25] Costa, et al. (2015).

[26] Van der Miesen, et al. (2020).

[27] Achille, et al. (2020).

31. Puberty blockers, thus, afford youth the opportunity to undergo a single, congruent pubertal process and avoid many of the surgical interventions previously necessary for assimilation into an authentic gender role. It is a simple reversible intervention that has the capacity to improve health outcomes and save lives. Over the course of my work in the past sixteen years with gender diverse and transgender youth, I have prescribed hormone suppression for over 350 patients. All of those patients have benefitted from putting their endogenous puberty process on pause, even the small handful who discontinued GnRH analogues and went through their endogenous puberty. Many of these young people were able to matriculate back into school environments, begin appropriate peer relationships, and participate meaningfully in therapy and family functions. Children who had contemplated or attempted suicide or self-harm (including cutting and burning) associated with monthly menstruation or the anxiety about their voice dropping were offered respite from those dark places of despair. GnRH analogues for puberty suppression are, in my opinion, a sentinel event in the history of transgender medicine, and have changed the landscape almost as much as the development of synthetic hormones.

2) Gender-Affirming Hormones

32. Cross-gender or gender-affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity) (estrogen for transfeminine individuals and testosterone for transmasculine individuals). The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, breast tissue development). Eligibility and medical necessity should be determined case-by-case, based on an assessment of the youth's unique cognitive and emotional maturation and ability to provide a knowing and informed consent. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy. The youth's primary care provider, therapist, or another experienced mental health professional can help document and confirm the patient's history of GD, the medical necessity of the intervention, and the youth's readiness to transition medically.

33. As with the use of puberty blockers, the data demonstrating the positive effects of gender affirming hormones (GAH) is well established and growing.

34. The Dutch team at The Center of Expertise on Gender Dysphoria at the VU University Medical Center Amsterdam continued to report out the improvement within their cohort of youth with gender dysphoria after GAH. De Vries et al reported in 2014 that their cohort of young adults who began care in adolescence had steadily improving mental health (including depression, anxiety, anger, internalizing and externalizing psychopathologic symptoms) following puberty blockade, GAH and gender affirming surgery.[28]

35. A German observational study reported that among the participants at follow-up, adolescents in the gender-affirming hormone (GAH) and surgery (GAS) group reported emotional and behavioral problems and physical quality of life scores similar to the German norm mean.[29]

[28] de Vries, et al. (2014).

[29] Becker-Hebly, I., Fahrenkrug, S., Campion, F., Richter-Appelt, H., Schulte-Markwort, M., & Barkmann, C. (2021). Psychosocial health in adolescents and young adults with gender dysphoria before and after gender-affirming medical interventions: A descriptive study from the Hamburg Gender Identity Service. *European Child & Adolescent Psychiatry*, 30(11), 1755–1767.

36. Also from Germany, Neider et al. reported that among a group of 75 adolescents with gender dysphoria satisfaction improved the further along the treatment course had progressed.[30]

37. From the United States, Kuper et al. carried out a prospective study and reported their cohort of transgender and non-binary youth starting either pubertal blockade or GAH demonstrated improvement at follow up (around a year) in depression, anxiety and body esteem.[31]

38. While small, Grannis et al. demonstrated decreased depression and anxiety in a group of transmasculine youth taking testosterone versus an untreated control group.[32]

39. Most recently our team at the Trans Youth Care United States (TYC-US) reported in the New England Journal of Medicine an improvement among

[30] Nieder, T. O., Mayer, T. K., Hinz, S., Fahrenkrug, S., Herrmann, L., & Becker-Hebly, I. (2021). Individual treatment progress predicts satisfaction with transition-related care for youth with gender dysphoria: A prospective clinical cohort study. *The Journal of Sexual Medicine*, 18(3), 632–645.

[31] Kuper, L. E., Stewart, S., Preston, S., Lau, M., & Lopez, X. (2020). Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. *Pediatrics*, 145(4).

[32] Grannis, C., Leibowitz, S. F., Gahn, S., Nahata, L., Morningstar, M., Mattson, W. I., Chen, D., Strang, J. F., & Nelson, E. E. (2021). Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys. *Psychoneuroendocrinology*, 132, 105358, 1-8.

315 youth in positive affect and life satisfaction as well as a decrease in depressive and anxiety symptoms after two years of GAH.[33]

40. The data documenting the efficacy of hormone treatment in transgender adults is as robust and goes back even further. Numerous longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning.[34]

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[33] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Med.* 2023 Jan 19;388(3):240-250.

[34] See for example: Colizzi, M., et al. (2014). Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: results from a longitudinal study. *Psychoneuroendocrinology*, *39*, 65–73; Colizzi, M., et al. (2013). Hormonal treatment reduces psychobiological distress in gender identity disorder, independently of the attachment style. *The journal of sexual medicine*, *10*(12), 3049–3058; Corda, E., et al. (2016). Body image and gender role perceived in gender dysphoria: Cross-sex hormone therapy effects. *European Psychiatry*, 33(S1), S589-S589; Fisher, A. D., et al. (2016). Cross-Sex Hormone Treatment and Psychobiological Changes in Transsexual Persons: Two-Year Follow-Up Data. *The Journal of clinical endocrinology and metabolism*, *101*(11), 4260–4269; Heylens, G., et al. (2014). Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *The journal of sexual medicine*, *11*(1), 119–126; Keo-Meier, C. L., et al. (2015). Testosterone treatment and MMPI-2 improvement in transgender men: a prospective controlled study. *Journal of consulting and clinical psychology*, *83*(1), 143–156; Manieri, C., et al. (2014) Medical Treatment of Subjects with Gender Identity Disorder: The Experience in an Italian Public Health Center, *International Journal of Transgenderism*, 15:2, 53-65; Motta, G., et al. (2018). Does Testosterone Treatment Increase Anger Expression in a Population of Transgender Men?. *The journal of sexual medicine*, *15*(1), 94–101; Oda, H., & Kinoshita, T. (2017). Efficacy of hormonal and mental treatments with MMPI in FtM individuals: cross-sectional and longitudinal studies. *BMC psychiatry*, *17*(1), 256; and Turan, Ş., et al. (2018). Alterations in Body Uneasiness, Eating Attitudes, and Psychopathology Before and After Cross-Sex Hormonal Treatment in Patients with Female-to-Male Gender Dysphoria. *Archives of sexual behavior*, *47*(8), 2349–2361.

41. An established and growing body of evidence combined with decades of clinical evidence demonstrate the positive effect of gender affirming hormones in adolescents and adults with gender dysphoria.

3) Gender-Affirming Surgeries

42. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include vaginoplasty, tracheal shave, liposuction, breast implants, and orchiectomy for transfeminine individuals and chest reconstruction, hysterectomy, oophorectomy, salpingectomy, construction of a neoscrotum, and metoidioplasty or phalloplasty for transmasculine individuals.

43. The current WPATH SOC recommend that surgical interventions may occur when appropriate for an individual.

44. Decades of research confirms that gender confirmation surgery is therapeutic and therefore an effective treatment for gender dysphoria.[35] In a 1998

[35] *See*, *e.g.*, Almazan, A. N., & Keuroghlian, A. S. (2021). Association Between Gender-Affirming Surgeries and Mental Health Outcomes. *JAMA surgery*, 156(7), 611–618; Almazan, et al. (2021); Murad, M. H., et al. (2010). Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology*, 72(2), 214-231; Smith, Y., et al. (2005). Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychological Medicine* 35(1): 89-99; and Pfafflin, F., & Junge, A. (1998). Sex reassignment: Thirty years of international follow-up studies after sex reassignment surgery, a comprehensive review, 1961-1991.

meta-analysis, Pfafflin and Junge reviewed data from 80 studies, from 12 countries, spanning 30 years. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes."[36]

45. Subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective."[37] The authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared." Similarly, a recent systematic review that included data from 1,052 transmasculine patients who obtained chest surgery found that pooled overall postoperative satisfaction was 92%.[38]

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[36] Pfafflin & Junge (1998).

[37] Smith, et al. (2005).

[38] Bustos, V. P., Bustos, S. S., Mascaro, A., Del Corral, G., Forte, A. J., Ciudad, P., Kim, E. A., Langstein, H. N., & Manrique, O. J. (2021). Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery. Global open*, *9*(3), e3477.

46. With regards to transgender adolescents, peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery for transgender males with gender dysphoria where medically indicated.[39]

* * *

47. Recognizing the importance of individualized care, the SOC 8 has this to say about all gender affirming interventions: "The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research

[39] Mehringer, J. E., et al. (2021). Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth. *Pediatrics*, *147*(3), e2020013300; Olson-Kennedy, J., et al. (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA pediatrics*, *172*(5), 431–436.

protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection."

48. Gender-affirming medical interventions are considered medically necessary and are recognized as such by many major professional organizations. The denial of this care results in negative health consequences.

49. There are those (see GAPMS Memo at 12-13) who would make the argument that the recent uptick in youth presenting for services related to GD is the result of "social contagion." But if social contagion theory applied to gender and gender identity, there would be zero transgender people, because of the consistent exposure to an overwhelming majority of cisgender people. The social contagion argument that is posited by some confuses the relationship between one's recognition of their gender and their exposure to gender related information and community, particularly with regard to internet activity, asserting that youth are declaring themselves to be transgender or gender diverse because they were exposed to this online, or they have multiple friends who are also experiencing GD. Adolescent development includes finding like groups of peers, which extends to finding friend groups who are also gender diverse. Finally, attributing

GD to "social contagion" is a simplistic perspective that discounts that the process of doing something about one's gender dysphoria is complex and difficult and involves parental consent for minors.

50. There is no scientific evidence that one develops gender dysphoria from being exposed to people with GD. To the contrary, most evidence shows that gender identity has a biological basis[40] and is affixed by early childhood.[41]

C. Critiques of the GAPMS Memo and the Attached "Assessments"

51. The GAPMS Memo and the attached assessments contain a number of inaccurate assertions or misrepresentations, in addition to those noted above.

Misunderstandings and Misrepresentations of Desistance

52. The GAPMS Memo falsely states that "the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects." (GAPMS Memo at 14). This is a blatant misrepresentation of the scientific literature. The studies pertaining to desistance upon which the GAPMS Memo

[40] Korpaisarn, S., & Safer, J. D. (2019). Etiology of Gender Identity. Endocrinology and metabolism clinics of North America, 48(2), 323–329. https://doi.org/10.1016/j.ecl.2019.01.002; Saraswat, A., Weinand, J.D., & Safer, J. (2015). Evidence supporting the biologic nature of gender identity. Endocrine practice, 21 2, 199-204.

[41] Slaby, R., Frey, K. (1975). Development of Gender Constancy and Selective Attention to Same Sex Models, *Child Development*, 46(4): 849-856.

relies pertain to *pre-pubertal* youth, not adolescents. In fact, contrary to the GAPMS Memo's assertion, studies show that if gender dysphoria is present in adolescence, it usually persists.[42]

53. To be sure, there are a significant number of *pre-pubertal* children who demonstrate an interest or preference for clothing, toys, and games that are stereotypically of interest to members of the "other" gender. Some of these children are transgender and some are not. It is the study of such *pre-pubertal* children that has created confusion about the persistence of gender dysphoria into adolescence and adulthood. Specifically, the *pre-pubertal* children who were the subject of research endeavors in the late 20th century included both children who are transgender and children who are not, i.e., those who would have met current criteria for a diagnosis of "Gender Dysphoria in Children" and those who would be considered "sub-threshold" for this diagnosis.

54. At the time of these studies, the diagnosis of "Gender Dysphoria in Children" did not exist and therefore the study subjects did not need to meet criteria B, which is "the presence of clinically significant distress associated with the condition." In addition, the criteria for the then-used "gender identity disorder

[42] de Vries, et al. (2011).

in children" diagnosis did not require a child to have "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)," which the current "Gender Dysphoria in Children" diagnosis requires.

55. Thus, given the broader criteria used at the time, it is unsurprising that some of the research undertaken toward the end of the 20th century demonstrated that most children who exhibited gender-nonconforming behavior did not go on to have a transgender identity in adolescence. Yet, notwithstanding its inapplicability and faulty underpinnings, this "evidence" has been used to argue against gender affirmation for children and adolescents.

56. What is more, these arguments about desistance in *pre-pubertal* children are wholly irrelevant to the question of coverage and provision of medical care as treatment for GD. That is because research to date shows that if transgender identification persists into adolescence, then desistance is incredibly rare, and no medical or surgical treatments are recommended for *pre-pubertal* children.

57. Additionally, no studies have ever demonstrated that gender affirmation in childhood "leads to" a child being transgender who otherwise might not have been. Studies have demonstrated that the majority of youth whose

GD and cross-gender identity continue to be present, or those whose GD emerges in adolescence, are highly unlikely to identify and live as cisgender individuals. Youth with GD, particularly those who are unaffirmed and denied care, are at high risk for depression, anxiety, isolation, self-harm and suicidality at the onset of puberty-related changes that feel wrong to them.

The Myth of Social Contagion and Rapid-Onset Gender Dysphoria (ROGD)

58. The GAPMS memo asserts that gender-affirming care should not be provided because the causes of GD are uncertain. It suggests that "exposure to 'social and peer contagion'" accounts for the rise in numbers of adolescents who identify as transgender, pointing to research that has identified so-called "rapid-onset gender dysphoria" (ROGD). (GAPMS Memo at 12-13; see also Cantor ¶ 48-49). However, ROGD is not a diagnosis recognized by any medical or scientific institution, and there is no scientific evidence in support of it.

59. The concept of ROGD originated from a single article authored by Lisa Littman, a researcher who had no experience in the field of gender medicine, transgender issues, or gender dysphoria, prior to the publication of her article.[43]

[43] Littman L. (2018). Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PloS one*, *13*(8), e0202330.

60. Littman's article was heavily criticized for its flawed methodology, potential for bias, and overrepresentation of its findings.[44] For example, Littman's study was based solely on "parent observations and interpretations." But parental reports are not necessarily a reliable basis for understanding a particular youth's experience with their gender, let alone whether the youth has gender dysphoria.[45] Moreover, most of the parents who participated in the study were recruited from websites targeted to parents likely to question their child's gender self-identification and the current best health care approaches. In addition, the study also failed to collect data from the adolescents and young adults (AYAs) or clinicians, which would have been necessary in order to come up with and validate ROGD as a new phenomenon.

[44] *See*, *e.g.*, Brandelli Costa, A. (2019) Formal comment on: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS ONE 14(3): e0212578; Restar A. J. (2020). Methodological Critique of Littman's (2018) Parental-Respondents Accounts of "Rapid-Onset Gender Dysphoria". *Archives of sexual behavior*, *49*(1), 61–66.

[45] *See*, *e.g.*, Kennedy, N. (2022) Deferral: the sociology of young trans people's epiphanies and coming out. *Journal of LGBT Youth*, 19:1, 53-75; Brandelli Costa (2019).

61. Following the numerous critiques of the Littman study, the journal that published the study retracted it, ordered a post-publication review, and republished the article with a correction notice,[46] along with an apology.[47]

62. The correction notice acknowledged, among other things, that: [48]

a. "there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives" and that "consideration of what information parents may or may not have access to is an important element of the findings";

b. "the study's output was hypothesis-generating rather than hypothesis-testing";

c. "three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults

[46] Littman L. (2019) Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS ONE*, 14(3): e0214157.

[47] Heber, J. Correcting the scientific record on gender incongruence – and an apology, PLoS ONE (Mar. 19, 2019), https://everyone.plos.org/2019/03/19/correcting-the-scientific-record-and-anapology/.

[48] Littman (2019).

and cautious or negative views about categorizing gender dysphoric youth as transgender"; and

d. "There is expected variation in how objective parents can be about their own children" and that the "descriptive study was not designed to explore or measure the objectivity of participants."

63. Thus, the correction notice ultimately acknowledged that the study "does not validate the phenomenon" of ROGD and that the term ROGD "should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals."[49] In the end, aside from the correction notice, the journal that published the study issued an apology "for oversights that occurred during the original assessment of the study."[50]

64. To date, no study has been published that validates or proves the hypothesis of ROGD presented by the Littman study. Indeed, Lisa Littman herself said at the GenSpect 2021 Conference that ROGD was not a new phenomenon, but rather a re-naming of late onset GD.

[49] *Id.*

[50] Heber (2019).

65. The GAPMS Memo, Dr. Cantor, and Dr. Van Meter incorrectly allege that an increase in numbers of youth presenting for care related to GD provides support for the social contagion theory. (See GAPMS Memo at 12-13; Van Meter at 9-10). For one, varying estimates of prevalence are the result of inconsistent measures of transgender populations. Some studies have assessed the fraction of a population which had received the DSM-IV diagnosis of GID or the ICD 10 diagnosis of transsexualism, both of which were limited to clinical populations who sought a binary transition (male-to-female or female-to-male). For example, the prevalence reported in DSM-5 (0.005–0.014% for birth-assigned males; 0.002–0.003% for birth-assigned females) are based on people who received a diagnosis of GID or transsexualism and were seeking hormone treatment and surgery from gender specialty clinics, and, therefore, do not reflect the number of all individuals with gender dysphoria or who identify as transgender.[51] Other studies have reported on those who self-identified as transgender or gender incongruent and found that measuring self-identity yields much higher numbers. In 2016, data from the Center for Disease Control's Behavioral Risk Factor Surveillance System suggested that 0.6% of U.S. adults

[51] Coleman, et al. (2022).

identify as transgender, double the estimate utilizing data from the previous decade.[52] Ultimately, there is nothing surprising about the fact that more transgender people have begun identifying themselves to others as societal stigma has started to abate, and nothing about that lends support to the "social contagion" theory.

Dr. Cantor's False Assertion of Transition-on-Demand

66. In his "assessment," Dr. Cantor, a psychologist with no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria, states that "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks. (Cantor ¶ 21).

67. His claim is wholly divorced from the reality of care for transgender people. First, like all health care, gender-affirming care for every transgender person is individualized. There simply is no one specific route.

68. Second, Dr. Cantor inaccurately assumes that every transgender person wants and receives rapid access to services. For most transgender individuals seeking care, nothing about their process has been rapid, even when

[52] Byne, W., Karasic, D. H., Coleman, E., Eyler, A. E., Kidd, J. D., Meyer-Bahlburg, H. F. L., … Pula, J. (2018). Gender dysphoria in adults: An overview and primer for psychiatrists. *Transgender Health*, *3*(1), 57-70.

they are young. Most individuals with gender dysphoria have engaged in a long, arduous and private process of understanding their gender to be different from the one assumed at birth. Dr. Cantor gives no credibility to transgender patients regarding their right to bodily autonomy nor their capacity to make sound and informed decisions.

69. Finally, Dr. Cantor is wrong to assert that affirmation "increases the probability of unnecessary transition and unnecessary medical risks." (Cantor ¶ 21). There is no evidence to support the notion that affirmation of gender in pre-pubertal children, or at any age, leads to transition. Medical interventions are not recommended and are not appropriate for pre-pubertal children. If one's gender could be impacted by the role of rearing, there would be few transgender people who transition in adulthood, as most were reared in the gender role that corresponded with their sex assigned at birth. It is not logical to think that while we have been epically failing at convincing transgender people to be cisgender, we would be able to make someone who is cisgender into someone who is transgender, a directionality that may correspond with higher rates of discrimination, harassment, and even violence. There is no data to support any such notion that children who are socially transitioned in a pre-pubertal time

period who then go on to embrace their assumed gender at birth are damaged. I know several such young people who are healthy and happy.

The Quality of the Evidence and Lack of Randomized Controlled Trials

70. The care of transgender individuals has a long history. As with all medical care, there is a range of quality in the existing data regarding the treatment of gender dysphoria,[53] and there is certainly a need for additional studies of a longitudinal nature. But again, that is true with most medical care.

71. Between 1963 and 1979, over 20 university-based gender identity clinics opened in the United States.[54] These clinics provided interdisciplinary care that included psychiatrists and other mental health professionals and played an important role in the provision of medical services to transgender people and in promoting research to improve their care. The majority of these clinics closed following a 1981 decision of the U.S. Department of Health and Human Services (HHS) that labeled sex reassignment surgery as experimental, in large part due to advocacy by Dr. Paul McHugh.[55] That decision was overturned by HHS in 2014 in a determination that concluded that the 1981 decision was "not

[53] See Deutsch (ed.) (2016) (UCSF Guidelines).

[54] Byne, et al. (2018).

[55] In this way, Dr. McHugh actively attempted to suppress the research that he complains is lacking in this field of care.

reasonable" and found that gender-affirming surgery is "a safe and effective treatment option."[56]

72. Over the last four decades: research has continued to occur in the United States and internationally; WPATH (formerly the Henry Benjamin International Gender Dysphoria Association) published the first iteration of the Standards of Care in 1979, which is now in its 8th version; the DSM and ICD stopped classifying transgender identification as a mental disorder; the American Psychological Association and Endocrine Society, as well as other medical organizations, adopted clinical guidelines consistent with the WPATH Standards of Care; and dozens of interdisciplinary gender clinics associated with research institutions and teaching hospitals have been providing gender-affirming care for transgender youth and adults across the United States.

73. Drs. Brignardello-Petersen and Wiercioch repeatedly refer to an apparent lack of data comparing treated vs. untreated individuals with gender dysphoria. Their report continually places emphasis on data that they rated as "low certainty" based on GRADE criteria. These observations about the data do not mean that gender-affirming care is experimental or investigational.

[56] U.S. Dep't Health & Hum. Servs., NCD 140.3, Transsexual Surgery 18, 21 (2014); Byne, et al. (2018).

74. One of the intrinsic elements of rating the quality of evidence is the study design. Randomized controlled trials (RCTs) are considered the highest quality in the grading of evidence. Many of the research studies on gender-affirming care get a "low quality" grade due to the lack of RCTs.

75. But it is well-established that utilizing an untreated control group is unethical in this context – gender-affirming medical interventions have been used for decades, resulting in a vast amount of clinical knowledge about their efficacy. That said, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care.

76. Clinicians who are competent in the care of transgender individuals practice according to a "first do no harm" ethic which understands that doing nothing is not a neutral option for those with gender dysphoria. Multiple studies have demonstrated the safety of gender-affirming hormones, and a growing body

of evidence does the same with regards to the safety of GnRH analogues.[57] The same is true with regards to surgery.[58]

77. In addition, RCTs are ill-suited to studying the effects of gender-affirming interventions on psychological wellbeing and quality of life of trans people. Adequate masking, adherence, and generalizability are severely impeded in transgender care, thereby negating the superior scientific value of RCTs.

78. Gender-affirming interventions have physiologically evident effects, making it impossible to mask RCTs. The purpose of puberty blockers, hormone therapy, and transition-related surgeries is to inhibit or produce visible bodily changes.

79. In an RCT, adolescents who are on puberty blockers would notice that their endogenous pubertal development had stopped, whereas those not on puberty blockers will notice that they had not. Hormonal suppression is achieved

[57] Kuper, et al. (2020); Chew, D., Anderson, J., Williams, K., May, T., & Pang, K. (2018). Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. *Pediatrics*, *141*(4), e20173742; Colton-Meier, S. L., Fitzgerald, K. M., Pardo, S. T., & Babcock, J. (2011). The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *Journal of Gay & Lesbian Mental Health*, 15(3), 281-299.

[58] Marano, A. A., Louis, M. R., & Coon, D. (2021). Gender-Affirming Surgeries and Improved Psychosocial Health Outcomes. *JAMA surgery*, *156*(7), 685–687; Olson-Kennedy, et al. (2018); Murad, et al. (2010); Smith, et al. (2005); Pfafflin & Junge (1998).

around four weeks after treatment is initiated, but it may take multiple months before participants notice that pubertal development has ceased.

80. Similarly, transgender people given hormone therapy would notice bodily changes from taking estrogen or testosterone, whereas transgender people in the control arm would notice no such changes. The onset of visible effects from hormone therapy varies from person-to-person. The first changes typically appear between one and six months of initiation, whereas other desired changes may not begin for up to a year.

81. Although it may take some time before participants are able to ascertain which treatment they were allocated to due to the delayed effect of puberty blockers and the progressive effect of and hormone therapy, large-scale unmasking is inevitable. Because the physiological changes are the primary purpose of gender-affirming care, meaningful effects on psychological wellbeing and quality of life are not expected until unmasking occurs. As such, while RCTs can be utilized to examine the effects of gender-affirming care on physiology, using RCTs to measure the effect of gender-affirming care on psychological wellbeing and quality of life would be inappropriate.

82. Unmasking an RCT of gender-affirming care would lead to non-compliance, cross-over, and response bias in the control arm of the study.

Transgender people with gender dysphoria who pursue gender-affirming care are typically insistent and persistent in seeking the interventions. They are not ambivalent as to whether they are assigned to the intervention or control arm of the study. Upon realizing that they are in the control arm due to physiological effects or lack thereof, a large proportion of the study participants would likely withdraw from the study or pursue alternative sources of gender-affirming interventions.

83. Withdrawing from the study and noncompliance with the study protocol is most likely among people who have alternative means of securing gender-affirming care and who experience more severe bodily gender dysphoria, raising grave concerns of systematic bias. Gender-affirming interventions can be obtained from parents, peers, illicit or unauthorized sources, other providers within or outside of the health care system, and through medication-sharing with participants from the active arm of the study. Some of these options are associated with elevated safety risks, giving rise to additional ethical concerns about the use of RCTs. Intentional withdrawal with the goal of forcing the study to end is also possible. Resentment towards researchers for not allowing all participants to receive gender-affirming interventions may also increase the risk of response bias compared to observational studies, and the experimental design

may motivate youths to engage in self-harm or suicidal behavior to influence the study results, aggravating scientific and ethical concerns.

84. Given that withdrawal rates could be high enough for studies to be terminated before they are concluded, RCTs may prove impossible to conduct altogether. The likelihood of withdrawal, non-adherence, and response bias in the context of transgender care undermines RCTs' ability to detect true associations and avoid specious associations between the intervention and the outcomes.

85. Many disciplines and areas of research rely on observational studies because RCTs are considered impracticable or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

86. Thus, while the GAPMS Memo correctly notes that "[p]resently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available," the lack of RCTs is easily understood considering the above

observations about RCTs in this context. (See GAPMS Memo at 15). And, the GAPMS Memo fails to mention that "[d]espite GnRH analogue treatment being used in precocious puberty for more than 20 years, there are no randomized controlled trials to evaluate the effect of GnRHa on a final height compared with untreated controls."[59]

87. In addition, the GAPMS Memo's focus on RCTs reveals AHCA's fundamental misunderstanding of "evidence-based medicine." (GAPMS Memo at 9).

88. Evidence-based medicine, which originated in the second half of the 19th Century, means the conscientious, explicit, judicious, and reasonable use of current best evidence in making decisions about the care of individual patients. Since its inception, evidence-based medicine has included an element of clinician expertise. Indeed, the modern understanding of evidence-based medicine is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with *clinical expertise and patient values*.[60]

[59] Mul & Hughes (2008).

[60] Masic, I., Miokovic, M., & Muhamedagic, B. (2008). Evidence based medicine - new approaches and challenges. *Acta informatica medica : AIM : journal of the Society for Medical Informatics of Bosnia & Herzegovina : casopis Drustva za medicinsku informatiku BiH*, *16*(4), 219–225.

89. Contemporaneous evidence-based medicine is defined by the *integration of clinical knowledge and skills* with the best critically-appraised-evidence available *as well as patient values and preferences in order to make a clinical decision*. The research literature is continually growing as new discoveries unravel.

90. The GAPMS Memo assigns no value to clinician expertise, experience, and skill, nor to the desires of the individual seeking services. In fact, the GAPMS Memo repeatedly and broadly asserts that recommendations for treatment of GD by well-established professional associations do not rely on evidence-based medicine, but rather on the recommendations outlined by WPATH, the Endocrine Society or others. But these two organizations not only examine best available evidence, but the guidelines and standards of care are updated by clinicians and scientists at the top of the field.

The Use of "Off-Label" Medications

91. Both the GAPMS Memo and Dr. Van Meter repeatedly express concern that the U.S. Food and Drug Administration (FDA) has not approved puberty blockers or hormone therapy for the treatment of GD. (See, e.g., GAPMS Memo at 8, 19; Van Meter at 8). Indeed, Dr. Van Meter asserts that the mere use of these medications "off-label" amounts to "uncontrolled, non-consentable

experimentation on children." (Van Meter at 8). These concerns are misleading and false.

92. The use of "off-label" medications is extremely common across all fields in medicine and there are many medications that are used "off-label" in the pediatric population. Most of the therapies prescribed to children are on an off-label or unlicensed basis.[61] Common medications that are used "off-label" in pediatrics include antibiotics, antihistamines, and antidepressants. That is because the majority of drugs prescribed have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence. This is explained by the lack of clinical research in this population, caused by ethical, scientific, and technical issues, as well as commercial priorities.

93. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."[62] Indeed, for

[61] Allen, H.C., Garbe, M.C., Lees, J., Aziz, N., Chaaban, H., Miller, J.L., Johnson, P., & DeLeon, S. (2018). Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature. *The Journal of the Oklahoma State Medical Association*, *111*(8), 776–783.

[62] U.S. Food and Drug Admin. Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatmentoptions/understanding-unapproved-use-approved-drugs-label.

over 40 years, the FDA has informed the medical community that "once a [drug] product has been approved …, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling."[63] Accordingly, the American Academy of Pediatrics has stated that "off-label use of medications is neither experimentation nor research."[64] Thus, "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interests."

Concerns about the Diagnosis of Gender Dysphoria and the Use of Self-Reports

94. The GAPMS Memo and Dr. Cantor criticize that the diagnosis of gender dysphoria is based, at least in part, on a patient's self-report. (GAPMS Memo at 19, 24, 28; Cantor ¶¶ 42, 49). This critique demonstrates a fundamental misunderstanding of how gender-affirming care is provided.

95. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not self-diagnose, as Dr. Cantor

[63] U.S. Food and Drug Admin, "Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments," 59 Fed. Reg. 59,820 (Nov. 18, 1994).

[64] Frattarelli, D. A., Galinkin, J. L., Green, T. P., Johnson, T. D., Neville, K. A., Paul, I. M., Van Den Anker, J. N., & American Academy of Pediatrics Committee on Drugs (2014). Off-label use of drugs in children. *Pediatrics*, *133*(3), 563–567.

suggests. (Cantor ¶¶ 42, 49). However, it is not unusual or extraordinary in medicine for a provider to consider patients' reports of their symptoms as part of the medical assessment. Much like the diagnosis of many clinical conditions, providers rely on self-report to ascertain accurate diagnoses. Consider the diagnosis of chronic fatigue. The diagnostic criteria for this diagnosis include the following: fatigue so severe that it interferes with the ability to engage in pre-illness activities; of new or definite onset (not lifelong); not substantially alleviated by rest; worsened by physical, mental or emotional exertion. Like gender dysphoria, these diagnostic criteria are a subjective telling of an individual's personal experience. It is incumbent upon providers of gender-affirming care to acquire skills that help them ascertain many details about their patient's gender experience including but not limited to the history, developmental trajectory, and expectations regarding treatment options.

96. The provision of gender-affirming care occurs in multi-disciplinary settings, and indeed, the WPATH SOC recommend such an approach.[65] The

[65] Chen, D., Hidalgo, M. A., Leibowitz, S., Leininger, J., Simons, L., Finlayson, C., & Garofalo, R. (2016). Multidisciplinary Care for Gender-Diverse Youth: A Narrative Review and Unique Model of Gender-Affirming Care. *Transgender health*, *1*(1), 117–123; Coleman, et al. (2022); Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., ... & Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gendernonconforming people, version 7. *International Journal of Transgenderism*, 13(4), 165-232.

multiple health providers involved, from various fields, are well trained to conduct clinical interviews and to assess a patient's report to determine whether they meet the diagnostic criteria for GD.

Particular Concerns about the Use of Puberty Delaying Medications

97. The GAPMS Memo and Dr. Cantor allege that the provision of puberty delaying medications for the treatment of GD is not effective. This is not true.

98. A substantial body of evidence shows that gender-affirming medical interventions improve mental health outcomes for transgender persons with GD, who, without treatment, experience higher levels of depression, anxiety, and suicidality. Each of these studies—as with all studies in medicine—has strengths and limitations, and no one study design can answer all questions regarding an intervention. But taken together, these studies indicate that gender-affirming medical care improves mental health for adolescents who require such care.

99. Keeping this in mind, peer-reviewed cross-sectional and longitudinal studies have found that pubertal suppression is associated with a range of improved mental health outcomes for transgender adolescents, including statistically significant improvements in internalizing psychopathology (*e.g.*,

anxiety and depression), externalizing psychopathology (*e.g.*, disruptive behaviors), global functioning, and suicidality.[66]

100. For example, in the realm of cross-sectional studies, Turban et al. *Pediatrics* 2020 found that, after controlling for a range of other variables, those who accessed pubertal suppression had lower odds of lifetime suicidal ideation than those who desired but were unable to access this intervention during adolescence. A similar study by van der Miesen et al. in the *Journal of Adolescent Health*, noted above, compared 272 adolescents who had not yet received pubertal suppression with 178 adolescents who had been treated with pubertal suppression. Those who had received pubertal suppression had statistically significant lower "internalizing psychopathology" scores (a measure of anxiety and depression).[67]

101. Longitudinal studies have yielded similar results. For example, de Vries et al. in the *Journal of Sexual Medicine* (discussed above) found statistically significant improvements in symptoms of depression and general

[66] *See*, *e.g.*, Tordoff, D. M., Wanta, J. W., Collin, A., Stepney, C., Inwards-Breland, D. J., & Ahrens, K. (2022). Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. *JAMA network open*, *5*(2), e220978; Turban, et al. (2020); van der Miesen, et al. (2020); Achille, et al. (2020); de Vries, et al. (2014); de Vries, et al. (2011). *See also* paragraphs 25-30, *supra*.

[67] van der Miesen, et al. (2020).

functioning following pubertal suppression for adolescents with gender dysphoria.[68]

102. The GAPMS Memo, as well as the "assessments" by Dr. Brignardello-Petersen and Dr. Wiercioch and by Dr. Cantor, emphasize the possible risks and side effects associated with the provision of gender-affirming care. Every single medication, however, has potential negative side effects, in addition to the possibility of new side effects that have not been historically documented. This is one of the reasons that evidence-based medicine relies heavily on experienced clinicians to exercise their expertise and judgement.

103. The risks associated with the provision of GnRH analogues are comparable when used for transgender and non-transgender patients alike. For example, many of the side effects and risks associated with the provision of GnRH analogues have been well-studied with regards to the use of these medications for the treatment of central precocious puberty (CPP).[69]

104. Given than puberty blockers are reversible, permanent sterility is not a side effect. There is no data to support that patients who have been treated with

[68] de Vries, et al. (2011).

[69] Eugster E. A. (2019). Treatment of Central Precocious Puberty. *Journal of the Endocrine Society*, *3*(5), 965–972.

blockers for central precocious puberty are "sterilized" following its use. To the contrary, information regarding long-term outcomes of patients treated with GnRH analogues with respect to gonadal function are reassuring. In fact, some studies have shown that assigned males had normal sperm function following treatment and cisgender women treated as children did not need assisted reproductive techniques.

105. In addition, while during the course of treatment with pubertal delaying medication, there is some loss in bone density, which is a side effect that we discuss with all patients and their families, studies show that with removal of the blocking agent or addition of gender affirming hormone therapy, bone mineral density begins to improve.[70] Studies regarding the use of GnRH analogues for the treatment of CPP document that following cessation of therapy with puberty delaying medications bone mineral accrual appears to be within the normal range compared with population norms. Indeed, patients treated with pubertal suppression for CPP are on pubertal blockades without affirming

[70] Vlot, M. C., et al. (2017). Effect of pubertal suppression and cross-sex hormone therapy on bone turnover markers and bone mineral apparent density (BMAD) in transgender adolescents. *Bone*, *95*, 11–19; Klink, D., et al. (2015). Bone mass in young adulthood following gonadotropin-releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. *The Journal of clinical endocrinology and metabolism*, *100*(2), E270–E275.

hormones for longer periods of time than patients treated with puberty blockers for the treatment of gender dysphoria and the same risks are present.[71]

Particular Concerns about the Use of Cross-Sex Hormones

106. The claim that treating gender dysphoria with medically supervised and recommended hormone treatment is particularly risky or causes serious mental health effects is not supported by data.

107. Peer-reviewed research studies have found improved mental health outcomes following gender-affirming hormone treatment (*e.g.*, estrogen or testosterone) for individuals with gender dysphoria, including adolescents.[72] These include statistically significant improvements in internalizing psychopathology (*e.g.*, anxiety and depression), general well-being, and suicidality. For example, Allen et al. followed a cohort of 47 adolescents with gender dysphoria, and found statistically significant improvements in general well-being and suicidality, as measured by the National Institutes of Health "Ask Suicide Screening Questions" instrument.[73]

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[71] Eugster (2019).

[72] *See*, *e.g.*, Achille, et al. (2020); de Lara, D.L., Rodríguez, O.P., Flores, I.C., *et al*. (2020). Psychosocial Assessment in Transgender Adolescents. *Anales de Pediatría (English Edition)*, 93(1), 41-48; Grannis, et al. (2021); Allen, L.R., Watson, L.B., Egan, A.M., & Moser, C.N. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302-311.

[73] Allen, et al. (2019).

108. What is more, the side effects and risks associated with these treatments are not unique to transgender individuals placed on these therapies.

109. The WPATH SOC require that fertility preservation is offered to all transgender patients prior to the initiation of gender affirming hormones. However, data shows that treatment with testosterone is not sterilizing.[74] And many transgender men become pregnant on their own.

110. It is also important to note that when these risks are reported, they are rare risks. While starting a transgender individual with GD on gender affirming hormones can raise their risk, their risk profile remains similar to their cisgender counterparts. Many times, the lipid profiles, hematologic profiles, and findings are equivalent to that of the gender these individuals identify with, as opposed to that of their sex assigned at birth.

The Misconceived Notion that Psychotherapy Alone Is Sufficient for the Treatment of Gender Dysphoria

111. Dr. Cantor describes several studies and claims that because the study subjects who were recipients of both gender-affirming hormones or puberty blockers, on the one hand, and psychotherapy, on the other hand, demonstrated

[74] Yaish, I., et al. (2021). Functional ovarian reserve in transgender men receiving testosterone therapy: evidence for preserved anti-Müllerian hormone and antral follicle count under prolonged treatment. *Human reproduction (Oxford, England)*, *36*(10), 2753–2760.

improvements in mental health, that the medical interventions could not be differentiated as responsible for the improvement. (Cantor ¶¶ 40-41).

112. Historically the psychotherapy professional world advocated for a "therapy only" model to address gender dysphoria. As early as the 1920's and 1930's it became evident to the preeminent scholars in the field that gender dysphoria (named something else at that time) was refractory to psychotherapy. As noted in 1966 in Harry Benjamin's The Transsexual Phenomenon, "Allegedly, transsexualism, although basically a psychiatric condition, is paradoxically resistant to psychiatric help."[75] In this statement, Harry Benjamin acknowledges that psychiatric intervention cannot alter people's gender, nor does it lead to a diminishing of the distress that arises from gender incongruence. There has been an abundance of opportunity to demonstrate unequivocally that gender dysphoria is best treated with psychotherapy alone, and yet it never has been. To suggest this is now an appropriate approach simply because transgender people are coming out at younger ages is illogical.

[75] Benjamin (1966).

Dr. Lappert's Critique of My Published Work

113. In his "assessment," Dr. Lappert criticizes a 2018 article I co-wrote that was published in JAMA Pediatrics, which he acknowledges to be a "leading journal." He refers to the article as "reckless" and using "low-quality data." (Lappert, p. 7).

114. Dr. Lappert takes issue with the claim in this article that regret for surgery is "rare." (Lappert p. 7). The manuscript describes that no individual who had undergone chest reconstruction in this cohort regretted this decision. While no single study can capture all experiences, the data reported in this study and clinical experience support the claim that regret after chest surgery is rare.

115. Dr. Lappert additionally calls surgery on minors a "reckless, experimental practice" and, without citing any evidence to support his claims, states that it has "apparently been abandoned as unethical" in England, Sweden, and Finland. (Lappert p. 7). Chest surgery for transmasculine youth younger than the age of majority is not experimental. While the scientific study of the care of transgender youth is still ongoing and growing, this does not make such care experimental. By its very nature, science is ever growing and ongoing. Moreover, Dr. Lappert's claim completely discounts the clinical experiences of both community members and providers of such care.

116. Dr. Lappert seems to take issue with the methods my study used to recruit participants, which he terms "convenience sampling" and suggests constitutes "self-selection" and confirmation bias. (Lappert p. 7). While it is true that the participants were recruited from our practice, individuals seeking such a surgical intervention will also be enrolled in care at clinics familiar with gender affirming care, therefore, they are "self-selecting" to become patients. As noted in my manuscript, we made an attempt to reach all patients in our clinic who had been referred for chest surgery.

117. Dr. Lappert emphasizes that 26% of study participants who had undergone surgery could not be reached during follow-up phone calls. (Lappert p. 7). He further highlights that of the individuals we were able to reach by phone, 72% completed our survey. Again Dr. Lappert bemoans these facts as demonstrating self-selection and confirmation bias. Our Center provides services for youth and young adults up to the age of 25. Some participants who were unable to be reached had aged out of services, moved, changed their phone numbers, or simply didn't answer a phone call. This is common among all research.

118. Dr. Lappert additionally criticizes our paper for using a novel measure of gender dysphoria, which he claims is "entirely unvalidated" and "junk

science." (Lappert p. 8). When no measures exist to gain understanding about an experience, measures need to be created. Chest dysphoria is a latent construct, and as such needs to be captured through a collective of questions. The chest dysphoria scale components were developed through both content and face validity. The scale was not validated, as I clearly reported in the manuscript. In a manuscript by Sood et al., Chest Dysphoria, as measured by the scale I created, among 156 transmasculine youth, showed a significant, positive association with anxiety and depression.[76]

119. Dr. Lappert suggests that our findings, which looked at satisfaction with gender-affirming surgery for patients who had undergone surgery between less than 1 to 5 years prior to the survey, are "misleading" and "deceptive" because they are not completely consistent with other long-term longitudinal population studies. (Lappert p. 8). I have not seen any longitudinal studies looking at chest surgery that dispute the findings laid out in my manuscript. In a meta-analysis related to satisfaction following masculinizing chest surgery,

[76] Sood, R., Chen, D., Muldoon, A. L., Chen, L., Kwasny, M. J., Simons, L. K., Gangopadhyay, N., Corcoran, J. F., & Jordan, S. W. (2021). Association of Chest Dysphoria With Anxiety and Depression in Transmasculine and Nonbinary Adolescents Seeking Gender-Affirming Care. *The Journal of adolescent health: official publication of the Society for Adolescent Medicine*, *68*(6), 1135–1141.

Bustos et al. found that among 1,052 transmasculine patients, the overall satisfaction rate was 92%.[77]

120. Based on his review of my study, Dr. Lappert concludes that it "is essentially useless in making any clinical decisions regarding who should be offered surgery, what is the likelihood they will benefit from it, and what is the likelihood they will regret their decision." (Lappert p. 8). There have been at least two studies since my manuscript that have duplicated the findings laid out in my manuscript in addition to the meta-analysis conducted by Bustos et al. described above.

CONCLUSION

121. Gender-affirming medical and surgical care is effective, beneficial, and necessary for transgender people suffering with gender dysphoria, including transgender youth after the onset of puberty. It is well documented and studied, through years of clinical experience, observational scientific studies, and even some longitudinal studies. It is also the accepted standard of care by all major medical organizations in the United States.

[77] Bustos, et al. (2021).

122. The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms.

123. The GAPMS memo is misguided and informed by individuals with no experience or knowledge base regarding the provision of gender-affirming care, not to mention well-documented biases against transgender people and/or the provision of gender-affirming care. The report leans heavily on manuscripts that are not contemporaneous with our modern understanding of gender identity and gender dysphoria, demonstrated by outdated and incorrect terminology.

124. While data may be described as weak due to the lack of randomized controlled trials, many disciplines and areas of research rely on observational studies because RCTs are considered impractical or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

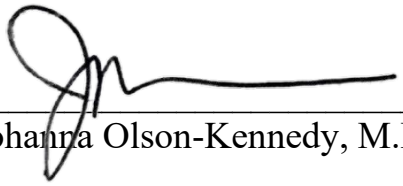
125. Finally, the reports completely overlook bodily autonomy. Given the repeated conflation of children and adolescents, it is not surprising that the "assessments" relied upon by the GAPMS Memo and the GAPMS Memo itself view adolescents as too immature to understand their own gender. However, many studies have demonstrated that cisgender children as young as age 2 know their gender. Denying medical care to adolescent youth with gender dysphoria is an act of acquiescence to the fear of what is not understood.

126. I do not disagree that, as with every field of medicine, there is more to learn in the field of transgender youth care. That is why I became an investigator. However, there is room to provide gender-affirming medical interventions in a thoughtful manner that extrapolates from relevant fields of science and medicine, existing data and clinical expertise while simultaneously carrying out necessary investigations.

127. The denial of much needed care only serves to harm transgender people.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16 day of February, 2023.



Johanna Olson-Kennedy, M.D., M.S.

Exhibit A

Curriculum Vitae

CURRICULUM VITAE

JOHANNA OLSON-KENNEDY MS, MD

FEBRUARY 14, 2023

PERSONAL INFORMATION:

Work
4650 Sunset Blvd. MS 2 Los Angeles, CA 90027
Phone: 323-361-3128
Fax: 323-953-8116
Work Email: jolson@chla.usc.edu

EDUCATION AND PROFESSIONAL APPOINTMENTS

EDUCATION:

Year	*Degree, Field, Institution, City*
1992	BA, Mammalian Physiology, UC San Diego, San Diego
1993	MS, Animal Physiology, The Chicago Medical School, Chicago
1997	MD, Medical Doctor, The Chicago Medical Shool, Chicago
2015	MS, Clinical and Biomedical Investigations in Translational Science, USC, Los Angeles

POST-GRADUATE TRAINING:

Year-Year	*Training Type, Field, Mentor, Department, Institution, City*
1997 - 1998	Internship, Pediatrics, Children's Hospital Orange County, Orange
1998 - 2000	Residency, Pediatrics, Antonio Arrieta, Children's Hosptial Orange County, Orange
2000 - 2003	Fellowship, Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles
2012 - 2015	Master's Degree, Clinical and Biomedical Investigations in Translational Science, USC

ACADEMIC APPOINTMENTS:

Year-Year	*Appointment*	*Department, Institution, City, Country*
2006 - 2016	Assistant Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA
2016 - Present	Associate Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA

CLINICAL/ADMINISTRATIVE APPOINTMENTS:

2008 - 2012	Fellowship Director	Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA
2012 - present	Medical Director	The Center for Transyouth Health and Development, Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA

2021 - present	Clinical consultant	Santa Barbara Neighborhood Clinics

LICENSURE, CERTIFICATIONS

LICENSURE:

Year	*License number, State, Status*
2000	A-67352, California, Active

BOARD CERTIFICATION OR ELIGIBILITY:

Year	*Board, State, Status*
2001, 2009, 2015	Pediatrics, California, active

SPECIALTY CERTIFICATION:

Year	*Specialty Certification, Status*
2003, 2013	Adolescent Medicine, California, active

HONORS, AWARDS:

Year	*Description*	*Awarding agency, address, city*
2009	Health Care Advocacy Champion	Democratic Advocates for Disability Issues, Los Angeles
2010	Clinical Research Academic Career Development Award	Saban Research Center TSRI Program: Community Health Outcomes and Intervention, Los Angeles
2012	Extraordinary Service Award	Equality California, 202 W 1st St., Suite 3-0130, Los Angeles
2013	Top Doctor	Castle Connolly
2014	Anne Marie Staas Ally Award	Stonewall Democratic Club; 1049 Havenhurst Drive #325, West Hollywood
2014	Top Doctor	Castle Connolly
2014	Recognition Award for Outstanding, Compassionate and Innovative Service	SoCal Society for Adolescent Health and Medicine Regional Chapter, Los Angeles
2015	The Champion Award	The Division of Adolescent Medicine; CHAMPION FUND 5000 Sunset Blvd. Los Angeles
2016	America's Most Honored Professional's – Top 10%	America's Most Honored Professional's
2016	Regional Top Doctor	Castle Connolly
2017	Exceptional Women in Medicine	Castle Connolly
2017	Regional Top Doctor	Castle Connolly
2017	America's Most Honored Professional's – Top 5%	America's Most Honored Professional's
2018	Regional Top Doctor	Castle Connolly
2019	Benjamin Meaker Visiting Professorship	University of Bristol, Bristol UK
2019	Regional Top Doctor	Castle Connolly
2019	L.A's Top Docs	Los Angeles Magazine
2019	Top Docs	Pasadena Health
2019	America's Most Honored Professional's – Top 1%	America's Most Honored Professional's
2020	Regional Top Doctor	Castle Connolly
2020	Southern California Top Doc	Castle Connolly

2020	Southern California Top Doctors	
2020	L.A's Top Docs	Los Angeles Magazine
2020	America's Most Honored Professional's – Top 1%	America's Most Honored
2021	Southern California Top Doc	Castle Connolly
2021	America's Most Honored Doctors – Top 1%	America's Most Honored
2021	Top Doctors	Castle Connolly
2022	America's Most Honored Doctors – Top 1%	America's Most Honored
2022	Top Doctors	Castle Connolly

TEACHING

DIDACTIC TEACHING:

Keck School of Medicine at USC

Year-Year	*Course Name*	*Units/Hrs*	*Role*
2019	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth	One hour	Curriculum development and delivery
2020, 2021, 2022	Approach to the Care of Gender Non-conforming Children and Transgender Youth	One hour	Curriculum development and delivery
2023	Transgender and Non-binary Youth and Young Adults 101	One hour	Curriculum development and delivery

CalState Fullerton

Year-Year	*Course Name*	*Units/Hrs*	*Role*
2017	Gender Nonconforming and Transgender Youth	One hour	Curriculum development and delivery

UNDERADUATE, GRADUATE AND MEDICAL STUDENT (OR OTHER) MENTORSHIP:

Year-Year	*Trainee Name*	*Trainee Type*	*Dissertation/Thesis/Project Title*
2015 - 2016	David Lyons	MD	Transgender Youth Clinical Clerkship
2016 - 2019	Jonathan Warus	MD	Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts
2019 - 2021	Laer Streeter	MD	Comparison of Histrelin Implants
2020 - Present	Richard Mateo Mora	MD	Fertility Preservation Among Transgender Women
2022	Avery Everhart	PhD	Incomplete Data & Insufficient Methods: Transgender Population Health Research in the US

GRADUATE STUDENT THESIS, EXAM AND DISSERTATION COMMITTEES:

Year-Year	*Trainee Name*	*Committee Type*	*Student Department*
2022	Avery Everhart	Dissertation	Social Work

POSTGRADUATE MENTORSHIP:

Year-Year	*Trainee Name*	*If past trainee, current position and location*
2012-2013	Lisa Simons, MD	Clinical Instructor – Lurie Children's Hospital
2013	Shelley Aggarwal, MD	Clinical Instructor – Stanford University School of Medicine
2014	Julie Spencer, MD	Adolescent Medicine Provider Kaiser Hospital
2014-2015	Michael Haymer, MD	Program Director, Psychiatry Department UCLA
2015-2017	Patrick Shepherd, MD	CHLA Endocrinology Fellow
2015-2018	Jonathan Warus, MD	Faculty, CHLA/USC Keck School of Medicine
2015-2020	Shannon Dunlap, PhD	Postdoctoral Scholar - Research Associate, University of Southern California, Suzanne Dworak-Peck School of Social Work
2020-Present	Marianela Gomez-Rincon, MD	Adolescent Medicine Fellow
2020-Present	Jonathan Warus, MD	CHLA, Assistant Professor of Clinical Pediatrics
2022	Emmett Henderson, PhD, MS	USC Suzanne Dworak-Peck School of Social Work Senior mentor K99; USC

MENTORSHIP OF FACULTY:

Year-Year	*Mentee Name*	*Mentee Department*
2021 - present	Jonathan Warus, MD	Division of Adolescent Medicine, CHLA
2022	Brigid Conn, PhD	Clinical Psychologist, CHLA

SERVICE

DEPARTMENT SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2010-2015	Secretary, The CHAMPION Fund Executive Board	The Division of Adolescent Medicine, Children's Hospital Los Angeles

HOSPITAL OR MEDICAL GROUP SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2021 - present	Committee Member	SOGI work group, CHLA

PROFESSIONAL SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2012-present	Member, LGBT Special Interest Group	Society for Adolescent Health and Medicine
2022	Secretary, Executive Board of Directors	US Professional Association of Transgender Health

CONSULTANTSHIPS AND ADVISORY BOARDS:

Year	*Position, Board*	*Organization/Hospital/School, Institution*
2010-2017	Member, Advisory Board	Transyouth Family Allies
2017-present	Member, National Medical Committee	Planned Parenthood
2017 - Present	Board Member	US Professional Association of Transgender Health
2021	Expert Panelist	Robert Wood Johnson Foundation - National Commission on Data Transformation for Health Equity
2021	Member, Advisory Board	The National LGBTQIA+ Health Education Center

PROFESSIONAL SOCIETY MEMBERSHIPS:

Year- Year	*Society*
2003 - present	Society for Adolescent Health and Medicine
2005 - present	American Academy of Pediatrics
2006 - 2011	Los Angeles Pediatric Society (Past president 2010)
2010 - present	Professional Association for Transgender Health
2014 - present	Society for Pediatric Research
2017 - present	US Professional Association for Transgender Health

MAJOR LEADERSHIP POSITIONS: (E.G., DEAN, CHAIR, INSTITUTE DIRECTOR, HOSPITAL ADMINISTRATION, ETC.)

RESEARCH AND SCHOLARSHIP

EDITORSHIPS AND EDITORIAL BOARDS:

Year-Year	*Position*	*Journal/Board Name*
2015 - present	Associate Editor	Journal of Transgender Health

MANUSCRIPT REVIEW:

Year-Year	*Journal*
2014 - present	Pediatrics
2014 - present	Journal of Adolescent Health
2014 - present	LGBT Health
2014 - present	International Journal of Transgenderism
2015 - present	Journal of Transgender Health
2018 - present	Clinical Child Psychology and Psychiatry
2018 - present	Journal of Sexual Medicine
2018 - present	Journal of Transgender Health
2021 - present	JAMA Peds

GRANT REVIEWS:

Year	*Description*	*Awarding agency, City, State, Country*
2017	Cognition and Perception Study Section	National Institutes of Health, Bethesda, Maryland, USA
2017	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2019	Special Emphasis Panel Review of Research Conference (R13) Grants	National Institutes of Health, Bethesda, Maryland, USA
2019	The Einstein Foundation Award for Promoting Quality in Research	Einstein Foundation, Berlin
2020	Biobehavioral and Behavioral Sciences Study Section	National Institutes of Health, Bethesda, Maryland, USA
2021	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA

MAJOR AREAS OF RESEARCH INTEREST

Research Areas
1. Transgender and non-binary children, adolescents and young adults
2. HIV medication adherence

GRANT SUPPORT - CURRENT:

Grant No. (PI)2R01HD082554-06A1 (Olson-Kennedy)	*Dates of Award: 2021-2026*
Agency: NICHD	*Percent Effort 25%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is the continuations of a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	

Role: Principle Investigator
*Total Direct Costs: $*4,918,586

Grant No. 1R01HD097122-01 (Hidalgo)	*Dates of Award: 2019-2024*
Agency: NICHD	*Percent Effort 2.5%*
Title: A Longitudinal Study of Gender Nonconformity in Prepubescent Children	
Description: The purpose of this study is to establish a national cohort of prepubertal transgender/gender nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.	
Role: Site PI	
Total Direct Costs: $2,884,950	

GRANT SUPPORT - PAST:

Grant No. (PI) 1RO1HD082554-01A1	*Dates of Award: 2015-2020*
Agency: NICHD	*Percent Effort 45%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	
Role: Principle Investigator	
*Total Direct Costs: $*4,631,970	
Grant No. (COI) R01AI128796-01	Dates of Award: 2/24/17-1/31/18
Agency: NIAID	Percent Effort: 5%
Title: Maturation, Infectibility and Trauma Contributes to HIV Susceptibility in Adolescents	
Description: This proposal explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal trauma, and vaginal proteins will be determined and modeled.	
Role: Co-Investigator	
Total Direct Costs: $44,816	

Grant No. (PI) U01HD040463	*Dates of Award* 2006 – 2016
Agency: NIH/NICHD	*Percent Effort: 10%*
Title: Adolescent Medicine Trials Network for HIV/AIDS	
Description: Adolescent Medicine Trials Network for HIV/AIDS	

Role: Co-Investigator
Total Direct Costs: 2,225,674

Grant No. (PI) SC CTSI 8KL2TR000131	*Dates of Award: 2012-2014*
Agency: KL2 Mentored Career Research Development Program of the Center for Education, Training and Career Development	*Percent Effort: 37.5%*
Title: The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender Non-Conforming Peri-Pubertal Youth	
Description: This study aimed to understand the impact of puberty blocking medications on mental health and physiolgic parameters in peri-pubertal transgender youth.	
Role: Principal Investigator	
Total Direct Costs: 191,525	

Invited Lectures, Symposia, keynote addresses

Date	***Type***	***Title, Location***
2014	Invited Lecture	Transgender Youth; Needs, Risks, Outcomes and the Role of the System, Including Permanency and Inclusion for Our Youth, Administrative Office of the Courts, Center for Families and Children, San Diego, California
2015	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Lopez Family Foundation Special Lecture for Puerto Rico and Panama, Lopez Family Foundation, Children's Hospital Los Angeles, Los Angeles, California
2015	Symposium	Transgender Youth – An Overview of Medical and Mental Health Needs of Gender Non-Conforming Children and Transgender Adolescents, Public Child Welfare Training Academy, Academy for Professional Excellence at San Diego State University School of Social Work, San Diego, California
2015	Invited Lecture	Meeting the Needs of Transgender Adolescents; 1st Annual Southern California LGBT Health Symposium; USC/UCLA, Los Angeles, California
2015	Symposium	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; GetReal California's Initiative; "Integrating Sexual Orientation, Gender Identity, and Expression (SOGIE) into California's Child Welfare System," Oakland, California
2016	Invited Symposium	Caring for Gender Nonconforming and Transgender Youth; Idyllwild, California
2016	Educational symposium	Gender 101: A Primer; Vista Mar, California
2016	Invited Lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, California Association of Marriage and Family Therapists, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming Children and Transgender Youth, California Psychological Association, Continuing Education Institute, Irvine, California
2016	Invited Lecture	Health Issues Related to Transgender Youth; LA City Health Commission, Los Angeles, California

2016	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Medical Directors 12th Annual Update on Reproductive Health and Medical Leadership, Planned Parenthood, Steamboat Springs, Colorado
2016	Invited Lecture	Caring For Transgender Teens, UCLA Meet the Professor, Los Angeles, CA
2017	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Santa Barbara, CA
2017	Invited Lecture	Healthcare for TGNC Youth, Expanding Competency for LGBT Youth in the System, Washington DC
2017	Invited Lecture	Gender Non-conforming and Transgender Children and Youth; Center for Early Education, West Hollywood, CA
2017	Invited Lecture	Rethinking Gender, University of Massachusetts, Annual Convocation Welcome Luncheon, Worcester, MA
2017	Invited Lecture	Gender Non-Conforming Children and Transgender Youth, Board of Behavioral Sciences, Orange, CA
2017	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, Santa Monica Rape Treatment Center, Santa Monica, CA
2017	Invited Lecture	Transgender Youth Care in the New Millennium, USC Law and Global Health Initiative, Los Angeles, CA
2018	Invited Lecture	Supporting Gender Diverse and Transgender Youth: A Deeper Look at Gender Dysphoria, Studio City, CA
2018	Invited Lecture	Working with Trans and Gender Non-Conforming Youth, Children's Hospital Orange County, CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, Ascend Residential, Encino CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, California State University Northridge, Northridge, CA
2018	Invited Lecture	Gender Dysphoria; School Nurse Organization of Idaho Annual Conference, Idaho
2018	Invited Lecture	Gender and What You Should Know, Archer School for Girls, Brentwood, CA
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Oceanside, CA
2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Advance LA, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Andrology Society of America Clinical Symposium, Portland, OR
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Center for Early Education, Los Angeles, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	Symposium	TransYouth Care; Flagstaff, AZ
2019	Invited Lecture	Transgender and Gender Non-conforming Youth, Ascend Residential Treatment, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah

2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, UCLA Olive View, CA
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, Good Samaritan, CA
2019	Invited Lecture	Puberty Suppression in Youth with Gender Dysphoria, Fenway Trans Health Program, Boston
2019	Invited Lecture	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Ventura, CA
2019	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Education Demystification Symposium, GA
2019	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Los Angeles Superior Court/Los Angeles Bar Association Training, CA
2019	Invited Lecture	Supporting Gender Diverse and Transgender Youth; A Deeper Look at Gender Dysphoria, Oakwood School, CA
2020	Symposium	Trans Youth Care, Chico Transgender Week, Virtual Presentation
2020	Invited Lecture	Gender Nonconforming and Transgender Youth, Novartis, Virtual Presentation
2020	Invited Lecture	Advanced Hormones; More than Just T and E, CHLA, Virtual Presentation
2020	Invited Lecture	Video Telehealth and Transgender Youth, Telehealth Best Practices for the Trans Community, The Central Texas Transgender Health Coalition, Virtual Presentation
2020	Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture
2020	Invited Lecture	Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation
2020	Invited Lecture	Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2020	Invited Lecture	USC Medical School, Los Angeles, CA
2020	Invited Lecture	Medical Interventions for transgender youth, Cal State Los Angeles, Los Angeles
2020	Plenary Session	Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2021	Invited Lecture	Gender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los Angeles
2021	Invited Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lecture
2021	Invited Lecture	Caring for Gender Diverse and Transgender Youth. SLO Acceptance, Cal Poly, Virtual Presentation
2022	Invited Lecture	Transgender and Non-binary children and youth, Board of Behavioral Sciences
2022	Invited Lecture	Gender Affirmation through a Social Justice Lens; University of Arizona Health Sciences LGBTQ+ Symposium & Health Fair

2022	Invited Lecture	Gender Dysphoria in Children, Adolescents and Young Adults, MedLambda and PsychSIG Keck USC School of Medicine, Virtual Lecture
2022	Invited Lecture	Caring for Transgender and Gender Nonconforming Youth, Presbyterian Healthcare Services, New Mexico, Virtual lecture
2022	Invited Lecture	Transgender and Non-Binary Youth, Rogers Behavioral Health, Virtual Lecture
2023	Invited Lecture	**Transgender and Non-binary Youth and Young Adults 101,** When Healthcare Gets Political; Health Justice and Systems of Care course, Keck USC School of Medicine, Los Angeles

Invited Grand Rounds, CME Lectures

Date	***Type***	***Title, Location***
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach; Seattle Children's Hospital, Seattle, Washington
2014	CME lecture	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; Eisenhower Medical Center Transgender Health Symposium, Palm Springs, California
2014	Grand Rounds	Toddlers to Teens: Comprehensive Health Care for the Transgender Child, Cultural Psychiatry Lecture Series, University of Iowa Carver College of Medicine, Iowa City, Iowa
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium; A Multidisciplinary Team Approach, Children's Hospital Los Angeles, Los Angeles, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Cross-sex Hormones for Teenagers, How Young is Too Young? Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2014	CME lecture	Pediatric Update, Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, Stanford Division of Adolescent Medicine, Palo Alto, CA
2015	CME Educational Lecture	The Transgender Experience, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Update on the Transgender Patient for the PCP, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Teens, Providence Tarzana, CA
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, University of Southern California, Los Angeles, California

2015	Grand Rounds	Puberty Blockers and Cross Sex Hormones, Pediatric Endocrinology, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Youth and Hormones, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Transyouth Healthcare, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Supporting Transgender Youth, Southern Oregon University Student Health and Wellness Center Workshop, Southern Oregon University, Ashland, Oregon
2015	PCS Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Medical Care for Gender Non-Conforming Children, Transgender Adolescents and Young Adults in the New Millennium, Continuing Medical Education of Southern Oregon, Medford, Oregon
2015	Grand Rounds	Medical Care for Gender Non-Conforming Children and Transgender Youth, Olive View Medical Center-UCLA, Sylmar, California
2015	Grand Rounds	Caring for Gender Non-conforming Children and Transgender Teens, Harbor-UCLA Department of Pediatrics, Torrance, California
2015	CME lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium, Healthcare Partners Pediatric Town Hall Meeting, Healthcare Partners CME, Glendale, California
2016	Pediatric Grand Rounds	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth; Children's Hospital Los Angeles, Los Angeles, California
2016	Endocrine Grand Rounds	Approach to Care of Gender Non-Conforming Children and Transgender Adolescents; Cedars Sinai Hospital, Los Angeles, California
2016	Pediatric Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, Stanford Lucille Packard Children's Hospital, Palo Alto, California
2016	Pediatric Update	Caring for Gender Variant Children and Adolescents, St. Louis, Missouri
2016	Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, St. Jude's Grand Rounds, Memphis, Tennessee
2016	CME Educational Lecture	Transgender and Gender Non-Conforming Youth: Innovative Approaches to Care in 2016; Integrating Substance Use, Mental Health, and Primary Care Services: Courageous and Compassionate Care, Los Angeles, California
2016	CME; professional conference	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, Arizona Psychiatric Society, Tempe, Arizona
2016	CME/Educational Symposium	Caring for Gender Nonconforming and Transgender Youth, San Diego, California
2016	CME/CEU Educational Training	Medical Interventions for Transgender Youth and Young Adults, San Diego State University, San Diego, California
2016	Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Mt. Sinai Hospital, Pediatric Grand Rounds George J. Ginandes Lecture, New York, New York

2016	CME Educational Lecture	The Transgender Experience, Providence Tarzana, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2017	CME Educational Seminar	The Care of Gender Non-Conforming children and Transgender Youth; Orange County Health Care Agency, Orange County, CA
2017	CME Educational Lecture	Rethinking Gender, Adolescent Grand Rounds, Children's Hospital Los Angeles, Los Angeles, CA
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth, Pasadena CA
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents, Developmental Pediatrics continuing education lecture, Children's Hospital Los Angeles, CA
2017	CME Educational Lecture	Care of Gender Non-Conforming Children and Transgender Adolescents, Lopez Family Foundation Educational Lecture, Los Angeles, CA
2017	CME Educational Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health, Los Angeles, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2018	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Glendale Unified School District, CA
2018	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Youth, CME by the Sea, CA
2018	CME Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Austin, TX
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Desert Oasis Healthcare, Palm Desert, CA
2018	CME Workshop	Mental and Medical Healthcare for Transgender Adolescents, California Association of Marriage and Family Therapists, Garden Grove, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Keck School of Medicine, Los Angeles, CA
2018	Grand Rounds	Caring for Gender Non-Conforming Children and Transgender Adolescents, Primary Children's Hospital, Salt Lake City, UT
2018	CME Educational Lecture	Caring for Transgender Youth, Chico Trans Week, Chico, CA

2018	CME Educational Lecture	Rethinking Gender, UCSD Medical School, San Diego, CA
2018	CME Educational Lecture	Rethinking Gender, UCLA Medical School, Los Angeles, CA
2019	Symposium	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Stockton, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	CME Lecture	Gender Diverse and Transgender Youth, Harbor UCLA Medical Center Grand Rounds, Torrance, CA
2019	CME Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey San Diego, San Diego, CA
2019	Grand Rounds	Transgender Youth; What's New in 2019?, Children's Hospital Los Angeles, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Children's Hospital Orange County, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Stanislaus County Behavioral Health and Recovery Services, CA
2019	CME Eduational Lecture	Rethinking Gender, Olive View Medical Center Grand Rounds, CA
2020	CME Lecture	Gender Affirmation Through a Social Justice Lens, SAHM Conference, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, AAP Conference, Virtual Lecture
2020	CME Lecture	Conversations with LGBTQ youth; the role of the pediatrician, AAP Conference, Virtual Lecture
2020	Grand Rounds	Creating Affirming Environments for Trans and Gender Diverse Patients, USC OB/Gyn Grand Rounds, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Resident Lecture, CHLA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Facey Medical Group, Los Angeles, CA
2020	Plenary Lecture	Reframing Gender Dysphoria, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Gender Affirming Care for Pre and Peri-pubertal Trans and Gender Diverse Youth, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Division of Endocrinology, USC, Los Angeles, CA
2021	CME Lecture	Transitioning: From Invalidation and Trauma to Gender Affirming Care; Department of Anesthesiology at CHLA

2021	CME Lecture	Transitioning from Invalidation and Trauma to Gender Affirming Care; ACCM Grand Rounds, Children's Hospital Los Angeles, Virtual presentation
2021	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium
2021	Symposium	TransYouth Care for Parents; Santa Clara, CA
2022	CME Lecture	Gender affirming medical interventions; An Evolving landscape, Critical Issues in Child and Adolescent Mental Health Conference, San Diego, California
2022	CME Symposium	TransYouth Care for Mental Health Providers; Santa Clara, CA
2022	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium

International Lectures

Date	***Type***	***Title, Location***
2013	Keynote	Caring for Gender Non-conforming Children and Adolescents in the New Millennium, Vancouver, Canada
2016	CME; professional conference	Social Transitions in Pre-pubertal Children; What do we know? World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities, World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Workgroup on Gender Nonconforming/Transgender Youth: Biopsychosocial Outcomes and Development of Gender Identity, World Professional Association of Transgedner Health, Amsterdam, The Netherlands
2017	Invited Lecture	Gender Dysphoria, Beyond the Diagnosis, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-Conforming Children and Transgender Adolescents: A United States Perspective, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-conforming and Transgender youth and Young Adults, Diverse Families Forum: The Importance of Family Support in The Trans And LGBT Children, Organized by COPRED and The International Association Of Families For Diversity (FDS), Mexico City, Mexico
2018	Invited Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults: Comparison of Nonsurgical and Postsurgical Cohorts, Buenos Aires, Argentina
2018	Invited Lecture	Transgender Youth and Gender Affirming Hormones; A 6-8 year follow-up, Buenos Aires, Argentina
2018	Invited Lecture	Transyouth Care – An NIH Multisite Study About the Impact of Early Medical Treatment in Transgender Youth in the US, Buenos Aires, Argentina

2018	Invited Lecture	Uso de Hormonas Reaffirmantes de Genero en Adolescentes Transgenero, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Bloquedores de la Pubertad, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	CME Educational Lecture	Puberty Blockers and Gender Affirming Hormones for Transgender Youth: What Do We Know, and What Have We Learned, Pediatric Academic Societies, Toronto, Canada
2019	Grand Rounds	Rethinking Gender, Grand Rounds, The Hospital for Sick Children, Toronto, Canada
2019	Keynote	***Gender Dysphoria; Beyond the Diagnosis,*** Promoting Innovation and Collaboration to Support Gender Diverse Youth Conference, The Hospital for Sick Children, Toronto, Canada, December 2019
2019	Invited Lecture	Hormonas que Affirman el Genero pasa Juventud y Adultos Menores Trans, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Infancia Trans y da Genero Diverso, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Transgender Youth: Medical and Mental Health Needs, Bristol, United Kingdom
2019	Invited Lecture	Rethinking Gender, University of Bristol, United Kingdom
2019	CME; professional conference	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, European Professional Association of Transgender Health, Rome Italy
2019	CME; professional conference	Transgender Youth and Gender Affirming Hormones; 5-7 Year Follow Up, European Professional Association of Transgender Health, Rome Italy
2019	CME Educational Lecture	Gender Dysphoria; Beyond the Diagnosis, European Professional Association of Transgender Health, Rome Italy
2022	Plenary Session	The Landscape of Gender Affirming Care for Youth in the US, AusPATH, Virtual
2022	CME; professional conference	Emotional Functioning of Adolescents with Gender Dysphoria After Two Years of Treatment; WPATH Conference, Montreal, Canada
2022	CME; Professional Conference	Creating Enduring Materials; WPATH Conference, Montreal, Canada
2023		

Keynote/Plenary Presentations

Date	*Type*	*Title, Location*
2015	Keynote	The Future of Trans Care in the New Millennium, Gender Infinity Conference, Houston, Texas
2016	Plenary Session	Caring for Trans Youth and Gender Non-Conforming Children, Transgender Spectrum Conference, St. Louis, Missouri
2018	Keynote	Future Directions, USPATH, Washington DC
2019	Keynote	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Inaugural LGBTQ summit, Santa Clara CA
2021	CME; professional conference	Advances and Challenges in the Care of Transgender/Gender Diverse Youth; USPATH Conference, Virtual presentation
2022	Keynote	Gender Affirmation Through a Social Justice Lens, Indiana University School of Medicine
2022	Invited Lecture	Transgender and Non-Binary Youth, Supporting the Well-Being of LGBTQ Youth Certificate Program Center for Juvenile Justice Reform Georgetown University, virtual training
2022	Invited Lecture	Transgender and Non-Binary Youth, Young Women's Career Conference (YWCC) for the Girls Academic Leadership Academy; virtual lecture

PUBLICATIONS:

*** INDICATES TRAINEES**
**** INDICATE YOURSELF AS CO-FIRST OR CO-CORRESPONDING OR SENIOR AUTHORS**

REFEREED JOURNAL ARTICLES:

1. Belzer M, Sanchez K, **Olson J**, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. J Pediatr Adolesc Gynecol. 2005 Oct;18(5):347-54. PubMed PMID: 16202939.

2. Puccio JA, Belzer M, **Olson J**, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV-infected adolescents and young adults to adhere to highly active antiretroviral therapy: a pilot study. AIDS Patient Care STDS. 2006 Jun;20(6):438-44. PubMed PMID: 16789857.

3. **Olson J**,** Forbes C, Belzer M. Management of the transgender adolescent. Arch Pediatr Adolesc Med. 2011 Feb;165(2):171-6. doi: 10.1001/archpediatrics.2010.275. Review. PubMed PMID: 21300658.

4. Simons L*, Schrager SM, Clark LF, Belzer M, **Olson J**.** Parental support and mental health among transgender adolescents. J Adolesc Health. 2013 Dec;53(6):791-3. DOI: 10.1016/j.jadohealth.2013.07.019. Epub 2013 Sep 4. PubMed PMID: 24012067; PubMed Central PMCID: PMC3838484.

5. Belzer ME, Naar-King S, **Olson J**, Sarr M, Thornton S, Kahana SY, Gaur AH, Clark LF; Adolescent Medicine Trials Network for HIV/AIDS Interventions. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trial. AIDS Behav. 2014 Apr;18(4):686-96. doi: 10.1007/s10461-013-0661-3. PubMed PMID: 24271347; PubMed Central PMCID: PMC3962719.

6. **Olson J****, Garofalo R. The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7. doi: 10.3928/00904481-20140522-08. PMID: 24972421.

7. **Olson J****, Schrager SM, Clark LF, Dunlap SL, Belzer M. Subcutaneous Testosterone: An Effective Delivery Mechanism for Masculinizing Young Transgender Men. LGBT Health. 2014 Sep;1(3):165-7. doi: 10.1089/lgbt.2014.0018. Epub 2014 Jun 26. PMID: 26789709.

8. Schrager SM, **Olson J,** Beharry M*, Belzer M, Goldsich K*, Desai M, Clark LF. Young men and the morning after: a missed opportunity for emergency contraception provision? J Fam Plann Reprod Health Care. 2015 Jan;41(1):33-7. doi: 10.1136/jfprhc-2013-100617. Epub 2014 Jan 24. PubMed PMID: 24465024.

9. Belzer M, Kolmodin MacDonell K, Clark L, Huang J, **Olson J**, Kahana S, Naar S, Sarr M, Thornton S. Acceptability and Feasibility of a Cell Phone Support Intervention for Youth Living with HIV with Nonadherence to Antiretroviral Therapy, AIDS Patient Care and STDs, Vol. 29, No. 6, June 2015: 338-345. doi: 10.1089/apc.2014.0282;

10. Klein DA, Ellzy JA, **Olson J****. Care of a Transgender Adolescent. Am Fam Physician. 2015 Jul 15;92(2):142-8. PMID: 26176373.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF DANIEL SHUMER, M.D.

I, Daniel Shumer, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. I am a Pediatric Endocrinologist, Associate Professor of Pediatrics, and the Clinical Director of the Child and Adolescent Gender Clinic at Mott Children's Hospital at Michigan Medicine. I am also the Medical Director of the

Comprehensive Gender Services Program at Michigan Medicine, University of Michigan.

4. I am Board Certified in Pediatrics and Pediatric Endocrinology by the American Board of Pediatrics and licensed to practice medicine in the state of Michigan.

5. I received my medical degree from Northwestern University in 2008. After completing a Residency in Pediatrics at Vermont Children's Hospital, I began a Fellowship in Pediatric Endocrinology at Harvard University's Boston Children's Hospital. Concurrent with the Fellowship, I completed a Master of Public Health from Harvard's T.H. Chan School of Public Health. I completed both the Fellowship and the MPH degree in 2015.

6. I have extensive experience in working with and treating children and adolescents with endocrine conditions including differences in sex development (DSD) (also referred to as intersex conditions), gender dysphoria, type 1 diabetes, thyroid disorders, growth problems, and delayed or precocious puberty. I have been treating patients with gender dysphoria since 2015.

7. A major focus of my clinical, teaching, and research work pertains to the assessment and management of transgender adolescents.

8. I have published extensively on the topic of gender identity in pediatrics and the treatment of gender dysphoria, as well as reviewed the peer-reviewed literature concerning medical treatments for gender dysphoria, the current standards of care the treatment of gender dysphoria, and research articles on a variety of topics with a focus on mental health in transgender adolescents.

9. I am involved in education of medical trainees. I am the Fellowship Director in the Division of Pediatric Endocrinology, Education Lead for the Division of Pediatric Endocrinology, and Course Director for a medical student elective in Transgender Medicine. My additional academic duties as an Associate Professor include teaching several lectures, including those entitled "Puberty," "Transgender Medicine," and "Pediatric Growth and Development."

10. As a Fellow at Harvard, I was mentored by Dr. Norman Spack. Dr. Spack established the Gender Management Services Clinic (GeMS) at Boston Children's Hospital. While working and training at GeMS, I became a clinical expert in the field of transgender medicine within Pediatric Endocrinology and began conducting research on gender identity, gender dysphoria, and the evaluation and management of gender dysphoria in children and adolescents.

11. Based on my work at GeMS, I was recruited to establish a similar program assessing and treating gender diverse and transgender children and

adolescents at the C.S. Mott Children's Hospital in Ann Arbor. In October 2015, I founded the hospital's Child and Adolescent Gender Services Clinic.

12. The Child and Adolescent Gender Services Clinic has treated over 600 patients since its founding. The clinic provides comprehensive assessment, and when appropriate, treatment with pubertal suppression and hormonal therapies, to patients diagnosed with gender dysphoria. I have personally evaluated and treated over 400 patients with gender dysphoria. The majority of the patients receiving care range between 10 and 21 years old. Most patients attending clinic live in Michigan or Ohio. As the Clinical Director, I oversee the clinical practice, which currently includes 4 physicians (including 1 psychiatrist), 1 nurse practitioner, 2 social workers, 1 research coordinator, as well as nursing and administrative staff. I also actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.

13. I also provide care in in the Differences/Disorders of Sex Development (DSD) Clinic at Michigan Medicine at Mott Children's Hospital. The DSD Clinic is a multidisciplinary clinic focused on providing care to infants and children with differences in the typical path of sex development, which may be influence by the arrangement of sex chromosomes, the functioning of our gonads (i.e. testes, ovaries), and our bodies' response to hormones. The clinic is comprised of members from

Pediatric Endocrinology, Genetics, Psychology, Urology, Gynecology, Surgery, and Social Work. In this clinic I have assessed and treated over 100 patients with DSD. In my role as Medical Director of the Comprehensive Gender Services Program (CGSP), I lead Michigan Medicine's broader efforts related to transgender services. CGSP is comprised of providers from across the health system including pediatric care, adult hormone provision, gynecologic services, adult surgical services, speech/language therapy, mental health services, and primary care. I run monthly meetings with representatives from these areas to help coordinate communication between Departments. I coordinate strategic planning aimed to improve care within the health system related to our transgender population. I also serve as the medical representative for CGSP in discussions with health system administrators and outside entities.

14. I have authored numerous peer-reviewed articles related to treatment of transgender youth. I have also co-authored chapters of medical textbooks related to medical management of transgender patients. I have been invited to speak at numerous hospitals, clinics, and conferences on topics related to clinical care and standards for treating transgender children and youth.

15. The information provided regarding my professional background, experiences, publications, and presentations is detailed in my curriculum vitae, a true and correct copy of the most up-to-date version of which is attached as **Exhibit A**.

B. Prior Testimony

16. In the past four years, I have been retained as an expert and provided testimony at trial or by deposition in the following cases: *Roe et al v. Utah High School Activities Association et al* (Third District Court in and for Salt Lake County, UT); and *Menefee v. City of Huntsville Bd. of Educ.*, No. 5:18-cv-01481 (N.D. Ala.). I also provided expert witness testimony on behalf of a parent in a custody dispute involving a transgender child in the following case: *In the Interest of Younger*, No. DF-15-09887 (Dallas County, Texas).

C. Compensation

17. I am being compensated at an hourly rate for the actual time that I devote to this case, at the rate of $325 per hour for any review of records, preparation of reports, declarations, and deposition and trial testimony. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

D. Bases for Opinions

18. This report sets forth my opinions in this case and the bases for my opinions.

19. In preparing this report, I reviewed the text of *Florida Medicaid – Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, including the attachments, as well as the Complaint in this case.

20. I have also reviewed the materials listed in the bibliography attached as **Exhibit B** to this report, as well as the materials listed within my curriculum vitae, which is attached as **Exhibit A**. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report. I may rely on these materials as additional support for my opinions.

21. In addition, I have relied on my scientific education, training, and years of clinical and research experience, and my knowledge of the scientific literature in the pertinent fields.

22. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.

23. To the best of my knowledge, I have not met or spoken with the Plaintiffs or their parents. My opinions are based solely on my extensive background and experience treating transgender patients.

24. I may wish to supplement or revise these opinions or the bases for them due to new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

II. EXPERT OPINIONS

A. MEDICAL AND SCIENTIFIC BACKGROUND ON SEX AND GENDER IDENTITY

25. *Sex* is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary sex characteristics (IOM, 2011).

26. *Gender identity* is the medical term for a person's internal, innate sense of belonging to a particular sex. Everyone has a gender identity. Diversity of gender identity and incongruence between assigned sex at birth and gender identity are naturally occurring sources of human biological diversity (IOM, 2011). The term *transgender* refers to individuals whose gender identity does not align with their sex assigned at birth (Shumer, et al., 2013).

27. The terms *gender role* and *gender identity* refer to different things. *Gender roles* are behaviors, attitudes, and personality traits that a particular society

considers masculine or feminine, or associates with male or female social roles. For example, the convention that girls wear pink and have longer hair, or that boys wear blue and have shorter hair, are socially constructed gender roles from a particular culture and historical period. By contrast, *gender identity* does not refer to socially contingent behaviors, attitudes, or personality traits. It is an internal and largely biological phenomenon, as reviewed below. Living consistent with one's gender identity is critical to the health and well-being of any person, including transgender people (Hidalgo, et al., 2013; Shumer, et al., 2013; White Hughto, et al., 2015).

28. A person's understanding of their gender identity may evolve over time in the natural course of their life, however, attempts to "cure" transgender individuals by forcing their gender identity into alignment with their birth sex (sometimes descried as "conversion therapy") has been found to be both harmful and ineffective. In one study, transgender adults who recall previous attempts from healthcare professionals to alter their gender identity reported an increase in lifetime suicide attempts and higher rates of severe psychological distress in the present (Turban, et al., 2020a). In another study, exposure to these types of attempts were found to increase the likelihood that a transgender adolescent will attempt suicide by 55% and more than double the risk for running away from home (Campbell, et al., 2002). Those practices have been denounced as unethical by all major

professional associations of medical and mental health professionals, such as the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, and the American Psychological Association, among others (Fish, et al., 2022).

29. Scientific research and medical literature across disciplines demonstrates that gender identity, like other components of sex, has a strong biological foundation. For example, there are numerous studies detailing the similarities in the brain structures of transgender and non-transgender people with the same gender identity (Luders, et al., 2009; Rametti, et al., 2011; Berglund, et al., 2008; Savic, et al., 2011). In one such study, the volume of the bed nucleus of the *stria terminalis* (a collection of cells in the central brain) in transgender women was equivalent to the volume found in cisgender women (Chung, et al., 2002).

30. There are also studies highlighting the genetic components of gender identity. Twin studies are a helpful way to understand genetic influences on human diversity. Identical twins share the same DNA, while fraternal twins share roughly 50% of the same DNA, however both types of twins share the same environment. Therefore, studies comparing differences between identical and fraternal twin pairs can help isolate the genetic contribution of human characteristics. Twin studies have shown that if an identical twin is transgender, the other twin is much more likely to

be transgender compared to fraternal twins, a finding which points to genetic underpinnings to gender identity development (Heylens, et al., 2012).

31. There is also ongoing research on how differences in fetal exposures to hormones may influence gender identity. This influence can be examined by studying a medical condition called congenital adrenal hyperplasia. Female fetuses affected by congenital adrenal hyperplasia produce much higher levels of testosterone compared to fetuses without the condition. While most females with congenital adrenal hyperplasia have a female gender identity in adulthood, the percentage of those with gender dysphoria is higher than that of the general population. This suggests that fetal hormone exposures contribute to the later development of gender identity (Dessens, et al, 2005).

32. There has also been research examining specific genetic differences that appear associated with gender identity formation (Rosenthal, 2014). For example, one study examining differences in the estrogen receptor gene among transgender women and cisgender male controls found that the transgender individuals were more likely to have a genetic difference in this gene (Henningsson, et al., 2005).

33. The above studies are representative examples of scientific research demonstrating biological influences on gender identity. Gender identity, like other

complex human characteristics, is rooted in biology with important contributions from neuroanatomic, genetic and hormonal variation (Roselli, 2018).

B. RATIONALE FOR MEDICAL TREATMENT OF GENDER DYSPHORIA IN ADOLECENTS AND ADULTS

34. All medical interventions, including treatment for gender dysphoria, require rigorous study and evidence base.

35. There are several studies demonstrating positive results of gender-affirming care in adolescents and adults (de Vries, et al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et al., 2022). These studies consistently demonstrate improvement of gender dysphoria with associated improvement of psychological functioning. A 2014 long-term follow-up study following patients from early adolescence through young adulthood showed that gender-affirming treatment allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014). More recently, Green et al. (2022) describe that gender-affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

C. ASSESSMENT OF GENDER DYSPHORIA IN CHILDREN, ADOLESCENTS, AND ADULTS

36. Due to the incongruence between their assigned sex and gender identity, transgender people experience varying degrees of gender dysphoria, a serious medical condition defined in both the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5 TR) (APA, 2022). *Gender Dysphoria* is defined as an incongruence between a patient's assigned sex and their gender identity present for at least six months, which causes clinically important distress in the person's life. This distress is further defined as impairment in social, occupational, or other important areas of functioning (APA, 2022). Additional features may include a strong desire to be rid of one's primary or secondary sex characteristics, a strong desire to be treated as a member of the identified gender, or a strong conviction that one has the typical feelings of identified gender (APA, 2022).

37. The World Health Organization's International Classification of Diseases (ICD), the diagnostic and coding compendia for mental health and medical professionals, codifies Gender Incongruence as the diagnosis resulting from the incongruity between one's gender identity and sex assigned at birth. The Gender Incongruence diagnosis is part of a new "Conditions related to sexual health" chapter in the ICD-11, which is the most recent iteration of the ICD published in 2019

(Costa, et al., 2015; WHO, 2019). This reflects evidence that transgender and gender diverse identities are not conditions of mental ill health and classifying them as such can cause enormous stigma.

38. In children and adolescents, the diagnosis of gender dysphoria is made by a health provider including but not limited to a psychiatrist, psychologist, social worker, or therapist with expertise in gender identity concerns. It is recommended that children and adolescents diagnosed with gender dysphoria engage with a multidisciplinary team of mental health and medical professionals to formulate a treatment plan, in coordination with the parent(s) or guardian(s), with a goal of reduction of gender dysphoria. The *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* ("SOC 8"), published by the World Professional Association for Transgender Health (WPATH), provides guidance to providers on how to provide comprehensive assessment and care to this patient population based on medical evidence. These standards recommend involving relevant disciplines, including mental health and medical professionals, to reach a decision with families about whether medical interventions are appropriate and remain indicated through the course of treatment. Multidisciplinary clinics, such as the Child and Adolescent Gender Clinic where I practice, have structured their programs around this model, as guided by the WPATH SOC.

39. In transgender adults, the WPATH SOC recommends that a health care provider assessing and treating a transgender patient should ensure diagnostic criteria are met prior to initiating gender-affirming treatments and ensure that any health conditions that could negatively impact the outcome of treatment are assessed, with risks and benefits discussed, before a decision is made regarding treatment. The capacity of the adult. to consent for the specific treatment should be confirmed prior to initiation (Coleman, et al., 2022).

D. EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES FOR THE TREATMENT OF GENDER DYSPHORIA IN CHILDREN, ADOLESCENTS AND ADULTS

40. The goal of any intervention for gender dysphoria is to reduce dysphoria, improve functioning, and prevent the harms caused by untreated gender dysphoria.

41. Gender dysphoria is highly treatable and can be effectively managed. If left untreated, however, it can result in severe anxiety and depression, eating disorders, substance abuse, self-harm, and suicidality (Reisner, et al., 2015).

42. Based on longitudinal data, and my own clinical experience, when transgender adolescents are provided with appropriate medical treatment and have parental and social support, they are more likely to thrive and grow into healthy adults (de Vries, et al., 2014).

43. In children and adolescents, a comprehensive biopsychosocial assessment is typically the first step in evaluation, performed by a mental health provider with experience in gender identity. The goals of this assessment are to develop a deep understanding of the young person's experience with gender identity, to consider whether the child or adolescent meets criteria for a diagnosis of gender dysphoria, and to understand what options may be desired and helpful for the adolescent (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009).

44. For children younger than pubertal age, the only recommended treatments do not involve medications. For adolescents, additional treatments involving medications may be appropriate.

45. For pre-pubertal children with gender dysphoria, treatments may include supportive therapy, encouraging support from loved ones, and assisting the young person through elements of a social transition. Social transition may include adopting a new name and pronouns, appearance, and clothing, and correcting identity documents.

46. Options for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists ("GnRHa") for purposes of preventing progression of pubertal development, and hormonal interventions such as

testosterone and estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy.

47. Clinical practice guidelines have been published by several long-standing and well-respected medical bodies: the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009), as well as the UCSF Center for Excellence in Transgender Health (Deutsch (ed.), 2016). The clinical practice guidelines and standards of care published by these organizations provide a framework for treatment of gender dysphoria in adolescents.

48. WPATH has been recognized as the standard-setting organization for the treatment of gender dysphoria since its founding in 1979. The most recent WPATH Standards of Care (SOC 8) were published in 2022 and represent expert consensus for clinicians related to medical care for transgender people, based on the best available science and clinical experience (Coleman, et al., 2022).

49. The purpose of the WPATH Standards of Care is to assist health providers in delivering necessary medical care to transgender people, to maximize their patients' overall health, psychological well-being, and self-fulfillment. The

WPATH Standards of Care serve as one of the foundations for the care provided in my own clinic.

50. The WPATH SOC 8 is based on rigorous review of the best available science and expert professional consensus in transgender health. International professionals were selected to serve on the SOC 8 writing committee. Recommendation statements were developed based on data derived from independent systemic literature reviews. Grading of evidence was performed by an Evidence Review Team which determined the strength of evidence presented in each individual study relied upon in the document (Coleman, et al., 2022).

51. The previous version (SOC 7), published in 2012 (Coleman, et al., 2012), was the most recent version at the time of the adoption of Florida Administrative Code, 59G-1.050(7) (the "Challenged Exclusion"). SOC 7 was similar to SOC 8 in the basic tenets of management for transgender adolescents and adults; however, SOC 8 further reinforces these guidelines with data published since the release of SOC 7.

52. In addition, the Endocrine Society is a 100-year-old global membership organization representing professionals in the field of adult and pediatric endocrinology. In 2017, the Endocrine Society published clinical practice guidelines on treatment recommendations for the medical management of gender dysphoria, in

collaboration with Pediatric Endocrine Society, the European Societies for Endocrinology and Pediatric Endocrinology, and WPATH, among others (Hembree, et al, 2017).

53. The Endocrine Society Clinical Guidelines were developed through rigorous scientific processes that "followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines." The guidelines affirm that patients with gender dysphoria often must be treated with "a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender." (Hembree, et al., 2017).

54. The AAP is the preeminent professional body of pediatricians in the United States, with over 67,000 members. The AAP endorses a commitment to the optimal physical, mental, and social health and well-being for youth. The 2018 policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* further lends support to the treatment options outlined in the WPATH Standards of Care and the Endocrine Society's Clinical Practice Guidelines (Rafferty, et al., 2018).

55. Aside from the AAP, the tenets set forth by the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care are supported by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Psychological Association, the American Psychiatric Association, and American Academy of Family Physicians, among others (e.g., AMA, 2019; American Psychological Association, 2015; Drescher, et al., 2018 (American Psychiatric Association); Hembree, et al., 2017 (Endocrine Society); Klein, et al., 2018 (AAFP); National Academies, 2020; WPATH, 2016).

56. As a board-certified pediatric endocrinologist, I follow the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care when treating my patients.

E. TREATMENT PROTOCOLS FOR GENDER DYSPHORIA

57. Undergoing treatment to alleviate gender dysphoria is commonly referred to as a transition. The transition process in adolescence typically includes (i) social transition and/or (ii) medications, including puberty-delaying medication and hormone therapy. The steps that make up a person's transition and their sequence will depend on that individual's medical and mental health needs and decisions made between the patient, family, and multidisciplinary care team.

58. There are no medications considered for transition until after the onset of puberty. Puberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics. Secondary sex characteristics include testosterone-induced effects such as deepening of the voice, muscular changes, facial and body hair, and estrogen-induced effects such as breast development. There is diversity in the age of pubertal onset; however, most adolescents begin puberty between ages 10 and 12 years.

59. Gender exploration in childhood is expected and healthy. The majority of prepubertal children exploring their gender do not develop gender dysphoria and are not expected to become transgender adolescents or adults. In contrast, data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender (van der Loos, et al., 2022). Some individuals in this field misinterpret older studies showing that a large percentage of children diagnosed with gender identity disorder did not grow up to be transgender (e.g., GAPMS Memo at 14; Attachment D (Cantor) to GAPMS Memo at 6-9). Those studies include children who would not fulfill the current diagnostic criteria for gender dysphoria and, in any case, have no relevance to this case because no medications are prescribed to prepubertal children.

60. Puberty-delaying medication and hormone-replacement therapy—both individually and in combination—can significantly improve a transgender young person's mental health. These treatments allow for a physical appearance more closely aligning with gender identity and decreases the likelihood that a transgender young person will be incorrectly identified with their assigned sex, further alleviating their gender dysphoria, and bolstering the effectiveness of their social transition.

61. At the onset of puberty, adolescents begin to experience the onset of secondary sex characteristics. Adolescents with differences in gender identity may have intensification of gender dysphoria during this time due to development of secondary sex characteristics incongruent with gender identity. Persistence or intensification of gender dysphoria as puberty begins is used as a helpful diagnostic tool as it becomes more predictive of gender identity persistence into adolescence and adulthood (de Vries, et al., 2012).

i. Treatment with puberty-delaying medications

62. Adolescents diagnosed with gender dysphoria who have entered puberty (Tanner Stage 2) may be prescribed puberty-delaying medications (GnRHa) to prevent the distress of developing permanent, unwanted physical characteristics that do not align with the adolescent's gender identity. Tanner Stage 2 refers to the

stage in puberty whereby the physical effects of testosterone or estrogen production are first apparent on physical exam. Specifically, this is heralded by the onset of breast budding in an individual assigned female at birth, or the onset of testicular enlargement in an individual assigned male at birth. For individuals assigned male at birth, Tanner Stage 2 typically occurs between age 9-14, and for those assigned female at birth between age 8-12.

63. The treatment works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the influence of a person's endogenous hormones on their body. For example, a transgender girl will experience no progression of physical changes caused by testosterone, including facial and body hair, an Adam's apple, or masculinized facial structures. And, in a transgender boy, those medications would prevent progression of breast development, menstruation, and widening of the hips (Coleman, et al., 2022; de Vries, et al., 2012; Deutsch (ed.), 2016; Hembree, et al., 2017; Rosenthal, 2014).

64. GnRHa have been used extensively in pediatrics for several decades. Prior to their use for gender dysphoria, they were used (and still are used) to treat precocious puberty. GnRHa work by suppressing the signal hormones from the pituitary gland (luteinizing hormone [LH] and follicle stimulating hormone [FSH])

that stimulate the testes or ovaries to produce sex hormones. Upon discontinuation of GnRHa, LH and FSH production resume and puberty will also resume.

65. GnRHa have no long-term implications on fertility. In transgender youth, it is most typical to use GnRHa from the onset of puberty (Tanner Stage 2) until mid-adolescence. While treating, the decision to continue treatment will be continually evaluated. Should pubertal suppression no longer be desired, GnRHa would be discontinued, and puberty would re-commence.

66. Prior to initiation of GnRHa, providers counsel patients and their families extensively on potential benefits and risks. Designed benefit of treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. More specifically, use of GnRHa in transmasculine adolescents allows for decreased chest development, reducing the need for breast binding and surgical intervention in adulthood. For transfeminine adolescents GnRHa limits facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery.

67. The goal in using GnRHa is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. When a patient presents to care, the provider assesses the patient's

pubertal stage, pubertal history, and individual needs. A patient may present prior to the onset of puberty (Tanner Stage 1), at the onset of puberty (Tanner Stage 2), or further along in puberty (Tanner Stages 3-5). The pubertal stage and individual needs of the patient then direct conversations regarding care options. A patient at Tanner Stage 2 may benefit from GnRHa, while an older patient who has completed puberty may benefit from pubertal initiation with hormones, as described below. I have observed that providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation of this care, provides significant benefit to patients, minimizes gender dysphoria, and can eliminate the need for surgical treatments in adulthood.

68. As an experienced pediatric endocrinologist, I treat patients with these same medications for both precocious puberty and gender dysphoria and in both cases the side effects are comparable and easily managed. And for both patient populations the risks are greatly outweighed by the benefits of treatment.

69. In addition, I regularly prescribe GnRHa for patients who do not meet criteria for precocious puberty but who require pubertal suppression. Examples include patients with disabilities who are unable to tolerate puberty at the typical age due to hygienic concerns; minors with growth hormone deficiency who despite growth hormone treatment will have a very short adult height; and young women

with endometriosis. As with gender dysphoria, the prescription of GnRHa to treat these conditions is "off-label," yet it is widely accepted within the field of endocrinology and not considered experimental. The same holds true for other common medications used in pediatric endocrinology: using metformin for weight loss; growth hormone for short stature not caused by growth hormone deficiency; countless medications used to control type 2 diabetes which have an adult indication but whose manufacturers have not applied for a pediatric indication.

ii. Treatment with hormone therapy

70. In mid-adolescence, the patient, their parents, and the patient's care team may discuss the possibility of beginning the use of testosterone or estrogen. In my practice we discuss these treatments for a patient who is currently receiving GnRHa, or patients who have already gone through their endogenous puberty and either did not have access to, desire, or elect for GnRHa treatment. In adult patients, use of GnRHa is uncommon, but rather medical decisions are focused more on testosterone or estrogen therapy.

71. These hormone therapies are used to treat gender dysphoria in adolescents and adults to facilitate development of sex-specific physical changes congruent with their gender identity. For example, a transgender man prescribed testosterone will develop a lower voice as well as facial and body hair, while a

transgender woman prescribed estrogen will experience breast growth, female fat distribution, and softer skin.

72. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adolescents with gender dysphoria when the experience of dysphoria is marked and sustained over time, the adolescent demonstrates emotional and cognitive maturity required to provide and informed consent/assent for treatment, other mental health concerns (if any) that may interfere with diagnostic clarity and capacity to consent have been addressed, the adolescent has discussed reproductive options with their provider. SOC 8 also highlights the importance of involving parent(s)/guardian(s) in the assessment and treatment process for minors (Coleman, et al., 2022; Hembree, et al., 2017).

73. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adults with gender dysphoria when the experience of dysphoria is marked and sustained, other possible causes of apparent gender dysphoria are excluded, any mental and physical health conditions that could negatively impact the outcome of treatment are assessed, the adult has capacity to understand risks and benefits of treatment and provide consent for treatment (Coleman, et al., 2022; Hembree, et al., 2017).

74. Similar to GnRHa, the risks and benefits of hormone treatment are discussed with patients (and families, if the patient is a minor) prior to initiation of testosterone or estrogen. When treated with testosterone or estrogen, the goal is to maintain the patient's hormone levels within the normal range for their gender. Laboratory testing is recommended to ensure proper dosing and hormonal levels. If starting hormonal care after completing puberty, discussion of egg or sperm preservation prior to starting treatment is recommended.

75. Regardless of the treatment plan prescribed, at every encounter with the care team there is a re-evaluation of the patient's gender identity and their transition goals. Should a patient desire to discontinue a medical intervention, the intervention is discontinued. Discontinuation of GnRHa will result in commencement of puberty. Findings from studies in which participants have undergone comprehensive evaluation prior to gender care show low levels of regret (de Vries, et al., 2011; van der Loos, et al., 2022; Wiepjes, et al., 2018).

F. SAFETY AND EFFICACY OF PUBERTY-DELAYING MEDICATIONS AND HORMONE THERAPY TO TREAT GENDER DYSPHORIA

76. GnRHa, prescribed for delaying puberty in transgender adolescents, is both a safe and effective treatment. Patients under consideration for treatment are working within a multidisciplinary team of providers all dedicated to making

informed and appropriate decisions with the patient and family in the best interest of the adolescent. Physicians providing this intervention are trained and qualified in gender identity concerns and childhood growth and development and are participating in this care out of a desire to improve the health and wellness of transgender youth and prevent negative outcomes such as depression and suicide.

77. GnRHa, including injectable leuprolide and implantable histrelin, have rare side effects which are discussed with patients and families prior to initiation. Mild negative effects may include pain at the injection or implantation site, sterile abscess formation, weight gain, hot flashes, abdominal pain, and headaches. These effects can be seen in patients receiving GnRHa for gender dysphoria, or for other indications such as precocious puberty. I counsel patients on maintaining a healthy diet and promote physical activity, and regularly document height and weight during treatment. Nutritional support can be provided for patients at risk for obesity.

78. Risk of lower bone mineral density in prolonged use of GnRHa can be mitigated by screening for, and treating, vitamin D deficiency when present, and by limiting the number of years of treatment based on a patient's clinical course (Rosenthal, 2014). An exceptionally rare but significant side effect, increased intracranial pressure, has been reported in six patients (five treated for precocious puberty, one for transgender care), prompting an FDA warning in July 2022 (AAP,

2022). These cases represent an extremely small fraction of the thousands of patients who have been treated with GnRHa over decades. Symptoms of this side effect (headache, vomiting, visual changes) are reviewed with families and if they occur the medication is discontinued.

79. GnRHa do not have long-term implications on fertility. This is clearly proven from decades of use in the treatment of precocious puberty (Guaraldi, et al., 2016; Martinerie, et al, 2021). Progression through natal puberty is required for maturation of egg or sperm. If attempting fertility after previous treatment with GnRHa followed by hormone therapy is desired, an adult patient would withdraw from hormones and allow pubertal progression. Assistive reproduction could be employed if needed (T'Sjoen, et al., 2013).

80. Patients who initiate hormones after completing puberty are offered gamete preservation prior to hormonal initiation (Coleman, et al., 2022), but even when not undertaken, withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired (Light, et al., 2014; Knudson, et al., 2017).

81. Discussing the topic of fertility is important, and not specifically unique to treatment of gender dysphoria. Medications used for other medical conditions, such as chemotherapeutics used in cancer treatment, can affect fertility. For all medications with potential impacts on fertility, the potential risks and benefits of

both treatment and non-treatment should be reviewed and data regarding risk for infertility clearly articulated prior to the consent or assent of the patient. Risk for fertility changes must be balanced with the risk of withholding treatment.

82. Review of relevant medical literature clearly supports the benefits of GnRHa treatment on both short-term and long-term psychological functioning and quality of life (e.g., Achille, et al., 2020; Carmichael, et al., 2021; Costa, et al., 2015; de Vries, et al., 2014; de Vries, et al., 2011; Kuper, et al., 2020; Turban, et al., 2020b; van der Miesen, et al., 2020). For example, a 2014 long-term follow-up study following patients from early adolescence through young adulthood showed that gender-affirming treatment allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014).

83. In my own practice, adolescent patients struggling with significant distress at the onset of puberty routinely have dramatic improvements in mood, school performance, and quality of life with appropriate use of GnRHa. Side effects encountered are similar to those seen in other patients treated with these medications and easily managed.

84. Hormone therapy (testosterone or estrogen) is prescribed to older adolescents with gender dysphoria. As is the case with GnRHa, the need for hormone

therapy is not unique to transgender adolescents. Patients with conditions such as delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development all require treatment with these hormones, often times starting in adolescence and continuing lifelong. Without testosterone or estrogen treatment, these patients would be unable to progress through puberty normally, which would have serious medical and social consequences. Whether used in adolescents to treat gender dysphoria, or to treat any of these other conditions, testosterone and estrogen are prescribed with a goal to raise the testosterone or estrogen level into the normal male or female range for the patient's age. Careful monitoring of blood levels and clinical progress are required. Side effects are rare, but most often related to overtreatment, which can be minimized with this monitoring. Additionally, side effects are considered, discussed, and easily managed in all individuals needing hormone therapy regardless of the diagnosis necessitating these medications.

85. Venous thromboembolism (blood clotting) is a known side effect of estrogen therapy in all individuals placed on it including transgender women. Risk is increased in old age, in patients with cancer, and in patients who smoke nicotine. This side effect is mitigated by careful and accurate prescribing and monitoring. In my career, no patient has suffered a thromboembolism while on estrogen therapy.

86. Treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria and withholding treatment from those who need it is harmful (e.g., Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020). To highlight examples, Green et al. (2022) describe that gender-affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

87. I treat many patients with gender dysphoria GnRHa, testosterone, and estrogen. Side effects related to these medications is very rare and can be treated with dose adjustment and/or lifestyle changes.

88. The efficacy of hormone treatment in transgender adults is similarly robust. At least 11 longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning (e.g., Colizzi, et al., 2013; Colizzi, et al., 2014; Corda, et al., 2016; Defreyne, et al., 2018; Fisher, et al., 2016; Heylens, et

al., 2014; Keo-Meier, et al., 2015; Manieri, et al., 2014; Motta, et al., 2018; Oda, et al., 2017; Turan, et al., 2018).

89. In sum, the use of GnRHa and hormones in adolescents, and hormones in adults for the treatment of gender dysphoria is the current standard of care and certainly not experimental. This is due to robust evidence of safety and efficacy. The sum of the data supports the conclusion that treatment of gender dysphoria with these interventions promotes wellness and helps to prevent negative mental health outcomes, including suicidality in adolescent and adult age groups. The data to support these interventions are so strong that withholding such interventions would be negligent and unethical.

G. HARMS ASSOCIATED WITH PROHIBITING AND DISCONTINUING TREATMENT

90. Prohibition of gender-affirming care, or coverage thereof, for adolescents and adults is likely to have devastating consequences. I am concerned that the Challenged Exclusion might lead to a staggering increase in mental health problems including suicidality for transgender Floridians. One study which highlights my concern is a study of over 21,000 patients who report ever desiring gender-affirming hormone care. When comparing those who were able to access this care to those desiring but never accessing care, those able to access care had lower odds of suicidality within the past year. In addition, those individuals where were

able to access care in adolescence had lower odds of suicidality compared to those waiting to access until adulthood (Turban, et al., 2022).

91. Even more concerning is a situation where patients currently receiving care and thriving would be forced to discontinue this care.

III. CONCLUSION

92. In summary, banning coverage of gender-affirming care runs counter to evidence-based best practices and standards of care for the treatment of gender dysphoria in adolescence and adulthood.

93. Gender dysphoria is a challenging condition, but it is treatable through individualized assessment and treatment, which may include social transition, psychotherapy, pubertal suppression, and hormonal therapy. These treatments are not experimental and are supported by all major medical bodies in the field of transgender medicine and pediatrics.

94. Lack of access to these treatments will result in worse outcomes for countless individuals in Florida. Furthermore, banning coverage for evidence-based treatment for gender dysphoria sends a message that transgender people are not valid and should be stigmatized.

95. In my own clinical practice in Michigan, I have seen an influx of patients from states banning medically proven treatments for gender dysphoria who

report not feeling safe living in the community that they have always called home. Adult patients, and parents who love and support their transgender children, have described themselves as "refugees" in their own country, moving to avoid discriminatory laws which they know would clearly harm their health or the health of their child.

96. Banning coverage of effective treatment for gender dysphoria will not eliminate transgender people, but will, unfortunately, lead to an increase in mental health problems and suicidality in an already vulnerable population.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16th day of February 2023.

Daniel Shumer, M.D.

Exhibit A

Curriculum Vitae

Daniel Shumer, MD MPH

Clinical Associate Professor in Pediatrics - Endocrinology

Email: dshumer@umich.edu

EDUCATION AND TRAINING

Education

08/2000-08/2003	BA, Northwestern University, Evanston, United States
08/2004-05/2008	MD, Northwestern University, Feinberg School of Medicine, Chicago, United States
07/2013-05/2015	MPH, Harvard T.H. Chan School of Public Health, Boston, United States

Postdoctoral Training

06/2008-06/2011	Residency, Pediatrics, Vermont Children's Hospital at Fletcher Allen Health Care, Burlington, VT
07/2011-06/2012	Chief Resident, Chief Resident, Vermont Children's Hospital at Fletcher Allen Health Care, Burlington, VT
07/2012-06/2015	Clinical Fellow, Pediatric Endocrinology, Boston Children's Hospital, Boston, MA

CERTIFICATION AND LICENSURE

Certification

10/2011-Present	American Board of Pediatrics, General

Licensure

	Michigan, Medical License
	Michigan, Controlled Substance
08/2015-Present	Michigan, Medical License

09/2015-Present Michigan, DEA Registration

09/2015-Present Michigan, Controlled Substance

WORK EXPERIENCE

Academic Appointment

10/2015-9/2022 Clinical Assistant Professor in Pediatrics - Endocrinology, University of Michigan - Ann Arbor, Ann Arbor

09/2022-Present Clinical Associate Professor in Pediatrics - Endocrinology, University of Michigan - Ann Arbor, Ann Arbor

Administrative Appointment

07/2019-Present Fellowship Director - Pediatric Endocrinology, Michigan Medicine, Department of Pediatrics, Ann Arbor

07/2020-Present Medical Director of the University of Michigan Comprehensive Gender Services Program, Michigan Medicine, Ann Arbor

Oversee the provision of care to transgender and gender non-conforming patients at Michigan Medicine.

07/2020-Present Education Lead - Pediatric Endocrinology, University of Michigan - Department of Pediatrics, Ann Arbor

Clinical Appointments

04/2022-05/2023 Medical Director in UMMG Faculty Benefits Appt., University of Michigan - Ann Arbor, Ann Arbor

Private Practice

08/2013-09/2015 Staff Physician, Harvard Vanguard Medical Associates, Braintree

RESEARCH INTERESTS

- Gender dysphoria
- Prader Willi Syndrome

CLINICAL INTERESTS

- Gender dysphoria
- Disorders of Sex Development
- Prader Willi Syndrome

GRANTS

Past Grants

A Phase 2b/3 study to evaluate the safety, tolerability, and effects of Livoletide (AZP-531), an unacylated ghrelin analog, on food-related behaviors in patients with Prader-Willi syndrome
PI
Millendo Therapeutics
04/2019 - 04/2021

HONORS AND AWARDS

National

2014	Annual Pediatric Endocrine Society Essay Competition: Ethical Dilemmas in Pediatric Endocrinology: competition winner - The Role of Assent in the Treatment of Transgender Adolescents

Institutional

2012 - 2015	Harvard Pediatric Health Services Research Fellowship; funded my final two years of pediatric endocrine fellowship and provided tuition support for my public health degree

2016	The University of Michigan Distinguished Diversity Leaders Award, awarded by The Office of Diversity, Equity and Inclusion to the Child and Adolescent Gender Services Team under my leadership
2019	Lecturer of the Month, Department of Pediatrics, Michigan Medicine

TEACHING MENTORSHIP

Resident

07/2020-Present	Rebecca Warwick, Michigan Medicine (co-author on publication #22)

Clinical Fellow

07/2017-06/2020	Adrian Araya, Michigan Medicine (co-author on publication #22, book chapter #4)
12/2020-Present	Jessica Jary, Michigan Medicine - Division of Adolescent Medicine

Medical Student

09/2017-06/2020	Michael Ho, Michigan Medicine
07/2019-Present	Hadrian Kinnear, University of Michigan Medical School (co-author on book chapter #3, abstract #3)
07/2019-Present	Jourdin Batchelor, University of Michigan

TEACHING ACTIVITY

Regional

08/2018-Present	Pediatric Boards Review Course sponsored by U-M: "Thyroid Disorders and Diabetes". Ann Arbor, MI

Institutional

12/2015-12/2015	Pediatric Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Medical Student Education: Panelist for M1 Class Session on LGBT Health, Doctoring Curriculum. Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Psychiatry Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
03/2016-03/2017	Pharmacy School Education: "LGBT Health". University of Michigan School of Pharmacy, Ann Arbor, MI
04/2016-Present	Course Director: Medical Student (M4) Elective in Transgender Medicine. Michigan Medicine, Ann Arbor, MI
04/2016-04/2016	Rheumatology Grand Rounds: "Gender Identity". Michigan Medicine, Ann Arbor, MI
05/2016-05/2016	Lecture to Pediatric Rheumatology Division: "Gender Dysphoria". Michigan Medicine, Ann Arbor, MI
07/2016-07/2016	Internal Medicine Resident Education: "Gender Identity". Michigan Medicine, Ann Arbor, MI
09/2016-09/2016	Presentation to ACU Leadership: "Gender Identity Cultural Competencies". Michigan Medicine, Ann Arbor, MI
10/2016-10/2016	Presentation to Department of Dermatology: "The iPledge Program and Transgender Patients". Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Swartz Rounds Presenter. Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Lecture to Division of General Medicine: "Transgender Health". Michigan Medicine, Ann Arbor, MI

02/2017-02/2017	Presentation at Collaborative Office Rounds: "Transgender Health". Michigan Medicine, Ann Arbor, MI
10/2017-10/2017	Family Medicine Annual Conference: "Transgender Medicine". Michigan Medicine, Ann Arbor, MI
12/2017-12/2017	Presenter at Nursing Unit 12-West Annual Educational Retreat: "Gender Identity at the Children's Hospital". Michigan Medicine, Ann Arbor, MI
02/2018-Present	Pediatrics Residency Lecturer: "Puberty". Michigan Medicine, Ann Arbor, MI
02/2019-Present	Medical Student (M1) Lecturer: "Pediatric Growth and Development". Michigan Medicine, Ann Arbor, MI
02/2019-Present	Doctors of Tomorrow Preceptor: offering shadowing opportunities to students from Cass Technical High School in Detroit. Michigan Medicine, Ann Arbor, MI
03/2019-03/2019	Lecture to Division of Orthopedic Surgery: "Transgender Health". Michigan Medicine, Ann Arbor, MI

MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012 - Present	Pediatric Endocrine Society

COMMITTEE SERVICE

National

2014 - 2016	Pediatric Endocrine Society - Ethics Committee, Other, Member
2017 - present	Pediatric Endocrine Society - Special Interest Group on Gender Identity, Other, Member
2018 - present	Pediatric Endocrine Society - Program Directors Education Committee, Other, Member

Regional

2013 - 2015 Investigational Review Board - The Fenway Institute, Boston, MA, Other, Voting Member

Institutional

2017 - 2019 Department of Pediatrics at Michigan Medicine; Diversity, Equity, and Inclusion Committee, Other, Fellowship Lead

2017 - 2019 University of Michigan Transgender Research Group, Other, Director

VOLUNTEER SERVICE

2014 Camp Physician, Massachusetts, Served at a camp for youth with Type 1 Diabetes

SCHOLARLY ACTIVITIES

PRESENTATIONS

Extramural Invited Presentation Speaker

1. Grand Rounds, Shumer D, Loyola University School of Medicine, 07/2022, Chicago, Illinois

Other

1. Gender Identity, Groton School, 04/2015, Groton, MA

2. Television Appearance: Gender Identity in Youth, Channel 7 WXYZ Detroit, 04/2016, Southfield, MI

3. It Gets Better: Promoting Safe and Supportive Healthcare Environments for Sexual Minority and Gender Non-Conforming Youth, Adolescent Health Initiative: Conference on Adolescent Health, 05/2016, Ypsilanti, MI

4. Gender Identity, Humanists of Southeast Michigan, 09/2016, Farmington Hills, MI

5. Gender Identity, Pine Rest Christian Mental Health Services, 10/2016, Grand Rapids, MI

6. Pediatric Grand Rounds - Hormonal Management of Transgender Youth, Beaumont Children's Hospital, 11/2016, Royal Oak, MI

7. Transgender Youth: A Field in Transition, Temple Beth Emeth, 11/2016, Ann Arbor, MI

8. Transgender Youth: A Field in Transition, Washtenaw County Medical Society, 11/2016, Ann Arbor, MI

9. Pediatric Grand Rounds: Transgender Youth - A Field in Transition, St. John Hospital, 02/2017, Detroit, MI

10. Transgender Medicine, Veterans Administration - Ann Arbor Healthcare System, 05/2017, Ann Arbor, MI

11. Gender Identity, Hegira Programs, 05/2017, Detroit, MI

12. Care of the Transgender Adolescent, Partners in Pediatric Care, 06/2017, Traverse City, MI

13. Conference planner, host, and presenter: Transgender and Gender Non-Conforming Youth: Best Practices for Mental Health Clinicians, Educators, & School Staff; 200+ attendees from fields of mental health and education from across Michigan, Michigan Medicine, 10/2017, Ypsilanti, MI

14. Endocrinology Grand Rounds: Transgender Medicine, Wayne State University, 11/2017, Detroit, MI

15. Care of the Transgender Adolescent, St. John Hospital Conference: Transgender Patients: Providing Compassionate, Affirmative and Evidence Based Care, 11/2017, Grosse Pointe Farms, MI

16. Hormonal Care in Transgender Adolescents, Michigan State University School of Osteopathic Medicine, 11/2017, East Lansing, MI

17. Working with Transgender and Gender Non-Conforming Youth, Michigan Association of Osteopathic Family Physicians, 01/2018, Bellaire, MI

18. Community Conversations, Lake Orion, 01/2018, Lake Orion, MI

19. "I Am Jazz" Reading and Discussion, St. James Episcopal Church, 03/2019, Dexter, MI

20. Gender Identity, Michigan Organization on Adolescent Sexual Health, 10/2019, Brighton, MI; Port Huron, MI

21. Ask The Expert, Stand With Trans, 05/2020, Farmington Hills, MI (Virtual due to COVID)

22. Transgender Medicine, Michigan Association of Clinical Endocrinologists Annual Symposium, 10/2020, Grand Rapids, MI (Virtual due to COVID)

23. Transgender Youth in Primary Care, Michigan Child Care Collaborative (MC3), 10/2020, Ann Arbor, MI (Virtual due to COVID)

24. Lets Talk About Hormones, Stand With Trans, 10/2020, Farmington Hills, MI (Virtual due to COVID)

25. Gender Identity, Universalist Unitarian Church of East Liberty, 04/2021, Virtual due to COVID

26. Unconscious Bias, Ascension St. John Hospital, 05/2021, Virtual due to COVID

PUBLICATIONS/SCHOLARSHIP

Peer-Reviewed Articles

1. Vengalil N, Shumer D, Wang F: Developing an LGBT curriculum and evaluating its impact on dermatology residents, *Int J Dermatol*.61: 99-102, 01/2022. PM34416015

Chapters

1. Shumer: Coma. In Schwartz MW6, Lippincott Williams & Wilkins, Philadelphia, PA, (2012)

2. Shumer, Spack: Medical Treatment of the Adolescent Transgender Patient. In Đorđević M; Monstrey SJ; Salgado CJ Eds. CRC Press/Taylor & Francis, (2016)

3. Kinnear HA, **Shumer DE**: Duration of Pubertal Suppression and Initiation of Gender-Affirming Hormone Treatment in Youth. In FinlaysonElsevier, (2018)

4. Araya, **Shumer DE**: Endocrinology of Transgender Care – Children and Adolescents. In Poretsky; Hembree Ed. Springer, (2019)

Non-Peer Reviewed Articles

1. Shumer D: The Effect of Race and Gender Labels in the Induction of Traits, *Northwestern Journal of Race and Gender Criticism*.NA01/2014

2. Shumer D: A Tribute to Medical Stereotypes, *The Pharos, Journal of the Alpha Omega Alpha Medical Society*.Summer07/2017

3. Mohnach L, Mazzola S, Shumer D, Berman DR: Prenatal diagnosis of 17-hydroxylase/17,20-lyase deficiency (17OHD) in a case of 46,XY sex discordance and low maternal serum estriol, *Case Reports in Perinatal Medicine*.8(1)01/2018

4. Mohnach L, Mazzola S, Shumer D, Berman DR: Prenatal Diagnosis of 17-hydroxylase/17,20-lyase deficiency (17OHD) in a case of 46,XY sex discordance and low maternal serum estriol, *Case Reports in Perinatal Medicine*.8(1)12/2018

5. Kim C, Harrall KK, Glueck DH, **Shumer DE**, Dabelea D: Childhood adiposity and adolescent sex steroids in the EPOCH (Exploring Perinatal Outcomes among Children) study, *Clin Endocrinol (Oxf)*.91(4): 525-533, 01/2019. PM31278867

6. Araya A, Shumer D, Warwick R, Selkie E: 37. “I’ve Been Happily Dating For 5 Years” - Romantic and Sexual Health, Experience and Expectations in Transgender Youth, *Journal of Adolescent Health*.66(2): s20, 02/2020

7. Araya A, Shumer D, Warwick R, Selkie E: 73. "I think sex is different for everybody" - Sexual Experiences and Expectations in Transgender Youth, *Journal of Pediatric and Adolescent Gynecology*.33(2): 209-210, 04/2020

8. Araya AC, Warwick R, Shumer D, Selkie E, Rath T, Ibrahim M, Srinivasan A: Romantic Health in Transgender Adolescents, *Pediatrics*.Pediatrics01/2021

9. Martin S, Sandberg ES, **Shumer DE**: Criminalization of Gender-Affirming Care - Interfering with Essential Treatment for Transgender Children and

Adolescents, *New England Journal of Medicine*.385(7): 579-581, 08/2021. PM34010528

Editorial Comment

1. **Shumer DE**, Harris LH, Opipari VP: The Effect of Lesbian, Gay, Bisexual, and Transgender-Related Legislation on Children, 01/2016. PM27575000

2. **Shumer DE**: Health Disparities Facing Transgender and Gender Nonconforming Youth Are Not Inevitable, 01/2018. PM29437859

3. Martin S, Sandberg ES, Shumer DE: Criminalization of Gender-Affirming Care - Interfering with Essential Treatment for Transgender Children and Adolescents, 01/2021

Erratum

1. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Correction to Serving Transgender Youth: Challenges, Dilemmas, and Clinical Examples, [Professional Psychology: Research and Practice, 46(1), (2015) 37-45], *Professional Psychology: Research and Practice*.46(4): 249, 08/2015

Journal Articles

1. **Shumer DE**, Thaker V, Taylor GA, Wassner AJ: Severe hypercalcaemia due to subcutaneous fat necrosis: Presentation, management and complications, *Archives of Disease in Childhood: Fetal and Neonatal Edition*.99(5)01/2014. PM24907163

2. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Serving transgender youth: Challenges, dilemmas, and clinical examples, *Professional Psychology: Research and Practice*.46(1): 37-45, 02/2015. PM26807001

3. Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, **Shumer DE**, Mimiaga MJ: Mental health of transgender youth in care at an adolescent Urban community health center: A matched retrospective cohort study, *Journal of Adolescent Health*.56(3): 274-279, 03/2015. PM25577670

4. **Shumer DE**, Tishelman AC: The Role of Assent in the Treatment of Transgender Adolescents, *International Journal of Transgenderism*.16(2): 97-102, 04/2015. PM27175107

5. **Shumer DE**, Roberts AL, Reisner SL, Lyall K, Austin SB: Brief Report: Autistic Traits in Mothers and Children Associated with Child's Gender Nonconformity, *Journal of Autism and Developmental Disorders*.45(5): 1489-1494, 05/2015. PM25358249

6. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, **Shumer DE**, Spack NP: Reply to comment on "serving transgender youth: Challenges, dilemmas, and clinical examples" by Tishelman et al. (2015), *Professional Psychology: Research and Practice*.46(4): 307, 08/2015. PM26858509

7. **Shumer DE**, Reisner SL, Edwards-Leeper L, Tishelman A: Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, *LGBT Health*.3(5): 387-390, 10/2016. PM26651183

8. Tishelman AC, **Shumer DE**, Nahata L: Disorders of sex development: Pediatric psychology and the genital exam, *Journal of Pediatric Psychology*.42(5): 530-543, 01/2017. PM27098964

9. Edwards-Leeper L, **Shumer DE**, Feldman HA, Lash BR, Tishelman AC: Psychological profile of the first sample of transgender youth presenting for medical intervention in a U.S. pediatric gender center, *Psychology of Sexual Orientation and Gender Diversity*.4(3): 374-382, 01/2017

10. **Shumer DE**, Abrha A, Feldman HA, Carswell J: Overrepresentation of adopted adolescents at a hospital-based gender dysphoria clinic, *Transgender Health*.2(1): 76-79, 07/2017. PM28861549

11. Strang JF, Meagher H, Kenworthy L, de Vries AL C, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, **Shumer DE**, Edwards-Leeper L, Pleak RR, Spack N, Karasic DH, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG: Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents, *Journal of Clinical Child and Adolescent Psychology*.47(1): 105-115, 01/2018. PM27775428

12. Selkie E, Adkins V, Masters E, Bajpai A, **Shumer DE**: Transgender Adolescents' Uses of Social Media for Social Support, *Journal of Adolescent Health*.66(3): 275-280, 03/2020. PM31690534

13. Warwick RM, **Shumer DE**: Gender-affirming multidisciplinary care for transgender and non-binary children and adolescents, *Children's Health Care*.01/2021

14. Araya AC, Warwick R, **Shumer DE**, Selkie E: Romantic relationships in transgender adolescents: A qualitative study, *Pediatrics*.147(2)02/2021. PM33468600

15. Warwick RM, Araya AC, **Shumer DE**, Selkie EM: Transgender Youths' Sexual Health and Education: A Qualitative Analysis, *Journal of Pediatric and Adolescent Gynecology*.35(2): 138-146, 04/2022. PM34619356

Letters

1. Strang JF, Janssen A, Tishelman A, Leibowitz SF, Kenworthy L, McGuire JK, Edwards-Leeper L, Mazefsky CA, Rofey D, Bascom J, Caplan R, Gomez-Lobo V, Berg D, Zaks Z, Wallace GL, Wimms H, Pine-Twaddell E, **Shumer DE**, Register-Brown K, Sadikova E, Anthony LG: Revisiting the Link: Evidence of the Rates of Autism in Studies of Gender Diverse Individuals, *Journal of the American Academy of Child and Adolescent Psychiatry*.57(11): 885-887, 11/2018. PM30392631

Letters to editor

1. **Shumer DE**: Doctor as environmental steward, 01/2009. PM19364173

Notes

1. **Shumer DE**, Mehringer J, Braverman L, Dauber A: Acquired hypothyroidism in an infant related to excessive maternal iodine intake: Food for thought, *Endocrine Practice*.19(4): 729-731, 07/2013. PM23512394

Podcasts

1. Gaggino L, Shumer WG D: Pediatric Meltdown: Caring for Transgender Youth with Compassion: What Pediatricians Must Know, 01/2020

Reviews

1. **Shumer DE**, Spack NP: Current management of gender identity disorder in childhood and adolescence: Guidelines, barriers and areas of controversy, *Current Opinion in Endocrinology, Diabetes and Obesity*.20(1): 69-73, 02/2013. PM23221495

2. Guss C, **Shumer DE**, Katz-Wise SL: Transgender and gender nonconforming adolescent care: Psychosocial and medical considerations, *Current Opinion in Pediatrics*.27(4): 421-426, 08/2015. PM26087416

3. **Shumer DE**, Nokoff NJ, Spack NP: Advances in the Care of Transgender Children and Adolescents, *Advances in Pediatrics*.63(1): 79-102, 08/2016. PM27426896

Short Surveys

1. **Shumer DE**, Spack NP: Transgender medicine-long-term outcomes from 'the Dutch model', *Nature Reviews Urology*.12(1): 12-13, 01/2015. PM25403246

Abstracts/Posters

1. Shumer D, Kinnear H, McLain K, Morgan H: Development of a Transgender Medicine Elective for 4th Year Medical Students, National Transgender Health Summitt, Oakland, CA, 2017

2. Shumer D: Overrepresentation of Adopted Children in a Hospital Based Gender Program, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016

3. Shumer D: Mental Health Presentation of Transgender Youth Seeking Medical Intervention, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016

4. Adkins V, Masters E, Shumer D, Selkie E: Exploring Transgender Adolescents' Use of Social Media for Support and Health Information Seeking (Poster Presentation), Pediatric Research Symposium, Ann Arbor, MI, 2017

Exhibit B

Bibliography

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Allen, N. G., Krishna, K. B., & Lee, P. A. (2021). Use of gonadotropin-releasing hormone analogs in children. *Current opinion in pediatrics*, *33*(4), 442–448.

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Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Med.* 2023 Jan 19;388(3):240-250.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF KELLAN E. BAKER, MA, MPH, PhD

I, Kellan E. Baker, MA, MPH, PhD, declare and state as follows:

1. I have been retained by counsel for Plaintiffs in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. I am the Executive Director and Chief Learning Officer of the Whitman-Walker Institute. In this role I oversee the Whitman-Walker Institute, which is the research, policy, and educational arm of Whitman-Walker, a community health system that includes Whitman-Walker Health, a federally qualified

community health center with 50 years of expertise in serving diverse communities across the Washington, D.C. metro area, particularly LGBTQ+ people and people living with HIV.

4. In 2021, I received my Doctor of Philosophy in Health Policy and Management from the Johns Hopkins Bloomberg School of Public Health, where I focused on Health Services Research and Policy as a Centennial Scholar and a Robert Wood Johnson Health Policy Research Scholar. I also completed a three-year Certificate Program in Public Health Economics at the Johns Hopkins Bloomberg School of Public Health and received an Executive Certificate in Health Care Leadership and Management from the Johns Hopkins Carey Business School.

5. In 2011, I received my Master of Public Health in Global Health Policy from The George Washington University Milken Institute School of Public Health and in the same year received my Master of Arts in International Development Studies from The George Washington University Elliott School of International Affairs.

6. Through my academic training and professional experience, I have extensive experience as a researcher and health policy expert regarding topics such as insurance reform and the Patient Protection and Affordable Care Act ("Affordable Care Act"), federal and state regulatory policy, public health, and government statistics. I have expertise in developing and analyzing health policy; conducting,

synthesizing, and communicating scientific research; and working with government, philanthropy, and other partners toward health policy objectives.

7. A significant part of my scholarship, research, and experience has focused on ensuring health equity for medically underserved populations, including sexual and gender minority communities, communities of color, and people with disabilities. My work has a particular emphasis on health care access and insurance issues in relation to the transgender population.

8. I have also worked with the National Academies of Sciences, Engineering, and Medicine ("National Academies") in several capacities. In 2017-2018, I served as a Steering Committee Member for the National Academies Project on Demography of Sexual and Gender Minority Populations. In 2019-2021, I served as a consultant to the National Academies Committee on Population on the convening of a National Academies Consensus Study Committee to assess the health and well-being of sexual and gender diverse populations. In this capacity, I advised on the preparation, creation, and dissemination of the Consensus Study Report "Understanding the Well-Being of LGBTQI+ Populations," which was published in 2020. As part of my role I participated in Consensus Study Committee discussions and authored and edited report components related to physical and mental health,

health services access and use, health policy, data collection, and demography.[1] As a consensus study report by the National Academies, the report documents the evidence-based consensus on the study's statement of task, was subjected to a rigorous and independent peer-review process, and represents the position of the National Academies on the statement of task.

9. Of relevance to this case, the National Academies 2020 consensus study report states that:

a. "Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines";

b. Each of the guidelines published by the World Professional Association for Transgender Health ("WPATH") (Coleman et al., 2012); the Endocrine Society (Hembree et al., 2017); and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016) "is informed by the best available data and is intended to be flexible and holistic in application to individual people"; and

c. "Mental and physical health problems need not be resolved before a person can begin a process of medical gender affirmation, but they

[1] National Academies of Sciences, Engineering, and Medicine. (2020). Understanding the Well-Being of LGBTQI+ Populations. Washington, DC: The National Academies Press. https://doi.org/10.17226/25877.

should be managed sufficiently such that they do not interfere with treatment."

10. In 2021, I was appointed as a member of the National Academies Consensus Study Committee on Measuring Sex, Gender Identity, and Sexual Orientation, which was charged with developing recommendations for the National Institutes of Health on the measurement of sex, gender identity, and sexual orientation. In March 2022, the Committee published the report "Measuring Sex, Gender Identity and Sexual Orientation."[2]

11. In 2013, I co-founded Out2Enroll, which is a nationwide nonprofit initiative focused on connecting low- and middle-income LGBT people with health insurance coverage under the Affordable Care Act. Over the last decade, Out2Enroll has provided technical assistance to enrollment organizations, federal and state governments, and other stakeholders on insurance coverage issues related to LGBT populations; trained more than 15,000 enrollment assisters in all 50 states; and conducted annual research on the content of coverage sold through the Health Insurance Marketplaces.

[2] National Academies of Sciences, Engineering, and Medicine. 2022. Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: The National Academies Press. https://doi.org/10.17226/26424.

12. For the last two years, I have been an appointed consumer representative to the National Association of Insurance Commissioners (NAIC), where I bring expert and consumer perspectives to inform the activities and policy positions of the NAIC.

13. I am the author of 22 peer-reviewed journal articles, 42 non-peer-reviewed articles and reports, and three book chapters. My peer-reviewed journal articles have been published in high-impact journals such as the *Journal of the American Medical Association*, *New England Journal of Medicine*, and *American Journal of Public Health*, among others.

14. Among my peer-reviewed publications are the following: "Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population," published in 2022 in the *Journal of Law, Medicine, and Ethics*; "Health and Health Care Among Transgender Adults in the United States," published in 2021 in the *Annual Review of Public Health*; "Hormone Therapy, Mental Health, and Quality of Life among Transgender People: A Systematic Review," published in 2021 in the *Journal of the Endocrine Society*; "The Future of Transgender Coverage," published in 2017 in the *New England Journal of Medicine*; and "Coverage for Gender Affirmation: Making Health Insurance Work for Transgender Americans," published in 2017 in *LGBT Health*.

15. I am also a senior researcher with the What We Know Project, a Cornell University–based initiative that conducts scoping reviews of the evidence in relation to complex legal and social issues involving LGBTQ populations in order to present the public and other stakeholders with primary source materials and summary findings. In 2018, I was the lead author of the What We Know Project's review of the effects of gender affirmation on the well-being of transgender people.[3]

16. This project included a systematic literature review of all peer-reviewed articles published in English between 1991 and June 2017 that assessed the effects of gender-affirming medical care on health-related outcomes among transgender people. We identified 55 studies that consisted of primary research on this topic, of which 51 (93%) found that gender-affirming medical care improves outcomes for transgender people, while 4 (7%) reported mixed or null findings. We found no studies concluding that gender-affirming care causes overall harm.

17. In addition, I am an author of multiple policy statements and technical reports, and I have served as a reviewer for 30 peer-reviewed journals, including the *New England Journal of Medicine*, *Journal of the American Medical Association*, and *Transgender Health*.

[3] What We Know Project. (2018). What Does the Scholarly Research Say About the Effect of Gender Transition on Transgender Wellbeing? Cornell University Center for the Study of Inequality. https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/

18. I have taught courses in LGBTQ health policy and health equity, as well as given dozens of invited lectures, presentations, keynotes, and plenaries related to health policy, health coverage, health disparities, and transgender health.

19. More detailed information regarding my professional background, experiences, publications, and presentations is outlined in my curriculum vitae, a true and correct copy of which is attached as **Exhibit B**.

B. Prior Testimony

20. I have not testified as an expert at deposition or trial within the last four years.

C. Compensation

21. I am being compensated at an hourly rate of $200 per hour for preparation of expert declarations and reports and time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

BASES FOR OPINIONS

22. This report sets forth my opinions in this case and the bases for my opinions.

23. In preparing this report, I reviewed Florida's Administrative Rule governing the determination of generally accepted professional medical standards under Florida Medicaid coverage (Fla. Admin. Code R. 59G-1.035); the text of

"Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" ("GAPMS Memo"),[4] including all attachments; Fla. Admin. Code. R. 59G-1.050(7), which prohibits Medicaid coverage of puberty-delaying medications (commonly referred to as "puberty blockers"), hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics, on the basis that the services do not meet Florida's definition of "medical necessity" for purposes of its Medicaid program; and the Complaint in this Case.

24. I also reviewed the materials listed in the attached Bibliography (**Exhibit A**), as well as the materials listed within my curriculum vitae (attached as **Exhibit B**). I may rely on those documents as additional support for my opinions.

25. In addition, I have relied on my education, training, and years of professional and research experience, as well as my knowledge of the scientific literature in the pertinent fields.

26. The materials I have relied upon in preparing this declaration are the same types of materials that experts in health and public policy regularly rely upon when forming opinions on this type of subject. I may wish to supplement these

[4] June 2022. Accessed February 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

opinions or the bases for them due to new scientific research or publications, or in response to statements and issues that may arise in my area of expertise.

TRANSGENDER PEOPLE AND GENDER DYSPHORIA

27. Transgender people are individuals whose gender identity, meaning their innate, deeply seated knowledge of their own gender, is different from that typically associated with the sex they were assigned at birth.[5]

28. There are approximately 1.6 million transgender people in the United States today, comprising approximately 0.6 percent of the U.S. population.[6] This estimate has remained steady since the authors' initial assessments of this population size in 2016[7] and 2017.[8] Compared to the general U.S. population, transgender people are more likely to not have health insurance coverage, to be unemployed and living in poverty, and to have a disability.[9] Scientific studies consistently identify experiences of discrimination and a lack of access to appropriate medical care as

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[5] National Academies of Sciences, Engineering, and Medicine. (2022). *Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health*. Washington, DC: National Academies Press.

[6] Herman JL, Flores AR, O'Neill KK. (2022). *How Many Adults and Youth Identify as Transgender in the United States?* Los Angeles: The Williams Institute. https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/

[7] Flores AR, Herman JL, Gates GJ, Brown TNT. (2016). *How Many Adults Identify as Transgender in the United States?* Los Angeles: The Williams Institute. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf

[8] Herman JL, Flores AR, Brown TNT, Wilson BDM, Conron KJ. (2017). *Age of Individuals Who Identify as Transgender in the United States.* Los Angeles: The Williams Institute. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Age-Trans-Individuals-Jan-2017.pdf

[9] James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality. https://www.ustranssurvey.org/reports

major drivers of these disparities.[10] Because of these systematic and well-documented gaps in health and overall well-being, the transgender population is designated as a health disparity population by the National Institutes of Health.[11]

29. Many transgender people seek medical treatment to physically transition from the sex that they were assigned at birth to the sex that aligns with their gender. According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR), the diagnostic term that describes the medical necessity of transition is gender dysphoria, which refers to the distress and impairment transgender individuals may experience due to a profound misalignment between their gender and their assigned birth sex.[12]

30. Gender dysphoria is recognized as a serious medical condition by major medical associations such as the American Medical Association (AMA), the American Psychiatric Association, and the American Psychological Association, among many others.[13] A 2008 AMA resolution notes that the consequences of gender dysphoria can include "clinically significant psychological distress,

[10] National Academies of Sciences, Engineering, and Medicine. (2020). *Understanding the Well-Being of LGBTQI+ Populations*. Washington, D.C.: National Academies Press.
[11] National Institute for Minority Health and Health Disparities. (2016). Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes. https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html
[12] American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed, revised). Arlington, VA: American Psychiatric Publishing.
[13] See https://transhealthproject.org/resources/medical-organization-statements/

dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death."[14]

31. Treatment for gender dysphoria, which may include mental health counseling, hormone therapy, and surgeries, is provided in the United States by licensed clinicians according to expert standards developed by professional medical associations such as the Endocrine Society[15] and the World Professional Association for Transgender Health (WPATH).[16] Interventions to treat gender dysphoria have been linked to multiple positive health outcomes, including better quality of life; lower rates of mental health conditions such as depression, anxiety, and psychological distress; decrease in or elimination of distress associated with gender dysphoria; and mitigation of stigma and discrimination.[17]

INSURANCE COVERAGE OF TREATMENT FOR GENDER DYSPHORIA

32. The first U.S. clinics opened to provide treatment for gender dysphoria to transgender individuals in the 1960s and 1970s, and the first edition of the

[14] American Medical Association House of Delegates. (2008). Removing Barriers to Care for Transgender Patients. H-185.950 (Res. 122; A-08). https://www.tgender.net/taw/ama_resolutions.pdf

[15] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. (2017). Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, *102*(11), 3869–903.

[16] Coleman E, Radix AE, Bouman WP, et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*, *23*(Suppl 1), S1-S259.

[17] National Academies of Sciences, Engineering, and Medicine. (2020). Understanding the Well-Being of LGBTQI+ Populations. Washington, DC: The National Academies Press.

WPATH Standards of Care was published in 1979.[18] By the late 1970s, nationwide trends favored insurance coverage for treatment of gender dysphoria, particularly through state Medicaid programs.

Private Health Coverage

State-Regulated Individual and Group Coverage

33. In the U.S., the states are the traditional regulators of private insurance coverage sold in the individual, small group, and large group markets. Over the last two decades, many states have required plans under their jurisdiction to remove exclusions of coverage for gender dysphoria.

34. In 2005, California became the first state to prohibit discrimination against transgender individuals by state-regulated individual and group plans by enacting the Insurance Gender Nondiscrimination Act (IGNA), which bans discrimination in health insurance coverage because of gender identity.

35. In 2012, the California Department of Insurance issued a regulation under IGNA defining gender identity discrimination in health insurance coverage to mean "denying or limiting coverage, or denying a claim, for…health care services related to gender transition if coverage is available for those services under the policy when the services are not related to gender transition, including but not limited to

[18] Allee KM. (2009). Harry Benjamin International Gender Dysphoria Association. In *Encyclopedia of gender and society, volume 1* (Ed. J O'Brien). Thousand Oaks, CA: SAGE.

hormone therapy, hysterectomy, mastectomy, and vocal training."[19] Since 2012, 24 other states and the District of Columbia have prohibited exclusions of coverage for gender dysphoria in state-regulated individual and group plans.[20]

36. Most recently, Colorado added new explicit coverage requirements for plans in its state-regulated individual and small group markets.[21] Those plans in Colorado are now required to cover the following procedures for transgender people: gender-affirming hormone therapy, chest reconstruction, augmentation mammoplasty, genital surgeries, facial feminization surgeries, and laser or electrolysis hair removal. An actuarial analysis commissioned by the state to assess the cost of these procedures estimated that their long-term steady state cost is 0.04% of total allowed claims.[22]

37. Similarly, in 2022, 21 state regulators wrote a joint letter to the U.S. Department of Health and Human Services (HHS) stating, "Transgender people should have equal access to the same health insurance and care as every other insured American. This includes health care related to gender affirmation, which for years

[19] CAL. CODE REGS., tit. 10, § 2561.2(a)(4)(A).
[20] LGBT Movement Advancement Project. (2023). Equality Maps. https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/private_insurance
[21] Keith K. (2021). Unpacking Colorado's New Guidance on Transgender Health. Commonwealth Fund Blog. https://www.commonwealthfund.org/blog/2021/unpacking-colorados-new-guidance-transgender-health
[22] Colorado Benchmark Plan for 2023. https://www.cms.gov/files/zip/co-ehb-benchmark.zip

has been recognized by every major U.S. medical society as effective and medically necessary for many individuals."[23]

38. In addition to state regulators, insurance carriers themselves have also spoken strongly about their interest in ensuring that transgender enrollees can access treatment for gender dysphoria. In 2022, America's Health Insurance Plans (AHIP), the professional trade association that represents 1,300 member companies that sell health insurance coverage for more than 200 million people nationwide, wrote in a letter to HHS that they "strongly support ensuring that appropriate gender-affirming care is available and accessible to enrollees. We [are committed] to ensuring benefit designs and coverage decisions reflect evidence-based guidelines and recommendations and do not restrict coverage related to gender identity."[24]

Employer-Sponsored Coverage

39. Employee coverage through large employers in the U.S. is primarily regulated by the federal government under the Employee Retirement Income Security Act (ERISA), though states retain authority over the plans they offer to their employees. The federal government also oversees coverage requirements for federal

[23] Letter from state insurance commissioners to U.S. Department of Health and Human Services Secretary Xavier Becerra. (2022). http://www.insurance.ca.gov/0400-news/0100-press-releases/2022/upload/joint-Letter-Final_ACA_SECTION_1557_NPRM_sign-on_letter_2022-2.pdf

[24] America's Health Insurance Plans. (2022). Letter to Dr. Ellen Montz, Administrator, Center for Consumer Information and Insurance Oversight, U.S. Department of Health and Human Services. https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Letter-to-CMS-on-Nondiscrimination-2.16.22.pdf

employees nationwide through the Federal Employees Health Benefits Program (FEHBP). Trends in employer coverage of treatment for gender dysphoria parallel the expansion of coverage evident in state-regulated individual and group coverage.

40. Among state employee benefit plans, 42 states and territories do not have categorical transgender-specific exclusions in their plans; of these, 24 states and D.C. affirmatively spell out the gender-affirming services that their state employee plans cover.[25]

41. According to the Corporate Equality Index (CEI), which has tracked the status of private employer-sponsored coverage for treatment of gender dysphoria since 2002, 67 percent of the entire Fortune 500—and 86 percent of all CEI-rated businesses (1,088 of 1,271)—offered employee benefits with no transgender-specific exclusions in 2022.[26] In 2015, 54 percent (421 of 781) companies offered at least one fully inclusive plan to their employees, and by 2022 that number had reached 91 percent (1,160 out of 1,271).

42. In 2016, the White House Office of Personnel Management (OPM) required all FEBHP carriers to remove blanket exclusions of services, drugs, or

[25] LGBT Movement Advancement Project. (2023). Equality Maps. https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/state_employees. West Virginia's exclusion was recently removed as a result of a settlement agreement.
[26] Human Rights Campaign Foundation. (2022). Corporate Equality Index. https://reports.hrc.org/corporate-equality-index-2022

supplies related to the treatment of gender dysphoria. For plan year 2023, OPM instituted the following requirements for FEHB carriers:[27]

a. Have adopted one or more recognized entities in order to guide evidence-based benefits coverage and medical policies pertaining to gender affirming care and services, such as the World Professional Association of Transgender Health (WPATH) Standards of Care, the Endocrine Society, and the Fenway Institute. These entities provide evidence-based clinical guidelines for health professionals to assist transgender and gender diverse people with safe and effective pathways that maximize their overall health, including physical and psychological well-being.

b. Will provide individuals diagnosed with and/or undergoing evaluation for gender dysphoria the option to use a Care Coordinator to assist and support them as they seek gender-affirming care and services. If network providers are not available to provide medically necessary treatment of gender dysphoria, FEHB Carriers will provide members direction on how to find qualified providers with experience delivering this specialized care.

c. Have reviewed their formularies to ensure that transgender and gender diverse individuals have equitable access to medications and provide coverage of medically necessary hormonal therapies for gender transition care.

Health Insurance Marketplace Coverage

43. Another major source of individual and small group insurance beyond traditional state-regulated private markets are the Health Insurance Marketplaces established by the Patient Protection and Affordable Care Act (ACA), where

[27] United States Office of Personnel Management. (2022). Federal Benefits Open Season November 14, 2022 – December 12, 2022. https://cdn.govexec.com/media/gbc/docs/pdfs_edit/093022ew1.pdf

income-eligible consumers can purchase plans with government financial subsidies. Approximately one-third of states operate their own Marketplace, while the federal government operates the Marketplace for the remaining states, including Florida, through the HealthCare.gov platform.

44. Since 2017, the Out2Enroll initiative has conducted research on the prevalence of exclusions for gender dysphoria in plans sold through HealthCare.gov. Over the past seven years, this research has documented that the vast majority of plans sold through HealthCare.gov do not have transgender-specific exclusions.[28]

45. In 2023, for instance, 92% of 1,429 HealthCare.gov plans reviewed from 33 states, including Florida, did not have categorical exclusions of gender dysphoria treatment. Almost half (47%) of all plans reviewed explicitly stated that medically necessary treatment for gender dysphoria is covered.

46. Of the eight carriers selling coverage through HealthCare.gov in Florida, seven (88%) expressly cover medical care related to gender affirmation. The remaining carrier excludes coverage only for some gender-affirming services, and no carriers offer plans with categorical exclusions of the type established in Fla. Admin. Code R. 59G-1.035.[29]

[28] Out2Enroll. (2022). Summary of Findings: 2023 Marketplace Plan Compliance with Section 1557 of the Affordable Care Act. https://out2enroll.org/2023-cocs/

[29] Out2Enroll. (2022). Transgender Health Insurance Guide to the Marketplace: Florida. https://drive.google.com/file/d/1XliTnjuwi_6pCQuOj3Nm9vlGalAdTOaE/view

Public Health Coverage

Medicare

47. An exclusion of Medicare coverage for "transsexual surgery" was introduced in 1981 and codified in a 1989 National Coverage Determination. In 2014, the HHS Departmental Appeals Board (DAB) ruled that this exclusion of treatment for gender dysphoria was invalid on the grounds that it was based on outdated evidence that was not complete or adequate to support the determination that this treatment was never medically necessary.[30]

48. In its ruling, the DAB rejected the assertion that gender-affirming surgeries are "experimental" and "controversial," finding instead that current evidence "indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism." Following the rescinding of the exclusion, Medicare covers surgeries and other gender-affirming care for transgender individuals according to case-by-case assessments of medical necessity.

49. An example of this coverage policy in practice is a 2016 ruling by the Medicare Appeals Council ("the Council"), which is part of the DAB, finding that a Medicare Advantage plan's decision to deny coverage for gender-affirming surgery

[30] Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf.

to a transgender Medicare beneficiary did not comport with Medicare's statutory "reasonable and necessary" coverage criterion.[31]

50. The Council asserted that the WPATH Standards of Care are "reasonable guidelines to determine medical necessity" and found that, inasmuch as the enrollee "satisfies all of the WPATH clinical requirements for gender reassignment surgery…the requested vaginoplasty is medically reasonable and necessary for treatment of this enrollee's gender dysphoria under Section 1862(a)(1)(A) of the [Social Security] Act and is covered under existing [Centers for Medicare & Medicaid Services] guidance."

Medicaid

51. Medicaid coverage for gender-affirming care predates the first iteration of WPATH's Standards of Care. For example, Medicaid coverage for such care in California can be documented as far back as the 1970s. In a pair of cases decided in 1978 (*J.D. v. Lackner* and *G.B. v. Lackner*) pertaining to Medicaid coverage of vaginoplasty for transgender women, a California court found that the plaintiff "has an illness and … as far as her illness affects her, the proposed surgery is medically reasonable and necessary and…there is no other effective treatment method." The judges further asserted that "the proposed surgery is medically reasonable and

[31] In the Case of United Health Care / AARP Medicare Complete, No. M-15-1069 at 8 (Jan. 21, 2016), https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf.

necessary" and should thus be covered by Medicaid, and they added that "we do not believe, by the wildest stretch of the imagination, that such surgery can reasonably and logically be characterized as cosmetic."

52. Other states likewise provided Medicaid coverage for gender-affirming care as far back as the 1970s and 1980s.[32] When the federal Medicare program instituted its exclusion in 1981, however, many Medicaid programs followed suit.

53. Beginning in the early 2000s and over the course of the next 20 years, categorical exclusions of coverage in many state Medicaid programs began to be removed—whether administratively, by statute, or after court orders—in response to successive iterations of the standards of care and increasingly sophisticated clinical practice guidelines for the treatment of gender dysphoria.

54. As of present, the overwhelming majority of states do not exclude coverage of gender-affirming care from Medicaid. As of early 2023, 47 states and territories, as well as D.C., no longer have categorical exclusions of gender dysphoria treatment in their Medicaid programs. Of these, 27 states and D.C. explicitly and affirmatively delineate coverage of a range of gender-affirming services.

[32] *See*, *e.g.*, *Pinneke v. Preisser*, 623 F.2d 546 (8th Cir. 1980) (pertaining to Iowa's Medicaid program); *Doe v. State, Dep't of Pub. Welfare*, 257 N.W.2d 816 (Minn. 1977) (pertaining to Minnesota's Medicaid program).

55. The GAPMS Memo outlines that there are eight states that explicitly ban coverage for treatment of gender dysphoria. However, these limitations are typically not as broad or all-encompassing as Fla. Admin. Code. R. 59G-1.050(7). For example, the exclusions in Missouri, Nebraska, and Texas are limited to surgery and do not extend to coverage for puberty delay medications and hormone therapy, while the exclusion in Arkansas is limited to minors.[33] Meanwhile, the exclusion in Ohio appears to be inoperative, as officials in Ohio do not appear to be enforcing the exclusion and managed care organizations operating under Ohio's Medicaid program have clinical policy guidelines for covering gender-affirming care; thus, the scope of coverage is unclear. Finally, the GAPMS Memo erroneously states that Georgia excludes coverage of gender-affirming care in Medicaid.

56. Taking stock of Medicaid coverage policies requires assessment not just of a state's regulations and statutes, but also operative guidance, managed care organizations' policies, and relevant administrative and court decisions in the state.

57. When one does so, Florida stands apart as one of less than a handful of states with exclusions of similar breadth and scope among the 56 jurisdictions in the United States that operate Medicaid programs (i.e., the 50 states, five U.S. territories, and D.C.). Florida's recently adopted exclusion therefore runs counter to the clear and overwhelming trend among Medicaid programs to remove such exclusions and, as

[33] ARK. CODE § 20-9-1503(d).

outlined further below, to affirmatively provide guidance on coverage for treatment of gender dysphoria.

58. Some states have recently explicitly broadened and clarified the scope of Medicaid coverage for gender dysphoria. In Washington State, for instance, 2021 legislation codified that the state's Medicaid program covers a range of "surgical and ancillary services," as well as puberty-delaying medications, for transgender people.[34] The legislation indicates that the list of covered services is not exhaustive and requires that a "health care provider with experience prescribing and/or delivering gender affirming treatment must review and confirm the appropriateness of any adverse benefit determination.[35]

COSTS AND UTILIZATION OF TREATMENT FOR GENDER DYSPHORIA

59. While the number of people with transgender-specific diagnostic codes in commercial insurance claims databases has increased over the last decade, the increase is attributable to national policy trends that have made coverage for gender-affirming care more accessible. As such, more transgender people are now able to access coverage for treatment of gender dysphoria, and more providers are able to appropriately code for these encounters without triggering coverage exclusions.

[34] Washington State Legislature. SB 5313 (2021-2022). https://app.leg.wa.gov/billsummary?BillNumber=5313&Initiative=false&Year=2021
[35] Washington State Healthcare Authority. (2022). Transhealth Program. https://www.hca.wa.gov/billers-providers-partners/programs-and-services/transhealth-program

60. Even as coverage has become more accessible, utilization rates remain low. Moreover, evidence indicates that insurance coverage of treatment for gender dysphoria is low-cost and highly cost-effective. The impact of gender-affirming care on payer budgets has thus remained nominal even as coverage has become more available, standardized, and routine.

61. A California Department of Insurance assessment of IGNA, the state law that broadly prohibited insurance discrimination against transgender beneficiaries, for instance, showed that a major state university-sponsored plan had a utilization rate of only 0.062 per 1,000 covered persons for this care over the 6.5 years following the law's enactment; across the state, impacts on premium costs were "immaterial," leading the Department to conclude that "the benefits of eliminating discrimination far exceed the insignificant costs."[36]

62. A 2016 economic model evaluating the cost-effectiveness of care for transgender men that included hormone replacement therapy, mastectomy, abdominoplasty, hysterectomy, genital reconstruction, and other services underscores this conclusion, finding that the incremental cost-effectiveness ratio

[36] State of California Department of Insurance. (2012). Economic Impact Assessment: Gender Nondiscrimination in Health Insurance. http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf

(ICER) of these services was less than $8,000 per quality-adjusted life year (QALY) gained over a ten-year time horizon.[37]

63. This is far below a typical U.S. "willingness to pay" threshold of $100,000 per QALY.[38] This study also found that, on a per member per month (PMPM) basis, coverage of surgical and other services for transgender men and women together cost $0.016.

64. My own recent research indicates that each covered transgender person in a major national commercial insurance database incurred an average of less than $1,800 in costs per year for hormone therapy (including puberty delay medications) and surgeries (including facial surgeries) combined to treat gender dysphoria.[39] Considered on a PMPM basis, the budget impact of covering this care was $0.73 per year, or $0.06 PMPM.

[37] Padula, W. V., Heru, S., & Campbell, J. D. (2016). Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis. Journal of General Internal Medicine, 31(4), 394–401. https://doi.org/10.1007/s11606-015-3529-6

[38] Cameron, D., Ubels, J., & Norström, F. (2018). On what basis are medical cost-effectiveness thresholds set? Clashing opinions and an absence of data: a systematic review. Global health action, 11(1), 1447828. https://doi.org/10.1080/16549716.2018.1447828

[39] Baker, K., & Restar, A. (2022). Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. Journal of Law, Medicine & Ethics, 50(3), 456-470. doi:10.1017/jme.2022.87

65. Similarly, an actuarial assessment conducted for the North Carolina State Health Plan estimated a PMPM cost range of $0.06-$0.15 (0.011% to 0.027% of premiums).[40]

66. Estimates from other states show equally low utilization and related low costs, with Alaska estimating that coverage for gender dysphoria would result in increases of 0.03% to 0.04% of total costs for its state employee plan[41] and Wisconsin noting costs to its state employee plan are "immaterial, since it represents less than 0.1% of the overall costs of medical care."[42]

67. Cost estimates of coverage for gender-affirming care under Wisconsin Medicaid were "actuarially immaterial, as they are equal to approximately 0.008% to 0.03%" of Wisconsin's share of its Medicaid budget.[43]

68. An analysis in the military context concluded that the cost of covering gender-affirming care was "too low to matter"[44] or, as military leadership noted, "'budget dust,' hardly even a rounding error.[45]

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[40] Schatten, K. R., & Viera, K. C. (2016). Memorandum to Mona Moon, Administrator, North Carolina State Health Plan, re: Transgender Cost Estimate. https://www.shpnc.org/media/22/download

[41] Plaintiffs' Motion for Partial Summary Judgment, Fletcher v. Alaska, No. 1:18-cv-00007-HRH (D. Alaska July 1, 2019), https://www.lambdalegal.org/sites/default/files/legal-docs/downloads/fletcher_ak_20190701_plaintiffs-motion-for-partial-summary-judgment.pdf.

[42] Boyden v. Conlin, 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[43] Flack v. Wis. Dept of Health Servs., 395 F. Supp. 3d 1001, 1008 (W.D. Wis. 2019).

[44] Belkin A. (2015). Caring for our transgender troops – The negligible cost of transition-related care. *New Eng J Med, 373*, 1089–1092. https://www.nejm.org/doi/full/10.1056/NEJMp1509230

[45] Declaration of Raymond Edwin Mabus, Jr., Former U.S. Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction, Doe v. Trump, No. 17-cv-1597-CKK (D.D.C.) filed Aug. 31, 2017, at 41). http://files.eqcf.org/wp-content/uploads/2017/09/13-Ps-App-PI.pdf

69. Overall, the actuarial evidence indicates that gender-affirming care is not expensive when considered from a payer or societal perspective, but it can easily be beyond the individual reach of transgender people, particularly those who rely on public coverage programs such as Medicaid.

CONCLUSION

70. The transgender population, at a steady 0.6% of the U.S. population, is a small and medically vulnerable population for whom decades of scientific research and medical practice have established a robust consensus on the appropriateness of gender-affirming care. Over the last 20 years, state regulators, Medicaid programs, insurance carriers, and employers have increasingly taken affirmative action to ensure that transgender people do not face barriers to coverage for the medically necessary treatment of gender dysphoria. The exclusion recently instituted at Fla. Admin. Code. R. 59G-1.050(7) thus is both out-of-step with expert medical standards used by both public and private health insurance programs and runs counter to prevailing nationwide trends in every form of insurance, including Medicaid, Medicare, and private coverage.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 17th day of February 2023.

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Swarthmore College 2000-2004
Bachelor of Arts with High Honors in Astrophysics and Russian Literature
Activities: External Honors Program

PROFESSIONAL EXPERIENCE

Whitman-Walker Institute
Executive Director and Chief Learning Officer 2021-present

- Lead the research, policy, and education activities of Whitman-Walker, a community health system in Washington, DC that also includes Whitman-Walker Health, a Federally Qualified Health Center with 50+ years of experience serving diverse patient populations across the DC metro area, with a particular focus on people living with HIV and sexual and gender minority populations.
- Oversee daily operations for the Institute, including personnel, grants management, financial reporting and fiscal accountability, strategic planning, quality assurance for training and research activities, and development of internal and external partnerships.
- Oversee a 55-person team of researchers, policy analysts, and administrative staff in conducting epidemiologic, econometric, clinical, and policy research; translating research findings into policy, practice, and programming recommendations; and advancing methodology for research centering the impact of structural factors on individual and population health.
- Partner with clinicians and clinic management at Whitman-Walker on health services research using clinical data for quality assessment and practice improvement.
- Represent Whitman-Walker in interactions with media, government, academic institutions, public and private payers, professional societies, community members, and other stakeholders.

Johns Hopkins School of Public Health
Affiliate Faculty, Department of Health Policy and Management 2021-present

George Washington University School of Public Health and Health Services
Affiliate Faculty, Department of Health Policy and Management 2021-present

National Academy of Sciences, Division of Behavioral and Social Sciences and Education
Consultant 2019-2021

- Advised the Committee on Population on the development, funding, and coordination of a consensus study project on health and other domains of well-being in sexual and gender diverse populations.
- Authored and edited report components related to physical and mental health; health services access and use; health policy; data collection; and demography.
- Led report dissemination to policy, academic, medical, media, and community audiences.

Johns Hopkins Evidence-Based Practice Center
Research Associate 2018-2021

Designed and conducted systematic reviews to support the revision of the leading expert treatment guidelines in the field of transgender health.

Cornell University Center for the Study of Inequality
Senior Researcher 2017-2019

Designed and conducted systematic reviews of social inequality and health policy issues.

Johns Hopkins School of Public Health, Department of Epidemiology
Research Associate 2017-2018

Built economic models assessing the cost-effectiveness of integrating HIV testing, prevention, and treatment into primary care in low-resource settings.

Center for American Progress
Senior Fellow 2014-2017

- Designed and implemented strategies to advance policy goals around health equity, Affordable Care Act (ACA) implementation, health system transformation, health insurance reform, appropriations and budget, nondiscrimination, and data collection and research at all levels of government and with hospitals, health insurance carriers, and other private stakeholders.
- With Fenway Community Health, co-founded and directed a project that secured new data elements in the federal regulations governing the Meaningful Use of Electronic Health Records program.
- Coordinated and represented coalitions of diverse organizations focusing on civil rights, health care, and public health in regulatory and legislative policymaking activities with decisionmakers and staff at all levels of government.
- Developed and published original research, policy analyses, and policy and practice recommendations for audiences such as the White House, the federal agencies, the Presidential Advisory Council on HIV/AIDS, congressional and other legislative staff, state and local health departments, and state and federal insurance regulators.
- Regularly quoted and published in venues such as *Washington Post*, *New York Times*, *Reuters*, *Time*, *Scientific American*, *US News and World Report*, and National Public Radio.

Out2Enroll Founding Steering Committee Member 2013-2017

- Conceived and co-led Out2Enroll, a $1-million national communications, training, and policy partnership with the U.S. Department of Health & Human Services (HHS) and the White House to connect low-income sexual and gender minority people with insurance coverage under the ACA.
- Managed strategic and daily operations, including overseeing a coalition of more than 70 partners, developing communications strategies, fundraising, and grants management.
- Created the training "Reaching and Assisting LGBT Communities" (in-person and online) and trained more than 15,000 enrollment assisters in all 50 states, the US territories, and Washington, DC.
- At the request of the HHS Office for Civil Rights, created and presented trainings on the ACA and civil rights to the HHS Regional Offices.

Associate Director 2013-2014

- Led the health policy portfolio of the Federal Agencies Project, a national funder collaborative pursuing health reform and health equity objectives via federal regulatory policy.
- Managed a staff of research and policy analysts.

Senior Policy Analyst 2011-2013

- Conducted policy analyses and wrote reports, memos, regulatory comments, and media pieces on issues such as health reform, HIV/AIDS, health disparities, and health information technology.
- Created and oversaw the LGBT State Exchanges Project, a training and technical assistance partnership with five states to address coverage gaps through the implementation of the ACA.

Astraea Lesbian Foundation for Justice
Consultant 2014
Managed strategic planning activities of the Global Philanthropy Project, a group of 15 international funders supporting the human rights of sexual and gender minorities.

Kaiser Foundation Health Plan
Consultant 2013-2014
Advised on the development of Kaiser's industry-leading LGBTI Health Equity Program.

The Joint Commission
Consultant 2010
Co-authored "Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide."

Open Society Foundations
Consultant 2010-2013
Authored "Transforming Health: International Rights-Based Advocacy for Trans Health," featuring case studies from nine countries and the World Health Organization.

Danish Refugee Council
Fellow 2010
Conducted French-language focus group research in the Central African Republic and wrote a needs assessment about addressing sexual and gender-based violence in conflict situations.

National Coalition for LGBT Health
Policy Analyst 2009-2011
In coordination with 75 member organizations in 22 states and other stakeholders, developed and implemented a national policy strategy for advancing LGBT health equity.

The White House
Intern 2009
Staffed the Special Assistant to the President for Disability Policy.

Wonder Sprachinstitut (Vienna, Austria)
TOEFL Preparation Instructor 2007-2008
Taught beginning and advanced English.

Vienna University of Economics and Business (Vienna, Austria)
Executive MBA Program Tutor 2007-2008
Tutored students on English and economics topics.

Kommersant **Newspaper (Moscow, Russia)**
Russian–English Translator 2006-2007
Translated international news, politics, business, and editorial content for a leading daily newspaper.

Nauka/Interperiodica (Moscow, Russia)
Russian–English Translation Editor 2004-2005
Edited translated scientific journal articles in the areas of physics, chemistry, geology, and biology under a contract with the Russian Academy of Sciences.

SERVICE TO PROFESSIONAL ORGANIZATIONS

National Institutes of Health 2022-present
Appointed Member, Sexual and Gender Minority Working Group of the NIH Council of Councils

Public Health AmeriCorps 2022-present
Member, Technical Working Group for National Process, Outcomes, and Impact Evaluation

AcademyHealth 2022-present
Member, Advisory Group on Health Services Research Innovation, Inclusion, and Impact

UnitedHealthcare 2022-present
Member, Ambassadors for the Community (health equity initiative focused on dual eligibles in DC)

Personalized Medicine Coalition 2022-present
Member, Health Equity Task Force

National Association of Insurance Commissioners 2022-present
Appointed Consumer Representative

California Health Interview Survey 2022-present
Member, Sexual Orientation and Gender Identity Working Group

National Academies of Sciences, Engineering, and Medicine 2021-present
Appointed Member, Consensus Study Committee on Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health

Agency for Healthcare Research and Quality 2021-present
Invited Participant, AHRQ Health Equity Summits

National Institutes of Health, Inter-Society Coordinating Committee for Practitioner Education in Genomics 2021-present
Founder and Co-Chair, Project on LGBTQI+ Issues in Genomics and Genomics Education

European Research Council 2021-present
Grant Reviewer

National Academies of Sciences, Engineering, and Medicine 2021-present
Partner, Assessing Meaningful Community Engagement in Health & Health Care Leadership Consortium

AcademyHealth 2020-present
Appointed Member, National Advisory Group on Diversity, Equity, and Inclusion

Harvard Medical School 2020-present
Professional Advisory Council Member, Sexual and Gender Minority Health Equity Initiative

National Center for Transgender Equality 2019-present
Scientific Advisory Council Member, 2022 US Transgender Survey

National Institutes of Health 2016-present
Community Engagement Working Group Member, National Human Genome Research Institute

American Councils for International Education 2016-present
Flagship Program Orientation Facilitator (Russia, Kazakhstan, Azerbaijan, Tajikistan)

Equality Federation 2015-present
Board of Directors (current Immediate Past Chair, past Treasurer)

TEDMED 2020
Invited Health Equity Expert

Biden-Harris Presidential Campaign 2020
Equity Review Board Member, Health Policy Committee

Biden-Harris Presidential Campaign 2020
Co-Chair, LGBTQ Health Policy Committee

Congressional Tri-Caucus, Families USA, and UnidosUS 2016-2020
Steering Committee Member, Health Equity and Accountability Act

10.10.10 Cities: Health Social Entrepreneurship Program 2019
Health Start-Up Team "Ninja"

Community Catalyst and the Robert Wood Johnson Foundation 2017-2019
National Advisory Council Member, Consumer Advocacy for Health System Transformation

Gilead Sciences 2017-2019
Transgender Advisory Council Member

American Association for the Advancement of Science 2016-2019
Selection Committee Member, Executive Branch Science and Technology Policy Fellowship

Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services 2014-2019
Appointed Member, Advisory Panel on Outreach and Education

National Academies of Sciences, Engineering, and Medicine 2017-2018
Steering Committee Member, Project on Demography of Sexual and Gender Minority Populations

Johns Hopkins Bloomberg School of Public Health 2018
Member, Schoolwide Honors and Awards Committee

National Institutes of Health 2018
Invited Participant, Expert Workshop on Methods in Sexual & Gender Minority Health Research

Johns Hopkins Medicine and Harvard University School of Medicine 2013-2018
Member, EQUALITY Study Stakeholder Advisory Board

Robert Wood Johnson Foundation 2017
Application Reviewer, Culture of Health Program

U.S. Professional Association for Transgender Health 2016-2017
Scientific Program Committee Member, Inaugural USPATH Scientific Conference

AcademyHealth 2015-2017
Advisory Council Member and Grant Reviewer, Community Health Peer Learning Program

Center for Consumer Information & Insurance Oversight, U.S. Department of Health & Human Services 2015
Grant Reviewer, HealthCare.gov Enrollment Navigator Program

Robert Carr Civil Society Networks 2015
Grant Reviewer

University of California at San Francisco Center of Excellence for Transgender Health 2013, 2015
Policy Track Co-Chair, National Transgender Health Summit

National Action Alliance for Suicide Prevention 2012
Member, LGBT Task Force

The Fenway Institute 2011-2016
Affiliated Faculty for LGBT Health Policy

U.S. Department of State 2009-2013
National Security Language Initiative for Youth Program Orientation Facilitator (Russia)

The DC Center for the LGBT Community 2009-2011
Board of Directors (DC for Marriage Campaign Co-Chair)

OTHER PROFESSIONAL ACTIVITIES

Ad Hoc Journal Reviews

- *New England Journal of Medicine*
- *Journal of the American Medical Association*
- *JAMA Psychiatry*
- *JAMA Internal Medicine*
- *Health Affairs*
- *American Journal of Public Health*
- *Journal of the American Medical Informatics Association*
- *Medical Informatics*
- *Milbank Quarterly*
- *Journal of Official Statistics*
- *Social Science & Medicine*
- *American Journal of Epidemiology*
- *American Journal of Preventive Medicine*
- *Preventive Medicine*
- *Quality of Life Research*
- *Sexuality Research and Social Policy*
- *Sexual and Reproductive Health Matters*
- *Journal of Homosexuality*
- *Journal of Public Health Dentistry*
- *Frontiers in Oncology*
- *Psychology of Sexual Orientation and Gender Diversity*
- *LGBT Health*
- *Transgender Health*
- *BMC Health Services Research*
- *Family Practice*
- *Journal of Patient Safety and Risk Management*
- *Progress in Community Health Partnerships: Research, Education, and Action*
- *Media and Communication*
- *Patient Education & Counseling*
- *The Physician and Sports Medicine*

Memberships

- DC Center for AIDS Research (2021-present)
- Johns Hopkins Center for AIDS Research (2020-present)
- Association for Public Policy Analysis and Management (2018-present)
- International Society for Pharmacoeconomics and Outcomes Research (2018-present)
- World Professional Association for Transgender Health (2018-present)
- Society for Medical Decision Making (2017-present)
- AcademyHealth (2012-present)
- American Public Health Association (2009-present)

Conference Abstract Reviews

- International Society for Pharmacoeconomics and Outcomes Research
- AcademyHealth (theme reviewer for "Disparities and Health Equity" track)
- American Public Health Association
- Society for Medical Decision Making
- U.S. Professional Association for Transgender Health

HONORS AND AWARDS

First Place, Research and Translation Virtual Ideas Exchange Competition 2020
OptumLabs

Golden Apple Award for Excellence in Teaching 2020
Public Health Studies Program, Johns Hopkins University
Awarded for the class "Policy, Politics, and Power in Health Equity," designed through the Gordis Teaching Fellowship

Alice S. Hersh Scholarship 2020
AcademyHealth

Victor P. Raymond Memorial Fund Award 2019
Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health

Delta Omega Policy and Practice Scholarship Award 2019
Johns Hopkins Bloomberg School of Public Health

Out to Innovate Award 2019
National Organization of Gay & Lesbian Scientists and Technical Professionals

Distinguished Service Award 2019
10.10.10 Cities: Health

Science Writing Fellowship 2019
Johns Hopkins Bloomberg School of Public Health

Gordis Teaching Fellowship 2018
Public Health Studies Program, Johns Hopkins University

Health Policy Research Scholarship 2017
Robert Wood Johnson Foundation
Health Policy Research Scholars is a national leadership program that invests in scholars from populations traditionally underrepresented in graduate programs whose work will inform and influence policy for building a Culture of Health

Featured Speaker 2017
National March for Science (Washington, DC)

Centennial Scholarship 2016
Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health
Awarded to the outstanding entering doctoral student in each department to mark the school's centennial in 2016

Achievement Award 2015
GLMA: Health Professionals Advancing LGBT Equality

Andrew Cray Memorial Transgender Health Advocacy Award 2015
National Center for Transgender Equality

LGBTQ Leadership Fellowship 2011-2012
The Rockwood Institute

Delta Omega Public Health Honors Society 2010
George Washington University School of Public Health and Health Sciences

Eric Rofes Memorial Scholarship 2009
National Gay & Lesbian Task Force

High Honors 2004
Swarthmore College Honors Program

PUBLICATIONS

Journal Articles (Peer-Reviewed)

Baker KE, Restar A. (2022). Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. *J Law Med Ethics, 50*, 456–470.

Baker KE, Compton D, Fechter-Leggett ED, Grasso C, Kronk CA. (2022). Will clinical standards not be part of the choir? Harmonization between the HL7 gender harmony project model and the NASEM measuring sex, gender identity, and sexual orientation report in the United States. *JAMIA*, *30*(1), 83–93.

Restar A, Dusic E, Garrison-Desany H, Lett E, Everhart A, **Baker KE**, Scheim A, Beckham SW, Reisner S, Rose A, Mimiaga M, Radix A, Operario D, Hughto J. (2022) Gender Affirming Hormone Therapy Dosing Behaviors among Transgender and Nonbinary Adults. *Humanit Soc Sci Commun, 9*(304).

Tran NK, **Baker KE**, Lett E, Scheim AI. (2022). State-level heterogeneity in associations between structural stigma and individual healthcare access: A multilevel analysis of transgender adults in the United States. *J Health Serv Res Policy*. doi:10.1177/13558196221123413.

Scheim AI, **Baker KE**, Restar AJ, Sell RL. (2021). Health and Health Care Among Transgender Adults in the United States. *Annual Review of Public Health*. doi:10.1146/annurev-publhealth-052620-100313

Restar A, Garrison-Desany HM, **Baker KE**, Adamson T, Howell S, Baral SD, Operario D, Beckham W. (2021). Prevalence and associations of COVID-19 testing in an online sample of transgender and non-binary individuals. *British Medical Journal - Global Health*, *6*, e006808.

Baker KE, Durso LE, Streed CG. (2021). Ensuring that LGBTQI+ People Count: Collecting Data on Sexual Orientation, Gender Identity, and Intersex Status. *New England J Med, 384*, 1184–1186.

Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. (2021). Hormone Therapy, Mental Health, and Quality of Life among Transgender People: A Systematic Review. *J Endocr Soc, 5*(4), bvab001.

Wiegmann AL, Young EI, **Baker KE**, Khalid SI, Shenaq DS, Dorafshar AH, Schechter LS. (2021). The Affordable Care Act and Its Impact on Plastic and Gender-Affirmation Surgery. *Plastic Reconstr Surg*, *147*(1), 135e–153e.

Baker KE, Harris AC. (2020). Terminology should accurately reflect complexities of sexual orientation and identity. *Am J Public Health, 110*(11), 1668–1669.

Lett E, Dowshen NL, **Baker KE**. (2020). Intersectionality and Health Inequities for Gender Minority Blacks in the U.S. *Am J Prev Med*, *59*(5), 639–647.

Wilson LM, **Baker KE**, Sharma R, Dukhanin V, McArthur K, Robinson KA. (2020). Effects of antiandrogens on prolactin levels among transgender women on estrogen therapy: A systematic review. *Int J Transgend Health*, *21*(4), 391–402.

Baker KE. (2019). Findings from the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life among U.S. Transgender Adults, 2014-2017. *JAMA Intern Med, 179*(8), 1141–1144.

Tabaac AR, Sutter ME, Wall CSJ, **Baker KE**. (2018). Gender Identity Disparities in Cancer Screening. *Am J Prev Med, 54*(3), 385–393.

Baker KE. (2017). The Future of Transgender Coverage. *New England J Med, 376*(19), 1801–1804.

Padula WV, **Baker KE**. (2017). Coverage for Gender Affirmation: Making Health Insurance Work for Transgender Americans. *LGBT Health, 4*(4), 244–247.

Cahill S, **Baker KE**, Deutsch MB, Keatley J, Makadon HJ. (2016). Inclusion of Sexual Orientation and Gender Identity in Stage 3 Meaningful Use Guidelines: A Huge Step Forward for LGBT Health. *LGBT Health, 3*(2), 100–102.

Reisner SL, Conron KJ, Scout Nfn, **Baker KE**, et al. (2015). Counting transgender and gender nonconforming adults in health research: Recommendations from the Gender Identity in U.S. Surveillance (GenIUSS) Group. *Transgender Studies Quarterly, 2*(1), 34–57.

Cahill S, Singal R, Grasso C, King D, Mayer K, **Baker KE**, Makadon H. (2014). Do ask, do tell: High levels of acceptability by patients of routine collection of sexual orientation and gender identity data in four diverse American community health centers. *PLoS ONE, 9*(9), e107104.

Baker KE, Minter S, Wertz K. (2012). Nondiscrimination in Insurance: The Case of California's Insurance Gender Nondiscrimination Act. *Harvard University LGBTQ Policy Journal, 2*.

Baker KE. (2012). Where Do We Go from Here: LGBT-Inclusive Health Policy in Affordable Care Act Implementation. *Harvard University LGBTQ Policy Journal,* 2.

Baker KE, Krehely J. (2011). How Health Care Reform Will Help LGBT Elders. *Public Policy & Aging Report, 21*(3), 19–23.

Book Chapters

Baker KE. (2019). The Politics of LGBT Health. In: Schneider JS and V Silenzio, eds. *Gay & Lesbian Medical Association Handbook on LGBT Health*. Washington, DC: ABC-CLIO Press.

Bau I and **Baker KE**. (2016). Legal and Policy Issues in LGBTI Health. In: Ehrenfeld J and K Eckstrand, eds. *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Nashville: Vanderbilt University Press.

Baker KE. (2011). Data Collection and Use. In: The Joint Commission. *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide*. Oakbrook Terrace, IL: The Joint Commission. Available at: www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf

Reports, Issue Briefs, Articles, and Editorials

Organizing Committee for Assessing Meaningful Community Engagement in Health & Health Care Programs & Policies. (2022). Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health. *NAM Perspectives*. Commentary, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/202202c

Frank NF, **Baker KE**. (2019). Anti-LGBT Discrimination Has a Huge Human Toll. Research Proves It. *Washington Post*. Available at: www.washingtonpost.com/outlook/2019/12/19/anti-lgbt-discrimination-has-huge-human-toll-research-proves-it/

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What We Know Project. (2018). What Does the Scholarly Research Say About the Effect of Gender Transition on Transgender Wellbeing? Cornell University Center for the Study of Inequality. Available at: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/

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Baker KE. (2017). Trans People in the Health Reform Fight: What's at Stake. *TheBody.com*. Available at: www.thebody.com/content/80046/trans-people-in-the-health-reform-fight-whats-at-s.html

Calsyn M, **Baker KE**, Spiro T. (2017). For the Insurance Lobby, Old Habits Are Hard to Break. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/healthcare/news/2017/02/15/415237/for-the-insurance-lobby-old-habits-are-hard-to-break/

Baker KE, Durso LE. (2017). Why Repealing the Affordable Care Act Is Bad Medicine for LGBT Communities. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2017/03/22/428970/repealing-affordable-care-act-bad-medicine-lgbt-communities/

Baker KE, Singh S, Mirza SA, Durso LE. (2017). The Senate Health Care Bill Would Be Devastating for LGBTQ People. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2017/07/06/435452/senate-health-care-bill-devastating-lgbtq-people/

Baker KE. (2016). LGBT Protections in Affordable Care Act Section 1557. *Health Affairs Blog*. Available at: http://healthaffairs.org/blog/2016/06/06/lgbt-protections-in-affordable-care-act-section-1557

Baker KE, McGovern A, Gruberg S, Cray A. (2016). The Medicaid Program and LGBT Communities: Overview and Policy Recommendations. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2016/08/09/142424/the-medicaid-program-and-lgbt-communities-overview-and-policy-recommendations/

Mirza SA, **Baker KE**. (2016). The Impact of the Affordable Care Act on LGBTQ Youth Experiencing Homelessness. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/reports/2016/08/31/143226/the-impact-of-the-affordable-care-act-on-lgbtq-youth-experiencing-homelessness/

Baker KE, Durso LE, Ridings AM. (2016). How to Collect Data about LGBT Communities. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2016/03/15/133223/how-to-collect-data-about-lgbt-communities/

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Baker KE. (2015). Open Doors for All: Sexual Orientation and Gender Identity Protections in Health Care. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/

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Out2Enroll. (2014). Key Lessons for LGBT Outreach and Enrollment. Washington, DC: Out2Enroll. Available at: https://out2enroll.org/out2enroll/wp-content/uploads/2014/07/O2E_KeyLessons_FINAL.pdf

The Fenway Institute, Center for American Progress, GLMA: Health Professionals Advancing LGBT Equality, Human Rights Campaign. (2014). The Case for Designating LGBT People as a Medically Underserved Population and as a Health Professional Shortage Area Population Group. Boston, MA: The Fenway Institute. Available at: www.fenwayhealth.org/documents/the-fenway-institute/policy-briefs/MUP_HPSA-Brief_v11-FINAL-081914.pdf

Baker KE. (2014). 12 Holiday Reasons to Be #Out2Enroll and #GetCovered. *Huffington Post*. Available at: www.huffingtonpost.com/entry/12-holiday-reasons-to-be-_b_6330590.html

Baker KE. (2013). Transforming Health: International Rights-Based Advocacy for Transgender Health. New York: Open Society Foundations. Available at: www.opensocietyfoundations.org/sites/default/files/transforming-health-20130213.pdf

Durso LE, **Baker KE**, Cray A. (2013). LGBT Communities and the Affordable Care Act: Findings from a National Survey. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbtq-rights/reports/2013/10/10/76693/lgbt-communities-and-the-affordable-care-act/

Cahill SR, Makadon HM, **Baker KE**, Keatley J. (2013). End LGBT Invisibility in Health Care Now: Do Ask, Do Tell. *Huffington Post*. Available at: www.huffingtonpost.com/entry/lgbt-health-care_b_2744388.html

Baker KE, Cray A. (2013). Why Gender Identity Nondiscrimination in Insurance Makes Sense. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2013/05/02/62214/why-gender-identity-nondiscrimination-in-insurance-makes-sense/

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Baker KE, Frost C. (2013). Addressing Gay and Transgender and HIV/AIDS Issues in Health Care Reform. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2013/03/22/57845/addressing-gay-and-transgender-and-hivaids-issues-in-health-care-reform/

Durso LE, **Baker KE**, Cray A. (2013). Affordable Care Act Outreach: Targeted Communication Strategies for LGBT Communities. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2013/11/22/79762/affordable-care-act-outreach-targeted-communication-strategies-for-lgbt-communities/

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Greenesmith H, Cray A, **Baker KE**. (2013). The Affordable Care Act and LGBT Families: Everything You Need to Know. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2013/05/23/64225/the-affordable-care-act-and-lgbt-families-everything-you-need-to-know/

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Baker KE, Cray A. (2012). Collecting Sexual Orientation and Gender Identity Data. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2012/10/16/41620/faq-collecting-sexual-orientation-and-gender-identity-data/

Cray A, **Baker KE**. (2012). Health Insurance Needs for Transgender Americans. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2012/10/03/40334/faq-health-insurance-needs-for-transgender-americans/

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Baker KE, Cray A. (2012). Ensuring Benefits Parity and Gender Identity Nondiscrimination in Essential Health Benefits. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/report/2012/11/15/44948/ensuring-benefits-parity-and-gender-identity-nondiscrimination-in-essential-health-benefits/

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Baker KE. (2011). Winning a Healthier Future: LGBT Communities in the Health Equity and Accountability Act. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2011/09/29/10361/winning-a-healthier-future/

Baker KE, Krehely J. (2011). Changing the Game: What Health Care Reform Means for Gay, Lesbian, Bisexual, and Transgender Americans. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/wp-content/uploads/issues/2011/03/pdf/aca_lgbt.pdf

Baker KE, Britt Z. (2011). Super Committee Cuts Could Lead to Worse Health for Gay and Transgender Americans. Washington, DC: Center for American Progress. Available at: www.americanprogress.org/issues/lgbt/news/2011/11/18/10592/super-committee-cuts-could-lead-to-worse-health-for-gay-and-transgender-americans/

National Coalition for LGBT Health and Sexuality Information and Education Council of the United States. (2010). Report on the United States of America. United Nations Universal Periodic Review on Sexual Rights, 9th Round. Available at: https://lib.ohchr.org/HRBodies/UPR/Documents/session9/US/JS10_JointSubmission10.pdf

Baker KE, Bower L, Lake S. (2010). Security, Development, and Sexual and Gender-Based Violence in Ndélé, Central African Republic. Washington, DC: The Elliott School of International Affairs. Available at: https://elliott.gwu.edu/sites/elliott.gwu.edu/files/downloads/acad/ids/ndele-car.pdf

GRANT SUPPORT

DC Center for AIDS Research 2022-2023
Developing Best Practices for Integrating HIV Prevention into Gender-Affirming Care for Transgender Adults
Amount: $49,961
Role: Principal Investigator

Wellspring Advisors 2015-2017
Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign
Amount: $200,000
Role: Project Co-Director

Robert Wood Johnson Foundation 2015-2016
Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign
Amount: $199,472
Role: Project Co-Director

Robert Wood Johnson Foundation 2014-2015
Building the Out2Enroll online enrollment assistance tool
Amount: $148,800
Role: Project Co-Director

Wellspring Advisors 2014-2015
Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign
Amount: $100,000
Role: Project Co-Director

Arcus Foundation 2014-2015
Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign
Amount: $100,000
Role: Project Co-Director

Robert Wood Johnson Foundation 2014-2015
Establishing the "Do Ask, Do Tell" project
Amount: $84,000
Role: Co-Principal Investigator

Wellspring Advisors 2013-2016
Impact of the Affordable Care Act on LGBT Communities
Amount: $600,000
Role: Co-Principal Investigator

Palette Fund 2013-2014
Launching the Out2Enroll campaign
Amount: $10,000
Role: Project Co-Director

Nathan Cummings Foundation 2013-2014
Launching the Out2Enroll campaign
Amount: $10,000
Role: Project Co-Director

Open Society Foundations 2013-2014
Transgender Medical Policy Reform in Russia and the Former Soviet Union
Amount: $88,000
Role: Co-Principal Investigator

Elliott School of International Affairs 2010
Investigating sexual- and gender-based violence in conflict situations
Amount: $10,000
Role: Co-Principal Investigator

TEACHING

Classes Taught

Issues in LGBTQ Health Policy Fall 2021, Fall 2022
Johns Hopkins School of Public Health (Baltimore, MD)

Policy, Politics, and Power in Health Equity Fall 2019, Spring 2020
Johns Hopkins University (Baltimore, MD)
Upper-division undergraduate seminar designed and taught through the Gordis Teaching Fellowship

Guest Lectures

Sexuality, Gender Identity, & The Law 02/2022
American University Washington College of Law (Washington, DC)

Epidemiology of LGBTQIA Health 02/2022
George Washington University (Washington, DC)

O'Neill Institute for National and Global Health Law Colloquium 11/2021
Georgetown Law Center (Washington, DC)

Health Equity Policy 10/2021
Georgetown University (Washington, DC)

Social Epidemiology 10/2021
Temple University College of Public Health (Philadelphia, PA)

Advanced Topics in Health Promotion and Behavioral Sciences 04/2021
University of Louisville (Louisville, KY)

LGBT Health Law and Policy 03/2021
Georgetown Law School (Washington, DC)

Health Policy and Advocacy 02/2021
SUNY Upstate Medical College (Syracuse, NY)

Issues in LGBTQ Health Policy 12/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Epidemiology of LGBT Health 11/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Issues in LGBTQ Health Policy 11/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBTQ Politics and Policy 10/2020
American University (Washington, DC)

Research Ethics and Integrity 03/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBT Health Policy 03/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBT Health Law and Policy 02/2020
Georgetown Law School (Washington, DC)

LGBT Health Policy 02/2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Epidemiology of LGBT Health 12/2019
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Economic Evaluation II 12/2018
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Epidemiology of LGBT Health 12/2018
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Public Health Policy 11/2018
SUNY Upstate Medical College (Syracuse, NY)

LGBTQI Health: Research, Policies, and Best Practices 05/2018
Mt. Sinai Icahn School of Medicine (New York, NY)

Epidemiology of LGBT Health 12/2017
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBTQ Issues in Public Policy 11/2017
New York University Wagner School of Public Service (New York, NY)

Health Policy and Public Health 10/2017
Baldwin Wallace University (Berea, OH)

LGBT Health Law and Policy 09/2017
Georgetown Law School (Washington, DC)

Epidemiology of LGBT Health 12/2016
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBT Health Policy and Practice Graduate Certificate Program 01/2016
George Washington University (Washington, DC)

Epidemiology of LGBT Health 12/2015
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

LGBT Health Policy and Practice Graduate Certificate Program 01/2015
George Washington University (Washington, DC)

Health Policy and Public Health 10/2014
Baldwin Wallace University (Berea, OH)

Teaching Assistant Positions

Teaching Assistant, Department of Health Policy and Management 2017-2020
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

- Economic Evaluation I and II
- Health Economics for Managers

- Fundamentals of Health Policy and Management
- Introduction to Bioethics in Public Health Practice and Research
- Research Ethics and Integrity: U.S. and International Issues
- Science of Patient Safety
- The Political Economy of Social Inequalities and Its Consequences for Health and Quality of Life

MPH Capstone Teaching Assistant 2019
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)

Teaching Assistant, Pfizer Executive Program in Economic Evaluation 2018
University of Chicago (New York, NY)

Trainings

"Reaching and Assisting LGBT Communities" – in-person and online training developed for Out2Enroll and presented to Health Insurance Marketplace Navigators and other enrollment assisters

Arkansans for Coverage	12/2015
Alaska Primary Care Association	11/2015
Cognosante, Cleveland, OH	11/2015
Cognosante, Miami, FL	11/2015
Cognosante, Philadelphia, PA	11/2015
Enroll Virginia Coalition	11/2015
Council on Aging of Buncombe County, Asheville, NC	11/2015
Navigators for a Healthy Louisiana, Shreveport, LA	10/2015
Navigators for a Healthy Louisiana, Baton Rouge, LA	10/2015
Navigators for a Healthy Louisiana, New Orleans, LA	10/2015
Covered California University, Sacramento, CA	09/2015
HealthCare.gov	09/2015
Nebraska Primary Care Association	08/2015
Michigan Primary Care Association	08/2015
Florida Association of Community Health Centers	07/2015
Get Covered Arkansas Coalition, Little Rock, AR	06/2015
Kentuckiana Regional Planning and Development Agency, Louisville, KY	05/2015
Kentucky Primary Care Association, Hazard, KY	05/2015
Cognosante, Cleveland, OH	01/2015
Cognosante, Philadelphia, PA	01/2015
Utah Health Policy Project, Salt Lake City, UT	12/2014
Cognosante, New Orleans, LA	12/2014
Cognosante, Miami, FL	11/2014
Planned Parenthood Federation of America	10/2014
United Way Worldwide	10/2014
Nebraska Primary Care Association	07/2014
HealthCare.gov	07/2014

"Opening the Door: Assisting LGBT People"

U.S. Department of Health and Human Services Office for Civil Rights Region IV Office, Atlanta, GA	10/2015
U.S. Department of Health and Human Services Office for Civil Rights Region II Office, New York, NY	10/2015

U.S. Department of Health and Human Services Office for Civil Rights Region VIII Office, Denver, CO 10/2015
U.S. Department of Health and Human Services Office for Civil Rights Region IX Office, San Francisco, CA 09/2015
U.S. Department of Health and Human Services Office for Civil Rights Region III Office, Philadelphia, PA 08/2015
U.S. Department of Health and Human Services Office for Civil Rights Region I Office, Boston, MA 06/2015
U.S. Department of Health and Human Services Office for Civil Rights Region VI Office, Dallas, TX 05/2015

PRESENTATIONS

Oral Abstracts and Issue Panels

Baker, KE, Segal J. Clinically Documented Social Risk Factors and Mental and Behavioral Health Diagnoses in a Commercially Insured Transgender Population. American Public Health Association Conference (online) 10/2021

Wolfson D, **Baker KE**, Platt J, Fields C, Ramiah K. Rebuilding Trust in Health Care: What We Know and What We Need to Know. AcademyHealth Annual Research Meeting (online) 06/2021

Baker KE, Badgett MVL, Gates G, Patterson C, Russell S, Umberson D, White J. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. Population Association of America Annual Meeting (online) 05/2021

Baker KE, Russell S. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. American Educational Research Association Annual Meeting (online) 04/2021

Terndrup CP, Siegel J, Streed C, Ufomata E, **Baker KE**. Transforming General Internal Medicine for Improved LGBTQ Healthcare: Strategies from the Bedside to the Legislature. Society for General Internal Medicine Annual Meeting (online) 04/2021

Hedian H, Terndrup CP, Siegel J, McNamara M, **Baker KE**. Teaching about Transgender Health: How to Navigate Challenging Small Group Discussions. Society for General Internal Medicine Meeting (online) 04/2021

Baker KE, Reisner SL, Dalke K, Harris AC. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. National Health Policy Conference (online) 02/2021

Badgett MVL, Flores AR, Dibner K, **Baker KE**. Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report. Association for Public Policy Analysis and Management Conference (online) 11/2020

Baker KE, Russell S, Reisner SL, Dalke K, Harris AC. Violence and the Well-Being of LGBTQI+ People: A Role for Public Health. American Public Health Association Conference (online) 10/2020

Baker KE. Leveraging the Behavioral Risk Factor Surveillance System for Transgender Health Research. American Public Health Association Conference, Philadelphia, PA 11/2019

Baker KE. Cracking the Code: Using Machine Learning to Identify Transgender People in Medical Claims Data. American Public Health Association Conference, Philadelphia, PA 11/2019

Pardo S, **Baker KE**, Wilkinson W. Advancing Sexual Orientation and Gender Identity Cultural Humility in Public Health Care: Policy, Research, and Practice Strategies. National Trans Health Summit, Oakland, CA 04/2019

Gorton N, **Baker KE**, Tescher J, Jaffe JM. Transgender Health Insurance Reform. World Professional Association for Transgender Health Inaugural USPATH Scientific Conference, Los Angeles, CA 01/2017

Baker KE, Cahill SR. Sexual Orientation and Gender Identity Data in EHRs. Critical Conversation, America's Essential Hospitals VITAL 2016 Conference, Boston, MA 06/2016

Baker KE. Role of Public Health Policy in Gender Affirmation and Health Equity for Trans/Gender-Variant People in the U.S. American Public Health Association Conference, Chicago, IL 11/2015

Baker KE. Do Ask, Do Tell: Collecting and Using LGBT Data. AcademyHealth Annual Research Meeting, San Diego, CA 04/2014

Allensworth-Davies D, Badgett MVL, **Baker KE**, Bean-Mayberry B, Bowleg L, Mattocks K. The Role of Health Services Research and Policy in Addressing the Health and Health Care Needs of LGBT Individuals. AcademyHealth Annual Research Meeting, Baltimore, MD 06/2013

Cain VS, Miller KS, **Baker KE**, Pearlman AJ. Understanding LGBT Health: Overview, Methodological Challenges, and Policy Implications. National Conference on Health Statistics, Washington, DC — 08/2012

Baker KE. Not Waving, But Drowning? Barriers and Challenges in Access to Sexual Health Services for MSM. Centers for Disease Control and Prevention National STD Conference, Minneapolis, MN — 03/2012

Baker KE. LGBT Health as a Tool for Social Justice. American Public Health Association Conference, Denver, CO — 11/2010

Poster Abstracts

Hindorff L, Madden E, Jackson A, Akintobi T, **Baker KE**, et al. (2022). Advancing Health Equity in Genomics: Reflections and Recommendations for Future Research Directions from an NHGRI Workshop. American Society of Human Genetics, Los Angeles, CA — 10/2022

Baker KE, Segal J. Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. AcademyHealth Annual Research Meeting (online) — 06/2021

Kasaie P, Weir B, Dowdy D, **Baker KE**, Holmes L, Labossiere S, Beyrer C. Mobile Multi-Disease Screening at Scale: Modelling the Effects in Kenya, Nigeria, and India. 22nd International AIDS Conference, Amsterdam, Netherlands — 07/2018

Baker KE, Chidambaram P, Colrick I, Padula WV. Implications of Health Insurance Coverage for Care Related to Gender Transition for Transgender Adolescents. Society for Medical Decision Making Annual Meeting, Pittsburgh, PA — 10/2017

Fox RF, **Baker KE**. LGBT Inclusion in Health Care Reform. American Public Health Association Conference, Philadelphia, PA — 11/2009

Interviews and Recordings

"Dr. Kellan Baker and Health Equity for the LGBTQ+ Community," Inside Health Care #79, National Committee on Quality Assurance. Available at: https://www.ncqa.org/blog/inside-health-care-79-dr-kellan-baker-health-equity-for-the-lgbt-community/ — 05/2022

"Patient Story: Kellan Baker," American Board of Internal Medicine Foundation Forum. Available at: https://abimfoundation.org/video/patient-story-kellan-baker — 10/2021

"Core to Who I Am," *Tradeoffs* Podcast, University of Pennsylvania. Available at: https://tradeoffs.org/2020/07/14/core-to-who-i-am/ — 07/2020

"A Conversation with Kellan Baker," Health Policy Research Scholars. Available at: www.youtube.com/watch?v=trLC992Q7bc — 09/2019

"Meet the Scholars: Kellan Baker," Health Policy Research Scholars. Available at: https://healthpolicyresearch-scholars.org/meet-the-scholars-kellan-baker/ — 06/2019

"Transgender Health Care Access and Policy," HealthLink on Air, SUNY Upstate Medical University. Available at: www.upstate.edu/hloa/2018/1127-transgender-people-face-health-care-challenges-of-both-access-and-policy.php — 11/2018

"The Future of Transgender Coverage," *New England Journal of Medicine*. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp1702427 — 05/2017

National March for Science Speech, Washington, DC. Available at: https://www.youtube.com/watch?v=Qin3q4dp7DQ — 04/2017

"A New Era of Inclusion: How to Address LGBT and HIV/AIDS Issues in Health Reform Implementation," Center for American Progress. Available at: www.c-span.org/video/?311574-1/lgbt-health-advocates-examine-afforable-care-act — 03/2013

"Queery: Kellan Baker." *Washington Blade*. Available at: www.washingtonblade.com/2010/05/20/queery-kellan-baker/ — 05/2010

Testimony

Hearing on Trans Health Equity Act of 2022 (House Bill 746), Public Health and Minority Health Disparities Subcommittee, Health and Government Operations Committee, Maryland General Assembly	03/2022
Hearing on Trans Health Equity Act of 2022 (House Bill 746), Health and Government Operations Committee, Maryland General Assembly	03/2022
Hearing on Trans Health Equity Act of 2022 (Senate Bill 682), Senate Finance Committee, Maryland State Senate	03/2022
DC Health Benefit Exchange Authority Performance Oversight Hearing, Committee on Health and Human Services, Council of the District of Columbia	02/2016

Invited Lectures, Presentations, Keynotes, and Plenaries

Public Health and Health Systems Policy for Federal Policymakers

"Addressing Structural Factors Needed to Support Health Equity Research," Future Directions in Genomics and Health Equity Research Workshop, National Human Genome Research Institute (online)	03/2022
"Collecting Sex, Gender Identity, and Sexual Orientation Data: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," White House Office of Personnel Management (online)	03/2022
"Sexual and Gender Minority Health: Evidence and Recommendations," Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," U.S. Department of Justice (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," Civil Rights Division, U.S. Department of Justice (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," National Institutes of Health Bioethics Interest Group (online)	02/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," National Institutes of Health Committee on Sexual and Gender Minority Research (online)	12/2020
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," Federal Committee on Statistical Methodology (online)	12/2020
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," U.S. Department of Health and Human Services LGBT Coordinating Committee (online)	11/2020
"Access to Care for the LGBT Community," Centers for Disease Control and Prevention National STD Conference (online)	09/2020
"LGBT Populations in Cancer Clinical Trials," U.S. Food and Drug Administration (online)	06/2020
"LGBT Issues in Public Health and Genomics," National Human Genome Research Institute (online)	06/2020
Health Equity and Accountability Act Congressional Briefing, Washington, DC	04/2018
"LGBT Communities in Genomics Research and Outreach," National Institutes of Health, Bethesda, MD	03/2018
"LGBT Federal Health Policy," White House LGBT Summit, Dearborn, MI	04/2016
"Two-Spirit and Native LGBT Communities," Indian Health Service (online)	12/2015
"Enrollment Resources for LGBTQ Youth," Centers for Medicare & Medicaid Services (online)	12/2015
"Transgender Issues in Federal Policy," Health Resources and Services Administration Special Projects of National Significance Meeting, Washington, DC	10/2015
"LGBT Data Collection," White House LGBT Summit, St. Louis, MO	10/2015
"New Frontiers in Health Disparities: Medicare and Medicaid in a Post-*Heckler* World," Centers for Medicare & Medicaid Services Health Equity Conference, Baltimore, MD	09/2015

"LGBT Outreach and Enrollment under the Affordable Care Act," The White House, Washington, DC	07/2014
Health Equity and Accountability Act Congressional Briefing, Washington, DC	07/2014
"The ACA and LGBT Individuals: Delivering Culturally Competent Quality Care in Clinical Settings," Health Resources and Services Administration, Washington, DC	05/2014
"The Out2Enroll Initiative and LGBT Priorities in Health Reform," The White House, Washington, DC	09/2013
"What Health Reform Means for LGBT Communities," U.S. Government Accountability Office, Washington, DC	06/2013
"Policy Approaches for Addressing Transgender Health Disparities," Presidential Advisory Council on HIV/AIDS, Washington, DC	02/2013
"LGBT Health Policy," White House Summit on LGBT Health, Philadelphia, PA	02/2012
"Sexual Orientation and Gender Identity Data Collection in the Youth Risk Behavior Surveillance System," Federal LGBT Youth Summit, Washington, DC	06/2011
"If You Don't Count Us, We Don't Count: Using Data for Advocacy," Federal LGBT Youth Summit, Washington, DC	06/2011

Health Disparities Research and Policy

Measuring Sex, Gender Identity, and Sexual Orientation," Sexual and Gender Minority Interest Group, National Cancer Institute Cohort Consortium (online)	03/2022
"Measuring Sex, Gender Identity, and Sexual Orientation," Sexual and Gender Minority Task Force, American Society of Clinical Oncology (online)	03/2022
"Health Policy for Transgender and Gender-Diverse Youth," Policy & Issues Forum, National Association of Community Health Centers (online)	02/2022
"End Stigma, End HIV: World AIDS Day 2021," Smithsonian Natural History Museum (online)	12/2021
"The State of Trans Men and Transmasculine Community," Brothers Obtaining and Navigating Dynamic Solidarity (online)	11/2021
"The Impact of COVID-19 on Trans Men and Transmasculine Communities," Brothers Obtaining and Navigating Dynamic Solidarity (online)	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Medical Association LGBTQ Committee (online)	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Medical Association LGBTQ and Allies Caucus	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," University of Minnesota Ethics Grand Rounds (online)	10/2021
Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," LGBTQIA Health Conference (online)	10/2021
"The Health of Sexual and Gender Diverse Populations: Addressing Inequities at the Intersections," National Academies of Sciences, Engineering, and Medicine (online)	07/2021
"LGBTQI+ Communities in the COVID-19 Pandemic," National Academies of Sciences, Engineering, and Medicine (online)	06/2021
"Advancing the Well-Being of LGBTQI+ Populations," Hauser Policy Fund Webinar Series, National Academies of Sciences, Engineering, and Medicine (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Educational Research Association Presidential Session (online)	04/2021
"2021 Opportunities for Strengthening HIV Programs and Improving Health Equity," O'Neill Institute at Georgetown School of Law (online)	02/2021
"LGBT Health Research and Policy," LGBT Litigators Roundtable (online)	12/2020
"Cancer in LGBT Populations: Differences, Disparities, and Strategies for Change," American Association for Cancer Research Conference (online)	10/2020

"Transgender Patient Narratives," American Board of Internal Medicine Foundation Forum (online)	08/2020
"Influencing LGBT Health Policy," Columbia University Program for the Study of LGBT Health (online)	07/2020
"Challenges and Barriers in Closing the Evidence Gap for Underrepresented and Vulnerable Populations in Clinical Research," Conquer Cancer Council Meeting, Alexandria, VA	12/2019
"Public Health Issues Before the U.S. Supreme Court: LGBT Rights, Reproductive Rights, and Firearms," Johns Hopkins School of Public Health, Baltimore, MD	11/2019
"How Patients' Identities Impact Trust," National Patient Advocate Foundation Policy Consortium, Washington, DC	11/2019
"Federal LGBTQ Health Policy in the Trump Administration," US Professional Association for Transgender Health, Washington, DC	09/2019
"Barriers and Solutions to Access to Genomic Medicine: Realizing the Benefits of Genomic Medicine for All," National Patient Advocate Foundation Policy Consortium, Washington, DC	05/2019
"Challenges and Opportunities in Trans Health Policy," SUNY Upstate Medical College, Syracuse, NY	11/2018
"Challenges and Opportunities in Advancing Federal LGBTQ Health Policy in the Trump Administration," GLMA: Health Professionals Advancing LGBT Equality Conference, Las Vegas, NV	10/2018
"Together Ahead: Accelerating Progress to End HIV," US Conference on AIDS, Orlando, FL	09/2018
"Research Ethics and Policy Intersections," National Transgender Health Summit, Oakland, CA	11/2017
"SOGI Data Collection," National Transgender Health Summit, Oakland, CA	11/2017
"United States of Trans Health Policy," National Transgender Health Summit, Oakland, CA	11/2017
"Ethical Issues in the Care of LGBTQ Youth and Families," American Academy of Pediatrics National Conference, Chicago, IL	10/2017
"Rollback of Protections Impacting the Quality of Hospice and Palliative Care for LGBTQ Patients and Families," GLMA: Health Professionals Advancing LGBT Equality Conference, Philadelphia, PA	10/2017
"The Assault on Federal LGBT Health Policy in the Trump Administration," GLMA: Health Professionals Advancing LGBT Equality Conference, Philadelphia, PA	10/2017
"Sexual Orientation and Gender Identity Data Collection," National Alliance of State and Territorial AIDS Directors National Prevention and Care Technical Assistance Meeting, Arlington, VA	07/2017
"Health Privacy in the LGBTQIA Community, Electronic Health Records Systems and Sensitive Data," Health Privacy Summit, Washington, DC	06/2017
"LGBTQ Health Policy Update," Health Action, Washington, DC	02/2017
"Transgender Health Policy and Research Ethics," World Professional Association for Transgender Health Inaugural USPATH Scientific Conference, Los Angeles, CA	01/2017
"Deep Dive: What the Affordable Care Act Means for LGBT People," The Fenway Institute (online)	07/2016
"LGBT Outreach and Enrollment: New Developments," Cognosante National Training, Phoenix, AZ	07/2016
"LGBT Health under the Affordable Care Act," Equality Federation Leadership Conference, Portland, OR	07/2016
"Times of Change: The Latest Dynamics in LGBT Outreach, Enrollment, and Coverage," Enroll America National Conference, Washington, DC	05/2016
"Beyond HIV/AIDS: Reporting on the LGBT Community," American Health Journalists Association Conference, Cleveland, OH	04/2016
"SOGI Data Collection and LGBT Health," National Association of State and Territorial AIDS Directions Midwestern Regional Meeting, Detroit, MI	04/2016
"Cultural Competency and the ACA: Maximizing Outreach," American Federation of Teachers Professional Issues Conference, Washington, DC	04/2016
"LGBT Health Policy: Current Landscape and Latest News," The Fenway Institute (online)	03/2016
"Cutting Edge Issues in LGBT Health Research and Policy," Johns Hopkins Bloomberg School of Public Health LGBT Public Health Research Day, Baltimore, MD	03/2016

"Affirmatively Transgender: The Role of Law and Policy," O'Neill Institute Colloquium at Georgetown Law School, Washington, DC	09/2015
"Transgender Health Insurance Policy," Stanley Biber Memorial Lecture, GLMA: Health Professionals Advancing LGBT Equality Conference, Portland, OR	09/2015
"Transgender Health Insurance Coverage," Pride at Work Conference, Orlando, FL	08/2015
"Effective LGBT Outreach," Cognosante National Training, Baltimore, MD	07/2015
"Culturally Competent Outreach and Enrollment Assistance," Enroll America State of Enrollment Conference, Washington, DC	06/2015
"What LGBT Communities Need to Know about the Affordable Care Act," Equal Care for Equal Lives LGBT Health Summit, Little Rock, AR	06/2015
"LGBT Outreach and Enrollment," Southern Health Partners Meeting, Atlanta, GA	06/2015
"Healthcare Hallelujah: Trans Health and the ACA," Black Trans Advocacy Conference, Dallas, TX	05/2015
"Transgender Health Issues," Rutgers University Law School, Newark, NJ	04/2015
"Data Collection to Advance Transgender Health," National Transgender Health Summit, Oakland, CA	04/2015
"Winning Access to Trans Health Coverage and Care," National Transgender Health Summit, Oakland, CA	04/2015
"The ACA and LGBT Communities," EverThrive Illinois	03/2015
"Using Data to Advance Public Policy," Creating Change Conference, Denver, CO	02/2015
"Top Issues in LGBT Health Policy," Harvard School of Public Health LGBTQ Conference, Boston, MA	02/2015
"LGBT Health Disparities," Thomson Reuters, New York, NY	01/2015
"Update on LGBTQ People of Color: Focus on Transgender Health," Health Action, Washington, DC	01/2015
"LGBT Enrollment Challenges," Get Covered Illinois LGBT Marketing Campaign Launch, Chicago, IL	01/2015
"LGBT Health: Challenges and Opportunities," Diversity, Inc. Healthcare Event, New York, NY	10/2014
"LGBT People in Health System Transformation," Consumer Voices for Coverage, Philadelphia, PA	09/2014
"LGBTI Health Policy," LGBTI Health Research Conference, Cleveland, OH	08/2014
"LGBT Health Disparities and ACA Enrollment," Cognosante National Meeting, Baltimore, MD	07/2014
"Do Ask, Do Tell: LGBT Data Collection in Electronic Health Records," The Center for LGBTQ Studies at the City University of New York Graduate Center, New York, NY	06/2014
"Understanding LGBT Health," University of Pennsylvania, Philadelphia, PA	04/2014
"Introduction to Transgender Healthcare," Medical College of Wisconsin, Milwaukee, WI	04/2014
"The Affordable Care Act: Implications for Trans Consumers," FORGE, Inc., Milwaukee, WI	04/2014
"Access to Health Care," Civil Liberties and Public Policy Conference, Amherst, MA	04/2014
"Reaching and Assisting LGBT Communities," Rutgers School of Nursing, Newark, NJ	03/2014
"Connecting with Coverage: LGBT Communities and the ACA," Pennsylvania Health Access Network	03/2014
"The Affordable Care Act and the LGBT Community," Oklahoma Equality, Tulsa, OK	03/2014
"The Affordable Care Act and the LGBT Community," The Dallas Resource Center, Dallas, TX	03/2014
"Connecting with Coverage: LGBT Communities and the ACA," Black AIDS Institute (online)	03/2014
"LGBT Federal Health Policy," National Summit on Cancer in the LGBT Communities, Memorial Sloane Kettering Cancer Center, New York, NY	01/2014
"LGBT Health Policy and Advocacy," Creating Change Conference, Houston, TX	01/2014
"Enrollment 2.0: Effective Strategies for Specific Populations," Health Action, Washington, DC	01/2014
"Implementing the Affordable Care Act," International Gay & Lesbian Leadership Conference, Denver, CO	12/2013
"Out2Enroll: The Affordable Care Act and the LGBT Community," The Johns Hopkins Center for Health Disparities Solutions (online)	11/2013
"The LGBT Community and the Affordable Care Act," Marquette University, Milwaukee, WI	11/2013

"Connecting with Coverage: LGBT Communities and the ACA," AIDS Resource Center of Wisconsin, Milwaukee, WI	11/2013
"Connecting LGBT Communities to Benefits under the ACA," Children's Hospital Los Angeles (online)	10/2013
"Nondiscrimination under the Affordable Care Act," Consumer Voices for Coverage, Philadelphia, PA	10/2013
"Outreach, Engagement and Enrollment into ACA Coverage," U.S. Conference on AIDS, New Orleans, LA	09/2013
"LGBT Community Benefits from the ACA," Q Health Initiative Conference, Salt Lake City, UT	09/2013
"Leading on Meaningful Use: Next Steps in SO/GI Data Policy," Gay & Lesbian Medical Association Conference, Denver, CO	09/2013
"Enrollment for LGBT Communities," Gay & Lesbian Medical Association Conference, Denver, CO	09/2013
"The Promise of Reform: How Obamacare Affects LGBT Communities," Federal AIDS Policy Partnership, Washington, DC	08/2013
"Optimizing LGBT Health under the ACA," National LGBT Health Education Center (online)	08/2013
"Building a Healthy and Inclusive Society," Young Elected Officials National Convening, Washington, DC	07/2013
"Transgender Health Issues in Health Care Reform," National Transgender Health Summit, Oakland, CA	04/2013
"Transgender Diagnoses in ICD-11," Global Action for Transgender Equality Strategy Meeting, Buenos Aires, Argentina	04/2013
"Organizing LGBT Communities around the ACA," Fair Wisconsin Leadership Conference, Milwaukee, WI	02/2013
"The Affordable Care Act and LGBT Consumers," Michigan Consumers for Healthcare and Equality Michigan, Kalamazoo, MI	02/2013
"LGBT Legal and Policy Issues in the Affordable Care Act," Eastern Michigan University, Ypsilanti, MI	02/2013
"LGBT Legal and Policy Issues in the Affordable Care Act," University of Michigan, Ann Arbor, MI	02/2013
"LGBT Community Health Center Advocacy and Policy," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"LGBT Health in Health Care Reform," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"Closing the LGBT Health Disparities Gap through Electronic Health Records," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"The LGBT State Exchanges Project: Building Community and Advocacy Tools for LGBT Health," Equality Federation Summer Institute, Portland, ME	08/2012
"Transgender Health," Johns Hopkins School of Nursing, Baltimore, MD	04/2012
"LGBT Health Disparities," National Health Law Program Health Advocates Conference, Washington, DC	12/2011
"The Picture of Health: How Statistics Will Change LGBT Health Care," International Gay & Lesbian Leadership Conference, Houston, TX	12/2011
"International Transgender Health," World Professional Association for Transgender Health Conference, Atlanta, GA	11/2011
"No Data, Big Problem: LGBT Health Equity at Kaiser Permanente," Kaiser Permanente Diversity Conference, San Francisco, CA	10/2011
"2011 Federal LGBT Health Initiatives," Gay & Lesbian Medical Association Conference, Atlanta, GA	09/2011
"Transgender Health Policy Advocacy," National Transgender Health Summit, San Francisco, CA	04/2011
"Advancing LGBT Health through Health Care Reform Implementation," Gay & Lesbian Medical Association Conference, San Diego, CA	10/2010
"Health as a Social Justice Issue," Creating Change Conference, Dallas, TX	02/2010
"LGBT Federal Youth Policy," Creating Change Conference, Dallas, TX	02/2010
"Transgender Issues in Russia," Transgender Europe Conference, Berlin, Germany	05/2008

Philanthropy

"Protections and Barriers in Access to Care," AIDS Philanthropy Summit, Washington, DC	12/2016

"LGBT Health Policy Opportunities," OutGiving Funders Meeting, Dallas, TX 05/2015

"Expanding Coverage and Access," LGBT Health Funding Summit, New York, NY 01/2015

"International Transgender Health Priorities," Advancing Transgender Movements Worldwide Funders Conference, Berlin, Germany 12/2013

"LGBT Health Reform Priorities," Health Care for All New York and the New York State Health Foundation, New York, NY 06/2013

"The Promise of Reform: How Obamacare Affects LGBTQ Communities," LGBTQ Grantmakers Retreat, Albuquerque, NM 03/2013

"Transforming Health: International Rights Based Advocacy for Trans Health," Open Society Foundations, New York, NY 02/2013

"LGBT Health Issues in U.S. Health Reform," Rockefeller Foundation, Bellagio, Italy 05/2012

Education and Career Development

"Health Science Policy," Health Science Communications and Policy Workshop, Office of Intramural Training and Education, National Institutes of Health (online) 03/2022

"Living Intersectionality in Academia: Emerging Scholars," Davis Center for Russian and Eurasian Studies, Harvard University (online) 01/2022

Postbac Career Exploration Series: Careers in Public Health, Office of Intramural Training and Education, National Institutes of Health (online) 10/2021

"LGBTQI+ Health Disparities: Research, Interventions, and Policy," Amgen Scholars Health Disparities Seminar, National Institutes of Health (online) 06/2021

Professional Advisory Panel on Sexual and Gender Minority Health in Medical Education, Harvard Medical School (online) 05/2021

"Innovations in Cancer Disparities Research," San Diego State University (online) 04/2021

Russian Tea, Swarthmore College (online) 04/2021

Summer Social Justice Institute, Swarthmore and Haverford Colleges, Swarthmore, PA 08/2018

"Science Outside the Lab: Science and Technology Policy Careers," Arizona State University Honors College, Washington, DC 06/2018

"Gay for Pay: Swarthmore Alumni in Queer Careers," Swarthmore College, Swarthmore, PA 03/2017

"Science Outside the Lab: Science and Technology Policy Careers," Arizona State University Honors College, Washington, DC 05/2016

VOLUNTEER ACTIVITIES

Co-Founder 2008-present
FtM Phoenix (Moscow, Russia)
FtM Phoenix (https://www.transsovetnik.com) advocates for the health and human rights of transgender people in Russia and Eurasia. In 2013-2014, we hosted the 1st and 2nd Eurasian Trans Health Conferences in Moscow, which brought together health care providers, advocates, and government officials from 8 countries in the former Soviet Union.

HIV/AIDS Peer Support Program Developer 2008-2009
Whitman-Walker Health (Washington, DC)

Community Clinics Campaign Coordinator 2006
FTM Alliance of Los Angeles (Los Angeles, CA)

Recreational Therapist 2005
Baskakov Center for Children with Special Needs (Moscow, Russia)

English–Russian Translator and Program Assistant 2004-2005
Special Olympics Russia (Moscow, Russia)

Certified Coach and Unified Team Player (basketball, bocce, long-distance running) 1997-2004
Special Olympics USA (Thousand Oaks, CA and Philadelphia, PA)

SKILLS AND PROFICIENCIES

Software/Programs: R, SQL, Stata, DbVisualizer, Mplus, TreeAge, heRo3, DistillerSR, AHRQ Systematic Data Review Repository, Covidence, ArcGIS, WordPress, Quickbooks, Microsoft Office
Languages: Russian (fluent), German (working proficiency), French (working proficiency), Spanish (basic proficiency)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C, have been retained by counsel for Plaintiffs in connection with the above-captioned litigation.

1. This declaration provides the following expert opinions, which are explained in further detail below:

2. General Medicaid Policy Rule 59G-1.050 ("the Exclusion") excludes from coverage certain medical services, which I will refer to as gender-affirming medical care, when these interventions are used to treat gender dysphoria.[1]

[1] Gender dysphoria is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American

3. Gender-affirming medical care is consistent with generally accepted professional medical standards and is not experimental or investigational. It is endorsed by evidence-based clinical practice guidelines that are themselves based on studies published in the peer-reviewed literature demonstrating that it improves individuals' health outcomes. Gender-affirming medical care is also supported by increasing utilization trends and coverage by other creditable insurance payors.

4. In the Exclusion and other supporting documents, the Florida Agency for Health Care Administration (AHCA) persistently mischaracterizes these treatments and singles them out for anomalous treatment by withholding Medicaid coverage for them only when they are used to treat gender dysphoria. Specifically, AHCA mischaracterizes

a. individuals as diagnosing themselves with gender dysphoria,

b. treatments for gender dysphoria and "off-label" treatments as experimental,

c. treatments of gender dysphoria as "eminence-based medicine" and the evidence base supporting many medical treatments, and

d. the informed consent process for the treatment of gender dysphoria in minors.

Psychiatric Publishing; 2022.

5. I have actual knowledge of the matters stated in this declaration. In preparing this declaration, I reviewed the Exclusion, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" ("GAPMS Memo"),[2] including Attachment G, a commissioned, unpublished paper written by G. Kevin Donovan, MD, MA, entitled "Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children."[3] I also reviewed the materials listed in the attached Bibliography (Exhibit A), and I may rely on those documents as additional support for my opinions. I have also relied on my years of research and clinical practice, as set out in my curriculum vitae (Exhibit B), and on the materials listed therein. The materials I have relied upon in preparing this declaration are the same types of materials that experts in medicine and bioethics regularly rely upon when forming opinions on this type of subject. I may wish to supplement these opinions or the bases for them due to new scientific research or publications, or in response to statements and issues that may arise in my area of expertise.

[2] June 2022. Accessed September 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

[3] May 12, 2022. Accessed September 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Attachment_G.pdf.

BACKGROUND AND QUALIFICATIONS

6. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

7. In 2000, I received both my medical degree from Washington University School of Medicine in St. Louis, Missouri and my PhD in Religious Ethics from The University of Chicago Divinity School. I completed my pediatrics residency at the University of Utah in 2003.

8. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

9. I have extensive experience as a practicing physician. I have been in clinical practice since 2003 and approximately 30 percent of my current work is dedicated to caring for hospitalized patients. Cincinnati Children's is a nonprofit pediatric academic medical center with 622 total registered beds. It admits patients up to age 25 and older patients under certain conditions, including patients in the

Adults with Congenital Heart Disease and Young Adults with Cancer programs. I routinely admit and care for adult patients.

10. I also have extensive experience as a bioethicist. Bioethicists examine the ethical issues that arise in medicine and the life sciences. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012.

11. I regularly consult on patients in the Transgender Health Clinic at Cincinnati Children's whose care presents unique ethical issues and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of individuals with gender dysphoria, particularly minors. I am also the Chair of Cincinnati Children's Fetal Care Center's Oversight Committee which provides the Center with recommendations on the use of innovative treatments and experimental interventions.

12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP's Committee on Bioethics from 2005 to 2011. I have also served as a member of the ASBH's Clinical Ethics Consultation Affairs Committee from 2009

to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.

13. I am the author of 41 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, six book chapters, and 28 commentaries. My peer-reviewed journal articles have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine.* I am also an author of 17 policy statements and technical reports, including four as lead author, by the AAP.

14. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics*. *Pediatrics* is the AAP's flagship journal and Ethics Rounds is a type of article in which commentators analyze cases that raise ethical issues. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for the annual meetings of professional organizations, including the Pediatric Academic Societies and ABSH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.

15. I previously testified as an expert witness at trial or deposition in the following cases: *Brant v. Rutledge*, Case No. 4:21CV450-JM (E.D. Ark.), *Doe v. Abbott*, No. D-1-GN-22-000977, 2022 WL 628912 (Tex. Dist. 353rd Judicial

District, March 2, 2022), and *Eknes-Tucker* v *Marshall*, Case No. 2:22-cv-184-LCB (M.D. Ala. May 13, 2022).

16. I am being compensated at an hourly rate of $250 per hour for preparation of expert declarations and reports, and $400 per hour for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

GENDER-AFFIRMING MEDICAL CARE IS SUPPORTED BY EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

17. Medical care for individuals with gender dysphoria is evidence-based and is supported by clinical practice guidelines developed by medical professional organizations including the Endocrine Society ("the Society").

18. The Society was established in 1916[4] and is an international medical organization whose membership is comprised of over 18,000 endocrinology researchers and clinicians.[5] It uses rigorous methods to develop guidelines on a variety of clinical conditions. Members of guideline development panels are nominated by the Society's Board of Directors, its Clinical Guidelines Committee, and any co-sponsoring organizations; they are selected based on their clinical

[4] Endocrine Society. Our History. Accessed December 31, 2022. Available at https://www.endocrine.org/our-community/advancing-endocrinology-and-public-health/history/.
[5] Endocrine Society. Who We Are. Accessed December 31, 2022. Available at https://www.endocrine.org/about-us.

expertise and other skills; and they are screened for conflicts of interest. Panels are multidisciplinary and include a patient representative and a methodologist—someone trained in the methods for developing clinical practice guidelines. The Society uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. Guidelines undergo both internal and external review including a public comment period. After any revisions, the proposed guidelines undergo a second review by the Society's Clinical Guidelines Committee, its Board of Directors Reviewer, and an expert reviewer. If approved, they undergo peer review prior to publication. Guidelines are periodically reviewed and may be updated or retired.[6]

19. The GRADE approach is a widely utilized method for developing clinical practice guidelines.[7] It involves both rating the quality of the evidence and the strength of the recommendations.[8] In this context, evidence is the studies' relevant to a recommendation. It is best practice to ascertain the studies via systematic reviews of the literature.[9] The evidence provides an estimate of the effect

[6] Endocrine Society Guideline Methodology. Accessed November 25, 2022. Available at https://www.endocrine.org/-/media/endocrine/files/cpg/methodology-page-refresh/endocrine_society_guideline_methodology_links.pdf.
[7] GRADE: Welcome to the GRADE working group. Accessed November 23, 2022. Available at https://www.gradeworkinggroup.org/#pub.
[8] Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64(4):383-394.
[9] Systematic reviews use exhaustive, transparent, and repeatable methods to identify, select, and appraise the relevant research. For example, medical librarians may help develop strategies to search multiple databases and several investigators may screen each articles' title and abstract

of an intervention both in terms of the size of the effect and the certainty of the knowledge about it. The quality of the evidence rating reflects "the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation."[10] The higher the quality of the evidence, the more confidence there is in our knowledge about the estimated magnitude of the effect and the more likely the true magnitude of the effect is the same as the estimate. The lower the quality of the evidence, the less confidence there is in the estimate of the effect and the more likely the true effect differs from the estimate. The GRADE approach uses four categories to rate the quality of the evidence: "high," "moderate," "low," and "very low."[11]

20. In the rating process, randomized trials are initially rated as high quality and observational studies as low quality.[12] In randomized trials, participants are randomly assigned to an intervention or a control group. Randomization is like flipping a coin. In double blind or masked randomized trials, neither the investigators nor the participants know to which group the participants are assigned.

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against inclusion and exclusion criteria. Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med*. 1997;127(3):210-6.

[10] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):403.

[11] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

[12] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

Observational studies include cross-sectional and cohort studies. In cross-sectional studies, investigators collect data at a single point in time or within a short period of time. In cohort studies, researchers identify a group of participants and then make measurements over time. The measurements may be retrospective and/or prospective.[13]

21. The initial rating of the evidence may subsequently be modified based on additional factors. The rating of randomized trials may, for example, be decreased if they have serious risks of bias[14] like a lack of masking.[15] The rating of observational trials may be increased if they have large effects, e.g., those receiving the intervention are more than two times or less than one-half as likely to experience the outcome.[16]

22. The strength of a recommendation is related to the confidence that a treatment's desirable outcomes outweigh its undesirable ones. The GRADE approach conceptualizes recommendations on a continuum: "strong against," "weak against," "only in research," "weak for," and "strong for." Strong recommendations are ones where all or almost all informed people would make the recommended

[13] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.
[14] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.
[15] Guyatt GH, Oxman AD, Vist G, et al. GRADE guidelines: 4. Rating the quality of evidence—study limitations (risk of bias). *J Clin Epidemiol*. 2011;64(4):407-415.
[16] Guyatt GH, Oxman AD, Sultan S, et al. GRADE guidelines: 9. Rating up the quality of evidence. *J Clin Epidemiol*. 2011;64(12):1311-1316.

choice and weak recommendations are ones where most informed people would, but a substantial number would not, make the recommended choice.[17] The strength of a recommendation is based on the balance between desirable and undesirable outcomes, confidence in the magnitude of estimates of the intervention's effect, confidence in values and preferences, and resource use.[18] Low quality evidence may be sufficient to justify a strong recommendation.[19] Because of the potential to confuse low quality evidence and weak recommendations, the GRADE approach offers the following alternative ways to describe a weak recommendation: "conditional," "discretionary," and "qualified."[20]

23. The Society's clinical practice guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons makes 28 recommendations.[21] Ten are strong, 12 are weak, and six are ungraded good practice statements; three are

[17] Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.
[18] Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.
[19] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-6; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.
[20] Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.
[21] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

based on moderate, 14 on low, and five on very low-quality evidence. Table 1 (Exhibit C). The recommendation, "We suggest that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development," for example, is a weak recommendation based on low-quality evidence. Recall that a weak recommendation is one where most informed people would make the recommended choice. The evidence includes cohort studies conducted at VU University Medical Center in the Netherlands demonstrating that gender-affirming medical care improves individuals' mental health outcomes.[22] The recommendation "We recommend that clinicians confirm the diagnostic criteria of [gender dysphoria]/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment" is a strong recommendation based on moderate quality evidence. The evidence includes a randomized trial of three different testosterone formulations in transgender men (individuals who were assigned female at birth and identify as male).[23]

24. Professional associations' treatment recommendations for pediatric

[22] Cohen-Kettenis PT, van Goozen SHM. Sex reassignment of adolescent transsexuals: A follow-up study. *J Am Acad Child Adolesc Psychiatry*. 1997;36(2):263–271; Smith YLS, Van Goozen SHM, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005;35(1):89–99; and de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

[23] Pelusi C, Costantino A, Martelli V, et al. Effects of three different testosterone formulations in female-to-male transsexual persons. *J Sex Med*. 2014;11(12):3002-3011.

patients are infrequently based on well-designed and conducted randomized controlled trials due to their rarity and are frequently based on observational studies. For example, the Society has developed two other guidelines that focus on the pediatric population: guidelines on pediatric obesity and congenital adrenal hyperplasia. They contain 84 recommendations. None are based on high, 24 (29%) on moderate, and 49 (58%) on low or very low-quality evidence. Forty-three (51%) recommendations are strong and 30 (36%) weak. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.[24] Table 1 (Exhibit C).

25. Medical research on children is less likely to use randomized trials than is medical research for adults. Reasons for this disparity include the low prevalence of childhood disease or conditions, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.[25]

26. It may also, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater.

[24] Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

[25] Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high-quality study design. *Pediatrics*. 2008;122(1):52-57.

It would be unethical to knowingly expose some participants to an inferior intervention. Trials must also be feasible. It would be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to enroll enough participants because they believe they might be randomized to an inferior intervention would be unethical because it could not generate generalizable knowledge due to an inadequate sample size.[26]

27. Under the applicable ethical standards, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of individuals with gender dysphoria are currently unethical. Potential investigators no longer have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that enough participants would enroll in such randomized controlled trials for them to be informative.[27]

28. Even if randomized, placebo-controlled trials of gender-affirming health care were ethical, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to mask

[26] Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

[27] Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

which participants were receiving an active medication or a placebo; the investigators and the participant would know if the participant was in the intervention or control group due to the physical changes in the participant's body, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.[28]

29. Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8th version ("SOC-8").[29] WPATH is an international interdisciplinary professional and educational organization[30] whose over 2,500 members include physicians, psychologists, lawyers, and social workers.[31] The SOC-8 revision committee included subject matter experts, stakeholders, and an expert in developing clinical practice guidelines each of whom completed conflict of interest declarations. An independent, evidence review team conducted selected systematic reviews of the literature. Consensus on recommendations was attained using a Delphi process; a voting process requiring approval by 75% of participating committee members. If

[28] Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.
[29] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.
[30] WPATH. Mission and Vision. Accessed December 31, 2022. Available at https://www.wpath.org/about/mission-and-vision.
[31] WPATH. Member Search. Accessed February 13, 2023. Available at https://www.wpath.org/member/search/results?showAll=1.

a recommendation was not approved, it was revised and was removed if not approved in 3 rounds of voting. Approved recommendations were subsequently graded. A draft of the revision was reviewed by an International Advisory Committee and open to public comment.[32]

30. In addition to these clinical practice guidelines, gender-affirming medical care is endorsed by other types of statements by numerous medical professional associations including the American Academy of Family Physicians,[33] the AAP,[34] the American College of Obstetricians and Gynecologists,[35] the American Medical Association,[36] the American Psychiatric Association,[37] the

[32] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1): S1-S259.
[33] American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed January 8, 2023. Available at https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents.
[34] Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4): e20182162.
[35] American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed January 8, 2023. Available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol*. 2021;137(3):e75-e88.
[36] American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed January 8, 2023. Available at https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Madara JL to McBride B. April 26, 2021. Accessed January 8, 2023. Available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf.
[37] American Psychiatric Association. Position statement on treatment of transgender (trans) and

American Psychological Association,[38] the Endocrine Society and Pediatric Endocrine Society,[39] and WPATH.[40]

GENDER-AFFIRMING MEDICAL CARE IS NOT EXPERIMENTAL

31. Clinical practice and research are distinguished by their goals and methods. The goal of clinical practice is to benefit individual patients, and its method is individualized decision-making. The goal of research is to contribute to generalizable knowledge, and its method uses formal protocols that describe the research study's objectives and procedures.[41]

32. To the extent that the GAPMS Memo uses the term "experimental" or "investigational" to convey that gender-affirming medical care is new, untested, or different, that suggestion is baseless. GAPMS Memo at 29, 30; Attachment G at 1, 4. Hormone treatment for gender dysphoria began after estrogen and testosterone

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gender diverse youth. July 2020. Accessed January 8, 2023. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

[38] American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed January 8, 2023, Available at https://www.apa.org/about/policy/transgender.pdf.

[39] Endocrine Society and Pediatric Endocrine Society. Transgender health: Position Statement. December 2020. Accessed January 8, 2023. Available at https://www.endocrine.org/advocacy/position-statements/transgender-health; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol.* 2009;64:372-453.

[40] WPATH. Position statement on medical necessity of treatment, sex reassignment, and insurance coverage in the U.S.A. December 21, 2016. Accessed January 8, 2023. Available at https://www.wpath.org/newsroom/medical-necessity-statement.

[41] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Commission; 1978.

became commercially available in the 1930's. The first documented male to female gender-affirming genital surgery was performed in 1931 and Christine Jorgensen famously underwent gender-affirming surgery in 1952.[42] The use of gonadotropin releasing hormone analogues, also known as puberty blockers or puberty-delaying medications, to treat gender dysphoria in adolescents, while a somewhat more recent treatment, is also not new. The first reference to this treatment in the medical literature was in 1998, approximately 25 years ago.[43] Observational studies of puberty blockers began recruiting participants in 2000.[44] As described above, gender-affirming medical care is supported by clinical studies, the same type of studies that support many other widely accepted medical treatments.

33. The clinical use of puberty blockers, gender-affirming hormone treatment and surgeries are not research or experimentation. When administering these treatments, clinicians seek to benefit individual patients and adjust the treatment based on individual patients' responses.

34. The GAPMS Memo's suggestion that, because puberty blockers and gender-affirming hormone treatment are being used "off-label," they are experimental, untested, or unsafe is also misleading. GAPMS Memo at 8, 14, 16, 19,

[42] Stryker S. *Transgender History*. 2nd ed. Seal Press; 2017.
[43] Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248.
[44] de Vries AL, Steensma TD, Doreleijers TA, Cohen- Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

21; Attachment G at 4. Off-label use of medications is legal, common, and often evidence-based.

35. Approval by the United States (US) Food and Drug Administration (FDA) is not required for all uses of a medication. Once the FDA has approved a medication for one indication,[45] thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications.[46] Prescribing an approved medication for an unapproved indication is colloquially referred to as "off-label" use. The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does

[45] According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed August 25, 2022. Available at https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

[46] U.S. Food & Drug Administration. Understanding unapproved use of approved drugs "off label." February 5, 2018. Accessed August 25, 2022. Available at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

not warrant special consent or review if it is deemed to be in the individual patient's best interest."[47]

36. The AAP Committee on Drugs further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."[48] Among the reasons for this is that, even if there is substantial evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it because the sponsor does not expect that the future revenue will offset the costs of obtaining approval.[49]

37. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. For example, magnesium sulfate is only approved by the FDA for replacement therapy in magnesium deficiency, in nutrition given by vein to correct or prevent low magnesium levels, or to prevent or control seizures due to high blood pressure during pregnancy.[50] It is, nonetheless, recommended for the short-term prolongation of pregnancy and to prevent neurologic injuries to the fetus and newborn [51] and as an adjunct treatment in severe, unresponsive asthma

[47] Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3): 563, 565.
[48] Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3): 564.
[49] Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc*. 2012;87(10):982-990.
[50] Magnesium Sulfate. February 2016. Accessed August 31, 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019316s024lbl.pdf.
[51] Committee Opinion No 652: Magnesium sulfate use in obstetrics. *Obstet Gynecol*. 2016;127(1): e52-e53.

exacerbations.[52] A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed.[53] Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used to treat gastrointestinal reflux. The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.

38. The GAPMS Memo misleadingly notes that testosterone is a Schedule III controlled substance because of its "high probability of abuse." GAPMS Memo at 19. But there is no evidence of abuse or dependence of anabolic-androgenic steroids from therapeutic use. And Schedule III drugs have a moderate to low potential for physical and psychological dependence.[54] Dependence has only been reported among weightlifters and bodybuilders receiving non-therapeutic, supraphysiologic doses.[55]

SUBSTANTIAL INCREASES IN THE UTILIZATION OF GENDER-AFFIRMING MEDICAL CARE

[52] National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2007. Accessed August 31, 2022. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/EPR-3_Asthma_Full_Report_2007.pdf.
[53] Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193.
[54] United States Drug Enforcement Administration. Drug scheduling. July 10, 2018. Accessed August 25, 2022. Available at https://www.dea.gov/drug-information/drug-scheduling.
[55] Brower KJ. Anabolic steroid abuse and dependence. *Curr Psychiatry Rep*. 2002;4(5):377-387.

39. In addition to evidence-based clinical practice guidelines, utilization trends and insurance coverage policies provide further evidence that gender-affirming medical care is a consistent with generally accepted medical standards. The peer-reviewed evidence of the efficacy of gender-affirming medical care and the recommendations of it by clinical practice guidelines are likely to increase the utilization of gender-affirming medical care and coverage by insurance companies. There have been substantial increases in the utilization of gender-affirming medical care in the last 30 years. This has included increases in referrals for care as well as the use of different forms of care. Evidence for these changes comes from a variety of sources and investigators use different ways to describe the increases in utilization. Studies demonstrate increasing referrals to children's hospitals and specialized gender clinics.[56] Handler and colleagues, for example, report that between February 2015 and June 2018 there was a significant increase in the volume of pediatric referrals to the specialized gender clinic at Kaiser Permanente North California; the average number of monthly referrals increased from 5.1 to 25.7 individuals per month which is an increase of 504%.[57]

[56] Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425; Chen M, Fuqua J, Eugster EA. Characteristics of referrals for gender dysphoria over a 13-year period. *J Adolesc Health*. 2016;58(3):369-371.

[57] Handler T, Hojilla JC, Varghese R, Wellenstein W, Satre DD, Zaritsky E. Trends in referrals to a pediatric transgender clinic. *Pediatrics*. 2019;144(5): e20191368.

40. Studies have also demonstrated significant increases in the utilization of various forms of gender-affirming medical care including puberty blockers,[58] hormone therapy,[59] and surgery.[60] Baker and colleagues, for example, conducted a study using the OptumLabs Data Warehouse. The Warehouse includes de-identified administrative claims data for commercially insured enrollees in a large, private US health plan. They found that the percentage of transgender people who were receiving hormone therapy or underwent surgery increased from 17% and 0.5% respectively in 2011 to 65% and 8% by 2019. This percentile increase represents a substantial number of individuals as the number of transgender people with coverage increased from 71 per million enrollees in 1993 to 411 per million in 2019.[61] The Society for Plastic Surgery reports also that the number of gender-affirming

[58] Lopez CM, Solomon D, Boulware SD, Christison-Lagay ER. Trends in the use of puberty blockers among transgender children in the United States. *J Pediatr Endocrinol Metab*. 2018;31(6):665-670.
[59] Leinung MC, Joseph J. Changing demographics in transgender individuals seeking hormonal therapy: Are trans women more common than trans men? *Transgend Health*. 2020;5(4):241-245.
[60] Das RK, Perdikis G, Al Kassis S, Drolet BC. Gender-affirming chest reconstruction among transgender and gender-diverse adolescents in the US from 2016 to 2019. *JAMA Pediatr*. 2023;177(1):89-90.
[60] Canner JK, Harfouch O, Kodadek LM, et al. Temporal trends in gender-affirming surgery among transgender patients in the United States. *JAMA Surg*. 2018;153(7):609-616; Lane M, Ives GC, Sluiter EC, et al. Trends in gender-affirming surgery in insured patients in the United States. *Plast Reconstr Surg Glob Open*. 2018;6(4):e1738; Das RK, Evans AG, Kalmar CL, Al Kassis S, Drolet BC, Perdikis G. Nationwide estimates of gender-affirming chest reconstruction in the United States, 2016-2019. *Aesthet Surg J*. 2022;42(12):NP758-NP762; Das RK, Perdikis G, Al Kassis S, Drolet BC. Gender-affirming chest reconstruction among transgender and gender-diverse adolescents in the US from 2016 to 2019. *JAMA Pediatr*. 2023;177(1):89-90; Tang A, Hojilla JC, Jackson JE, et al. Gender-affirming mastectomy trends and surgical outcomes in adolescents. *Ann Plast Surg*. May 2022;88(4 Suppl): S325-S331.
[61] Baker K, Restar A. Utilization and costs of gender-affirming care in a commercially insured transgender population. *J Law Med Ethics*. 2022;50(3):456-470.

surgeries performed by its members increased from 2,470 in 2015[62] to 16,353 in 2020,[63] which is an increase of 562%.

COVERAGE BY OTHER CREDITABLE INSURANCE PAYORS

41. Coverage of gender-affirming medical care is provided by other creditable insurance payors. In 2014, the Department of Health and Human Services' Departmental Appeals Board determined that the National Coverage Determination denying Medicare coverage of gender-affirming surgery was invalid.[64] A 2018 analysis of Medicare prescription drug plans found that the proportion of plans providing coverage of hormone therapy varied by hormone with 100/75% providing coverage/unrestricted coverage of testosterone-cypionate, 89/89% estradiol-valerate, and 100/100% spironolactone.[65] A study of state Medicaid programs published in 2021 found that 67% covered gender affirming

[62] American Society of Plastic Surgeons. Plastic surgery statistics report 2016. Accessed January 8, 2023. Available at https://www.plasticsurgery.org/documents/News/Statistics/2016/plastic-surgery-statistics-full-report-2016.pdf.

[63] American Society of Plastic Surgeons. Plastic surgery statistics report 2020. Accessed January 8, 2023. Available at https://www.plasticsurgery.org/documents/News/Statistics/2020/plastic-surgery-statistics-full-report-2020.pdf.

[64] Department of Health and Human Services Departmental Appeals Board Appellate Division. NCD 140.3 Transexual Surgery. May 30, 2014. Accessed January 8, 2023. Available at https://www.hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf; Centers for Medicare & Medicaid Services. National coverage determination: Gender dysphoria and gender reassignment surgery 140.9. August 30, 2016. Accessed January 8, 2023. Available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=368.

[65] Solotke MT, Liu P, Dhruva SS, Gulanski B, Shah ND, Ross JS. Medicare prescription drug plan coverage of hormone therapies used by transgender individuals. *LGBT Health*. 2020;7(3):137-145. Spironolactone is an anti-androgen used in the treatment of transgender women in conjunction with estrogen to reduce testosterone production.

hormone treatment, 18% did not cover it, and 16% were indeterminate. With respect to gender affirming surgery, the results were 51%, 43%, and 8% respectively.[66]

42. Gender-affirming medical care is also covered by private health insurance plans. A study of self-insured, corporate health insurance benefit plans conducted in 2019 found that 56.4% covered transition care, 8.8% did not cover it, 5.8% were ambiguous, and 29.1% were silent. The investigators did not differentiate between gender-affirming hormone treatment and surgery.[67] Coverage for surgery is highest for bilateral mastectomy for transgender men and genital surgery for transgender men and women (transgender women are individuals assigned male at birth who identify as female). National surveys of private insurance plans found 96% covered mastectomy[68] and 91% genital surgery.[69] Private insurance plans cover other types of gender-affirming surgery,[70] such as breast augmentation,[71]

[66] Zaliznyak M, Jung EE, Bresee C, Garcia MM. Which U.S. states' Medicaid programs provide coverage for gender-affirming hormone therapy and gender-affirming genital surgery for transgender patients?: A state-by-state review, and a study detailing the patient experience to confirm coverage of services. *J Sex Med*. 2021;18(2):410-422.
[67] Kirkland A, Talesh S, Perone AK. Transition coverage and clarity in self-insured corporate health insurance benefit plans. *Transgend Health*. 2021;6(4):207-216.
[68] Ngaage LM, Knighton BJ, McGlone KL, et al. Health insurance coverage of gender-affirming top surgery in the United States. *Plast Reconstr Surg*. 2019;144(4):824-833.
[69] Ngaage LM, Knighton BJ, Benzel CA, et al. A review of insurance coverage of gender-affirming genital surgery. *Plast Reconstr Surg*. 2020;145(3):803-812.
[70] Ngaage LM, McGlone KL, Xue S, et al. Gender surgery beyond chest and genitals: Current insurance landscape. *Aesthet Surg J*. 2020;40(4):NP202-NP210.
[71] Ngaage LM, Knighton BJ, McGlone KL, et al. Health insurance coverage of gender-affirming top surgery in the United States. *Plast Reconstr Surg*. 2019;144(4):824-833.

facial feminization surgery,[72] voice surgery,[73] and hair removal procedures[74] for transgender women albeit at lower rates.

GENDER DYSPHORIA IS A MEDICAL DIAGNOSIS

43. Several other mischaracterizations of gender-affirming medical care in the GAPMS Memo should be addressed. While the GAPMS Memo correctly acknowledges that gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM)* 5th ed,[75] it falsely characterizes individuals with gender dysphoria as "self-diagnosing." GAPMS Memo at 30; Attachment G at 5. The diagnosis of gender dysphoria in adolescents and adults, like many other common medical diagnoses, relies on individuals' self-report of their symptoms. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. The characteristics include the

[72] Gorbea E, Gidumal S, Kozato A, Pang JH, Safer JD, Rosenberg J. Insurance coverage of facial gender affirmation surgery: A review of Medicaid and commercial insurance. *Otolaryngol Head Neck Surg*. 2021;165(6):791-797; Gadkaree SK, DeVore EK, Richburg K, et al. National variation of insurance coverage for gender-affirming facial feminization surgery. *Facial Plast Surg Aesthet Med*. 2021;23(4):270-277.

[73] DeVore EK, Gadkaree SK, Richburg K, et al. Coverage for gender-affirming voice surgery and therapy for transgender individuals. *Laryngoscope*. 2021;131(3):E896-E902.

[74] Peloza K, Kahn B, Stoff BK, Yeung H. Insurance coverage for hair removal procedures in the treatment of gender dysphoria. *Dermatol Surg*. 2021;47(2):306-308.

[75] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Publishing; 2013. A text revision, which contains the same diagnosis and diagnostic criteria, has subsequently been published. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity. It is common for diagnostic criteria to utilize qualitative terms, e.g., the intensity of migraine headaches is moderate to severe.[76] Like gender dysphoria, there is no confirmatory laboratory or radiographic study for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is secondary to another condition, e.g., meningitis or subarachnoid hemorrhage.[77]

44. Individuals with symptoms of gender dysphoria may anticipate their diagnosis in the same way that individuals with fever, cough, and difficulty breathing may reasonably suspect that they have pneumonia. It is, however, incorrect to suggest that these patients "self-diagnose," or that such suspicions serve as the basis for the diagnosis or subsequent treatment. Only licensed healthcare providers or teams of providers, based on patient reports and, in the case of minors, parent reports, make the diagnosis of gender dysphoria and any subsequent treatment recommendations.

[76] Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
[77] Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57.

PARENTS AND LEGAL GUARDIANS ARE CAPABLE OF PROVIDING INFORMED CONSENT FOR GENDER-AFFIRMING MEDICAL CARE

45. The GAPMS Memo and attachments incorrectly claim that parents or legal guardians are unable to understand and appreciate the potential risks of gender-affirming health care and, therefore, are incapable of providing informed consent. GAPMS Memo at 18, 29; Attachment G at 3-4.

46. First and foremost, the current standard of care for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making.

47. Parents or legal guardians generally must provide informed consent for medical treatment for their minor children, including for gender-affirming medical care. AHCA and Dr. Donovan cite no evidence in support of the assertion that parents or guardians of adolescents with gender dysphoria, nor the adolescents themselves, are unable to understand or appreciate the potential risks of gender-affirming medical care. ACHA and Dr. Donovan also cite to no evidence that clinicians are not sufficiently disclosing the risks of gender-affirming medical care to parents or legal guardians, or to minor patients. GAPMS Memo p. 29-30; Attachment G at 2-4.

48. Parents and legal guardians frequently consent to medical treatments for minors unrelated to gender dysphoria which have comparable risks, uncertainty,

or levels of evidence. For example, parents and legal guardians consent to the treatment of nonmalignant medical conditions for their minor children, including some rheumatologic disorders and hematologic conditions, which may impair fertility.[78]

49. Adolescents generally possess comparable medical decision-making capacity to adults.[79] There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers.[80] And there are steps that healthcare providers take to promote adolescents' decision-making capacity.[81]

50. The Society's clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to gender-affirming medical care, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that informed consent for pubertal blockers and gender-

[78] Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-77.
[79] Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev*. 1982;53(6):1589-98.
[80] Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6): e2020049643.
[81] Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161485.

affirming hormones include a discussion of the implications for fertility and options for fertility preservation.[82]

51. The Society's clinical guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent has developed sufficient medical decision-making capacity. The guideline states clinicians should individualize decision-making for chest surgery in transgender males and that chest surgery may be considered in some instances for individuals under 18 years old. The guideline recommends gender-affirming genital surgery involving gonadectomy and/or hysterectomy only in individuals 18 years old or older. [83]

THE EXCLUSION SINGLES OUT GENDER-AFFIRMING CARE FOR ANOMALOUS TREATMENT

52. The Exclusion does not provide a basis for excluding coverage of the provision of gender-affirming medical care to individuals with gender dysphoria and treating it differently from other comparable medical interventions. For example, while the Exclusion would eliminate coverage of chest surgery for the treatment of gender dysphoria for transgender Medicaid beneficiaries, cisgender Medicaid

[82] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[83] Or the legal age of majority in his or her country. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

beneficiaries are provided coverage for comparable surgeries, such as those for gynecomastia.[84] Gynecomastia is the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals whose sex assigned at birth is male. While surgery to treat gynecomastia may at times lessen pain, it also commonly reduces psychosocial distress. The surgery has the effect of affirming cisgender male patients' gender identity, that is, to help individuals assigned male at birth feel their bodies are more typically masculine. Risks associated with the procedure include bruising, bleeding, infection, scarring, poor cosmetic outcome, and loss of sensation.[85]

53. There is nothing unique about chest surgery for gender dysphoria that justifies singling this treatment, or other medical treatments for gender dysphoria, out for non-coverage based on a concern regarding evidence of safety or efficacy; adult patients', or parents' or guardians' ability to consent; or adolescents' ability to assent. As with other conditions, medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adult patients, or parents or legal guardians and their minor children, and their healthcare providers.

[84] State of Florida Agency for Health Care Administration. Florida Medicaid's Covered Services and HCBS Waivers: Integumentary Services. Accessed February 16, 2023. Available at https://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/primary_care_policy/Integumentary.shtml.

[85] Nordt CA, DiVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr*. 2008;20(4):375-382.

CONCLUSION

54. Based on my research and experience as a physician and bioethicist, treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. There is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on February 16, 2023

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

EXHIBIT A

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EXHIBIT B

Curriculum Vitae

Last Updated: January 24, 2023

PERSONAL DATA

Armand H. Matheny Antommaria, MD, PhD, FAAP, HEC-C
Birth Place: Pittsburgh, Pennsylvania
Citizenship: United States of America

CONTACT INFORMATION

Address: 3333 Burnet Ave, ML 15006, Cincinnati, OH 45229
Telephone Number: (513) 636-4939
Electronic Mail Address: armand.antommaria@cchmc.org

EDUCATION

1983-1987	BSEE	Valparaiso University, with High Distinction Valparaiso, IN
1983-1987	BS	Valparaiso University (Chemistry), with High Distinction Valparaiso, IN
1987-1989	MD	Washington University School of Medicine
1998-2000		Saint Louis, MO
1989-2000	PhD	The University of Chicago Divinity School (Religious Ethics) Chicago, IL
2000-2003	Resident	University of Utah (Pediatrics) Salt Lake City, UT
2005-2006	Certificate	Conflict Resolution Certificate Program, University of Utah Salt Lake City, UT

BOARD CERTIFICATION

2019 Pediatric Hospital Medicine, American Board of Pediatrics
2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation Certification Commission
2004 General Pediatrics, American Board of Pediatrics

PROFESSIONAL LICENSES

2012-Present	Doctor of Medicine, Ohio
2006-2010	Alternative Dispute Resolution Provider—Mediator, Utah
2001-2014	Physician and Surgeon, Utah
2001-2014	Physician and Surgeon Controlled Substance, Utah

PROFESSIONAL EXPERIENCE

Full Time Positions

2019-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Department of Surgery

2019-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Surgery

2017-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Division of Pediatric Hospital Medicine

2017-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2016-2017 *Associate Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2012-2017 *Associate Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Division of Pediatric Hospital Medicine

2012-Present *Lee Ault Carter Chair in Pediatric Ethics*
Cincinnati Children's Hospital Medical Center

2012-2016 *Associate Professor-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2010-2012 *Associate Professor of Pediatrics* (with Tenure)
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2010-2012 *Adjunct Associate Professor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics and Humanities

2004-2010 *Assistant Professor of Pediatrics* (Tenure Track)
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2004-2010 *Adjunct Assistant Professor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics and Humanities

2003-2004 *Instructor of Pediatrics* (Clinical Track)
University of Utah School of Medicine, Salt Lake City, UT
Divisions of Inpatient Medicine and Medical Ethics

2003-2004 *Adjunct Instructor of Medicine*
University of Utah School of Medicine, Salt Lake City, UT
Division of Medical Ethics

Part Time Positions

2022- Present *Expert Witness,* Testimony
Eknes-Tucker, et al., v. Marshall, et al., United States District Court Middle District of Alabama Northern Division, Case No. 2:22-cv0-184-LCB.

2022-Present	*Expert Witness,* Testimony Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County, Texas 353rd Judicial District, Case No. D-1-GN-22-000977
2021-2022	*Expert Witness*, Deposition and Testimony Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District Court, Eastern District of Arkansas, Case No.: 5:21-CV-00450-JM-1
2021	*Consultant* Proctor & Gamble, Cincinnati, OH
2019	*Consultant* Sanofi Genzyme, Cambridge, MA
2018-Present	*Consultant* Center for Conflict Resolution in Healthcare, Memphis, TN
2017-2020	*Consultant* Amicus Therapeutics, Cranbury, NJ
2017	*Consultant* Sarepta Therapeutics, Cambridge, MA
2014	*Consultant* Genzyme, A Sanofi Company, Cambridge, MA

Editorial Experience

Editorial Board

2020-Present	*Pediatrics,* Associate Editor for Ethics Rounds and Member of the Executive Editorial Board
2015-2020	*Journal of Clinical Ethics*
2009-2020	*Journal of Medical Humanities*

Guest Academic Editor

2017	*PLOS|ONE*

Ad Hoc Reviewer: *Academic Medicine, Academic Pediatrics, AJOB Primary Research, American Journal of Bioethics, American Journal of Law & Medicine, American Journal of Medical Genetics, American Journal of Transplantation, BMC Medical Ethics, BMJ Open, Canadian Journal of Bioethics, CHEST, Clinical Transplantation, European Journal of Human Genetics, European Journal of Pediatrics, Frontiers in Genetics, Hospital Medicine, International Journal of Health Policy and Management, International Journal of Nursing Studies, Journal of Adolescent and Young Adult Oncology, Journal of Clinical Ethics, Journal of Empirical Research on Human Research Ethics, Journal of General Internal Medicine, Journal of Healthcare Leadership, Journal of Hospital Medicine, Journal of the Kennedy Institute of Ethics, Journal of Law, Medicine & Ethics, Journal of Medical Ethics, Journal of Medical Humanities, Journal of Medicine and Life, Journal of Palliative Care, Journal of Pediatrics, Journal of Pediatric Surgery, Mayo Clinic Proceedings, Medicine, Healthcare and Philosophy, Molecular Diagnosis & Therapy, New England Journal of Medicine, Patient Preference and Adherence, Pediatrics, Pediatrics in Review, Personalized Medicine, PLOS\|ONE, Risk Management and Healthcare Policy, Saudi Medical Journal, SSM - Qualitative Research in Health,* and *Theoretical Medicine and Bioethics*

SCHOLASTIC AND PROFESSIONAL HONORS

2021	*Hidden Gem Award,* Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2019-2022	*Presidential Citation,* American Society for Bioethics and Humanities, Chicago, IL
2016	*Laura Mirkinson, MD, FAAP Lecturer,* Section on Hospital Medicine, American Academy of Pediatrics, Elk Grove Village, IL
2016, 2018	*Certificate of Excellence*, American Society for Bioethics and Humanities, Glenview, IL
2013, 2016	*Senior Resident Division Teaching Award,* Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012	*Role Model*, Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2011	*Member*, Society for Pediatric Research, The Woodlands, TX
2011	*Presidential Citation*, American Society for Bioethics and Humanities, Glenview, IL
2009	*Role Model*, Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2008	*Nominee,* Physician of the Year, Primary Children's Medical Center, Salt Lake City, UT
2005-2006	*Fellow,* Medical Scholars Program, University of Utah School of Medicine, Salt Lake City, UT
1995-1997	*Doctoral Scholar*, Crossroads, A Program of Evangelicals for Social Action, Philadelphia PA
1989-1992	*Fellow*, The Pew Program in Medicine, Arts, and the Social Sciences, University of Chicago, Chicago, IL

ADMINISTRATIVE EXPERIENCE

Administrative Duties

2019-Present	*Chair,* Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH
2014-Present	*Chair*, Ethics Committee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	*Director*, Ethics Center, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	*Chair,* Ethics Consultation Subcommittee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2010	*Co-Chair,* Ethics Subcommittee, Work Group for Emergency Mass Critical Care in Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA
2009	*Chair*, Ethics Working Group, H1N1 and Winter Surge, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	*Chair*, Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	*Chair*, Ethics Consultation Subcommittee, Primary Children's Medical Center, Salt Lake City, UT
2003-4	*Chair*, Clinical Pertinence Committee, Primary Children's Medical Center, Salt Lake City, UT

Professional & Scientific Committees

Committees

2021	*Member*, EMCO Capacity Collaboration, Ohio Hospital Association, Columbus, OH
2020-2021	*Member*, Allocation of Scarce Resources Work Group, Ohio Hospital Association, Columbus, OH
2020-Present	*Member,* Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD
2020	*Member*, Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH
2019-Present	*Member,* Healthcare Ethics Consultant Certification Commission, Oak Park, IL

2019	*Member,* Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL
2018	*Member,* Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH
2012-Present	*Member*, Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA
2009-2014	*Member,* Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL
2005-2011	*Member,* Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL

Data Safety and Monitoring Boards

2019-Present	*Member,* Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart, Lung, and Blood Institute, Bethesda, MD
2018-2019	*Member,* Standing Safety Committee for P-188-NF (Carmeseal-MD™) in Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI
2017-Present	*Member*, Observational Study Monitoring Board, Sickle Cell Disease Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD
2016-2018	*Member,* Observational Study Monitoring Board, Long Term Effects of Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and Blood Institute, Bethesda, MD

Reviewer

2020-Present	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2020	*Grant Reviewer,* The Croatian Science Foundation, Hvatska zaklada za znanost (HRZZ)
2018	*Book Proposal Reviewer*, Elsevier
2018-2019	*Category Leader,* Religion, Culture, and Social Sciences, American Society for Bioethics and Humanities Annual Meeting
2017	*Timekeeper,* American Society for Bioethics and Humanities Annual Meeting
2017-Present	*Abstract Reviewer,* Pediatric Academic Societies Annual Meeting
2016-2021	*Workshop Reviewer*, Pediatric Academic Societies Annual Meeting
2016	*Grant Reviewer*, Innovation Research Incentives Scheme, The Netherlands Organisation for Health Research and Development
2016-2017	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2014, 2016	*External Peer Reviewer*, PSI Foundation, Toronto, Ontario, Canada
2014	*Member,* Scientific Committee, International Conference on Clinical Ethics and Consultation
2013	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2013	*Reviewer*, Open Research Area Plus, Agence Nationale de la Research, Deutsche Forschungsgemeinschaft, Economic and Social Research Council, National Science Foundation, and Organization for Scientific Research
2011-2012	*Abstract Reviewer,* Pediatric Academic Societies Annual Meeting
2011-2013	*Workshop Reviewer*, Pediatric Academic Societies Annual Meeting
2011-2014	*Abstract Reviewer*, Pediatric Hospital Medicine Annual Meeting
2011-2012	*Religious Studies Subcommittee Leader,* Program Committee, American Society for Bioethics and Humanities Annual Meeting
2010	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting

Other

2021	*Timekeeper,* American Society for Bioethics and Humanities Annual Meeting
2021	*Mentor,* Early Career Advisor Professional Development Track, American Society for Bioethics and Humanities.

2021	*Mentor,* Early Career Advisor Paper or Project Track, American Society for Bioethics and Humanities.
2109	*Mentor*, Early Career Advising Program, American Society for Bioethics and Humanities
2018	*Passing Point Determination*, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission
2018	*Member*, Examination Committee, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission
2018	*Item Writer*, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission

UNIVERSITY COMMUNITY ACTIVITIES

Cincinnati Children's Hospital Medical Center

2020-Present	*Member*, Faculty Diversity and Inclusion Steering Committee
2020-Present	*Member*, Medical Management of COVID-19 Committee
2020-2021	*Member,* Caregiver Refusal Team
2020-2021	*Member,* COVID-19 Vaccine Allocation Committee
2020	*Member*, Personal Protective Equipment Subcommittee of the COVID-19 Steering. Committee
2018-2019	*Member,* Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference
2017-Present	*Member*, Donor Selection Committee
2017-2020	*Member,* Employee Emergency Fund Review Committee
2017	*Member,* Root Cause Analysis Team
2016-2017	*Member,* Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference
2015-2019	*Member,* Destination Excellence Medical Advisory Committee
2015-Present	*Member,* Disorders of Sexual Development Case Review Committee
2015-2019	*Member,* Destination Excellence Case Review Committee
2014-2018	*Member,* Genomics Review Group, Institutional Review Board
2014-2017	*Member,* Center for Pediatric Genomics Leadership Committee
2013-2017	*Member,* Genetic Testing Subcommittee, Health Network
2013-2016	*Member,* Schwartz Center Rounds Planning Committee
2013-2014	*Member*, Genomics Ad Hoc Subcommittee, Board of Directors
2012-Present	*Member,* Cincinnati Fetal Center Oversight Committee
2012-Present	*Member,* Ethics Committee
2012-Present	*Member,* G-23
2012-2016	*Member,* Integrated Solid Organ Transplant Steering Committee

University of Utah

2009-2012	*Member,* Consolidated Hearing Committee

University of Utah School of Medicine

2010-2012	*Member,* Medical Ethics, Humanities, and Cultural Competence Thread Committee
2008-2010	*Member,* Fourth Year Curriculum Committee

University of Utah Department of Pediatrics

2010-2011	*Member,* Planning Committee, 25th Annual Biological Basis of Children's Health Conference, "Sex, Gender, and Sexuality"
2009-2012	*Member,* Medical Executive Committee
2005-2012	*Member,* Retention, Promotion, and Tenure Committee
2004-2012	*Interviewer,* Residency Program

2003-2012 *Member,* Education Committee

Intermountain Healthcare
2009-2012 *Member,* System-Wide Bioethics Resource Service
2009-2012 *Member,* Pediatric Guidance Council

Primary Children's Medical Center
2012-2012 *Member,* Shared Accountability Organization Steering Committee
2009 *Member*, H1N1 and Winter Surge Executive Planning Team
2005-2010 *Member,* Continuing Medical Education Committee
2005-2010 *Member*, Grand Rounds Planning Committee
2003-2012 *Member*, Ethics Committee

ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012-Present Association of Bioethics Program Directors
2011-Present Society for Pediatric Research
2000-Present American Academy of Pediatrics
1999-Present American Society of Bioethics and Humanities

FUNDING

Past Grants

2015-2019 "Better Outcomes for Children: Promoting Excellence in Healthcare Genomics to Inform Policy."
Percent Effort: 9%
National Human Genome Research Institute
Grant Number: 1U01 HG008666-01
Role: Investigator

2015-2016 "Ethics of Informed Consent for Youth in Foster Care"
Direct Costs: $10,000
Ethics Grant, Center for Clinical and Translational Science and Training
University of Cincinnati Academic Health Center
Role: Co-Investigator

2014-2015 "Extreme Personal Exposure Biomarker Levels: Engaging Community Physicians and Ethicists for Guidance"
Direct Costs: $11,640
Center for Environmental Genetics
University of Cincinnati College of Medicine
Role: Investigator

2014-2015 "Child, Adolescent, and Parent Opinions on Disclosure Policies for Incidental Findings in Clinical Whole Exome Sequencing"
Direct Costs: $4,434
Ethics Grant, Center for Clinical and Translational Science and Training, University of Cincinnati Academic Health Center
Role: Principal Investigator

2013-2014 "Better Outcomes for Children: GWAS & PheWAS in eMERGEII
Percent Effort: 5%
National Human Genome Research Institute
Grant Number: 3U01HG006828-0251
Role: Investigator

2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding Participating in Medical Education: Can They be Interpreted in Terms of Presumed Consent?"
Direct Costs: $8,000
Interdisciplinary Research in Applied Ethics and Human Values, University Research Committee, University of Utah
Role: Principal Investigator

TEACHING RESPONSIBILITIES/ASSIGNMENTS

Course and Curriculum Development

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Course Lectures

2018, 2021 Introduction to Biotechnology, "Ethics and Biotechnology" and "Clinical Ethics," BIOL 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.

2018-Present Biomedical Ethics, "Conscientious Objection in Healthcare" and "Ethical Issues in the Care of Transgender Adolescents," MEDS 4035 & MEDS 4036, University of Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.

2016 Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.

2014-Present Physicians and Society, "Transfusion and the Jehovah's Witness Faith," "Obesity Management: Ethics, Policy, and Physician Implicit Bias," "Embryos and Ethics: The Ethics of Designer Babies," "Ethics and Genetic Testing," and "Ethics and Direct to Consumer Genetic Testing," 26950112 and 26950116, University of Cincinnati School of Medicine, Taken by first and second year medical students, Enrollment 100.

2014-Present Ethical Issues in Health Care, "Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels," HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.

2009 Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

Small Group Teaching

2018-Present Ethics in Research, GNTD 7003-001, University of Cincinnati School of Medicine, Taught 1 time per year, Taken by fellows, MS, and PhD students, Enrollment 110.

2007 Physical Diagnosis I, Internal Medicine 7150, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth medical students, Enrollment 100

2003 Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Graduate Student Committees

2018-2022 *Chair,* Scholarship Oversight Committee, William Sveen, Pediatric Critical Care Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2018-2020 *Member*, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2017-2019 *Chair*, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2013-2015 *Mentor*, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2013-2015 *Co-Chair,* Scholarship Oversight Committee, Andrea Murad, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2013-2014 *Member*, Scholarship Oversight Committee, Grace Tran, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2011-2012 *Chair,* Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

Continuing Education Lectures

2008 Choosing Healthplans All Together (CHAT) Exercise Facilitator, 18th Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.

2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.

2007 *Faculty Scholar-in Residence,* Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.

2006 *Workshop Leader,* Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.

2006 *Breakout Session,* 16th Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

Other Educational Activities

2008 *Instructor*, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.

2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

PEER-REVIEWED JOURNAL ARTICLES

1. William N. Sveen, Armand H. Matheny Antommaria, Stephen Gilene, and Erika L. Stalets. (Forthcoming) "Adverse Events During Apnea Testing for the Determination of Death by Neurologic Criteria: A Single Center, Retrospective Pediatric Cohort." *Pediatric Critical Care Medicine.*
2. Erica K. Salter, Jay R. Malone, Amanda Berg, Annie Friedrich, Alexandra Hucker, Hillary King, and Armand H. Matheny Antommaria. (Online ahead of print) "Triage Policies at U.S. Hospitals with Pediatric Intensive Care Units." *AJOB Empirical Bioethics.* PMID: 36576201.
3. Armand H. Matheny Antommaria, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (2023). "A mixed methods analysis of requests for religious exemptions to a COVID-19 vaccine requirement." *AJOB Empirical Bioethics.* 14: 15-22. PMID: 36161802.

4. Anne C Heuerman, Danielle Bessett, Armand H. Matheny Antommaria, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
5. Armand H. Matheny Antommaria and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust. *Journal of Hospital Medicine.* 16: 182-3. PMID 33617445.
6. Gregory A. Grabowski, Armand H. Matheny Antommaria, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism*. 132: 59-75. PMID: 33419694.
7. Armand H. Matheny Antommaria, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal of Clinical Ethics.* 32(1): 35-44. PMID 33416516.
8. Armand H. Matheny Antommaria (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine.* 15(S1): 120-121.
9. Armand H. Matheny Antommaria, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the Association of Bioethics Program Directors." *Annals of Internal Medicine.* 173(3): 188-194. PMID: 32330224.
10. Armand H. Matheny Antommaria (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine.* 5:284-286. PMID: 32379030.
11. Mary V. Greiner, Sarah J. Beal, and Armand H. Matheny Antommaria (2020) "Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth." *Pediatrics*. 45:e20192845. PMID: 32156772.
12. Jennifer deSante-Bertkau, Michelle McGowan, and Armand H. Matheny Antommaria (2018) "Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations." *Journal of Clinical Ethics.* 29:291-304. PMID: 30605439.
13. Andrew J. Redmann, Melissa Schopper, Armand H. Matheny Antommaria, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) "To Transfuse or Not to Transfuse? Jehovah's Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology." *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
14. Armand H. Matheny Antommaria, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) "Parents' Attitudes toward Consent and Data Sharing in Biobanks: A Multi-Site Experimental Survey." *AJOB Empirical Research.* 21:1-15. PMID: 30240342.
15. Armand H. Matheny Antommaria and Cynthia A. Prows. (2018) "Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel" *Journal of Medical Ethics.* 44: 389-391. PMID: 29463693.
16. Armand H. Matheny Antommaria (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics.* 28: 217-221. PMID: 28930708.

17. Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and Armand H. Matheny Antommaria (2017) "A Qualitative Study of Adolescents' Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing." *American Journal of Medical Genetics: Part A.* 173: 930-937. PMID: 28328120.
18. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, Armand Antommaria, Sharon Aufox, Murray Brillant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Cahterine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) "Public Attitudes Towards Consent and Data Sharing in Biobank Research: A Large Multisite Experimental Survey in the US." *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
19. Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, Armand H. Matheny Antommaria, Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) "Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions." *BMC Medical Research Methodology.* 16: 162. PMID: 27881091.
20. Angela Lorts, Thomas D. Ryan, Armand H. Matheny Antommaria, Michael Lake, and John Bucuvalas (2016) "Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States." *Pediatric Transplant.* 20: 774-777. PMID: 27477950.
21. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and Armand H. Matheny Antommaria (2016) "Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood." *American Journal of Medical Genetics Part A*. 170: 2083-2088. PMID: 27149544.
22. Nanibaa' A. Garrison, Nila A. Sathe, Armand H. Matheny Antommaria, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine.* 18: 663-71. PMID: 26583683.
23. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, Armand H. Matheny Antommaria, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) "When Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority." *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
24. Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, Armand H. Matheny Antommaria, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." *Pediatric Critical Care Medicine.* 16: 814-820. PMID: 26237656.
25. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) "A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field." *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.
26. Armand H. Matheny Antommaria, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
27. Stefanie Benoit, Armand H. Matheny Antommaria, Norbert Weidner, and Angela Lorts (2015) "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" *Pediatric Transplantation* 19: 139-43. PMID: 25557132.

28. Kyle B. Brothers, John A. Lynch, Sharon A. Aufox, John J. Connolly, Bruce D. Gelb, Ingrid A. Holm, Saskia C. Sanderson, Jennifer B. McCormick, Janet L. Williams, Wendy A. Wolf, Armand H. Matheny Antommaria, and Ellen W. Clayton (2014) "Practical Guidance on Informed Consent for Pediatric Participants in a Biorepository." *Mayo Clinic Proceedings,* 89: 1471-80. PMID: 25264176.
29. Sophia M. Bous Hufnagel and Armand H. Matheny Antommaria (2014) "Laboratory Policies on Reporting Secondary Findings in Clinical Whole Exome Sequencing: Initial Uptake of the ACMG's Recommendations." *American Journal of Medical Genetics Part A*, 164: 1328-31. PMID: 24458369.
30. Wylie Burke, Armand H. Matheny Antommaria, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wold, and Ron Zimmern (2013) "Recommendations for Returning Genomic Incidental Findings? We Need to Talk!" *Genetics in Medicine*, 15: 854-859. PMID: 23907645.
31. Armand H. Matheny Antommaria (2013) "An Ethical Analysis of Mandatory Influenza Vaccination of Health Care Personnel: Implementing Fairly and Balancing Benefits and Burdens," *American Journal of Bioethics*, 13: 30-37. PMID: 23952830.
32. Joseph A. Carrese and the Members of the American Society for Bioethics and Humanities Clinical Ethics Consultation Affairs Standing Committee (2012) "HCEC Pearls and Pitfalls: Suggested Do's and Don't's for Healthcare Ethics Consultants," *Journal of Clinical Ethics*, 23: 234-240. PMID: 23256404.
33. Christopher G Maloney, Armand H Matheny Antommaria, James F Bale Jr., Jian Ying, Tom Greene and Rajendu Srivastiva (2012) "Factors Associated with Intern Noncompliance with the 2003 Accreditation Council for Graduate Medical Education's 30-hour Duty Period Requirement," *BMC Medical Education* 12: 33. PMID: 22621439.
34. Armand H. Matheny Antommaria, Jill Sweney, and W. Bradley Poss (2010) "Critical Appraisal of: Triaging Pediatric Critical Care Resources During a Pandemic: Ethical and Medical Considerations," *Pediatric Critical Care Medicine,* 11:396-400. PMID: 20453611.
35. Armand H. Matheny Antommaria, Karen Trotochaud, Kathy Kinlaw, Paul N. Hopkins, and Joel Frader (2009) "Policies on Donation After Cardiac Death at Children's Hospitals: A Mixed-Methods Analysis of Variation," *Journal of the American Medical Association,* 301: 1902-8. PMID: 19436017.
36. Kristine M. Pleacher, Elizabeth S. Roach, Willem Van der Werf, Armand H. Matheny Antommaria, and Susan L. Bratton (2009) "Impact of a Pediatric Donation after Cardiac Death Program," *Pediatric Critical Care Medicine,* 10: 166-70. PMID: 19188881.
37. Flory L. Nkoy, Sarah Petersen, Armand H Matheny Antommaria, and Christopher G. Maloney (2008) "Validation of an Electronic System for Recording Medical Student Patient Encounters," *AMIA [American Medical Informatics Association] Annual Symposium Proceedings*, 6: 510-14. PMID: 18999155. Nominated for the Distinguished Paper Award
38. Armand H. Matheny Antommaria, Sean D. Firth, and Christopher G. Maloney (2007) "The Evaluation of an Innovative Pediatric Clerkship Structure Using Multiple Outcome Variables including Career Choice" *Journal of Hospital Medicine*, 2: 401-408. PMID: 18081170.
39. Armand H. Matheny Antommaria (2006) "'Who Should Survive?: One of the Choices on Our Conscience:' Mental Retardation and the History of Contemporary Bioethics." *Kennedy Institute of Ethics Journal*, 16: 205-224. PMID: 17091558.
40. Armand H. Matheny Antommaria (2004) "Do as I Say Not as I Do: Why Bioethicists Should Seek Informed Consent for Some Case Studies." *Hastings Center Report,* 34 (3): 28-34. PMID: 15281724.
41. Armand H. Matheny Antommaria (2004) "A Gower Maneuver: The American Society for Bioethics and Humanities' Resolution of the 'Taking Stands' Debate." *American Journal of Bioethics,* 4 (Winter): W24-27. PMID: 15035934.

NON PEER-REVIEWED JOURNAL ARTICLES

1. Katherine Wade and Armand H. Matheny Antommaria (2016) "Inducing HIV Remission in Neonates: Children's Rights and Research Ethics." *Journal of Medicine and Biology*, 58(3): 348-54. PMID 27157354.
2. Armand H. Matheny Antommaria (2014) "Response to Open Peer Commentaries on 'An Ethical Analysis of Mandatory Influenza." *American Journal of Bioethics,* 14(7): W1-4. PMID: 24978422.
3. Armand H. Matheny Antommaria and Brent D. Kaziny (2012) "Ethical Issues in Pediatric Emergency Medicine's Preparation for and Response to Disasters." *Virtual* Mentor, 14: 801-4. PMID: 23351860.
4. Armand H. Matheny Antommaria, Tia Powell, Jennifer E. Miller, and Michael D. Christian (2011) "Ethical Issues in Pediatric Emergency Mass Critical Care," *Pediatric Critical Care Medicine*, 12(6 Suppl): S163-8. PMID: 22067926.
5. Armand H. Matheny Antommaria and Emily A. Thorell (2011) "Non-Pharmaceutical Interventions to Limit Transmission of a Pandemic Virus: The Need for Complementary Programs to Address Children's Diverse Needs." *Journal of Clinical Ethics,* 22: 25-32. PMID: 21595352.
6. Armand H. Matheny Antommaria (2010) "Conscientious Objection in Clinical Practice: Notice, Informed Consent, Referral, and Emergency Treatment." *Ave Maria Law Review*, 9: 81-99.
7. Armand H. Matheny Antommaria (2008) "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," *Theoretical Medicine and Bioethics,* 29: 201-12. PMID: 18821078.
8. Armand H. Matheny Antommaria (2008) "How can I give her IV antibiotics at home when I have three other children to care for?: Using Dispute System Design to Address Patient-Provider Conflicts in Health Care." *Hamline Journal of Public Law & Policy*, 29: 273-86.
9. Armand H. Matheny Antommaria (2007) "Alternative Dispute Resolution and Pediatric Clinical Ethics Consultation: Why the Limits of Ethical Expertise and the Indeterminacy of the Best Interests Standard Favor Mediation." *Ohio State Journal on Dispute Resolution,* 23: 17-59.
10. Armand H. Matheny Antommaria (2006) "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," *Journal of Law and Family Studies,* 8: 293-316.
11. Armand H. Matheny Antommaria and James F. Bale, Jr. (2002) "Ethical Issues in Clinical Practice: Cases and Analyses," *Seminars in Pediatric Neurology* 9: 67-76. PMID: 11931129.

REVIEW ARTICLES

Armand H. Matheny Antommaria (2010) "Conceptual and Ethical Issues in the Declaration of Death: Current Consensus and Controversies." *Pediatrics in Review* 31: 427-430. PMID: 20889737.

BOOKS

Armand H. Matheny Antommaria (1998) *A Retrospective, Political and Ethical Analysis of State Intervention into Parental Healthcare Decisions for Infants with Disabilities*. Wynnewood, Pennsylvania: Evangelicals for Social Action.

BOOK CHAPTERS

1. Armand H. Matheny Antommaria (2018) "Against Medical Advice Discharges: Pediatric Considerations." In *Against-Medical-Advice Discharges from the Hospital: Optimizing Prevention and Management to Promote High-Quality, Patient-Centered Care.* David Alfandre. New York, Springer: 143-157.
2. Armand H. Matheny Antommaria (2016) "Conscientious Objection in Reproductive Medicine." In *The Oxford Handbook of Reproductive Ethics.* Leslie Francis. Oxford, Oxford University Press: 209-225.
3. Armand H. Matheny Antommaria (2011) "Patient Participation in Medical Education." In *Clinical Ethics in Pediatrics: A Case-based Approach.* Douglas Diekema, Mark Mercurio, and Mary Beth Adam. Cambridge, Cambridge University Press: 221-225.

4. Armand H. Matheny Antommaria (2011) "State Intervention in Parental Decision Making: *Gone Baby Gone*." In *The Picture of Health: Medical Ethics and the Movies.* Henri Colt, Silvia Quadrelli, and Lester Friedman. Oxford, Oxford University Press: 308-12.
5. Armand H. Matheny Antommaria (2009) "Managing Conflicts of Interest: A Perspective from a Pediatrician." In *Professionalism in Medicine: The Case-Based Guide for Medical Students*. John Spandorfer, Charles Pohl, Thomas Nasca and Susan Lee Rattner. Cambridge, Cambridge University Press: 376-7.
6. Armand H. Matheny Antommaria (2007) "Do-Not-Resuscitate Orders." In *Comprehensive Pediatric Hospital Medicine*. L. B. Zaoutis and V. W. Chiang. Philadelphia, Mosby Elsevier**:** 1200-4.

OTHER

Policy Statements and Technical Reports

1. American Academy of Pediatrics Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2013) "Conflicts between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding." *Pediatrics.* 132: 962-965. PMID: 24167167.
2. American Academy of Pediatrics Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2013) "Ethical Controversies in Organ Donation After Circulatory Death." *Pediatrics.* 131: 1021-1026. PMID: 23629612.
3. American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Policy Statement: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Pediatrics.* 131: 620-622. PMID: 23428972.
4. Lainie Friedman Ross, Howard M. Saal, Karen L. David, Rebecca R. Anderson and the American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Genetics in Medicine.* 15: 234-245. PMID: 23429433.
5. American Academy of Pediatrics Committee for Pediatric Research and Committee on Bioethics (2012) "Human Embryonic Stem Cell (hESC) and Human Embryo Research." *Pediatrics* 130: 972-977. PMID: 23109685.
6. American College of Obstetricians and Gynecologists, Committee on Ethics and American Academy of Pediatrics, Committee on Bioethics (2011) "Maternal-Fetal Intervention and Fetal Care Centers," *Pediatrics* 128; e473-e478. PMID: 21788223.
7. American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Committee on Bioethics (2011) "Consent for Emergency Medical Services for Children and Adolescents." *Pediatrics* 128: 427-433. PMID: 21788221.
8. Council on School Health and Committee on Bioethics. Robert Murray and Armand H. Matheny Antommaria Lead Authors. (2010) "Honoring –Do-Not-Attempt Resuscitation Requests in Schools." *Pediatrics* 125; 1073-1077. PMID: 20421255.
9. Committee on Bioethics (2010) "Ritual Genital Cutting of Female Minors." *Pediatrics* 125; 1088-1093. PMID: 20421257.
10. Committee on Bioethics. (2010) "Children as Hematopoietic Stem Cell Donors," *Pediatrics* 125; 392-40. PMID: 20100753.
11. Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2009) "Physician Refusal to Provide Information or Treatment Based on Claims of Conscience." *Pediatrics.* 124; 1689-93. PMID: 19948636.
12. Committee on Bioethics (2009) "Pediatrician-Family-Patient Relationships: Managing the Boundaries." *Pediatrics* 124; 1685-8. PMID: 19948635.
13. Douglas S. Diekema, Jeffrey R. Botkin, and Committee on Bioethics (2009) "Forgoing Medically Provided Nutrition and Hydration in Children." *Pediatrics* 124; 813-22. PMID: 19651596.

14. Lainie Friedman Ross, J. Richard Thistlethwaite, Jr., and the Committee on Bioethics (2008) "Minors as Living Solid-Organ Donors." *Pediatrics* 122: 454-61. PMID: 18676567.
15. Mary E. Fallat, John Hutter, and Section on Hematology Oncology and Section on Surgery the Committee on Bioethics (2008) "Preservation of Fertility in Pediatric and Adolescent Patients with Cancer." *Pediatrics* 121: 1461-9. PMID: 18450888.
16. Marcia Levetown and Bioethics and the Committee on Bioethics (2008) "Communicating With Children and Families: From Everyday Interactions to Skill in Conveying Distressing Information." *Pediatrics* 121: 1441-60. PMID: 18450887.
17. American Academy of Pediatrics. Committee on Bioethics (2007) "Professionalism in Pediatrics: Statement of Principles." *Pediatrics* 120:895-7. PMID: 17908776.

Ethics Rounds

1. Erwin Jiayuan Khoo, Devan M. Duenas, Benjamin S. Wilfond, Luke Gelinas, Armand H. Matheny Antommaria. (Online ahead of print) "Incentives in Pediatric Research in Developing Countries: When Are They Too Much?" *Pediatrics*. 2023 Jan 20: e2021055702. PMID: 36660851.
2. Kim Mooney-Doyle, Kimberly A. Pyke-Grimm, Ashley Foster Lanzel, Kathleen E. Montgomery, Jamila Hassan, Anisha Thompson, Rebecca Rouselle, and Armand H. Matheny Antommaria. (2022) "Balancing Protection and Progress in Pediatric Palliative Care Research: Stakeholder Perspectives." *Pediatrics*. 150: e2022057502. PMID: 36069137.
3. Megan H. Pesch, Phoebe Dazinger, Lainie Friedman Ross, and Armand H. Matheny Antommaria. (2022) "An Ethical Analysis of Newborn Congenital Cytomegalovirus Screening." *Pediatrics*. 149: e2021055368. PMID: 35641472.
4. Ian D. Wolfe, Don Brunnquell, Rena Sorensen, and Armand H. Matheny Antommaria. (2022) "Should Tactile Defensiveness Exclude a Life-Sustaining Intervention in an Adolescent With Autism?" *Pediatrics.* 149: e2021054469. PMID: 35229117.
5. Jennifer E. deSante-Bertkau, Timothy K. Knilans, Govind Persad, Patricia J. Zettler, Holly Fernandez Lynch, and Armand H. Matheny Antommaria. (2021) "Off-Label Prescription of COVID-19 Vaccines in Children: Clinical, Ethical, and Legal Issues." *Pediatrics.* 149: e2021054578. PMID: 34615694.
6. Jamilah M. Hackworth, Meera Kotagal, O. N. Ray Bignal, 2nd, Ndidi Unaka, and Armand H. Matheny Antommaria. (2021) "Microaggressions: Privileged Observers' Duty to Act and What They Can Do." *Pediatrics*. 148: e2021052758. PMID: 34417286.
7. Elizabeth Lanphier, Luke Mosley, and Armand H. Matheny Antommaria. (2021) "Assessing Visitor Policy Exemption Requests During the COVID-19 Pandemic." *Pediatrics.* 148: e2021051254. PMID: 33990461.
8. Natalie Lanocha, Tyler Tate, Erica Salter, Nanette Elster, and Armand H. Matheny Antommaria. (2021) "Can Parents Restrict Access to Their Adolescent's Voice?: Deciding About a Tracheostomy." *Pediatrics*. 147: e2021050358. PMID 33785636.
9. Timothy Crisci, Zeynep N. Inanc Salih, Ndidi Unaka, Jehanna Peerzada, and Armand H. Matheny Antommaria. (2021) "What Should an Intern Do When She Disagrees With the Attending?" *Pediatrics.* 147: e2020049646. PMID 33627371.
10. Liza-Marie Johnson, Erica C. Kaye, Kimberly Sawyer, Alex M. Brenner, Stefan J. Friedrichsdorf, Abby R. Rosenberg, Armand H. Mathey Antommaria. (2021) "Opioid Management in the Dying Child With Addiction." *Pediatrics* 147: e2020046219. PMID 33446508.

Continuing Medical Education

1. Armand H. Matheny Antommaria (2014) Authored 4 questions. NEJM Knowledge+ Family Medicine Board Review. NEJM Group.
2. Armand H. Matheny Antommaria (2009) "Hot Topics: Ethics and Donation After Cardiac Death [online course]. PediaLink. American Academy of Pediatrics. October 24. http://ethics.ht.courses.aap.org/. Accessed December 14. 2009.

Editorials

1. Armand H. Matheny Antommaria, Chris Feudtner, Mary Beth Benner, and Felicia Cohn on Behalf of the Healthcare Ethics Consultant-Certified Certification Commission (2020) "The Healthcare Ethics Consultant-Certified Program: Fair, Feasible, and Defensible, But Neither Definite Nor Finished," *American Journal of Bioethics* 20:1-5. PMID: 32105202.
2. Armand H. Matheny Antommaria and Pamela W. Popp (2020) "The Potential Roles of Surrogacy Ladders, Standby Guardians, and Medicolegal Partnerships, in Surrogate Decision Making for Parents of Minor Children," *Journal of Pediatrics* 220:11-13. PMID 31952849.

Commentaries

1. Jerry Schwartz, Dawn Nebrig, Laura Monhollen, and Armand H. Matheny Antommaria. (2023) "Transforming Behavior Contracts into Collaborative Commitments with Families." *American Journal of Bioethics.* 23(1): 73-75. PMID: 36594997.
2. Armand H. Matheny Antommaria and Elizabeth Lanphier. (2022) "Supporting Marginalized Decision-Marker's Autonom(ies)." *American Journal of Bioethics*. 22(6):22-24. PMID: 35616965.
3. Mary V. Greiner and Armand H. Matheny Antommaria. (2022) "Enrolling Foster Youth in Clinical Trials: Avoiding the Harm of Exclusion." *American Journal of Bioethics.* 22(4):85-86. PMID: 35420526.
4. William Sveen and Armand H. Matheny Antommaria. (2020) "Why Healthcare Workers Should Not Be Prioritized in Ventilator Triage." *American Journal of Bioethics.* 20(7): 133-135. PMID: 32716811.
5. Armand H. Matheny Antommaria, William Sveen, and Erika L. Stalets (2020) "Informed Consent Should Not Be Required for Apnea Testing and Arguing It Should Misses the Point," *American Journal of Bioethics.* 20: 25-27. PMID: 32441602.
6. Armand H. Matheny Antommaria (2019) "Relational Potential versus the Parent-Child Relationship," *Hastings Center Report*. 49(3): 26-27. PMID: 31269255.
7. Armand H. Matheny Antommaria, Robert A. Shapiro, and Lee Ann E. Conard (2019) "Psychological Maltreatment and Medical Neglect of Transgender Adolescents: The Need for Recognition and Individualized Assessment." *American Journal of Bioethics.* 19: 72-74. PMID: 31543011.
8. Armand H. Matheny Antommaria (2018) "Accepting Things at Face Value: Insurance Coverage for Transgender Healthcare." *American Journal of Bioethics.* 18: 21-23. PMID: 31159689.
9. Armand H. Matheny Antommaria and Judith R. Ragsdale (2018) "Shaken, not Stirred: What are Ethicists Licensed to Do?" *American Journal of Bioethics* 18: 56-58. PMID: 29697345.
10. Armand H. Matheny Antommaria (2017) "Issues of Fidelity and Trust Are Intrinsic to Uncontrolled Donation after Circulatory Determination of Death and Arise Again with Each New Resuscitation Method," *American Journal of Bioethics* 17: 20-22. PMID: 28430053.
11. Armand H. Matheny Antommaria (2016) "Conscientious Objection: Widening the Temporal and Organizational Horizons," *The Journal of Clinical Ethics* 27: 248-250. PMID: 27658282.
12. Armand H. Matheny Antommaria and Ron King. (2016) "Moral Hazard and Transparency in Pediatrics: A Different Problem Requiring a Different Solution." *American Journal of Bioethics* 16: 39-40. PMID: 27292846.
13. Armand H. Matheny Antommaria and Richard F. Ittenabch (2016) "Quality Attestation's Portfolio Evaluation Is Feasible, But Is It Reliable and Valid?" *American Journal of Bioethics* 16: 35-38. PMID: 26913658.
14. Armand H. Matheny Antommaria and Kristin Stanley Bramlage (2015) "Enrolling Research Participants in Private Practice: Conflicts of Interest, Consistency, Therapeutic Misconception, and Informed Consent." *AMA Journal of Ethics*. 17:1122-1126. PMID: 26698585.
15. Armand H. Matheny Antommaria (2015) "Characterizing Clinical Ethics Consultations: The Need for a Standardized Typology of Cases." *American Journal of Bioethics* 15: 18-20. PMID: 25970383.

16. Armand H. Matheny Antommaria (2015) "Intensified Conflict Instead of Closure: Clinical Ethics Consultants' Recommendations' Potential to Exacerbate Ethical Conflicts." *American Journal of Bioethics* 15: 52-4. PMID: 25562231.
17. Lainie Friedman Ross and Armand H. Matheny Antommaria (2014) "The need to promote all pediatric stem cell donors' understanding and interests." *Pediatrics* 133: e1356-e1357. PMID: 24777208.
18. Armand H. Matheny Antommaria (2014) "Pubertal Suppression and Professional Obligations: May a Pediatric Endocrinologist Refuse to Treat an Adolescent with Gender Dysphoria." *American Journal of Bioethics* 13: 43-46. PMID: 24422933.
19. Armand H. Matheny Antommaria (2012) "Empowering, Teaching, and Occasionally Advocating: Clinical Ethics Consultants' Duties to All of the Participants in the Process." *American Journal of Bioethics* 12 11-3. PMID: 22852533.
20. Armand H. Matheny Antommaria (2010) "Dying but not Killing: Donation after Cardiac Death Donors and the Recovery of Organs." *Journal of Clinical Ethics* 21: 229-31. PMID: 21089993.
21. Armand H. Matheny Antommaria and Julie Melini (2010) "Is it Reasonable to Refuse to be Seen by a Nurse Practitioner in the Emergency Department?" *American Journal of Bioethics* 10: 15-17. PMID: 20694899.
22. William Meadow, Chris Feudtner, Armand H. Matheny Antommaria, Dane Sommer, John Lantos (2010) "A Premature Baby with Necrotizing Enterocolitis Whose Parents Are Jehovah's Witnesses." *Pediatrics.* 216: 151-155. PMID: 20566607.
23. C. C. Weitzman, S. Schlegel, Nancy Murphy, Armand H. Matheny Antommaria, J. P. Brosco, Martin T. Stein (2009) "When Clinicians and a Parent Disagree on the Extent of Medical Care." *Journal of Developmental and Behavioral Pediatrics.* 30: 242-3. PMID: 19525718. Reprinted as (2010) *Journal of Developmental and Behavioral Pediatrics.* 31: S92-5. PMID: 20414087
24. Armand H. Matheny Antommaria and Susan Bratton (2008) "Nurses' Attitudes toward Donation after Cardiac Death: Implications for Nurses' Roles and Moral Distress." *Pediatric Critical Care Medicine,* 9: 339-40. PMID: 18446100.
25. Armand H. Matheny Antommaria and Nannette C. Dudley (2007) "Should Families Be Present During CPR?" *AAP Grand Rounds,* 17: 4-5.
26. Armand H. Matheny Antommaria (2006) "The Proper Scope of Analysis of Conscientious Objection in Healthcare: Individual Rights or Professional Obligations" *Teaching Ethics*, 7: 127-31.
27. Armand H. Matheny Antommaria and Rajendu Srivastava (2006) "If Cardiologists Take Care of Patients with Heart Disease, What do Hospitalists Treat?: Hospitalists and the Doctor-Patient Relationship." *American Journal of Bioethics*, 6: 47-9. PMID: 16423793.
28. Armand H. Matheny Antommaria (2003) "I Paid Out-of-Pocket for My Son's Circumcision at Happy Valley Tattoo and Piercing: Alternative Framings of the Debate over Routine Neonatal Male Circumcision," *American Journal of Bioethics* 3: 51-3. PMID: 12859817.

Letters

1. Benjamin S. Wilfond, David Magnus, Armand H Matheny Antommaria, Paul Appelbaum, Judy Aschner, Keith J. Barrington, Tom Beauchamp, Renee D. Boss, Wylie Burke, Arthur L. Caplan, Alexander M. Capron, Mildred Cho, Ellen Wright Clayton, F. Sessions Cole, Brian A. Darlow, Douglas Diekema, Ruth R. Faden, Chris Feudtner, Joseph J. Fins, Norman C. Fost, Joel Frader, D. Micah Hester, Annie Janvier, Steven Joffe, Jeffrey Kahn, Nancy E. Kass, Eric Kodish, John D. Lantos, Laurence McCullough, Ross McKinney, Jr., William Deadow, P. Pearl O'Rourke, Kathleen E. Powderly, DeWayne M. Pursley, Lainie Friedman Ross, Sadath Sayeed, Richard R. Sharp, Jeremy Sugarman, William O. Tarnow-Mordi, Holly Taylor, Tom Tomlison, Robert D. Truog, Yoram T. Unguru, Kathryn L. Weise, David Woodrum, Stuart Youngner (2013) "The OHRP and SUPPORT," *New England Journal of Medicine,* 368: e36. PMID: 23738513.

2. Lainie Friedman Ross and Armand H. Matheny Antommaria (2011) "In Further Defense of the American Academy of Pediatrics Committee on Bioethics 'Children as Hematopoietic Stem Cell Donors' Statement." *Pediatric Blood & Cancer*. 57: 1088-9.
3. Armand H. Matheny Antommaria (2011) "Growth Attenuation: Health Outcomes and Social Services." *Hastings Center Report*, 41(5): 4. PMID: 21980886.
4. Susan Bratton and Armand H. Matheny Antommaria (2010) "Dead Donor Rule and Organ Procurement: The Authors Reply." *Pediatric Critical Care Medicine*, 11: 314-5.
5. Armand H. Matheny Antommaria and Joel Frader (2009) "Policies of Children's Hospitals on Donation After Cardiac Death—Reply." *Journal of the American Medical Association*, 302: 845.

Case Reports

Armand H. Matheny Antommaria (2002) "Case 4.9: Inappropriate Access to a Celebrity's Medical Records." In *Ethics and Information Technology: A Case-Based Approach to a Health Care System in Transition*, James G. Anderson and Kenneth W. Goodman, 79-80. New York: Springer-Verlag.

Book Reviews

1. Armand H. Matheny Antommaria (Forthcoming) Review of *Disability's Challenge to Theology: Genes, Eugenics, and the Metaphysics of Modern Medicine* by Devan Stahl. *Hastings Center Report.*
2. Armand H. Matheny Antommaria (2021) Review of *When Harry Became Sally: Responding to the Transgender Moment,* by Ryan T. Anderson. *Journal of Medical Humanities* 42: 195-9. PMID 31808021.
3. Armand H. Matheny Antommaria (2012) Review of *The Ethics of Organ Transplantation*, by Steven J. Jensen, ed., *Journal of the American Medical Association* 308: 1482-3.
4. Armand H Matheny Antommaria (2012) Review of *The Soul of Medicine: Spiritual Perspectives and Clinical Practice*, by John R. Peteet and Michael N. D'Ambra, ed., *Journal of the American Medical Association* 308: 87.
5. Armand H. Matheny Antommaria (2009) Review of *Conflicts of Conscience in Health Care: An Institutional Compromise,* by Holly Fernandez Lynch. *American Journal of Bioethics* 9: 63-4.
6. Armand H. Matheny Antommaria (2008) Review of *A Practical Guide to Clinical Ethics Consulting: Expertise, Ethos, and Power*, by Christopher Meyers. *American Journal of Bioethics* 8: 72-3.
7. Armand H. Matheny Antommaria (2004) Review of *Children, Ethics, and Modern Medicine*, by Richard B. Miller. *American Journal of Bioethics* 4: 127-8.
8. Armand H. Matheny Antommaria (2002) Review of *Ward Ethics: Dilemmas for Medical Students and Doctors in Training*, by Thomasine Kushner and David Thomasma, ed. *American Journal of Bioethics* 2: 70-1. PMID: 22494193.
9. Armand H. Matheny Antommaria (1999) Review of *Human Cloning: Religious Responses*, by Ronald Cole-Turner, ed. *Prism* 6 (March/April): 21.
10. Armand H. Matheny Antommaria (1999) Review of *Christian Theology and Medical Ethics: Four Contemporary Approaches*, by James B. Tubbs, Jr. *Journal of Religion* 79 (April): 333-5.
11. Armand H. Matheny Antommaria (1997) Review of *Body, Soul, and Bioethics*, by Gilbert C. Meilaender. *Prism* 4 (May/June): 28.

Newspaper Articles

1. W. Bradley Poss and Armand H. Matheny Antommaria (2010) "Mass casualty planning must incorporate needs of children." *AAP News* 31 (July): 38.
2. Robert Murray and Armand H. Matheny Antommaria (2010) "Pediatricians should work with school nurses to develop action plans for children with DNAR orders." *AAP News* 31 (May): 30..
3. Armand H. Matheny Antommaria (2009) "Addressing physicians' conscientious objections in health care." *AAP News* 30 (December): 32.

UNPUBLISHED POSTER PRESENTATIONS

1. Armand H. Matheny Antommaria. (2018) "Ethical Issues in the Care of International Patients: A Case Study." International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
1. Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and Armand H Matheny Antommaria, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
2. Christopher G. Maloney, Armand H. Matheny Antommaria, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) "Why Do Pediatric Interns Violate the 30 Hour Work Rule?" Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596
3. Armand H. Matheny Antommaria and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3rd International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
4. Elizabeth Tyson, Tracy Hill, Armand Antommaria, Gena Fletcher, and Flory Nkoy (2007) "Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients." Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

ORAL PRESENTATIONS

Keynote/Plenary Lectures

International

1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, "Ethical Issues," Webinar, April 6.
2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
3. 2014, *Invited Speaker,* CIC 2013 CCI: Canadian Immunization Conference, "Condition-of-Service Influenza Prevention in Health Care Settings," Ottawa, Canada, December 2.
4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, "A Brief Introduction to Pediatric Research and Clinical Ethics," Chongqing, China, September 12.

National

1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
3. 2019, *Panelist,* National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
4. 2017, *Invited Participant,* American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
5. 2016, *Invited Speaker,* American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
6. 2016, *Invited Speaker*, 26th Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
7. 2015, *Invited Speaker,* Extracorporeal Life Support Organization (ELSO) 26th Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.

8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.
9. 2014, *Invited Speaker,* 6th Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
10. 2010, *Invited Speaker,* Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.
14. 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," Chicago, IL, March 18.
15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, "The Representation of Children in Disputes at the End-of-Life," Columbus, Ohio, January 18.
16. 2005, *Keynote Speaker*, Decisions and Families, *Journal of Law and Family Studies* and The University of Utah S.J. Quinney College of Law, "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," Salt Lake City, Utah, September 23.

Regional/Local

1. 2021, *Panelist*, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, "Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents," Memphis, Tennessee, September 21.
2. 2020, *Keynote Speaker*, 53rd Annual Clinical Advances in Pediatrics, "Referral to a Fetal Care Center: How You Can Help Patients' Mothers Address the Ethical Issues," Kansas City, Kansas, September 16.
3. 2019, *Speaker,* Patient and Family Support Services, Primary Children's Hospital, "Ethical Issues in the Care of Trans Adolescents," Salt Lake City, Utah, December 5.
4. 2019, *Speaker,* Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, "Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents," Salt Lake City, Utah, December 4.
5. 2019, *Speaker,* Pediatric Hospital Medicine Board Review Course, "Ethics, Legal Issues, and Human Rights including Ethics in Research," Cincinnati, Ohio, September 8.
6. 2019, *Speaker,* Advances in Fetology, "Evolving Attitudes Toward the Treatment of Children with Trisomies," Cincinnati, Ohio, September 6.
7. 2019, *Speaker,* Half-Day Ethics Training: Ethics Consultation & Ethics Committees, "Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation," Salt Lake City, Utah, June 1.

8. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, "What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies," Cranbury, New Jersey, March 7.
9. 2018, *Panelist*, Periviability, 17th Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
10. 2018, *Speaker,* Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
11. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
12. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.
13. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
14. 2016, *Speaker*, 26th Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
15. 2014, *Speaker,* Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
16. 2014, *Speaker,* Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
17. 2014, *Speaker,* Advances in Fetology 2014, "'Can you tell me …?': Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
18. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
19. 2014, *Speaker,* Office for Human Research Protections Research Community Forum: Clinical Research … and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
20. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21st Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
21. 2012, *Videoconference,* New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
22. 2011, *Presenter,* Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions, " Salt Lake City, Utah, November 14.
23. 2011, *Speaker,* 15th Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
24. 2011, *Speaker*, Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.
25. 2009, *Speaker,* Medical Staff Leadership Conference, Intermountain Healthcare, "The Ethics of Leadership," Park City, Utah, October 30.
26. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children's Medical Center, "Medically Provided Hydration and Nutrition: Ethical Considerations," Salt Lake City, Utah, February 25.
27. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, "Immunization Update," Salt Lake City, Utah, August 18.
28. 2005, *Keynote Speaker,* 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, "Brain Death: Accommodation and Consultation," Salt Lake City, March 18.
29. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), "Febrile Seizures," Salt Lake City, Utah, April 22.

30. 2004, *Speaker,* Advocacy Workshop for Primary Care Providers, "Ethics of Advocacy," Park City, Utah, April 3.
31. 2002, *Speaker,* 16th Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

Meeting Presentations

International

1. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, "A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations," Oxford, United Kingdom, June 21.

National

1. 2022, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement." Portland, Oregon, October 27.
2. 2022, *Panelist,* American Society for Bioethics and Humanities Annual Meeting, Pediatric Ethics Affinity Group, "When Ethical Healthcare Is Prohibited By Law, How Do We Respond?" Portland, Oregon, October 27.
3. 2022, *Speaker,* APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, "From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research," Denver, Colorado, April 22.
4. 2021, *Panelist,* Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
5. 2020, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.
6. 2020, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
7. 2020, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.
8. 2019, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
9. 2019, *Moderator,* Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
10. 2018, *Presenter,* American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities' Engagement with Transgender Health," Anaheim, California, October 19.
11. 2018, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
12. 2018, Lindsey Douglas, Armand H. Matheny Antommaria, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
13. 2018, Alan Schroeder, Armand H. Matheny Antommaria, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker,* Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.

14. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, Armand H. Matheny Antommaria. *Workshop Speaker,* Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
15. 2017, *Speaker,* American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
16. Lindsey Douglas, Armand H. Matheny Antommaria, and Derek Williams. 2017, *Workshop Leader,* PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
17. 2016, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
18. 2015, *Coauthor,* The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
19. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
20. Armand H. Matheny Antommaria, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, *Moderator*, American Society for Bioethics and Humanities Annual Meeting, "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
21. 2012, *Platform Presentation,* Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.
22. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
23. Armand H. Matheny Antommaria and Joel Frader. 2010, *Workshop Leader,* Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
24. 2009, *Workshop Leader,* American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.
25. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
26. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
27. 2007, *Participant,* Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
28. *2007*, *Speaker,* American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
29. 2007, *Speaker,* American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.

30. Armand H. Matheny Antommaria and Jeannie DePaulis. 2007, *Speaker,* National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
31. 2006, *Speaker,* American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
32. 2005, *Panelist,* American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain,'" Washington, DC, October 20.
33. 2005, *Paper Presentation,* Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death,'" Cleveland, Ohio, September 9.
34. 2004, *Speaker,* American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
35. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "'Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

Invited/Visiting Professor Presentations

1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.
2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

Grand Round Presentations

1. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
2. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
3. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.
4. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.
5. 2017, Heart Institute, "'Have you ever thought about what you would want—if god forbid—you became sicker?': Talking with adult patients about advance directives," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 16.
6. 2017, Pediatrics, "Respectful, Effective Treatment of Jehovah's Witnesses," with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, March 14.
7. 2017, Pediatrics, "Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety," Seattle Children's Hospital, Seattle, Washington, January 19.
8. 2015, Pediatrics, "'Nonbeneficial' Treatment: What must providers offer and what can they withhold?," Greenville Health System, Greenville, South Carolina, May 10.
9. 2014, Advance Practice Providers, "Common Ethical Issues," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, August 13.
10. 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
11. 2013, Heart Institute, "No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 21.
12. 2013, Division of Neonatology, "This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 11.

13. 2013, Department of Pediatrics, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, February 26.
14. 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.
15. 2011, Division of Pediatric Neurology Friday Lecture Series, "Inducing or Treating 'Seizures' with Placebos: Is It Ever Ethical?," University of Utah, Salt Lake City, Utah, October 7.
16. 2011, Department of Surgery, "DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions," Primary Children's Medical Center, Salt Lake City, Utah, October 3.
17. 2009, Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Bioethical Mediation," Primary Children's Medical Center, Salt Lake City, Utah, September 17.
18. 2008, Division of Pulmonology and Critical Care, "Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?" Utah Valley Regional Medical Center, Provo, Utah, April 17.
19. 2007, Division of Otolaryngology-Head and Neck Surgery, "Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!," University of Utah School of Medicine, Salt Lake City, Utah, June 20.

Outreach Presentations

1. 2019, *Panelist*, Cincinnati Edition, WVXU, "The Ethics of Human Gene Editing," Cincinnati, Ohio, June 13.
2. 2019, *Speaker,* Adult Forum, Indian Hill Church, "Medical Ethics," Indian Hill, Ohio, March 24.
3. 2016, *Speaker,* Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
4. 2008, *Speaker,* Science in Society, Co-sponsored by KCPW and the City Library, "Death—Choices," Salt Lake City, Utah, November 20.
5. 2003, *Panelist,* Utah Symposium in Science and Literature, "The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?" Salt Lake City, Utah, October 10.
6. 2002, *Respondent*, H. Tristram Englehardt, Jr. "The Culture Wars in Bioethics," Salt Lake Community College, Salt Lake City, Utah, March 29.

Podcasts

1. 2021, "Ethics of COVID Vaccines in Kids," PHM from Pittsburgh, August 12.
2. 2020, COVID Quandaries: Episode 1, "Is Getting Sick Just Part of the Job?" Hard Call, October 6.

EXHIBIT C

TABLE 1: Strength of Recommendation and Quality of Evidence in Recommendations Made by the Endocrine Society

Strength of the Recommendation/ Quality of the Evidence[1]	Endocrine Treatment of Gender-Dysphoric/Gender-	Pediatric Obesity-Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase
Strong|High	0 (0)[2]	0 (0)	0 (0)
Strong|Moderate	3 (11)	4 (13)	18 (33)
Strong|Low	5 (18)	6 (20)	13 (25)
Strong|Very Low	2 (7)	1 (3)	1 (2)
Weak|High	0 (0)	0 (0)	0 (0)
Weak|Moderate	0 (0)	0 (0)	2 (4)
Weak|Low	9 (32)	5 (17)	4 (7)
Weak|Very Low	3 (11)	12 (40)	7 (13)
Ungraded Good Practice Statement[3]	6 (21)	2 (7)	9 (17)
Weak	12 (43)	17 (57)	13 (24)
Either Low or Very Low	19 (68)	24 (80)	25 (46)
Total	28	30	54

[1] Quality of the Evidence
High: "Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies"
Moderate: "Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies"
Low: "Evidence for at least one critical outcomes from observational studies, from RCTs with serious flaws, or indirect evidence"
Very Low: "Evidence for at least one of the critical outcomes from unsystematic

clinical observations or very indirect evidence"
See Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the grading of recommendations, assessment, development, and evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-73.

[2] n (%)

[3]Ungraded Good Practice Statement: "Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles." See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

Guidelines:
Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.
Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REPORT OF DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my CV is attached as **Exhibit A**.

4. I am a Professor Emeritus of Psychiatry at the University of California – San Francisco (UCSF) Weill Institute for Neurosciences. I have been on faculty at UCSF since 1991. I have also had a telepsychiatry private practice since 2020.

5. I received my Doctor of Medicine (M.D.) degree from the Yale Medical School in 1987. In 1991, I completed my residency in psychiatry at the University of California – Los Angeles (UCLA) Neuropsychiatric Institute, and from 1990 to 1991, I was a postdoctoral fellow in a training program in mental health services for persons living with AIDS at UCLA.

6. For over 30 years, I have worked with patients with gender dysphoria. I am a Distinguished Life Fellow of the American Psychiatric Association and currently the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, as well as the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

7. Over the past 30 years, I have provided care for thousands of transgender patients. For 17 years, I was the psychiatrist for the Dimensions Clinic for transgender youth in San Francisco. The clinic treats trans youth 12-25 years old.

8. I previously sat on the Board of Directors of the World Professional Association for Transgender Health (WPATH) and am a co-author of WPATH's *Standards of Care for the Health of Transsexual, Transgender, and Gender*

Nonconforming People, Versions 7 and 8, which are the internationally accepted guidelines designed to promote the health and welfare of transgender, transsexual, and gender variant persons. For the Version 8, I was the lead author on the Mental Health chapter.

9. As a member of the WPATH Global Education Initiative, I helped develop a specialty certification program in transgender health and helped train over 2,000 health care providers.

10. At UCSF, I developed protocols and outcome measures for the Transgender Surgery Program at the UCSF Medical Center. I also served on the Medical Advisory Board for the UCSF Center of Excellence for Transgender Care and co-wrote the mental health section of the original *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* and the revision in 2016.

11. I have also worked with the San Francisco Department of Public Health, having helped develop and implement their program for the care of transgender patients and for mental health assessments for gender-affirming surgery. I served on the City and County of San Francisco Human Rights Commission's LGBT Advisory Committee, and I have been an expert consultant for California state agencies and on multiple occasions for the United Nations Development Programme on international issues in transgender care.

12. I have held numerous clinical positions concurrent to my clinical professorship at UCSF. Among these, I served as an attending psychiatrist for San Francisco General Hospital's consultation-liaison service for AIDS care, as an outpatient psychiatrist for HIV-AIDS patients at UCSF, as a psychiatrist for the Transgender Life Care Program and the Dimensions Clinic at Castro Mission Health Center, and the founder and co-lead of the UCSF Alliance Health Project's Transgender Team. In these clinical roles, I specialized in the evaluation and treatment of transgender, gender dysphoric, and HIV-positive patients. I also regularly provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients. I have been a consultant in transgender care to the California Department of State Hospitals and am currently a consultant for the California Department of Corrections and Rehabilitation on the care of incarcerated transgender people.

13. As part of my psychiatric practice treating individuals diagnosed with gender dysphoria and who receive other medical and surgical treatment for that condition, as well as a co-author of the WPATH Standards of Care and UCSF's *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*, I am and must be familiar with additional aspects of medical care for the diagnosis of gender dysphoria, beyond mental health treatment, assessment, and diagnosis.

14. In addition to this work, I have done research on the treatment of depression. I have authored many articles and book chapters and edited the book *Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation*.

15. Since 2018, I have performed over 100 independent medical reviews for the State of California to determine the medical necessity of transgender care in appeals of denial of insurance coverage.

B. Compensation

16. I am being compensated for my work on this matter at a rate of $400.00 per hour for preparation of declarations and expert reports. I will be compensated $3,200.00 per day for any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

C. Previous Testimony

17. Over the past four years, I have given expert testimony at trial or by deposition in the following cases: *C.P. v. Blue Cross Blue Shield of Illinois*, No. 3:20-cv-06145-RJB (W.D. Wash.); *Kadel v. Folwell*, No. 1:19-cv-00272 (M.D.N.C.); *Fain v. Crouch*, 3:20-cv-00740 (S.D.W. Va.); and *Brandt v. Rutledge*, No. 4:21-cv-00450 (E.D. Ark.). To the best of my recollection, I have not given expert testimony at a trial or at a deposition in any other case during this period.

II. BASES FOR OPINIONS

18. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein, as documented in my curriculum vitae, which is attached hereto as **Exhibit A**.

19. I have also reviewed the materials listed in the bibliography attached hereto as **Exhibit B**. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report.

20. Additionally, I have reviewed Florida's Administrative Rule governing the determination of generally accepted professional medical standards under Florida Medicaid coverage (Fla. Admin. Code R. 59G-1.035); the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments, including the reports of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty-delaying medications (commonly referred

to as "puberty blockers"), hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics, on the basis that the services do not meet Florida's definition of "medical necessity" for purposes of its Medicaid program.

21. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

III. EXPERT OPINIONS

A. Gender Identity

22. Sex assigned at birth refers to the sex assigned to a person at the time of their birth, typically based on the appearance of external genital characteristics. While the terms "male sex" and "female sex" are sometimes used in reference to a person's genitals, chromosomes, and hormones, the reality is that sex is complicated and multifactorial. Aside from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include gonads, gender identity, and variations in brain structure and function. Because these factors may not always be in alignment as typically male or typically female, "the terms biological sex and

biological male or female are imprecise and should be avoided." (Hembree, et al., 2017).

23. Gender identity is "a person's deeply felt, inherent sense of being a girl, woman, or female; a man, or male; a blend of male or female; or an alternative gender" (American Psychological Association, 2015, at 834). Gender identity does not always align with sex assigned at birth. Gender identity, which has biological bases, is not a product of external influence and not subject to voluntary change. As documented by multiple leading medical authorities, efforts to change a person's gender identity are ineffective, can cause harm, and are unethical. (American Psychological Association, 2021; Byne, et al., 2018; Coleman, et al., 2022).

B. Gender Dysphoria

24. The term "gender dysphoria" is distress related to the incongruence between one's gender identity and attributes related to one's sex assigned at birth.

25. The diagnosis of Gender Dysphoria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022), involves two major diagnostic criteria for adolescents and adults:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as

manifested by at least two of the following (one of which must be Criterion A1):

1. A marked incongruence between one's experienced/expressed gender and primary or secondary sex characteristics.
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

26. Given that gender dysphoria can cause such distress, many transgender individuals face depression, anxiety, and higher rates of suicidality than cisgender people. This is noted both in adults and adolescents. However, gender dysphoria is a condition that is highly amenable to treatment, and the prevailing treatment for it is highly effective. These risks decline when transgender individuals are supported and live according to their gender identity. And with access to medically indicated care, transgender people can experience significant and potentially complete relief from their symptoms of gender dysphoria. Not only is this documented in scientific literature and published data, but I witness this each time I see my patients being supported by their community, family, school, and medical providers.

C. Evidence-Based Guidelines for Treatment of Gender Dysphoria

27. The World Professional Association of Transgender Health (WPATH) has issued *Standards of Care for the Health of Transgender and Gender Diverse People* ("WPATH SOC") since 1979. The current version is WPATH SOC 8, published in 2022. The WPATH SOC provide guidelines for multidisciplinary care of transgender individuals and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated.

28. The SOC 8 is based upon a more rigorous and methodological evidence-based approach than previous versions. (Coleman, et al., 2022). This

evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Its recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. The process for development of the SOC 8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

29. While SOC 8 includes important updates, it does not change the substance of any of the opinions I expressed in my previous declaration. Indeed, SOC 8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as medically appropriate and necessary treatments for gender dysphoria, based on an individual patient's needs.

30. WPATH SOC 8 also states, "Gender identity change efforts (gender reparative or gender conversion programs aimed at making the person cisgender) are widespread, cause harm to TGD people, and (like efforts targeting sexual orientation) are considered unethical." (Coleman, et al., 2022).

31. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guidelines) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al., 2017).

32. Guidelines from other organizations, including those developed by the UCSF Center of Excellence for Transgender Care, also list similar protocols for the medically necessary treatment of gender dysphoria.

33. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

34. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guidelines are endorsed and cited as authoritative by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others.

35. To be sure, being transgender is widely accepted as a variation in human development and is not considered a mental illness. People who are transgender have no impairment in their ability to be productive, contributing members of society simply because of their transgender status.

a. The American Psychiatric Association's DSM 5 states: Gender dysphoria "is more descriptive than the previous DSM-IV term 'gender identity disorder' and focuses on dysphoria as the clinical problem, not identity per se." (APA, 2013).

b. WPATH SOC 8 states: "The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. … It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical interventions." (Coleman, et al. 2022).

c. The American Psychological Association states: "Whereas diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy, incongruence between one's sex and gender is neither pathological nor a mental health disorder." (American Psychological Association, 2021).

d. The World Health Organization states: "Gender incongruence has thus broadly been moved out of the 'Mental and behavioural disorders' chapter and into the new 'Conditions related to sexual health' chapter. This reflects evidence that trans-related and gender diverse identities are not conditions of mental ill health, and classifying them as such can cause enormous stigma." (WHO Europe).

36. Thus, the overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

37. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective. The American Psychological Association states that gender identity change efforts provide no benefit and instead do harm. (American Psychological Association, 2021).

38. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, the Endocrine Society,

American College of Obstetricians and Gynecologists, and American Academy of Family Physicians oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2021; American Psychiatric Association, 2018; Endocrine Society, 2020; American College of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020).

D. Treatment of Gender Dysphoria

39. The WPATH SOC 8 and the Endocrine Society Guidelines establish authoritative protocols for the treatment of gender dysphoria.

40. In accordance with the WPATH SOC 8 and the Endocrine Society Guidelines, medical interventions to treat gender dysphoria may include treatment with pubertal suppression and/or hormones, and treatment with surgery.

41. No medical or surgical treatment for gender dysphoria is provided to pre-pubertal children.

42. Once a patient enters puberty, treatment options include pubertal suppression therapy and gender-affirming hormones. Pubertal blocking involves methods of temporarily suppressing endogenous puberty to alleviate gender dysphoria and give the patient more time to work with their mental health providers to assess treatment needs. These blockers are reversible medications and once

stopped, a patient returns to the stage of pubertal development that had begun when the treatment was initiated.

43. If a patient is assessed to have a medical need for hormone therapy, gender-affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity), such as testosterone in transgender male individuals and estrogen in transgender female individuals, to treat gender dysphoria later in puberty. The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. For adolescents, this treatment allows patients to have pubertal changes and development consistent with their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, decreased testicular mass).

44. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include, *inter alia*, vaginoplasty and orchiectomy for transgender female individuals, and chest reconstruction and hysterectomy for transgender male individuals.

45. According to WPATH SOC 8, "Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined

by a multidisciplinary team experienced in adolescent and gender development" (Coleman, et al. 2022).

46. The treatment protocols for gender dysphoria are comparable to those for other mental health and medical conditions. Indeed, these or similar procedures are provided for cisgender people with other diagnoses.

E. Assessments of Patients with Gender Dysphoria.

47. WPATH SOC 8 recommends that health care professionals working with transgender and non-binary adolescents be licensed, hold a postgraduate degree in relevant clinical field, have received training and developed expertise in working with children and adolescents, including those with autism spectrum disorder, and have received training and developed expertise in gender identity and diversity in youth, and in the ability of youth to assent/consent to care (Coleman, et al., 2022).

48. WPATH SOC 8 recommends a "comprehensive biopsychosocial assessment" for adolescents "prior to any medically necessary medical or surgical intervention" for gender dysphoria. The assessment should include gender identity development, social development and support, diagnostic assessment of co-occurring mental health or developmental concerns, and capacity for decision-making (Coleman, et al., 2022).

49. For assessing an adult for gender-affirming medical care, WPATH SOC 8 states that the health professional should be licensed and trained in identifying

gender dysphoria as well as co-existing mental health and psychosocial concerns, and that medical or surgical treatment should only be recommended when "gender incongruence is marked and sustained," when there is capacity for consent, when other conditions that might affect outcomes have been assessed, and when diagnostic criteria for Gender Dysphoria of DSM 5-TR (in the US) or Gender Incongruence of ICD-11(outside the US) are met.

50. Before gender affirming care is provided, WPATH SOC 8 recommends that impacts on fertility of care, and fertility preservation options be discussed thoroughly with the patient, and in the case of a minor, with parents or guardians.

51. Affirming care for transgender youth does not mean steering them in any particular direction, but rather supporting them through their period of exploration of gender expression and increasing self-awareness of their identity (Ehrensaft, 2017). WPATH SOC 8 states, "We recommend health professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particularly in favored." (Coleman, et al., 2022). WPATH SOC 8 states "For some youth, obtaining gender-affirming medical care is important while for others these steps might not be necessary." (Coleman, et al., 2022). In my clinical experience, some adolescent patients have a critical need for medical interventions at or at some point after the onset of puberty

and others do not. As with all medical interventions, it is highly individualized and responsive to the particular medical and mental health needs of each patient.

52. The Endocrine Society Guidelines state that only "[mental health professionals] who ha[ve] training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis," which usually includes "a complete psychodiagnostic assessment." (Hembree, et al., 2017, at 3877). It further provides that because gender dysphoria "may be accompanied with psychological or psychiatric problems" it is necessary that clinicians involved in diagnosis and psychosocial assessment meet specific competency requirements and that they undertake or refer for appropriate psychological or psychiatric treatment. *Id.*, at 3876. And "in cases in which severe psychopathology" "interfere[s] with diagnostic work or make[s] satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues." *Id*.

F. Gender-Affirming Medical and Surgical Care Is Safe and Effective.

53. Gender-affirming medical and surgical interventions in accordance with the WPATH SOC and Endocrine Society Guidelines are widely recognized in the medical community as safe, effective, and medically necessary for many transgender people with gender dysphoria. (See American Academy of Pediatrics, 2018; the American Medical Association, 2021; the Endocrine Society, 2020; the

Pediatric Endocrine Society, 2021; the American Psychiatric Association, 2018; the American Psychological Association, 2021; the American Congress of Obstetricians and Gynecologists, 2021; the American Academy of Family Physicians, 2020; WPATH, 2016).

54. There is substantial evidence that gender-affirming medical and surgical care is effective in treating gender dysphoria. This evidence includes scientific studies assessing mental health outcomes for transgender people who are treated with these interventions, including adolescents, and decades of clinical experience.

55. The research and studies supporting the necessity, safety, and effectiveness of medical and surgical care for gender dysphoria are the same type of evidence-based data that the medical community routinely relies upon when treating other medical conditions.

56. Medical treatment for gender dysphoria has been studied for over half a century, and there is substantial evidence that it improves quality of life and measures of mental health. (Aldridge et al., 2021; Almazan, et al., 2021; Baker et al., 2021; Murad, et al., 2010; Nobili et al., 2018; Pfafflin & Junge, 1998; T'Sjoen et al. 2019; van de Grift et al., 2018; White Hughto and Reisner, 2016; Wierckx et al., 2014).

57. A systematic review of 20 studies showed improved quality of life, decreased depression, and decreased anxiety with hormonal treatment in transgender people. (Baker, et al., 2021). Another systematic review showed improvement in mental health and quality of life measures in transgender people with hormonal treatment (White Hughto and Reisner, 2016). In the United Kingdom, one study demonstrated that depression and anxiety were substantially reduced over 18 months of gender-affirming hormonal treatment. (Aldridge, et al., 2021). In a secondary analysis of data from the US Transgender Survey, having had genital surgery was associated with decreased psychological distress and suicidal ideation. (Almazan, et al., 2021). In transgender patients followed 4-6 years after surgery, satisfaction was very high (over 90%) and regret was low. (van de Grift et al., 2018). The Cornell "What We Know" systematic review of 55 studies from 1991-2017 strongly supported that gender-affirming hormone and surgical treatment improved the well-being of transgender individuals. (What We Know, 2018).

58. Transgender people have been benefiting from gender-affirming medical and surgical care for decades. Researchers interviewed fifteen transgender people 40 years after they had received gender-affirming surgical care at University of Virginia. Participants reported continued benefits over 40 years from gender affirming care, including improved mental health, reduced suicidality, reduced

gender dysphoria, and high patient satisfaction, with no reported cases of regret (Park, et al. 2022).

59. The studies on gender-affirming medical care for treatment of dysphoria are consistent with decades of clinical experience of mental health providers across the U.S. and around the world. At professional conferences and other settings in which I interact with colleagues, clinicians report that gender-affirming medical care, for those for whom it is indicated, provides great clinical benefit. In my 30 years of clinical experience treating gender dysphoric patients, I have seen the benefits of gender-affirming medical care on my patients' health and well-being. I have seen many patients show improvements in mental health, as well as in performance in school, in social functioning with peers, and in family relationships when they experience relief from gender dysphoria with gender-affirming medical care.

60. Accordingly, treatments for gender dysphoria are not considered elective or cosmetic. Indeed, as WPATH (2016) states, "The medical procedures attendant to gender-affirming/confirming surgeries are not 'cosmetic' or 'elective' or 'for the mere convenience of the patient.' These reconstructive procedures are not optional in any meaningful sense but are understood to be medically necessary for the treatment of the diagnosed condition. In some cases, such surgery is the only

effective treatment for the condition, and for some people genital surgery is essential and life-saving."

61. As part of the treatment process for gender dysphoria, patients provide informed consent to their care. In addition, a treating doctor will not offer gender-affirming medical treatments unless they have concluded after weighing the risks and benefits of care for the specific patient that treatment is appropriate. The risks and benefits of care are discussed with the transgender patient, who must consent or assent, as appropriate. This process is no different than the informed consent process for other medical treatments. However, for gender-affirming medical care, there is the additional safeguard of the recommended assessments by a health care professional, who must not only be experienced in the assessment of gender dysphoria, but also in the assessment of a patient's capacity to consent/assent to treatment and ability to understand the risks and benefits of treatment. Indeed, SOC 8 notes that mental health professionals are the best positioned practitioners to conduct these assessments for adolescents and also recommends, for all patients, that a mental health professional address any mental health issues that may interfere with a patient's ability to consent prior to the initiation of gender-affirming care.

62. Regret among those who are treated with gender-affirming medical care is rare. For example, in one study in the Netherlands, none of the youth who received puberty-delaying treatment, hormones, and surgery, and were followed over an 8-

year period expressed regret. (DeVries, 2014.) Zucker, et al., (2010), summarizing key studies on regret for adolescents referred for surgery when they reached the age of majority in the Netherlands, states, "there was virtually no evidence of regret, suggesting that the intervention was effective."

63. A study of 209 gender-affirming mastectomies in transmasculine adolescents aged 12-17, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Tang, et al 2022).

64. Regret rates for gender-affirming surgery in adults are also very low. A pooled review across multiple studies of 7,928 patients receiving gender-affirming surgery showed a regret rate of 1%. (Bustos, et al., 2021). Over 50 years of gender-affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Dhejne, et al., 2014). These are very low regret rates for surgery. For example, 47% of women expressed at least some regret after reconstructive breast surgery following mastectomy for breast cancer. (Sheehan, et al., 2008).

65. For all the reasons above, I am aware of no basis in medicine or science for categorical exclusion of coverage for gender-affirming care.

66. One misperception is that puberty-delaying medications and hormone therapy are experimental because they are not FDA-approved for the specific application of treating Gender Dysphoria. Medications very commonly are prescribed for off-label uses. All gender-affirming hormone treatments are approved

for treatment of other conditions and have been used to treat those conditions, as well as for gender-affirming care, for many years, supporting their safety and efficacy. The U.S. Department of Health and Human Services Agency for Healthcare Research and Quality states, "[Off-label prescribing] is legal and common. In fact, one in five prescriptions written today are for off-label use."[1]

67. Finally, the cost of providing coverage for gender-affirming care is generally very low. To begin, transgender people constitute a small percentage of the overall population, approximately 0.5%. (Crissman, et. al., 2017). Furthermore, the fraction of the population receiving clinical care for Gender Dysphoria is much smaller, well under one in a thousand patients (Zhang, et al., 2020). As a result, one study estimated an average cost of $0.016 cents per member per month to provide gender-affirming care (Padula, et al., 2016). A study by Herman (2013) similarly found low costs to providing health coverage for gender-affirming care. Additionally, when a form of treatment is covered for cisgender people under an insurance plan, it is generally not disproportionately costly to cover the same treatment for transgender people simply because it is provided to treat gender dysphoria.

[1] See https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html.

G. Harms of Denying Gender-Affirming Care

68. The overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. The prevalence of these mental health conditions is also thought to be a consequence of minority stress, the chronic stress from coping with societal stigma and discrimination because of one's identity, including gender identity and gender expression. (American Medical Association, 2019). In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

69. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, and American College of Obstetricians and Gynecologists, oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2019).

70. Denial of this appropriate care for transgender adolescents is also opposed by mainstream organizations responsible for the care of youth, including

the American Academy of Pediatrics, the Academy of Child and Adolescent Psychiatry, and the Pediatric Endocrine Society.

71. Familial and social support and the provision of gender-affirming medical treatment have been associated with dramatically less suicidal ideation in transgender people. (Bauer, et al., 2015). Provision of puberty blockers and gender-affirming hormones for transgender youth likewise decreases suicidality (Tordoff, et al., 2022; Turban, et al., 2020; Green, et al., 2022; Allen, et al., 2019). The American Academy of Child and Adolescent Psychiatry states, "Research consistently demonstrates that gender diverse youth who are supported to live and/or explore the gender role that is consistent with their gender identity have better mental health outcomes than those who are not." (AACAP, 2019).

72. In a multicenter NIH-funded study, 315 transgender and nonbinary youth followed over two years showed a decrease in anxiety and depression and an improvement in appearance congruence and life satisfaction with gender affirming medical treatment. (Chen, et al., 2023).

73. In a University of Washington study of 104 transgender and nonbinary youth, treatment with puberty blockers or hormones was associated with 60% less moderate to severe depression and 73% less suicidal ideation over 12 months, compared to youth not treated. (Tordoff, et al. 2022).

74. In a University of Texas Southwestern study, treatment with gender-affirming hormones in transgender youth was associated with a substantial reduction in body dissatisfaction, as well as improvement on measures of depression and anxiety. (Kuper, et al., 2020).

75. In a University of Southern California and Children's Hospital Los Angeles study of 136 transgender male youth, the half that had received chest masculinizing surgery had far less gender dysphoria than those who had not yet had surgery. (Olson-Kennedy, et al., 2018).

76. In a University of Pennsylvania and University of Rochester study, transgender male youth aged 13-21 suffered substantial emotional distress and functional impairment from dysphoria related to their chest. Chest dysphoria resolved with surgery. Youth reported improvement functionally and in quality of life (Mehringer, et al., 2021).

77. In the past 10 years, there has been a reversal in longstanding coverage policies that had excluded reimbursement of gender-affirming care for transgender people. There are many more clinics providing care to transgender youth and adults in academic medical centers than a decade ago, because funding is now available. This change is allowing clinical researchers to expand the body of research in the United States, as well as increasing access to care.

H. The GAPMS Memo and AHCA's Decision to Prohibit Medicaid Coverage of Gender-Affirming Care

78. According to criteria of the Florida Administrative Code 59G-1.035, the Agency for Health Care Administration (AHCA) makes coverage determinations based on "Generally accepted professional medical standards—standards based on reliable scientific evidence published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations' recommendations." It is my understanding that AHCA purports to have used the standards set forth in this rule to reach the conclusion set forth in its June 2022 GAPMS Memo that gender-affirming care, including puberty blockers, hormone replacement therapy, and gender-affirming surgery does not meet generally accepted professional medical standards and is therefore, experimental and investigational.

79. To craft the GAPMS Memo (which served as the basis for AHCA's decision to ban gender-affirming care in accordance with Fla. Admin. Code R. 59G-1.050(7)), AHCA enlisted Drs. Romina Brignardello-Petersen and Wojtek Wiercioch. Dr. Brignardello-Petersen is a dentist who is an assistant professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Canada. Dr. Wiercioch is a post-doctoral research fellow in the same department as Dr. Brignardello-Petersen. Both authors report no academic interests in the care of people with gender dysphoria.

80. Drs. Brignardello-Petersen and Wiercioch performed a manual search of websites that includes only one non-governmental organization site: the Society for Evidence-Based Gender Medicine (SEGM). The fact that SEGM was chosen instead of much larger and more established organizations representing the mainstream of care, e.g., the American Psychological Association, the American Medical Association, or the American Psychiatric Association, raises a concern for bias, as SEGM is a small group founded recently specifically in opposition to gender-affirming care.

81. To support the conclusions provided to AHCA, Drs. Brignardello-Petersen and Wiercioch preferentially relied on studies that only included participants under age 25. Drs. Brignardello-Petersen and Wiercioch do not provide a basis to support their selection of only these studies, or of leaving out a multitude of other studies that include participants that are over age 25. In my experience working with patients with gender dysphoria, many of those who seek gender-affirming surgery are over 25. The average age of 7,905 transgender patients who had gender-affirming surgery in the US from 2009-2015, identified by insurance data, was 29.8 years old (Lane, et al., 2018). Thus, reliance on studies related preferentially to those under age 25 does not accurately capture the full body of scientific evidence pertaining to this form of care. This is especially important given

that the GAPMS memo concludes that gender-affirming care is not a generally accepted professional medical standard for individuals at any age.

82. Brignardello-Petersen and Wiercioch excluded from consideration the vast majority of studies on transgender health. They state, "After screening 1854 records found through our searches, we found 10 eligible studies."

83. Drs. Brignardello-Petersen and Wiercioch relied on an overview of a very small sample of systematic reviews of studies of transgender care (they looked at only 10 of 61 systematic reviews), for which they purported to rank the quality of evidence using GRADE criteria. GRADE criteria assigns low quality scores to studies not performed by randomized, blinded clinical trials. However, randomly selecting people to receive or not receive gender-affirming medical or surgical interventions is impossible, for practical and ethical reasons. Notably, many treatments for other conditions are in widely accepted use without having been studied through randomized, controlled clinical trials. Many drugs for cancer and hematologic disorders have been FDA approved without a randomized controlled trial (Hatswell, et al., 2016). Many other drugs have been FDA approved with randomized controlled trials for one indication but are commonly used for another condition or in a different population than the one for which it was approved (Wittich, et. al., 2012).

84. People have been receiving gender-affirming medical and surgical treatment for well over half a century, with very low regret rates (Dhejne, et al., 2014), and there is substantial research and clinical experience that supports gender-affirming care as treatment for gender dysphoria. The scientific evidence "published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" led the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, and other mainstream medical organizations to conclude that the provision of gender-affirming medical and surgical interventions falls within generally accepted professional medical standards.

85. Another person enlisted to provide an opinion to AHCA in drafting its GAPMS memo is James Cantor, PhD, a forensic psychologist in Toronto, Canada. Dr. Cantor's report indicates that his work at the University of Toronto from 1998 to 2018 was limited to its adult forensic program, that is, Dr. Cantor worked with people with paraphilias,[2] and in particular with pedophiles. Dr. Cantor is well known for this work, but not for his work with transgender people. In testimony in *Eknes-Tucker v. Marshall*, Dr. Cantor stated that he had not personally diagnosed any child or

[2] Paraphilias are persistent and recurrent sexual interests, urges, fantasies, or behaviors of marked intensity involving objects, activities, or even situations that are atypical in nature. Being transgender is not a paraphilic disorder.

adolescent with gender dysphoria, and that he had personally never treated any child or adolescent for gender dysphoria.

86. Dr. Cantor agrees that transgender adults "adjust well to life as the opposite sex" if they are otherwise mentally healthy. Dr. Cantor is also correct to report that regret rates are low.

87. Dr. Cantor focuses on desistance rates of prepubertal children brought into clinics in Toronto and Amsterdam. However, given that these prior longitudinal studies included gender nonconforming children who were not transgender due to the broad criteria for the since-abandoned "gender identity disorder in children" diagnosis, or who did not qualify even for the gender identity disorder in children diagnosis, these studies shed little light into questions of persistence and desistance of gender dysphoria in pre-pubertal children. In fact, a more recent study, which is the only large American prospective study that has been published in the past 35 years, showed much lower desistance rates (Olson, et al., 2022). Specifically, only 2.5% of the youth studied identified with their sex assigned at birth.[3]

88. In any event, longitudinal studies show that gender dysphoria in adolescence usually persists (DeVries, et al., 2011; van der Loos, et al., 2022). And

[3] Of these, youth with cisgender identities were more common among youth whose initial social transition occurred before age 6 years; their retransitions often occurred before age 10 years. And, again, no medical treatment is recommended for any transgender person prior to the onset of puberty.

no medical treatment, let alone irreversible medical and surgical interventions, is used prior to puberty. Even in the clinics with higher desistance rates for *pre-pubertal* children upon which Dr. Cantor relies, puberty blockers and hormones were used when gender dysphoria persisted after the onset of puberty. In sum, the desistance statistics of *pre-pubertal* children do not inform the decision whether to initiate these treatments in adolescents and adults.

89. The WPATH Standards of Care and the American Psychiatric Association each recommend that transgender people who also suffer from depression, anxiety, and other mental health symptoms should seek out treatment for these symptoms. However, in most cases, having a history of mental illness should not prevent people from receiving gender-affirming medical and surgical treatment. (Coleman, et al., 2022; Byne, et al., 2018).

90. Dr. Cantor's uses the term "affirmation on demand" as a straw man. The WPATH Standards of Care require a comprehensive mental health assessment for patients who are minors, and clinical assessments are also required for adults. (Coleman, et al., 2022).

91. Dr. Cantor cites a Finnish study as evidence for his conclusion that adolescents should not be prescribed gender-affirming hormones because they are supposedly not effective in the treatment of gender dysphoria. (Kaltiala, et al., 2020). However, in that study, the need for treatment for depression dropped from 54% of

the youth to 15%; the need for treatment for anxiety dropped from 48% of the youth to 15%; and the need for treatment for suicidality/self-harm dropped from 35% to 4%. All of these were statistically highly significant changes.

92. Dr. Cantor states that the study by Kuper, et al. 2020 did not show benefit from treatment. This statement is misleading at best. The article concludes, "Youth reported large improvements in body dissatisfaction ($P < .001$), small to moderate improvements in self-report of depressive symptoms ($P < .001$), and small improvements in total anxiety symptoms ($P < .01$)." Dr. Cantor further states that the study by Achille et al. does not show that those studied benefitted from endocrine treatment. Again, Cantor's characterization of this study's conclusion is misleading. The results of the paper show that, "Mean depression scores and suicidal ideation decreased over time while mean quality of life scores improved over time. When controlling for psychiatric medications and engagement in counseling, regression analysis suggested improvement with endocrine intervention. This reached significance in male-to-female participants."

93. In reviewing the international health care consensus regarding gender-affirming care, Dr. Cantor refers to an interim report on care of transgender youth in the United Kingdom's National Health System which is currently being compiled by Dr. Hilary Cass. The interim report states that the final report will synthesize published evidence with expert opinion and stakeholder input. Notably, the interim

report recommends increasing the number of health providers, shortening wait times, and increasing the number of centers across the country providing care to transgender youth.

94. Swedish and Finnish national health authorities, which Dr. Cantor also references, have recommended caution and more research but have not banned care for transgender youth. In these countries, gender-affirming care for adults and for youth who qualify is fully paid for by the national health system of each country.

95. There remains strong international support for the continued provision of gender-affirming medical and surgical care. Experts from the around the world collaborated on the new WPATH Standards of Care Version 8. I was chapter lead of the Mental Health chapter of this version, and the authors of that chapter included psychiatrists who are leaders of transgender health programs in Belgium, Sweden, and Turkey. There is broad agreement in philosophy of care, including support for gender-affirming care and opposition to conversion therapy.

96. The ethics of providing transgender care are discussed by one expert, Dr. G. Kevin Donovan. Dr. Donovan ignores the larger ethical question raised by Florida's actions to terminate Medicaid coverage of gender-affirming care for those who were previously approved for that same coverage. Florida's actions amount to forced detransition. As Dr. Donovan states, the principles of ethical care include autonomy, beneficence, and justice. There has been little research on those forced to

detransition, but abruptly terminating Medicaid coverage for low-income and disabled Floridians will force these Medicaid recipients into detransition, an experiment to which they did not consent. Autonomy, beneficence, and justice are entirely ignored in this experiment, with no respect for the autonomy of the individual to decide their course, no concern for "do no harm" or maximizing benefits and minimizing harm, and no justice—fairness in distribution of risks and benefits—as the poor and those with disabilities will be forced into this detransition experiment while those with resources will be spared.

97. I have only had a few patients over the years who have been forced to detransition, because of incarceration or institutionalization, or other circumstances, and results have been uniformly disastrous, with suicide and self-harm attempts, depression, and deterioration of functioning. Some of my patients forced to detransition were receiving intensive mental health care at the time, on psychiatric wards. But no amount of psychotherapy could counter the deleterious effects of forced detransition and the withholding of needed gender-affirming medical and surgical care.

IV. CONCLUSION

98. The categorical exclusion of coverage for gender-affirming medical care adopted by Florida's Agency for Health Care Administration, which bars coverage for medical treatments for gender dysphoria, is contrary to widely accepted

medical protocols for the treatment of transgender people with gender dysphoria that are recognized by major medical and mental health professional associations in the United States.

99. The accepted protocols for the treatment of transgender people with gender dysphoria provide for mental health assessments, including of co-occurring conditions; criteria for eligibility for each treatment; and an informed consent process before medical interventions are initiated.

100. Decades of medical research and clinical experience have demonstrated that the medical treatments AHCA has barred from Medicaid coverage are safe, effective, and medically necessary to relieve gender dysphoria for transgender people. AHCA's conclusion otherwise is not supported by medical evidence or consensus.

101. Denying gender-affirming medical care to transgender people for whom it is medically indicated puts them at risk of significant harm to their health and wellbeing, including heightened risk of depression and suicidality.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 15th day of February 2023.

Dan H. Karasic, M.D.

Exhibit A

Curriculum Vitae

University of California, San Francisco

CURRICULUM VITAE

Name: Dan H. Karasic, MD

Position: Professor Emeritus
Psychiatry
School of Medicine

Voice: 415-935-1511
Fax: 888-232-9336

EDUCATION

1978 - 1982	Occidental College, Los Angeles	A.B.; Summa Cum Laude	Biology
1982 - 1987	Yale University School of Medicine	M.D.	Medicine
1987 - 1988	University of California, Los Angeles	Intern	Medicine, Psychiatry, and Neurology
1988 - 1991	University of California, Los Angeles; Neuropsychiatric Institute	Resident	Psychiatry
1990 - 1991	University of California, Los Angeles; Department of Sociology	Postdoctoral Fellow	Training Program in Mental Health Services for Persons with AIDS

LICENSES, CERTIFICATION

1990	Medical Licensure, California, License Number G65105
1990	Drug Enforcement Administration Registration Number BK1765354
1993	American Board of Psychiatry and Neurology, Board Certified in Psychiatry

PRINCIPAL POSITIONS HELD

1991 - 1993	University of California, San Francisco	Health Sciences Psychiatry Clincial Instructor
1993 - 1999	University of California, San Francisco	Health Sciences Psychiatry Assistant Clinical Professor
1999 - 2005	University of California, San Francisco	Health Sciences Psychiatry

		Associate Clinical Professor	
2005 - present	University of California, San Francisco	Health Sciences Psychiatry Clinical Professor	

OTHER POSITIONS HELD CONCURRENTLY

1980 - 1980	Associated Western Universities / U.S. Department of Energy	Honors Undergraduate Research Fellow	UCLA Medicine
1981 - 1981	University of California, Los Angeles; Medicine American Heart Association, California Affiliate	Summer Student Research Fellow	UCLA
1986 - 1987	Yale University School of Medicine; American Heart Association, Connecticut Affiliate	Medical Student Research Fellow	Psychiatry
1990 - 1991	University of California, Los Angeles Postdoctoral	Sociology Fellow	
1991 - 2001	SFGH Consultation-Liaison Service; AIDS Care	Attending Psychiatrist	Psychiatry
1991 - 2001	AIDS Consultation-Liaison Medical Student Elective	Course Director	Psychiatry
1991 - present	UCSF Positive Health Program at San General Hospital (Ward 86)	HIV/AIDS Outpatient Psychiatrist	Psychiatry Francisco
1991 - present	UCSF AHP (AIDS Health Project/Alliance Health Project)	HIV/AIDS Outpatient Psychiatrist	Psychiatry
1994 - 2002	St. Mary's Medical Center CARE Unit. The CARE Unit specializes in the care of patients with AIDS dementia.	Consultant	Psychiatry
2001 - 2010	Depression and Antiretroviral Adherence Study (The H.O.M.E. study: Health Outcomes of Mood Enhancement)	Clinical Director	Psychiatry and Medicine
2003 - 2020	Transgender Life Care Program and Clinic, Castro Mission Health Center	Psychiatrist Dimensions Clinic	Dimensions
2013 - 2020	UCSF Alliance Health Project, Co-lead, Transgender Team	Co-Lead and Psychiatrist	Psychiatry

HONORS AND AWARDS

1981	Phi Beta Kappa Honor Society	Phi Beta Kappa
1990	NIMH Postdoctoral Fellowship in Mental Health Services for People with	National Institute of Mental Health

	AIDS (1990-1991)	
2001	Lesbian Gay Bisexual Transgender Leadership Award, LGBT Task Force of the Cultural Competence and Diversity Program	SFGH Department of Psychiatry
2006	Distinguished Fellow	American Psychiatric Association
2012	Chancellor's Award for Leadership in LGBT Health	UCSF
2023	Alumni Seal Award for Professional Achievement	Occidental College

MEMBERSHIPS

1992 - present Northern California Psychiatric Society

1992 - present American Psychiatric Association

2000 - 2019 Bay Area Gender Associates (an organization of psychotherapists working with transgendered clients)

2001 - present World Professional Association for Transgender Health

SERVICE TO PROFESSIONAL ORGANIZATIONS

1981 - 1982	The Occidental	News Editor
1984 - 1985	Yale University School of Medicine	Class President
1989 - 1991	Kaposi's Sarcoma Group, AIDS Project Los Angeles	Volunteer Facilitator
1992 - 1996	Early Career Psychiatrist Committee, Association of Gay Lesbian Psychiatrists	Chair and
1992 - 1996	Board of Directors, Association of Gay and Lesbian Psychiatrists	Member
1993 - 1993	Local Arrangements Committee, Association of Gay and Psychiatrists	Chair Lesbian
1994 - 1995	Educational Program, Association of Gay and Lesbian 1995 Annual Meeting	Director Psychiatrists,
1994 - 1998	Board of Directors, BAY Positives	Member
1994 - present	Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society	Member
1995 - 1997	Board of Directors, Bay Area Young Positives. BAY	President

	Positives is the nation's first community-based organization providing psychosocial and recreational services to HIV-positive youth	
1995 - 1997	Executive Committee, Bay Area Young Positives.	Chair
1996 - 2004	Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society	Chair
1998 - 2002	City of San Francisco Human Rights Commission, Lesbian, Gay Bisexual Transgender Advisory Committee	Member
2000 - 2004	Association of Gay and Lesbian Psychiatrists.	Vice President Responsible for the organization's educational programs
2004 - 2005	Association of Gay and Lesbian Psychiatrists	President-elect
2005 - 2007	Caucus of Lesbian, Gay, and Bisexual Psychiatrists of the American Psychiatric Association	Chair
2005 - 2007	Association of Gay and Lesbian Psychiatrists	President
2007 - 2009	Association of Gay and Lesbian Psychiatrists	Immediate Past President
2009 - 2010	Consensus Committee for Revision of the Sexual and Gender Identity Disorders for DSM-V, GID of Adults subcommittee. (Wrote WPATH recommendations as advisory body to the APA DSM V Committee for the Sexual and Gender Identity Disorders chapter revision.)	Member
2010 - 2011	Scientific Committee, 2011 WPATH Biennial Symposium, Atlanta	Member
2010 -2022	World Professional Association for Transgender Care Standards of Care Workgroup and Committee (writing seventh and eighth revisions of the WPATH Standards of Care, which is used internationally for transgender care.)	Member
2010 - 2018	ICD 11 Advisory Committee, World Professional Association for Transgender Health	Member
2012 - 2014	Psychiatry and Diagnosis Track Co-chair, Scientific 2014 WPATH Biennial Symposium, Bangkok	Member Committee,
2014 - 2016	Scientific Committee, 2016 WPATH Biennial Symposium, Amsterdam	Member
2014 - 2018	Board of Directors (elected to 4 year term), World Professional Association for Transgender Health	Member
2014 - 2018	Public Policy Committee, World Professional Association for Transgender Health	Chair
2014 - 2018	WPATH Global Education Initiative: Training providers specialty certification in transgender health	Trainer and and Steering Committee Member
2014 - 2016	American Psychiatric Association Workgroup on Gender Dysphoria	Member

2016 - present	American Psychiatric Association Workgroup on Gender Dysphoria	Chair
2016	USPATH: Inaugural WPATH U.S. Conference, Los Angeles, 2017	Conference Chair

SERVICE TO PROFESSIONAL PUBLICATIONS

2011 - present Journal of Sexual Medicine, reviewer

2014 - present International Journal of Transgenderism, reviewer

2016 - present LGBT Health, reviewer

INVITED PRESENTATIONS - INTERNATIONAL

2009	World Professional Association for Transgender Health, Oslo, Norway	Plenary Session Speaker
2009	World Professional Association for Transgender Health, Oslo, Norway	Symposium Speaker
2009	Karolinska Institutet, Stockholm Sweden	Invited Lecturer
2012	Cuban National Center for Sex Education (CENESEX), Havana, Cuba	Invited Speaker
2013	Swedish Gender Clinics Annual Meeting, Stockholm, Sweden	Keynote Speaker
2013	Conference on International Issues in Transgender care, United Nations Development Programme - The Lancet, Beijing, China	Expert Consultant
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Track Chair
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Symposium Chair
2015	Israeli Center for Human Sexuality and Gender Identity, Aviv	Invited Speaker Tel
2016	World Professional Association for Transgender Health, Amsterdam	Symposium Chair
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker

2017	Brazil Professional Association for Transgender Health, Sao Paulo	
2017	Vietnam- United Nations Development Programme Asia Transgender Health Conference, Hanoi	
2018	United Nations Development Programme Asia Conference on Transgender Health and Human Rights, Bangkok	
2018	World Professional Association for Transgender Health, Buenos Aires	Invited Speaker
2021	Manitoba Psychiatric Association, Keynote Speaker	

INVITED PRESENTATIONS - NATIONAL

1990	Being Alive Medical Update, Century Cable Television	Televised Lecturer
1992	Institute on Hospital and Community Psychiatry, Toronto	Symposium Speaker
1992	Academy of Psychosomatic Medicine Annual Meeting, San Diego	Symposium Speaker
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Workshop Chair
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Workshop Speaker
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Paper Session Co-chair
1995	Spring Meeting of the Association of Gay and Lesbian Psychiatrists, Miami Beach	Symposium Chair
1996	American Psychiatric Association 152nd Annual Meeting, New York	Workshop Speaker
1997	American Psychiatric Association Annual Meeting, San Diego	Workshop Speaker
1997	Gay and Lesbian Medical Association Annual	Invited Speaker Symposium
1998	American Psychiatric Association Annual Meeting, Toronto	Workshop Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Workshop Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair

1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Presenter
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Workshop Chair
2000	American Psychiatric Association Annual Meeting, Chicago	Workshop Chair
2000	National Youth Leadership Forum On Medicine, University of California, Berkeley	Invited Speaker
2001	American Psychiatric Association Annual Meeting, New Orleans	Workshop Chair
2001	American Psychiatric Association Annual Meeting, New Orleans	Media Program Chair
2001	Association of Gay and Lesbian Psychiatrists Symposium, New Orleans	Chair
2001	Harry Benjamin International Gender Dysphoria Association Biennial Meeting, Galveston, Texas	Invited Speaker
2002	American Psychiatric Association Annual Meeting, Philadelphia	Media Program Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2003	Association of Gay and Lesbian Psychiatrists CME	Chair Conference
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Co-Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Workshop Chair
2003	American Public Health Association Annual Meeting, San Francisco	Invited Speaker
2004	Mission Mental Health Clinic Clinical Conference	Invited Speaker
2004	Association of Gay and Lesbian Psychiatrists Conference, New York	Co-Chair
2004	Mental Health Care Provider Education Program: Los Angeles. Sponsored by the American Psychiatric Association Office of HIV Psychiatry	Invited Speaker

2005	American Psychiatric Association Annual Meeting, Atlanta	Workshop Speaker
2005	Association of Gay and Lesbian Psychiatrists Saturday Symposium	Invited Speaker
2008	Society for the Study of Psychiatry and Culture, San Francisco	Invited Speaker
2009	American Psychiatric Association Annual Meeting, San Francisco	Symposium Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Chair
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker

Invited Speaker

2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	
2011	Institute on Psychiatric Services, San Francisco	Invited Speaker
2012	Gay and Lesbian Medical Association Annual Meeting	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	American Psychiatric Association Annual Meeting, San Francisco	Invited Speaker
2013	Gay and Lesbian Medical Association, Denver, CO	Invited Speaker
2014	American Psychiatric Association Annual Meeting, New	Invited Speaker York
2014	Institute on Psychiatric Services, San Francisco	Moderator
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Workshop Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Course Faculty
2016	American Psychiatric Association Annual Meeting	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Atlanta	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Springfield, MO	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Fort Lauderdale, FL	Course Faculty
2017	World Professional Association for Transgender Health, GEI, Los Angeles Course Faculty	
	World Professional Association for Transgender Health	

Surgeon's Training, Irvine, CA Course Faculty

2017 American Urological Association Annual Meeting, San Francisco CA Invited Speaker

2018 World Professional Association for Transgender Health GEI, Portland OR, Course Faculty

2018 World Professional Association for Transgender Health GEI, Palm Springs, Course Faculty

2019 American Society for Adolescent Psychiatry Annual Meeting, San Francisco, Speaker

2019 American Psychiatric Association Annual Meeting, San Francisco, Session Chair

2020 Psychiatric Congress, Invited Speaker

2022 World Professional Association for Transgender Health, Montreal, invited speaker

2023 National Transgender Health Summit, San Francisco, invited speaker

2023 American Psychiatric Association Annual Meeting, San Francisco, invited speaker

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

1990 Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute Invited Lecturer

1991 Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine Symposium Speaker

1991 Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine Workshop Panelist

1992 Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute Invited Lecturer

1993 UCSF School of Nursing Invited Lecturer

1995 UCSF/SFGH Department of Medicine Clinical Care Conference Invited Speaker

1996 UCSF School of Nursing Invited Speaker

		Invited Speaker
1996	Psychopharmacology for the Primary Care AIDS/Clinician, series of four lectures, UCSF Department of Medicine	Invited Lecturer
1996	UCSF AIDS Health Project Psychotherapy Internship Training Program	
1996	UCSF/SFGH Department of Medicine AIDS Quarterly Update	Invited Speaker
1996	San Francisco General Hospital, Division of Addiction Medicine	Invited Speaker
1996	UCSF Langley Porter Psychiatric Hospital and Clinics	Invited Speaker Grand Rounds
1997	UCSF School of Nursing	Invited Speaker
1997	UCSF Department of Medicine AIDS Program	Invited Speaker
1997	Northern California Psychiatric Society Annual Meeting, Monterey	Workshop Speaker
1997	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1997	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1997	Northern California Psychiatric Society LGBT Committee Chair Fall Symposium	
1997	Progress Foundation, San Francisco	Invited Speaker
1998	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1999	Northern California Psychiatric Society Annual Meeting, Santa Rosa	Invited Speaker
1999	Northern California Psychiatric Society Annual Meeting, Santa Rosa	Invited Speaker
1999	University of California, Davis, Department of Psychiatry	Invited Speaker Grand Rounds
1999	California Pacific Medical Center Department of Psychiatry Grand Rounds	Invited Speaker
1999	San Francisco General Hospital Department of Psychiatry Departmental Case Conference	Discussant
2000	Langley Porter Psychiatric Hospital and Clinics Consultation Liaison Seminar	Invited Speaker
2000	San Francisco General Hospital, Psychopharmacology Seminar	Invited Speaker

2000	UCSF Transgender Health Conference, Laurel Heights Conference Center	Invited Speaker
2000	Psychiatry Course for UCSF Second Year Medical Students	Invited Lecturer
2000	Community Consortium Treatment Update Symposium, California Pacific Medical Center, Davies Campus	Invited Speaker
2000	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
2001	Psychiatry Course for UCSF Second Year Medical Students	Invited Lecturer
2003	Tom Waddell Health Center Inservice	Invited Speaker
2003	San Francisco Veterans Affairs Outpatient Clinic	Invited Speaker
2004	San Francisco General Hospital Psychiatric Emergency Service Clinical Conference	Invited Speaker
2004	South of Market Mental Health Clinic, San Francisco	Invited Speaker
2005	Northern Psychiatric Psychiatric Society Annual Meeting	Invited Speaker
2005	Equality and Parity: A Statewide Action for Transgender Prevention and Care, San Francisco	Invited Speaker HIV
2005	San Francisco General Hospital Department of Psychiatry Grand Rounds.	Invited Speaker
2006	SFGH/UCSF Department of Psychiatry Grand Rounds	Invited Speaker
2007	UCSF Department of Medicine, HIV/AIDS Grand Rounds, Positive Health Program	Invited Speaker
2007	California Pacific Medical Center LGBT Health Symposium, San Francisco LGBT Community Center	Invited Speaker
2007	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2008	UCSF Department of Medicine, Positive Health Program, HIV/AIDS Grand Rounds	Invited Speaker
2008	San Francisco General Hospital Psychiatry Grand Rounds	Invited Speaker
2008	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2010	Northern California Psychiatric Society Annual Meeting, Monterey, CA	Invited Speaker
2011	Transgender Mental Health Care Across the Life Span, Stanford University	Invited Speaker
2011	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker

2012	UCSF AIDS Health Project Veterans Affairs Medical Center.	Invited Speaker 2012 San Francisco Invited Speaker
2013	Association of Family and Conciliation Courts Conference, Los Angeles, CA	Invited Speaker
2014	UCSF Transgender Health elective	Invited Speaker
2014	UCSF Department of Psychiatry Grand Rounds	Invited Speaker
2014	California Pacific Medical Center Department of Psychaitry Grand Rounds	Invited Speaker
2014	UCLA Semel Institute Department of Psychiatry Grand Rounds	Invited Speaker
2015	UCSF Transgender Health elective	Invited Speaker
2015	Fenway Health Center Boston, MA (webinar)	Invited Speaker
2015	Transgender Health Symposium, Palm Springs	Invited Speaker
2015	Transgender Health Symposium, Palm Springs	Co-Chair
2015	Santa Clara Valley Medical Center Grand Rounds	Invited Speaker
2016	UCSF School of Medicine Transgender Health elective	Invited Speaker
2016	Langley Porter Psychiatric Institute APC Case Conference	Invited Speaker (2 session series)
2016	Zuckerberg San Francisco General Department of Psychiatry Grand Rounds	Invited Speaker
2016	UCSF Mini-Medical School Lectures to the Public	Invited Speaker
2021	Los Angeles County Department of Mental Health,	Invited Speaker

CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2005	Northern California Psychiatric Society
2005	Northern California Psychiatric Society Annual Meeting, Napa
2005	Association of Gay and Lesbian Psychiatrist Annual Conference
2006	Annual Meeting, American Psychiatric Association, Atlanta
2006	Annual Meeting, American Psychiatric Association, Toronto
2006	Institute on Psychiatric Services, New York
2007	Association of Gay and Lesbian Psychiatrists Annual Conference
2007	American Psychiatric Association Annual Meeting, San Diego

2007	The Medical Management of HIV/AIDS, a UCSF CME Conference
2008	Society for the Study of Psychiatry and Culture, San Francisco
2009	American Psychiatric Association, San Francisco
2009	World Professional Association for Transgender Health, Oslo, Norway
2010	Annual Meeting of the Northern California Psychiatric Society, Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Stanford University
2011	National Transgender Health Summit, San Francisco
2011	American Psychiatric Association Annual Meeting, Honolulu, HI
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA
2011	Institute on Psychiatric Services, San Francisco
2012	Gay and Lesbian Medical Association Annual Meeting, San Francisco
2013	National Transgender Health Summit, Oakland, CA
2013	American Psychiatric Association Annual Meeting, San Francisco
2013	Gay and Lesbian Medical Association, Denver, CO
2014	American Psychiatric Association Annual Meeting, New York
2014	Institute on Psychiatric Services, San Francisco
2015	European Professional Association for Transgender Health, Ghent, Belgium
2015	National Transgender Health Summit, Oakland
2015	American Psychiatric Association Annual Meeting, Toronto
2016	American Psychiatric Association Annual Meeting, Atlanta
2016	World Professional Association for Transgender Health, Amsterdam

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

1998 - 2002	City and County of San Francisco Human Rights Member Commission LGBT Advisory Committee

I am the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, which developed a CME course fort the 2015 and 2016 APA Annual Meetings, and is now embarking on a larger educational mission to train American psychiatrists to better care for transgender patients. I have been leading education efforts in transgender health at APA meetings since 1998. On the APA Workgroup on Gender Dysphoria, I am a co-author of a paper of transgender issues that has been approved by the American Psychiatric Association as a resource document and is in press for the American Journal of Psychiatry. I am also the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

I have been active internationally in transgender health through my work as a member of the Board of Directors of the World Professional Association for Transgender Health. I am an author of the WPATH Standards of Care, Version 7, and am Chapter Lead for the Mental Health Chapter of SOC 8.
I chaired of the WPATH Public Policy Committee and was a member of the Global Education Initiative, which developed a specialty certification program in transgender health. I helped plan the 2016 WPATH Amsterdam conference, and was on the scientific committee for the last four biennial international conferences. I was on the founding committee of USPATH, the national affiliate of WPATH, and I chaired the inaugural USPATH conference, in Los Angeles in 2017. As a member of the steering committee of the WPATH Global Educational Initiative, I helped train over 2000 health providers in transgender health, and helped develop a board certification program and examination in transgender health.

UNIVERSITY SERVICE UC SYSTEM AND MULTI-CAMPUS SERVICE

1991 - present HIV/AIDS Task Force Member

1992 - 1993 HIV Research Group Member

1992 - 1997 Space Committee Member

1992 - present Gay, Lesbian and Bisexual Issues Task Force Member

1994 - 1997 SFGH Residency Training Committee Member

1996 - 1997 Domestic Partners Benefits Subcommittee. Chair

1996 - 2000 Chancellor's Advisory Committee on Gay, Lesbian, and Transgender Issues. Member Bisexual

1996 - 2003 HIV/AIDS Task Force Co-Chair

1996 - 2003 Cultural Competence and Diversity Program Member

2009 - present Medical Advisory Board, UCSF Center of Excellence for Transgender Health Member

2010 - 2013 Steering Committee, Child Adolescent Gender Center Member

2011 – 2017 Mental Health Track, National Transgender Health Summit Chair

DEPARTMENTAL SERVICE

1991 - present San Francisco General Hospital, Department of Psychiatry, Member
HIV/AIDS Task Force

1992 - 1993 San Francisco General Hospital, Department of Psychiatry, Member HIV Research Group

1992 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Space Committee

1992 - 2003 San Francisco General Hospital, Department of Psychiatry, Member GLBT Issues Task Force

1994 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Residency Training Committee

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Member Cultural Competence and Diversity Program

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Co-Chair HIV/AIDS Task Force

2012 - 2020 San Francisco Department of Public Health Gender Member Competence Trainings Committee

2013 - 2020 San Francisco Department of Public Health Transgender Member Health Implementation Task Force

2014 - 2020San Francisco General Hospital, Department of Psychiatry, Member Transgender Surgery Planning Workgroup

PEER REVIEWED PUBLICATIONS

1. Berliner JA, Frank HJL, **Karasic D**, Capdeville M. Lipoprotein-induced insulin resistance in aortic endothelium. Diabetes. 1984; 33:1039-44.
2. Bradberry CW, **Karasic DH**, Deutch AY, Roth RH. Regionally-specific alterations in mesotelencephalic dopamine synthesis in diabetic rats: association with precursor tyrosine. Journal of Neural Transmission. General Section, 1989; 78:221-9.
3. Targ EF, **Karasic DH**, Bystritsky A, Diefenbach PN, Anderson DA, Fawzy FI. Structured group therapy and fluoxetine to treat depression in HIV-positive persons. Psychosomatics. 1994; 35:132-7.
4. Karasic DH. Homophobia and self-destructive behaviors. The Northern California Psychiatric Physician. 1996; 37 Nov.-Dec. Reprinted by the Washington State Psychiatric Society and the Southern California Psychiatric Society newsletters.
5. Karasic D. Anxiety and anxiety disorders. Focus. 1996 Nov; 11(12):5-6. PMID: 12206111
6. Polansky JS, **Karasic DH**, Speier PL, Hastik KL, Haller E. Homophobia: Therapeutic and training considerations for psychiatry. Journal of the Gay and Lesbian Medical Association. 1997 1(1) 41-47.
7. Karasic DH. Progress in health care for transgendered people. Editorial. Journal of the Gay and Lesbian Medical Association, 4(4) 2000 157-8.
8. Perry S, **Karasic D**. Depression, adherence to HAART, and survival. Focus: A Guide to AIDS Research and Counseling. 2002 17(9) 5-6.

9. Fraser L, **Karasic DH**, Meyer WJ, Wylie, K. Recommendations for Revision of the DSM Diagnosis of Gender Identity Disorder in Adults. International Journal of Transgenderism. Volume 12, Issue 2. 2010, Pages 80-85.

10. Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W., Monstrey, S., **Karasic D** and 22 others. (2011). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. International Journal of Transgenderism, 13:165-232, 2011

11. Tsai AC, **Karasic DH**, et al. Directly Observed Antidepressant Medication Treatment and HIV Outcomes Among Homeless and Marginally Housed HIV-Positive Adults: A Randomized Controlled Trial. American Journal of Public Health. February 2013, Vol. 103, No. 2, pp. 308-315.

12. Tsai AC, Mimmiaga MJ, Dilley JW, Hammer GP, **Karasic DH**, Charlebois ED, Sorenson JL, Safren SA, Bangsberg DR. Does Effective Depression Treatment Alone Reduce Secondary HIV Transmission Risk? Equivocal Findings from a Randomized Controlled Trial. AIDS and Behavior, October 2013, Volume 17, Issue 8, pp 2765-2772.

13. **Karasic DH**. Protecting Transgender Rights Promotes Transgender Health. LGBT Health. 2016 Aug; 3(4):245-7. PMID: 27458863

14. Winter S, Diamond M, Green J, **Karasic D**, Reed T, Whittle S, Wylie K. Transgender people: health at the margins of society. Lancet. 2016 Jul 23;388(10042):390-400. doi: 10.1016/S0140-6736(16)00683-8. Review./> PMID: 27323925

15. Grelotti DJ, Hammer GP, Dilley JW, **Karasic DH**, Sorensen JL, Bangsberg DR, Tsai AC. Does substance use compromise depression treatment in persons with HIV? Findings from a randomized controlled trial. AIDS Care. 2016 Sep 2:1-7. [Epub ahead of print]/> PMID: 27590273

16. Strang JF, Meagher H, Kenworthy L, de Vries AL, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, Shumer DE, Edwards-Leeper L, Pleak RR, Spack N, **Karasic DH**, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG.
Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents. J Clin Child Adolesc Psychol. 2016 Oct 24:1-11. [Epub ahead of print]/> PMID: 27775428

17. Milrod C, **Karasic DH**. Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States. J Sex Med 2017;14:624–634.

18. William Byne, Dan H. Karasic, Eli Coleman, A. Evan Eyler, Jeremy D. Kidd, Heino F.L. Meyer-Bahlburg, Richard R. Pleak, and Jack Pula.Gender Dysphoria in Adults: An Overview and Primer for Psychiatrists.Transgender Health.Dec 2018.57-A3.http://doi.org/10.1089/trgh.2017.0053

19. Identity recognition statement of the world professional association for transgender health (WPATH). International Journal of Transgenderism. 2018 Jul 3; 19(3):1-2. Knudson KG, Green GJ, Tangpricha TV, Ettner ER, Bouman BW, Adrian AT, Allen AL, De Cuypere DG, Fraser

FL, Hansen HT, **Karasic KD**, Kreukels KB, Rachlin RK, Schechter SL, Winter WS, Committee and Board of Direct

20. **Karasic, DH** & Fraser, L Multidisciplinary Care and the Standards of Care for Transgender and Gender Non-conforming Individuals. Schechter, L & Safa, B. (Eds.) Gender Confirmation Surgery, Clinics in Plastic Surgery Special Issue, Vol 45, Issue 3, pp 295-299. 2018 Elsevier,Philadelphia**.** https://doi.org/10.1016/j.cps.2018.03.016
21. Milrod C, Monto M, **Karasic DH.** Recommending or Rejecting "the Dimple": WPATHAffiliated Medical Professionals' Experiences and Attitudes Toward Gender-Confirming Vulvoplasty in Transgender Women. J Sex Med. 2019 Apr;16(4):586-595. doi: 10.1016/j.jsxm.2019.01.316. Epub 2019 Mar 2.

22. ICD-11 and gender incongruence of childhood: a rethink is needed. Lancet Child Adolesc Health. 2019 10; 3(10):671-673. Winter S, Ehrensaft D, Telfer M, T'Sjoen G, Koh J, Pickstone-Taylor S, Kruger A, Griffin L, Foigel M, De Cuypere G, **Karasic D**. PMID: 31439494.

23. Gender Dysphoria in Adults: An Overview and Primer for Psychiatrists. Focus (Am Psychiatr Publ). 2020 Jul; 18(3):336-350. Byne W, **Karasic DH**, Coleman E, Eyler AE, Kidd JD, Meyer-Bahlburg HFL, Pleak RR, Pula J. PMID: 33343244; PMCID: PMC7587914.

24. E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, **D. H. Karasic**, G. A. Knudson, S. F. Leibowitz, H. F. L. Meyer-Bahlburg, S. J. Monstrey, J. Motmans, L. Nahata, T. O. Nieder, S. L. Reisner, C. Richards, L. S. Schechter, V. Tangpricha, A. C. Tishelman, M. A. A. Van Trotsenburg, S. Winter, K. Ducheny, N. J. Adams, T. M. Adrián, L. R. Allen, D. Azul, H. Bagga, K. Başar, D. S. Bathory, J. J. Belinky, D. R. Berg, J. U. Berli, R. O. Bluebond-Langner, M.- B. Bouman, M. L. Bowers, P. J. Brassard, J. Byrne, L. Capitán, C. J. Cargill, J. M. Carswell, S. C. Chang, G. Chelvakumar, T. Corneil, K. B. Dalke, G. De Cuypere, E. de Vries, M. Den Heijer, A. H. Devor, C. Dhejne, A. D'Marco, E. K. Edmiston, L. Edwards-Leeper, R. Ehrbar, D. Ehrensaft, J. Eisfeld, E. Elaut, L. Erickson-Schroth, J. L. Feldman, A. D. Fisher, M. M. Garcia, L. Gijs, S. E. Green, B. P. Hall, T. L. D. Hardy, M. S. Irwig, L. A. Jacobs, A. C. Janssen, K. Johnson, D. T. Klink, B. P. C. Kreukels, L. E. Kuper, E. J. Kvach, M. A. Malouf, R. Massey, T. Mazur, C. McLachlan, S. D. Morrison, S. W. Mosser, P. M. Neira, U. Nygren, J. M. Oates, J. Obedin-Maliver, G. Pagkalos, J. Patton, N. Phanuphak, K. Rachlin, T. Reed, G. N. Rider, J. Ristori, S. Robbins-Cherry, S. A. Roberts, K. A. Rodriguez-Wallberg, S. M. Rosenthal, K. Sabir, J. D. Safer, A. I. Scheim, L. J. Seal, T. J. Sehoole, K. Spencer, C. St. Amand, T. D. Steensma, J. F. Strang, G. B. Taylor, K. Tilleman, G. G. T'Sjoen, L. N. Vala, N. M. Van Mello, J. F. Veale, J. A. Vencill, B. Vincent, L. M. Wesp, M. A. West & J. Arcelus (2022) Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health, 23:sup1, S1-S259, DOI: 10.1080/26895269.2022.2100644

BOOKS AND CHAPTERS

1. **Karasic DH**, Dilley JW. Anxiety and depression: Mood and HIV disease. In: The UCSF AIDS Health Project Guide to Counseling: Perspectives on Psychotherapy, Prevention, and Therapeutic Practice. Dilley JW and Marks R, eds. Jossey-Bass. San Francisco, 1998, pp.227-248.
2. **Karasic DH**, Dilley JW. Human immunodeficiency-associated psychiatric disorders. In: The AIDS Knowledge Base, Third Edition. Cohen PT, Sande MA, Volberding PA, eds. Lippincott-Williams &Wilkens, Philadelphia, 1999, pp. 577-584.
3. **Karasic DH** and Drescher J. eds. Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation. 2005. Haworth Press, Binghamton, NY. (Book Co-Editor)
4. **Karasic DH**. Transgender and Gender Nonconforming Patients. In: Clinical Manual of Cultural Psychiatry, Second Edition. Lim RF ed. pp 397-410. American Psychiatric Publishing, Arlington VA. 2015.
5. **Karasic DH**. Mental Health Care of the Transgender Patient. In: Comprehensive Care of the Transgender Patient, Ferrando CA ed. pp. 8-11. Elsevier, 2019.
6. **Karasic DH.** The Mental Health Assessment for Surgery. In: Gender Confirmation Surgery – Principles and Techniques for an Emerging Field. Schechter L ed. Springer Nature, in press 2019.

OTHER PUBLICATIONS

1. **Karasic DH**, Dilley JW. HIV-associated psychiatric disorders: Treatment issues. In: Cohen P, Sande MA, Volberding P, eds., The AIDS Knowledge Base. Waltham, MA: The Medical Publishing Group/ Massachusetts Medical Society. 1994. pp. 5.31-1-5.
2. **Karasic DH**, Dilley JW. HIV-associated psychiatric disorders: Clinical syndromes and diagnosis. In: Cohen P, Sande MA, Volberding P, eds., The AIDS Knowledge Base, Second Edition. Waltham, MA: The Medical Publishing Group/Massachusetts Medical Society. 1994 pp. 5.30-1-5.
3. **Karasic DH**. A primer on transgender care. In: Gender and sexuality. The Carlat Report Psychiatry. April 2012. Vol 10, Issue 4.
4. **Karasic D and Ehrensaft D.** We must put an end to gender conversion therapy for kids. Wired. 7/6/15.

EXPERT WITNESS AND CONSULTATION ON TRANSGENDER CARE AND RIGHTS

2008 Consultant, California Department of State Hospitals

2012 Dugan v. Lake, Logan UT

2012 XY v. Ontario http://www.canlii.org/en/on/onhrt/doc/2012/2012hrto726/2012hrto726.html

2014 Cabading v California Baptist University

2014 CF v. Alberta
http://www.canlii.org/en/ab/abqb/doc/2014/2014abqb237/2014abqb237.html

2017 United Nations Development Programme consultant, transgender health care and legal rights in the Republic of Vietnam; Hanoi.

2017- Forsberg v Saskatchewan; Saskatchewan Human Rights v Saskatchewan
2018 https://canliiconnects.org/en/summaries/54130
https://canliiconnects.org/en/cases/2018skqb159

2018 United Nations Development Programme consultant, transgender legal rights in Southeast Asia; Bangkok.

2018 Consultant, California Department of State Hospitals

2019, 2021 Consultant/Expert, Disability Rights Washington

2019, 2021 Consultant/Expert, ACLU Washington

2021 Consultant, California Department of Corrections and Rehabilitation

2021 Expert, Kadel v. Folwell, 1:19-cv-00272 (M.D.N.C.).

2021 Expert, Drew Glass v. City of Forest Park - Case No. 1:20-cv-914 (Southern District Ohio)

2021-2022 Expert, Brandt et al v. Rutledge et al. 4:21-cv-00450 (E.D. Ark.)

2021-2022 Expert, Fain v. Crouch, 3:20-cv-00740 (S.D.W. Va.)

2022 Expert, C.P. v. Blue Cross Blue Shield of Illinois, No. 3:20-cv-06145-RJB (W.D. Wash.)

Exhibit B

Bibliography

BIBLIOGRAPHY

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D.

Preliminary Statement

1. I am a board-certified plastic surgeon. I specialize in performing gender confirming surgeries[1] (including chest reconstruction surgeries, genital reconstruction surgeries, and other procedures to feminize or masculinize the face

[1] I refer to the family of procedures discussed in this report as "gender confirmation," "gender confirming surgeries," or "gender affirming surgeries" because they are one of the therapeutic tools used to enable people to be comfortable living in accordance with their gender identities. Out of the myriad of labels I've heard for these procedures—"sex reassignment surgery," "gender reassignment surgery," and "sex change operation," to name but a few—none is as accurate when it comes to describing what is actually taking place as "gender confirmation" or "gender affirmation surgery." Most, if not all, of the other names used for these procedures suggest that a person is making a choice to switch genders, or that there is a single "surgery" involved. From the hundreds of discussions I have had with patients over the years, nothing could be further from the truth. This is not about choice; it is about using one or more surgical procedures as therapeutic tools to enable people to live authentically.

and body, as described in more detail below), and I am a recognized expert in this field.

2. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide an expert opinion on the standards of care for treating individuals diagnosed with gender dysphoria. In particular, I have been asked: 1) whether gender confirming surgeries are safe and effective medical treatment for gender dysphoria experienced by transgender people, including adults age 21 and over and adolescents up to age 21; 2) whether gender confirming surgeries are experimental or investigational; and 3) whether a categorical exclusion on Medicaid coverage for gender confirming surgeries violates the prevailing standards of care for treating transgender people, including for adults age 21 and over and for adolescents up to age 21, who have been diagnosed with gender dysphoria. Additionally, I submit this declaration to respond to points raised in the Florida Agency for Health Care Administration's "Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" report ("GAPMS Report") and the assessment drafted by Patrick W. Lappert, M.D. that was attached to the GAPMS Report ("Lappert Assessment").

Qualifications and Experience

3. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

4. I received my medical degree from the University of Chicago, Pritzker School of Medicine. I completed my residency and chief residency in plastic and reconstructive surgery and a fellowship in reconstructive microsurgery at the University of Chicago Hospitals.

5. I previously served as a Clinical Professor of Surgery at the University of Illinois at Chicago. I resigned that position to become the Director of Gender Affirmation Surgery at Rush University Medical Center in April 2022. I am also a Professor of Surgery and Urology at Rush University Medical Center. In addition, I maintain a clinical practice in plastic surgery in Illinois where I treat patients from around the country, as well as from around the world.

6. I have been performing gender confirming surgeries for more than 28 years. For at least the past five years, I have been performing approximately 150 gender confirmation procedures every year. I have performed over 1,500 gender confirmation surgeries during my medical career. Currently,

approximately 90 percent of the patients in my clinical practice are transgender people seeking gender confirmation surgeries.

7. I was a contributing author to the World Professional Association for Transgender Health's ("WPATH") Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version Seven, which were published in 2012. In particular, I wrote the section focused on the relationship of the surgeon with the treating mental health professional and the physician prescribing hormone therapy. In September 2022, WPATH published the Standards of Care for the Health of Transgender and Gender Diverse People, Version Eight ("Standards of Care") in the International Journal of Transgender Health.[2] I was the co-lead author of the surgical and postoperative care chapter of Version Eight.

8. The Standards of Care provide clinical guidance for health professionals based on the best available science and expert professional consensus. The purpose of the Standards of Care is to assist health providers in delivering medical care to transgender people in order to provide them with safe

[2] Coleman, E. et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int'l J. of Transgender Health, 23: S1-S259, doi: 10.1080/26895269.2022.2100644 [hereinafter "Standards of Care"].

and effective treatment for gender dysphoria, in order to maximize their overall health, psychological well-being, and self-fulfillment.

9. In addition, I have written a number of peer-reviewed journal articles and chapters in professional textbooks about gender confirmation surgeries. In 2016, I published Surgical Management of the Transgender Patient, the first surgical atlas (a reference guide for surgeons on how to perform surgical procedures using safe, well-established techniques) dedicated to gender confirming surgeries. In 2020, I published a guide for surgeons entitled Gender Confirmation Surgery: Principles and Techniques for an Emerging Field. I am also a co-investigator on a study regarding uterine transplantation for transgender women. A full and complete list of my publications is included in my CV.

10. I am a guest reviewer for several peer-reviewed medical journals, including the Journal of Plastic and Reconstructive Surgery, the Journal of Reconstructive Microsurgery, the Journal of the American College of Plastic Surgeons, the Journal of Plastic and Aesthetic Research, and the Journal of Sexual Medicine. I also serve on the editorial board of both Transgender Health and the International Journal of Transgender Health. Each of these publications is a peer-reviewed medical journal. A full and complete list of my reviewerships and editorial roles is included in my CV.

11. I am actively involved in training other surgeons to perform gender confirmation surgeries. In 2017, I started the surgical fellowship in gender surgery, now placed at Rush University Medical Center in Chicago. I am currently the Director of that fellowship.

12. I have given dozens of public addresses, seminars, and lectures on gender confirming surgery, including many through the American Society of Plastic Surgeons. I have also taught a number of courses through WPATH's Gender Education Institute, which provides training courses toward a member certification program in transgender health for practitioners around the world. In addition, in 2018, I co-directed the first live surgery course in gender confirming procedures at Mount Sinai Hospital in New York City, and I am the Director for this upcoming live surgery course in 2023. In 2019, I directed the inaugural Gender Affirming Breast, Chest, and Body Master Class for the American Society of Plastic Surgeons.

13. I am also a founding member and president of the Society for Gender Surgeons; a current member of the Executive Committee of the Board of Directors of WPATH, where I serve as treasurer; and a former member of the Board of Governors of the American College of Surgeons. I am a guest examiner for the American Board of Plastic Surgery, which involves administering the

plastic surgery oral board exam to surgeons who have completed their plastic surgery training and seek board certification.

14. I am the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons, and current Patient Safety Officer for the Division of Plastic Surgery at Rush University Medical Center. In 2017, I was an invited discussant at the Pentagon regarding transgender service members. I recently delivered the Bevan 2023 Lecture at the Chicago Surgical Society, which is a lecture that began in 1928 and was established by Arthur Bevan, a former President of the American Medical Association and Founder of the American Board of Surgery.

Previous Testimony

15. In the past four years, I have provided expert testimony in the following matters: *Kadel v. Folwell*, M.D.N.C. (deposition); *Toomey v. State of Arizona*, D. Ariz. (deposition); and *Fain v. Crouch*, S.D.W.V. (deposition).

Compensation

16. I am being compensated at an hourly rate of $400/hour plus expenses for my time spent preparing this declaration and for providing any local testimony (including deposition or hearing testimony by telephone or video-teleconference). I will be compensated a flat daily rate of $7,500 for any out-of-

town deposition or hearing testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Basis for Opinions

17. My opinions contained in this report are based on all of the following: (1) my clinical experience of over 28 years of caring for transgender patients, including my experience teaching other surgeons and medical students to care for this population; (2) my review and familiarity with relevant peer-reviewed literature,[3] including my own, regarding gender confirming surgeries, which reflects the clinical advancements in these procedures and the corresponding growth in research related to the safety and effectiveness of these procedures in treating gender dysphoria; and (3) discussions with colleagues and other experts in the field, including attendance and participation in various educational conferences both nationally and internationally. The research and

[3] I regularly and routinely perform literature searches as an educator, including in my roles as a Professor of Surgery at Rush University Medical Center and an attending surgeon at Rush University, where I participate in fellow, resident, and student education; Director of Gender Affirmation Surgery at Rush University Medical Center; lecturer for the Global Education Initiative for WPATH; invited lecturer at national and international conferences; co-lead author of the surgery and post-operative care chapter of the WPATH Standards of Care Version 8; an editor and reviewer for peer-reviewed publications; and a course director for various educational opportunities for WPATH, American Society of Plastic Surgeons, and other organizations.

materials I relied on in preparing this declaration are cited in the footnotes and detailed in the reference list attached as **Exhibit B** to this declaration.

18. Additionally, in preparing this declaration, I reviewed the GAPMS Report and the Lappert Assessment, as well as the coverage exclusion challenged in this case (Fla. Admin. Code R. 59G-1.050(7)).

DISCUSSION

Background on Gender Identity and Gender Dysphoria

19. The term "transgender" is used to describe a diverse group of individuals whose gender identity, or internal sense of gender, differs from the sex they were assigned at birth.

20. Many transgender people experience gender dysphoria at some point in their lives. Gender dysphoria is a serious medical condition, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5TR) published by the American Psychiatric Association as clinically significant distress or impairment related to gender incongruence, which may include desire to change primary and/or secondary sex characteristics. Gender dysphoria is also recognized by the International Classification of Diseases-11 (ICD-11), under the label of gender incongruence, and the International Classification of Diseases-10 (ICD-10).

21. Individuals diagnosed with gender dysphoria have an intense and persistent discomfort with the primary and/or secondary sex characteristics of the sex they were assigned at birth. Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide.

22. Appropriate medical care, including mental health services, hormone therapy, and gender confirmation surgeries can help alleviate gender dysphoria. Gender confirmation surgeries, which bring a person's body into better alignment with their gender identity, have been shown to be a safe and effective treatment for gender dysphoria.

Gender Confirming Surgeries are Standard, Medically Accepted, and Medically Necessary Treatments for Gender Dysphoria for Transgender People

23. It is my professional opinion, supported by the prevailing consensus of the medical community, that surgical procedures used to treat gender dysphoria are medically necessary treatments for many transgender people. Decades of clinical practice and peer-reviewed research have demonstrated that these procedures are safe and effective treatments for gender dysphoria.

Applicable Standards of Care for Treating Gender Dysphoria

24. WPATH is a non-profit professional and educational organization devoted to transgender health. WPATH's mission is "to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health."[4] As described above, WPATH publishes the Standards of Care, which are based on the best available scientific evidence and expert professional consensus.[5] WPATH published the first version of the Standards of Care in 1979. Since that time, the guidelines have been updated through eight versions, reflecting the significant advances made in the understanding, management, and care of transgender individuals. The Standards of Care are widely recognized guidelines for the clinical management of transgender people with gender dysphoria. Most surgeons who are actively involved in academic training and research in the field and regularly treat people experiencing gender dysphoria, including myself, practice in accordance with the Standards of Care.

25. As indicated in the Standards of Care, medically necessary gender affirming treatments include mental health care, puberty suppression, hormone therapy, and various surgical procedures to align a person's primary and/or

[4] WPATH, Mission and Vision, https://www.wpath.org/about/mission-and-vision.
[5] *See* Standards of Care at S247-251 (describing the methodology used to develop the Standards of Care).

secondary sex characteristics with the person's gender identity.[6] Surgery is often the last and most considered of the treatment options for gender dysphoria in transgender people. Not every transgender person may undergo every available surgical procedure. As highlighted in the seventh version of the Standards of Care, and as now well-accepted, "[t]he number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs."[7] Evidence shows that while some transgender people do not require surgery, "for many others surgery is essential and medically necessary to alleviate their gender dysphoria. For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity."[8]

26. The Endocrine Society—the leading professional organization devoted to research on hormones and the clinical practice of endocrinology—has also issued clinical guidelines for the treatment of transgender people.[9] The

[6] Standards of Care at S18, S128.
[7] Coleman, E. et al. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People. Version 7, Int'l J. of Transgenderism, 13(4): 165-232, 201 doi: 10.1080/15532739.2011.70087358.
[8] *Id*. at 199. *See also* Standards of Care at S18.
[9] Hembree, W.C. et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, J. Clin. Endocrinology & Metabolism, 102(11): 3869-3903, doi: 10.1210/jc.2017-01658.

guidelines indicate, that for transgender people, gender confirming surgeries often are necessary and effective treatments.[10]

27. The broader medical community, including the American Medical Association, American Academy of Pediatrics, American Psychological Association, American Psychiatric Association, American College of Obstetricians and Gynecologists, American Academy of Family Physicians, and World Health Organization, recognizes that gender confirming surgeries are standard, appropriate, and often necessary treatments for adults and adolescents with gender dysphoria.

Surgical Treatments for Gender Dysphoria

28. Surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Breast/chest surgery: augmentation (breast implants) and mastectomy/liposuction (chest masculinizing);
- Genital surgeries: phalloplasty and/or metoidioplasty (creation of the penis and/or scrotum), vaginoplasty, and/or vulvoplasty (creation of the vulva and/or vagina, including the labia minora and majora);

[10] *Id.*

- Gonadectomy: hysterectomy (removal of the uterus), orchiectomy (removal of the testes);
- Other surgical interventions: gender affirming facial surgery, body contouring, voice surgery, thyroid cartilage reduction, and hair reconstruction, among others.

29. The Standards of Care set forth criteria for initiation of any gender affirming medical treatment, including surgery. For adults, the criteria for surgery are:

- The patient's experience with gender incongruence is marked and sustained.
- In regions where a diagnosis is necessary to access health care (as it is in the United States), the patient fulfills the diagnostic criteria for gender incongruence.
- Other possible causes of apparent gender incongruences have been identified and excluded prior to the initiation of treatment.
- Any physical or mental health conditions "that could negatively impact the outcome" of treatment were assessed, "with risks and benefits discussed, before a decision was made regarding treatment."

- The patient has the capacity to consent for the specific gender affirming treatment.
- The patient understands "the effect of the treatment on reproduction" and has explored reproductive options.
- "[P]rofessionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider[ed] the role of social transition" with the patient.
- The patient has a recommendation for the initiation of the treatment "from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment."
- Prior to genital reconstruction surgery, the patient has received a minimum of 6 months of hormone therapy as appropriate to their gender goals prior to undergoing the surgery.[11]

30. The Standards of Care recognize that chest masculinization surgery "can be considered in minors when clinically and developmentally appropriate

[11] Standards of Care at S32; *see also id*. at S256.

as determined by a multidisciplinary team experienced in adolescent and gender development"[12] They also indicate that breast augmentation may be needed by adolescents. In addition, while it is rare to perform genital surgeries on adolescents, the Standards of Care recognize that studies suggest that some adolescents may benefit from vaginoplasty procedures.[13] They recommend that clinicians undertake a "comprehensive biopsychosocial assessment of adolescents" seeking gender-affirming treatment "to guide treatment decisions and optimize outcomes."[14] As they do for adults, the Standards of Care set forth criteria for initiation of surgery in adolescents.[15]

Gender Confirmation Surgeries Are Medically Necessary

31. The medical community and insurance providers recognize a distinction between surgery which is medically necessary, and cosmetic surgery, which generally is not. No particular procedure is inherently cosmetic or inherently medically necessary; rather, the underlying diagnosis determines whether the procedure is considered cosmetic or medically necessary.

[12] *Id.*at S66.
[13] *Id.*
[14] *Id.* at S50.
[15] *Id.* at S48, S256.

32. With respect to surgical treatments for gender dysphoria, the medical community generally considers those surgeries to be medically necessary. This is true even though the same surgical procedures might be considered cosmetic when performed on someone without gender dysphoria (e.g., a cisgender woman obtaining a breast augmentation for aesthetic reasons). Gender confirming surgeries are not cosmetic because, when performed in accordance with the Standards of Care, they are clinically indicated to treat the underlying medical condition of gender dysphoria. Because these medically necessary procedures help transgender people live and present in a manner more consistent with their gender identity and therefore reduce and/or treat their gender dysphoria, the professional medical consensus is that these are appropriately categorized as medically necessary.

33. Dr. Lappert asserts that distinguishing "cosmetic breast surgery from 'medically necessary' surgery is based upon the diagnosis of the underlying pathology."[16] I agree. What Dr. Lappert fails to acknowledge, however, is that

[16] Lappert Assessment at 13.

breast augmentation or mastectomy may be medically indicated for the treatment of gender dysphoria, in addition to other pathologies.[17]

34. Dr. Lappert misunderstands that gender dysphoria is a medical condition for which there are effective medical and surgical treatments. While plastic surgeons may encounter individuals with mental health conditions, such as body dysmorphic disorder, surgery for this condition is highly ineffective. This is in contrast to surgery as treatment for gender dysphoria; where medically indicated, surgical procedures for gender dysphoria are both safe and medically effective.

35. Dr. Lappert also wrongly suggests that a mastectomy performed to treat gender dysphoria is cosmetic because it results in a "complete loss of function" that is "two fold (breast feeding and erotic sensibility)."[18] Here, he makes several incorrect assumptions. First, he fails to recognize that for many transgender people (especially transgender men), nipple sensation is rarely a source of erotic sensibility, and the presence of breasts may interfere with romantic relationships. In fact, my research, as well as my clinical experience,

[17] Dr. Lappert incorrectly refers to breast growth in transgender women as "gynecomastia." Gynecomastia refers to enlargement of the male breast, not to breast growth in transgender women.
[18] Lappert Assessment at 10.

shows that gender-affirming mastectomy is associated with an increase in sexual satisfaction.[19] What is more, Dr. Lappert ignores that a mastectomy performed to treat breast cancer or a breast reduction performed in a cisgender woman to relieve symptoms of breast hypertrophy or macromastia may also result in the loss of nipple sensation. A mastectomy performed to treat breast cancer will likewise result in the loss of the ability to breast feed. So, his assertion that any procedure that causes a loss of function is cosmetic cannot be correct. As another example, a prostatectomy performed to treat prostate cancer in a cisgender man may result in the loss of erectile function and impotence.

Gender Confirming Surgeries Are Safe and Effective

36. The prevailing peer-reviewed clinical research, as well as my own clinical expertise as a plastic surgeon specializing in gender confirmation surgeries for nearly three decades, shows that surgical procedures for gender dysphoria are safe, effective, and medically accepted. Indeed, many of these procedures are analogous to surgical procedures used to treat other medical conditions.

[19] *See, e.g.*, Agarwal, C.A. et al. (2018). Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test, J. Plastic, Reconstructive & Aesthetic Surgery, 71(5): 651-657, doi: 10.1016/j.bjps.2018.01.003.

Safety

37. It is my professional opinion that gender confirmation surgeries are safe. My opinion is informed in part by my experience as the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons and the current Patient Safety Officer for the Division of Plastic Surgery at Rush University Medical Center. Notably, when performing gender confirmation surgeries, surgeons use many of the same procedures that they use to treat other medical conditions. The fact that the medical community deems these analogous procedures sufficiently safe to treat conditions other than gender dysphoria is by itself more than sufficient to support the safety of those surgeries to treat gender dysphoria. There is no medical basis to conclude that the same surgical procedures are more or less safe simply because they are used to treat gender dysphoria, versus other underlying medical conditions.

38. For example, surgeons regularly perform mastectomies and chest/breast reconstruction, hysterectomies/salpingo-oophorectomies (which includes removal of the fallopian tubes and ovaries), and orchiectomies to treat individuals with cancer, or a genetic predisposition to cancer (BRCA 1, 2 genes in the case of prophylactic mastectomy or oophorectomy). Similarly, surgeons perform procedures to reconstruct external genitalia for individuals who have

certain medical conditions (e.g., cancer) or who have suffered traumatic injuries or disabling infections to their genitalia. This would include procedures to correct conditions such as hypospadias (a disorder in which the urinary opening is not in the typical location on the glans penis), epispadias (a condition where the urethra is not properly developed), exstrophy (where the bladder develops outside the fetus), fournier's gangrene (where tissue dies because of an infection), penile webbing, or buried penis (which can occur as a result of obesity, diabetes, or recurrent infections). This would also include procedures to correct conditions such as congenital absence of the vagina or reconstruction of the vagina/vulva following oncologic resection, traumatic injury, or infection.

Notably, Dr. Lappert concedes that chest reconstructive surgery in the form of a mastectomy is "very safe, and typically performed in the outpatient setting."[20] Dr. Lappert also concedes that "[s]urgical enhancement procedures are exactly the same in both men and women."[21]

[20] Lappert Assessment at 13.
[21] *Id*.

Efficacy

39. It is my professional opinion that standard surgical treatments for gender dysphoria are effective when performed in accordance with the Standards of Care.

40. Peer-reviewed studies find that transgender women who undergo one or more gender confirmation surgeries report positive health outcomes.[22] For example, a peer-reviewed study of transgender women found that those who underwent breast reconstruction surgeries experienced statistically significant improvements in their psychosocial well-being.[23] In a study published in 2019 by Miller, et al., 100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and "would undergo the operation again."[24] Another peer-reviewed study of transgender women who had vaginoplasty found that study participants' mean improvement in quality of life

[22] *See* Standards of Care at S128-129 (gathering studies on breast augmentation and vaginoplasty).
[23] Weigert, R. et al. (2013). Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male-to-Female Transsexuals. Plastic and Reconstructive Surgery, 132(6): 1421-1429. doi: 10.1097/01.prs.0000434415.70711.49.
[24] Miller. T.J. et al. (2019). Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes. JPRAS Open, 21: 63-74, doi: 10.1016/j.jpra.2019.03.003.

after surgery was 7.9 on a scale from one to ten.[25] Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria.[26] A recent literature review concluded that in appropriately selected individuals, gender confirmation surgery is effective at improving quality of life, overall happiness, and sexual functioning in transgender women who are diagnosed with gender dysphoria.[27] Another recent post-operative and six-month follow-up survey of transgender female patients found improvements in quality of life in a significant majority of patients.[28]

41. The available peer-reviewed literature likewise concludes that when performed in accordance with the prevailing standards of care, male chest reconstruction surgery is safe and effective in alleviating gender dysphoria.[29] For example, one study found that transgender men who received chest reconstruction experienced few clinical complications and were overwhelmingly

[25] Horbach, S. E. R. et al. (2015). Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques. J. Sexual Medicine, 12(6): 1499-1512, doi: 10.1111/jsm.12868.
[26] Hess, J. et al. (2014). Satisfaction with Male-to-Female Gender Reassignment Surgery. Deutsches Arzteblatt Int'l, 111: 795-801, doi: 10.3238/arztebl.2014.0795 (Among survey respondents, the majority (90.2%) said that that their expectations for life as a woman were fulfilled after surgery. A similarly high percentage (85.4%) saw themselves as women.)
[27] Hadj-Moussa, M., et al. (2018). Feminizing Genital Gender-Confirmation Surgery. Sexual Medicine Reviews, 6(3): 457-468.e2, doi: 10.1016/j.sxmr.2017.11.005.
[28] Papadopulos, N.A., et al. (2017). Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increased Quality of Life in a Prospective Study. Plastic and Reconstructive Surgery, 140(2): 286-294. doi: 10.1097/PRS.0000000000003529.
[29] *See* Standards of Care at 128 (gathering studies).

satisfied with their surgical outcomes.[30] Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.[31] A 2021 study using a validated quality of life assessment tool demonstrated significant improvements in quality of life among transgender men up to one year following chest surgery.[32] The authors indicated that "the effect sizes were large and…exhibited excellent internal validity." The authors report that "every patient surveyed at 1 year reported that gender-affirming surgery changed their life for the better" and that, "every patient surveyed after surgery said they would choose it [surgery] again knowing what they know." Numerous other studies have reached similar conclusions.[33]

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[30] Frederick, M. et al. (2017). Chest Surgery in Female to Male Transgender Individuals. Annals of Plastic Surgery, 78(3): 249-253, doi: 10.1097/SAP.0000000000000882.

[31] Agarwal, C.A. et al. (2018). Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test, J. Plastic, Reconstructive & Aesthetic Surgery, 71(5): 651-657, doi: 10.1016/j.bjps.2018.01.003.

[32] Alcon, A. et al. (2012). Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes: The University of California, San Francisco, Gender Quality of Life Survey. Plastic and Reconstructive Surgery, 147(5): 731e-740e, doi: 10.1097/PRS.0000000000007883. *See also* Schechter, L.S. (2012). Discussion: Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes: The University of California, San Francisco, Gender Quality of Life Survey. Plastic and Reconstructive Surgery, 147(5): 741e-742e. doi: 10.1097/PRS.0000000000007902.

[33] *See, e.g.,* Olson-Kennedy, J. et al. (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults. JAMA Pediatrics, 172(5): 431-436, doi: doi:10.1001/jamapediatrics.2017.5440; Van de Grift, T., et al. (2017). Surgical Indications and

42. These findings extend to adolescents; for example, a recent study in JAMA Pediatrics concluded that: "Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults."[34] In addition, a 2022 study in JAMA Pediatrics found that in transgender and nonbinary adolescents and young adults, top surgery is associated with low complication rates and improved chest dysphoria, gender congruence, and body image satisfaction.[35]

43. In my clinical experience, the overwhelming majority of patients who obtain gender confirmation surgery in a manner consistent with the Standards of Care are both satisfied and experience a reduction of gender dysphoria. For the vast majority of transgender people who seek such surgery, the surgery is successful at treating gender dysphoria and alleviating a lifelong struggle to find peace of mind and comfort with their bodies.

Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures. Plastic and Reconstructive Surgery, 140(3): 415e-424e. doi:10.1097/PRS.0000000000003607; Berry, M.G. et al. (2012). Female-to-male transgender chest reconstruction: A large consecutive, single-surgeon experience. J. Plastic, Reconstructive & Aesthetic Surgery, 65: 711-719, doi: 10.1016/j.bjps.2011.11.053; Newfield, E. et al. (2006). Female-to-Male Transgender Quality of Life Quality of Life Research, 15(9): 1447-1457. doi: 0.1007/s11136-006-0002-3.

[34] Olson-Kennedy, J. supra note 33. Additionally, Frederick et al., *supra* note 30, included adolescents aged 15-17, as well as adults.

[35] Ascha, M. et al. (2022). Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults. JAMA Pediatrics, 176(11): 1115-1122, doi:10.1001/jamapediatrics.2022.3424.

Gender Confirmation Surgeries Are Not Experimental

44. It is my professional medical opinion that Dr. Lappert's contention that gender-confirming surgeries are experimental is unsupported by the professional medical consensus and prevailing standards of care for treating gender dysphoria. To the contrary, the prevailing consensus of the medical community recognizes that procedures used to treat gender dysphoria are medically necessary and not experimental or investigational.

45. Surgical care is not considered experimental when it uses accepted techniques and has demonstrative benefits. The techniques used in gender affirming care are employed in other surgeries and are well-established. For example, urethroplasties, orchiectomies, skin grafts, and mastectomies are all accepted techniques for congenital, oncological, and traumatic conditions. They are not experimental simply because they are applied to the well-established diagnosis of gender dysphoria.

46. Gender affirming surgery has been performed for almost 100 years, utilizes accepted surgical techniques, and yields demonstrated benefits for patients. Sir Harold Gilles, the 'father' of plastic surgery performed a phalloplasty on a transgender man in 1946. Sir Harold Gilles also performed a vaginoplasty on a patient in the 1950s. Subsequent to that, the gynecologist

Georges Borou in Casablanca, developed the pedicled flap for vaginoplasty. This technique remains the mainstay of modern procedures. In fact, pioneering work in gender affirming surgery was performed at Eastern Virginia Medical School in Norfolk, Virginia, where Dr. Lappert was noted to have a faculty appointment. The Center for Gender Reassignment was established in 1984 at Eastern Virginia Medical School. The founder of the program, Dr. David Gilbert, indicated that by 1992, he and his colleagues had performed more than 50 microsurgical phalloplasty procedures. Many of the techniques used in gender affirming surgery were developed in Norfolk, including the 'Norfolk Glansplasty' used in gender affirming phalloplasty.

47. In addition, gender affirming surgeries are: 1) part of the core curriculum in plastic surgery resident education; and 2) a component of both the written and oral board exams in plastic surgery. I have given presentations at multiple professional societies—including, the American Society of Plastic Surgeons, American Association of Plastic Surgeons, American Society for Reconstructive Microsurgery, American College of Surgeons—and none of those societies consider gender affirming surgery experimental. In the disclosures required to give presentations of this kind there is no requirement that they be called experimental. It is widely accepted by professional surgical societies that

gender affirming surgeries are not experimental. Indeed, gender affirming surgery is part of the standard resident education in plastic surgery and is included in both the written and oral exams (in order to obtain board certification).

The Opinions of Dr. Lappert Are Inconsistent With the Mainstream Medical Consensus and Scientific Literature and Are Fatally Flawed

Qualifications of Dr. Lappert

48. Based on the disclosures in Dr. Lappert's Assessment, he appears to lack the requisite qualifications to offer his opinions. Dr. Lappert's board certification with the American Board of Plastic Surgery is expired. Dr. Lappert is neither board-certified in plastic surgery, nor does he appear to hold any board-certification from a member board of the American Board of Medical Specialties.

49. Dr. Lappert is not a member of the American Society of Plastic Surgeons (ASPS), despite its role as the largest plastic surgery specialty organization in the world. ASPS represents 92% of all board-certified plastic surgeons in the United States, and more than 11,000 plastic surgeons worldwide.[36] Dr. Lappert does not appear to be a member of any other major or relevant surgical organization, such as the American College of Surgeons.

[36] *See* American Society of Plastic Surgeons, About ASPS, plasticsurgery.org/about-asps (2023).

50. Dr. Lappert lists no current hospital affiliations, nor does he appear to perform surgical procedures any longer. Dr. Lappert has no recent or relevant scientific publications pertaining to the field of gender-affirming surgery. Dr. Lappert references having performed an unspecified number of surgeries for patients who previously identified as transgender, however, he does not disclose any experience in treating individuals in a manner consistent with the Standards of Care.

51. Additionally, Dr. Lappert is not a member of WPATH, which is recognized by the mainstream medical community as the authoritative entity that has established comprehensive Standards of Care in this field.

Quality of Evidence

52. Dr. Lappert repeatedly contends that the body of evidence supporting gender affirming surgery is low-quality, and as a result, the treatment is considered experimental. But that is incorrect. The quality of the evidence supporting gender affirming surgeries is comparable to that supporting many surgeries and clinical procedures. Prospective, randomized, double-blind, placebo-controlled studies cannot be used to evaluate many clinical procedures, especially surgical procedures. For example, there are simply inherent limitations to our ability to conduct such studies in clinical medicine. First, it is unethical to

withhold medically necessary care. As such, in many situations, clinicians cannot conduct a study that uses a control group who is deprived of the treatment being studied. Practice guidelines published in 2013 by the Royal College of Psychiatrists indicated that a randomized controlled study to evaluate feminizing vaginoplasty would be "impossible to carry out."[37] The withholding of medically necessary care that would be required for such a comparison would be considered unethical.

53. Second, it is not possible to perform a double-blind study of surgeries that modify body parts, nor is there a placebo that can mimic such a surgery – unlike studies that use placebo drug regimens, for example, people will know if they have had an operation or not. Third, for relatively uncommon conditions like gender dysphoria, sample sizes of individuals with the condition who are available to participate in a clinical study tend to be small. This is especially true where treatment for a condition has not been covered by insurance programs and plans, and where additional barriers (such as ongoing stigmatization) prevent patients from accessing care. That very lack of access to

[37] Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria, Royal College of Psychiatrists, at 50 (2013).

the procedure results in there being fewer people who have received treatment and who can participate in a prospective study of that treatment's effect.

54. Put simply, the scientific literature pertaining to gender affirming surgical interventions is similar to that of other accepted plastic surgery procedures. For example, Dr. Lappert points to his experience performing surgery to treat cleft palate and craniofacial differences.[38] However, there are only a small number of Level 1 (randomized controlled trials) for that treatment.[39] Scientific ratings of evidence generally employ extremely high standards that are not satisfied for many commonly-prescribed treatments and procedures.[40] Such ratings do not mean that the treatment is unsupported in the literature and clinical practice, or that it is not medically necessary.

55. The recommendation for ongoing research is a standard recommendation in many, if not most or all clinical scenarios. This recommendation for ongoing study in a particular clinical area does not mean that surgical care is withheld.

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[38] *See* Lappert Assessment as 15.

[39] *See, e.g.*, Bekisz, J.M. (2018). A Review of Randomized Controlled Trials in Cleft and Craniofacial Surgery. J. Craniofacial Surgery, 29(2): 293-301, doi: 10.1097/SCS.0000000000004100.

[40] *See, e.g.*, Lee, B.T., et al. (2017). Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps, Plastic and Reconstructive Surgery. 140(5): 651e-664e, doi: 10.1097/PRS.0000000000003768.

56. In addition, Dr. Lappert is wrong to suggest that studies are the only way for surgeons to determine the appropriate course of treatment for a particular condition. Critical review of the scientific literature is certainly an important component as to how surgeons evaluate whether a particular procedure is generally safe and effective and whether it is appropriate or recommended for an individual patient. But in addition to considering the literature en masse, we must also account for our own clinical experience and that of our colleagues, as well as our patients' experiences and input. Here, the existing literature, taken as a whole, combined with my own experience and that of many colleagues, indicates that gender affirming surgery is a safe and effective treatment for individuals with gender dysphoria.

57. In fact, in his effort to discredit the research on gender affirming surgery, Dr. Lappert reveals that his lack of experience in the area of gender affirming care is coloring his ability to properly interpret the results of the relevant studies. For example, he suggests that flaws in the methodology of one study could be masking significant numbers of patients who had poor outcomes or regretted having surgery.[41] If significant numbers of patients were having poor outcomes or experiencing regret, those of us who regularly perform gender

[41] *See* Lappert Assessment at 7-8.

affirming procedures, consult with our colleagues in the field, and attend lectures and conferences on gender affirming care would know about it. We would see many transgender patients requesting revision surgery. That is simply not happening. In contrast, I am aware that some cisgender women who undergo implant-based breast reconstruction subsequently request implant removal.

58. Finally, while criticizing the existing body of research on gender affirming surgical procedures, neither the GAPMS Report nor Dr. Lappert point to any research demonstrating a safe and effective alternative to gender affirming treatment for gender dysphoria.

Informed Consent

59. Dr. Lappert appears to assert that patients cannot provide informed consent for surgical procedures to treat gender dysphoria because of the purported insufficiency of the evidence supporting this care.[42] Dr. Lappert misunderstands informed consent, both generally and in the context of gender-affirming surgery. And, his view directly contradicts that of the American Society of Plastic Surgeons, which offers documents for surgeons to use to memorialize the process of obtaining informed consent for gender affirming care.

[42] Lappert Assessment at 4.

60. Gender affirming surgeries are not experimental, as discussed above. Gender affirming surgical procedures have been shown beneficial by multiple surgeons, in multiple countries, over many decades. The risks of gender affirming surgical procedures are well-known and well-described in the literature.[43]

61. The Standards of Care specifically discuss the importance of a shared decision-making approach (between the patient and the surgeon) that is multidisciplinary and includes a discussion of the patient's goals and expectations, the surgical options and associated risks and benefits, and a plan for care after surgery.[44] For adolescents, these discussions include the caregiver or parents who must consent as well.[45]

62. The process of securing informed consent is done in a multidisciplinary way. The health care team, which could consistent of a mental health professional, a primary care provider, an endocrinologist, and a surgeon, must assess the ability of the patient to provide informed consent.[46] And, as noted

[43] *See, e.g.*, Schechter, L.S. (2009). The Surgeon's Relationship with the Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association for Transgender Health's Standards of Care. Int'l J. of Transgenderism, 11(4): 222-225, doi: 10.1080/15532730903439468.
[44] *See* Standards of Care at S130-132.
[45] *See id.* at S57-58.
[46] *See id*. at S38-39, S61-62.

above, a competent health care professional must assess a patient seeking gender affirming surgery prior to the initiation of the treatment. This represents a clinical standard which exceeds the threshold to perform many surgical interventions to treat conditions other than gender dysphoria, including those that are sterilizing. However, this kind of multidisciplinary approach is not unique to gender affirming care. A psychosocial assessment is often performed in other areas of surgery, including transplantation and bariatrics, and has been shown to improve patient outcomes.

Few Patients Experience Regret When Gender Confirming Surgery is Provided in Accordance with the Standards of Care

63. Dr. Lappert suggests that gender confirming surgery is not safe and effective because some patients could later regret their transition and the procedure.[47] All available research—as well as my own clinical experience—indicates that very few patients experience regret when gender confirming surgery is provided in accordance with the Standards of Care and by a qualified surgeon. Regret of any kind is rare (0.6% in transgender women and 0.3% in transgender men),[48] but "true regrets," as opposed to regrets due to lack of social

[47] *See, e.g.*, Lappert Assessment at 7-8, 10-11.
[48] Wiepjes, C.M. et. al. (2018). The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, And Regrets. J. of Sexual Medicine, 15(4): 582-590. doi: 10.1016/j.jsxm.2018.01.016.

or familial acceptance, comprise an even smaller percentage (approximately half this group, roughly 0.3% in transgender women and 0.15% in transgender men).[49] Having performed gender confirming surgeries for over 20 years, I have only seen two individuals who have requested a reversal of gender affirming surgery.

64. In a recent study I co-authored regarding regret following gender affirming surgery, Narayan, et al. queried 154 surgeons surgically treating between 18,125 to 27,325 individuals.[50] The rate of regret was found to be between 0.2-0.3%, consistent with previous literature.

65. Moreover, issues pertaining to regret following surgical procedures are not limited to gender-affirming surgical interventions.[51] Some cisgender women experience regret following breast reconstruction (40%)[52], prophylactic

[49] *Id*. at 585, 587 (Researchers classified transgender women as having "social regrets" when they still identified as women, but reported feeling "ignored by surroundings" or they regretted loss of relatives. Researchers classified "true regrets" as those experienced by individuals who "thought gender affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment.").

[50] Narayan, S.K. et al. (2021). Guiding the Conversation—Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies. Annals of Translational Medicine, 9(7): 605-616, doi: 10.21037/atm-20-6204.

[51] *See, e.g.*, Christie, D.R.H. et al. (2015). Why do patients regret their prostate cancer treatment? A systematic review of regret after treatment for localized prostate cancer. Psycho-Oncology 24(9): 1002-1011. doi: 10.1002/pon.3776.

[52] Zhong, T. et al. (2013). Decision regret following breast reconstruction: the role of self-efficacy and satisfaction with information in the preoperative period. Plastic and Reconstructive Surgery, 132(5): 724e-734e, doi: 10.1097/PRS.0b013e3182a3bf5d.

mastectomy (6%),[53] and prophylactic oophorectomy (7%).[54] A study of breast cancer survivors found that five years after diagnosis, 24% expressed regret about primary surgery, and nearly 18% expressed regret about reconstruction.[55]

66. Even if we were to assume that some small percentage of patients who undergo gender-affirming surgery will experience regret, that does not mean that the surgery should never be performed. For example, some patients who undergo an appendectomy are found to have a normal appendix. No one would suggest that surgeons stop performing this procedure altogether. Rather, the appropriate response is to further refine our ability to accurately determine who is most likely to benefit from the procedure.

67. Finally, Dr. Lappert fails to consider that regret can be bidirectional. In other words, a patient may regret not having surgery. In my practice, it is far more common to see a patient who regretted not having access to surgery due to lack of insurance coverage than a patient who regretted having gender affirming surgery.

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[53] Montgomery, L.L. et al. (1999). Issues of regret in women with contralateral prophylactic mastectomies. Annals of Surgical Oncology, 6(6): 546-552, doi: 10.1007/s10434-999-0542-1.
[54] Swisher, E.M. et al. (2001). Prophylactic oophorectomy and ovarian cancer surveillance. J. of Reproductive Medicine, 46(2): 87-94 (2001).
[55] Fernandes-Taylor, S. & Bloom, J.R. (2011). Post-treatment regret among young breast cancer survivors. Psycho-Oncology 20(5): 506-516, doi: 10.1002/pon.1749.

Patient Self-Reporting

68. Dr. Lappert claims that gender confirming surgeries are based on "the patient's subjective report of dysphoria."[56] Dr. Lappert misrepresents the preoperative process and multidisciplinary assessment that occurs prior to gender affirming surgical interventions.[57] He demonstrates a lack of familiarity with both the assessment process done before the transgender patient is eligible for surgery and the role and responsibility of the surgeon in providing this care.

69. When a person is referred to a surgeon to receive gender confirming surgery, the surgeon receives in writing one or more assessments from one or more health professionals outlining the patient's diagnosis and the medical necessity of the care, as required under the Standards of Care.[58] But that is only one step in the assessment for surgical interventions. Contrary to Dr. Lappert's suggestions, the surgeon remains ultimately responsible for deciding whether a particular surgical intervention is medically indicated. The surgeon evaluates the patient and makes the final decision about whether it is safe and medically indicated to proceed. This includes an evaluation of the patient's understanding

[56] Lappert Assessment at 13.
[57] *See* Standards of Care at S133; Schechter, L.S., *supra* note 43.
[58] The Standards of Care recommend that health care professionals assessing patients for gender-affirming surgical care have specific qualifications. *See* Standards of Care at S33-35.

of the condition, their self-awareness, and their goals and expectations for the intervention. The surgeon also evaluates other factors that would affect the patient's fitness for the surgery, such as obesity or smoking, and determines whether additional information might be required, such as x-rays or laboratory work. The surgeon also typically obtains an assessment from the person's primary care physician about their overall health. In my own clinical practice, I have declined to perform a requested intervention based on my exercise of professional judgment.

70. What is more, his reliance on "objective" tests is misplaced. What he considers to be objective tests – an x-ray, pathology report or lab value – are open to interpretation. It is not uncommon to have conflicting opinions regarding an x-ray or a pathology report. In addition, while various tests may be considered in regards to establishing a diagnosis, the tests are usually interpreted within the clinical context. For example, x-ray reports typically include the phrase "clinical correlation is recommended."

71. Finally, Dr. Lappert ignores that once a diagnosis is established, treatment then depends on a discussion with the patient. That discussion includes information from the literature, but also includes other clinical considerations,

such as the patient's values, preferences, choices, and autonomy, which Dr. Lappert disregards.

72. Finally, Dr. Lappert also suggests that the difference between reconstructive surgery (which he states that insurance will cover) and cosmetic surgery (which he states that insurance will not) turns on pathology reports, using surgery to treat gynecomastia as an example.[59] Similarly, he alleges that the need for breast reduction surgery is determined by objective tests, including the weight of the specimen which is removed.[60] But, for both of those procedures, the American Society of Plastic Surgeons states that symptomatology – not pathology reports or the weight of the specimen which is removed – is the important determinant for insurance coverage.[61]

The GAPMS Report Misrepresents the Literature in Medical Necessity, Safety, and Effectiveness

73. The overwhelming weight of the scientific and medical literature supports the benefits of gender affirming surgical interventions. Gender

[59] *See* Lappert Assessment at 9.
[60] *Id*. at 10.
[61] *See* American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Reduction Mammaplasty (2021), https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021-reduction-mammaplasty.pdf; American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Gynecomastia, https://www.plasticsurgery.org/documents/Health-Policy/Positions/Gynecomastia_ICC.pdf.

affirming interventions have been performed for decades, and the safety and efficacy of these procedures have been reported by multiple surgeons practicing at different institutions in different countries and continents.

74. The GAPMS Report cites a study by Dhejne, et al. to imply that because individuals who received gender confirming surgeries had higher morbidity and mortality rates compared to the general population, the surgeries are not effective.[62] The Agency misunderstands that study. First, while the study itself clearly states that it is not intended to evaluate whether gender affirming surgeries are "an effective treatment or not," it did conclude that surgeries alleviate gender dysphoria. Second, the study found that those who receive medically necessary surgery generally have reduced morbidity and mortality compared to those with the same condition who do not, even if morbidity and mortality for both groups is higher than average. Third, the study includes patients who had surgery prior to the development of the current standards of care. Finally, the fact that gender confirming surgeries do not entirely resolve all possible causes of morbidity and mortality among transgender individuals is completely unsurprising. While surgery can treat gender dysphoria by aligning transgender people's bodies with their gender identity, surgery alone cannot fully

[62] GAPMS Report at 24-25.

eliminate the stigma and discrimination that transgender people face. Surgery does not occur in a vacuum. The Standards of Care specifically recognize the need for patients to receive continued social and medical support after surgery.[63]

75. Moreover, it is rare for any surgery to eliminate morbidity and mortality. For example, people who have surgery to remove a cancerous tumor may still experience higher rates of morbidity and mortality than the general population, but that does not mean that they should not undergo the surgery. In addition, individuals suffering from other medical conditions (including chronic conditions and traumatic injuries such as burns) are also at elevated risk of suicide. The increased risk of suicide does not preclude treatment of burn patients.[64]

76. The fact that surgery does not always reduce morbidity for everyone who receives it does not mean that the surgery is not safe or effective, particularly given the number of potential confounding factors that can impact

[63] *See* Standards of Care at S131 (recommending that prior to surgery, surgeons inform patients about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up care), S133 (recommending that surgeons encourage life-long urological follow-up for patients who have undergone metoidioplasty/phalloplasty), S134 (recommending surgeons encourage patients who have undergone vaginoplasty follow-up with their primary surgeon, primary care physician, or gynecologist).

[64] Lerman, S.F. et al. (2021). Suicidality After Burn Injuries: A Systematic Review. J. of Burn Care & Research, 42(3): 357-364, doi: 10.1093/jbcr/irab014.

morbidity. Similarly, the continued existence of elevated morbidity and mortality rates, compared to the population at large, say nothing about whether a treatment is a safe and effective way to treat a particular condition. Moreover, while suicide is not necessarily the correct marker for efficacy of treatment, in the Dhejne study, suicide attempts in the years 1989-2003 were reduced (and death by suicide during that time is listed as NA). Additionally, the number of mental health visits following surgical care is not a marker for treatment efficacy. For example, people receiving care for cancer will continue to see their oncologist – this does not imply that care received for the treatment of cancer was not successful. We continue to provide care to patients with cancer even though treatments may be "temporary" (i.e., some forms of care may extend the lifespan of a patient with cancer for several years). This does not suggest that withholding medically necessary care is appropriate for patients with cancer, any more than it is for transgender people.

77. The GAPMS Report also misunderstands Medicare policy on coverage of gender-affirming surgery. In 2014, an impartial adjudicative board in the Department of Health & Human Services concluded, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and

medically necessary.[65] As a result, the Centers for Medicare & Medicaid Services (CMS) within HHS started covering surgical care for gender dysphoria and continues to provide that coverage, including for patients in my practice.

78. In 2016, CMS decided not to issue national standards (called a National Coverage Determination or "NCD") for determining under what circumstances Medicare will cover gender confirming surgical care because "the clinical evidence . . . was inconclusive *for the Medicare population*."[66] The result of CMS's review of the evidence is not applicable to other population groups. For the most part, the Medicare population consists of individuals over the age of 65. While the number of older adults who have gender affirming surgery is increasing, most individuals who undergo gender affirming surgery are under age 65, meaning that fewer older adults have been included in studies assessing the effectiveness of the treatment. That was a significant factor in CMS's decision. As CMS articulated, "older adults may respond to health care treatments

[65] *See* Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf. That decision also discussed the quality of data demonstrating the efficacy of surgical care to treat gender dysphoria, noting regardless of whether the studies were randomized double-blind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for [gender dysphoria]." *Id.* at 20.

[66] Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (Aug. 30, 2016) (emphasis added) [hereinafter "CMS Decision Memo"].

differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility."[67]

79. What is more, CMS acknowledged that gender confirming surgery may be necessary for certain Medicare beneficiaries and concluded that the appropriateness of surgical care for this population should continue to be determined on a case-by-case basis, as is already required by the Standards of Care. Many widely accepted surgical procedures and surgical conditions do not have NCDs under Medicare. The fact that gender confirming surgery does not have an NCD is not unusual.

80. Notably, I have performed gender confirming surgeries on a number of Medicare beneficiaries in recent years, and Medicare has covered the cost of that care. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. In contrast, the exclusion challenged in this case does not evaluate the medical necessity of surgical care for gender dysphoria on a case-by-case basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

[67] *Id*. at 57.

Summary of Opinions and Conclusions

81. Based on over 28 years of clinical experience performing gender confirmation procedures and caring for transgender people, my knowledge of the Standards of Care and relevant peer-reviewed literature, and my discussions and interactions with experts throughout the world, it is my professional opinion that gender confirmation surgeries are safe, effective, and medically necessary treatments for gender dysphoria in transgender people. Gender affirming surgeries are not experimental or investigational. In my experience, the overwhelming number of individuals who undergo gender confirmation procedures describe relief and/or reduction of their gender dysphoria and improvement in their quality of life and overall functioning.

82. Furthermore, based on my clinical and professional experience and my ongoing review of the literature, it is my professional opinion that the denial of necessary medical care is likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes, and even suicide.

83. In conclusion, it is my professional opinion that the categorical exclusion of transition-related surgical care in Florida's Medicaid program is: 1) inconsistent with the Standards of Care for treating transgender individuals

diagnosed with gender dysphoria; 2) inconsistent with the peer-reviewed scientific and medical research demonstrating that gender confirmation surgeries are safe and effective; and 3) inconsistent with expert medical and surgical consensus. To the extent the exclusion is premised on the conclusion in the GAPMS Report that gender confirming surgical care is experimental and not medically necessary, that conclusion is wrong. The Standards of Care confirm, based on clinical evidence, that gender confirmation surgeries are medically necessary to help people alleviate the often serious and life-threatening symptoms of gender dysphoria.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 16th day of February, 2023.

Loren S. Schechter, M.D.

Exhibit A

Curriculum Vitae

Curriculum Vitae

NAME: **LOREN SLONE SCHECHTER, MD, FACS**

OFFICE:
Rush University Medical Center
1725 W. Harrison St
Suite 758
Chicago, Il 60712
312.942.3640

E-MAIL:
loren_schechter@rush.edu
lorenschechter1@gmail.com

MARITAL STATUS: Married (Rebecca Brown Schechter, MD)

CERTIFICATION:
The American Board of Plastic Surgery 2001
Certificate Number 6271
Date Issued: September 2001
Maintenance of Certification: 2011
Maintenance of Certification: 2021

EDUCATION:

1986-1990	The University of Michigan	BS, 1990
1990-1994	The University of Chicago Pritzker School of Medicine	MD, 1994

POSTGRADUATE TRAINING:

Residency:	The University of Chicago Hospitals Coordinated Training Program in Plastic and Reconstructive Surgery	1994-1999
Chief Resident:	The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1998-1999
Fellowship:	Reconstructive Microsurgery The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1999-2000

TEACHING APPOINTMENT and CURRENT PRACTICE LOCATION:
Professor of Surgery (Department of Surgery, Division of Plastic Surgery with joint appointment in the Department of Urology), Chief Section of Gender-Affirmation Surgery, Rush University Medical Center
Director, Gender Affirmation Surgery-Rush University Medical Center

LICENSURE:
Illinois
Illinois Controlled Substance
DEA
Georgia

STAFF APPOINTMENTS:

	Rush University Medical Center
	Advocate Lutheran General Hospital
	Louis A. Weiss Memorial Hospital

HONORS AND AWARDS:

2022	WPATH award for Courage and Bravery
2022	Chicago Magazine Top Doctor
2021	Chicago Magazine Top Doctor-Surgery
2020	The University of Minnesota Program in Human Sexuality, recipient of 50 Distinguished Sexual and Gender Health Revolutionaries
2017-2020	Castle Connolly Top Doctor (Chicago)
2017	Chicago Consumer Checkbook Top Doctor
2015	University of Minnesota Program in Human Sexuality Leadership Council
2014-2015	Rosalind Franklin University of Medicine and Science Chicago Medical School Honors and recognizes for dedication and commitment to teaching
2014	National Center for Lesbian Rights honored guest
2013	Illinois State Bar Association Award for Community Leadership
2010	Advocate Lutheran General 2009 Physicians Philanthropy Leadership Committee-Outstanding Leadership
2009	Advocate Lutheran General Hospital Value Leader (received for compassion)
1994	Doctor of Medicine with Honors
1994	University of Chicago Department of Surgery Award for Outstanding Performance in the Field of Surgery
1994	Catherine Dobson Prize for the Best Oral Presentation Given at the 48th Annual Senior Scientific Session in The Area of Clinical Investigation
1993	Alpha Omega Alpha
1991	University of Chicago National Institutes Of Health Summer Research Award
1990	Bachelor of Science with High Distinction And Honors in Economics
1990	James B. Angell Award for Academic Distinction
1989	Omicron Delta Epsilon-National Economic Honor Society
1988	College Honors Program Sophomore Honors Award For Academic Distinction
1988	Class Honors (Dean's List)

MEMBERSHIPS:

2023-	Society of Gender Surgeons
2018-	The American Association of Plastic Surgeons
2016-	The American Society for Gender Surgeons (founding member and president-elect)
2010-	World Society for Reconstructive Microsurgery

2005-	The University of Chicago Plastic Surgery Alumni Association
2005-	The Chicago Surgical Society
2004-	The American Society for Reconstructive Microsurgery
2003-	The American College of Surgeons
2002-	The American Society of Plastic Surgeons
2001-	Illinois Society of Plastic Surgeons (formerly Chicago Society of Plastic Surgeons)
2001-	The American Society of Maxillofacial Surgeons
2001-	American Burn Association
2001-	Midwest Association of Plastic Surgeons
2001-	WPATH
1994-	The University of Chicago Surgical Society
1994-	The University of Chicago Alumni Association
1992-	American Medical Association
1992-	Illinois State Medical Society
1992-	Chicago Medical Society
1990-	The University of Michigan Alumni Association

CURRENT HOSPITAL COMMITTEES:

Patient Safety and Quality Officer, Division of Plastic Surgery, Rush University Medical Center

PROFESSIONAL SOCIETY COMMITTEES:

WPATH Executive Committee

Treasurer, The World Professional Association for Transgender Health

Chair, Finance and Investment Committee, The American Society of Plastic Surgeons

WPATH 2020 Biennial Meeting Steering Committee

American Society of Breast Surgeons Research Committee, ASPS representative

American Board of Plastic Surgery, Guest Oral Board Examiner

WPATH Ethics Committee

American College of Radiology Committee on Appropriateness Criteria Transgender Breast Imaging Topic, Expert Panel on Breast Imaging: Transgender Breast Cancer Screening Expert Panel on Breast Imaging

American Society of Plastic Surgeons, Finance and Investment Committee

Board of Directors, at-large, The World Professional Association for Transgender Health

PlastyPac, Board of Governors

Medicare Carrier Advisory Committee

OTHER:

American Board of Plastic Surgery-Oral Board Guest Examiner (2020, 2021)

Guest Reviewer, Pain Management

Guest Reviewer, Plastic and Aesthetic Research

Guest Reviewer, European Medical Journal

Guest Reviewer, Open Forum Infectious Diseases

Guest Reviewer, The Journal of The American College of Surgeons

Guest Book Reviewer, Plastic and Reconstructive Surgery

Editorial Board, Transgender Health

Editorial Board (Associate Editor), International Journal of Transgenderism

Fellow of the Maliniac Circle

Guest Reviewer, Journal of Reconstructive Microsurgery

Guest Reviewer, Journal of Plastic and Reconstructive Surgery

Guest Reviewer, Journal of Sexual Medicine

Guest Editor, Clinics in Plastic Surgery, Transgender Surgery (Elsevier Publishing)

Guest Reviewer, The Journal of Plastic and Reconstructive Surgery

PREVIOUS EDITORIAL ROLE:

Guest Reviewer, EPlasty, online Journal

Module Editor for Patient Safety, Plastic Surgery Hyperguide

Editorial Advisory Board, Plastic Surgery Practice

Guest Reviewer, International Journal of Transgenderism

Guest Reviewer, Pediatrics

PREVIOUS ACADEMIC APPOINTMENT:

Clinical Professor of Surgery, The University of Illinois at Chicago

Visiting Clinical Professor in Surgery, The University of Illinois at Chicago

Chief, Division of Plastic and Reconstructive Surgery, Chicago Medical School, Rosalind Franklin University of Medicine and Science

Associate Professor, Physician Assistant Program, College of Health Professionals, Rosalind Franklin University

Associate Professor of Surgery, The College of Health Professionals, Rosalind Franklin University

Clinical Associate in Surgery, The University of Chicago

PREVIOUS HOSPITAL COMMITTEES:

Director, Center for Gender Confirmation Surgery, Louis A. Weiss Memorial Hospital

Division Director, Plastic Surgery, Lutheran General Hospital

Division Director, Plastic Surgery, St. Francis Hospital

Medical Staff Executive Committee, Secretary, Advocate Lutheran General Hospital

Credentials Committee, Lutheran General Hospital

Pharmacy and Therapeutics Committee Lutheran General Hospital

Operating Room Committee, St. Francis Hospital

Cancer Committee, Lutheran General Hospital
-Director of Quality Control

Risk and Safety Assessment Committee, Lutheran General Hospital

Nominating Committee, Rush North Shore Medical Center

Surgical Advisory Committee, Rush North Shore Medical Center

Section Director, Plastic Surgery, Rush North Shore Medical Center

PREVIOUS SOCIETY COMMITTEES:

PlastyPac, Chair, Board of Governors

Chair of the Metro Chicago District #2 Committee on Applicants, American College of Surgeons

American Society of Plastic Surgery, Health Policy Committee

American Society of Plastic Surgery, Patient Safety Committee

American Society of Plastic Surgeons, Coding and Payment Policy Committee

American Society of Plastic Surgeons, Practice Management Education Committee

Board of Governors, Governor-at-large, The American College of Surgeons

American College of Surgeons, International Relations Committee

Chair, Government Affairs Committee, American Society of Plastic Surgeons

President, The Metropolitan Chicago Chapter of The American College of Surgeons

2012 Nominating Committee, American Society of Plastic Surgeons

Program Committee, The World Society for Reconstructive Microsurgery, 2013 Bi-Annual Meeting

President, Illinois Society of Plastic Surgeons

Vice-President, The Illinois Society of Plastic Surgeons (formerly the Chicago Society of Plastic Surgery)

Vice-President, The Metropolitan Chapter of the American College of Surgeons

American Society of Plastic Surgery, Chairman, Patient Safety Committee

2006-2007 Pathways to Leadership, The American Society of Plastic Surgery

2005 & 2006 President, The University of Chicago Plastic Surgery Alumni Association

2003 Leadership Tomorrow Program, The American Society of Plastic Surgery

Senior Residents Mentoring Program, The American Society of Plastic Surgery

American Society of Maxillofacial Surgery, Education Committee

Alternate Councilor, Chicago Medical Society

American Society of Aesthetic Plastic Surgery, Electronic Communications Committee

American Society of Aesthetic Plastic Surgery, Intranet Steering Committee

American Society of Aesthetic Plastic Surgery, International Committee

Membership Coordinator, The Chicago Society of Plastic Surgeons
The Illinois State Medical Society, Governmental Affairs Council

The Illinois State Medical Society, Council on Economics

Chicago Medical Society, Physician Review Committee
-Subcomittee on Fee Mediation

Chairman, Chicago Medical Society, Healthcare Economics Committee

Secretary/Treasurer, The Metropolitan Chicago Chapter of the American College of Surgeons

Scientific Committee, 2007 XX Biennial Symposium WPATH

Local Organizing Committee 2007 WPATH

Secretary, The Chicago Society of Plastic Surgeons

Treasurer, The Chicago Society of Plastic Surgeons

Council Member, The Metropolitan Chicago Chapter of the American College of Surgeons

INTERNATIONAL MEDICAL SERVICE:

Northwest Medical Teams
Manos de Ayuda (Oaxaca, Mexico)

Hospital de Los Ninos (San Juan, Puerto Rico)

COMMUNITY SERVICE:

Alumni Council, The University of Chicago Medical and Biological Sciences Alumni Association

The University of Minnesota Presidents Club Chancellors Society

Board of Directors, Chicago Plastic Surgery Research Foundation

National Center for Gender Spectrum Health Advisory Council

PREVIOUS COMMUNITY SERVICE:

Board of Directors, Committee on Jewish Genetic Diseases, Jewish United Fund, Chicago, Illinois

Governing Council, Lutheran General Hospital, Park Ridge, Il

Lutheran General Hospital Development Council, Park Ridge, Il

Lutheran General Hospital Men's Association, Park Ridge, Il

Advisory Board, Committee on Jewish Genetic Diseases, Cancer Genetics Subcommittee, Jewish United Fund, Chicago, Illinois

Health Care Advisory Board, Congressman Mark Kirk, 10th Congressional District, Illinois

Major Gifts Committee, Saint Francis Hospital Development Council, Evanston, Il

Visiting Professor:

1. University of Utah, Division of Plastic Surgery, November 6-8, 2014.
2. Northwestern University, Division of Plastic Surgery, April 21-22, 2016.
3. The University of North Carolina, Division of Plastic Surgery, March 28-29, 2017
4. Georgetown University, Department of Plastic Surgery, May 17-18, 2017

5. The University of Basel, Basel, Switzerland, August 31-September 1, 2018

6. The Ochsner Health System, New Orleans, LA January 28-January 30, 2019

7. The University of Toronto, Toronto, Ontario, Canada, February 21-22, 2019

8. The University of Michigan, October3-4, 2019, Ann Arbor, MI

9. Georgetown University, Department of Plastic Surgery, July 21, 2022

Invited Discussant:

1. Department of Defense, Military service by people who are transgender, Invitation from Terry Adirim, M.D., M.P.H.Deputy Assistant Secretary of Defense for Health Services Policy & Oversight, The Pentagon, November 9, 2017

2. Aesthetic Surgery Journal, Invited Discussant May 7, 2019, Journal Club. "What is "Nonbinary" and What Do I need to Know? A Primer for Surgeons Providing Chest Surgery for Transgender Patients."

Honorary Lecture:

1. 2023 Arthur D. Bevan Lectureship, The Chicago Surgical Society, February 2, 2023, Chicago, Il

Research Interests:

1. Role of Omental Stem Cells in Wound Healing (Grant: Tawani Foundation)

2. Robotic-Assisted Bilateral Prophylatic Nipple Sparing Mastectomy with Immediate Tissue Expander/Implant Reconstruction (Pending submission to the FDA for Investigational Device Exemption in association with Intuitive Surgical)

3. Transgender Health and Medicine Research Conference, National Institutes of Health, Bethesda, MD May 7-8, 2015

4. Uterine Transplantation, Rush University Medical Center (IRB pending)

5. Gender Affirmation Surgery Prospective Surveys (Rush University-IRB approved)

6. National Network for Gender Affirming Surgeries: Canadian Institute of Health Research, Training Grant – LGBQT 2S Stigma Reduction & Life Course Mental Wellness (application in process)

BIBLIOGRAPHY:

PEER REVIEWED ARTICLES:

1. E. Wall, D. A. Schoeller, **L. Schechter**, L.J. Gottlieb: Measured Total Energy Requirements of Adult Patients with Burns. *The Journal of Burn Care and Rehabilitation* 20:329, 1999.

2. David C. Cronin, II, **Loren Schechter**, Somchi Limrichramren, Charles G. Winans, Robert Lohman, and J. Michael Millis, Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow with an Implantable Doppler Probe. *Transplantation 74(6):887-889, 2002.*

3. Robert F. Lohman, **Loren S. Schechter**, Lawrence S. Zachary, Solomon Aronson: Evaluation of Changes in Skeletal Muscle Blood Flow in the Dog with Contrast Ultrasonography Revisited: Has the Technique Been Useful, and Where are We Headed Now? *The Journal of Plastic and Reconstructive Surgery* 111(4):1477-1480, 2003.

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4. **Loren Schechter, M.D.**, K. Alizadeh, M.D., M. McKinnon, M.D., Craniofacial Osseo-Distraction: A Bridge to Eucephaly, Abstracts of the 12th Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, p. 63, 1999.

5. McKay McKinnon, M.D., K. Alizadeh, M.D., **L. Schechter**, M.D., Ethnic Aesthetic Analysis and Surgery, Abstracts of the 12th Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, p. 89, 1999

6. Mark A. Grevious, **Loren S. Schechter**, David H. Song, and Robert Lohman: Sural Neurocutaneous Flaps for Reconstruction of Leg Wounds The American Society of Plastic Surgery Senior Residents' Conference 2001

7. **Loren S. Schechter**, Mark A. Grevious, David H. Song, Risal Djohan, and Robert F. Lohman: Comparing Sural Neurocutaneous and Free Flaps for Reconstruction of Leg Wounds: Indications and Outcomes, The World Society for Reconstructive Microsurgery p.29, 2001

8. LC Wu, **LS Schechter**, and RF Lohman: Negative Pressure Wound Therapy as a Bridge Between Debridement and Free Flap Reconstruction of Extremity Wounds, The World Society for Reconstructive Microsurgery p. 31, 2001

9. Mark A. Grevious, **Loren S. Schechter**, Risal Djohan, David H. Song, and Robert Lohman: Role of Free-Tissue Transfer and Sural Neurocutaneous Flaps for Reconstruction of Leg Wounds, The Journal of Reconstructive Microsurgery, 18(6):533, 2002.

10. Lawrence J. Gottlieb, Alex Kaplan, Kirstin Stenson, **Loren Schechter**: The Thoracoacromial Trunk as a Recipient Vessels: A Lifeboat in Head and Neck Reconstruction, The Journal of Reconstructive Microsurgery, 18(6):563, 2002.

11. Liza C. Wu M.D., **Loren S. Schechter, M.D.**,Robert F.Lohman M.D., Robin Wall, P.A., Mieczyslawa Franczyk, P.T., Ph.D.: Defining the Role for Negative Pressure Therapy in the Treatment Algorithm of Extremity Wounds, Plastic Surgical Forum, Vol. XXV, p.245 2002.

12. Liza C. Wu, **Loren S. Schechter**, Robert F. Lohman, Somchai Limsrichamren, Charles G. Winans, J. Michael Millis, and David C. Cronin: Implantable Doppler Probe for Continuous Monitoring of Hepatic Artery and Portal Vein Blood Flow in Pediatric Liver Transplantation, The Journal of Reconstructive Microsurgery, 19(7): 517, 2003.

13. **Loren S. Schechter, MD**, John C. Layke, MD, Wayne M. Goldstein, MD, Lawrence J. Gottlieb, MD: The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An 18 Year Experience, Plastic Surgery Forum, Vol. XXVII, P. 133.

14. Joseph Talarico, MD, Wayne Lee, MD, **Loren Schechter, MD**: When Component Separation Isn't Enough, American Hernia Society, Inc, Hernia Repair 2005, P. 194

15. **Loren S. Schechter, MD, FACS**, James Boffa, MD, Randi Ettner, Ph.D., and Frederic Ettner, MD: Revision Vaginoplasty With Sigmoid Interposition: A Reliable Solution for a Difficult Problem, The World Professional Association for Transgender Health (WPATH) 2007 XX Biennial Symposium P. 31-32

16. Jacob M.P. Bloom, MS, Alvin B. Cohn, MD, Benjamin Schlechter, MD, Nancy Davis, MA, **Loren S. Schechter, MD**, Abdominoplasty and Intra-Abdominal Surgery: Safety First, Plastic Surgery Abstract Supplement vol. 120, no 4, p. 99

17. I.A. Seitz, C.S. Williams, T.A. Wiedrich, **L.S. Schechter**, Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap, Plastic Surgery At The Red Sea International Symposium Book Of Abstracts, March 24-28, 2009, p. 25

18. Michael Salvino, MD and **Loren S. Schechter, MD**, Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate, The Midwestern Association of Plastic Surgeons Book of Abstracts, April 18-19, 2009, p.65

19. Michelle Roughton, MD and **Loren Schechter, MD**, Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures, The Midwestern Association of Plastic Surgeons Book of Abstracts, April 18-19, 2009, p.65

20. Iris A. Seitz, MD, Phd, Sarah Friedewald, MD, Jonathon Rimler, BS, **Loren Schechter, MD, FACS**, Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex, Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010,p.26

21. Iris A. Seitz, MD, Phd, Craig Williams, MD, Daniel Resnick, MD, Manoj Shah, MD, **Loren Schechter, MD, FACS**, Achieving Soft Tissue Coverage of Complex Upper and Lower Extremity Defects with Omental Free Tissue Transfer, Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, p. 28

22. Iris A. Seitz, MD, Phd, Craig Williams, MD, **Loren Schechter, MD, FACS**, Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection, Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, p. 29

23. Michelle Roughton, MD, **Loren Schechter, MD, FACS**, Patient Safety: Abdominoplasty and Intra-Abdominal Procedures,
Advocate Research Forum, Research and Case Report Presentation Abstracts, Advocate Lutheran General Hospital, May 5, 2010, p. 20

24. Iris A. Seitz, MD, PhD., Sarah M. Friedewald, MD, Jonathon Rimler, BS, **Loren S. Schechter, MD, FACS**, Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, Abstract, P. 44.

25. Loren S. Schechter, MD, FACS, Gender Confirmation Surgery in the Male-to-Female Individual: A Single Surgeon's Fourteen Year Experience, Annals of Plastic Surgery, Vol. 74, Suppl. 3, June 2015, p. s187.

26. 25th WPATH Symposium, Surgeons Only, November 1, 2018, Buenos Aires, Argentina, A Novel Approach for Neovagina Configuration During Vaginoplasty for Gender Confirmation Surgery

27. 25th WPATH Symposium, Surgeons Only, November 1, 2018, Buenos Aires, Argentina, IPP Implantation Post-Phalloplasty: The Chicago Experience

28. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, The Role of Pelvic Floor Physical Terhapy in Patients Undergoing Gender Confirming Vaginoplasty Procedures

29. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Establishing Guidelines for VTE Prophylaxis in Gender Confirmation Surgery

30. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Gender Surgeons Experience with Detransition and Regret

PRESENTATIONS:

1. Student Summer Research Poster Forum-The University of Chicago, Jan. 21, 1992: "A Comparison of Dynamic Energy Expenditure Versus Resting Energy Expenditure in Burn Patients Using The Doubly Labeled Water Method"

2. American Association for the Surgery of Trauma, Sept. 17-19, 1992, Louisville, KY: "Routine HIV Testing in A Burn Center: A Five Year Experience"

3. American Burn Association Poster Session, April 20-23, 1994, Orlando, Fl: "Calculated Versus Measured Energy Requirements in Adult Burn Patients"

4. 48th Annual Senior Scientific Session: The University of Chicago, May 19, 1994: "Calculated Versus Measured Energy Requirements in Adult Burn Patients"

5. Plastic Surgery Senior Residents Conference, April 20-25, 1999, Galveston, TX: "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

6. The Chicago Society of Plastic Surgery, May 6, 1999, "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

7. The American Society for Aesthetic Plastic Surgery, May 14-19, 1999, Dallas, TX: "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

8. XIII Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, June 27-July 2, 1999, San Francisco, CA: "Craniofacial Osseo-Distraction: A Bridge to Eucephaly"

9. XIII Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, June 27-July 2, 1999 San Francisco, CA: "Ethnic Aesthetic Analysis and Surgery"

10. Inaugural Congress of the World Society for Reconstructive Microsurgery, October 31-November 3, 2001, Taipei, Taiwan: "Comparing Sural Neurocutaneous and Free Flaps for Reconstruction of Leg Wounds: Indications and Outcomes"

11. American Society for Reconstructive Microsurgery, January 12-15, 2002, Cancun, Mexico: "The Role to Free Tissue Transfer and Sural Neurocutaneous flaps for Reconstruction of Leg Wounds"

12. American Society of Plastic Surgery, 71st Annual Scientific Meeting, November 2-6, 2002, San Antonio, Texas: "Defining the Role for Negative Pressure Therapy in the Treatment Algorithm of Extremity Wounds"

13. American Society of Reconstructive Microsurgery, Annual Scientific Meeting, January 11-15, 2003, Kauai, Hawaii: "Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow With an Implantable Doppler Probe"

14. The 5th Annual Chicago Trauma Symposium, August 8-10, 2003, Chicago, Illinois: "Soft Tissue Salvage: Where Are We in 2003?"

15. The Midwestern Association of Plastic Surgeons, 42nd Annual Meeting, Chicago, Il May 1-2, 2004: "The Gastrocnemius-Achilles Tendon Myocutaneous

Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

16. The 6th Annual Chicago Trauma Sympsoium, August 12-15, 2004, Chicago, Il "Complex Wound Management"

17. The American Society of Plastic Surgery, October 9-13, 2004, Philadelphia, Pennsylvania: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

18. The American Society for Reconstructive Microsurgery, January 15-18, 2005, Fajardo, Puerto Rico: "Surviving as a Plastic Surgeon"

19. American Hernia Society, Poster Presentation, February 9-12, 2005, San Diego, California: "When Component Separation Isn't Enough"

20. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Hereditary Gingival Fibromatosis in Monozygotic Twins: First Reported Case"

21. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Modified Components Separation Technique for Two Massive Ventral Hernias"

22. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Mucormycosis of the Head and Neck: A Fatal Disease?"

23. The 7th Annual Chicago Trauma Symposium, August 11-14, 2005, Chicago, Il "Management of Complex Injuries"

24. Current Concepts in Advanced Wound Healing: *A Practical Overview*, Rush North Shore Medical Center, Skokie, Il September 18, 2005 "From Flaps to Grafts"

25. Taizoon Baxamusa, M and Loren S.Schechter, MD, Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity, The American Association For Hand Surgery Annual Scientific Meeting, January 11-14, 2006, Tucson, Arizona.

26. The American Academy of Orthopedic Surgeons 2006 Annual Meeting, March 22-26, 2006, Chicago, Il "Methods of Patella-Femoral and Extensor Mechanism Reconstruction for Fracture and Disruption After Total Knee Arthroplasty"

27. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Elective Abdominal Plastic Surgery Procedures Combined with Concomitant Intra-abdominal Operations: A Single Surgeon's Four Year Experience"

28. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection Versus Traditional Therapy"

29. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Abdominoplasty Graft & VAC Therapy: Two Useful Adjuncts in Full-Thickness Grafting of the Mangled Upper Extremity"

30. The American Association of Plastic Surgeons 85th Annual Meeting, May 6-9, 2006 Hilton Head, South Carolina "Excision of Giant Neurofibromas"

31. The 8th Annual Chicago Trauma Symposium, July 27-30, 2006, Chicago, Il "Management of Complex Injuries"

32. The American Society of Plastic Surgeons Annual Meeting, October 6-12, 2006, San Francisco, California "Excision of Giant Neurofibromas"

33. The American College of Surgeons Poster Presentation, October, 2006, Chicago, Il "Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity"

34. American Medical Association-RFS 3rd Annual Poster Symposium, November 10, Las Vegas, NV, 2006 "Abdominal Wall Reconstruction With Alloderm"

35. Advocate Injury Institute: "Trauma 2006: The Spectrum of Care), November 30-December 2, 2006, Lisle, Il, "Pit Bull Mauling: A Case Study"

36. The 9th Annual Chicago Trauma Symposium, August 10-12, 2007, Chicago, Il "Management of Complex Injuries"

37. The World Professional Association for Transgender Health (WPATH) 2007 XX Biennial Symposium, September 5-8. 2007, Chicago, Il Revision Vaginoplasty With Sigmoid Interposition: "A Reliable Solution for a Difficult Problem"

38. Metropolitan Chicago Chapter of the American College of Surgeons, 2008 Annual Meeting, March 15, 2008 "ER Call: Who's Job is it Anyway"

39. The 10th Annual Chicago Trauma Symposium, August 7-10, 2008, Chicago, Il "Management of Complex Injuries"

40. 23nd Annual Clinical Symposium on Advances in Skin & Wound Care: The Conference for Prevention and Healing October 26-30, 2008, Las Vegas, Nevada,poster presentation "Use of Dual Therapies Consisting of Negative Pressure Wound Therapy (NPWT) and Small Intestine Mucosa (SIS) on a Complex Degloving Injury With an Expose Achilles Tendon: A Case Report."

41. The American Society of Plastic Surgeons Annual Meeting, October 31-November 3, 2008, Chicago, Il "Panel: Fresh Faces, Real Cases"

42. The American Association for Hand Surgery Annual Meeting, January 7-13, 2009, Maui, Hawaii, poster session: "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

43. Plastic Surgery At The Red Sea Symposium, March 24-28, 2009 Eilat, Israel, "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

44. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Advertising in Plastic Surgery?"

45. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Cost-Effectiveness of Physician Extenders in Plastic Surgery"

46. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il, "Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate"

47. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il,"Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures"

48. The 11th Annual Chicago Trauma Symposium, August 1, 2009, Chicago, Il "Management of Complex Injuries"

49. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Omental Free Tissue Transfer for Coverage of Complex Extremity Defects: The Forgotten Flap."

50. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Challenging Cases."

51. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, "President's Panel: The Future of the Solo Practice-Can We, Should We Survive?"

52. The 12th Annual Chicago Trauma Symposium, August 5-8, 2010, Chicago, Il "Management of Complex Injuries"

53. Breast MRI to Define The Blood Supply to the Nipple-Areolar Complex. German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPRAEC), Dresden, Germany, September 2010

54. Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA

55. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA.

56. ASPS/ASPSN Joint Patient Safety Panel: Patient Selection and Managing Patient Expectations, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA

57. Lunch and Learn: Prevention of VTE in Plastic Surgery Patients, The American Society of Plastic Surgeons Annual Meeting, October 5, 2010, Toronto, CA

58. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, 16th Congress of The International Confederation for Plastic Reconstructive and Aesthetic Surgery, May 22-27, 2011, Vancouver, Canada

59. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

60. Applications of the Omentum for Limb Salvage: The Largest Reported Series, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

61. Successful Tongue Replantation Following Auto-Amputation Using Supermicrosurgical Technique, Poster Session, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

62. The 13th Annual Chicago Trauma Symposium, August 25-28, 2011, Chicago, Il "Soft Tissue Defects-Getting Coverage"

63. WPATH: Pre-conference Symposium, September 24, 2011, Atlanta, GA "Surgical Options and Decision-Making"

64. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part I: Patient Selection and Preventing Adverse Events in the Ambulatory Surgical Setting

65. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part III: Preventing VTE

66. XXIV Congresso Nazionale della Societa Italiana di Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: 3 Step Approach to Lower Extremity Trauma

67. XXIV Congresso Nazionale della Societa Italiana Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: Applications of the Omentum for Limb Salvage: The Largest Reported Series

68. American Society for Reconstructive Microsurgery, Poster Presentation, January 14-17, 2012, Las Vegas, NV: Neonatal Limb Salvage: When Conservative Management is Surgical Intervention

69. The 14th Annual Chicago Trauma Symposium, August 2-5, 2012, Chicago, Il "Soft Tissue Defects-Getting Coverage"

70. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Reimbursement in Breast Reconstruction"

71. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Thriving in a New Economic Reality: Business Relationships and Integration in the Marketplace"

72. The 15th Annual Chicago Trauma Symposium, August 2-5, 2013, Chicago, Il "Soft Tissue Defects-Getting Coverage"

73. 2014 WPATH Symposium, Tansgender Health from Global Perspectives, February 14-18, 2014, "Short Scar Chest Surgery."

74. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, "Intestinal Vaginoplasty with Right and Left Colon."

75. 24th Annual Southern Comfort Conference, September 3-7, 2014, Atlanta, Georgia, "Gender Confirmation Surgery: State of the Art."

76. The 15th Annual Chicago Trauma Symposium, September 4-7, 2014, Chicago, Il "Soft Tissue Defects-Getting Coverage"

77. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il "Gender Confirmation Surgery: A Single-Surgeon's Experience"

78. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il, Moderator, Gender Reassignment.

79. the American Society of Plastic Surgeons 2015 Professional Liability Insurance and Patient Safety Committee Meeting, July 17, 2015, "Gender Confirmation Surgery."

80. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. From Fee-for-Service to Bundled Payments

81. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Moderator, Transgender Surgery

82. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Efficient Use of Physician Assistants in Plastic Surgery.

83. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Patient Safety: Prevention of VTE

84. The World Professional Association for Transgender Health, Objective Quality Parameters for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

85. The World Professional Association for Transgender Health, Resident Education Curriculum for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

86. The World Professional Association for Transgender Health, Urologic Management of a Reconstructed Urethra(Poster session #195), June 18-22, 2016, Amsterdam, Netherlands

87. The World Professional Association for Transgender Health, Construction of a neovagina for male-to-female gender reassignment surgery using a modified intestinal vaginoplasty technique, poster session (Poster session #198), June 18-22, 2016, Amsterdam, Netherlands

88. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Genital Aesthetics: What are we trying to achieve?, Washington, DC June 23-25, 2016

89. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Female to Male Gender Reassignment, Washington, DC June 23-25, 2016

90. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The journal of retractions, what I no longer do, Washington, DC June 23-25, 2016

91. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The three minute drill, tips and tricks, Washington, DC June 23-25, 2016

92. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Moderator, Mini master class: Male genital plastic surgery, Washington, DC June 23-25, 2016

93. The 16th Annual Chicago Trauma Symposium, August 18-21, 2016, Chicago, Il "Soft Tissue Defects-Getting Coverage"

94. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Partial Flap Failure Five Weeks Following Radial Forearm Phalloplasty: Case Report and Review of the Literature

95. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Urethroplasty for Stricture after Phalloplasty in Transmen Surgery for Urethral Stricture Disease after Radial Forearm Flap Phalloplasty–Management Options in Gender Confirmation Surgery

96. USPATH, Feb 2-5, 2017, Los Angeles, CA, Patient Evaluation and Chest Surgery in Transmen: A Pre-operative Classification

97. USPATH, Feb 2-5, 2017, Los Angeles, CA Single Stage Urethral Reconstruction in Flap Phalloplasty: Modification of Technique for Construction of Proximal Urethra

98. USPATH, Feb 2-5, 2017, Los Angeles, CA, Use of Bilayer Wound Matrix on Forearm Donor Site Following Phalloplasty

99. USPATH, Feb 2-5, 2017, Los Angeles, CA, Vaginoplasty: Surgical Techniques

100. USPATH, Feb 2-5, 2017, Los Angeles, CA, Positioning of a Penile Prosthesis with an Acellular Dermal Matrix Wrap following Radial Forearm Phalloplasty

101. USPATH, Feb 2-5, 2017, Los Angeles, CA, Principles for a Gender Surgery Program

102. USPATH, Feb 2-5, 2017, Los Angeles, CA, Construction of a Neovagina Using a Modified Intestinal Vaginoplasty Technique

103. The 18th Annual Chicago Orthopedic Symposium, July 6-9, 2017, Chicago, Il "Soft Tissue Defects-Getting Coverage"

104. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Moderator: Genital Surgery Trends for Women

105. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Adding Transgender Surgery to Your Practice, Moderator and Speaker

106. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Transbottom Surgery

107. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 A Novel Approach to IPP Implantation Post Phalloplasty: The Chicago Experience

108. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018, A Novel Approach for Neovagina Configuration During Vaginoplasty for Gender Confirmation Surgery

109. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Developlment of a Pelvic Floor Physical Therapy Protocol for Patients Undergoing Vaginoplasty for Gender Confirmation

110. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Establishing Guidelines for Gender Confirmation Surgery: The Perioperative Risk of Asymptomatic Deep Venous Thrombosis for Vaginoplasty

111. The 19th Annual Chicago Trauma Symposium, August 16-19, 2018, Chicago, Il "Soft Tissue Defects-Getting Coverage"

112. Midwest LGBTQ Health Symposium, September 14-15, 2018, Chicago, Il "Quality Parameters in Gender Confirmation Surgery"

113. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Poster Session, Proposed Guidelines for Medical Tattoo Following Phalloplasty; An Interdisciplinary Approach

114. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Establishment of the First Gender Confirmation Surgery Fellowship

115. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, ISSM Lecture, The Importance of Surgical Training

116. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Tracking Patient-Reported Outcomes in Gender Confirmation Surgery

117. "Theorizing the Phantom Penis," The Psychotherapy Center for Gender and Sexuality's 6th Biannual Conference, Transformations, March 29-March 30, 2019, NY, NY

118. "Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept," World Professional Association for Transgender Health 27th Scientific Symposium, September 16-20, 2022, Montreal, Canada

119. Differences and Similarities of Vaginoplasty Techniques Throughout the World: Is There a Consensus?, World Professional Association for Transgender Health 27th Scientific Symposium, September 16-20, 2022, Montreal, Canada

INSTRUCTIONAL COURSES:

1. Emory University and WPATH: Contemporary Management of Transgender Patients: Surgical Options and Decision-Making, September 5, 2007 Chicago, Il

2. Craniomaxillofacial Trauma Surgery: An Interdisciplinary Approach, February 16-17, 2008, Burr Ridge, Il

3. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, Moderator: Free Papers, Lower Extremity

4. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Moderator: ASPS/ASPSN Patient Panel: Effective Communication-A Key to Patient Safety and Prevention of Malpractice Claims

5. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Instructional Course: Strategies to Identify and Prevent Errors and Near Misses in Your Practice

6. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons

7. 10th Congress of The European Federation of Societies for Microsurgery, May 2—22, 2010, Genoa, Italy, "The Mangled Lower Extremities: An Algorithm for Soft Tissue Reconstruction."

8. Mulitspecialty Course for Operating Room Personnel-Craniomaxillofacial, Orthopaedics, and Spine, A Team Approach, AO North American, June 26-27, 2010, The Westin Lombard Yorktown Center.

9. Management of Emergency Cases in the Operating Room, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA.

10. Surgical Approaches and Techniques in Craniomaxillofacial Trauma, November 6, 2010, Burr Ridge, Il.

11. The Business of Reconstructive Microsurgery: Maximizing Economic value (Chair)The American Society for Reconstructive Microsurgery, January 14-17, 2012, Las Vegas, Nevada.

12. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30th, 2012, New Orleans, LA

13. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

14. Mythbusters: Microsurgical Breast Reconstruction in Private Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

15. Minimizing Complications in Perioperative Care, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

16. Genitourinary and Perineal Reconstruction, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

17. Transgender Breast Surgery, The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA

18. Gender Confirmation Surgery, The School of the Art Institute (recipient of American College Health Fund's Gallagher Koster Innovative Practices in College Health Award), October 27, 2015, Chicago, Il

19. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Overview of Surgical Treatment Options

20. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015 Chicago, Il Surgical Procedures

21. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Surgical Complications

22. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Post-operative Care

23. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Case Discussions: The Multidisciplinary Team

24. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23,2016, Atlanta, GA Overview of Surgical Treatment Options

25. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Surgical Treatment Options

26. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Surgical Treatment Options.

27. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Multi-disciplinary Case Discussion.

28. Introduction to Transgender Surgery, ASPS Breast Surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

29. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, September 28, 2016, Ft. Lauderdale, FL.

30. Cirugias de Confirmacion de Sexo Paso a Paso, XXXV Congreso Confederacion Americana de Urologia (CAU), Panama City, Panama, October 4-8, 2016.

31. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, December 3, 2016, Arlington, VA.

32. PSEN (sponsored by ASPS and endorsed by WPATH), Transgender 101 for Surgeons, January 2017-March 2017

33. Surgical Anatomy and Surgical Approaches to M-to-F Genital Gender Affirming Surgery and the Management of the Patient Before, During and After Surgery: A Human Cadaver Based Course, Orange County, CA, Feb. 1, 2017

34. Gender Confirmation Surgery, ALAPP, 2 Congreso Internacional de la Asociacion Latinoamericana de Piso Pelvico, Sao Paulo, Brasil, 9-11 de marzo de 2017

35. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, Overview of Surgical Treatment, March 31-April 2, 2017, Minneapolois Minnesota.

36. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, The Multi-Disciplinary Team Case Discussions, March 31-April 2, 2017, Minneapolois Minnesota.

37. Transfeminine Cadaver Course, WPATH, May 19-20, 2017, Chicago, Il

38. Transgender/Penile Reconstruction-Penile Reconstruction: Radial Forearm Flap Vs. Anterolateral Thigh Flap, Moderator and Presenter, The World Society for Reconstructive Microsurgery, June 14-17, 2017, Seoul, Korea

39. Primer of Transgender Breast Surgery, ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

40. Confirmation Surgery in Gender Dysphoria: current state and future developments, International Continence Society, Florence, Italy, September 12-15, 2017

41. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, ASPS/WPATH Joint Session, Session Planner and Moderator

42.Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course: Overview of Surgical Treatment, Columbus, OH, October 20-21, 2017

43. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course: Medical Care in the Perioperative Period, Aftercare: Identifying Potential Complications, Columbus, OH, October 20-21, 2017

44. Webinar: Gender Affirming Surgeries 101: Explore The Latest Topics in Gender Affirmation Surgery, PSEN, April 18, 2018

45. Course Director: MT. Sinai/WPATH Live Surgery Training Course for Gender Affirmation Procedures, April 26-28, 2018, New York, NY

46. Philadelphia Trans Wellness Conference, Perioperative Care of the Transgender Woman Undergoing Vaginoplasty (Workshop), Philadelphia, PA, August 3, 2018

47. Philadelphia Trans Wellness Conference, Gender Confirmation Surgery (Workshop), Philadelphia, PA, August 3, 2018

48. Gender Confirmation Surgery, 2018 Oral and Written Board Preparation Course, The American Society of Plastic Surgeons, August 16-18, 2018, Rosemont, Il

49. Confirmation Surgery in Gender Dysphoria: Current State and Future Developments, The International Continence Society, Philadelphia, PA August 28, 2018

50. WPATH Global Education Initiative, Foundations Training Course, "Overview of Surgical Treatment," Cincinnati, OH, September 14-15, 2018

51. WPATH Global Education Initiative, Foundations Training Course, "The Multi-Disciplinary Team: Case Discussions," Cincinnati, OH, September 14-15, 2018

52. WPATH Global Education Initiative, Advanced Training Course, "Medical Care in the Perioperative Period After Care: Identifying Potential Complications," Cincinnati, OH, September 14-15, 2018

53. 25th WPATH Symposium, Surgeons Conference, November 1, 2018, Buenos Aires, Argentina, Moderator

54. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Global Education Initiative (GEI): Surgery and Ethics

55. WPATH GEI: Best Practices in Medical and Mental Health Care, Foundations in Surgery, New Orleans, March 22, 2019

56. WPATH GEI: Best Practices in Medical and Mental Health Care, Advanced Surgery, New Orleans, March 22, 2019

57. Program Chair: ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

58. Overview of Surgical Management and The Standards of Care (WPATH, v. 7) ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

59. Program Director, Gender Affirming Breast,Chest, and Body Master Class, The American Society of Plastic Surgeons, Miami, Fl, July 20, 2019

60. Gender Confirmation Surgery, The American Society of Plastic Surgeons Oral and Written Board Preparation Course, August 15, 2019, Rosemont, Il

61. Upper Surgeries (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

62. Preparing for Upper Surgeries-Case Based (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

63. Preparing for Feminizing Lower Surgeries-Case Based (vaginoplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

64. Lower Surgeries-Masculinizing (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

65. Preparing for Masculinizing Lower Surgeries-Case Based (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

66. Panel Discussion about Ethics in Surgery and Interdisciplinary Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

67. Discussion about Ethics and Tensions in Child and Adolescent Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

68. Transgender Health: Best Practices in Medical and Mental Health Care Foundation Training Courses, Hanoi, Viet Nam, Jan 14-17, 2020 (Foundations in Surgery, Advanced Medical-surgery and complicated case studies), Planning & Documentation (upper surgeries-chest surgery and breast augmentation, preparing for upper surgeries-case based (chest surgery and breast augmentation), lower surgeries (feminizing-vaginoplasty), preparing for feminizing lower surgeries-case based, lower surgeries-masculinizing (phalloplasty and metoidioplasty), preparing for masculinizing lower surgeries-case-based (phalloplasty and metoidioplasty), Ethics-panel discussion about ethics in surgery and interdisciplinary care)

69. WPATH GEI Panel Cases Discussion, via Webinar, May 29, 30, 31, 2020

70. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, November 20, 2020

71. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, November 20, 2020

72. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, February 26, 2021

73. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, February 26, 2021.

74. Current Concepts in Gender Affirming Surgery for Women in Transition, March 11-12, 2021 (online event), Moderator, Transgender Health.

75. GEI Foundations Course, Live Q&A, March 21, 2021

76. GEI Foundations Course, Live Case Panel Discussion, March 23, 2021

77. GEI Advanced Ethics Workshop; Surgical and Interdisciplinary care ethics panel, May 1, 2021 (virtual)

78. Wpath GEI Foundations course for the Illinois Dept of Corrections, Foundations in Surgery, May 21, 2021

79. Wpath GEI, Foundations course for the Illinois Dept of Corrections, Ethical considerations in Transgender Healthcare, May 21, 2021

80. WPATH GEI, Online GEI Foundations Course, Moderator, August 31, 2021.

81. WPATH Health Plan Provider (HPP) Training, Q&A Panel, September 13, 14, 21 2021, via Zoom

82. WPATH, GEI Advanced Medical Course, Upper and Lower Surgery (via zoom), December 9, 2021

83. I want to be a gender surgeon: where do I even start, American Society for Reconstructive Microsurgery, Annual Meeting, January 17, 2022, Carlsbad, CA

84. Faculty Instructor, Upper Extremity Flaps and Lower Extremity Trauma, 1st Annual Rush University – University of Chicago Cadaver Lab, June 11, 2022

85. WPATH Health Plan Provider (HPP) Training, Q&A Panel, July 12, 2022, via Zoom

86. Nonbinary Workshop, WPATH GEI, July 23, 2022, via Zoom

87. WPATH GEI Advanced Ethics workshop (2022-2023), September 17-18, 2022, Montreal, Canada

SYMPOSIA:

1. Program Director, 2011 Chicago Breast Symposium, October 15, 2011, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL,

2. Fundamentals of Evidence-Based Medicine & How to Incorporate it Into Your Practice, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

3. Understanding Outcome Measures in Breast & Body Contouring Surgery, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

4. Benchmarking Complications: What We Know About Body Contouring Complication Rates from Established Databases, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

5. Special Lecture: VTE Prophylaxis for Plastic Surgery in 2011, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

6. Nipple Sparing Mastectomy: Unexpected Outcomes, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

7. Program Director, 2011 Chicago Breast Symposium, October 13-14, 2012, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, Il

8. Practice Strategies in a Changing Healthcare Environment, Moderator, Midwestern Association of Plastic Surgeons, April 27-28, 2013, Chicago, Il

9. Moderator: Breast Scientific Paper Session, The Annual Meeting of The American Society of Plastic Surgery, October 12, 2014, Chicago, Il.

10. Moderator: The World Professional Association for Transgender Health, Tuesday, June 21, Surgical Session (0945-1045), June 18-22, 2016, Amsterdam, Netherlands

11. Course Director: Transmale Genital Surgery: WPATH Gender Education Initiative, October 21-22, 2016 Chicago, Il

12. Co-Chair and Moderator: Surgeon’s Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

13. Vascular Anastomosis: Options for Lengthening Vascular Pedicle, Surgeon’s Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

14. Transgender Healthcare Mini-Symposium, Chicago Medical School of Rosalind Franklin University, North Chicago, Il March 10, 2017.

15. Moderator: Penile Transplant: Genito-urinary trauma/penile cancer, The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

16: 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Mini-Symposium: A Comprehensive Approach to Gender Confirming Surgery

17. Program Director, 2nd Annual Live Surgery Conference for Gender Affirmation Procedures, Ichan School of Medicine at Mt. Sinai, NY, NY February 28, 2019-March 2, 2019.

18. Moderator, "Genital Reassignment for Adolescents: Considerations and Conundrums," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

19. Moderator, "Reconstructive Urology and Genitourinary Options in Gender Affirming Surgery," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

20. Moderator, "Complications in Masculinizing Genital Reconstruction Surgery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

21. Moderator, "Preparing for Surgery and Recovery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

22. Discussant, "WPATH Standards of Care Version 8 Preview," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

23. Program Coordinator, Surgeon's Only Course, USPATH, September 5, 2019, Washington, DC

24. Master Series in Transgender Surgery 2020: Vaginoplasty and Top Surgery, course co-director, Mayo Clinic, Rochester, MN, August 7-8, 2020

25. WPATH 2020 Surgeons' Program, Co-Chair, November 6-7, 2020, Virtual Symposium (due to covid-19 cancellation of Hong Kong meeting)

26. WPATH Journal Club #3, Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept, December 13, 2021 (Zoom)

27. Program Coordinator and Moderator, Surgeon's Only Course, WPATH 27th Scientific Symposium, September 16-17, 2022, Montreal, Canada

FACULTY SPONSORED RESEARCH:

1. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery

Conference, Modena, Italy, October 1-3, 2009, "Free Tissue Transfer in the Treatment of Zygomycosis." Presented by Michelle Roughton, MD

2. Hines/North Chicago VA Research Day, Edward Hines, Jr., VA Hospital, Maywood, Il, April 29, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

3. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

4. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Achieving Soft Tissue Coverage of Complex Upper and Lower Extremity Defects with Omental Free Tissue Transfer." Presented by Iris A. Seitz, MD, PhD.

5. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection." Presented by Iris A. Seitz, MD, PhD.

6. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010,"Patient Safety: Abdominoplasty and Intra-Abdominal Procedures." Presented by Michelle Roughton, MD

7. The Midwestern Association of Plastic Surgeons, 49th Annual Scientific Meeting, May 15th, 2010, "Breast MRI Helps Define The Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

8. Jonathan M. Hagedorn, BA, **Loren S. Schechter**, MD, FACS, Dr. Manoj R. Shah, MD, FACS, Matthew L. Jimenez, MD, Justine Lee, MD, PhD, Varun Shah. Re-examining the Indications for Limb Salvage, 2011 All School Research Consortium at Rosalind Franklin University. Chicago Medical School of Rosalind Franklin University, 3/16/11.

9. Jonathan Bank, MD, Lucio A. Pavone, MD, Iris A. Seitz, Michelle C. Roughton, MD, Loren S. Schechter, MD Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominoplasty The Midwestern Association of Plastic Surgeons, 51st Annual Educational Meeting, April 21-22, 2012, Northwestern Memorial Hospital, Chicago, Illinois

10. Samuel Lake, Iris A. Seitz, MD, Phd, Loren S. Schechter, MD, Daniel Peterson, Phd Omentum and Subcutaneous Fat Derived Cell Populations Contain hMSCs Comparable to Bone Marrow-Derived hMSCsFirst Place, Rosalind Franklin University Summer Research Poster Session

11. J. Siwinski, MS II, Iris A. Seitz, MD PhD, Dana Rioux Forker, MD, Lucio A. Pavone, MD, Loren S Schechter, MD FACS. Upper and Lower Limb Salvage With Omental Free Flaps: A Long-Term Functional Outcome Analysis. Annual Dr. Kenneth A. Suarez Research Day, Midwestern University, Downers Grove, IL, May 2014

12. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. A Case Report: Penile Prosthesis With an Alloderm Wrap Positioned After Radial Forearm Phalloplasty. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

13. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. An Innovative Technique: Single Stage Urethral Reconstruction in Female-to-Male Patients. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

14. Whitehead, DM Inflatable Penile Prosthesis Implantation Post Phalloplasty: Surgical Technique, Challenges, and Outcomes, MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

15. Whitehead, DM, Inverted Penile Skin With Scrotal Graft And Omission of Sacrospinal Fixation: Our Novel Vaginoplasty Technique MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

16. S. Marecik, J. Singh. **L. Schechter**, M. Abdulhai, K. Kochar, J. Park, Robotic Repair of a Recto-Neovaginal Fistula in a Transgender Patient Utilizing Intestinal Vaginoplasty, The American College of Surgeons Clinical Congress 2020, October 7, 2020

17. Natalia Whitney, Randi Ettner, **Loren Schechter**, Sexual Function Expectations, Outcomes, and Discussions for Patients Undergoing Gender-Affirming Surgery, 2022 Trainee Research Day, Rush University Medical Center, The Irwin Press Patient Experience Research Poster Award

18. Natalia Whitney, Randi Ettner, **Loren Schechter**, Sexual Function Expectations, Outcomes, and Discussions for Patients Undergoing Gender-Affirming Surgery, 2022 Trainee Research Day, Rush University Medical Center, Peoples Choice-Third Place Poster Presentation

19. Adam Steur, Christy Ciesla, Clarion Mendes, Loren Schechter, The Need for a Comprehensive Interprofessional Postsurgical Rehabilitation Pathway: Initial Recommendations and Future Visions, The World Professional Association for Transgender Health, 27th Scientific Symposium, Surgeon's Only Program September 16-17, 2022, Montreal Canada

Keynote Address:

1. University of Utah, Gender Confirmation Surgery, Transgender Provider Summit, November 8, 2014

INVITED LECTURES:

1. Management of Soft Tissue Injuries of the Face, Grand Rounds, Emergency Medicine, The University of Chicago, August, 1999

2. Case Report: Excision of a Giant Neurofibroma, Operating Room Staff Lecture Series, Continuing Education Series, St. Francis Hospital, Evanston, Il March 2000

3. Wounds, Lincolnwood Family Practice, Lincolnwood, Il April 2000

4. The Junior Attending, Grand Rounds, Plastic and Reconstructive Surgery, The University of Chicago, June 2000

5. Case Report: Excision of a Giant Neurofibroma, Department of Medicine Grand Rounds, St. Francis Hospital, Evanston, Il June 2000

6. Facial Trauma, Resurrection Medical Center Emergency Medicine Residency, September 2000

7. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Evanston Hospital, September, 2000

8. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Rush North Shore Medical Center, October, 2000

9. Reconstructive Surgery of the Breast, Professional Lecture Series on Breast Cancer, St. Francis Hospital, October, 2000

10. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, December, 2000

11. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Lutheran General Hospital and The Arlington Heights Public Library, December, 2000

12. Updates in Breast Reconstruction, The Breast Center, Lutheran General Hospital, January 2001

13. Abdominal Wall Reconstruction, Trauma Conference, Lutheran General Hospital, February 2001

14. Wound Care, Rush North Shore Medical Center, March 2001

15. Breast Reconstruction, Diagnosis and Treatment Updates on Breast Cancer, Lutheran General Hospital, April 2001

16. Wound Care and V.A.C. Therapy, Double Tree Hotel, Skokie, Il October 2001

17. The Role of the V.A.C. in Reconstructive Surgery, LaCrosse, WI November 2001

18. Dressing for Success: The Role of the V.A.C. in Reconstructive Surgery, Grand Rounds, The University of Minnesota Section of Plastic and Reconstructive, Minneapolis, MN January, 2002

19. The Vacuum Assisted Closure Device in the Management of Complex Soft Tissue Defects, Eau Claire, WI February, 2002

20. The Vacuum Assisted Closure Device in Acute & Traumatic Soft Tissue Injuries, Orland Park, Il March, 2002

21. Body Contouring After Weight Loss, The Gurnee Weight Loss Support Group, Gurnee, Il April, 2002

22. An Algorithm to Complex Soft Tissue Reconstruction With Negative Pressure Therapy, Owensboro Mercy Medical Center, Owensboro, Ky, April, 2002

23. Breast and Body Contouring, St. Francis Hospital Weight Loss Support Group, Evanston, Il April, 2002

24. The Wound Closure Ladder vs. The Reconstructive Elevator, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il, May, 2002.

25. An Algorithm for Complex Soft Tissue Reconstruction with the Vacuum Assisted Closure Device, The Field Museum, Chicago,Il, May, 2002

26. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Kinetic Concepts, Inc. San Antonio, Texas, July 31, 2002

27. Management of Complex Soft Tissue Injuries of the Lower Extremity, Chicago Trauma Symposium, August 2-5, 2002, Chicago, Illinois:

28. Wound Bed Preparation, Smith Nephew, Oak Brook, Il, August 6, 2002

29. Getting Under Your Skin...Is Cosmetic Surgery for You?, Rush North Shore Adult Continuing Education Series, Skokie, Il August 28, 2002.

30. The Role of Negative Pressure Therapy in Complex Soft Tissue Wounds, Columbia/St. Mary's Wound, Ostomy, and Continence Nurse Program, Milwaukee, Wi, September 17, 2002

31. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy and Rehabilitation Medicine, Lutheran General Hospital, September 19, 2002

32. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Ann Arbor, Mi September 26, 2002

33. Dressing for Success: The Role of the Vaccuum Assisted Closure Device in Plastic Surgery, Indianopolis, In November 11, 2002

34. The Wound Closure Ladder Versus the Reconstructive Elevator, Crystal Lake, Il November 21, 2002

35. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy, Evanston Northwestern Healthcare, Evanston, Il February 13, 2003

36. Case Studies in Traumatic Wound Reconstruction, American Association of Critical Care Nurses, Northwest Chicago Area Chapter, Park Ridge, Il February 19, 2003

37. Reconstruction of Complex Soft Tissue Injuries of the Lower Extremity, Podiatry Lecture Series, Rush North Shore Medical Center, Skokie, Il March 5, 2003

38. The Use of Negative Pressure Wound Therapy in Reconstructive Surgery, Kalamazoo, Mi March 19, 2003

39. Updates in Breast Reconstruction, The Midwest Clinical Conference, The Chicago Medical Society, Chicago, Il March 21, 2003

40. Updates of Vacuum Assisted Closure, Grand Rounds, The Medical College of Wisconsin, Department of Plastic Surgery, Milwaukee, Wi March 26, 2003

41. Breast Reconstruction, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il March 27, 2003

42. Decision-Making in Breast Reconstruction: Plastic Surgeons as Members of a Multi-Disciplinary Team, 1st Annual Advocate Lutheran General Hospital Breast Cancer Symposium, Rosemont, Il, April 11, 2003

43. The Wound Closure Ladder Versus The Reconstructive Elevator, Duluth, Mn, April 24, 2003

44. Dressing For Successs: The Role of The Wound VAC in Reconstructive Surgery, Detroit, Mi, May 9, 2003

45. Plastic Surgery Pearls, Grand Rounds Orthopedic Surgery Physician Assistants Lutheran General Hospital and Finch University of Health Sciences, Park Ridge, Il, June 5, 2003

46. A Systematic Approach to Complex Reconstruction, 12th Annual Vendor Fair "Surgical Innovations," October 18, 2003, Lutheran General Hospital, Park Ridge, Il 2003

47. Dressing For Success: The Role of the Wound VAC in Reconstructive Surgery, American Society of Plastic Surgery, October 26, 2003, San Diego, CA

48. Beautiful You: From Botox to Weekend Surgeries, 21st Century Cosmetic Considerations, March 21, 2004 Hadassah Women's Health Symposium, Skokie, Il

49. Updates in Breast Reconstruction, The 2nd Annual Breast Cancer Symposium, Advocate Lutheran General, Hyatt Rosemont, April 2, 2004

50. Head and Neck Reconstruction, Grand Rounds, The University of Illinois Metropolitan Group Hospitals Residency in General Surgery, Advocate Lutheran General Hospital, May 6, 2004

51. Abdominal Wall Reconstruction, Surgeons Forum, LifeCell Corporation, May 15, 2004, Chicago, Il

52. 4th Annual Chicagoland Day of Sharing for Breast Cancer Awareness, Saturday, October 2, 2004, Hoffman Estates, Il

53. Abdominal Wall Reconstruction, University of Illinois Metropolitan Group Hospitals Residency in General Surgery, November 19, 2004, Skokie, Il

54. Advances in Wound Care, Wound and Skin Care Survival Skills, Advocate Good Samaritan Hospital, Tuesday, February 8, 2005, Downer's Grove, Il

55. Plastic Surgery: A Five Year Perspective in Practice, Grand Rounds, The University of Chicago, May 18, 2005, Chicago, Il

56. New Techniques in Breast Reconstruction, The Cancer Wellness Center, October 11, 2005 Northbrook, Il

57. Principles of Plastic Surgery; Soft Tissue Reconstruction of the Hand, Rehab Connections, Inc., Hand, Wrist, and Elbow Forum, October 28, 2005, Homer Glen, Il

58. Principles of Plastic Surgery, Lutheran General Hospital Quarterly Trauma Conference, November 9, 2005, Park Ridge, Il

59. Principles of Plastic Surgery, Continuing Medical Education, St. Francis Hospital, November 15, 2005, Evanston, Il

60. Dressing for Success: A Seven Year Experience with Negative Pressure Wound Therapy, Kinetic Concepts Inc, November 30, 2005, Glenview, Il.

61. Breast Reconstruction: The Next Generation, Breast Tumor Conference, Lutheran General Hospital, May 9, 2006.

62. Complex Wound Care: Skin Grafts, Flaps, and Reconstruction, The Elizabeth D. Wick Symposium on Wound Care, *Current Concepts in Advanced Healing: An Update*, Rush North Shore Medical Center, November 4, 2006.

63. An Approach to Maxillofacial Trauma: Grand Rounds, Lutheran General Hospital/Univ. of Illinois Metropolitan Group Hospital Residency in General Surgery, November 9, 2006.

64. "From Paris to Park Ridge", Northern Trust and Advocate Lutheran General Hospital, Northern Trust Bank, June 7, 2007.

65. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, The University of Chicago, Section of Plastic Surgery.

66. "Meet the Experts on Breast Cancer," 7th Annual Chicagoland Day of Sharing, Sunday, April 13th, 2008

67. Gender Confirmation Surgey: Surgical Options and Decision-Making, The University of Minnesota, Division of Human Sexuality, May 10, 2008, Minneapolis, Minnesota.

68. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, Loyola University, 2008 Section of Plastic Surgery.

69. "Management of Lower Extremity Trauma," Grand Rounds, The University of Chicago, Section of Plastic Surgery, October, 8, 2008.

70. "Concepts in Plastic Surgery: A Multi-Disciplinary Approach," Frontline Surgical Advancements, Lutheran General Hospital, November 1, 2008

71. "Surgical Techniques-New Surgical Techniques/Plastic Surgery/Prosthetics," Caldwell Breast Center CME Series, Advocate Lutheran General Hospital, November 12, 2008

72. "Genetics: *A Family Affair*" Panel Discussion: Predictive Genetic Testing, 23rd Annual Illinois Department of Public Health Conference, Oak Brook Hills Marriott Resort, Oak Brook, Il, March 18, 2009

73. "Gender Confirmation Surgery" Minnesota TransHealth and Wellness Conference, May 15, 2009, Metropolitan State University, Saint Paul, MN.

74. "The Role of Plastic Surgery in Wound Care, " Practical Wound Care A Multidisciplinary Approach, Advocate Lutheran General Hospital, October 9-10, 2009, Park Ridge, Il.

75. "In The Family," Panel, General Session III, 2009 Illinois Women's Health Conference, Illinois Dept. of Health, Office of Women's Health October 28-29, 2009, Oak Brook, Il.

76. "Patient Safety in Plastic Surgery," The University of Chicago, Section of Plastic Surgery, Grand Rounds, November 18, 2009.

77. "Compartment Syndrome," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

78. "Maxillofacial Trauma," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

79. "Management of Complex Lower Extremity Injuries," Grand Rounds, The Section of Plastic Surgery, The University of Chicago, December 16, 2009, Chicago, Il.

80. "Gender-Confirming MTF Surgery: Indications and Techniques," Working Group on Gender, New York State Psychiatric Institute, March 12, 2010

81. "Gender-Confirmation Surgery," Minnesota Trans Health and Wellness Conference, Metropolitan State University, St. Paul Campus, May 14th, 2010

82. "Physical Injuries and Impairments," Heroes Welcome Home The Chicago Association of Realtors, Rosemont, Illinois, May 25th, 2010.

83. "Genetics and Your Health," Hadassah Heals: Healing Mind, Body, & Soul, Wellness Fair, 2010, August 29, 2010, Wilmette, Illinois.

84. "GCS," Southern Comfort Conference 2010, September 6-11, 2010, Atlanta, GA.

85. "Gender Confirming Surgery," The Center, The LGBT Community Center, October 22, 2010 New York, NY.

86. "Gender Confirming Surgery," the Center, The LGBT Community Center, May 20, 2011, New York, NY.

87. "Gender Confirming Surgery," Roosevelt-St. Lukes Hospital, May 20, 2011, New York, NY

88. "Principles of Plastic Surgery," Learn about Ortho, Lutheran General Hospital, May 25, 2011, Park Ridge, Il.

89. "Forging Multidisciplinary Relationships in Private Practice," Chicago Breast Reconstruction Symposium 2011, September 9, 2011, Chicago, Il

90. "Gender Confirming Surgery," Minnesota TransHealth and Wellness Conference, Diverse Families: Health Through Community, September 10, 2011, Minneapolis, Minnesota

91. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 16, 2011, Chicago, Il

92. "Facial Trauma," 8th Annual Advocate Injury Institute Symposium, Trauma 2011: 40 years in the Making, Wyndham Lisle-Chicago, November 9-10, 2011

93. "Establishing a Community-Based Microsurgical Practice," QMP Reconstructive Symposium, November 18-20, 2011, Chicago, Il

94. "Surgery for Gender Identity Disorder," Grand Rounds, Dept. of Obstetrics and Gynecology, Northshore University Health System, December 7, 2011

95. "Managing Facial Fractures," Trauma Grand Rounds, Lutheran General Hospital, Park Ridge, Il July 17, 2012

96. "Principles of Transgender Medicine," The University of Chicago Pritzker School of Medicine, Chicago, Il, September 7, 2012

97. "State of the art breast reconstruction," Advocate Health Care, 11th Breast Imaging Symposium, January 26, 2013, Park Ridge, Il.

98. "State of the art breast reconstruction," Grand Rounds, Dept. of Surgery, Mount Sinai Hospital, April 25, 2013, Chicago, Il.

99. "Getting under your skin: is cosmetic surgery right for you?" Lutheran General Hospital community lecture series, May 7, 2013, Park Ridge, Il.

100. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 27, 2013, Chicago, Il

101. "State of the Art Breast Reconstruction," Edward Cancer Center, Edward Hospital, October 22, 2013, Naperville, Il

102. "Transgender Medicine and Ministry," Pastoral Voice, Advocate Lutheran General Hospital, October 23, 2013, Park Ridge, Il

103. "Principles of Transgender Medicine and Surgery," The University of Illinois at Chicago College of Medicine, January 28, 2014, Chicago, Il

104. "Principles of Transgender Medicine and Surgery," Latest Surgical Innovations and Considerations, 22nd Annual Educational Workshop, Advocate Lutheran General Hospital, March 1, 2014, Park Ridge, Il.

105. "Principles of Transgender Medicine: Gender Confirming Surgery," Loyola University Medical Center, March 12, 2014.

106. "Principles of Plastic Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, September 12, 2014.

107. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, October 3, 2014

108. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgical Administrators/The American Society of Plastic Surgery Assistants, Chicago, Il, October 11, 2014.

109. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgery Nurses, Chicago, Il, October 12, 2014.

110. "Gender Confirmation Surgery" Grand Rounds, The University of Minnesota, Dept. of Plastic Surgery, Minneapolis, MN, October 29, 2014.

111. "Body Contour After Massive Weight Loss," The Bariatric Support Group, Advocate Lutheran General Hospital, February 5, 2015, Lutheran General Hospital, Park Ridge, Il.

112. "Gender Confirmation Surgery," The School of the Art Institute of Chicago, February 1, 2015, Chicago, Il.

113. "Gender Confirmation Surgery," The Community Kinship Life/Bronx Lebanon Department of Family Medicine, Bronx, NY, March 6, 2015

114. "Gender Confirmation Surgery," Educational Inservice, Lutheran General Hospital, Park Ridge, Il, April 20, 2015

115. "Principles of Plastic Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

116. "Updates on Gender Confirmation Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

117. "Gender Confirmation Surgery," Lurie Childrens' Hospital, Chicago, Il, May 18, 2015,Chicago, Il 2015.

118. "Gender Confirmation Surgery," TransClinical Care and Management Track Philadelphia Trans-Health Conference, June 5, 2015, Philadelphia, Pa.

119. "Gender Confirmation Surgery: A Fifteen Year Experience," Grand Rounds, The University of Minnesota, Plastic and Reconstructive Surgery and the Program in Human Sexuality, July 30, 2015, Minneapolis, Mn

120. "Gender Confirmation Surgery," Grand Rounds, Tel Aviv Medical Center, Tel Aviv, Israel, August 13, 2015

121. "Gender Confirmation Surgery," Grand Rounds, University of Illinois, Dept of Family Medicine, September 2, 2015

122. "Principles of Plastic Surgery," Grand Rounds, St. Francis Hospital, Evanston, Il September 18, 2015

123. "Gender Confirmation Surgery," Midwest LGBTQ Health Symposium, Chicago, Il, October 2, 2015

124. "Gender Confirmation Surgery," Southern Comfort Conference, Weston, Fl, October 3, 2015

125. "Surgical Transitions for Transgender Patients," Transgender Health Training Institute, Rush University Medical Center, Chicago,Il, October 8, 2015

126. "Gender Confirmation Surgery," The Transgender Health Education Peach State Conference, Atlanta, GA, October 30, 2015

127. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 4, 2015, Chicago, Il

128. "Gender Confirmation Surgery," University of Illinois at Chicago, Operating Room Staff Inservice, November 18, 2015, Chicago, Il

129. "Gender Confirmation Surgery," University of Illinois at Chicago, Plastic Surgery and Urology Inservice, November 18, 2015, Chicago, Il

130. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 19, 2015, Chicago, Il

131. "Gender Confirmation Surgery," Section of Plastic Surgery, The University of Illinois at Chicago, January 13, 2016, Chicago, Il

132. "Gender Confirmation Surgery," Dept. of Medicine, Louis A. Weiss Memorial Hospital, February 18, 2016, Chicago, Il

133. "Gender Confirmation Surgery," BCBSIL Managed Care Roundtable March 2, 2016 Chicago, Il

134. "Gender Confirmation Surgery-MtF," Keystone Conference, March 10, 2016, Harrisburg, PA

135. "Gender Confirmation Surgery-FtM," Keystone Conference, March 10, 2016, Harrisburg, PA

136. "Gender Confirmation Surgery," Grand Rounds, Dept. of Ob-Gyn, March 25, 2016, Lutheran General Hospital, Park Ridge, Il 60068

137. "Surgical Management of the Transgender Patient," Spring Meeting, The New York Regional Society of Plastic Surgeons, April 16, 2016, New York, NY

138. "A Three Step Approach to Complex Lower Extremity Trauma," University of Illinois at Chicago, April 27, 2016, Chicago, Il.

139. "Gender Confirmation Surgery," Howard Brown Health Center, July 12, 2016, Chicago, Il

140. "Creating the Transgender Breast M-F; F-M", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

141. "Overview of Transgender Breast Surgery," ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

142. "VTE Chemoprophylaxis in Cosmetic Breast and Body Surgery: Science or Myth", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

143. "Gender Confirmation Surgery," Gender Program, Lurie Childrens', Parent Group, September 20, 201, 467 W. Deming, Chicago, Il

144. "Gender Confirmation Surgery," The American Society of Plastic Surgeons Expo, September 24, 2016, Los Angeles, CA

145. Transgender Surgery, Management of the Transgender Patient, Female to Male Surgery, Overview and Phalloplasty, The American College of Surgeons, Clinical Congress 2016 October 16-20,2016 Washington, DC

146. "Gender Confirmation Surgery," The Department of Anesthesia, The University of Illinois at Chicago, November 9, 2016

147. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 14, 2016

148. "Gender Confirmation Surgery," Nursing Education, The University of Illinois at Chicago, January 10, 2017

149. "F2M-Radial Forearm Total Phalloplasty: Plastic Surgeon's Point of View," The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

150. "Gender Confirmation Surgery," Grand Rounds, The Department of Surgery, The University of North Carolina, March 29, 2017.

151. "Transgender Facial Surgery," *The Aesthetic Meeting 2017 – 50 Years of Aesthetics* – in San Diego, California April 27– May 2, 2017.

152. "Gender Confirmation Surgery: A New Surgical Frontier," 15th Annual Morristown Surgical Symposium Gender and Surgery, Morristown, NJ, May 5, 2017.

153. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, The Medical College of Wisconsin, May 24, 2017

154. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, Howard Brown Health Center, August 8, 2017

155. "Current State of the Art: Gynecomastia," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

156. "Gender Confirmation Surgery-An Overview," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

157. "Gender Confirmation Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, The University of Chicago, August 25, 2017

158. "Gender Confirmation Surgery," Wake Forest School of Medicine, Transgender Health Conference, Winston-Salem, NC, September 28-29, 2017

159. "Phalloplasty," Brazilian Professional Association for Transgender Health, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

160. "Gender Confirmation Surgery," Brazlian Professional Association for Transgender Health/WPATH Session, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

161. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 13, 2017, Chicago, Il

162. "Gender Confirmation Surgery," Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, December 18, 2017, Chicago, Il

163. "Transgender Breast Augmentation," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

164. "Top Surgery: Transmasculine Chest Contouring," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

165. "Gender Confirmation Surgery," The 17th International Congress of Plastic and Reconstructive Surgery in Shanghai, March 18-25, 2018, Shanghai, China

166. "Gender Confirmation Surgery: Facial Feminization and Metoidioplasty," 97th Meeting of the American Association of Plastic Surgeons, Reconstructive Symposium, April 7-10, 2018, Seattle, WA

167. Moderator: "Gender Confirmation Surgery: Top Surgery", The Annual Meeting of The American Society of Aesthetic Plastic Surgery, April 26-May 1, 2018, New York, NY

168. "Gender Confirmation Surgery," Econsult monthly meeting, Dept. of Veterans' Affaris, May 24, 2018

169. "Gender Confirmation Surgery," Transgender Care Conference: Improving Care Across the Lifespan, Moses Cone Hospital, Greensboro, NC, June 8, 2018

170. "WPATH State of the Art," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018
171. "Facial Feminiztion Surgery: The New Frontier?" 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

172. "Current Techniques and Results in Mastectomies," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

173. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, September 7, 2018, Chicago, Il.

174. The Business End: Incorporating Gender Confirmation Surgery, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 29, 2018, Chicago, Il

175. Body Contouring in Men, Gynecomastia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 30, 2018, Chicago, Il

176. Moderator: Breast Augmentation and Chest Surgery in Gender Diverse Individuals, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

177. Moderator: Aesthetic Surgery of The Male Genitalia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

178. Moderator: Gender Confirmation Surgeries: The Standards of Care and Development of Gender Identity, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

179. The Center for Gender Confirmation Surgery Lecture Series, "Introduction to Gender Confirmation Surgery," Weiss Memorial Hospital, October 17, 2018, Chicago, Il

180. Institute 3: Gender Dysphoria Across Development: Multidisciplinary Perspectives on the Evidence, Ethics, and Efficacy of Gender Transition, Gender Confirming Care in Adolescence: Evidence, Timing, Options, and Outcomes, The American Academy of Child and Adolescent Psychiatry, 65th Annual Meeting, October 22-27, 2018, Seattle, WA

181. Gender Confirmation Surgery, Combined Endocrine Grand Rounds, The University of Illinois at Chicago, Rush University, Cook County Hospital, January 8, 2019

182. Gender Confirmation Surgery: An Update, Division of Plastic Surgery, The University of Illinois at Chicago, January 23, 2019

183. Gender Confirmation Surgery from Top to Bottom: A 20 Year Experience, Grand Rounds, The Department of Surgery, Ochsner Health System, January 30, 2019, New Orleans, LA

184. Master Series of Microsurgery: Battle of the Masters
One Reconstructive Problem – Two Masters with Two Different Approaches, Gender Affirmation, Male-to-Female Vaginoplasty: Intestinal Vaginoplasty, The American Society for Reconstructive Microsurgery, Palm Desert, California, February 2, 2019

185. Gender Confirmation Surgery: From Top to Bottom, The University of Toronto, Toronto, Canada, February 21, 2019

186. Gender Confirmation Surgery: Where are We, The University of Toronto, Toronto, Canada, February 21, 2019

187. Professors' Rounds: Gender Confirmation Surgery: A Twenty Year Experience, Princess Margaret Hospital, Toronto, Canada, February 22, 2019

188. A 3 Step Approach to Lower Extremity Trauma, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

189. Gender Surgery: Where are We Now?, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

190. Gender Confirmation Surgery, A Single Surgeon's 20 Year Experience, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

191. Gender Confirmation Surgery: Where We Have Been and Where We Are Going, Grand Rounds, The University of Chicago, Section of Plastic Surgery, March 13, 2019

192. Gender Confirmation Surgery: From Top To Bottom, Resident Core Curriculum Conference, The University of Chicago, Section of Plastic Surgery, March 13, 2019.

193. "Gender Confirmation Surgery," WPATH/AMSA Medical School Trans Health Elective, Webinar, March 13, 2019

194. Robotic Vaginoplasty: An Alternative to Penile Inversion Vaginoplasty in Cases of Insufficient Skin, Vaginal Stenosis, and Rectovaginal Fistula. The European Professional Association for Transgender Health, April 9-13, Rome, Italy

195. Current State of Gender-Affirming Surgery in the US and Beyond, Gender-affirming genital surgery presented by the American Urologic Association in collaboration with the Society for Genitourinary Reconstructive Surgeons (GURS), May 2, 2019, Chicago, Il

196. Surgical Training-How Can I get it, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

197. What is the Standard of Care in This New Frontier, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

198. The 20th Annual Chicago Orthopedic Symposium, August 15-18, 2019, Chicago, Il "Soft Tissue Defects-Getting Coverage"

199. Gender Confirmation Sugery, The Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, August 19, 2019

200. Anatomy, Embryology, and Surgery, The University of Chicago, First Year Medical Student Anatomy Lecture, September 9, 2019, The University of Chicago, Chicago, Il.

201. Gender Confirmation Surgery, Howard Brown Health Center Gender Affirming Learning Series, September 13, 2019, Chicago, Il.

202. Moderator, Patient Selection in Gender Affirming Survey Surgery, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

203. Breast Augmentation in Transwomen: Optimizing Aesthetics and Avoiding Revisions, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

204. Breast Reconstruction, State of the Art, NYU-Langone Health, NYU School of Medicine, Standards of Care and Insurance Coverage, Saturday, November 23, 2019, New York, NY.

205. ASRM Masters Series in Microsurgery: Think Big, Act Small: The Building Blocks for Success, "Building a Microsurgery Private Practice from the Ground Up", 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

206. ASPS/ASRM Combined Panel II: Gender Affirmation Surgery: Reconstruction Challenges of Function and Sensation, 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

207. Rush University Medical Center, Division of Urology, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," January 22, 2020

208. Rush University Medical Center, Department of General Surgery, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," February 5, 2020.

209. WPATH/AMSA (American Medical Association) Gender Scholar Course, Webinar, March 11, 2020

210. Rush University Medical Center, Division of Plastic Surgery, Weekly Presentation, Gender Confirmation Surgery: Can a Surgeon Provide Informed Consent?, April 29, 2020

211. Legal Issues Faced by the Transgender Community, ISBA Standing Committee on Women and The Law and the ISBA Standing Committee on Sexual

Orientation and Gender Identity, Co-Sponsored by the National Association of Women Judges District 8, Live Webinar, May 28, 2020

212. Principles of Transgender Surgery, National Association of Women's Judges, District 8, Webinar, June 4, 2020

213. Gender-Affirming Surgery, National Association of Women's Judges, District 8, Webinar, July 8, 2020

214. Gender-Affirming Surgery, The University of Chicago, Pritzker School of Medicine, 1st year Anatomy, September 15, 2020

215. Gender-Affirming Surgery, Rush University Medical School, 2nd year Genitourinary Anatomy, September 16, 2020.

216. Surgical Management of the Transgender Patient, Rosalind Franklin University, The Chicago Medical School, Plastic Surgery Interest Group, October 7, 2020

217. Breast Augmentation in Transgender Individuals, The American Society of Plastic Surgeons Spring Meeting, March 20, 2021

218. International Continence Society Institute of Physiotherapy Podcast 5-Pelvic Floor Most Common Disorders and Transgender Patients (recorded April 30, 2021)

219. The American Association of Plastic Surgeons Annual Meeting, Reconstructive Symposium, Gender Affirmation Panel, Complications of GCS, Miami, FL, May 15, 2021 (presented virtually)

220. Gender Confirmation Surgery, Grand Rounds, Rush University, Section of Urology, June 8, 2021.

221. Genitourinary introduction lecture, M2, Rush University School of Medicine, September 2, 2021 (by Zoom)

222. Demystifing Gender: Fostering Gender Friendly Healthcare, Gender Affirmative Care in Adults, Querencia (lady hardinge medical college, WHO Collaborating Center for Adolescent Health, Dept of Paediatrics, JSCH & LHMC, New Delhi, WPATH September 5, 2021 (by zoom)

223. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2021, Chicago Il.

224. Gender Confirmation Surgery, A Single Surgeon's 22 Year Experience: Where are We Now?, Research Seminar, Section of Endocrinology, The University of Chicago, Chicago, Il, October 4, 2021 (by Zoom)

225. Chest Surgery, The Illinois Dept. of Corrections (by zoom), October 13, 2021.

226. Vaginoplasty, The Illinois Dept. of Corrections (by zoom), October 15, 2021.

227. International Continence Society, 20th Physioforum, Pelvic Floor Physical Therapy and Gender-Affirming Surgery, October 16, 2021, Melbourne, Australia (by Zoom)

228. Rush University Division of Plastic Surgery, Gender Affirmation Surgery: Where Are We Now?, educational conference, November 23, 2021, Chicago, Il

229. 51 Congreso Argentino de Cirugia Plastica, Microsurgery Symposium, SACPER-FILACP, 3 Step Approach to Lower Extremity Trauma, November 29, 2021, Mar del Plata, Argentina

230. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery I, "Gestión Quirúrgica de la Disforia de Género: Descripción general del manejo quirúrgico y los estándares de atención," December 1, 2021, Mar del Plata, Argentina

231. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery II, Cirugía Genital Masculinizante (Metoidioplastia y Faloplastia), December 2, 2021, Mar del Plata, Argentina

232. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery III, Faloplastia: optimización de resultados y reducción de complicaciones, December 2, 2021, Mar del Plata, Argentina

233. Government of India, Ministry of Health and Welfare, National AIDS Control Organization, Meeting with AIIMS on Gender Affirmation Care (GAC) Clinic Pilot Intervention, December 21,2021, New Delhi (virtual)

234. Affirming Care for Gender Diverse Patients, Rosalind Franklin University, January 5, 2022, North Chicago, Il (Virtual by Zoom)

235. Sub-Unit Transplantation, Penile Transplant, WSRM/ASRT Mini-Symposium VCA Transplant, World Society for Reconstructive Microsurgery/American Society for Reconstructive Transplantation/American Society for Reconstructive Microsurgery Annual Meeting, January 14, 2022, Carlsbad, CA

236. Strategies for Penile Transplantation, American Society for Reconstructive Microsurgery, Annual Meeting, January 16, 2022, Carlsbad, CA

237. ASRM/WSRM/ASRT Battle of the Frontiers: To Transplant or Not? Conventional Reconstruction (Phalloplasty), American Society for Reconstructive Microsurgery, Annual Meeting, January 16, 2022, Carlsbad, CA

238. Strategies for Penile Innervation, American Society for Gender Surgeons, Annual Meeting, January 18, 2022, Carlsbad, CA

239. Pathway To Informed Consent: Vaginoplasty, Illinois Dept. of Corrections (virtual), February 10, 2022

240. Gender Confirmation Surgery From Top to Bottom: A Single Surgeon's 22 Year Experience, Where are We Now, Grand Rounds (virtual), Department of Plastic Surgery, University of South Florida, February 14, 2022

241. Vaginoplasty: Dissection of the vaginal canal and selection of technique, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022 (President of the session: Genital/Transgender Session 1)

242. Phalloplasty: Strategies to reduce complications and optimize outcomes, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022

243. Chest Surgery in Transgender Men, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022

244. Gender-Affirming Surgery: A 23 Year Experience Where are we now, 65th Annual Scientific Meeting, Southeastern Society of Plastic and Reconstructive Surgeons (Finding The Solutions Now and The Future), Orlando, Fl, June 11-15, 2022

245. Top Tips for Safety: The Culture of Safety, 65th Annual Scientific Meeting, Southeastern Society of Plastic and Reconstructive Surgeons (Finding The Solutions Now and The Future), Orlando, Fl, June 11-15, 2022

246. Uterine Transplantation, GAPS (Ghent Academy of Plastic Surgery) 2022: Bridging the Gap Between Reconstructive and Aesthetic Surgery, June 17-18, 2022, Ghent, Belgium

247. In Honor of Professor Stan Monstrey, GAPS (Ghent Academy of Plastic Surgery) 2022: Bridging the Gap Between Reconstructive and Aesthetic Surgery, June 17-18, 2022 Ghent, Belgium

248. "TRANS" Grand Rounds Panel Discussion (panel discussants: Loren S. Schechter, MD, Michaela West, MD, PhD, Courtney Cripps, MD, Ervin Kocjancic, MD), University of Chicago, Department of Surgery, July 6, 2022, Chicago, Il

249. Gender Affirming Surgery, Grand Rounds, July 12, 2022, Department of Urology, Rush University Medical Center, Chicago, Il

250. Gender Affirming Surgery, Gender Affirmation Lecture Series, Rush University Medical Center, July 15, 2022, Chicago, Il

251. Anatomy of A Lawsuit, Rush PRS Weekly Didactic Conference, Rush University Medical Center, Plastic and Reconstructive Surgery, July 20, 2022, Chicago, Il

252. Gender Affirmation Surgery: Where are We Now? The University of Chicago, Section of Plastic Surgery, Grand Rounds, August 10, 2022, Chicago, Il

253. Thriving in Sexual & Gender Diversity, The Transgender Patient, August 10, Virtual CME Event (broadcast from Dr. Shino Bay Aguilera's office in Miami, Fl)

254. Gender Affirming Medical and Surgical Therapies, Illinois College of Emergency Physicians Webinar, August 17, 2022

255. Gender Affirming Surgery Panel, Liebert Publishing, Webinar, August 26, 2022, Moderator: Jeffrey Spiegel, MD

256. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2022, Chicago Il

257. Gender Affirmation Surgery: Where We Have Been and Where We are Going: GURS-WPATH Invited Lecture, Society of Genitourinary Reconstructive Surgeons, Academic Congress, Montreal, Canada, September 15, 2022

258. Phalloplasty: Optimizing Outcomes and Reducing Complications, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022

259. Special Guest Lecture: Gender Affirmation Surgery: Where We've Been and Where We're Going, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022

260. Diversity in Practice, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022

261. Gender Affirming Surgery, Fenway/HMS Advances in Transgender Care, October 15, 2022

262. Genitourinary introduction lecture, M2, Rush University School of Medicine, October 26, 2022, Chicago, Il

263. Optimizing Aesthetics and Sensation in Vaginoplasty and Phalloplasty, The American Society of Plastic Surgeons 91st Annual Meeting (PSTM), Boston, MA, October 30, 2022

264. Gender-Affirming Surgery: From Top to Bottom, The Rush University Medical Center Departments of Emergency Medicine and Internal Medicine for the Emergency Medicine Grand Rounds Lecture, Chicago, Il, November 16, 2022

265. Dueling Perspectives in Transgender Surgery, New York Regional Society of Plastic Surgeons, New York, New York, November 19, 2022

266. Gender-Affirming Surgery: From Top to Bottom, Rush University Medical Center Department of Anesthesia Grand Rounds, November 30, 2022, Chicago, Il.

267. Gender-Affirming Surgery: Where We Have Been and Where We are Going, Mass General Brigham Center For Transgender Health, Grand Rounds, December 13, 2022 Boston, MA (lecture delivered virtually)

268. An Intro to Providing Gender Affirming Care to Gender Diverse Patients, Rosalind Franklin University, Chicago Medical School, December 21, 2022, North Chicago, Il (virtual by Zoom)

269. Surgical Techniques and Outcomes in Penile Reconstruction, WSRM/ ASRT Symposium on VCA in the Transgender Patient, Annual Meeting of The American Society for Reconstructive Microsurgery, January 20, 2023, Aventura, Fl

270. Argument for Transgender Transplantation, WSRM/ ASRT Symposium on VCA in the Transgender Patient, Annual Meeting of The American Society for Reconstructive Microsurgery, January 20, 2023, Aventura, Fl

271. Moderator: Gender Surgery Symposium, Society of Gender Surgeons, January 24, 2023, Aventura, Fl

272. Trans female top surgery, 38th Annual Atlanta Breast Surgery Symposium, January 27-29-2023, Atlanta, GA

273. Trans male top surgery, 38th Annual Atlanta Breast Surgery Symposium, January 27-29-2023, Atlanta, GA

Exhibit B

Bibliography

References

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3. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders (DSM-5TR) (2022).

4. American Society of Plastic Surgeons, About ASPS, plasticsurgery.org/about-asps (2023).

5. American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Reduction Mammaplasty (2021), https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021-reduction-mammaplasty.pdf.

6. American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Gynecomastia, https://www.plasticsurgery.org/documents/Health-Policy/Positions/Gynecomastia_ICC.pdf.

7. Ascha, M. et al. (2022). Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults. JAMA Pediatrics, 176(11): 1115-1122, doi:10.1001/jamapediatrics.2022.3424.

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12. Coleman, E. et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int'l J. of Transgender Health, 23: S1-S259, doi: 10.1080/26895269.2022.2100644.

13. Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (Aug. 30, 2016).

14. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf.

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16. Frederick, M. et al. (2017). Chest Surgery in Female to Male Transgender Individuals. Annals of Plastic Surgery, 78(3): 249-253, doi: 10.1097/SAP.0000000000000882.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

CORRECTED EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, PH.D.

I, E. Kale Edmiston, Ph.D., hereby declare and state as follows:

1. I am over the age of eighteen and submit this expert rebuttal report based on my expert opinion.

2. I have been retained by counsel for plaintiffs as an expert in connection with the above referenced litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

3. I have actual knowledge of the matters stated herein. If called to testify, I would testify truthfully based on my expert opinion.

Background and Qualifications

4. I am an Associate Professor of Psychiatry at the University of Massachusetts Chan Medical School. Prior to this appointment, I was an Assistant

Professor of Psychiatry at the University of Pittsburgh from 2019 to 2022. I have more than 15 years of experience conducting psychiatric neuroimaging research, with a focus on adolescence and young adulthood, mood and anxiety disorders, and impulsivity and emotional regulation. My methodological expertise lies in neuropsychological assessment, multimodal neuroimaging, psychophysiological measures such as heart rate variability, and measures of neuroendocrine function across adolescent development.

5. I completed a bachelor's degree from Hampshire College in 2007, where I studied cognitive science. I received postbaccalaureate training in psychiatric neuroimaging at the Yale School of Medicine. I earned a PhD in neuroscience from Vanderbilt University in 2015, as well as a graduate certificate in medical humanities, with a focus on bioethics and medical decision-making. I then completed post-doctoral training at China Medical University and the University of Pittsburgh.

6. In 2014, I co-founded the Trans Buddy Program at Vanderbilt University Medical Center, a peer navigator and support program for transgender people seeking healthcare. As a part of this program, my work primarily focused on supporting transgender adolescents experiencing mental health crisis. At this time, I also served as the Co-Director for the Vanderbilt University Program for LGBTI

Health. I later replicated the Trans Buddy Program at the University of Pittsburgh Department of Adolescent Medicine.

7. From 2018-2022, I served as a chapter author for the Assessment chapter of the World Professional Association for Transgender Health's *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*.

8. I have authored over 100 peer-reviewed manuscripts, book chapters, and conference proceedings in psychiatric neuroscience and transgender health.

9. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

Prior Testimony

10. I have not testified as an expert at trial or by deposition within the last four years.

Compensation

11. I am being compensated for my time at a rate of $175/hour. My compensation is in no way contingent on the conclusions reached as a part of my testimony or on the outcome of this case.

Basis for Opinions

12. In preparing this report, I have reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, and Dr. Daniel Shumer, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

13. My opinions are based on my years of research and academic experience, as well as my professional knowledge, as set out in my curriculum vitae (**Exhibit A**) and the materials listed therein; my knowledge of the peer-reviewed literature relating to neuropsychological assessment and brain development; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and my review of any of the materials cited herein.

14. I have also reviewed the materials listed in the bibliography attached as **Exhibit B**. I may rely on those documents as additional support for my opinions.

15. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Adolescent Brain Development

16. Dr. Scott's report stating that adolescents are more likely to engage in risky behaviors relative to adults fails to include the specific context in which this is true. That is, the literature indicates that there are *highly specific circumstances* in which adolescents are more likely to engage in risky or impulsive behavior. Indeed, Dr. Scott lists some of these circumstances in her testimony: driving, drinking alcohol, getting a tattoo. However, none of these examples are relevant to the issue at hand: protracted medical decision-making made in the context of adult guidance and consultation with a medical professional.

17. Dr. Scott fails to cite the large body of evidence indicating that adolescents are capable of deliberative decision making in the presence of adults (i.e., healthcare providers and caregivers) and when decision making occurs over a protracted period. This is the exact context in question: decisions about accessing gender-affirming medical care, such as gonadotropin releasing hormone agonists

(GnRHa) and hormone treatment, are made jointly among the adolescent patient, their caregiver(s), and medical professionals. These decisions are also made over time; data show that the typical time between an adolescent realizing they are transgender and coming out to an adult is three years (Bauer et al., 2022). Furthermore, once an adolescent discloses their identity to a supportive adult, they will then have to schedule a healthcare appointment and undergo assessment prior to accessing treatment. This process typically takes months and for some, even years.

18. Dr. Scott misrepresents the literature on adolescent decision making by generalizing findings made in "hot" contexts to those made in "cold" contexts. Indeed, the Blakemore and Robbins review from 2012 that she cites explicitly states that the literature concludes that adolescents demonstrate adult-typical decision-making abilities in cold contexts. It is not that adolescence is associated with a failure to engage cognitive control networks, but rather, that cognitive control networks are engaged with greater variability during this time than during adulthood. Decision-making is a multifactorial process that includes valuation of both risk and reward. While adolescents are more likely to overvalue reward and underestimate risk when peers are present or when decisions must be made quickly, they demonstrate deliberative and appropriate consideration of reward and risk valuation in the absence of peers, in the presence of adults, and when decisions are made over time.

This important difference in the contextual nature of decision-making in adolescence is an established finding that has been replicated across multiple studies (Chein et al., 2011; O'Brien et al., 2011; Simons-Morton et al., 2011; Smith et al., 2014; Weigard et al., 2014; Hartley & Somerville, 2015; Guassi Moreira & Telzer, 2018). Indeed, deliberative decision making in contexts without pressure to decide quickly has been repeatedly shown in adolescents (Byrnes, 2002; Figner et al., 2009; Wolff & Crockett, 2011; Icenogle & Cauffman, 2021).

19. Dr. Scott also states that "at 18yrs old, the connections to the frontal lobes are not myelinated[1] like a mature adult brain, and this is likely to affect frontal lobe functions." This is an oversimplification of an extremely complex literature. A study of over 10,000 participants has shown quite the opposite: that by the age of 18, adult-level cognition is established (Tervo-Clemmens et al., 2022), while other studies have shown mature integration of functional networks by late adolescence (Marek et al., 2015) and fractional anisotropy of prefrontal white matter (Lebel & Beaulieu, 2011, fractional anisotropy is an indirect measure of myelination). Even though, on average, there are developmental differences in prefrontal myelination,

[1] Myelin is a protein sheath that covers the axons of neurons. The axons comprise white matter in the brain, and bundles of these fibers transmit signals from region to region in the brain. When an axon is myelinated, the signal can travel faster down the axon.

there is not strong evidence that these differences are associated with an inability to make deliberative decisions with the support of caregivers and expert clinical guidance.

20. Furthermore, there is a great deal of variation in the timing of development between different prefrontal white matter tracts, as well as a great deal of variation between individuals. Indeed, in Lebel & Beaulieu's longitudinal study of over 100 individuals from childhood to young adulthood, many individuals showed decreases or no changes in fractional anisotropy (FA) during adolescence, and these differences also varied by prefrontal white matter tract (2011). This literature represents differences in group averages and should not be used to predict the behavior or development of an individual adolescent; we cannot draw conclusions about all 18-year-olds from these studies. This is why the WPATH SOC 8 recommends an individualized approach to joint decision-making regarding healthcare.

There is Little Evidence to Support Defendants' Designated Experts' Speculation about Negative Effects of GnRHas on Cognition

21. Dr. Scott cites a 2016 study by Wojniusz and colleagues as evidence of the negative effects of GnRHas on emotional reactivity in a sample of girls with central precocious puberty. This is puzzling because the authors of this paper explicitly state the opposite interpretation: "Overall, our findings do not provide firm

conclusions with regard to differences in emotional processing between the GnRHa treated CPP girls and age-matched controls." (pp13).

22. Perhaps Dr. Scott has misinterpreted the nature of the emotional flanker task. This task asks participants to determine if two simultaneously presented houses are the same or different. The houses are presented at the center of a screen, and emotional or neutral face distractors flank them. The outcome of interest is the reaction time for the determination of whether the houses are the same or different. The idea here is that people with poor emotional regulation will be more distracted during the emotional face condition and therefore take longer to respond. This interpretation can only be made when reaction times are increased in both the emotional face conditions. In this study, the CPP girls showed longer reaction time than controls during the emotional face condition only when the houses were different, but not when the houses were the same. Thus, the findings do not indicate an issue with emotional regulation. More likely, the results are incidental and due to statistical issues regarding false discovery rate correction, an argument that the authors of the paper themselves make.

23. The authors do find reduced heart rate and elevated heart rate variability (HRV) during the emotional task. HRV is distinct from heart rate and is a measure of cardiac vagal tone. HRV is a proxy for parasympathetic system or "rest and

digest" function. Thus, elevated HRV is associated with increased regulatory capacity and is a marker of health. Thus, these findings are a sign of *optimal* emotional regulation. Indeed, the authors state, "…the lower HR and higher HRV could suggest that treated CPP girls have better emotion regulation capacity and higher adaptability to changing contexts than controls" (pp13).

24. Dr. Scott then points out that, in a separate commentary on the article, Dr. Hayes states that there were "notably" lower scores on IQ measures in the CPP group relative to controls. However, Dr. Hayes's comment, and Dr. Scott's reliance on it, is not supported by the findings of the study. Specifically, none of the differences in IQ were statistically significant, and the mean IQ scores for both groups were within the normal range. Furthermore, the mean difference between groups in this study is within the realm of variation that may occur from repeated administration of the WISC-III, i.e., although scores for an individual tend to remain relatively stable over time, there is fluctuation that occurs even within an individual and small differences in IQ (Watkins & Smith, 2013), as reported in this study, are not only not statistically significant, they are not clinically significant. Dr. Scott has, again, offered a misrepresentation of the literature.

25. Dr. Levine cites a single case study as evidence for an effect of GnRHa treatment on IQ. Case studies are the lowest quality of evidence. Case studies can

provide important evidence for future areas of study or to provide an illustrative example of a common clinical phenomenon, but they should not be used to make general conclusions or policy positions. Putting aside the low quality of evidence typical of case studies in general, this case study does not even provide sufficient support for Dr. Levine's opinion as it describes a transgender girl who, prior to initiation of treatment, already had below average IQ. While Dr. Levine highlights the lack of change in fractional anisotropy values over the course of the study in this case, this could be due to developmental delays that are independent of treatment and are instead related to her low IQ. Therefore, the findings of this case study are simply not generalizable to the broader population.

26. Dr. Michael Biggs, a sociologist, also offers speculation regarding cognitive effects of GnRHa treatment as well, describing it as "…stopping normal sexual and cognitive development…" This statement regarding cognitive development appears to be pure speculation as he offers no citation regarding evidence for deleterious effects of GnRHa treatment on cognition. In reviewing the literature, including through specific searches, I have been unable to find compelling evidence of this. I was able to identify two studies that showed no effect of GnRHa treatment on executive function (Soleman et al., 2016; Staphorsius et al., 2015). The

lack of evidence for these effects is itself compelling, given that these medications have been used in adolescents with central precocious puberty for decades.

Evidence for Effects of GnRHa treatment on the Brain

27. Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both "unknown" and "likely negative." They do not cite any original research that supports this conclusion and thus it is unclear to me how they concluded that the effects are likely negative in the absence of evidence. Dr. Laidlaw even goes so far as to speculate on the individual brain maturation of three specific transgender individuals. Both Levine and Laidlaw admit that there is no evidence from the neuroimaging literature on negative effects of these treatments on brain development, but even if there was, any neuroimaging study that compares group averages would not support an inference about the brains of individual people. There is a great deal of variation between and within individuals in many commonly used neuroimaging measures. For this reason, neuroimaging methods commonly used in research, such as fMRI, cannot be used diagnostically for individual people in the absence of organic brain disease (Schleim & Roise, 2019).

28. Dr. Hruz also speculates in his testimony that there are negative effects of GnRHa treatment on the brain: "A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation". Dr. Hruz then cites a

2013 review paper that describes typical adolescent brain maturation but does not mention or describe any effects of blocking or delaying puberty on the brain (Arain et al., 2013). Dr. Hruz therefore has not cited any support for his conclusion, and I have not identified any studies relating to the evidence of negative longitudinal effects on brain development related to GnRHa treatment in central precocious puberty or in transgender adolescents, even after targeted searches for it.

29. There is not a large literature on the effects of GnRHa treatment on the brain in humans, but this does not render such care experimental. GnRHa treatments have been in used for decades, including for the treatment of gender dysphoria. That said, there are a few cross-sectional studies on this issue, and it is significant that none of the experts (nor the GAPMS memo) cited this literature in their testimonies. In a study that compared transgender adolescent boys and girls taking GnRH agonists to cisgender boys and girls, there were differences in brain function in some brain regions that would indicate congruence with gender identity and other differences that would indicate congruence with sex assigned at birth. However, there were no between-group differences in network function on the basis of GnRHa treatment. Furthermore, the authors searched for relationships between duration of GnRHa treatment in the transgender adolescents and brain function and *were unable to find any effects*. In a diffusion tensor imaging study of fractional anisotropy

values, an index of white matter myelination, *again there was no significant association between fractional anisotropy values and GnRHa treatment* (van Heesewijk et al., 2022). Similarly, in an fMRI study comparing cisgender boys and girls to transgender boys and girls, there were no significant differences in brain activity between transgender and cisgender adolescents during a verbal fluency task, and no deficits in verbal ability in transgender youth (Soleman et al., 2013). In a study of transgender individuals receiving GnRHa treatment and cisgender people, there were differences in brain activity between groups, but these differences were not associated with hormone levels, leading the authors to conclude that these differences are associated with group differences that predate GnRHa treatment (Soleman et al., 2016). In summary, to my knowledge, there have been three studies of brain structure and function of transgender adolescents receiving GnRHa treatment, and none of them have found any significant effects of treatment on the brain.

30. A recent primate study provides evidence for some regional neuroprotective effects of GnRHa treatment, although the results are complex (Godfrey et al., 2023). In this study, the authors compared dominant and subordinate adolescent rhesus monkeys. These monkeys form social hierarchies much like human adolescents, and subordinate monkeys are subjected to aggression from the

more dominant monkeys. Both dominant and subordinate monkeys were randomly assigned to a GnRHa treatment or control group and then followed longitudinally. In the primates exposed to chronic social subordination stress, GnRHa treatment rescued the negative effect of stress on regional brain volume over time. These differences were seen in brain regions such as the amygdala that are well-established in the pathophysiology of depression and anxiety. There were also effects of GnRHa treatment in general; treatment in both social groups was associated with smaller hippocampal volume than control animals. Regarding the prefrontal cortex, a critical region during adolescent development, GnRHa treatment was associated with greater prefrontal grey matter volume prepubertally but this difference decreased by adolescence. There was an effect of GnRHa treatment early in puberty on prefrontal white matter volume; however, this difference was no longer present by the end of the study. Importantly, there are species-specific differences in prefrontal volume changes across puberty; the generalizability of the prefrontal findings to humans should be made with caution. Finally, the authors also assessed social behavior in both submissive and dominant primates over time and were able to determine that, at prepuberty, submissive primates were more socially isolated, but that GnRHa-treated subordinate animals had normalized social behavior (reduced time spent alone) and normalized cortisol response to threat (cortisol is a stress hormone

associated with the hypothalamic pituitary adrenal axis). The authors conclude that "…delayed puberty and estrogen suppression may be protective against the impact of social stress" (pp12). This study provides strong evidence that GnRHa treatment normalizes brain structure, physiological stress reactivity, and social behavior in adolescent primates subjected to social subordination, an ecologically valid non-human primate model of the psychosocial environment for transgender youth.

31. There is a small body of literature on the effects of gender affirming hormone care on the brain in transgender adolescents. In a study comparing transgender boys receiving testosterone therapy and those who were not, testosterone treatment was associated with reductions in mood and anxiety symptoms, as well as reductions in body image dissatisfaction. Gender affirming hormone care was associated with an increase of functional coupling between the amygdala and prefrontal cortex while research participants viewed threatening emotional faces, likely indicating improved emotional regulation of the amygdala in the boys who were treated with testosterone. Indeed, in the boys who were treated with testosterone, greater coupling between these two regions was associated with lower anxiety symptom severity (Grannis et al., 2021). Another study of transgender boys receiving testosterone found that testosterone caused a shift in amygdala

activation, such that it became more typical of cisgender boys than cisgender girls (Beking et al., 2020).

32. 17. Both Dr. Scott and Dr. Biggs cite studies from the animal literature regarding the "side effects" of GnRHa treatment on the brain and behavior. However, they misinterpret or misrepresent the meaning of the term "side effect" in this context. Pharmacological agents have effects. The determination of what is a side effect and what is a desired effect is contextual. For example, Scott cites a 2021 rodent study of GnRHa treatment as an example of the "side effects" associated with GnRHa treatment (Anacker, et al., 2021). If one were to read the abstract of the study and not the full text, it may lead some to come to such a conclusion. However, what the study shows is that, prior to GnRHa treatment, there are sex differences in rodent behavior. Following GnRHa treatment, those sex differences are no longer present. This is the expected and desired outcome of GnRHa treatment, not a side effect. For example, female mice show greater locomotion behavior than male mice. Following GnRHa treatment, male mice show greater locomotion behavior than untreated male mice. Similarly, in a test of social interaction, GnRHa-treated males showed differences in the time spent with male versus female mice relative to untreated male mice, but not relative to untreated female mice. In both force-swim tests and a test of feeding behavior, female GnRHa-treated mice differed from control female mice,

but not from male mice. This is a consistent pattern across behavioral assays performed in the study, and this pattern was present in biological assays as well. GnRHa-treated male mice showed greater corticosterone stress response to novelty than control male mice but did not differ from female mice. GnRHa treatment increased neural activity in the hippocampus of female mice, but this activity increase did not differ from male mice. This is not a compelling study of the side effects of GnRHa treatment, but rather, a study that shows us exactly what we would expect: that blocking sex hormones decreases sex differences, the intended outcome for transgender youth.

33. Dr. Scott and Dr. Biggs cite a series of studies of GnRHa effects on sheep from a specific laboratory. One study from this group did show sex-specific changes in feeding behavior and HRV following GnRHa treatment. While Dr. Biggs opts to highlight changes in behavior in the female sheep that could be interpreted as an increase in anxiety-like behavior, he fails to mention that GnRHa treatment was associated with *improvements* in these behaviors in the treated male sheep (Wojniusz et al., 2011). They also fail to mention that other studies from this group show no effects of GnRHa treatment on cognition (Nuruddin et al., 2013; Wojniusz et al., 2013), and, like the Anacker study, brain differences are best explained by an expected reduction of sex differences following treatment (Nuruddin et al., 2013).

This issue of inappropriate reference group is a common problem in the GnRHa animal literature and its extrapolation to transgender youth (Edmiston & Juster, 2022). While the literature regarding the effects of GnRHa treatment on sheep behavior from this research group is complex, it by no means offers compelling evidence of negative effects of GnRHa treatment. Furthermore, Dr. Biggs highlights a negative effect from one study- an increase in anxiety-like behavior in female sheep only. However, we know from studies of transgender youth and young adults that anxiety and depression symptoms decrease with treatment (de Vries et al., 2014; Dhejne et al., 2016; Aldridge et al., 2021; Chen et al., 2023). This is more compelling evidence than a single animal study, as sheep do not have the complex psychosocial identities that humans do.

Evidence for Negative Consequences of Depression and Anxiety on the Developing Brain

34. The brain is more plastic during adolescence than during adulthood. This means that adolescents are particularly vulnerable and at increased risk for the onset of mood and anxiety disorders, and, if untreated, that the onset of mood and anxiety symptoms can permanently alter the developmental trajectory of the brain into adulthood (Holder & Blaustein, 2014). Termed the "kindling effect", the concept here is that, as the efficiency of neural circuits is reinforced over time (i.e., "neurons that fire together wire together"), each depressive episode or

environmental stressor increases the risk for later depressive episodes. This effect may be amplified during adolescence because of the greater plasticity of the brain.

35. There are well-documented disparities in mental health outcomes in transgender youth that are caused by minority stress (for review, see White Hughto et al., 2015). This includes evidence that transgender people who live in areas with more accepting political climates show reduced biological stress markers and fewer mental health symptoms than transgender people who live in less accepting areas (DuBois & Juster, 2022). Others have shown an association between decreased social support and biological markers of stress in transgender adolescents (McQuillan et al., 2021). Given that transgender adolescents report high chronic stress and high rates of depression, anxiety, and suicidality, transgender adolescents are particularly vulnerable to the effects of stress on brain development, stress system regulation, and long-term mental health outcomes (DuBois et al., 2021; Potter et al., 2021; Randall et al., 2022).

36. In Dr. Levine's testimony, he quotes the Hippocratic Oath, "Above All Do No Harm". He makes this argument on the assumption that GnRHa treatment must necessarily cause harm because it is an intervention. This assumes that the psychosocial environment and biology of transgender youth is like that of cisgender youth. There is a great deal of evidence that this is not the case. Instead, in my

opinion not offering an intervention to transgender individuals that require treatment actually does harm.

37. In this case, puberty blockers have demonstrated efficacy in reducing symptoms of depression in transgender adolescents (de Vries et al., 2011), and therefore may in fact be neuroprotective to the cumulative effects of stress caused by gender dysphoria.

Conclusion

38. There is little to support the Defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain. In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents. Furthermore, it is well-known that transgender adolescents face higher rates of psychosocial stress than their cisgender peers, and there is clear evidence for the negative effects of psychosocial stress and poor mental health on brain development. While the effects of GnRHa treatment on the brain are an important area for future research, this does not render such care experimental. To the contrary, this is treatment that has existed for decades and arguments that a purported lack of evidence is equivalent to known harm are spurious, particularly when there is a large literature indicating benefits of treatment and harm of withholding treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 22 day of March 2023.

E. Kale Edmiston, Ph.D.

Exhibit A

Curriculum Vitae

E. Kale Edmiston, PhD

Associate Professor
Department of Psychiatry
University of Massachusetts Chan Medical School
kale.edmiston@umassmed.edu

ACADEMIC APPOINTMENTS

Associate Professor of Psychiatry University of Massachusetts Chan Medical School	2022-present Worcester, MA
Assistant Professor of Psychiatry University of Pittsburgh School of Medicine	2019-2022 Pittsburgh, PA
Postdoctoral Scholar University of Pittsburgh Medical Center PI: Mary L. Phillips, MD, MD (CANTAB)	2016-2019 Pittsburgh, PA
Postdoctoral Fellow China Medical University PI: Fei Wang, MD, PhD	2016 Shenyang, China
Research Assistant Yale University School of Medicine PI: Hilary P. Blumberg, MD	2007-2010 New Haven, CT

EDUCATION

PhD, Neuroscience Vanderbilt University	2010-2015 Nashville, TN
Graduate Certificate Medicine, Health and Society Vanderbilt University	2015 Nashville, TN
BA, Cognitive Science Hampshire College	2005-2007 Amherst, MA

RESEARCH

CITATION METRICS (03/23):

Citations: 2087 H-Index: 25 i10 Index: 34

RESEARCH INTERESTS:

social and affective neuroscience, visual processing, anxiety disorders, multimodal MRI, neuromodulation

AWARDED GRANTS:

American Foundation for Suicide Prevention Award 2022

Title: *Real-time study of psychotherapy, suicide risk, and resilience in transgender and non-binary adults*
PI: Sarah Victor
Co-I: **E. Kale Edmiston**
Award amount: $90,000.00

K01 MH117290 Mentored Scientist Career Development Award 2019-2024
Title: *Feed forward visual system function in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $868,978.00

Brain and Behavior Research Foundation Early Career Award 2019-2021
Title: *Neuromodulation of visual cortex BOLD in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $69,401.00

The Opportunity Fund 2019
Title: *Trans Buddy PGH: Peer healthcare support program*
PI: Gerald Montano
Co-I: **E. Kale Edmiston**
Award amount: $15,000

Center for Interventional Psychiatry 2018
Title: *Neuromodulation of visual cortex and threat sensitivity in high anxiety*
PI: **E. Kale Edmiston**
Award amount: $9,900.00

Campaign for Southern Equality 2017
Title: *The Trans Buddy Program: Mental health advocacy for trans communities*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

University of Pittsburgh Office of Diversity and Inclusion Mini-Grant 2017
Title: *Developing health promotion materials for the transgender community*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

Trans Justice Funding Project 2017
Title: *The Trans Buddy Program: Peer advocacy solutions for mental health care access*
PI: **E. Kale Edmiston**
Award amount: $2,500.00

The Pollination Project 2016
Title: *The Trans Buddy Program: An innovative solution to transgender mental health disparity*
PI: **E. Kale Edmiston**
Award Amount: $1,500.00

Culture, Brain, and Development Grant 2006

Title: *Brain sex differences in mood disorders*
PI: **E. Kale Edmiston**
Award amount: $3,000.00

PEER-REVIEWED PUBLICATIONS (https://orcid.org/0000-0002-3548-6026):
2023:
48. Hoelscher EC, Victor SE, **Edmiston EK**. Gender minority resilience and suicidal ideation: a longitudinal and daily examination of transgender and non-binary adults. Behavior Therapist. (In Press).
47. Schroth-Erickson L, Levin R, Mak K, **Edmiston EK**. A review of the neurobiobehavioral literature of transgender identity. J Gay and Lesbian Mental Health. (In Press).
2022:
46. Coleman E, Radix AE, Bouman WP…**Edmiston EK**…Arcelus J. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23:1-258.
45. Juster RP, **Edmiston EK**. Refining research and representation of sexual and gender diversity in neuroscience. Biological Psychiatry: CNNI. 2022; 7(21):1251-7.
44. Colic L, Clark A, Sankar A, Rathi D, Goldman D, Kim JA, Villa LM, **Edmiston EK**, Lippard ETC, Mazure CM, Blumberg HP. Gender-related associations among childhood maltreatment on brain circuitry and clinical features of bipolar disorder. European Neuropsychopharmacology. 2022; 63:35-46.
43. **Edmiston EK**, Fournier JC, Chase HW, Aslam H, Lockovich J, Graur S, Bebko G, Bertocci M, Rozovsky R, Mak K, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortical activity during reward expectancy predicts mania risk up to one year post scan. J Affective Disorders. 2022; 319:325-8.
2021:
42. Bertocci MA, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman B, Greenberg T, Phillips ML. Reward circuitry-targeted cathodal transcranial direct current stimulation impacts reward circuitry and affect in bipolar disorder. Molecular Psychiatry. 2021; 26(8):4137-45.
2020:
41. Feng R, Womer FY, **Edmiston EK**, Chen Y, Wang Y, Chang M, Yin Z, Wei Y, Duan J, Ren S, Li C, Liu Z, Jiang X, Wei S, Li S, Zhang X, Nuo X, Tang Y, Wang F. Antipsychotic effects on cortical morphology in schizophrenia and bipolar disorders. Frontiers Neuroscience. 2020; 14:579139.
40. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S, Wang F. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2020; 10:923.
39. Wang Y, Wei Y, **Edmiston EK**, Womer FY, Zhang X, Duan J, Zhu Y, Zhang R, Zhang Y, Jiang X, Wei S, Liu Z, Zhang Y, Tang Y, Wang F. Altered structural connectivity and cytokines levels in schizophrenia and genetically high-risk individuals: associations with disease state and vulnerability. Schizophrenia Research. 2020; 223:158-165.
38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships

among impulsive sensation-seeking, reward circuitry activity, and risk for psychopathology: an fMRI replication and extension study. Biological Psychiatry: CNNI. 2020; 5(7):660-68.

37. Sha Z, Versace A, **Edmiston EK**, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler R, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Quirk G, Haber S, Phillips ML. Functional disruption in prefrontal-striatal network in obsessive compulsive disorder. Psychiatry Research: Neuroimaging. 2020; 300:111081.

36. **Edmiston EK,** Song Y, Chang M, Yin Z, Zhou Q, Zhou Y, Jiang X, Wei S, Xu K, Tang Y, Wang F. Hippocampal functional connectivity in patients with schizophrenia and unaffected family members. Frontiers in Psychiatry. 2020; 11:278.

35. Wei S, Womer F, **Edmiston EK**, Zhang R, Jiang X, Wu F, Kong L, Zhou Y, Tang Y. Structural alterations associated with suicide attempts in major depressive disorder and bipolar disorder: a diffusion tensor imaging study. Progress in Neuropsychopharmacology & Biological Psychiatry. 2020; 98.

34. Beach L, Eckstrand K, Ehrenfeld J, **Edmiston EK**, Ding J. A model for improving transgender healthcare quality. The Joint Commission Journal on Quality and Patient Safety. 2020; 46:37-43.

2019:

33. Sha Z*, **Edmiston EK***, Versace A, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler RS, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Buckner R, Quick G, Haber S, Phillips ML. Multimodal disruption of cerbello-thalamo-motor circuit in obsessive compulsive disorder. Biological Psychiatry: CNNI. 2019; 5(4):438-47. *co-first authors

32. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2019; 10:923.

30. Chang M, **Edmiston EK**, Womer F, Zhou Q, Shengnan W, Jiang X, Zhou Y, Ye Y, Huang H, Zui X, Xu K, Tang Y, Wang F. Spontaneous low-frequency fluctuations in the neural system for emotional perception in major psychiatric disorders: amplitude similarities and differences across frequency bands. Journal of Psychiatry and Neuroscience. 2019; 44:132-41.

29. Xia M, Womer FY, Chang M, Zhu Y, **Edmiston EK**, Jiang X, Wei S, Duan J, Xu K, Tang Y, He Y, Wang F. Shared and distinct functional architecture of brain networks across psychiatric disorders. Schizophr Bulletin. 2019; 47:450-63.

2018:

28. Li J, **Edmiston EK**, Tang Y, Fan G, Xu K, Wang F, Xu J. Shared facial emotion processing in medication-naive major depressive disorder and healthy individuals: detection by sICA. BMC Psychiatry, 2018; 18:96.

27. Chang M, Womer FY, **Edmiston EK**, Bai C, Zhou Q, Jiang X, Wei S, Wei Y, Ye Y, Huang H, He Y, Xu K, Tang Y, Wang F. Neurobiological commonalities among three major psychiatric diagnostic categories: a structural MRI study. Schizophrenia Bulletin. 2018; 44:65-74.

2017:

26. Wang N, **Edmiston EK**, Luo X, Yang H, Chang M, Wang F, Fan G. Comparing amplitude of low-frequency fluctuations in multiple system atrophy and idiopathic Parkinson's disease. Psychiatry Research Neuroimaging, 2017; 269:73-81.

25. Jiang X, **Edmiston EK**, Zhou Q, Xu K, Zhou Y, Wu F, Kong L, Wei S, Zhou Y, Chang M, Geng H, Wang D, Wang Y, Cui W, Tang Y, Wang F. Alteration of a cortico-striatal-limbic neural system in major depressive disorder and bipolar disorder. Journal of Affective Disorders, 2017; 221:297-303.

24. Corbett BA, Blain S, **Edmiston EK**. The role of context in psychosocial stress among adolescents with Autism Spectrum Disorder: piloting a semi-structured, video game-based paradigm. Journal of Intellectual & Developmental Disability. 2017; 43:20-8.

23. **Edmiston EK**, Muscatello RA, Corbett BA. Altered pre-ejection period response to social evaluative threat in adolescents with autism spectrum disorder. Research in Autism Spectrum Disorders. 2017; 36:57-65.

2016:

22. **Edmiston EK**, Donald CA, Sattler AR, Peebles JK, Ehrenfeld JM, Eckstrand KL. Opportunities and gaps in transgender primary healthcare: a systematic review. Transgender Health. 2016; 1(1):216-30.

21. **Edmiston EK**, Jones RM, Corbett BA. Physiological response to social evaluative threat in adolescents with autism spectrum disorder. Journal of Autism Developmental Disorders. 2016; 46(9):2992-3005.

20. **Edmiston EK**, Blain S, Corbett BA. Salivary cortisol and behavioral response to social evaluative threat in adolescents with autism spectrum disorder. Autism Research. 2016; Epub ahead of print.

2015:

19. Tang Y, Chen K, Zhou Y, Wang Y, Driesen N, **Edmiston EK**, Chen X, Jiang X, Kong L, Zhou Q, Li H, Wu F, Xu K, Wang Z, Tang Y, Wang F. Neural activity changes in unaffected children of patients with schizophrenia: a resting-state fMRI study. Schizophrenia Research. 2015; 168(1-2):360-5.

18. **Edmiston EK**, Merkle K, Corbett BA. Neural and cortisol responses during play with human and computer partners in children with autism. Social Cognitive Affective Neuroscience. 2015; 10(8):1074-83.

2014:

17. Corbett BA, Newsom C, Key AP, Qualls L, **Edmiston EK**. Examining the relationship between face processing and social interaction behavior in children with and without autism spectrum disorder. J Neurodevelopmental Disorders, 2014; 6(1):35.

16. Li J*, **Edmiston EK**,* Chen B, Tang Y, Ouyang X, Jiang Y, Fan G, Ren L, Liu J, Zhou Y, Jiang W, Liu Z, Xu K, Wang F. A comparative diffusion tensor imaging study of corpus callosum subregion integrity in bipolar disorder and schizophrenia. Psychiatry Res. 2014; 221(1):58-62.*co-first authors

2013:

15. **Edmiston EK***, McHugo M*, Dukic MS, Smith SD, Abou-Khalil B, Zald DH. Enhanced visual cortical activation for emotional stimuli is preserved in patients with unilateral amygdala resection. J Neuroscience, 2013; 33(27):11023-11031. *co-first authors

14. Liu H, **Edmiston EK**, Fan G, Ku X, Zhao B, Shang X, Wang F. Altered resting-state functional connectivity of the dentate nucleus in Parkinson's disease. Psychiatry Research: Neuroimaging. 2013; 211(1):64-71.

13. **Edmiston EK**, Blackford JU. Childhood maltreatment and response to novel face stimuli presented during functional magnetic resonance imaging in adults. Psychiatry Research: Neuroimaging. 2013; 212(1):36-42.

2012:

12. Fengrong O, Kai L, Qian G, Dan L, Jinghai L, Liwen H, Xian W, **Edmiston EK**; Yang L. An urban neo-poverty population-based quality of life and related social characteristics investigation from northeast china. PLoS One. 2012; 7(6):e38861.

11. Chepenik LG, Wang F, Spencer L, Spann MN, Kalmar JH, Womer F, **Edmiston EK**, Pittman B, Blumberg HP. Structure-function associations in hippocampus in bipolar disorder. Biological Psychiatry. 2012; 90(1):18-22.

2011:

10. Wang F, Kalmar JH, Womer FY, **Edmiston EK**, Chepenik LG, Chen R, Spencer L, Blumberg HP. Olfactocentric paralimbic cortex morphology in adolescents with bipolar disorder. Brain. 2011; 134(7):2005-12.

9. **Edmiston E**, Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. Archives of Pediatric and Adolescent Med. 2011; 165(12):1069-77.

8. **Edmiston E**, Wang F, Kalmar JH, Womer FY, Chepenik LG, Pittman B, Gueorguieva R, Hur E, Spencer L, Staib LH, Constable RT, Fulbright RK, Papademetris X, Blumberg HP. Lateral ventricle volume and psychotic features in adolescents and adults with bipolar disorder. Psychiatry Research. 2011; 194(3):400-2.

2009:

7. Womer FY, Wang F, Chepenik LG, Kalmar JH, Spencer L, **Edmiston E**, Constable RT, Papademetris X, Blumberg HP. Sexually dimorphic features of vermis morphology in bipolar disorder. Bipolar Disord 2009; 11(7):753-8.

6. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Papademetris X, Staib, LH. Improving the reliability of shape comparison by perturbation. IEEE Biomedical Imaging 2009; 1:686-9.

5. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Staib LH and Papademetris X. Shape comparison using perturbing shape registration. IEEE Computer Vision Pattern Recognition 2009;683-90.

4. Wang F, Kalmar JH, He Y, Jackowski M, Chepenik LG, **Edmiston E**, Tie K, Gong G, Shah MP, Jones M, Uderman J, Constable RT, Blumberg HP. Functional and structural connectivity between the perigenual anterior cingulate and amygdala in bipolar disorder. Biological Psychiatry 2009; 66(5):516-21.

3. Kalmar JH, Wang F, Spencer L, **Edmiston E**, Lacadie CM, Martin A, Constable RT, Duncan JS, Staib LH, Papademetris X, Blumberg HP. Preliminary evidence for progressive prefrontal abnormalities in adolescents and young adults with bipolar disorder. J Int Neuropsychol Soc. 2009; 15(3):476-81.

2008:

2. Blumberg HP, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Duman RS, Gelernter J. Influence of vascular endothelial growth factor variation on human hippocampus morphology. Biological Psychiatry 2008; 64(10):901-3.

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Bhagwagar Z, Spencer L, Pittman B, Jackowski M, Papademetris X, Constable RT, Blumberg HP. Abnormal corpus callosum

integrity in bipolar disorder: A diffusion tensor imaging study. Biological Psychiatry 2008; 64(8):730-3.

MANUSCRIPTS (IN PROGRESS):

Ravindranath O, Perica MI, Parr AC, Pjha A, McKeon SD, Montano G, Ullendorf N, Luna B, **Edmiston EK**. Adolescent neurocognitive development and decision-making regarding gender affirming care. (Submitted).

Soehner AM, **Edmiston EK**, Wallace M, Chase HW, Lockovich J, Aslam H, Stiffler R, Graur S, Skeba A, Bebko G, Benjamin OE, Wang Y, Phillips ML. Neurobehavioral reward and sleep-circadian phenotypes predict present and next-year mania/hypomania risk. (Submitted).

Sequiera S, Tervo-Clemmens B, Carmel T, **Edmiston EK.** Towards a biopsychosocial model for neurodevelopment in transgender and gender diverse adolescents: understanding risk and resilience for mood disorders. (Submitted).

POSTERS, ABSTRACTS, AND CONFERENCE PROCEEDINGS:

53. Victor SE, **Edmiston EK**. Ecological momentary assessment of gender-relevant versus other interpersonal stressors predicting self-injurious thoughts and behaviors among transgender and non-binary adults. *Association for Behavioral and Cognitive Therapy Annual Convention. Submitted.*

52. **Edmiston EK**, Fournier JC, Chase HW, Phillips ML. Ventral visual stream functional coupling during implicit emotional face perception is associated with internalizing symptoms: a double dissociation by face valence at baseline and six months post-scan. *American College of Neuropsychopharmacology.* 2023.

51. Victor SE, Hoelscher E, Sandel D, Trieu T, **Edmiston EK.** Interpersonal and intrapersonal gender minority stressors as contribution to suicidal ideation among transgender and non-binary adults. *Suicide Research Symposium.* 2022.

50. Aslam MA, Mak K, **Edmiston EK.** Piloting transcranial direct current stimulation to reduce threat sensitivity in high trait anxiety. *University of Pittsburgh Department of Psychology Undergraduate Directed Experiences in Research Poster Day*. 2022.

49. **Edmiston EK** & Strakowski S. Understanding diagnosis and assessment disparities in transgender populations. *Society of Biological Psychiatry Annual Meeting.* 2022. Discussant, Lunchtime “Fireside Chat” Series.

48. Bertocci M, Afriyie-Agyemang Y, Rosovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Network interference during emotion regulation in distressed adults consistently predicts depression symptoms. *Society of Biological Psychiatry Annual Meeting.* 2022.

47. Afriyie-Agyemang Y, Bertocci M, Rozovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Overcompensation of the central executive network during working memory may be a neural marker for youth at risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

46. Schumer MC, Bertocci MA, Bebko G, Stiffler RS, Lockovich JC, Aslam HA, Graur S, **Edmiston EK**, Chase HW, Johnson SL, Phillips ML. Trait urgency mediates associations between neural emotion-processing markers of emotion-triggered impulsivity and mania in young adults at-risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

45. Young J, Roepke T, Anacker C, Ehrensaft D, **Edmiston EK**, Guthman EM, Eshel N, Marrocco J. Challenges and opportunities for translational research and clinical strategies within the LGBTQIA2S+ community. *American College of Neuropsychopharmacology Annual Meeting.* 2021. Discussant, Study Group.

44. Phillips ML, Bertocci M, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman BA. Targeted non-invasive neuromodulation impacts reward expectancy-related reward circuitry activity and affect in bipolar disorder and healthy adults. *Society of Biological Psychiatry Annual Meeting.* 2021.

43. **Edmiston EK,** Fournier JC, Rozovsky R, Chase HW, Bertocci MA, Aslam HA, Lockovich J, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortex structure and reward-expectancy related activity predict manic symptom changes one year later. *American College of Neuropsychopharmacology Annual Meeting.* 2021.

42. **Edmiston EK**, Phillips ML, Mak K, Chase HW, Fournier JC. Visual cortex coupling and childhood maltreatment: associations with major depression and a compensatory mechanism. *Society of Biological Psychiatry Annual Meeting.* 2021.

41. Marrocco J, **Edmiston EK**, Anacker C, Bangasser D. The study of sex differences and gender bias, and trans inclusive research practices. *American College of Neuropsychopharmacology Annual Meeting.* 2020. Panelist, Networking Session.

40. Chase HW, Fournier JC, Bertocci MA, **Edmiston EK**, Lockovich JC, Aslam H, Stiffler RS, Graur S, Bebko G, Phillips ML. Decision-making variability in mood disorders: new insights for a replication attempt. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

39. **Edmiston EK,** Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. A double dissociation between anxiety and depression symptom improvement and fusiform coupling and positive and negative emotional face processing. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships among impulsive sensation-seeking, reward circuitry activity, and predisposition to bipolar disorder: an fMRI replication and extension study. *American College of Neuropsychopharmacology Annual Meeting. 2019.*

37. Paglisotti T, Montano G, Simpson A, **Edmiston EK**. Preliminary implementation of Trans Buddy PGH: establishing trust among transgender patients and healthcare providers. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day.* 2019.

36. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Phillips ML. Left ventrolateral prefrontal cortical BOLD signal during reward expectancy and impulsive sensation seeking: a replication study. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day. 2019.*

35. Chase HW, **Edmiston EK**, Bertocci M, Fournier JC, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Forbes EE, Phillips ML. Similar neural representation of appetitive and loss avoidance prediction errors across distressed and healthy individuals. *Society of Biological Psychiatry Annual Meeting.* 2019.

34. **Edmiston EK**, Simpson A. Progress report: Quality improvement programming for transgender mental health. Symposium. *TransPride PGH Professional Conference.* 2018.

33. Schroth-Erickson L, Levin R, **Edmiston EK**. Talking to your patients about the biological basis of transgender identity. *Philadelphia Trans Wellness Conference Professional Track. 2018*.

32. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Fusiform gyrus-salience network coupling during emotion processing predicts anxiety and depression symptom change. *University of Pittsburgh Medical Center Department of Psychiatry 18th Annual Research Day*. 2018.

31. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Salience network BOLD response to emotional faces predicts anxiety and depression symptom outcomes. *Society of Biological Psychiatry Annual Meeting.* 2018.

30. Chase HW, Qiu H, Kerestes R, Shah N, Alkhar H, **Edmiston EK**, Soehner A, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Pan L, Eickhoff SB, Phillips ML. Implication of the visual cortex in resting state fMRI studies of mood and anxiety disorders may relate to the propensity for within-scanner sleep. *Society of Biological Psychiatry Annual Meeting.* 2018.

29. Ding J, Ehrenfeld J, Raynor L, **Edmiston EK**, Eckstrand K, Beach L. A proposed systems level quality improvement model for transgender healthcare delivery. *The National Transgender Health Summit*. 2017.

28. **Edmiston EK.** Setting the agenda for transgender neuroimaging: a critical review and future directions. Symposium. *The National Transgender Health Summit.* 2017.

27. **Edmiston EK,** Fournier J, Greenberg T, Bertocci M, Stiffler R, Aslam H, Lockovich J, Phillips ML. Trait anxiety predicts visual system response to emotional faces. *Developmental Affective Neuroscience Symposium*. 2017.

26. **Edmiston EK.** The Trans Buddy Program: an innovative intervention for increasing health care utilization. Symposium. *TransPride PGH Professional Conference.* 2017.

25. Buchanan K, Richmond M, Sattler AR, **Edmiston EK**. Red state solutions for transgender health care access: provision in low resource areas. Symposium. *Philadelphia Transgender Health Conference.* 2017.

24. **Edmiston EK,** Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Predicting quality of life in distressed youth: Cortico-thalamic BOLD signal and reward processing. *University of Pittsburgh Medical Center Department of Psychiatry 17th Annual Research Day*. 2017.

23. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Cortico-thalamic BOLD signal during reward processing predicts quality of life at follow up in distressed young adults. *Society of Biological Psychiatry Annual Meeting.* 2017.

22. Eckstrand KL, Mitchell L, **Edmiston EK.** The Trans Buddy Program: Transgender Leadership and peer advocacy for reducing health disparities. *University of Pittsburgh Health Sciences Health Disparity Poster Competition.* 2017.

21. **Edmiston EK.** Reframing the search for transgender neuroimaging biomarkers. *New Materialisms Annual Meeting* Warsaw, Poland. 2016.

20. Corbett BA, Muscatello R, **Edmiston EK**, Muse I. Examining the Diurnal Profile of Children and Adolescents with Autism Spectrum Disorder (ASD) and Typical Development between 8 to 17 years of age. *International Society for Psychoneuroendocrinology.* 2016.

19. Corbett BA, Muse I, **Edmiston EK**, Muscatello R. Diurnal and Stress Hormonal Profiles of Testosterone and Cortisol in Adolescents with Autism Spectrum Disorder (ASD) and Typical Development (TD). *International Society for Psychoneuroendocrinology.* 2016.

18. **Edmiston EK**. Psychophysiological characterization of adolescents with Autism Spectrum Disorder. Presentation, *Chinese Psychiatric Association Annual Meeting.* 2016.

17. **Edmiston EK**, Jones RM, Blain S, Corbett BA. Neuroendocrine and physiological responsivity during social stress in adolescents with and without autism spectrum disorder. *Vanderbilt Kennedy Center Science Day.* 2015.

16. **Edmiston EK**, Valencia B, Corbett BA. Autonomic nervous system function in response to social judgment in adolescents with and without autism spectrum disorder. *International Meeting for Autism Research.* 2015.

15. Corbett BA, Newsom C, Key S, Qualls L, **Edmiston EK**. A randomized wait-list control trial of a peer-mediated, theatre-based intervention to improve social ability in children with autism spectrum disorder. *International Meeting for Autism Research.* 2015.

14. Singer B, Eckstrand K, Ehrenfeld J, **Edmiston EK**. Transgender health and advocacy in academic medicine: an empowerment model. Workshop; *Gay and Lesbian Medical Association Annual Meeting.* 2014.

13. **Edmiston EK**, Corbett BA. Behavioral and endocrine alterations in adolescents with autism spectrum disorder. Selected presentation; *Vanderbilt Kennedy Center Science Day*. 2014.

12. **Edmiston EK.** Effects of a neurobiological explanation of sexual orientation on student attitudes towards lesbian, gay and transgender people. *Society for Neuroscience.* 2013.

11. Corbett BA, **Edmiston EK**, Zald DH. Neural and physiological responses during play with human and computer partners in children with autism. *Society for Neuroscience.* 2013.

10. **Edmiston EK,** McHugo M, Dukic MS, Eggers E, Zald DH. Visuocortical BOLD response to emotional stimuli in the absence of a functional amygdala. *Society for Neuroscience.* 2012.

9. **Edmiston EK.** Pelvic and chest exams in transgender men. Workshop; *Philadelphia Trans Health.* 2011.

8. **Edmiston EK**, Blackford JU. Childhood maltreatment affects face processing. *Biology of Prosocial Behavior.* 2011.

7. **Edmiston E,** Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. *Vanderbilt Kennedy Center Science Day.* 2011.

6. Wang F, **Edmiston E**, Hur E, Kalmar JH, Womer FY, Chepenik LG, Blumberg HP. An Altered Developmental Trajectory of Frontotemporal Connectivity in Bipolar Disorder. *Biological Psychiatry* 2010; 67 (Supplement 9): 107.

5. Wang F, Chepenik LG, Shah MP, Kalmar JH**, Edmiston E**, Spencer L, Duman R, Gelernter J, Blumberg HP. Genes Regulating Neurotrophic Factors that Influence the Corticolimbic Connectivity in Mood Disorders: Treatment Implications. *Biological Psychiatry* 2009; 65 (Supplement 1): 174.

4. Kalmar JH, Wang F, Chepenik LG, Shah MP, McDonough A, **Edmiston E**, Blumberg HP. Amygdala functioning during emotional processing in adolescents with bipolar disorder or ADHD. *Biological Psychiatry* 2008; 63 (Supplement 1): 184.

3. Womer F, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Spencer L, Constable RT, Papademetris X, Blumberg HP. Structural abnormalities of the cerebellar vermis in bipolar disorder. *Biological Psychiatry* 2008; 63 (Supplement 1): 141.

2. Wang F, Kalmar JK, Womer F, He Y, Chepenik L, **Edmiston E**, Blumberg HP. Abnormal morphological correlations within a cortico-limbic neural system in adolescents with bipolar disorder. *American Academy of Childhood and Adolescent Psychiatry.*

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Tie K, Spencer L, Jackowski M, Papademetris X, Constable RT & Blumberg HP. Abnormal callosal integrity in bipolar disorder determined from diffusion tensor imaging. *Biological Psychiatry* 2008; 63 (Supplement 1): 43.

BOOK CHAPTERS:

Edmiston EK, Bertocci M, Phillips ML. Neuroimaging and Circuit Mechanisms of Bipolar Disorder. In *Neurobiology of Mental Illness*. 6th Ed. Eds: Eric Nestler & Alexander Charney. Oxford University Press. (In Press).

Tomson A & **Edmiston EK**. Understanding the basis of gender identity development: biological and psychosocial models. In *Trans Bodies, Trans Selves*. 2nd Ed. Ed: Sand Chang. Oxford University Press. 2022.

Edmiston EK. Community-led peer advocacy for transgender health care access in the southeastern United States: The Trans Buddy Program. In *Healthcare in Motion: Mobility forms in health service delivery and accessibility.* Berghahn Books. 2017.

Robles RJ & **Edmiston EK**. Community Responses to Trauma. In *Trauma, Resilience, and Health Promotion for LGBT Patients.* Springer Press. 2017.

Edmiston EK & Mitchell L. Trans Buddy: Innovation Profile. In *The Remedy: Queer and Trans Voices on Health and Health Care.** Arsenal Press. 2016. *Lambda Literary Award Winner, Non-Fiction Anthology

Eckstrand KL, **Edmiston EK**, Potter J. Obstetric and Gynecologic Care to LGBT Individuals. In *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Springer Press. 2015.

ADDITIONAL SCHOLARSHIP:

Edmiston EK. Letter to the Editor: The legacy of transgender surgery access is complex. *Annals of Plastic Surgery.* 2019.

Edmiston EK. Invited Commentary: Transgender health research must serve transgender people. *BJOG.* 2018.

Edmiston EK. Feminist bioethics and intersex medical interventions: A review of *Making Sense of Intersex*. *Catalyst: Feminism, Theory, Technoscience*. 2016; 2(1).

Jann JT, **Edmiston EK**, Ehrenfeld J. Letter to the Editor: Important considerations for addressing LGBT health care competency. *American J of Public Health* 2015; e1.

HONORS, AWARDS, AND FELLOWSHIPS:

American College of Neuropsychopharmacology Travel Award	2021
Society of Biological Psychiatry Early Career Investigator Travel Award	2019
NYC tDCS Fellowship City University of New York, New York, NY	2018
Trainee, T32 MH018951 Child and Adolescent Mental Health Research University of PIttsburgh, Pittsburgh, PA	2018-2019
Research Day Department of Psychiatry Outstanding Poster Award	2018
PLOS One Travel Award	2017
Fellow, Winter School in the Neuroscience of Consciousness Canadian Institute For Advanced Research	2017
Trainee, T32 MH16804 Transformative Discovery in Psychiatry	2016-2018

University of Pittsburgh, Pittsburgh, PA

WPATH Outstanding Student Award 2015
International honor for contributions to transgender health research

The Trans 100 2015
National honor for excellence in the transgender community

Point Foundation Scholar 2014-2015
One of 20 selected nationally for program that funds education of LGBT students

Vanderbilt Brain Institute Student Leadership and Service Award 2014

Graduate Student Travel Grant, Vanderbilt University 2013

Fellow, Summer Program in Neuroscience Ethics and Success 2013
Marine Biology Laboratory, Woods Hole, MA

Clinical Neuroscience Scholar for Translational Research 2012-2015
Dan Marino Foundation

Neurobiology of Social Behavior Travel Award 2011
Emory University, Atlanta, GA

President's Scholarship 2003-2005
Case Western Reserve University, Cleveland, OH

TEACHING AND MENTORSHIP

SELECTED TALKS:

Invited Speaker: *Neuroscience in Service of Our Community:* 2023
How Research Rooted in Empathy and Humility Makes Us Better Scientists
Neuroscience Diversity Seminar
University of Maryland School of Medicine

Invited Speaker: *Visual Cortex Distinguishes Anxiety and Depression* 2023
Fournier Group Lab Meeting
The Ohio State Medical School

Presenter: *Assessing Visual Perception in Depression and Anxiety* 2023
Department of Psychiatry Faculty Meeting
UMass Chan Medical School

Invited Speaker: *Neuroimaging Studies of Transgender People* 2022
The Friedman Brain Institute and oSTEM
The Icahn School of Medicine at Mount Sinai

Invited Speaker: *Impulsivity and Reward-related Activity:* 2022
A Stable Marker for Bipolar Disorder risk
STEP Seminar
Truman State University

Invited Speaker: *Assessing Relationships Among impulsivity, Reward Circuitry, and Risk for Psychopathology* Magnetic Resonance Research Center Forum Yale School of Medicine	2019
Presenter: *Fusiform Gyrus Alterations During Emotion Processing: Predicting the Future in Anxiety Disorders* Center for the Neural Basis of Cognition Seminar University of Pittsburgh and Carnegie Mellon University	2018
Panelist: *Setting the Research Agenda in Transgender Health* 27th Annual Issues in Medical Ethics Conference The Icahn School of Medicine at Mount Sinai	2017
Panelist: *Neuroimaging in Child and Adolescent Mental Disorders* Chinese Society of Psychiatry 14th Annual Meeting	2016
The Trans Buddy Program: An Innovative Model for Healthcare Access Medicine Health and Society Colloquium Series Vanderbilt University	2015
Panel Organizer: *Intra-community Stigma in LGBT Populations* 615Thrive Conference Tennessee Department of Health	2015
Transgender Health: Provider Considerations Department of Hearing and Speech Sciences Grand Rounds Vanderbilt University	2014
Sexual and Reproductive Health in LGBT Populations Sarah Fogel, PhD Department of Nurse Midwifery Vanderbilt University School of Nursing	2014, 2015
Panelist: *(Im)Possible Politics: Intersectional Trans Organizing* Ben Singer, PhD; Dean Spade, JD; Lisa Guenther PhD Department of Women and Gender Studies Vanderbilt University	2014
Plenary Speaker: *Creating Change for LGBTI Health* Gay and Lesbian Medical Association Annual Meeting	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Radiology Beijing Normal University	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Psychiatry China Medical University	2013

MEDICAL STUDENT TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulatory Interventions in Mood Disorders* 2022
Neuroscience Area of Concentration Seminar Series
University of Pittsburgh School of Medicine

Guest Lecturer: *Building Trust with your Transgender Patients* 2021,2022
Texas Christian University School of Medicine

Instructor of Record: *Introduction to Scientific Writing* 2016
China Medical University

Guest Lecturer: *Clinical and Biobehavioral Features of Autism* 2016
Clinical Medicine 400
China Medical University

Guest Lecturer: *Building an Inclusive Practice for LGB and T Patients* 2015
First Year Seminar
Meharry Medical College

Guest Lecturer: *Community Models for Improving Trans Healthcare* 2015
Intercession Course
Meharry Medical College

Guest Lecturer: *Providing Excellent Care for LGBT People* 2015
Capstone Series
Meharry Medical College

GRADUATE AND UNDERGRADUATE TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulation interventions for threat sensitivity* 2022
Biomedical Sciences First Year Seminar
Graduate School of Biomedical Sciences
UMass Chan Medical School

Guest Lecturer: *Impulsivity and reward-related activity: Predicting mania* 2021
Undergraduate Research Methods
Department of Psychology
University of California San Diego

Guest Lecturer: *Transgender people and neuroimaging: a critical review* 2021
Department of Psychology
Mount Holyoke College

Instructor of Record: PSY0205 Psychopathology 2021
Department of Psychology
University of Pittsburgh

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 2110: American Medicine and the World

Laura Stark, PhD, Vanderbilt University

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 3890: Documenting the Body
Odie Lindsey, PhD, Vanderbilt University

Guest Lecturer: *Introduction to Social Neuroscience* 2014
PSY3609: Educational Cognitive Neuroscience
Sasha Key, PhD, Vanderbilt University

Guest Lecturer: *Imagining Transgender Bodies in Healthcare* 2013
WGS 290: Theories of the Body
Aimi Hamraie, PhD, Vanderbilt University

Introduction to Cognitive Neuroscience 2013-2014
Vanderbilt Neuroscience Graduate Program Boot Camp

The Center for Teaching, Vanderbilt University 2013
Scholarship of Teaching and Learning Certificate

Teaching Assistant: NSC201 Introduction to Neuroscience 2011
Department of Neuroscience, Vanderbilt University

TRAINEE MENTORSHIP, CERTIFICATION, AND SUPERVISION:

Culturally Aware Mentorship Workshop 2022
University of Wisconsin Madison School of Medicine

Tiffany Nhan (post bac lab assistant) 2022-present

M. Ali Aslam (undergraduate lab assistant) 2022

Paloma Rueda (undergraduate lab assistant) 2020-2021

Shelby Gardner (undergraduate lab assistant) 2020

Kristie Mak (undergraduate lab assistant) 2019-2020

Taylor Pagliosotti, BA (graduate student, Department of Public Health) 2018-2019

Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) 2019

Alicyn Simpson, BA (research assistant, Adolescent Medicine) 2018-2019

Hana Choi, BA (intern, The Trans Buddy Program) 2016

William Horn, BA (intern, The Trans Buddy Program) 2015

RJ Robles, BA (student worker, Program for LGBTI Health) 2015-2016

Keanan Gottlieb, BA (summer intern, The Trans Buddy Program) 2014

Cameron Donald, BA (summer intern, Program for LGBTI Health) 2014

Jamieson Jann, BA (summer intern, Program for LGBTI Health) 2014

SERVICE

CURRENT MEMBERSHIPS:
Society of Biological Psychiatry

DEPARTMENTAL, INSTITUTIONAL, AND DISCIPLINARY SERVICE:

Editorial Board, *Journal of Mood and Anxiety Disorders* 2023-present

Member, Grand Rounds Committee 2023-present
Department of Psychiatry, UMass Chan Medical School

Interviewer, Graduate School of Biomedical Sciences 2023-present
UMass Chan Medical School

Co-Director, NeuroNexus Institute 2022-present
UMass Chan Medical School

Co-chair, Diversity, Equity and Inclusion Committee 2021-present
Society of Biological Psychiatry

Member, LGBTQIA+ Task Force 2021-present
American College of Neuropsychopharmacology

Editorial Board, *Bulletin of Applied Transgender Studies* 2021-present

Grant Reviewer, Lesbian Health Fund, GLMA 2021

Member, Diversity, Equity, and Inclusion Committee 2019-2021
Department of Psychiatry University of Pittsburgh School of Medicine

Chapter Author, Assessment of Adults with Gender Dysphoria 2018-2022
WPATH Standards of Care 8 Committee

Member, Diversity and Inclusion Committee 2018-2021
Society of Biological Psychiatry

Ad Hoc Member, Diversity and Inclusion Task Force 2020-2021
American College of Neuropsychopharmacology

Member, Cross-Network Transgender Working Group, 2017-2019
NIH Office of HIV/AIDS Network Coordination

Co-Founder, Trans Buddy Pittsburgh 2016-2018

Student Representative, Vanderbilt Brain Institute Diversity Committee 2015-2016

Founding Director, The Trans Buddy Program Nashville 2014-2016

Co-Director, Vanderbilt School of Medicine Program for LGBTI Health 2014-2015

Assoc. Director, Vanderbilt School of Medicine Program for LGBTI Health 2013-2014

Associate Editor, *Vanderbilt Reviews Neuroscience*	2013-2014
President, Vanderbilt Neuroscience Student Organization	2013-2014
Member, Vanderbilt Neuroscience Organization Academic Committee	2012-2013
Board Member, Vanderbilt School of Medicine Program for LGBTI Health	2012-2013
Affiliate, Vanderbilt Kennedy Center	2011-2016

AD HOC PEER REVIEW:
Acta Psychologica; American Journal of Psychiatry; American Journal of Sexuality Education; Annals of Internal Medicine; Biological Psychiatry: Cognitive Neuroscience Neuroimaging; BJOG: An International Journal of Obstetrics and Gynaecology; Bipolar Disorder; Brain and Behavior; Child Abuse & Neglect; Development and Psychopathology; Developmental Cognitive Neuroscience; Frontiers in Neuroscience; Frontiers in Sociology; Human Brain Mapping; Journal of Affective Disorders; Journal of Autism and Developmental Disorders; Journal of Homosexuality; Journal of Medical Systems; Journal of Neuroscience Research; Journal of Psychiatry, Depression, and Anxiety; LGBT Health; Molecular Autism; NeuroImage; Neuropsychologia; Neuropsychopharmacology; Neuroscience Letters; Psychiatry Research: Neuroimaging; PLOS One; Psychological Medicine; Psychology of Violence; Psychoneuroendocrinology; Scientific Reports; Schizophrenia Research; Transgender Health

REFERENCES

Mary L. Phillips, MD, MD (CANTAB), Pittsburgh Foundation-Emmerling Endowed Chair in Psychotic Disorders, Professor, Department of Psychiatry, University of Pittsburgh School of Medicine. email: phillipsml@upmc.edu

Jay C. Fournier, PhD, Associate Professor, Department of Psychiatry & Behavioral Health, The Ohio State University. email: jay.fournier@osumc.edu

Hilary P. Blumberg, MD, John and Hope Furth Professor of Psychiatric Neuroscience, Professor Departments of Psychiatry and Radiology and Biomedical Imaging, Yale School of Medicine. email: hilary.blumberg@yale.edu

Exhibit B

Bibliography

BIBLIOGRAPHY

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de Vries, A. L., McGuire, J. K., Steensma, T. D., Wagenaar, E. C., Doreleijers, T. A., & Cohen-Kettenis, P. T. (2014). Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*, *134*(4), 696–704. https://doi.org/10.1542/peds.2013-2958

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Wojniusz, S., Ropstad, E., Evans, N., Robinson, J., Solbakk, A. K., Endestad, T., & Haraldsen, I. R. (2013). Sex-specific development of spatial orientation is independent of peripubertal gonadal steroids. *Psychoneuroendocrinology*, *38*(9), 1709–1716. https://doi.org/10.1016/j.psyneuen.2013.02.005

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

EXPERT REBUTTAL REPORT OF ARON JANSSEN, M.D.

I, Aron Janssen, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BACKGROUND AND QUALIFICATIONS

A. Qualifications

4. I am the Vice Chair of the Pritzker Department of Psychiatry and Behavioral Health at the Ann and Robert H. Lurie Children's Hospital of Chicago

("Children's Hospital"), where I also serve as Clinical Associate Professor of Child and Adolescent Psychiatry. I maintain a clinical practice in Illinois where I treat patients from Illinois and the surrounding states.

5. I received my medical degree from the University of Colorado School of Medicine and completed by residency in psychiatry and fellowship in child and adolescent psychiatry at New York University Langone Medical Center.

6. In 2011, I founded the Gender and Sexuality Service at New York University, for which I served as Clinical Director. I also previously served as Co-Director of the New York University Pediatric Consultation Liaison Service for the New York University Department of Child and Adolescent Psychiatry.

7. I am board certified in Child and Adolescent Psychiatry and Adult Psychiatry.

8. I have been treating children and adolescents with gender dysphoria for over 12 years. I have seen and treated over 500 children and adolescents with gender dysphoria during my medical career. Currently, approximately 90 percent of the patients in my clinical practice are transgender children and adolescents.

9. As part of my practice, I stay current on medical research and literature relating to the care of transgender persons and patients with gender dysphoria. I am an Associate Editor of the peer-reviewed publication *Transgender Health* and a

reviewer for *LGBT Health* and *Journal of the American Academy of Child and Adolescent Psychiatry*, both of which are peer-reviewed journals.

10. I am the author or co-author of 16 articles on care for transgender patients and am the co-editor of *Affirmative Mental Health Care for Transgender and Gender Diverse Youth: A Clinical Casebook* (Springer Publishing, 2018), which is the first published clinical casebook on the mental health treatment for children and adolescents with gender dysphoria. I have also authored or co-authored numerous book chapters on treatment for transgender adults and youth.

11. I have been a member of the World Professional Association for Transgender Health ("WPATH") since 2011. I was actively involved in the revision of WPATH's *Standards of Care for the Health of Transgender and Gender Diverse People* ("Standards of Care"), serving as a member of revision committees for both the child and adult mental health chapters of version 8 of WPATH's Standards of Care (SOC 8), published in 2022.

12. In addition to the above, I am involved in training other medical and mental health providers in the treatment of children and adolescents with gender dysphoria. I have conducted trainings for over 1,000 medical and mental health providers and have given dozens of public addresses, seminars, and lectures on the treatment of gender dysphoria in children and adolescents.

13. I am also involved in a number of international, national, and regional committees that contribute to the scholarship and provision of care to transgender people. I am the Chair of the American Academy of Child and Adolescent Psychiatry's Sexual Orientation and Gender Identity Committee. I serve as a member of the Transgender Health Committee for the Association of Gay and Lesbian Psychiatrists. I was the Founder of the Gender Variant Youth and Family Network.

14. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

B. Prior Testimony

15. Within the last four years, I testified as an expert at trial or by deposition in: *B.P.J. v. W. Va. Bd. of Educ.*, Case No. 2:21-cv-00316 (S.D. W.Va.); and *L.E. v. Lee*, Case No. 3:21-CV-00835 (M.D. Tenn.).

C. Compensation

16.I am being compensated for my work on this matter at a rate of $400 per hour for preparation of this report and for time spent preparing for and giving local deposition or trial testimony. In addition, I would be compensated $2,500 per day for deposition or trial testimony requiring travel and $300 per hour for time spent

travelling, plus reasonable expenses. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

D. Bases for Opinions

17. In preparing this report, I reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, Daniel Shumer, and Kellan Baker, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

18. My opinions are based on: (1) my clinical experience as a psychiatrist treating patients with gender dysphoria, including transgender children, adolescents, and adults; (2) my knowledge of the peer-reviewed research, including my own, regarding the treatment of gender dysphoria, which reflects advancements in the field of transgender health; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and (4) my review of any of the materials cited herein.

19. I have also reviewed the materials listed in the bibliography attached as **Exhibit B**. I may rely on those documents as additional support for my opinions.

20. In addition, I have relied on my years of research and clinical experience in child, adolescent, and adult psychiatry, as well as my professional knowledge, as set out in **Exhibit A** and the materials listed therein.

21. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

22. I have not met or spoken with the Plaintiffs in this case.

SUMMARY OF OPINIONS

23. As with all of medicine, transgender medicine is a continuously evolving field. But this does not make medical treatment for gender dysphoria experimental or investigational. To the contrary, such treatment is well-established and large body of evidence (more so than exists for other non-experimental medical interventions) documents that safety and efficacy of these medical interventions.

24. Transgender people have always existed and the provision of medical care to address transgender people's gender incongruence/gender dysphoria goes back decades. In fact, the field of transgender medicine was built to increase

oversight around patient care, and often requires consent processes that go above and beyond what is expected for other medical decisions.

25. There is robust evidence demonstrating the value of social, medical and surgical interventions for children, adolescents, and adults when in the context of an appropriate psychosocial evaluation. And to be clear, no medical or surgical interventions are recommended or provided to anyone until after the onset of puberty, meaning such care is only available to adolescents and adults.

26. The Defendants and their designated experts spent much time arguing about hypothetical concerns, for which there is no proof, and the limitations of particular studies. But Defendants and their designated experts completely ignore that the evidence-base for the safety and efficacy for gender-affirming care is not based on any one particular study. Rather, as is the norm in all of science and medicine, we look at the entire body of research surrounding gender-affirming care. When one does so, the conclusion that gender-affirming medical care for the treatment of gender dysphoria in transgender adolescents and adults is safe and effective becomes inescapable. Decades on clinical experience further support this conclusion.

27. Defendants and their designated experts further ignore the robust evidence for the potential harm faced by transgender individuals when barred access to medically necessary gender-affirming care.

28. Defendants and their designated experts also ignore every transgender adult was once a child. The Defendants' designated experts focus on children and adolescents, but the Challenged Exclusion bans coverage for all care for an already vulnerable population, including adults. None of them explain why this case is experimental for transgender adults.

29. While there can be debate about the techniques and modalities of care to support transgender youth, it is important to keep in mind that the opposite of substandard care is excellent care, not no care. To be clear, however, gender-affirming care is safe and effective, it is not substandard or experimental.

30. Understanding patients' experience of distress around gender is a vital component of being an expert in this field. Without understanding the distress transgender patients face – as well as the joy and resilience they experience when they get the care they need – one is only spouting unmoored and unfounded opinions. Medicine and science demand more than just personal opinions, it demands study and experience in the field. For the most part, Defendants' designated experts lack both.

EXPERT OPINIONS

A. Defendants' experts lack the experience and/or training to opine on the diagnosis, assessment, and treatment of gender dysphoria of transgender children and adolescents.

Dr. Levine

31. Because Dr. Levine does not appear to be board certified in child and adolescent psychiatry, he lacks the related experience and training in specific developmental considerations for children and adolescents that is critical for working with transgender youth and their families.

32. Moreover, Dr. Levine repeatedly acknowledges in his report that he has no firsthand knowledge of how gender-affirming mental health care is actually provided to children and adolescents. His descriptions are based on second-hand conversations and often sensationalized media reports. (*See*, *e.g.*, Levine Report, at ¶49 (offering opinions based on anecdotal reports from the internet)). He speaks in his report with authority on developmental and family factors that shape identity development in youth despite lacking the requisite training and experience and even ascribes reasons for why boys and girls may pursue social transition despite no clinical experience in the relevant population.

Dr. Kaliebe

33. Similarly, Dr. Kaliebe is not qualified to opine as an expert on the care of transgender children and adolescents. There is a difference between having an

interest in a topic and having expertise in a clinical or research domain. Dr. Kaliebe's report of the number of transgender patients he has seen is consistent with what many of our child psychiatry trainees are exposed to in their residency, and is not consistent with the volume of patients necessary to demonstrate expertise on the clinical nuance of the field. In addition to a lack of clinical expertise, Dr. Kaliebe's report calls into question his expertise in research methods or ethics. As an example, throughout his report Dr. Kaliebe makes claims about the quality of the evidence for gender affirming care while describing unscientific survey questions asked outside of the IRB process as having the same weight as data published in a peer-reviewed journal. Furthermore, nowhere in his CV does it describe a history of expertise in evolutionary biology or early human behavior, but this doesn't stop him from making unsubstantiated and uncited assertions about adaptive behaviors in "ancient evolutionary environments."

Defendants' other experts

34. Expertise in mental health care requires specialized training and ongoing work in the field with appropriate certification and licensure. To my knowledge, and based on a review of their respective CV's, Drs. Hruz, Laidlaw, Lappert, Biggs, Donovan, and Zanga have neither had the training nor the certification and licensure to weigh in as experts on the appropriateness of a mental health assessment or treatment plan. This lack of expertise, however, has not

stopped them from making broad generalizations about mental health care that bear little resemblance to the care as typically delivered. As such, their characterizations of the practice of mental health care should be seen as a lay opinion based on secondhand knowledge at best. Furthermore, expertise in the treatment of transgender individuals requires experience in the care of transgender individuals, a characteristic in short supply with the aforementioned experts.

B. Gender Identity

35. At birth, infants are assigned a sex, either male or female, based on the appearance of their external genitalia. For most people, their sex assigned at birth, or assigned sex, matches that person's gender identity. For transgender people, their assigned sex does not align with their gender identity.

36. Gender identity is a person's core sense of belonging to a particular gender, such as male or female.

37. Gender identity is one of a person's multiple sex-related characteristics, which also include, among others, internal reproductive organs, external genitalia, chromosomes, hormones, and secondary sex characteristics.

38. In their reports, Defendants' designated experts state repeatedly that sex is binary and conditions of sexual differentiation are not a "third sex." This simplistic view, however, ignores that there is great variance among the multiple sex-related characteristics that a person possesses, including gender identity, and that such

variance is a natural phenomenon with biological underpinnings. While conditions of sexual differentiation (i.e., intersex conditions) are not a "third sex," they are indicative of the natural variance regarding certain sex-related characteristics. These are rare conditions with an estimated aggregate incidence of 0.1- 0.5% of live births (Arboleda, et al., 2013). What is more, many people cannot make either eggs or sperm, yet are recognized as female or male based on other sex-related characteristics.

39. Every person has a gender identity and it is not a personal decision, preference, or belief. A transgender boy cannot simply turn off his gender identity like a switch, any more than a nontransgender boy or anyone else could.

40. Living in a manner consistent with one's gender identity is critical to the health and wellbeing of any person, including transgender people.

41. The lack of evidence demonstrating that gender identity can be altered, either for transgender or for nontransgender individuals, further underscores the innate nature and immutability of gender identity. Past attempts to "cure" transgender individuals by using talk therapy, and even aversive therapy, to change their gender identity to match their birth-assigned sex were ineffective and caused extreme psychological damage.

42. A recent study found that experiencing those conversion efforts was associated with greater odds of attempting suicide, especially for those had those

experiences in childhood (Turban, et al., 2020b). That conclusion is further supported by the extensive evidence that rejection of a young person's gender identity from family and peers are the strongest predictors for adverse mental health outcomes. Every leading medical and mental health organization has issued clear statements that those practices are discredited, harmful, and ineffective, including the American Medical Association (2022), the American Psychiatric Association (2018), the American Academy of Child & Adolescent Psychiatry (2018), the American Psychological Association (2021), and the American Academy of Pediatrics (Rafferty, et al., 2018), among others.

43. Dr. Levine notes in his report "it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child." (Levine Report, at ¶50). This characterization mischaracterizes gender affirming therapy and calls into question his understanding of conversion efforts in the context of pre-pubertal youth. Within the model of gender affirming care, challenging assumptions based on stereotypes of gender and encouraging a child to build nuance around identity is inherent to the process of care. However, what Dr. Levine seems to be arguing for is not to encourage a psychotherapeutic process that helps a child come to a clear and nuanced sense of self, whatever the gender identity may be, but instead recommending a psychotherapeutic intervention that privileges a non-transgender identity as inherently preferred. While Dr. Levine focuses much of his report on

children who desist during puberty, inherent in the literature on desistance includes the substantial portion of prepubertal youth who persist in a transgender identity through puberty and into adulthood. By foreclosing the possibility of a healthy transgender identity and instead encouraging these transgender youth who will persist into transgender adults to strive towards a cisgender outcome, as Defendants and their experts argue, one is, by definition, practicing conversion therapy.

44. There is no one way by which people experience their gender identity development from early questioning to consolidation and affirmation. Though it is common for transgender youth to come out at puberty, for other transgender persons this is not true, and it may take them longer to come to recognize and acknowledge their gender identity. For the latter group, this is not due to some "late onset" of dysphoric feelings or sudden understanding themselves as transgender, it is the result of a long and difficult process toward accepting and understanding themselves in a social context where being transgender is still a difficult reality due to external stigma, fears of family and social rejection, and even internalized transphobia (Pullen Sansfaçon, et al., 2020).

45. Dr. Levine, Dr. Kaliebe, and Defendants' other designated experts devote a great deal of space to discussing a theory that an increasing number of people who are assigned female at birth are suddenly identifying as males in mid-to-late adolescence as a result of peer pressure and social contagion. (*See*, *e.g.*, Levine

Report, at ¶¶ 38, 96; Kaliebe Report, at ¶¶30-31, 40-43; Laidlaw Report, at ¶29; Hruz Report, at ¶¶ 117, 131). The theory that some adolescents experience "rapid-onset gender dysphoria" as a result of social influences is based almost exclusively on one highly controversial study (Littman, 2018). Although purporting to provide a basis for Dr. Levine's speculations, the study was based on an anonymous survey, allegedly of parents, about the etiology of their child's gender dysphoria. Participants were recruited from websites promoting this social contagion theory, and the children were not surveyed or assessed by a clinician. Those serious methodological flaws render the study meaningless. The only conclusion that can be drawn from that study is that a self-selected sample of anonymous people recruited through websites that predisposed participants to believe transgender identity can be influenced by social factors do, in fact, believe those social factors influence children to identify as transgender.[1]

46. Dr. Kaliebe seems to argue that the fact that transgender adolescents find other transgender adolescents online is proof of a "social contagion." He cites to no scientific study to support this speculation, other than Littman study discussed above. But Dr. Kaliebe ignores that online spaces often provide a safe place for transgender youth to come out and be themselves, allowing them to explore their

[1] Aside from these serious methodological flaws, Littman's hypothesis of "rapid onset gender dysphoria" focuses specifically on gender dysphoria in boys who are transgender and were assigned a female sex at birth.

identity. This is no different from a host of other affinity-type groupings one can find on social media. Just like many other minoritized youth, adolescents often search out groups that share core characteristics. Dr. Kaliebe's assertion that social media is a leading cause of the increased prevalence of transgender identifying youth is not demonstrated in the extant literature, and it is also beside the point. Part of an assessment of gender dysphoria includes an inquiry into the social context of the patient – this includes online spaces and potential positive and negative reinforcing factors, including social group status online. This also includes assessing for the concerns Dr. Kaliebe describes that assigned females at birth often face at puberty.

47. Notwithstanding the above, Dr. Kaliebe goes on to assert that "psychiatrists believe social media has significantly contributed to the rise in gender dysphoria." In support thereof, Dr. Kaliebe references conversations as his evidence and further asserts that "most child psychiatrists admit to me they will not speak publicly on this subject due to how sensitive the topic is." But such anecdotal evidence is not the type of evidence one would look to in answering scientific question nor whether a particular form of care is experimental or investigative. (Kaliebe Report, at ¶41). Dr. Kaliebe then cites not one but two unscientific polls of attendees to a particular session at a conference as support for the bold assertion that such data "confirm[] that the vast majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in

gender dysphoria." But this is not how scientific study is conducted in medicine. There is no plausible basis for Dr. Kaliebe to extrapolate the poll results of an unscientific survey of attendees to a panel as proof that a "majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in gender dysphoria." To the contrary, what Dr. Kaliebe is doing can hardly be considered science and illustrates how D. Kaliebe does not understand what selection bias is nor what a study is.

C. Gender Dysphoria and Its Diagnostic Criteria

48. The term "gender dysphoria" is the distress related to the incongruence between one's gender identity and one's sex assigned at birth.

49. Gender dysphoria is the clinical diagnosis for the significant distress that results from the incongruity between one's gender identity and sex assigned at birth. It is a serious medical condition, and it is codified in the American Psychiatric Association's in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022).

50. The DSM-5 defines gender dysphoria as a: "marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. In children, the desire to be of the other gender must be present and verbalized. This condition causes clinically

significant distress or impairment in social, occupational, or other important areas of functioning."

51. The DSM-5 also states that: "gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of the other gender."

52. "Gender Dysphoria in Children" is a diagnosis applied only to pre-pubertal children in the DSM-5. The DSM-5 has a separate diagnosis of "Gender Dysphoria in Adolescents and Adults." The diagnostic criteria for these diagnoses are distinct. Understanding that children have less capacity to articulate abstract concepts about the sense of self as well as a reflection of what can be a lack of specificity of gender nonconforming behaviors in childhood, there are more nuanced criteria to make the diagnosis for children. Furthermore, prepubertal youth are not eligible for medical or surgical intervention while the diagnosis of gender dysphoria in adolescents/adults is required for medical and/or surgical treatments,

53. Simply being transgender or gender diverse is not a medical condition or pathology to be treated. As the DSM-5 recognizes, diagnosis and treatment are "focus[ed] on dysphoria as the clinical problem, not identity per se." (DSM-5, at 451). The DSM-5 unequivocally repudiated the outdated view that being transgender is a pathology by revising the diagnostic criteria (and name) of gender

dysphoria to recognize the clinical distress as the focus of the treatment, not the patient's transgender status.

54. When untreated, gender dysphoria can cause significant distress including increased risk of depression, anxiety, and suicidality. This is noted both in adolescents and adults. However, these risks decline when transgender individuals are supported and live according to their gender identity. Not only is this documented in scientific literature and published data, but I witness this each time I see my patients being supported by their community, family, school, and medical providers.

D. The Guidelines for the Treatment of Gender Dysphoria Are Evidence-Based.

55. The World Professional Association of Transgender Health (WPATH) has issued Standards of Care for the Health of Transgender and Gender Diverse People ("WPATH Standards of Care") since 1979. The current version is SOC 8, published in 2022. The WPATH Standards of Care provide guidelines for multidisciplinary care of transgender individuals, including children and adolescents, and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated, for adolescents and adults.

56. The SOC 8 is based upon a rigorous and methodological evidence-based approach. (Coleman, et al., 2022). Its recommendations are evidence-based,

informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus via a Delphi procedure. The process for development of SOC 8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

57. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guidelines) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al., 2017).

58. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

59. Each of these guidelines also provides distinct guidance for age-appropriate care for children, adolescents, and adults with gender dysphoria. And none of these guidelines recommend medical treatment for prepubertal children, meaning no medical treatment is recommended until after the onset of puberty.

60. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guidelines are endorsed and cited as authoritative by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics,

the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others.

E. Assessment and Treatment of Gender Dysphoria in Children

61. Defendants' experts spend substantial portions of their expert reports to criticizing gender-affirming care for prepubertal transgender children. For example, according to Dr. Levine, studies have indicated that gender dysphoria in prepubertal gender diverse children may desist by the time the children reach puberty, and thus medical professionals should adopt a "watchful waiting" approach and avoid affirming a prepubertal child's gender identity.

62. However, with regards to prepubertal gender diverse children, the Standards of Care state that prepubertal gender diverse children "are not eligible to access medical intervention," and therefore focuses on developmentally appropriate psychosocial practices. However, this case concerns coverage of medical treatment, namely, puberty delaying medications, hormones, and surgery, and none of those treatments are recommended for transgender youth until *after* the onset of puberty (i.e., until adolescence), and even then it is only a subset of those, when it is medically necessary, age appropriate, and the legal caregivers consent.

63. As such, many of Dr. Levine's and Defendants' other designated experts' litany of criticisms is largely irrelevant to the population of people affected

by the Challenged Exclusion. For example, a significant number of Dr. Levine's and Defendants' other designated experts' arguments relate to prepubertal children who "desist" from expressing a transgender identity once they reach puberty. While the statements being made about this population are erroneous, they are also largely irrelevant.

64. That said, to avoid any confusion, I address some of Dr. Levine's and Defendants' other designated experts' arguments pertaining to transgender youth prepubertal here.

65. As with all health care, treatment of prepubertal gender diverse children is individualized based on the needs of the child and the family and other psychosocial considerations and is decided upon only after a discussion of possible benefits and risks (Hidalgo, et al., 2013). As part of those discussions, the child and their family are advised that prepubertal gender diverse children do not always go on to identify as transgender when they reach adolescence, and that children are encouraged to continue developing an understanding of their gender identity without expectation of a specific outcome even after social transition takes place (American Psychological Association, 2015; Edwards-Leeper and Spack, 2012).

66. The term "gender diverse" includes transgender children as well as children who will ultimately not identify as transgender later in life (Coleman, et al., 2022).

67. Dr. Levine and Defendants' other designated experts present a caricatured description of prevailing standards of care that reflects a profound misunderstanding of the subject with respect to prepubertal gender diverse children. Mental health providers cannot change a prepubertal child's gender identity or prevent them from being transgender, just as mental health providers cannot change a cisgender child's gender identity. Furthermore, it is far from the standard of care for clinicians to blindly support a child's potential social transition without careful assessment and a thorough discussion of the risks, benefits and alternatives of this intervention.

68. Prepubertal children who "desist" are children with nonconforming gender expression who realize with the onset of puberty that their gender identity is consistent with their sex assigned at birth. Their understanding of their gender identity changes with the onset of puberty, but their gender identity does not. We cannot definitively determine which prepubertal children will go on to identify as transgender when they reach adolescence, but we know that children with gender dysphoria who persist into puberty are more likely to have expressed a consistent, persistent, and insistent understanding of their gender identity from a young age (Steensma, et al., 2013).

69. The focus of gender-affirming care and SOC 8 is thus in supporting the overall health and wellbeing of the child. In this manner, the primary goal of

gender-affirming care is to help a child understand their own gender identity and build resilience and mental wellness in a child and family, without privileging any one outcome over another.

70. Important considerations in deciding whether social transition is in a child's best interest include: whether there is a consistent, stable articulation of a gender different from the child's sex assigned at birth, which should be distinguished from merely dressing or acting in a gender non-conforming manner; whether the child is expressing a strong desire or need to transition; the degree of distress the child is experiencing as a result of the gender dysphoria; and whether the child will be emotionally and physically safe during and following transition (Coleman, et al., 2022; American Psychological Association, 2015).

71. A treatment plan is informed by a psychosocial assessment, which may vary greatly depending on the patient's presentation and the complexity of the issues the patient is navigating. Further, in conducting that assessment, the mental health provider is drawing from their professional training and experience in working with transgender young people, exercising professional judgment, and tailoring the assessment to each individual patient.

72. There is also no requirement that prepubertal children who socially transition receive mental health therapy. Many prepubertal children who express a gender identity different from their sex assigned at birth do not experience any co-

occurring conditions or other psychological distress requiring treatment (Coleman, et al., 2022; de Vries, et al., 2011a). Mental health therapy may be useful for some prepubertal children but is not necessary or appropriate for everyone. Forcing children to undergo therapy when it is not medically indicated is both harmful and unethical.

73. What makes gender-affirming care "gender affirming" is that it does not presume that being transgender is incompatible with a young person's short- and long-term health and wellbeing. It is also important to note that clinicians utilizing gender affirming care do not assume that all children asserting a gender identity incongruent with their sex assigned at birth are inherently transgender. A clinician doing a careful assessment and recommending a child not socially transition or an adolescent not pursue medical care is fully aligned with this treatment paradigm.

74. Dr. Levine and Defendants' additional designated experts seem to think social transition is a single decision that irrevocably alters a child's trajectory over time. This belief belies their lack of clinical experience in working with gender diverse pre-pubertal youth. Clinically, social transition is often a series of steps taken gradually with feedback from the child, the family, and the clinician elicited over time. It is false that allowing prepubertal transgender children to socially transition puts these children on a path to becoming transgender adolescents and adults. Rather, the evidence shows that the same prepubertal children who are likely to have

a stable transgender identity into adolescence are the children who are most likely to articulate a strong and consistent need to socially transition (Steensma, et al., 2013). For example, a recent study found that a group of transgender children who transitioned before puberty and a group of transgender children who waited to transition until after puberty both showed the same intensity of cross-gender identification. In other words, socially transitioning before puberty did not increase children's cross-gender identification, and deferring transition did not decrease cross-gender identification (Rae, et al., 2019).

75. Intense cross-gender identification and a strong, persistent desire to transition is simply an indicator that a child is more likely to be transgender and not merely gender nonconforming.

F. Assessment and Treatment of Gender Dysphoria in Adolescents

76. WPATH SOC 8 recommends that health care professionals working with transgender and nonbinary adolescents be licensed, hold a postgraduate degree in relevant clinical field, have received training and developed expertise in working with children and adolescents, and have received training and developed expertise in gender identity and diversity in youth and in the ability of youth to assent/consent to care (Coleman, et al., 2022).

77. The Standards of Care also recommend a "comprehensive biopsychosocial assessment" for adolescents "prior to any medically necessary

medical or surgical intervention" for gender dysphoria. The assessment should include gender identity development, social development and support, diagnostic assessment of co-occurring mental health or developmental concerns, and capacity for decision-making (Coleman, et al., 2022). So do the Endocrine Society Guidelines (Hembree, et al., 2017).

78. Defendants' experts point to the rates of co-occurring psychiatric diagnoses among youth presenting with gender identity concerns. But not only are some of these co-occurring diagnoses, like anxiety and depression, often associated with dysphoria, but because youth experiencing gender identity concerns present for care before mental health providers more often, it is easier to diagnose other co-occurring diagnoses that would otherwise often go undiagnosed. In any event, it is precisely because of these co-occurring mental health diagnoses that specialized training is required to do a comprehensive biopsychosocial assessment that takes into account the possibility of diagnoses that may lead a child to experience confusion around gender identity that is inconsistent with a diagnosis of gender dysphoria. However, once properly assessed and the other conditions are properly managed, the presence of these diagnoses is not a contraindication to provide medical care to adolescents with gender dysphoria.

79. For transgender adolescents, the onset of puberty is often a painful and sometimes traumatic experience that brings increased dysphoria and the

potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality. It is notable that Dr. Levine acknowledges that many transgender adults have derived significant benefit from gender affirming medical and surgical care but fails to recognize that all transgender adults were once adolescents and that much of the stigma faced by transgender adults that he recognizes as a source of distress and dysfunction would be avoided had they had access to this care during adolescence.

80. Some transgender people who do not come forward until adolescence may have experienced symptoms of gender dysphoria for long periods of time but have been uncomfortable disclosing those feelings to parents. Other transgender people do not experience distress until they experience the physical changes accompanying puberty. In either case, gender-affirming care requires a comprehensive assessment and evidence of persistent, sustained gender dysphoria before medical treatment is recommended.

81. Gender-affirming treatment also requires a careful and thorough assessment of a patient's mental health, including co-occurring conditions, history of trauma, and substance use, among many other factors (Olson-Kennedy, et al., 2019; Edwards-Leeper and Spack, 2012). As a result, I have had patients who presented with some symptoms of gender dysphoria, but who ultimately did not meet

the diagnostic criteria for a variety of reasons, and therefore I recommended treatments other than transition to alleviate their psychological distress. I have also seen patients that did meet the diagnostic criteria for gender dysphoria but had mental health impairments that precluded proceeding with gender affirming hormonal and surgical care.

82. Studies on transgender young people have long reported data on co-occurring conditions, including some of my own (e.g., Janssen, et al., 2019; Olson, et al., 2015; Reisner, et al., 2015; Spack, et al., 2012; Mustanski, et al., 2010).

83. The existence—and prevalence—of co-occurring conditions among transgender young people is unsurprising. Transgender young people must cope with many stressors, from the fear of rejection by family and peers to pervasive societal discrimination. Not to mention, their underlying gender dysphoria can cause significant psychological distress which, if left untreated, can result in or exacerbate the co-occurring conditions identified in studies on transgender young people (van der Miesen, et al., 2020; Turban, et al., 2021). And, given that transgender young people typically delay disclosing their transgender status or initially experience family rejection following disclosure, it is not uncommon for transgender young people to engage with psychological or psychiatric care for other reasons prior to being diagnosed with gender dysphoria.

84. Transgender young people, however, are not outliers in this regard. Research and clinical experience show that most psychiatric conditions are highly correlated with other co-occurring psychiatric conditions. For example, young people with depression are very likely to have at least one other diagnosable condition, most often anxiety (Costello, et al., 2003). Likewise, a study on children diagnosed with Attention-Deficit/Hyperactivity Disorder found between 74-79% participants had additional co-occurring psychiatric conditions (Wilens, et al., 2002).

85. Requiring that a transgender patient resolve all co-occurring conditions, many of which are chronic with no reasonable expectation that they be "resolved," prior to receiving gender-affirming care is not possible, nor is it ethical. No relevant organizations cite the need for co-occurring mental health conditions to be resolved before a patient may receive gender-affirming care. Rather, such conditions should be reasonably well-controlled and not impair the ability of the patient to make an informed decision or interfere with the accuracy of the diagnosis of gender dysphoria. Indeed, some co-occurring conditions (for example, Attention Deficit Hyperactivity Disorder and Autism Spectrum Disorder, to name a few) could be chronic disorders where complete resolution is impossible and the goal of treatment is mitigating harm and improving functioning.

86. WPATH SOC 8 recommends that "mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-

affirming treatment before gender-affirming treatment is initiated," but note that "mental health symptoms such as anxiety or depressive symptoms that do not affect the capacity to give consent should not be a barrier for gender-affirming medical treatment, particularly as this treatment has been found to reduce mental health symptomatology" (Coleman, et al., 2022). Indeed, SOC 8's chapter on adolescents specifically notes that "while addressing mental health concerns is important during the course of treatment, it does not mean all mental health challenges can or should be resolved completely" (Coleman, et al., 2022).

87. The Endocrine Society Guidelines similarly provide that because gender dysphoria "may be accompanied with psychological or psychiatric problems," "in cases in which severe psychopathology" "interfere[s] with diagnostic work or make[s] satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues" (Hembree, et al., 2017). The Guidelines thus require that these issues be managed, not resolved.

88. Gender dysphoria, by definition, is accompanied by clinically significant psychological distress. That distress can take on many different forms (e.g., anxiety, mood disorders, and depression) and vary greatly in severity, resulting in co-occurring conditions. Because psychological distress is not easily compartmentalized, the distress associated with gender dysphoria can also amplify co-occurring conditions that developed independently of the gender dysphoria. In

either situation, gender dysphoria limits the effectiveness of treatment of any co-occurring mental health conditions. Thus, treating the underlying gender dysphoria is essential to alleviating the psychological distress associated with co-occurring conditions.

G. Efficacy of Gender-Affirming Treatment for Gender Dysphoria in Adolescents

89. "For some youth, obtaining gender-affirming medical care is important while for others these steps might not be necessary." (Coleman, et al., 2022). In my clinical experience, some adolescent patients have a critical need for medical interventions at or at some point after the onset of puberty and others do not. As with all medical interventions, it is highly individualized and responsive to the particular medical and mental health needs of each patient as well as the understanding and preferences of the legal guardians who ultimately make these healthcare decisions.

90. The criticisms of gender-affirming care for adolescents by Dr. Levine and Defendants' other designated experts reflect a distorted interpretation of the relevant scientific literature and what gender-affirming care is. Despite Dr. Levine's and Defendants' other designated experts' suggestion to the contrary, there is no "watchful waiting" approach for transgender adolescents. Even practitioners who oppose social transition in childhood provide gender-affirming care for transgender

adolescents, including puberty-delaying medication and gender-affirming hormone treatments for gender dysphoria (Turban, et al., 2018; Ehrensaft, 2017).

91. Dr. Levine and Defendants' other designated experts criticize the methodology of studies supporting gender-affirming care while proposing a "therapy only" treatment without any empirical or scientific support whatsoever. They also fail to understand that not all patients in a gender-affirming model of care will initiate medical or surgical care. The difference is that in the affirming care model, those decisions are made in concert with the young person and their family.

92. Adolescents with gender dysphoria who have entered puberty may be prescribed puberty-delaying medications (GnRHa) to prevent the distress of developing permanent, unwanted physical characteristics that do not align with the adolescent's gender identity. Puberty-delaying medications allow the adolescent time to better understand their gender identity, while delaying distress from the progression of the development of secondary sex characteristics such as breasts or facial hair.

93. Prior to initiation of puberty-delaying medications, providers counsel patients and their families extensively on potential benefits and risks. The intended benefit of treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. More specifically, use of puberty-delaying medications in transmasculine adolescents allows for decreased chest development, reducing the

need for breast binding and surgical intervention in adulthood. For transfeminine adolescents, puberty-delaying medications limit facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery. The goal in using puberty-delaying medications is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. The pubertal stage and individual needs of the patient direct conversations regarding care options.

94. A growing body of evidence, including peer-reviewed cross-sectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in adolescents with gender dysphoria on psychological functioning and quality of life, including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning (e.g., Achille, et al., 2020; Turban, et al., 2020a; van der Miesen, et al., 2020; Costa, et al., 2015; de Vries, et al., 2011b). Furthermore, studies show improvements in body satisfaction with gender-affirming treatment, and the extant literature recognizes that the body satisfaction is a mediator for improved quality of life and mental health outcomes. (Chen, et al., 2023).

95. In my own practice, I have had patients describe pubertal suppression as life saving and a vast majority have experienced a great deal of relief when the treatment is initiated. In contrast to Dr. Levine's assertion that starting pubertal suppression is a one-way road to hormones, I have also had patients who, through gender affirming psychotherapy, came to understand their gender identity to be congruent with their sex assigned at birth and discontinued this treatment with a resumption of puberty. While each patient and each family is unique, a thorough assessment and a clear discussion of the risks, benefits and alternatives of this interventions is consistent among all of my patients.

96. After ongoing work with mental health professionals and when the adolescent has lived in accordance with their gender identity for a significant period of time, they may start treatment with hormones (testosterone for transgender boys, estrogen and testosterone suppressants for transgender girls), if and when medically indicated.

97. There is no credible basis for Dr. Levine's assertion that an adolescent's decision to begin puberty-blocking medication "act[s] as a psychosocial 'switch,' decisively shifting many children to a persistent transgender identity." (Levine Report, ¶133). Studies showing that a high percentage of transgender adolescents who receive puberty blockers ultimately decide to move forward with gender-affirming hormone therapy more likely reflect the fact that participants were

rigorously screened and had demonstrated sustained, persistent gender dysphoria before receiving medical treatment.

98. Eligibility and medical necessity are determined case-by-case, based on an assessment of the adolescent's unique cognitive and emotional maturation and ability to provide a knowing and informed assent in addition to the informed consent of the legal medical decision maker, most often the parent or guardian. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy.

99. Under SOC 8 and the Endocrine Society Clinical Guidelines, hormone therapy is an appropriate treatment for transgender adolescents with gender dysphoria when the experience of dysphoria is marked and sustained over time, the adolescent demonstrates emotional and cognitive maturity required to provide and informed consent/assent for treatment, other mental health concerns (if any) that may interfere with diagnostic clarity and capacity to consent have been addressed, and the adolescent has discussed reproductive options with their provider. SOC 8 also highlights the importance of involving parent(s)/guardian(s) in the assessment and treatment process for minors (Coleman, et al., 2022; Hembree, et al., 2017).

100. As with puberty-delaying medications, the risks and benefits of hormone treatment are discussed with the patient and their families, prior to initiation of gender affirming hormone therapy.

101. And, as with the use of puberty-delaying medications, treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria and withholding treatment from those who need it is harmful (e.g., Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020).

102. In my own practice, I have seen youth with severe gender dysphoria who avoided all social contacts who were able to thrive with the initiation of gender affirming hormones and feel confident with the changes seen as they developed secondary sex characteristics aligned with their gender identity. I have seen my patients start hormones and find themselves more able to build social and romantic relationships, and begin to address underlying co-occurring psychiatric disorders.

103. For some older transgender adolescents, surgery may be provided prior to age 18 if medically indicated (typically, chest surgery for transgender male adolescents). Peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery for transgender males with gender dysphoria where medically indicated (Mehringer, et al., 2021; Olson-Kennedy, et al., 2018).

104. As part of the treatment process for gender dysphoria, adolescent patients provide assent to their care, while their parents or guardians provide informed consent. In addition, a treating doctor will not offer gender-affirming medical treatments unless they have concluded after weighing the risks and benefits of care for the specific patient that treatment is appropriate. The risks and benefits of care are discussed with the adolescent patient and their family. This process is no different than the informed consent process for other medical treatments. However, for gender-affirming medical care, there is the additional safeguard of the recommended assessments by a mental health care professional, who must not only be experienced in the assessment of gender dysphoria, but also in the assessment of a patient's capacity to consent/assent to treatment and ability to understand the risks and benefits of treatment. Indeed, SOC 8 notes that mental health professionals are the best positioned practitioners to conduct these assessments for adolescents and also recommends that a mental health professional address any mental health issues that may interfere with a patient's ability to consent prior to the initiation of gender-affirming care.

105. Dr. Levine and Dr Kaliebe fail to discuss many of the studies documenting the benefits of puberty-delaying medication and gender-affirming hormone therapy (Chen, et al., 2023; de Vries, 2023). When viewed as a comprehensive body of research, the weight of the evidence and the experience of

clinicians as well as from the experience of patients has demonstrated that puberty-delaying medication and hormones have been associated with a variety of mental health benefits across different contexts (Chen, et al., 2023).

106. Dr. Levine and Dr. Kaliebe also criticize the quality of evidence supporting treatment of gender dysphoria. (*See*, *e.g.*, Levine Report, at ¶¶136-141; Kaliebe Report, at 45-70). But treatments for gender dysphoria have the same or similar level of evidentiary support as many other well-established treatment protocols in psychiatry—and other disciplines of medicine. The evidentiary basis for those treatment protocols is developed, and regularly updated, using a combination of peer-reviewed research and the extensive clinical experience of providers who regularly treat patients with that condition. Those treatment protocols are considered the standard of care and are safe and effective for the conditions they are intended to treat.

107. Dr. Levine also suggests that the lack of FDA approval of gender-affirming medical treatments for these specific uses indicates that the treatments are not supported by evidence of safety. (*See*, *e.g.*, Levine Repport, ¶179). But off-label use of medication is common in medicine, especially treatments for children and adolescents. For example, in children, Zoloft is FDA approved to treat Obsessive-Compulsive Disorder, but is also regularly used to treat depression and anxiety, such that the use of Zoloft is considered the standard of care for children who require

medication to treat those conditions despite the lack of FDA approval for those indications.

108. In their reports, Dr. Levine and Dr. Kaliebe present a distorted picture of the gender affirming model of care where they imply that gender-affirming care requires the unquestioned and automatic affirmation of an adolescent's desires. But gender-affirming medical care such as GAH is only provided to an adolescent after working with the adolescent and their parents/guardians, who are the ones who provide the informed consent. Indeed, in my practice, I have had patients with unrealistic expectations of the impact of testosterone or estrogen including on a belief that initiation of gender affirming medical care would eradicate any co-occurring psychiatric disorders despite many of these being chronic and predating any symptoms of gender dysphoria. But in accordance with SOC 8 and Endocrine Society Guidelines, the gender-affirming model of care requires that these patients be provided with additional psychotherapy and psychoeducation to determine the appropriateness of moving forward, and for some of these youth a delay in initiation of hormones, or even potentially a recommendation to not pursue hormones, is aligned with the gender affirming model of care.

H. Assessment and Treatment of Gender Dysphoria in Adults

109. In the DSM-5, the diagnostic criteria for Gender Dysphoria are shared by adolescents and adults. The assessment and treatment of a gender dysphoric adolescent is very similar to the assessment of the gender dysphoric adult.

110. As with any condition that typically presents with symptoms in childhood or adolescence, collateral information from caregivers, partners, employers, etc. is often useful in informing the initial diagnostic assessment. For children and adolescents, the legal structures of consent and assent as well as best practice and ethics of care require parental involvement in ongoing mental health care, and standard practice is to gather history of the child from the parent and guardian. For adults, the individual patient can make decisions about whom they want involved in their care. That said, the assessment process of gathering a detailed history and developing a biopsychosocial assessment takes the same factors into account as one does with adolescents. And similar to adolescents, the risks, benefits and alternatives to social transition, hormonal care and surgical options are weighed in collaboration with the patient prior to making any recommendations. The evidence supporting this process of assessment and care is documented in the plaintiffs' experts' reports.

111. Despite that the Challenged Exclusion impacts the ability of both adolescent and adult Medicaid beneficiaries to get coverage, and therefore get

access, to medical treatment for gender dysphoria, neither Drs. Levine nor Kaliebe address the impact of losing access to medical care for transgender adults in the state of Florida. This same flaw characterizes all of the defendants' designated experts' reports, as well as the GAPMS Memo itself.

112. Their reports focus primarily on pre-pubertal youth, which are not subject to this ban, and seek to call into question practices in assessing and treating transgender adolescents. This report seeks to rebut their mischaracterization of the current standard of care for transgender adolescents as well as the mischaracterization of the current standard of care for transgender adults. However, neither expert in their report sought to undermine the evidence base for the treatment of transgender adults and Dr. Levine even acknowledges the benefit of hormonal and surgical care for some adults.

I. Additional Responses to Defendants' Designated Experts

113. In his report, Dr. Kaliebe states that the Chen et al. study did not address the suicides in the study population and that "the most research shows a much higher than expected rate of suicide in the condition of affirmative hormone treatment." (Kaliebe Repport, at ¶70). This is not true. For one, the Chen et al. study looked at the study population at baseline (pre-intervention), which shows that 66% endorsed lifetime suicidal ideation; 29% endorsed lifetime suicidal ideation with a plan, and a full 25% had reported having already had at least one suicide attempt prior to

engaging in care. This is not much different from the suicide completion rate in the Ghent clinic (5/235) compared to the NIH 4 site (2/315). For another, Dr. Kaliebe compares the study population in Chen et al. to apparent suicides of transgender youth purportedly associated with the Gender Identity Development Service (GIDS) in the United Kingdom. For these numbers, Dr. Kaliebe cites to a letter to the editor from a sociologist, not a peer-reviewed study or a letter from someone experienced in this care. But two of the GIDS youth never saw a doctor for gender-affirming care, and there is no evidence the two others were receiving care. What is more, even the letter to the editor Dr. Kaliebe cites states: "One final caveat is that these data shed no light on the question of whether counseling or endocrinological interventions—gonadotropin-releasing hormone agonist or cross-sex hormones—affect the risk of suicide." (Biggs, 2022).

114. Defendants' designated experts, including several who are not mental health professionals, continue to misconstrue the practice of psychiatry and misunderstand what occurs in a mental health assessment. They indicate that mental health clinicians believe without scrutiny what a patient is telling them on face value. In fact, mental health professionals are trained to assess not just the words being said, but also to recognize behaviors, gather collateral data from other informants, and assess the meaning of the inherent disparities between these various data points to help understand the patient's experience. These assessments require training and

skill which the non-mental health providers lack. As an example, it is not uncommon for a patient to deny suicidal intent despite having clear risk factors – this denial occurs even after some have been discovered post-suicide attempt. To argue that highly trained clinicians simply believe everything a patient says is a farce. Furthermore, many of the defendants' experts attempt to invalidate Gender Dysphoria, as well as nearly all psychiatric diagnoses because these diagnoses rely on a patient's description of their symptoms to make the diagnosis. Every mental condition, and many physical conditions, rely on the patient's self-expressed disclosure of phenomenology. Do migraines not exist because they require patient self-report? Is depression not a cause of disability unless there is a blood test to diagnose it? Did auto-immune encephalitis not exist as a phenomenon until the antibody test was developed? Mental health providers, as well as all physicians rely on patient reports of symptoms and an exercise of independent judgment based on training and experience to make a diagnosis.

115. Dr. Kaliebe criticizes AACAP for purportedly being inconsistent about the capacity of minors, suggesting there is a discrepancy between their arguments protecting adjudicated youth vis-à-vis the ability of transgender youth to obtain care. But this criticism has no basis and is more indicative of Dr. Kaliebe's lack of experience and familiarity with this field. In its amicus brief, AACAP argued the U.S. Supreme Court should have taken adolescents' mental capacity into account

when evaluating the question of whether adjudicated youth should be sentenced to life without the possibility of parole. Not only is the context of gender-affirming medical care entirely inapposite, but in such context, adolescents do not make decisions on their own. In order to access gender-affirming medical care, the adolescents work in conjunction with their parents/legal guardians and their doctors. And while adolescents provide assent to care, it is their parents/legal guardians who provide consent.

116. There appears to be a consistent lack of understanding of the consent process for pediatric medical care among the defendants' designated experts. This is most starkly demonstrated in Dr. Hruz's report. In his report, he highlights many potential reasons why adolescents may be unable to provide consent to gender affirming care. However, he neglects to understand that minors do not consent to gender affirming care. Parents/legal caregivers and at time the state maintain the capacity to consent on behalf of the adolescent, who depending on their age may provide assent. While his arguments are spurious, they are also irrelevant to the matter at hand.

117. Furthermore, there are also misstatements about the impact of psychiatric diagnoses on the capacity to consent. In Dr. Hruz's report, he notes "individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weigh

proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria." (Hruz Report, at ¶ 103). His reference justifying this sentence is an ethics analysis of participation in clinical research not in clinical care, and makes no reference to "psychological abilities criteria," which may sound official but has no bearing on evidence-based assessments of capacity to consent. Dr. Hruz further mischaracterizes Helmchen's paper which speaks specifically about excluding patients with "suicidal intentions" which is a separate phenomenology than clinical depression.

118. Similarly, Dr. Lappert reports "as is known by all surgeons, it is considered imprudent to obtain informed consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm, or to suicidal ideation." (Lappert Report, at ¶69). This uncited assertion is drawn from ignorance about the capacity to consent to care for psychiatric patients. First, capacity to consent is specific to the intervention at hand. While a patient with suicidal ideation may lack capacity to end life-saving medical care, they may still retain capacity to consent to an appendectomy. To assume that all patients with psychiatric illness lack capacity to consent across all contexts is both unfounded and unethical.

119. Even in the context of clinical research, when the question of retention of capacity is actually studied as opposed to assumed it is of concern, individuals with both severe depression and schizophrenia demonstrate relatively high-decision

making capacity as measured by the MacArthur Competence Assessment Tool-Clinical Research (Cohen, et al., 2004).

120. Dr. Kaliebe makes an assertion that medical academies are delegitimizing and politicizing care by convening expert committees to advise the organization on a topic. But this is well within the norms of academic medicine and speaks to a wish to be informed by experts in the field; it is not evidence of malfeasance. Speaking from personal experience as a member of several committees on transgender health, professional disagreements and debates about approaches, practices and priorities for care and research are commonplace, and dissenting opinions are welcomed, particularly when informed by their own expertise and a fair review of the literature.

121. Dr. Laidlaw makes many of the same mistakes about consent as the other experts, namely mistaking that children consent to gender affirming medical and surgical care. But he goes further and notes that in his opinion, even parents are unable to provide consent because the full accounting of the potential risks is, according to him, unknown. If Dr. Laidlaw's rubric were to be applied to the rest of medicine, medicine would never evolve. There are inherent unknown risks to every intervention, and it is the role of the provider to incorporate what is known and what is not known about these risks into a discussion about informed assent and informed consent. Moreover, the fact that we do not know *everything* about an intervention

does not make that intervention experimental. In medicine and in science, every day we discover something and with the advent of new techniques or investigative tools we are able to learn new information about the effects of well-established and longstanding medical interventions. None of this renders a medical intervention to be experimental.

122. Additionally, Dr. Laidlaw spends much of his report opining on the appropriateness of the psychiatric care of the patients involved in this case. However, Dr. Laidlaw is not a psychiatrist and has no authority to comment on the psychiatric care of either patient. It is unethical for him to do so.

J. Prohibiting Access to Gender-Affirming Care Harms Transgender People

123. Defendants' experts completely ignore the harms associated with prohibiting access to gender-affirming care to adolescents and adults with gender dysphoria for whom it is necessary and appropriate. They also ignore the harmful effects of governmental like the Challenged Exclusion adopted by Defendants.

124. The overarching goal of treatment for gender dysphoria is to eliminate clinically significant distress. For some, this is achieved by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender adolescents and adults not only frustrates this goal and results in the prolonging of their gender dysphoria, but also causes

additional distress and poses other health risks, such as depression, trauma, self-harm, and suicidality.

125. Defendants and their designated experts not only ignore the volumes of data showing the efficacy of gender-affirming medical care, but they also cannot deny that there are transgender adolescents that persist into transgender adults and who benefit from this care. But notwithstanding this latter undeniable fact neither Defendants nor their designated experts are interested in a nuanced discussion about prevalence, process, or technique, instead they advocate for a complete bar to the coverage of this safe, efficacious, and medically necessary care for *all* transgender adolescents and adults.

126. Lack of access to gender-affirming care therefore directly contributes to poorer mental health outcomes for transgender people (Owen-Smith, et al., 2018).

127. It is also well documented that experiencing discrimination has negative impacts on people's mental health and wellbeing. For example, a 2019 study found that experiencing discrimination in health care settings posed a unique risk factor for heightened suicidality among transgender individuals, a population already at heightened risk compared with the general population (Herman, et al., 2019). And of note, the 2022 National Survey on LGBTQ Youth Mental Health found that LGBTQ youth who had experienced discrimination based on sexual

orientation or gender identity had attempted suicide in the past year at nearly three times the rate as those who had not (19% vs. 7%) (The Trevor Project, 2022).

128. In addition, the 2022 National Survey on LGBTQ Youth Mental Health found that 93% of transgender and nonbinary youth said that they have worried about transgender people being denied access to gender-affirming medical care due to state or local laws (The Trevor Project, 2022).

129. Research has shown that the mere introduction, debate, and adoption of discriminatory laws and policies like the Challenged Exclusion negatively affects the mental health of transgender youth. A prospective study with sexual minority populations found that living in states with discriminatory policies was associated with a statistically significant increase in the number of psychiatric disorder diagnoses (Hatzenbuehler, et al., 2010). Other studies "shown that restrictive laws and policies are related to destructive health behaviors on the part of transgender individuals" (Cunningham, et al., 2022; Du Bois, et al., 2018).

130. Recent studies show the negative toll that anti-LGBTQ measures, like the Challenged Exclusion, and debates surrounding them have had on the mental health of transgender youth. For example, in a survey of youth in November 2022, 86% of transgender and nonbinary youth said that the debates about anti-transgender bills had negatively impacted their mental health (Movement Advancement Project, 2023; The Trevor Project and Morning Consult, 2023). And a study from 2022,

though with limitations, showed that the passage of anti-transgender bills is linked with Internet searches related to depression and suicide (Cunningham, et al., 2022).

131. Perhaps, more poignantly, those of us with clinical experience hear from our patients about how it feels to be targeted with this kind of legislation. As two of my transgender patients expressed to me within the past few weeks, "why does everyone hate me just for existing?" and "it's a hard time to be transgender right now."

CONCLUSION

132. By denying coverage and therefore access to necessary, safe, and effective medical care as treatment for gender dysphoria, the Challenged Exclusion endangers the mental health and well-being of transgender Medicaid beneficiaries in Florida.

133. Defendants and their designated experts, who for the most part have no experience in transgender health, not only ignore the robust evidence for the potential harm faced by transgender individuals when barred access to medically necessary gender-affirming care, but they also mischaracterize, misapprehend, and even ignore the robust body of evidence showing that gender-affirming medical care is safe, effective, and not experimental or investigational.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 9th day of March 2023.

Aron Janssen, M.D.

Exhibit A

Curriculum Vitae

Curriculum Vitae

Aron Janssen, M.D.
312-227-7783
aronjans@gmail.com

Personal Data

Born	Papillion, Nebraska
Citizenship	USA

Academic Appointments

2011-2017	Clinical Assistant Professor of Child and Adolescent Psychiatry
2011-2019	Founder & Clinical Director, NYU Gender and Sexuality Service Director, LGBT Mental Health Elective, NYULMC
2015-2019	Co-Director, NYU Pediatric Consultation Liaison Service New York University Department of Child and Adolescent Psychiatry
2017-present	Clinical Associate Professor of Child and Adolescent Psychiatry
2019-present	Vice Chair, Pritzker Department of Psychiatry and Behavioral Health Ann and Robert H. Lurie Children's Hospital of Chicago
2020-present	Medical Director, Outpatient Psychiatric Services Ann and Robert H. Lurie Children's Hospital of Chicago

Education

Year	Degree	Field	Institution
6/97	Diploma		Liberty High School
5/01	B.A.	Biochemistry	University of Colorado
5/06	M.D.	Medicine	University of Colorado

Postdoctoral Training

2006-2009	Psychiatry Residency	Ze'ev Levin, M.D.	NYU Department of Psychiatry
2009-2011	Child and Adolescent Psychiatry Fellowship – Fellow and Clinical Instructor		
		Jess Shatkin, M.D.	NYU Dept of Child/Adolescent Psychiatry

Licensure and Certification

2007-2018	New York State Medical License
2017-present	Illinois Medical License
2011-present	Certification in Adult Psychiatry, American Board of Psychiatry and Neurology
2013-present	Certification in Child and Adolescent Psychiatry, ABPN

Academic Appointments

2009-2011	Clinical Instructor, NYU Department of Child and Adolescent Psychiatry
2011-2017	Clinical Asst Professor, NYU Dept of Child and Adolescent Psychiatry
2017-2019	Clinical Assoc Professor, NYU Dept of Child and Adolescent Psychiatry
2011-2019	Clinical Director, NYU Gender and Sexuality Service
2015-2019	Co-Director, NYU Pediatric Consultation-Liaison Service
2019-present	Associate Professor of Child and Adolescent Psychiatry, Northwestern University
2019-present	Vice Chair of Clinical Affairs, Pritzker Department of Psychiatry and Behavioral Health, Lurie Children's Hospital of Chicago

Major Committee Assignments

International, National and Regional

2021-present	Sexual Orientation and Gender Identity Committee, Chair, AACAP
2019-present	WPATH Standards of Care Revision Committee, Children
2019-present	WPATH Standards of Care Revision Committee, Adult Mental Health
2015-2019	Department of Child Psychiatry Diversity Ambassador
2013-2021	Sexual Orientation and Gender Identity Committee Member, AACAP
2012-2019	Founder and Director, Gender Variant Youth and Family Network
2012-present	Association of Gay and Lesbian Psychiatrists, Transgender Health Committee
2012-2019	NYULMC, Chair LGBTQ Advisory Council
2012-2019	NYULMC, Child Abuse and Protection Committee
2013-2015	NYULMC, Pediatric Palliative Care Team
2003-2004	American Association of Medical Colleges (AAMC), Medical Education Delegate
2004-2006	AAMC, Western Regional Chair

Psychiatry Residency

2006-2009	Resident Member, Education Committee
2007-2008	Resident Member, Veterans Affairs (VA) Committee

Medical School

2002-2006	Chair, Diversity Curriculum Development Committee
2002-2006	AAMC, Student Representative
2003-2004	American Medical Student Assoc. (AMSA) World AIDS Day Coordinator
2003-2004	AMSA, Primary Care Week Coordinator
2004-2006	Chair, Humanism in Medicine Committee

Memberships, Offices, and Committee Assignments in Professional Societies

2006-present	American Psychiatric Association (APA)
2009-present	American Academy of Child and Adolescent Psychiatry (AACAP)
2011-present	World Professional Association for Transgender Health (WPATH)
2011-2019	Director, Gender Variant Youth and Family Network, NYC
2013-2019	Chair, NYU Langone Medical Center LGBTQ Council

Editorial Positions

2016-2018	Clinical Assistant Editor, *Transgender Health*
2014-present	Ad Hoc Reviewer, *LGBT Health.*
2016-present	Ad Hoc Reviewer, *JAACAP*
2018-present	Associate Editor, *Transgender Health*
2020-present	Ad Hoc Reviewer, *Pediatrics*

Principal Clinical and Hospital Service Responsibilities

2011-2019	Staff Psychiatrist, Pediatric Consultation Liaison Service
2011-2019	Faculty Physician, NYU Child Study Center
2011-2019	Founder and Clinical Director, NYU Gender & Sexuality Service
2015-2019	Co-Director, Pediatric Consultation Liaison Service
2019-present	Vice Chair, Pritzker Dept of Psychiatry and Behavioral Health
2019-present	Chief Psychiatrist, Gender Development Program

2020-present Medical Director, Outpatient Psychiatry Services

Relevant Program Development

Gender and Sexuality Service

-founded by Aron Janssen in 2011, who continues to direct the service
-first mental health service dedicated to transgender youth in NYC
-served over 200 families in consultation, with 2-3 referrals to the gender clinic per week
-trained over 500 mental health practitioners in transgender mental health – 1 or 2 full day trainings in partnership with the Ackerman Institute's Gender and Family Project (GFP) and with WPATH Global Educational Initiative (GEI)
-New hires in Adolescent Medicine, Psychology, Plastic Surgery, Urology, Gynecology, Endocrinology, Social Work, Department of Population Health with focus on transgender care has led to expansion of available services for transgender youth at NYULMC in partnership with the Gender and Sexuality Service
-development of partnerships with Ackerman Institute, Callen-Lorde Health Center – both institutions have been granted access to our IRB and have agreed to develop shared research and clinical priorities with the Gender and Sexuality Service.
-multiple IRB research projects underway, including in partnership with national and international clinics
-model has been internationally recognized

Clinical Specialties/Interests

Gender and Sexual Identity Development
Co-Occurring Mental Health Disorders in Transgender children, adolescents and adults
Pediatric Consultation/Liaison Psychiatry
Psychotherapy
-Gender Affirmative Therapy, Supportive Psychotherapy, CBT, MI

Teaching Experience

2002-2006 Course Developer and Instructor, LGBT Health (University of Colorado School of Medicine
2011-2019 Instructor, Cultural Competency in Child Psychiatry (NYU Department of Child and Adolescent Psychiatry) – 4 hours per year
2011-2019 Course Director, Instructor "Sex Matters: Identity, Behavior and Development" – 100 hours per year
2011-2019 Course Director, LGBT Mental Health Elective (NYU Department of Psychiatry) - 50 hours of direct supervision/instruction per year
2011-2019 Course Director, Transgender Mental Health (NYU Department of Child and Adolescent Psychiatry – course to begin in Spring 2018.
2015-2019 Instructor, Gender & Health Selective (NYU School of Medicine) – 4 hours per year.

Academic Assignments/Course Development

New York University Department of Child and Adolescent Mental Health Studies

-Teacher and Course Director: "Sex Matters: Identity, Behavior and Development." A full semester 4 credit course, taught to approximately 50 student per year since 2011, with several students now in graduate school studying sexual and gender

identity development as a result of my mentorship.

NYU Department of Child and Adolescent Psychiatry
-Instructor: Cultural Competency in Child and Adolescent Psychiatry
-Director: LGBTQ Mental Health Elective
World Professional Association of Transgender Health
-Official Trainer: Global Education Initiative – one of two child psychiatrists charged with training providers in care of transgender youth and adults.

Peer Reviewed Publications

1. Janssen, A., Erickson-Schroth, L., "A New Generation of Gender: Learning Patience from our Gender Non-Conforming Patients," Journal of the American Academy of Child and Adolescent Psychiatry, Volume 52, Issue 10, pp. 995-997, October, 2013.
2. Janssen, A., et. al. "Theory of Mind and the Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning Autism Spectrum
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6. Janssen A., et. al., "Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents," Journal of Child & Adolescent Psychology, 105-115, January 2018.
7. Janssen A., et. al., "A Review of Evidence Based Treatments for Transgender Youth Diagnosed with Social Anxiety Disorder," Transgender Health, 3:1, 27–33, DOI: 10.1089/ trgh.2017.0037.
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19. Busa, S., Wernick, J.,…Janssen, A. A Descriptive Case Study of a Cognitive Behavioral Therapy Group Intervention Adaptation for Transgender Youth With Social Anxiety Disorder, Behavioral Therapy, April, 2022
20. Ramsden SC, Pergjika A, Janssen AC, Mudahar S, Fawcett A, Walkup JT, Hoffmann JA. A Systematic Review of the Effectiveness and Safety of Droperidol for Pediatric Agitation in Acute Care Settings. Acad Emerg Med. May, 2022.
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23. Coleman, E., Radix, A…. Janssen, A., et. al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health, 23:sup1, S1-2259, September 2022. doiL 10.1080/26895269.2022.2100644
24. Westley, L., Richey, K.,.. Janssen, A., Using Hospital Incident Command Systems to Respond to the Pediatric Mental and Behavioral Health Crisis of the COVID-19 Pandemic, Journal of Nursing Administration, Feb 2023.

Published Abstracts

1. Thrun, M., Janssen A., et. al. "Frequency of Patronage and Choice of Sexual Partners may Impact Likelihood of HIV Transmission in Bathhouses," original research poster

presented at the 2007 Conference on Retroviruses and Opportunistic Infections, February, 2007.

2. Janssen, A., "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting, October 2012.
3. Janssen, A., "Gender Variance in Childhood and Adolescents: Training the Next Generation of Psychiatrists," 23rd Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, February 2014.
4. Janssen, A., "When Gender and Psychiatric Acuity/Comorbidities Overlap: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," AACAP Annual Meeting, October 2014.
5. Janssen, A., "Patient Experiences as Drivers of Change: A unique model for reducing transgender health disparities as an academic medical center," Philadelphia Transgender Health Conference, June 2016.
6. Janssen, A., "How much is too much? Assessments & the Affirmative Approach to TGNC Youth," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
7. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
8. Janssen, A., "Gender Variance Among Youth with Autism: A Retrospective Chart Review," Research Poster, 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
9. Janssen, A., "Gender Fluidity and Gender Identity Development," Center for Disease Control – STD Prevention Conference, September 2016.
10. Janssen, A., "Transgender Identities Emerging During Adolescents' Struggles With Mental Health Problems," AACAP Annual Conference, October 2016.
11. Janssen, A., "How Much is Too Much? Assessments and the Affirmative Approach to Transgender and Gender Diverse Youth," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
12. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
13. Sutter ME, Bowman-Curci M, Nahata L, Tishelman AC, Janssen AC, Salas-Humara C, Quinn GP. Sexual and reproductive health among transgender and gender-expansive AYA: Implications for quality of life and cancer prevention. Oral presentation at the Oncofertility Consortium Conference, Chicago, IL. November 14, 2017.
14. Janssen, A., Sidhu, S., Gwynette, M., Turban, J., Myint, M., Petersen, D., "It's Complicated: Tackling Gender Dysphoria in Youth with Autism Spectrum Disorders from the Bible Belt to New York City," AACAP Annual Conference, October 2017.
15. May 2018: "A Primer in Working with Parents of Transgender Youth," APA Annual Meeting.
16. October 2018: "Gender Dysphoria Across Development" – Institute for AACAP Annual Conference.

17. November 2018: "Gender Variance Among Youth with Autism," World Professional Association for Transgender Health Biannual Conference.
18. March 2019: "Gender Trajectories in Child and Adolescent Development and Identity," Austin Riggs Grand Rounds.
19. Janssen, A., et. al., "Ethical Principles in Gender Affirming Care," AACAP Annual Conference, October 2019.
20. Janssen, A., "Gender Diversity and Gender Dysphoria in Youth," EPATH Conference, April 2019
21. Englander, E., Janssen A., et. al., "The Good, The Bad, and The Risky: Sexual Behaviors Online," AACAP Annual Conference, October 2020
22. Englander, E., Janssen, A., et. al., "Love in Quarantine," AACAP Annual Conference, October 2021
23. Janssen, A., Leibowitz, S., et. al., "The Evidence and Ethics for Transgender Youth Care: Updates on the International Standards of Care, 8th Edition," AACAP Annual Conference, October 2021
24. Turban, J., Janssen, A., et. al., "Transgender Youth: Understanding "Detransition," Nonlinear Gender Trajectories, and Dynamic Gender Identities," AACAP Annual Conference, October 2021
25. Hoffmann JA, Pergjika, A, Liu X, Janssen AC, Walkup JT, Alpern ER, Johnson EJ, Corboy JB. Standardizing and Optimizing Care for Pediatric Acute Agitation Management in the Emergency Department. Oral Abstract Presentation. Academic Pediatric Association Annual Conference on Advancing Quality Improvement Science for Children's Healthcare. New Orleans. Accepted for presentation on April 22, 2022.
26. Janssen, A., Malpas, J., Glaeser, E., "Family-Based Interventions with Transgender and Gender Nonbinary Youth," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022.
27. Tishelman, A., Janssen A., et. al., WPATH Standards of Care – "Child Chapter," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022
28. Janssen, A., Leibowitz, S., et al, "The Evidence and Ethics for Transgender Youth Care: Updates on the New International Standards of Care, Eighth Edition. AACAP Annual Conference, October 2022.
29. Turban, J., Janssen, A., et al, "Transgender Youth: Evolving Gender Identities and "Detransition," AACAP Annual Conference, October 2022.

Books

1. Janssen, A., Leibowitz, S (editors), Affirmative Mental Health Care for Transgender and Gender Diverse Youth: A Clinical Casebook, Springer Publishing, 2018.

Book Chapters

1. Janssen, A., Shatkin, J., "Atypical and Adjunctive Agents," Pharmacotherapy for Child and Adolescent Psychiatric Disorders, 3rd Edition, Marcel Dekker, Inc, New York, 2012.
2. Janssen, A; Liaw, K: "Not by Convention: Working with People on the Sexual & Gender Continuum," book chapter in The Massachusetts General Hospital Textbook on Cultural Sensitivity and Diversity in Mental Health. Humana Press, New York, Editor R. Parekh, January 2014.

3. Janssen, A; Glaeser, E., Liaw, K: "Paving their own paths: What kids & teens can teach us about sexual and gender identity," book chapter in Cultural Sensitivity in Child and Adolescent Mental Health, MGH Psychiatry Academy Press, Editor R. Parekh, 2016
4. Janssen A., "Gender Identity," Textbook of Mental and Behavioral Disorders in Adolescence, February 2018.
5. Busa S., Wernick, J., & Janssen, A. (In Review) Gender Dysphoria in Childhood. Encyclopedia of Child and Adolescent Development. Wiley, 2018.
6. Janssen A., Busa S., "Gender Dysphoria in Childhood and Adolescence," Complex Disorders in Pediatric Psychiatry: A Clinician's Guide, Elsevier, Editors Driver D., Thomas, S., 2018.
7. Wernick J.A., Busa S.M., Janssen A., Liaw K.RL. "Not by Convention: Working with People on the Sexual and Gender Continuum." Book chapter in The Massachusetts General Hospital Textbook on Diversity and Cultural Sensitivity in Mental Health, editors Parekh R., Trinh NH. August, 2019.
8. Weis, R., Janssen, A., & Wernick, J. The implications of trauma for sexual and reproductive health in adolescence. In *Not Just a nightmare: Thinking beyond PTSD to help teens exposed to trauma.* 2019
9. Connors J., Irastorza, I., Janssen A., Kelly, B., "Child and Adolescent Medicine," The Equal Curriculum: The Student and Educator Guide to LGBTQ Health, editors Lehman J., et al. November 2019.
10. Janssen, A., et. al., "Gender and Sexual Diversity in Childhood and Adolescence," Dulcan's Textbook of Child and Adolescent Psychiatry, 3rd edition, editor Dulcan, M., (in press)
11. Busa S., Wernick J, Janssen, A., "Gender Dysphoria," The Encyclopedia of Child and Adolescent Development, DOI: 10.1002/9781119171492. Wiley, December 2020.

Invited Academic Seminars/Lectures

1. April 2006: "How to Talk to a Gay Medical Student" – presented at the National AAMC Meeting.
2. March 2011: "Kindling Inspiration: Two Model Curricula for Expanding the Role of Residents as Educators" – workshop presented at National AADPRT Meeting.
3. May 2011: Janssen, A., Shuster, A., "Sex Matters: Identity, Behavior and Development," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
4. March 2012: Janssen, A., Lothringer, L., "Gender Variance in Children and Adolescents," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
5. June 2012: Janssen, A., "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, Woodhull Department of Psychiatry
6. October 2012: "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting.
7. March 2013: "Gender Variance in Childhood and Adolescence," Sexual Health Across the Lifespan: Practical Applications, Denver, CO.
8. October 18th, 2013: "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, NYU Department of Endocrinology.

9. October, 2014: GLMA Annual Conference: "Theory of Mind and Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning ASD," Invited Presentation
10. October 2014: New York Transgender Health Conference: "Mental Health Assessment in Gender Variant Children," Invited Presentation.
11. November, 2014: Gender Spectrum East: "Affirmative Clinical Work with Gender-Expansive Children and Youth: Complex Situations."
12. October 2015: "Gender Dysphoria and Complex Psychiatric Co-Morbidity," LGBT Health Conference, Invited Speaker
13. October 2015: "Transgender Health Disparities: Challenges and Opportunities," Grand Rounds, Illinois Masonic Department of Medicine
14. November 2015: "Autism and Gender Variance," Gender Conference East, Invited Speaker
15. February 2016: "Working with Gender Variant Youth," New York State Office of Mental Health State Wide Grand Rounds, Invited Speaker
16. March, 2016: "Working with Gender Variant Youth," National Council for Behavioral Health Annual Meeting, Invited Speaker
17. March 2016: "Gender Variance Among Youth with Autism: A Retrospective Chart Review and Case Presentation," Working Group on Gender, Columbia University, Invited Speaker.
18. September, 2016: "Best Practices in Transgender Mental Health: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," DeWitt Wallace Institute for the History of Psychiatry, Weill Cornell.
19. October, 2016: "LGBTQ Youth Psychiatric Care," Midwest LGBTQ Health Symposim
20. October, 2016: "Gender Fluidity and Gender Identity Development," NYU Health Disparities Conference.
21. February, 2017: "Best Practices in Transgender Mental Health," Maimonides Grand Rounds
22. March, 2017: "Transgender Health: Challenges and Opportunities," Invited speaker, Center for Disease Control STD Prevention Science Series.
23. September 2017: "Autism and Gender Dysphoria," Grand Rounds, NYU Department of Neurology.
24. November 2017: "Consent and Assent in Transgender Adolescents," Gender Conference East.
25. November 2017: "Transgender Mental Health: Challenges and Opportunities," Grand Rounds, Lenox Hill Hospital.
26. April 2018: "Gender Trajectories in Childhood and Adolescent Development and Identity," Sex, Sexuality and Gender Conference, Harvard Medical School.
27. September 2019: "Social and Psychological Challenges of Gender Diverse Youth," Affirmative Mental Health Care for Gender Diverse Youth, University of Haifa.
28. October 2019: "Best Practices in Transgender Mental Health," Grand Rounds, Rush Department of Psychiatry.
29. February 2020: "The Overlap of Autism and Gender Dysphoria," Grand Rounds, Northwestern University Feinberg School of Medicine Department of Psychiatry
30. February 2020: "Gender Dysphoria and Autism," Grand Rounds, University of Illinois at Chicago Department of Psychiatry
31. September 2021: "Gender Diversity and Autism," Grand Rounds, Kaiser Permanente Department of Pediatrics

32. October 2021: Gender Dysphoria and Autism," Grand Rounds, Case Western Reserve University Department of Psychiatry.

Selected Invited Community Seminars/Lectures

1. April 2012: "Gender and Sexuality in Childhood and Adolescence," Commission on Race, Gender and Ethnicity, NYU Steinhardt Speakers Series.
2. February 2013: "Supporting Transgender Students in School," NYC Independent School LGBT Educators Panel, New York, NY.
3. June 2013: "LGBT Health," Presentation for Neuropsychology Department
4. August 2013: "Chronic Fatigue Syndrome: Etiology, Diagnosis and Management," invited presentation.
5. September 2013: Panelist, "LGBTQ Inclusive Sex Education."
6. April 2015: Transgender Children, BBC News, BBCTwo, invited expert
7. January 2016: Gender Dysphoria and Autism – Ackerman Podcast - http://ackerman.podbean.com/e/the-ackerman-podcast-22-gender-dysphoria-autism-with-aron-janssen-md/
8. February 2016: "Best Practices in Transgender Mental Health," APA District Branch Meeting, Invited Speaker.
9. May 2016: "Best Practices in Transgender Mental Health," Washington D.C., District Branch, APA, Invited Speaker
10. July 2016: "Transgender Youth," Union Square West
11. November 2017: "Understanding Gender: Raising Open, Accepting and Diverse Children," Heard in Rye, Conversations in Parenting.
12. January 2018: "The Emotional Life of Boys," Saint David's School Panel, Invited Speaker
13. June 2018: "Supporting Youth Engaged in Gender Affirming Care," NYU Child Study Center Workshop.
14. October 2018: "Medicine in Transition: Advances in Transgender Mental Health," NYCPS HIV Psychiatry and LGBT Committee Meeting.
15. October 2018: "Understanding Gender Fluidity in Kids," NYU Slope Pediatrics.
16. October, 2021: Issues of Ethical Importance: Health Care for Pediatric LGBTQ+ Patients, American Medical Association, Invited Talk

Major Research Interests

Gender and Sexual Identity Development
Member, Research Consortium for Gender Identity Development
Delirium: Assessment, Treatment and Management
Suicide Prevention

Research Studies

Study Title	IRB Study#	Dates
Suicide Attempts Identified in a Children's Hospital Before and During COVID-19	2021-4428	2/26/21-present
Lurie Children's Sex & Gender Development Program Clinical Measure Collection	2019-2898	2019-present

Adolescent Gender Identity Research Study (principal investigator) - unfunded	s15-00431	4/15-5/19
Co-Occurrence of Autism Spectrum Disorders and Gender Variance: Retrospective Chart Review (principal investigator) - unfunded	s14-01930	10/14-5/19
Expert Consensus on Social Transitioning Among Prepubertal Children Presenting with Transgender Identity and/or Gender Variance: A Delphi Procedure Study (principal investigator) - unfunded	s13-00576	3/16-5/19
Co-Occurrence of ADHD/Gender Dysphoria (principal investigator) - unfunded	s16-00001	1/16-5/19
PICU Early Mobility- unfunded	s16-02261	12/16-5/19
Metformin for Overweight and Obese Children and Adolescents with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics – Funded by PCORI	s16-01571	8/16-5/19

Other

Grant Funding:
Zero Suicide Initiative, PI Aron Janssen, M.D.
Awarded by Cardinal Health Foundation, 9/2020
Total amount: $100,000

Catalyst Fund, PI Aron Janssen, M.D.
Suicide Prevention in Pediatric Primary Care
Total amount: $750,000

Selected Media Appearances:

Guest Expert on Gender Identity on Anderson, "When Your Husband Becomes Your Wife," Air Date February 8th, 2012
Guest Host, NYU About Our Kids on Sirius XM, 2011
NYU Doctor Radio: LGBT Health, September 2013
NYU Doctor Radio: LGBT Kids, November 2013
NYU Doctor Radio: LGBT Health, July 2014
NYU Doctor Radio: Gender Variance in Childhood, December 2014
BBC Two: Transgender Youth, April 2015
NYU Doctor Radio: Transgender Youth, June 2015
Fox-5 News: Trump's proposed military ban and Transgender Youth, July, 2017
Healthline.com: Mental Health Experts Call President's Tweets 'Devastating' for Trans Teens, July, 2017
Huffington Post: What the Military Ban Says to Our Transgender Youth: August, 2017
Metro: How to talk to your transgender kid about Trump, August 2017
NYU Doctor Radio: Transgender Youth, August 2017

Exhibit B

Bibliography

BIBLIOGRAPHY

Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results. *International journal of pediatric endocrinology*, *2020*, 8.

Allen, L.R., Watson, L.B., Egan, A.M., & Moser, C.N. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302-311.

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American Medical Association and GLMA. (2022). Issue Brief: Sexual orientation and gender identity change efforts (so-called "conversion therapy"). Available at: https://www.ama-assn.org/system/files/conversion-therapy-issue-brief.pdf.

American Medical Association and GLMA. (2019). Issue Brief: Health insurance coverage for gender- affirming care of transgender patients. Available at: https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf.

American Psychiatric Association. (2022). Diagnostic and statistical manual of mental disorders (5th ed., text rev.). Arlington, VA: American Psychiatric Publishing.

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American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders (5th ed.). Arlington, VA: American Psychiatric Publishing.

American Psychological Association (2021). APA Resolution on Gender Identity Change Efforts. Available at: https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf.

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Biggs M. (2022). Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Archives of sexual behavior*, *51*(2), 685–690.

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Medicine,* 2023 Jan 19;388(3):240-250.

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Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F. L., Monstrey, S. J., Motmans, J., Nahata, L., Nieder, T. O., … Arcelus, J. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International journal of transgender health*, *23*(Suppl 1), S1–S259.

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Costello, E. J., Mustillo, S., Erkanli, A., Keeler, G., & Angold, A. (2003). Prevalence and development of psychiatric disorders in childhood and adolescence. *Archives of general psychiatry*, *60*(8), 837–844.

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de Vries, A. L. C., McGuire, J. K., Steensma, T. D., Wagenaar, E. C. F., Doreleijers, T. A. H., & Cohen-Kettenis, P. T. (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*, *134*(4), 696-704.

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Du Bois, S. N., Yoder, W., Guy, A. A., Manser, K., & Ramos, S. (2018). Examining Associations Between State-Level Transgender Policies and Transgender Health. *Transgender health*, *3*(1), 220–224.

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https://www.wpath.org/soc8/Revision-Committee

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

Establishing the soc8 Revision committee and meet the chairs and lead evidence team

2.1 Establishing SOC Revision Committee Process

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select the members of the SOC8 review committee:

2.1.1 Establish Guideline Steering Committee

The WPATH Guideline Steering Committee provided oversight of the guideline development process for all chapters of the Standards of Care. Except for the Chair (Dr Eli Coleman) who was selected by WPATH to provide continuity from previous SOC, the two co-chairs were selected by the WPATH Board from WPATH members applying for these positions. The Chairs of the Guideline Steering Committee:

- Appointed the Chapter Leads and Members for each chapter
- Selected topics for the chapters

The Guideline Steering Committee (chairs and Co-chairs) provided general oversight of the guideline development process. The Committee reviewed all chapters of the Standards of Care to confirm adherence to the WPATH guideline methodology and to ensure consistency of statements across the Standards of Care.

2.1.2 Nomination Procedures and selection for Co-Chairs

- A member of WPATH proposed a candidate for co-chair by sending a letter of nomination and the address of the recommended co-chair, to the Executive Director of the Society.
- A Member of WPATH could self-nominate, by sending a letter of self-nomination to the Executive Director of the Society.
- The Executive Director (ED) sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Board of Directors.
- The BOD discussed each application and assigns a score in a blinded ballot only seen by the office staff across the application criteria with the three top candidates moving to the next round of voting.
- Any conflict of interest was declared and in the case of a conflict of interest, the conflicted person did not vote.
- The BOD discussed the nominees with the Chair, and best fit for the group was chosen.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.2.1 Key Criteria Used for the Selection of Co-Chair on the SOC8 Revision Committee (2 positions)

- Longstanding WPATH Full Member in good standing
- Well recognized advocate for WPATH and the SOC
- Well known expert in transgender health
- Extensive experience in leading consensus building projects and guideline development
- Accomplished clinician, scholar, and researcher in trans health with a publication record
- Able to assess the evidence-based and peer review literature and peer and contribute specific recommendations from an evidence-based perspective
- Able to select and supervise chapter leads

2.1.2.1 Results

A total of 8 individuals applied for two positions and 2 people were selected, Dr. Asa Radix and Dr. Jon Arcelus.

2.1.3 Nomination and selection procedures for Chapter Leads

- A member of WPATH proposed a candidate for a chapter lead by sending a letter of nomination, including address of the recommended chapter lead (and indicated chapter(s)), to the Executive Director (ED) of the Society.
- A member of WPATH could self-nominate by sending a letter of self-nomination to the ED of the Society.
- The ED sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributes copies of the nominating letter, completed application, and curriculum vitae to the Chair and Co-Chairs.
- The Chair and Co-Chairs discussed the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 2 candidates moving to the next round of voting. The Chair and Co-Chairs discussed the top 2 candidates with the goal of selecting the best fit for the topic and the other members of the workgroup.
- The Chair and Co-Chairs informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.3.1 Key Criteria for Chapter Lead on the SOC Revision Committee

- WPATH Full Member in good standing
- Well recognized advocate for WPATH and the SOC
- Well known expert in transgender health
- Accomplished scholar and researcher in trans health with a publication record related to the chapter
- Accomplished clinician, scholar, and researcher in trans health with a publication record
- Able to assess the evidence-based literature and write chapters based on peer review or contribute

2.1.3.2 Results

A total of 39 applicants and 24 were selected.

2.1.4 Nomination Procedures and selection for Chapter Workgroup Members

- A member of WPATH proposed a candidate for a chapter workgroup member by sending a letter of nomination, including address of the recommended new member, to the Executive Director (ED) of the Society
- A member of WPATH could self-nominate, by sending a letter of self-nomination to the ED of the Society
- The ED sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Chapter Leads.
- The Chair and Co-Chairs and Chapter Leads discuss the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 5-7 candidates (number to be determined prior to voting) within each chapter being chosen.
- The Chair, Co-Chairs and Chapter Lead informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.4.1 Key Criteria for Chapter Workgroup Member on the SOC8 Revision Committee (5-7 people per chapter)

- WPATH Full Member in good standing
- Well known expert in transgender health
- Accomplished scholar and researcher in trans health with a publication record related to the chapter
- Able to assess the evidence-based literature and write chapters related to peer review or contribute specific recommendations from an evidence-based perspective
- Able and willing to work collaboratively with chapter leads and other committee members
- Applicants could apply to work on more than one workgroup and rank their chapter interests.

2.1.4.2 Results

A total of 149 applicants for workgroup members applied and 127 were selected (link it to a page with names of the chairs, leads)

2.1.5 Nomination and selection procedures for Chapter Stakeholder Members

- A member of WPATH proposed a candidate for a chapter workgroup member by sending a letter of nomination, including address of the recommended new member, to the Executive Director (ED) of the Society
- A person could self-nominate, by sending a letter of self-nomination to the ED of the Society
- The ED sent a committee membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Chapter Leads.

- The Chair and Co-Chairs and Chapter Leads discussed the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 2 candidates (number to be determined prior to voting) per chapter being chosen.
- The Chair, Co-Chairs and Chapter Leads discussed the top 2 candidates and the best fit within each chapter group were chosen.
- The Chair, Co-Chairs and Chapter Lead informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.5.1 Key Criteria for Stakeholder Membership on the SOC8 Revision Committee

Our intent was that by involving experts (with or without lived experience) that work outside of the scientific publishing arena, we will be able to provide input from those working directly in community health or in policy making and in NGOs around the globe.

- Associate Members of WPATH (with or without lived transgender experience) and other individuals (with or without lived transgender experience) with expertise due to accomplishments in trans health advocacy and a history of work in the community, or a member of a family that includes a transgender child, sibling, partner, parent, etc.
- Able to review the drafts of the SOC committee and contribute specific recommendations from a community health perspective

2.1.5.2 Results

A total of 57 and 20 were selected.

2.1.6 Selection of the evidence review team

The WPATH Board released a request for proposals (RFP) for the WPATH Standards of Care 8th Version Evidence Review Team. The Board received four complete proposals in response to the RFP. After careful review and discussions of each submitted proposal, the WPATH Board selected and engaged an Evidence Review Team at Johns Hopkins University. Dr Karen Robinson was the lead of the evidence-based review.

Conflict of Interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team are asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, were personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

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GRADE Handbook

Introduction to GRADE Handbook

Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013.

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About the Handbook

The GRADE handbook describes the process of rating the quality of the best available evidence and developing health care recommendations following the approach proposed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group (www.gradeworkinggroup.org). The Working Group is a collaboration of health care methodologists, guideline developers, clinicians, health services researchers, health economists, public health officers and other interested members. Beginning in the year 2000, the working group developed, evaluated and implemented a common, transparent and sensible approach to grading the quality of evidence and strength of recommendations in health care. The group interacts through meetings by producing methodological guidance, developing evidence syntheses and guidelines. Members collaborate on research projects, such as the DECIDE project (www.decide-collaboration.eu) with other members and other scientists or organizations (e.g. www.rarebestpractices.eu). Membership is open and free. See www.gradeworkinggroup.org and Chapter The GRADE working group in this handbook for more information about the Working Group and a list of the organizations that have endorsed and adopted the GRADE approach.

The handbook is intended to be used as a guide by those responsible for using the GRADE approach to produce GRADE's output, which includes evidence summaries and graded recommendations. Target users of the handbook are systematic review and health technology assessment (HTA) authors, guideline panelists and methodologists who provide support for guideline panels. While many of the examples offered in the handbook are clinical examples, we also aimed to include a broader range of examples from public health and health policy. Finally, specific sections refer to interpreting recommendations for users of recommendations.

Using the Handbook

The handbook is divided into chapters that correspond to the steps of applying the GRADE approach. The Chapter Overview of the GRADE approach provides a brief overview of guideline development processes and where the GRADE approach fits in. Chapters Framing the health care question and Selecting and rating the importance of outcomes provide guidance on formulating health care questions for guidelines and systematic reviews and for rating the importance of outcomes in guidelines. The Chapter Summarizing the evidence covers evidence summaries produced using the GRADE software. GRADE acknowledges that alternative terms or expressions to what GRADE called quality of evidence are often appropriate. Therefore, we interpret and will use the phrases quality of evidence, strength of evidence, certainty in evidence or confidence in estimates interchangeably. When GRADE uses the phrase "confidence in estimates" it does not refer to statistical confidence intervals, although the width of this interval is part of the considerations for judging the GRADE criterion imprecision. When GRADE refers to confidence in the estimates it refers to the how certain one can be that the effect estimates are adequate to support a recommendation (in the context of guideline development) or that the effect estimate is close to that of the true effect (in the context of evidence synthesis). Chapter Quality of evidence provides instructions for rating the evidence and addresses the five factors outlined in the GRADE approach that may result in rating down the quality of evidence and the three factors that may increase the quality of evidence. Chapter Going from evidence to recommendations deals with moving from evidence to recommendations in guidelines and whether to classify recommendations as strong or weak according to the criteria outlined in the GRADE evidence to recommendation frameworks. The Chapter The GRADE approach for diagnostic tests and strategies addresses how to use the GRADE approach specifically for questions about diagnostic tests and strategies. Finally, the Chapter Criteria for determining whether the GRADE approach was used provides the suggested criteria that should be met in order to state that the GRADE approach was used.

Throughout the handbook certain terms and concepts are hyperlinked to access definitions and the specific sections elaborating on those concepts. The glossary of terms and concepts is provided in the Chapter Glossary of terms and concepts. Where applicable, the handbook highlights guidance that is specific to guideline developers or to systematic review authors as well as important notes pertaining to specific topics. HTA practitioners, depending on their mandate, can decide which approach is more suitable for their goals. Furthermore, examples demonstrating the application of the concepts are provided for each topic. The examples are cited if readers wish to learn more about them from the source documents.

Updating the Handbook

The handbook is updated to reflect advances in the GRADE approach and based on feedback from handbook users. It includes information from the published documents about the GRADE approach, which are listed in the Chapter Articles about GRADE, and links to resources in the Chapter Additional resources.

We encourage users of the handbook to provide feedback and corrections to the handbook editors via email.

Accompanying software: GRADEpro and the Guideline Development Tool (GDT)

This handbook is intended to accompany the GRADE profiler (GRADEpro) – software to facilitate development of evidence summaries and health care recommendations using the GRADE approach –

integrated in the Guideline Development Tool (GDT) "Das tool". Please refer to www.guidelinedevelopment.org for more information.

Reproduction and translation

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We would particularly like to acknowledge the contributions of Roman Jaeschke, Robin Harbour and Elie Akl to earlier versions of the handbook.

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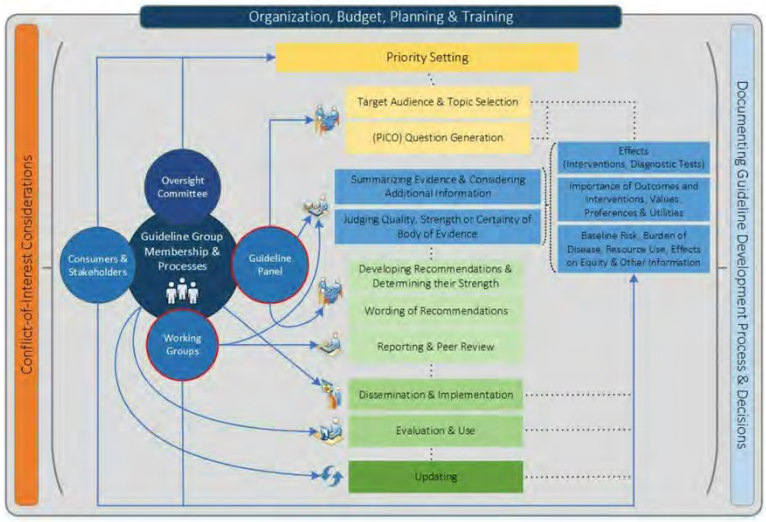
The following authors have made major contributions to the current version of the handbook: Elie Akl, Reem Mustafa, Nancy Santesso Wojtek Wiercioch, and. Many other members of the GRADE Working Group have also contributed to this handbook by providing feedback and through discussion.

1. Overview of the GRADE Approach

The GRADE approach is a system for rating the quality of a body of evidence in systematic reviews and other evidence syntheses, such as health technology assessments, and guidelines and grading recommendations in health care. GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations. It can be used to develop clinical practice guidelines (CPG) and other health care recommendations (e.g. in public health, health policy and systems and coverage decisions).

Figure 1 shows the steps and involvement in a guideline development process (Schünemann H et al., CMAJ, 2013).



Steps and processes are interrelated and not necessarily sequential. The guideline panel and supporting groups (e.g. methodologist, health economist, systematic review team, secretariat for administrative support) work collaboratively, informed through consumer and stakeholder involvement. They typically report to an oversight committee or board overseeing the process. For example, while deciding how to involve stakeholders early for priority setting and topic selection, the guideline group must also consider how developing formal relationships with the stakeholders will enable effective dissemination and implementation to support uptake of the guideline. Furthermore, considerations for organization, planning and training encompass the entire guideline development project, and steps such as documenting the methodology used and decisions made, as well as considering conflict-of-interest occur throughout the entire process.

The system is designed for reviews and guidelines that examine alternative management strategies or interventions, which may include no intervention or current best management as well as multiple comparisons. GRADE has considered a wide range of clinical questions, including diagnosis, screening, prevention, and therapy. Guidance specific to applying the GRADE approach to questions about diagnosis is offered in Chapter The GRADE approach for diagnostic tests and strategies

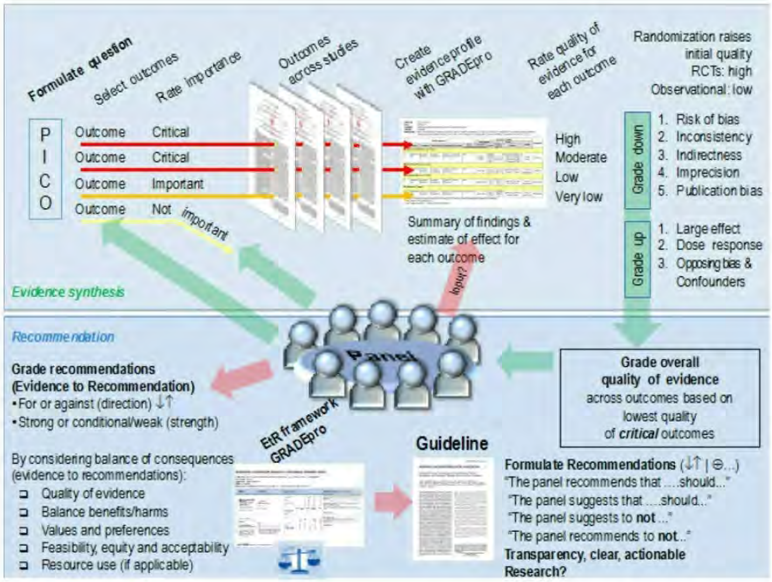
GRADE provides a framework for specifying health care questions, choosing outcomes of interest and rating their importance, evaluating the available evidence, and bringing together the evidence with considerations of values and preferences of patients and society to arrive at recommendations.

Furthermore, the system provides clinicians and patients with a guide to using those recommendations in clinical practice and policy makers with a guide to their use in health policy.

Application of the GRADE approach begins by defining the health care question in terms of the population of interest, the alternative management strategies (intervention and comparator), and all patient-important outcomes. As a specific step for guideline developers, the outcomes are rated according to their importance, as either critical or important but not critical. A systematic search is preformed to identify all relevant studies and data from the individual included studies is used to generate an estimate of the effect for each patient-important outcome as well as a measure of the uncertainty associated with that estimate (typically a confidence interval). The quality of evidence for each outcome across all the studies (i.e. the body of evidence for an outcome) is rated according to the factors outlined in the GRADE approach, including five factors that may lead to rating down the quality of evidence and three factors that may lead to rating up. Authors of systematic reviews complete the process up to this step, while guideline developers continue with the subsequent steps. Health care related related tests and strategies are considered interventions (or comparators) as utilizing a test inevitably has consequences that can be considered outcomes (see Chapter The GRADE approach for diagnostic tests and strategies).

Next, guideline developers review all the information from the systematic search and, if needed, reassess and make a final decision about which outcomes are critical and which are important given the recommendations that they aim to formulate. The overall quality of evidence across all outcomes is assigned based on this assessment. Guideline developers then formulate the recommendation(s) and consider the direction (for or against) and grade the strength (strong or weak) of the recommendation(s) based on the criteria outlined in the GRADE approach. **Figure 2** provides a schematic view of the GRADE approach.

Figure 2: A schematic view of the GRADE approach for synthesizing evidence and developing recommendations. The upper half describe steps in the process common to systematic reviews and making health care recommendations and the lower half describe steps that are specific to making recommendations (based on GRADE meeting, Edingburgh 2009).



For authors of systematic reviews:

Systematic reviews should provide a comprehensive summary of the evidence but they should typically not include health care recommendations. Therefore, use of the GRADE approach by systematic review authors terminates after rating the quality of evidence for outcomes and clearly presenting the results in an evidence table, i.e. an GRADE Evidence Profile or a Summary of Findings table. Those developing health care recommendations, e.g. a guideline panel, will have to complete the subsequent steps.

The following chapters will provide detailed guidance about the factors that influence the quality of evidence and strength of recommendations as well as instructions and examples for each step in the application of the GRADE approach. A detailed description of the GRADE approach for authors of systematic reviews and those making recommendations in health care is also available in a series of articles published in the Journal of Clinical Epidemiology. An additional overview of the GRADE approach as well as quality of evidence and strength of recommendations in guidelines is available in a previously published six-part series in the British Medical Journal. Briefer overviews have appeared in other journals, primarily with examples for relevant specialties. The articles are listed in Chapter 10. This handbook, however, as a resource that exists primarily in electronic format, will include GRADE's innovations and be kept up to date as journal publications become outdated.

1.1 Purpose and advantages of the GRADE approach

Clinical practice guidelines offer recommendations for the management of typical patients. These management decisions involve balancing the desirable and undesirable consequences of a given course of action. In order to help clinicians make evidence-based medical decisions, guideline developers often

grade the strength of their recommendations and rate the quality of the evidence informing those recommendations.

Prior grading systems had many disadvantages including the lack of separation between the quality of evidence and strength of recommendation, the lack of transparency about judgments, and the lack of explicit acknowledgment of values and preferences underlying the recommendations. In addition, the existence of many, often scientifically outdated, grading systems has created confusion among guideline developers and end users.

The GRADE approach was developed to overcome these shortcomings of previous grading systems. Advantages of GRADE over other grading systems include:

- Developed by a widely representative group of international guideline developers
- Clear separation between judging confidence in the effect estimates and strength of recommendations
- Explicit evaluation of the importance of outcomes of alternative management strategies
- Explicit, comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Transparent process of moving from evidence to recommendations
- Explicit acknowledgment of values and preferences
- Clear, pragmatic interpretation of strong versus weak recommendations for clinicians, patients, and policy makers
- Useful for systematic reviews and health technology assessments, as well as guidelines

Note:

Although the GRADE approach makes judgments about quality of evidence, that is confidence in the effect estimates, and strength of recommendations in a systematic and transparent manner, it **does not eliminate** the need for judgments. Thus, applying the GRADE approach does not minimize the importance of judgment or as suggesting that quality can always be objectively determined.

Although evidence suggests that these judgments, after appropriate methodological training, lead to reliable assessment of the quality of evidence (Mustafa R et al., Journal of Clinical Epidemiology, 2013). There will be cases in which those making judgments will have legitimate disagreement about the interpretation of evidence. GRADE provides a framework guiding through the critical components of the assessment in a structured way. By allowing to make the judgments explicit rather than implicit it ensures transparency and a clear basis for discussion.

1.2 Separation of confidence in effect estimates from strength of recommendations

A number of criteria should be used when moving from evidence to recommendations (see Chapter on Going from evidence to recommendations). During that process, separate judgements are required for each of these criteria. In particular, separating judgements about the confidence in estimates or quality of evidence from judgements about the strength of recommendations is important as high confidence in effect estimates does not necessarily imply strong recommendations, and strong recommendations can result from low or even very low confidence in effect estimates (insert link to paradigmatic situations for when strong recommendations are justified in the context of low or very low confidence in effect estimates). Grading systems that fail to separate these judgements create confusion, while it is the defining feature of GRADE.

The GRADE approach stresses the necessity to consider the balance between desirable and undesirable consequences and acknowledge other factors, for example the values and preferences underlying the recommendations. As patients with varying values and preferences for outcomes and interventions will make different choices, guideline panels facing important variability in patient values and preferences are likely to offer a weak recommendation despite high quality evidence. Considering importance of outcomes and interventions, values, preferences and utilities includes integrating in the process of developing a recommendation, how those affected by its recommendations assess the possible consequences. These include patient and carer knowledge, attitudes, expectations, moral and ethical values, and beliefs; patient goals for life and health; prior experience with the intervention and the condition; symptom experience (for example breathlessness, pain, dyspnoea, weight loss); preferences for and importance of desirable and undesirable health outcomes; perceived impact of the condition or interventions on quality of life, well-being or satisfaction and interactions between the work of implementing the intervention, the intervention itself, and other contexts the patient may be experiencing; preferences for alternative courses of action; and preferences relating to communication content and styles, information and involvement in decision-making and care. This can be related to what in the economic literature is considered utilities. An intervention itself can be considered a consequence of a recommendation (e.g. the burden of taking a medication or undergoing surgery) and a level of importance or value is associated with that. Both the direction and the strength of a recommendation may be modified after taking into account the implications for resource utilization, equity, acceptability and feasibility of alternative management strategies.

Therefore, unlike many other grading systems, the GRADE approach emphasizes that weak also known as conditional recommendations in the face of high confidence in effect estimates of an intervention are common because of these factors other than the quality of evidence influencing the strength of a recommendation. For the same reason it allows for strong recommendations on the basis of low or very confidence in effect estimates.

Example 1: Weak recommendation based on high quality evidence

Several RCTs compared the use of combination chemotherapy and radiotherapy versus radiotherapy alone in unresectable, locally advanced non-small cell lung cancer (Stage IIIA). The overall quality of evidence for the body of evidence was rated high. Compared with radiotherapy alone, the combination of chemotherapy and radiotherapy reduces the risk of death corresponding to a mean gain in life expectancy of a few months, but increases harm and burden related to chemotherapy. Thus, considering the values

and preferences patients would place on the small survival benefit in view of the harms and burdens, guideline panels may offer a weak recommendation despite the high quality of the available evidence (Schünemann et al. AJRCCM 2006).

Example 2: Weak recommendation based on high quality evidence

Patients who experience a first deep venous thrombosis with no obvious provoking factor must, after the first months of anticoagulation, decide whether to continue taking the anticoagulant warfarin long term. High quality randomized controlled trials show that continuing warfarin will decrease the risk of recurrent thrombosis but at the cost of increased risk of bleeding and inconvenience. Because patients with varying values and preferences will make different choices, guideline panels addressing whether patients should continue or terminate warfarin should, despite the high quality evidence, offer a weak recommendation.

Example 3: Strong recommendation based on low or very low quality evidence

The principle of administering appropriate antibiotics rapidly in the setting of severe infection or sepsis has not been tested against its alternative of no rush of delivering antibiotics in randomized controlled trials. Yet, guideline panels would be very likely to make a strong recommendation for the rapid use of antibiotics in this setting on the basis of available observational studies rated as low quality evidence because the benefits of antibiotic therapy clearly outweigh the downsides in most patients independent of the quality assessment (Schünemann et al. AJRCCM 2006)..

1.3 Special challenges in applying the the GRADE approach

Those applying GRADE to questions about diagnostic tests, public health or health systems will face some special challenges. This handbook will address these challenges and undergo revisions when new developments prompt the GRADE working group to agree on changes to the approach. Moreover, there will be methodological advances and refinements in the future not only of innovations but also of the established concepts.

1.4 Modifications to the GRADE approach

GRADE recommends against making modifications to the approach because the elements of the GRADE process are interlinked, because modifications may confuse some users of evidence summaries and guidelines, and because such changes compromise the goal of a single system with which clinicians, policy makers, and patients can become familiar. However, the literature on different approaches to ***applying*** GRADE is growing and are useful to determine when pragmatism is appropriate.

2. Framing the health care question

A guideline panel should define the scope of the guideline and the planned recommendations. Each recommendation should answer a focused and sensible health care question that leads to an action. Similarly, authors of systematic reviews should formulate focused health care question(s) that the review will answer. A systematic review may answer one or more health care questions, depending on the scope of the review.

The **PICO** framework presents a well accepted methodology for framing health care questions. It mandates carefully specifying four components:

- **Patient**: the patients or population to whom the recommendations are meant to apply
- **Intervention**: the therapeutic, diagnostic, or other intervention under investigation (e.g. the experimental intervention, or in observational studies the exposure factor)
- **Comparison**: the alternative intervention; intervention in the control group
- **Outcome**: the outcome(s) of interest

A number of derivatives of this approach exist, for example adding a T for time or S for study design. These modifications are neither helpful nor necessary. The issue of time (e.g. duration of treatment, when an outcome should be assessed, etc) is covered in the elements by specifying the intervention(s) and outcome(s) appropriately (e.g. mortality at one year). In addition, the studies, and therefore the study design, that inform an answer are often not known when the question is asked. That is, observational studies may inform a question when randomized trials are no available or not associated with high confidence in the estimates. Thus, it is usually not sensible to define a study design beforehand. A guideline question often involves another specification: the **setting** in which the guideline will be implemented. For instance, guidelines intended for resource-rich environments will often be inapplicable to resource-poor environments. Even the setting, however, can be defined as part of the definition of the population (e.g. women in low income countries or man with myocardial infarction in a primary or rural health care setting).

Errors that are frequently made in formulating the health care question include failure to include all patient-important outcomes (e.g. adverse effects or toxicity), as well as failure to fully consider all relevant alternatives (this may be particularly problematic when guidelines target a global audience).

2.1 Defining the patient population and intervention

The most challenging decision in framing the question is how broadly the patients and intervention should be defined (*see Example 1*). For the patients and interventions defined, the underlying biology should

suggest that across the range of patients and interventions it is plausible that the magnitude of effect on the key outcomes is more or less the same. If that is not the case the review or guideline will generate misleading estimates for at least some subpopulations of patients and interventions. For instance, based on the information presented in Example 1, if antiplatelet agents differ in effectiveness in those with peripheral vascular disease vs. those with myocardial infarction, a single estimate across the range of patients and interventions will not well serve the decision-making needs of patients and clinicians. These subpopulations should, therefore, be defined separately.

Often, systematic reviews deal with the question of what breadth of population or intervention to choose by starting with a broad question but including a priori specification of subgroup effects that may explain any heterogeneity they find. The *a priori* hypotheses may relate to differences in patients, interventions, the choice of comparator, the outcome(s), or factors related to bias (e.g. high risk of bias studies yield different effects than low risk of bias studies).

Example 1: Deciding how to broadly to define the patients and intervention

Addressing the effects of antiplatelet agents on vascular disease, one might include only patients with transient ischemic attacks, those with ischemic attacks and strokes, or those with any vascular disease (cerebro-, cardio-, or peripheral vascular disease). The intervention might be a relatively narrow range of doses of aspirin, all doses of aspirin, or all antiplatelet agents.

Because the relative risk associated with an intervention vs. a specific comparator is usually similar across a wide variety of baseline risks, it is usually appropriate for systematic reviews to generate single pooled estimates (i.e. meta-analysis) of relative effects across a wide range of patient subgroups. Recommendations, however, **may differ across subgroups** of patients at different baseline risk of an outcome, **despite there being a single relative risk** that applies to all of them. For instance, the case for warfarin therapy, associated with both inconvenience and a higher risk of serious bleeding, is much stronger in atrial fibrillation patients at substantial vs. minimal risk of stroke. Thus, guideline panels must often define separate questions (and produce separate evidence summaries) for high- and low-risk patients, and patients in whom quality of evidence differs.

2.2 Dealing with multiple comparators

Another important challenge arises when there are multiple comparators to an intervention. Clarity in choice of the comparator makes for interpretable guidelines, and lack of clarity can cause confusion. Sometimes, the comparator is obvious, but when it is not guideline panels should specify the comparator explicitly. In particular, when multiple agents are involved, they should specify whether the recommendation is suggesting that all agents are equally recommended or that some agents are recommended over others (*see Example 1*).

Example 1: Clarity with multiple comparators

When making recommendations for use of anticoagulants in patients with non-ST elevation acute coronary syndromes receiving conservative (non-invasive) management, fondaparinux, heparin, and enoxaparin may be the agents being considered. Moreover, the estimate of effect for each agent may come from evidence of varying quality (e.g. high quality evidence for heparin, low quality of evidence for fondaparinux). Therefore, it must be made clear whether the recommendations formulated by the guideline panel will be for use of these agents vs. not using any anticoagulants, or also whether they will indicate a preference for one agent over the others or a gradient of preference.

2.3 Other considerations

GRADE has begun to tackle the question of determining the confidence in estimates for prognosis. They are often important for guideline development. For example, addressing interventions that may influence the outcome of influenza or multiple sclerosis will require establishing the natural history of the conditions. This will involve specifying the population (influenza or new-onset multiple sclerosis) and the outcome (mortality or relapse rate and progression). Such questions of prognosis may be refined to include multiple predictors, such as age, gender, or severity. The answers to these questions will be an important background for formulating recommendations and interpreting the evidence about the effects of treatments. In particular, guideline developers need to decide whether the prognosis of patients in the community is similar to those studied in the trials and whether there are important prognostic subgroups that they should consider in making recommendations. Judgments if the evidence is direct enough in terms of baseline risk affect the rating about indirectness of evidence.

2.4 Format of health care questions using the GRADE approach

Defining a health care question includes specifying all outcomes of interest. Those developing recommendations whether or not to use a given intervention (therapeutic or diagnostic) have to consider all relevant outcomes simultaneously. The Guideline Development Tool allows the selection of two different formats for questions about management:

- Should [intervention] vs. [comparison] be used for [health problem]?
- Should [intervention] vs. [comparison] be used in [population]?

As well as one format for questions about diagnosis:

- Should [intervention] vs. [comparison] be used to diagnose [target condition] in [health problem and/or population]?

Example Questions

1. Should manual toothbrushes vs. powered toothbrushes be used for dental health?

2. Should topical nasal steroids be used in children with persistent allergic rhinitis?

3. Should oseltamivir versus no antiviral treatment be used to treat influenza?

4. Should troponin I followed by appropriate management strategies or troponin T followed by appropriate management strategies be used to manage acute myocardial infarction?

3. Selecting and rating the importance of outcomes

Training modules and courses: http://cebgrade.mcmaster.ca/QuestionsAndOutcomes/index.html

Given that recommendations cannot be made on the basis of information about single outcomes and decision-making always involves a balance between health benefits and harms. Authors of systematic reviews will make their reviews more useful by looking at a comprehensive range of outcomes that allow decision making in health care. Many, if not most, systematic reviews fail to address some key outcomes, particularly harms, associated with an intervention.

On the contrary, to make sensible recommendations guideline panels must consider **all outcomes** that are important or critical to patients for decision making. In addition, they may require consideration of outcomes that are important to others, including the use of resources paid for by third parties, equity considerations, impacts on those who care for patients, and public health impacts (e.g. the spread of infections or antibiotic resistance).

Guideline developers must **base the choice of outcomes on what is important, not on what outcomes are measured** and for which evidence is available. If evidence is lacking for an important outcome, this should be acknowledged, rather than ignoring the outcome. Because most systematic reviews do not summarize the evidence for all important outcomes, guideline panels must often either use multiple systematic reviews from different sources, conduct their own systematic reviews or update existing reviews.

3.1 Steps for considering the relative importance of outcomes

Guideline developers must, and authors of systematic reviews are strongly encouraged to specify all potential patient-important outcomes as the first step in their endeavour. Guideline developers will also make a **preliminary classification** of the importance of the outcomes. GRADE specifies three categories of outcomes according to their **importance for decision-making**:

- critical
- important but not critical
- of limited importance.

Critical and important outcomes will bear on guideline recommendations, the third will in most situations not. Ranking outcomes by their relative importance can help to focus attention on those outcomes that are considered most important, and help to resolve or clarify disagreements. **Table 3.1** provides an overview of the steps for considering the relative importance of outcomes.

Guideline developers should first consider whether particular health benefits and harms of a therapy are **important** to the decision regarding the optimal management strategy, or whether they are **of limited importance**. If the guideline panel thinks that a particular outcome is important, then it should consider whether the outcome is critical to the decision, or only important, but not critical.

To facilitate ranking of outcomes according to their importance guideline developers may choose to rate outcomes numerically on a **1 to 9 scale** (7 to 9 – critical; 4 to 6 – important; 1 to 3 – of limited importance) to distinguish between importance categories.

Practically, to generate a list of relevant outcomes, one can use the following type of scales.

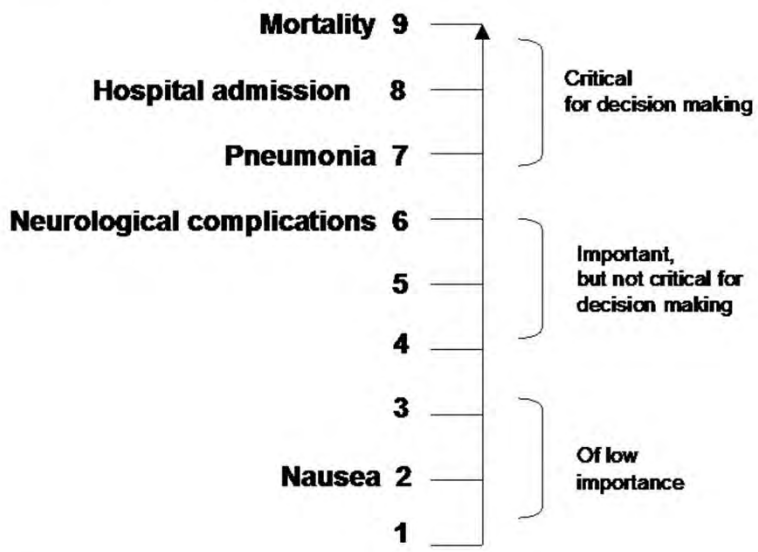
rating scale:								
1	2	3	4	5	6	7	8	9
of **least** importance								of **most** importance
of limited importance for making a decision (not included in evidence profile)			important, but not critical for making a decision (included in evidence profile)			Critical for making a decision (included in evidence profile)		

The first step of a classification of importance of outcomes should occur during protocol of a systematic review or when the panel agrees on the health care questions that should be addressed in a guideline. Thus, it should be done before a protocol is developed. When evidence becomes available a reassessment of importance may be necessary to ensure that important outcomes identified by reviews of the evidence that were not initially considered are included and to reconsider the relative importance of outcomes in light of the available evidence which will be influenced by the relative importance of the outcome. It is possible that there is no association between the outcome and the intervention of interest which supports to not consider that outcome further.

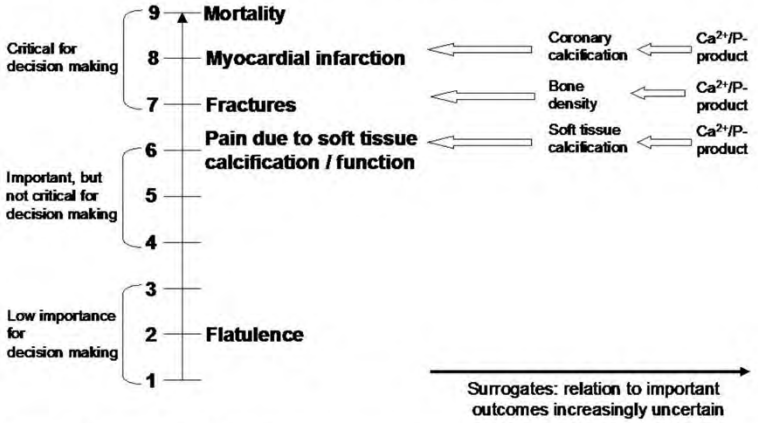
Guideline panels should be aware of the possibility that in some instances the importance of an outcome (e.g. a serious adverse effect) may only become known after the protocol is written, evidence is reviewed or the analyses were carried out, and should take appropriate actions to include these in the evidence tables.

Example 1: Hierarchy of outcomes according to their importance to assess the effect of oseltamivir in patients with H5N1 influenza. Mortality in patients affected with H5N1 is as high as 50%. Patient are usually affected by severe respiratory compromise and require ventilatory support. Complications of a

potentially useful medication, oseltamivir, are suspected to be of temporary neurological nature, other adverse effects such as nausea also occur during treatment.



Example 2. Hierarchy of outcomes according to their importance to assess the effect of phosphate-lowering drugs in patients with renal failure and hyperphosphatemia



Example 3: Reassessment of the relative importance of outcomes

Consider, for instance, a screening intervention, such as screening for aortic abdominal aneurysm. Initially, a guideline panel is likely to consider the intervention's impact on all-cause mortality as critical. Let us say, however, that the evidence summary establishes an important reduction in cause-specific mortality from abdominal aortic aneurysm but fails to definitively establish a reduction in all-cause mortality. The reduction in cause-specific mortality may be judged sufficiently compelling that, even in the absence of a demonstrated reduction in all-cause mortality (which may be undetected because of random error from other causes of death), the screening intervention is clearly worthwhile. All-cause mortality then becomes less relevant and ceases to be a critical outcome.

The relative importance of outcomes should be considered when determining the overall quality of evidence, which may depend on which outcomes are ranked as critical or important (see Chapter Quality of evidence), and judging the balance between the health benefits and harms of an intervention when formulating the recommendations (see Chapter Going from evidence to recommendations)

Only outcomes considered **critical** (rated 7-9) are the primary factors influencing a recommendation and will be used to determine the **overall quality of evidence** supporting a recommendation.

Table 3.1: Steps for considering the relative importance of outcomes

Step	What	Why	How	Evidence
1	Preliminary classification of outcomes as critical, important but not critical, or low importance, before reviewing the evidence	To focus attention on those outcomes that are considered most important when searching for and summarizing the evidence and to resolve or clarify disagreements.	Conducting a systematic review of the relevant literature. By asking panel members and possibly patients or members of the public to identify	These judgments are ideally informed by a systematic review of the literature focusing on what the target population considers as

			important outcomes, judging the relative importance of the outcomes and discussing disagreements.	critical or important outcomes for decision making. Literature about values, preferences or utilities is often used in these reviews, that should be systematic in nature. Alternatively the collective experience of the panel members, patients, and members of the public can be used using transparent methods for documenting and considering them (see Santesso N et al, IJOBGYN 2012). Prior knowledge of the research evidence or, ideally, a systematic review of that evidence is likely to be helpful.
2	Reassessment of the relative importance of outcomes after reviewing the evidence	To ensure that important outcomes identified by reviews of the evidence that were not initially considered are included and to reconsider the relative importance of outcomes in light of the available evidence	By asking the panel members (and, if relevant, patients and members of the public) to reconsider the relative importance of the outcomes included in the first step and any additional outcomes identified by reviews of the evidence	Experience of the panel members and other informants and systematic reviews of the effects of the intervention
3	Judging the balance between the desirable and undesirable health outcomes of an intervention	To support making a recommendation and to determine the strength of the recommendation	By asking the panel members to balance the desirable and undesirable health outcomes using an evidence to recommendation framework that includes a summary of findings table or evidence profile and, if relevant, based on a decision analysis	Experience of the panel members and other informants, systematic reviews of the effects of the intervention, evidence of the value that the target population attach to key outcomes (if relevant and available) and decision analysis or economic analyses (if relevant and available)

3.2 Influence of perspective

The **importance** of outcomes is **likely to vary** within and across cultures or when considered from the **perspective** of the target population (e.g. patients or the public), clinicians or policy-makers. Cultural diversity will often influence the relative importance of outcomes, particularly when developing recommendations for an international audience.

Guideline panels must decide what perspective they are taking. Although different panels may elect to take different perspectives (e.g. that of individual patients or a health systems perspective), the relative importance given to health outcomes should reflect the perspective of those who are affected. When the target audiences for a guideline are clinicians and the patients they treat, the perspective would generally be that of the patient. (see Chapter Going from evidence to recommendations that addresses the issue of perspective from the point of view of resource use)

3.3 Using evidence in rating the importance of outcomes

Guideline developers will ideally review evidence, or conduct a systematic review of the evidence, relating to patients' values and preferences about the intervention in question in order to inform the rating of the importance of outcomes. Reviewing the evidence may provide the panel with insight about the variability in patients' values, the patient experience of burden or side effects, and the weighing of desirable versus undesirable outcomes.

In the **absence of such evidence**, panel members should use their prior experiences with the target population to assume the relevant values and preferences.

3.4 Surrogate (substitute) outcomes

Not infrequently, outcomes of most importance to patients remain unexplored. When important outcomes are relatively infrequent, or occur over long periods of time, investigators often choose to measure substitutes, or surrogates, for those outcomes.

Guideline developers should **consider surrogate outcomes only when evidence about population-important outcomes is lacking**. When this is the case, they should specify the population-important outcomes and, if necessary, the surrogates they are using to substitute for those important outcomes. Guideline developers should not list the surrogates themselves as their measures of outcome. The necessity to substitute the surrogate may ultimately lead to rating down the quality of the evidence because of the indirectness (see Chapter Quality of evidence).

Outcomes selected by the guideline panel should be **included in an evidence profile whether or not information about them is available** (see Chapter Summarizing the evidence), that is an empty row in an evidence profile can be informative in that it identifies research gaps.

4. Summarizing the evidence

A guideline panel should base its recommendation on the **best available body of evidence** related to the health care question. A guideline panel can use already existing high quality **systematic reviews** or conduct its own systematic review depending on the specific circumstances such as availability of high quality systematic reviews and resources, but GRADE recommends that systematic reviews should form the basis for making health care recommendations. One should seek evidence relating to **all patient-important outcomes** and for the **values** patients place on these outcomes as well as related management options.

The endpoint for systematic reviews and for HTA restricted to evidence reports is a summary of the evidence, the quality rating for each outcome and the estimate of effect. For guideline developers and HTA that provide advice to policymakers, a summary of the evidence represents a key milestone on the path to a recommendation. The evidence collected from systematic reviews is used to produce GRADE evidence profile and summary of findings table.

4.1 Evidence Tables

An **evidence table** is a key tool in the presentation of evidence and the corresponding results. Evidence tables are a method for presenting the quality of the available evidence, the judgments that bear on the quality rating, and the effects of alternative management strategies on the outcomes of interest.

Clinicians, patients, the public, guideline developers, and policy-makers require succinct and transparent evidence summaries to support their decisions. While an unambiguous health care question is key to evidence summaries, the requirements for specific users may differ in content and detail. Therefore, the format of each table may be different depending on user needs.

Two approaches (with iterations) for evidence tables are available, which serve different purposes and are intended for different audiences:

- (GRADE) evidence profile
- Summary of Findings (SoF) table

The Guideline Development Tool facilitates the production of both Evidence Profiles and SoF tables. After completing the information to populate the tables, the information will be stored and can be updated accordingly. Different formats for each aproach, chosen according to what the target audience may prefer, are available.

Outcomes considered **important** (rated 4-6) or **critical** (rated 7-9) for decision-making should be included in the evidence profile and SoF table.

4.2 GRADE Evidence Profile

See online tutorials at: cebgrade.mcmaster.ca

The **GRADE evidence profile** contains detailed information about the quality of evidence assessment and the summary of findings for each of the included outcomes. It is intended for review authors, those preparing SoF tables and anyone who questions a quality assessment. It helps those preparing SoF tables to ensure that the judgments they make are systematic and transparent and it allows others to inspect those judgments. Guideline panels should use evidence profiles to ensure that they agree about the judgments underlying the quality assessments.

A GRADE evidence profile allows presentation of key information about all relevant outcomes for a given health care question. It presents **information about the body of evidence** (e.g. number of studies), the **judgments about the underlying quality of evidence**, key **statistical results**, and **the quality of evidence rating for each outcome**.

A GRADE evidence profile is particularly useful for presentation of evidence supporting a recommendation in clinical practice guidelines but also as summary of evidence for other purposes where users need or want to understand the judgments about the quality of evidence in more detail.

The standard format for the evidence profile includes:

- A list of the **outcomes**
- The **number of studies** and **study design(s)**
- Judgements about each of the **quality of evidence factors** assessed; risk of bias, inconsistency, indirectness, imprecision, other considerations (including publication bias and factors that increase the quality of evidence)
- The **assumed risk**; a measure of the typical burden of the outcomes, i.e. illustrative risk or also called baseline risk, baseline score, or control group risk
- The **corresponding risk;** a measure of the burden of the outcomes after the intervention is applied, i.e. the risk of an outcome in treated/exposed people based on the relative magnitude of an effect and assumed (baseline) risk
- The **relative effect**; for dichotomous outcomes the table will usually provide risk ratio, odds ratio, or hazard ratio
- The **absolute effect**; for dichotomous outcomes the number of fewer or more events in treated/exposed group as compared to the control group
- Rating of the **overall quality of evidence** for each outcome (which may vary by outcome)
- Classification of the **importance** of each outcome
- **Footnotes**, if needed, to provide explanations about information in the table such as elaboration on judgements about the quality of evidence

Example 1: GRADE Evidence Profile

[INSERT IMAGE]

4.3 Summary of Findings table

Summary of Findings tables provide a summary of findings for each of the included outcomes and the quality of evidence rating for each outcome in a quick and accessible format, without details of the judgements about the quality of evidence. They are intended for a broader audience, including end users of systematic reviews and guidelines. They provide a concise summary of the key information that is needed by someone making a decision and, in the context of a guideline, provide a summary of the key information underlying a recommendation

The format of SoF tables produced using the Guideline Development Tool has been refined over the past several years through wide consultation, user testing, and evaluation. It is designed to support the optimal presentation of the key findings of systematic reviews. The SoF table format has been developed with the aim of ensuring consistency and ease of use across reviews, inclusion of the most important information needed by decision makers, and optimal presentation of this information. However, there may be good reasons for modifying the format of a SoF table for some reviews.

The standard format for the SoF table includes:

- A list of the **outcomes**
- The **assumed risk**; a measure of the typical burden of the outcomes, i.e. illustrative risk or also called baseline risk, baseline score, or control group risk
- The **corresponding risk;** a measure of the burden of the outcomes after the intervention is applied, i.e. the risk of an outcome in treated/exposed people based on the relative magnitude of an effect and assumed (baseline) risk
- The **relative effect**; for dichotomous outcomes the table will usually provide risk ratio, odds ratio, or hazard ratio
- The **number of participants** and the **number of studies** and their **designs**
- Rating of the **overall quality of evidence** for each outcome (which may vary by outcome)
- **Footnotes or explanations**, if needed, to provide explanations about information in the table
- Comments (if needed)

Systematic reviews that address more than one main comparison (e.g. examining the effects of a number of interventions) will require **separate SoF tables** for each comparison. Moreover, for **each comparison** of alternative management strategies, **all outcomes should be presented** together in one evidence profile or SoF table. It is likely that all studies relevant to a health care question will not provide evidence regarding every outcome. Indeed, there may be no overlap between studies providing evidence for one outcome and those providing evidence for another. Because most existing systematic reviews do not adequately address all relevant outcomes, the GRADE process may require relying on more than one systematic review.

Example 2: GRADE Summary of Findings Table

[INSERT IMAGE]

heparin compared to no heparin for patients with cancer who have no other therapeutic or prophylactic indication for anticoagulation

Bibliography: Akl EA, Gunukula SK, van Doormaal FF, Barba M, Kuipers S, Middeldorp S, Yosuico VE D, Dickinson HO, Schünemann H. Parenteral anticoagulation in patients with cancer who have no therapeutic or prophylactic indication for anticoagulation. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No heparin	Risk difference with Heparin (95% CI)
Mortality	2531 (8 studies) 12 months	⨁⨁⨁⊖ **MODERATE**[1,2,3] due to inconsistency	**RR 0.93** (0.85 to 1.02)	**Moderate**	
				649 per 1000	**45 fewer per 1000** (from 97 fewer to 13 more)
Symptomatic VTE	2264 (7 studies) 12 months	⨁⨁⨁⨁ **HIGH**[1]	**RR 0.55** (0.37 to 0.82)	**Moderate**	
				29 per 1000	**13 fewer per 1000** (from 5 fewer to 18 fewer)
Major bleeding	2843 (9 studies) 12 months	⨁⨁⨁⊖ **MODERATE**[1,4] due to imprecision	**RR 1.3** (0.59 to 2.88)	**Moderate**	
				7 per 1000	**2 more per 1000** (from 3 fewer to 13 more)
Minor bleeding	2345 (7 studies) 12 weeks	⨁⨁⨁⊖ **MODERATE**[1,4] due to imprecision	**RR 1.05** (0.75 to 1.46)	**Moderate**	
				27 per 1000	**1 more per 1000** (from 7 fewer to 12 more)
Health related quality of life the Uniscale and the Symptom Distress Scale (SDS); Better indicated by lower values	0 (1 study) 12 months	⨁⨁⊖⊖ **LOW**[5] due to risk of bias, imprecision	Not estimable[6]	See comment	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Vast majority of studies had allocation concealment, and used blinded outcome and adjudication. We did not downgrade although there was some concern about lack of blinding in some studies, the overall risk of bias was felt to be very low.
[2] There is moderate heterogeneity among studies included in the analysis of death at 12 months (I2=35%). The subgroup analysis for mortality at 12 months was statistically significant and suggested survival benefit in patients with SCLC but not in patients with advanced cancer. Overall we decided to downgrade by one level when considering these issues along with imprecision.
[3] CI interval includes effects suggesting benefit as well as no benefit.
[4] CI includes possibility of both harms or benefits. [5] The scores for the 2 scales were similar for the 2 study groups, both at baseline and at follow-up. [6] High risk of bias and only 138 patients enrolled.

5. Quality of evidence

GRADE provides a specific definition of the quality of evidence that is different in the context of making recommendations and in the context of summarizing the findings of a systematic review.

As GRADE suggests somewhat different approaches for rating the quality of evidence for systematic reviews and for guidelines, the handbook highlights guidance that is specific to each group. HTA practitioners, depending on their mandate, can decide which approach is more suitable for their goals.

For guideline panels:

The quality of evidence reflects the extent to which our **confidence in an estimate of the effect** is adequate to **support a particular recommendation**.

Guideline panels must make judgments about the quality of evidence relative to the specific context for which they are using the evidence.

The GRADE approach involves separate grading of quality of evidence for each patient-important outcome followed by determining an overall quality of evidence across outcomes.

For authors of systematic reviews:

The quality of evidence reflects the extent to which we are **confident that an estimate of the effect is correct**.

Because systematic reviews do not, or at least should not, make recommendations, they require a different definition. Authors of systematic reviews grade quality of a body of evidence separately for each patient-important outcome.

The quality of evidence is rated for each outcome across studies (i.e. for a body of evidence). This does not mean rating each study as a single unit. Rather, GRADE is "**outcome centric**"; **rating is done for each outcome**, and quality may differ - indeed, is likely to differ - from one outcome to another within a single study and across a body of evidence.

Example 1: Quality of evidence may differ from one outcome to another within a single study

In a series of unblinded RCTs measuring both the occurrence of stroke and all-cause mortality, it is possible that stroke - much more vulnerable to biased judgments - will be rated down for risk of bias, whereas all-cause mortality will not. Similarly, a series of studies in which very few patients are lost to follow-up for the outcome of death, and very many for the outcome of quality of life, is likely to result in judgments of lower quality for the latter outcome. Problems with indirectness may lead to rating down

quality for one outcome and not another within a study or studies if, for example, fracture rates are measured using a surrogate (e.g. bone mineral density) but side effects are measured directly.

Although the quality of evidence represents a continuum, the GRADE approach results in an assessment of the quality of a body of evidence in one of **four grades**:

Table 5.1: Quality of Evidence Grades

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Quality of evidence is a continuum; any discrete categorisation involves some degree of arbitrariness. Nevertheless, advantages of simplicity, transparency, and vividness outweigh these limitations.

5.1 Factors determining the quality of evidence

The GRADE approach to rating the quality of evidence begins with the study design (trials or observational studies) and then addresses five reasons to possibly rate down the quality of evidence and three to possibly rate up the quality. The subsequent sections of the handbook will address each of the factors in detail.

Table 5.2: Factors that can reduce the quality of the evidence

Factor	Consequence
Limitations in study design or execution (risk of bias)	↓ 1 or 2 levels
Inconsistency of results	↓ 1 or 2 levels
Indirectness of evidence	↓ 1 or 2 levels
Imprecision	↓ 1 or 2 levels
Publication bias	↓ 1 or 2 levels

Table 5.3: Factors that can increase the quality of the evidence

Factor	Consequence
Large magnitude of effect	↑ 1 or 2 levels
All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed	↑ 1 level
Dose-response gradient	↑ 1 level

While factors influencing the quality of evidence are **additive** – such that the reduction or increase in each individual factor is added together with the other factors to reduce or increase the quality of evidence for an outcome – grading the quality of evidence involves judgements which are not exclusive. Therefore, GRADE is not a quantitative system for grading the quality of evidence. Each factor for downgrading or upgrading reflects **not discrete categories but a continuum** within each category and among the categories. When the body of evidence is intermediate with respect to a particular factor, the decision about whether a study falls above or below the threshold for up- or downgrading the quality (by one or more factors) depends on judgment.

For example, if there was some uncertainty about the three factors: study limitations, inconsistency, and imprecision, but not serious enough to downgrade each of them, one could reasonably make the case for downgrading, or for not doing so. A reviewer might in each category give the studies the benefit of the doubt and would interpret the evidence as high quality. Another reviewer, deciding to rate down the evidence by one level, would judge the evidence as moderate quality. Reviewers should grade the quality of the evidence by considering both the individual factors in the context of other judgments they made about the quality of evidence for the same outcome.

In such a case, you should pick one or two categories of limitations which you would offer as reasons for downgrading and explain your choice in the footnote. You should also provide a footnote next to the other factor, you decided not to downgrade, explaining that there was some uncertainty, but you already downgraded for the other factor and further lowering the quality of evidence for this outcome would seem inappropriate. GRADE strongly encourages review and guideline authors to be **explicit and transparent** when they find themselves in these situations by **acknowledging borderline decisions**.

Despite the limitations of breaking continua into categories, treating each criterion for rating quality up or down as discrete categories enhances transparency. Indeed, the **great merit of GRADE** is not that it ensures reproducible judgments but that it **requires explicit judgment** that is made **transparent to users**.

5.1.1 Study design

Study design is critical to judgments about the quality of evidence.

For recommendations regarding management strategies – as opposed to establishing prognosis or the accuracy of diagnostic tests – **randomized trials** provide, in general, far stronger evidence than observational studies, and rigorous **observational studies** provide stronger evidence than **uncontrolled case series**.

In the GRADE approach to quality of evidence:

- **randomized trials** without important limitations provide **high quality** evidence
- **observational studies** without special strengths or important limitations provide **low quality** evidence

Limitations or special strengths can, however, **modify** the quality of the evidence of both randomized trials and observational studies.

Note:

Non-randomised experimental trials (quasi-RCT) without important limitations also provide high quality evidence, but will automatically be downgraded for limitations in design (risk of bias) – such as lack of concealment of allocation and tie with a provider (e.g. chart number).

Case series and **case reports** are observational studies that investigate only patients exposed to the intervention. Source of control group results is implicit or unclear, thus, they will usually warrant downgrading from low to very low quality evidence.

Expert opinion is not a category of quality of evidence. Expert opinion represents an interpretation of evidence in the context of experts' experiences and knowledge. Experts may have opinion about evidence that may be based on interpretation of studies ranging from uncontrolled case series (e.g. observations in expert's own practice) to randomized trials and systematic reviews known to the expert. It is important to describe what type of evidence (whether published or unpublished) is being used as the basis for interpretation.

5.2 Factors that can reduce the quality of the evidence

The following sections discuss in detail the 5 factors that can result in rating down the quality of evidence for specific outcomes and, thereby, reduce confidence in the estimate of the effect.

5.2.1 Study limitations (Risk of Bias)

Limitations in the study design and execution may bias the estimates of the treatment effect. Our confidence in the estimate of the effect and in the following recommendation decreases if studies suffer from major limitations. The more serious the limitations are, the more likely it is that the quality of evidence will be downgraded. Numerous tools exist to evaluate the risk of bias in randomized trials and observational studies. This handbook describes the key criteria used in the GRADE approach.

Our confidence in an estimate of effect decreases if studies suffer from major limitations that are likely to result in a biased assessment of the intervention effect. For randomized trials, the limitations outlined in **Table 5.4**are likely to result in biased result.

Table 5.4: Study limitations in randomized controlled trials

	Explanation
Lack of allocation concealment	Those enrolling patients are aware of the group (or period in a crossover trial) to which the next enrolled patient will be allocated (a major problem in "pseudo" or "quasi" randomized trials with allocation by day of week, birth date, chart number, etc.).
Lack of blinding	Patient, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are allocated (or the medication currently being received in a crossover trial).
Incomplete accounting of patients and outcome events	Loss to follow-up and failure to adhere to the intention-to-treat principle in superiority trials; or in noninferiority trials, loss to follow-up, and failure to conduct both analyses considering only those who adhered to treatment, and all patients for whom outcome data are available. The significance of particular rates of loss to follow-up, however, varies widely and is dependent on the relation between loss to follow-up and number of events. The higher the proportion lost to follow-up in relation to intervention and control group event rates, and differences between intervention and control groups, the greater the threat of bias.
Selective outcome reporting	Incomplete or absent reporting of some outcomes and not others on the basis of the results.
Other limitations	• Stopping trial early for benefit. Substantial overestimates are likely in trials with fewer than 500 events and that large overestimates are likely in trials with fewer than 200 events. Empirical

	evidence suggests that formal stopping rules do not reduce this bias. • Use of unvalidated outcome measures (e.g. patient-reported outcomes) • Carryover effects in crossover trial • Recruitment bias in cluster-randomized trials

Systematic reviews of tools to assess the methodological quality of non-randomized studies have identified over 200 checklists and instruments. We summarize in **Table 5.5** the key criteria for observational studies that reflect the contents of these checklists.

Table 5.5: Study limitations in observational studies

	Explanation
Failure to develop and apply appropriate eligibility criteria (inclusion of control population)	• Under- or over-matching in case-control studies • Selection of exposed and unexposed in cohort studies from different populations
Flawed measurement of both exposure and outcome	• Differences in measurement of exposure (e.g. recall bias in case-control studies) • Differential surveillance for outcome in exposed and unexposed in cohort studies
Failure to adequately control confounding	• Failure of accurate measurement of all known prognostic factors • Failure to match for prognostic factors and/or adjustment in statistical analysis
Incomplete or inadequately short follow-up	Especially within prospective cohort studies, both groups should be followed for the same amount of time.

Depending on the context and study type, there can be additional limitations than those listed above. Guideline panels and authors of systematic reviews should consider all possible limitations.

Guideline panels or authors of systematic reviews should consider the extent to which study limitations may bias the results (*see Examples 1 to 7*). If the limitations are serious they may downgrade the quality rating by one or even two levels. Moving from risk of bias criteria for each individual study to a judgment about rating down for quality of evidence for risk of bias across a group of studies addressing a particular outcome presents challenges. We suggest the following principles:

1. In deciding on the overall quality of evidence, one does not average across studies (for instance if some studies have no serious limitations, some serious limitations, and some very serious limitations, one does not automatically rate quality down by one level because of an average rating of serious limitations). Rather, judicious consideration of the contribution of each study, with a general guide to focus on the high-quality studies, is warranted.

2. The judicious consideration requires evaluating the extent to which each trial contributes toward the estimate of magnitude of effect. This contribution will usually reflect study sample size and number of outcome events – larger trials with many events will contribute more, much larger trials with many more events will contribute much more.

3. One should be conservative in the judgment of rating down. That is, one should be confident that there is substantial risk of bias across most of the body of available evidence before one rates down for risk of bias.

4. The risk of bias should be considered in the context of other limitations. If, for instance, reviewers find themselves in a close-call situation with respect to two quality issues (risk of bias and, say, precision), we suggest rating down for at least one of the two.

5. Reviewers will face close-call situations. They should both acknowledge that they are in such a situation, make it explicit why they think this is the case, and make the reasons for their ultimate judgment apparent.

For authors of systematic reviews:

Systematic reviewers working within the context of Cochrane Systematic Reviews, can use the following guidance to assess study limitations (risk of bias) in Cochrane Reviews. Chapter 8 of the Cochrane Handbook provides a detailed discussion of study-level assessments of risk of bias in the context of a Cochrane review, and proposes an approach to assessing the risk of bias for an outcome across studies as 'low risk of bias', 'unclear risk of bias' and 'high risk of bias' (Cochrane Handbook Chapter 8, Section 8.7). These assessments should feed directly into the assessment of study limitations. In particular, 'low risk of bias' would indicate 'no limitation'; 'unclear risk of bias' would indicate either 'no limitation' or 'serious limitation'; and 'high risk of bias' would indicate either 'serious limitation' or 'very serious limitation' in the GRADE approach. Cochrane systematic review authors must use their judgment to decide between alternative categories, depending on the likely magnitude of the potential biases.

Every study addressing a particular outcome will differ, to some degree, in the risk of bias. Review authors must make an overall judgment on whether the quality of evidence for an outcome warrants downgrading on the basis of study limitations. The assessment of study limitations should apply to the studies contributing to the results in the Summary of Findings table, rather than to all studies that could potentially be included in the analysis.

Table 5.6: Guidance to assess study limitations (risk of bias) in Cochrane Reviews and corresponding GRADE assessment of quality of evidence

Risk of bias	Across studies	Interpretation	Considerations	GRADE assessment of study limitations

Low	Most information is from studies at low risk of bias.	Plausible bias unlikely to seriously alter the results.	No apparent limitations.	No serious limitations, do not downgrade
Unclear	Most information is from studies at low or unclear risk of bias.	Plausible bias that raises some doubt about the results.	Potential limitations are unlikely to lower confidence in the estimate of effect.	No serious limitations, do not downgrade
			Potential limitations are likely to lower confidence in the estimate of effect.	Serious limitations, downgrade one level.
High	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results.	Plausible bias that seriously weakens confidence in the results.	Crucial limitation for one criterion, or some limitations for multiple criteria, sufficient to lower confidence in the estimate of effect.	Serious limitations, downgrade one level
			Crucial limitation for one or more criteria sufficient to substantially lower confidence in the estimate of effect.	Very serious limitations, downgrade two levels

Example 1: Unclear Risk of Bias (Not Downgraded)

A systematic review investigated whether fewer people with cancer died when given anti-coagulants compared to a placebo. There were 5 RCTs. Three studies had unclear sequence generation as it was not reported by authors and one study (contributing few patients to the meta-analysis) had unclear allocation concealment, and incomplete outcome data. In this case, the overall limitations were not serious and the evidence was not downgraded for risk of bias.

Example 2: Unclear Risk of Bias (Downgraded by One Level)

A systematic review of the effects of testosterone on erection satisfaction in men with low testosterone identified four RCTs. The largest trial's results were reported only as "not significant" and could not, therefore, contribute to the meta-analysis. Data from the three smaller trials suggested a large treatment effect (1.3 standard deviations, 95% confidence interval 0.2, 2.3). The authors could not obtain the missing data, and could not be confident that the large treatment effect was certain, therefore, they rated down the body of evidence for selective reporting bias in the largest study.

In another scenario, the review authors did obtain the complete data from the larger trial. After including the less impressive results of the large trial, the magnitude of the effect was smaller and no longer statistically significant (0.8 standard deviations, 95% confidence interval 0.05, 1.63). In that case, the evidence would not be downgraded.

Example 3: High Risk of Bias due to lack of blinding (Downgraded by One Level)

RCTs of the effects of Intervention A on acute spinal injury measured both all-cause mortality and, based on a detailed physical examination, motor function. The outcome assessors were not blinded for any outcomes. Blinding of outcome assessors is less important for the assessment of all-cause mortality, but crucial for motor function. The quality of the evidence for the mortality outcome may not be downgraded. However, the quality may be downgraded for the motor function outcome.

Example 4: High Risk of Bias due to lack of allocation concealment (Downgraded by One Level)

A systematic review of 2 RCTs showed that family therapy for children with asthma improved daytime wheeze. However, allocation was clearly not concealed in the two included trials. This limitation might warrant downgrading the quality of evidence by one level.

Example 5: High Risk of Bias (Downgraded by One Level)

A review was conducted to assess the effects of early versus late treatment of influenza with oseltamivir in observational studies. Researchers found 8 observational studies which assessed the risk of mortality. The statistical analysis in all 8 studies did not adjust for potential confounding risk factors such as age, chronic lung conditions, vaccination or immune status. The quality of the evidence was therefore downgraded from low to very low for serious limitations in study design.

Example 6: High Risk of Bias (Downgraded by Two Levels)

Three RCTs of the effects of surgery on patients with lumbar disc prolapse measured symptoms after 1 year or longer. The RCTs suffered from inadequate concealment of allocation, and unblinded assessment of outcome by potentially biased raters (surgeons) using a non-validated rating instrument. The benefit of surgery is uncertain. The quality of the evidence was downgraded by two levels due to these study limitations quality.

Example 7: High Risk of Bias (Downgraded by Two Levels)

The evidence for the effect of sublingual immunotherapy in children with allergic rhinitis on the development of asthma comes from a single randomized trial with no description of randomization, concealment of allocation or type of analysis, there was no blinding and 21% of children were lost to follow-up. These very serious limitations would warrant downgrading the quality of evidence by two levels, from high to low.

5.2.2 Inconsistency of results

Inconsistency refers to an **unexplained heterogeneity** of results.

True differences in the underlying treatment effect may be likely when there are widely differing estimates of the treatment effect (i.e. heterogeneity or variability in results) across studies. Investigators should explore explanations for heterogeneity, and if they cannot identify a plausible explanation, the quality of evidence should be downgraded. Whether it is downgraded by one or two levels will depend on the magnitude of the inconsistency in the results.

Patients vary widely in their pre-intervention or baseline risk of the adverse outcomes that health care interventions are designed to prevent (e.g. death, stroke, myocardial infarction). As a result, risk differences (absolute risk reductions) in subpopulations tend to vary widely. Relative risk (RR) reductions, on the other hand, tend to be similar across subgroups, even if subgroups have substantial differences in baseline risk. Therefore, when we refer to **inconsistencies in effect size**, we are referring we are **referring to relative measures** (risk ratios and hazard ratios, which are preferred, or odds ratios).

When easily identifiable patient characteristics confidently permit classifying patients into subpopulations at appreciably different risk, absolute differences in outcome between intervention and control groups will differ substantially between these subpopulations. This may well warrant differences in recommendations across subpopulations, rather than downgrading the quality evidence for inconsistency in effect size.

Although there are statistical methods to measure heterogeneity, there are a variety of other criteria to assess heterogeneity, which can also be used when results cannot be pooled statistically. Criteria to determine whether to downgrade for inconsistency can be applied when results are from more than one study and include:

1. Wide variance of point estimates across studies (note: direction of effect is not a criterion for inconsistency)

2. Minimal or no overlap of confidence intervals (CI), which suggests variation is more than what one would expect by chance alone

3. Statistical criteria, including tests of heterogeneity which test the null hypothesis that all studies have the same underlying magnitude of effect, have a low p-value ($p < 0.05$), indicating to reject the null hypothesis

I^2 statistic, which quantifies the proportion of the variation in point estimates due to among-study differences, is large (see note below for decisions based on I^2 statistic)

Note:

While determining what constitutes a large I^2 value is subjective, the following rule-of thumb can be used:

- < 40% may be low
- 30-60% may be moderate
- 50-90% may be substantial
- 75-100% may be considerable

Overlaps in these ranges, and use of "may be" as terminology, illustrate the uncertainty involved in making such judgments. It is also important to note the implicit limitations in this statistic. When individual study sample sizes are small, point estimates may vary substantially, but because variation can be explained by chance, I^2 may be low. Conversely, when study sample sizes are large, a relatively small difference in point estimates can yield a large I^2. Another statistic, τ^2 (tau square) is a measure of the variability that has an advantage over other measures in that it is not dependent on sample size.

All statistical approaches have limitations, and their results should be seen in the context of a subjective examination of the variability in point estimates and the overlap in CIs.

Example 1: Differences in direction, but minimal heterogeneity

Consider the figure below; a forest plot with four studies, two on either side of the line of no effect. We would have no inclination to rate down for inconsistency. Differences in direction, in and of themselves, do not constitute a criterion for variability in effect if the magnitude of the differences in point estimates is small.

[INSERT IMAGE]

Example 2: When inconsistency is large, but differences are between small and large beneficial effects

As we define quality of evidence **for a guideline**, inconsistency is important only when it reduces confidence in results **in relation to a particular decision**. Even when inconsistency is large, it may not reduce confidence in results regarding a particular decision. Consider, the figure below in which variability is substantial, but the differences are between small and large treatment effects.

Guideline developers may or may not consider this degree of variability important. Systematic review authors, much less in a position to judge whether the apparent high heterogeneity can be dismissed on the grounds that it is unimportant, are more likely to rate down for inconsistency.

[INSERT IMAGE]

Example 3: Substantial heterogeneity, of unequivocal importance

Consider the figure below. The magnitude of the variability in results is identical to that of the figure presented in Example 2. However, because two studies suggest benefit and two suggest harm, we would unquestionably choose to rate down the quality of evidence as a result of inconsistency.

[INSERT IMAGE]

Example 4: Test a priori hypotheses about inconsistency even when inconsistency appears to be small

A meta-analysis of randomized trials of rofecoxib looking at the outcome of myocardial infarction found apparently consistent results (heterogeneity p=0.82, I^2=0%). Yet, when the investigators examined the effect in trials that used an external endpoint committee (RR 3.88, 95% CI: 1.88, 8.02) vs. trials that did not (RR 0.79, 95% CI: 0.29, 2.13), they found differences that were large and unlikely to be explained by chance (p=0.01).

Although the issue is controversial, we recommend that meta-analyses include formal tests of whether a priori hypotheses explain inconsistency between important subgroups even if the variability that exists appears to be explained by chance (e.g. high p-values in tests of heterogeneity, and low I^2 values).

If the effect size differs across studies, explanations for inconsistency may be due to differences in:

- **populations** (e.g. drugs may have larger relative effects in sicker populations)
- **interventions** (e.g. larger effects with higher drug doses)
- **outcomes** (e.g. duration of follow-up)
- **study methods** (e.g. RCTs with higher and lower risk of bias).

If inconsistency can be explained by **differences in populations**, **interventions** or **outcomes**, review authors should offer different estimates across patient groups, interventions, or outcomes. Guideline panelists are then likely to offer different recommendations for different patient groups and interventions. If **study methods** provide a compelling explanation for differences in results between studies, then authors should consider focusing on effect estimates from studies with a lower risk of bias.

If large variability in magnitude of effect remains unexplained and authors fail to attribute it to differences in one of these four variables, then the quality of evidence decreases. Review authors and guideline panels should also consider **the extent** to which they are uncertain about the underlying effect due to the inconsistency. Uncertainty relates to how important inconsistency is to the confidence in the result. The extent is used to decide whether to downgrade the quality rating by one or even two levels.

Example 5: Making separate recommendations for subpopulations

When the analysis for benefits of endarterectomy was pooled across patients with stenosis of the carotid artery, there was high heterogeneity. Heterogeneity was explored and was explained by separating out patients who were symptomatic with high degree stenosis (in which endarterectomy was beneficial), and patients who were asymptomatic with moderate degree stenosis (in which surgery was not beneficial). The authors presented and graded the evidence by patient group and did not downgrade the quality of the evidence for inconsistency. Two different recommendations were also made according to patient group by the guideline panel.

5.2.2.1 Deciding whether to use estimates from a subgroup analysis

Finding an explanation for inconsistency is preferable. An explanation can be based on differences in population, intervention, or outcomes which mandate two or more estimates of effect, possibly with separate recommendations. However, subgroups effects may prove spurious and may not explain all the variability in the extent of inconsistency. Indeed, most putative subgroup effects ultimately prove spurious. A cautionary note about subgroup analyses and their presentation is warranted; refer to Sun et al. 2010 and Guyatt et al. 2011 for further reading.

Review authors and guideline developers must exercise a high degree of skepticism regarding potential subgroup effect explanations, paying particular attention to criteria the following 7 criteria:

1. Is the subgroup variable a characteristic specified at baseline or after randomization? (subgroup hypotheses should be developed a priori)
2. Is the subgroup difference suggested by comparisons within rather than between studies?
3. Does statistical analysis suggest that chance is an unlikely explanation for the subgroup difference?
4. Did the hypothesis precede rather than follow the analysis and include a hypothesized direction that was subsequently confirmed?
5. Was the subgroup hypothesis one of a smaller number tested?
6. Is the subgroup difference consistent across studies and across important outcomes?
7. Does external evidence (biological or sociological rationale) support the hypothesized subgroup difference?

The credibility of subgroup effects is not a matter of yes or no, but a **continuum**. Judgement is required to determine how convincing a subgroup analysis is based on the above criteria.

Example 6: Subgroup analysis explaining inconsistency in results

A systematic review and individual patient data meta-analysis (IPDMA) addressed the impact of high vs. low positive end-expiratory pressures (PEEPs) in three randomized trials that enrolled 2,299 adult patients with severe acute lung injury requiring mechanical ventilation.

The results of this IPDMA suggested a possible reduction in deaths in hospital with the higher PEEP strategy, but the difference was not statistically significant (RR 0.94; 95% CI: 0.86, 1.04). In patients with severe disease (labeled acute respiratory distress syndrome), the effect more clearly favored the high PEEP strategy (RR 0.90; 95% CI: 0.81, 1.00; P50.049). In patients with mild disease, results suggested that the high PEEP strategy may be inferior (RR 1.37; 95% CI: 0.98, 1.92).

Applying the seven criteria (see table below), we find that six are met fully, and the seventh, consistency across trials and outcomes, partially: the results of the subgroup analysis were consistent across the three studies, but other ways of measuring severity of lung injury (for instance, treating severity as a continuous variable) failed to show a statistically significant interaction between the severity and the magnitude of effect. In this case, the subgroup analysis is relatively convincing.

[INSERT IMAGE]

Example 7: Subgroup analysis not very likely to explain inconsistency in results

Three randomized trials have tested the effects of vasopressin vs. epinephrine on survival in patients with cardiac arrest. The results show appreciable differences in point estimates, widely overlapping CIs, a p-value for the test of heterogeneity of 0.21 and an *I2* of 35%.

Two of the trials included both patients in whom asystole was responsible for the cardiac arrest and the patients in whom ventricular fibrillation was the offending rhythm. One of these two trials reported a borderline statistically significant benefit - our own analysis was borderline nonsignificant - of

vasopressin over epinephrine restricted to patients with asystole (in contrast to patients whose cardiac arrest was induced by ventricular fibrillation).

It is not very likely that the subgroup analysis can explain the moderate inconsistency in the results. Chance can explain the putative subgroup effect and the hypothesis fails other criteria (including small number of a priori hypotheses and consistency of effect). Here, guideline developers should make recommendations on the basis of the pooled estimate of data from both the groups. Whether the quality of evidence should be rated down for inconsistency is another judgment call; we would argue for not rating down for inconsistency.

[INSERT IMAGE]

5.2.3 Indirectness of evidence

We are more confident in the results when we have direct evidence. Direct evidence consists of research that directly compares the interventions which we are interested in, delivered to the populations in which we are interested, and measures the outcomes important to patients.

Authors of systematic reviews and guideline panels making recommendations should consider the extent to which they are uncertain about the applicability of the evidence to their relevant question and downgrade the quality rating by one or even two levels.

For authors of systematic reviews:

Directness is judged by the users of evidence tables, depending on the target population, intervention, and outcomes of interest. Authors of systematic reviews should answer the health care question they asked and, thus, they will rate the directness of evidence they found. The considerations made by the authors of systematic reviews may be different than those of guideline panels that use the systematic reviews. The more clearly and explicitly the health care question was formulated the easier it will be for the users to understand systematic review authors' judgments.

There are four sources of indirectness:

1. Differences in population (applicability)

Differences between study populations within a systematic review are a common problem for systematic review authors and guideline panels. When this occurs evidence is indirect. The effect on overall quality of evidence will vary depending on how different the study populations are, as a result quality may not decrease, decrease by a one level or decrease by two levels in extreme cases.

The above discussion refers to different human populations, but sometimes the only evidence will be from animal studies, such as rats or primates. In general, we would rate such evidence down two levels for indirectness. Animal studies may, however, provide an important indication of drug toxicity. Although toxicity data from animals does not reliably predict toxicity in humans, evidence of animal toxicity should engender caution in recommendations. Other types of nonhuman studies (e.g. laboratory evidence) may generate high quality evidence

Example 1: Indirectness in Populations (Downgraded by Two Levels)

High-quality randomized trials have demonstrated the effectiveness of antiviral treatment for seasonal influenza. The panel judged that the biology of seasonal influenza was sufficiently different from that of avian influenza (avian influenza organism may be far less responsive to antiviral agents than seasonal influenza) that the evidence required rating down quality by two levels, from high to low, due to indirectness.

Example 2: Non-human studies providing high quality evidence (Not Downgraded)

Consider laboratory evidence of change in resistance patterns of bacteria to antimicrobial agents (e.g. the emergence of methicillin-resistant staphylococcus aureus - MRSA). These laboratory findings may constitute high quality evidence for the superiority of antibiotics to which MRSA is sensitive vs. methicillin as the initial treatment of suspected staphylococcus sepsis in settings in which MRSA is highly prevalent.

2. Differences in interventions (applicability)

Systematic reviewers will make a concerted effort to ensure that only studies with directly relevant interventions are included in their review. However, exceptions may still occur. Generally, when interventions that are indirectly related to the study are included in systematic review, evidence quality will be decreased. In some instances the intervention used will be the same, but may be delivered in differently depending on the setting.

Example 3: Interventions delivered differently in different settings (Downgraded by One Level)

A systematic review of music therapies for autism found that trials tested structured approaches that are used more commonly in North America than in Europe. Because the interventions differ, the results from structured approaches are more applicable to North America and the results of less structured approaches are more applicable in Europe.

Guideline panelists should consider rating down the quality of the evidence if the intervention cannot be implemented with the same rigor or technical sophistication in their setting as in the RCTs from which the data come.

Example 4: Trials of related interventions (Downgraded by One or Two Levels)

Guideline developers may often find the best evidence addressing their question in trials of related, but different, interventions. A guideline addressing the value of colonoscopic screening for colon cancer will find the randomized control trials (RCTs) of fecal occult blood screening that showed a decrease in colon cancer mortality. Whether to rate down quality by one or two levels due to indirectness in this context is a matter of judgment.

Example 5: Indirectness in Interventions (Not Downgraded)

Older trials show a high efficacy of intramuscular penicillin for gonococcal infection, but guidelines might reasonably recommend alternative antibiotic regimes based on current local in vitro resistance patterns, which would not warrant downgrading the quality of evidence for indirectness.

Example 6: Interventions not sufficiently different (Not Downgraded)

Trials of simvastatin show cardiovascular mortality reduction. Suggesting night rather than morning dosing (because of greater cholesterol reduction) would not warrant rating down quality for differences in the intervention.

3. Differences in outcomes measures (surrogate outcomes)

GRADE specifies that both those conducting systematic reviews and those developing practice guidelines should begin by specifying every important outcome of interest. The available studies may have measured the impact of the intervention of interest on outcomes related to, but different from, those of primary importance to patients.

The difference between desired and measured outcomes may relate to time frame (e.g. outcome measured at 3-months vs. at 12-months). Another source of indirectness related to measurement of outcomes is the use of substitute or surrogate endpoints in place of the patient-important outcome of interest.

Table 5.7: Common surrogate measures and corresponding patient-important outcomes

Condition	Patient-important outcome(s)	Surrogate outcome(s)
Diabetes mellitus	Diabetic symptoms, hospital admission, complications (cardiovascular, eye, renal, neuropathic)	Blood glucose, A1C
Hypertension	Cardiovascular death, myocardial infarction, stroke	Blood pressure
Dementia	Patient function, behavior, caregiver burden	Cognitive function
Osteoporosis	Fractures	Bone density
Adult Respiratory Distress Syndrome	Mortality	Oxygenation
End-stage renal disease	Quality of life, morbidity (such as shunt thrombosis or heart failure), mortality	Hemoglobin
Venous thrombosis	Symptomatic venous thrombosis	Asymptomatic venous thrombosis
Chronic respiratory disease	Quality of life, exacerbations, mortality	Pulmonary function, exercise capacity
Cardiovascular disease	Myocardial infarction, vascular events, mortality	Serum lipids, coronary calcification, calcium/phosphate metabolism

In general, the use of a surrogate outcome requires rating down the quality of evidence by one, or even two, levels. Consideration of the biology, mechanism, and natural history of the disease can be helpful in making a decision about indirectness. For surrogates that are far removed in the putative causal pathway from the patient-important endpoints, we would rate down the quality of evidence with respect to this outcome by two levels. Surrogates that are closer in the putative causal pathway to the outcomes warrant rating down by only one level for indirectness.

Example 7: Time differences in outcomes (Downgraded by One Level)

A systematic review of behavioral and cognitive-behavioral interventions for outwardly directed aggressive behavior in people with learning disabilities showed that a program of 3-week relaxation training significantly reduced disruptive behaviors at 3 months. Unfortunately, no eligible trial assessed the review authors' predefined outcome of interest, the long-term impact defined as effect at 9 months or greater. The argument for rating down quality for indirectness becomes stronger when one considers that other types of behavioral interventions have shown an early beneficial effect that was not sustained at 6 months follow-up.

Example 8: Surrogate outcomes (Downgraded by One or Two Levels)

Calcium and phosphate metabolism are far removed in the causal pathway from patient-important outcomes such as myocardial infarction, and warrant rating down the quality of evidence by two levels. Surrogate outcomes that are closer in the causal pathway to the patient-important outcomes such as coronary calcification for myocardial infarction, bone density for fractures, and soft-tissue calcification for pain, warrant rating down quality by one level for indirectness.

Example 9: Uncertainty in the relationship between surrogate and Surrogate outcomes (Downgraded by One or Two Levels)

Investigators examined the "validity" of progression-free survival as a surrogate for overall survival for anthracycline- and taxine-based chemotherapy in advanced breast cancer. They found a statistically significant association between progression-free and overall survival in the randomized trials they analyzed, but predicting overall survival using progression-free survival remained uncertain. Rating down quality by one level for indirectness would be appropriate in this situation.

4. Indirect Comparisons)

Occurs when a comparison of intervention A versus B is not available, but A was compared with C and B was compared with C. Such studies allow indirect comparisons of the magnitude of effect of A versus B. As a result of the indirect comparison, this evidence is of lower quality than head-to-head comparisons of A and B would provide.

The validity of the indirect comparison rests on the assumption that factors in the design of the trial (the patients, co-interventions, measurement of outcomes) and the methodological quality are not sufficiently different to result in different effects (in other words, true differences in effect explain all apparent differences). Some authors refer to this as the "similarity assumption". Because this assumption is always in some doubt, indirect comparisons always warrant rating down by one level in quality of evidence. Whether to rate down two levels depends on the plausibility that alternative factors (population, interventions, co-interventions, outcomes, and study methods) explain or obscure differences in effect.

Example 10: Indirect comparison of low- vs. medium-dose aspirin (Downgraded by One Level)

A systematic review considered the relative merits of low dose vs. medium dose of aspirin to prevent graft occlusion after coronary artery bypass surgery. Authors found five relevant trials that compared aspirin with placebo, of which two tested medium dose and three low-dose aspirin. The pooled relative risk of the likelihood of a graft occlusion was 0.74 (95% CI: 0.60, 0.91) in the low-dose trial and 0.55 (95% CI: 0.28, 0.82) in the medium-dose trials. The RR of medium vs. low dose was 0.74 (95% CI: 0.52, 1.06; P = 0.10) suggesting the possibility of a larger effect with the medium-dose regimens. This comparison is weaker than if the randomized trials had compared the two aspirin dose regimens directly because there are other study characteristics that might be responsible for any differences found.

Example 11: Network meta-analysis (Downgraded by Two Levels)

Investigators conducted a simultaneous treatment comparison of 12 new generation antidepressants. The authors evaluated 117 randomized trials involving over 25,000 patients; their article provides no information about the similarity of the patients, or about co-intervention. In correspondence with the authors, however, they indicated that they excluded trials with treatment-resistant depression, argued that different types of depression have similar treatment responses, and that it is very likely that patients did not receive important co-intervention. With respect to risk of bias, the authors tell us, using the Cochrane collaboration approach to assessing risk of bias that risk of bias in most studies was “unclear”, and 12 were at low risk of bias; presumably a small number was at high risk of bias. This is helpful, although “unclear” represents a wide range of risk of bias. All studies involved head-to-head comparisons between at least two of the 12 drugs; the 117 trials involved 70 individual comparisons (e.g., two comparisons between fluoxetine and fluvoxamine). The authors reported statistically significant differences between direct and indirect comparisons in only three of 70 comparisons of drug response. The power of such tests was, however, not likely high. Overall, we would be inclined to take a cautious approach to this network meta-analysis and rate down two levels for indirectness.

5.2.4 Imprecision

In general, results are imprecise when studies include relatively few patients and few events and thus have a wide confidence interval (CI) around the estimate of the effect. In this case, one may judge the quality of the evidence lower than it otherwise would be considered because of resulting **uncertainty about the results**.

In addition to describing how the 95% confidence interval should be used as the primary criterion to make judgements about imprecision, we introduce theoptimal information size (OIS) as a second, necessary criterion for determining adequate precision.

Because GRADE **defines the quality of evidence differently** for systematic reviews and for guidelines, the criteria for downgrading for imprecision differ in that guideline panels need to consider the context of a recommendation and other outcomes, whereas judgments about specific outcomes in a systematic review are free of that context. The GRADE approach, therefore, suggests separate guidance for determining imprecision as is described in the following sections.

5.2.4.1 Imprecision in guidelines

For guideline panels:

Quality of evidence refers to the extent to which our **confidence in the estimate of an effect is adequate to support a particular decision**. In guidelines **all outcomes are considered together**, with attention to whether they are critical, or important but not critical.

For guideline panels, the decision to rate down the quality of evidence for imprecision is dependent on the threshold that represents the basis for a management decision and consideration of the trade-off between desirable and undesirable consequences. Determining the acceptable threshold inevitably involves judgement that must be made explicit.

For dichotomous outcomes

Guideline developers must consider the context of the particular recommendation to determine whether the results of a dichotomous (binary) outcome are sufficiently precise to support that recommendation. Setting a specific threshold for an acceptable estimate of treatment effect will involve judgement in the context of factors such as side effects, drug toxicity, and cost (*see Example 1*). Examining the lower and upper boundaries of the CI in relation to the threshold set by the guideline panel, then determining whether criteria for the optimal information size are met, will help in deciding whether to rate down for imprecision.

We suggest that guideline developers consider the following steps in deciding whether to rate down the quality of evidence for imprecision in guidelines:

1. First consider whether the boundaries of the CI are on the same side of their decision-making threshold. **Does the CI cross the clinical decision threshold between recommending and not recommending treatment**? If the answer is **yes** (i.e. the CI crosses the threshold), **rate down** for imprecision irrespective of where the point estimate and CI lie. (*see Example 1*)

2. If the threshold is **not crossed**, are criteria for an **optimal information size** met? (*see note on OIS and Example 3*)

3. **Or,**

4. Is the event rate very low and the sample size very large (at least 2000, and perhaps 4000 patients)? (*see Exception note*)

5. If **neither criterion is met**, **rate down** for imprecision.

While confidence intervals mostly capture the extent of imprecision, they can be misleading in certain circumstances because of fragility. Specifically, CIs may appear robust, but small numbers of events may render the results fragile. Confidence intervals assume all patients are at the same risk (i.e. there is prognostic balance), an assumption that is false. Randomization will ameliorate the problem by balancing prognostic factors between intervention and control groups, but we can be confident that a prognostic balance has been achieved only if sample sizes are large. Large treatment effects in the presence of small sample sizes, even in RCTs, may be because of prognostic imbalance and warrant caution.

Early trials addressing a particular question will, particularly if small, substantially overestimate the treatment effect. A systematic review of these trials will subsequently also generate an overestimated treatment effect. Examples of meta-analyses generating apparent beneficial or harmful effects refuted by subsequent larger trials include magnesium for mortality reduction after myocardial infarction, angiotensin-converting enzyme inhibitors for reducing the incidence of diabetes, nitrates for mortality reduction in myocardial infarction, and aspirin for reduction of pregnancy-induced hypertension. A similar circumstance occurs when trials are stopped early for benefit (i.e. prior to reaching the total number of events, or the sample size, needed as was calculated for an adequately powered trial). Simulation studies and empirical evidence suggest that trials stopped early overestimate treatment effects (*see Example 4*). When a treatment effect is overestimated, the CI around the effect may falsely appear suitable to meet the clinical decision threshold criterion by indicating adequate precision.

Therefore, the clinical decision threshold criterion is not completely sufficient to deal with issues of precision, and the second OIS criterion is required.

Note: The Optimal Information Size (OIS)

In order to address the vulnerability of confidence intervals as a criterion for adequate precision, we suggest the "optimal information size" as a **second, necessary criterion** to consider. The OIS is applied as a rule according to the following:

> • If the **total number of patients** included in a systematic review is **less than** the number of patients generated by a **conventional sample size calculation** for a single adequately powered trial, consider **rating down** for imprecision.

Many online calculators for sample size calculation are available. A simple one can be found at http://www.stat.ubc.ca/rollin/stats/ssize/b2.html. As an alternative to calculating the OIS, guideline developers can also consult figures that show the relationship between sample size required, or number of events needed, and effect size. See *Example 2* demonstrating how these figures can be used.

Exception: Low event rates with large sample size, an exception to the need for OIS

When **event rates are low**, CIs around relative effects may be wide, but if sample sizes are sufficiently large, it is likely that prognostic balance has indeed been achieved and CIs around **absolute effects may be narrow**. Under such circumstances, judgment about precision may be based on the CI around the absolute effect and one may **not downgrade** the quality of evidence for imprecision. (*see Examples 5 and 6*)

Example 1: Setting clinical decision thresholds to determine imprecision in guidelines

Refer to the figure below. A hypothetical systematic review of randomized control trials of an intervention to prevent major strokes yields a point estimate of the absolute reduction in strokes of 1.3%, with a 95% CI of 0.6% to 2.0%. This translates to a number needed to treat (NNT) of 77 (100÷1.3) patients for a year to prevent a single stroke. The 95% CI around the NNT is 50 to 167. Therefore, while 77 is our best estimate, we may need to treat as few as 50 or as many as 167 people to prevent a single stroke.

[INSERT IMAGE]

If we consider that the intervention is a drug with no serious adverse effects, minimal inconvenience, and modest cost, we may set a threshold for an absolute reduction in strokes of 0.5%, or NNT=200 (green line in the figure above), as even this small effect would warrant a recommendation. The entire CI (0.6% to 2.0%) lies to the left of the 0.5% threshold and, therefore, excludes any benefit smaller than the threshold. We can conclude that the precision of the evidence is sufficient to support a recommendation and do not rate down the quality of evidence for imprecision.

On the other hand, if the drug is associated with serious toxicity, we may be reluctant to make a recommendation unless the absolute stroke reduction is at least 1%, or NNT=100 (red line in the figure above). Under these circumstances, the precision is insufficient as the CI encompasses treatment effects smaller than this threshold (i.e. as small as 0.6%). A recommendation in favour of the intervention would still be appropriate as the point estimate of 1.3% meets the threshold, but we would rate down the quality of evidence supporting the recommendation by one level for imprecision (e.g. from high to moderate).

Example 2: Using figures to determine Optimal Information Size

As an alternative to calculating the OIS, review and guideline authors can also consult a figure to determine the OIS. The figure below presents the required sample size (assuming α of 0.05, and β of 0.2) for RRR of 20%, 25%, and 30% across varying control group risks. For example, if the best estimate of control group risk was 0.2 and one specifies an RRR of 25%, the OIS is approximately 2000 patients.

[INSERT IMAGE]

Power is, however, more closely related to number of events than to sample size. The figure below presents the same relationships using total number of events across all studies in both treatment and control groups instead of total number of patients. Using the same choices of a control group risk of 0.2 and RRR 25%, one requires approximately 325 events to meet OIS criteria.

[INSERT IMAGE]

Note: Choice of Relative Risk Reduction

We have suggested using RRRs of 20% to 30% for calculating OIS. The choice of RRR is a matter of judgment, and there may be instances in which compelling prior information would suggest choosing a smaller or larger value for the RRR for the OIS calculation.

Example 3: Applying the OIS Criterion

A systematic review of flavonoids for treatment of hemorrhoids examined the outcome of failure to achieve an important symptom reduction. In calculating the OIS, the authors chose a conservative α of 0.01 and RRR of 20%, a β of 0.2, and a control group risk of 50%. The calculated OIS was marginally larger than the total sample size included (1194 vs. 1102 patients).

A more dramatic example comes from a systematic review and meta-analysis of fluoroquinolone prophylaxis for patients with neutropenia. Only one of eight studies that contributed to the meta-analysis met conventional criteria for statistical significance, but the pooled estimate suggested an impressive and robust reduction in infection-related mortality with prophylaxis (RR: 0.38; 95% CI: 0.21, 0.69). The total number of events was only 69 and the total number of patients 1022. Considering the control group risk of 6.9% and setting α of 0.05, β of 0.02, and RRR of 25% results in an OIS of 6400 patients. This meta-analysis fails to meet OIS criteria, and rating down for imprecision may be warranted.

Example 4: Stopping trials early may result in overestimated treatment effects and incorrect judgements about precision

Consider a randomized trial of β blockers in 112 patients undergoing surgery for peripheral vascular diseases that fulfilled preplanned O'Briene-Fleming criteria for early stopping. Of 59 patients given bisoprolol, 2 suffered a death or nonfatal myocardial infarction, as did 18 of 53 control patients. Despite a total of only 20 events, the 95% CI around the RR (0.02 to 0.41) excludes all but a large treatment effect. The CI suggests that the smallest plausible effect is a 59% RRR. A recommendation to administer treatment based on this result would be deemed to have adequate precision.

However, there are reasons to doubt the estimate of the magnitude of effect from this trial. First, it is much larger than what we might expect on the basis of β blockers effects in a wide variety of other situations. Second, the study was terminated early on the basis of the large effect. Third, we have a sense of the fragility of these results as concluding that an RRR less than 59% is implausible on the basis of only 20 events violates common sense. If one moves just five events from the control to the intervention group, the results lose their statistical significance, and the new point estimate (an RRR of 52%) is outside of the original CI.

Example 5: Focusing on absolute effects when event rates are low and sample size is large

A systematic review of seven randomized trials of angioplasty versus carotid endarterectomy for cerebrovascular disease found that a total of 16 of 1482 (1.1%) patients receiving angioplasty died, as did 19 of 1465 (1.3%) undergoing endarterectomy. Looking at the 95% CI (0.43, 1.66) around the point estimate of the RR (0.85), the results are consistent with substantial benefit and substantial harm, suggesting the need to rate down for imprecision.

The absolute difference, however, suggests a different conclusion. The absolute difference in death rates between the two procedures is very small (absolute difference of 0.2% with a 95% CI ranging from -0.5% to 1.0%). Setting a clinical decision threshold boundary of 1% absolute difference (the smallest difference important to patients), the results of the systematic review exclude a difference favoring either procedure. If one accepted this clinical decision threshold as appropriate, one would not rate down for imprecision. One could argue that a difference of less than 1% could be important to patients: if so, one would rate down for imprecision, even after considering the CI around the absolute difference, as the CI would cross that threshold.

Example 6: No need to rate down for imprecision when sample sizes are very large

A meta-analysis of randomized trials of β blockade for preventing cardiovascular events in patients undergoing non-cardiac surgery suggested a doubling of the risk of strokes with β blockers (RR: 2.22; 95% CI: 1.39, 3.56). Most trials in this meta-analysis do not suffer from important limitations, the evidence is direct and consistent, and publication bias is undetected. Given the lower boundary of the CI (an increase in RR of 39%), the threshold for adequate precision would not be crossed if one believed that most patients would be reluctant to use β blockers with an increase in RR of stroke of 39%.

The total number of events (75), however, appears insufficient, an inference that is confirmed with an OIS calculation (α 0.05, β 0.20, using the β-blocker group's 1% event rate as the control, and Δ 0.25, total sample size 43586 in comparison to the 10889 patients actually enrolled). The guidelines for calculating precision we have suggested would, therefore, mandate rating down quality for imprecision.

With a sample size of over 5000 patients per group, however, it is very likely that randomization has succeeded in creating prognostic balance. If that is true, β blockers really do increase the risk of stroke. Not rating down for imprecision in this situation is therefore appropriate. Preliminary information suggests that for low baseline risk (<5%) one will be safe with regard to prognostic balance with a total of 4000 patients (2000 patients per group). Availability of this number of patients would mandate not rating down for imprecision despite not meeting the OIS criterion.

For continuous outcomes

Considerations of rating down quality because of imprecision for continuous variables follow the **same logic as for binary variables**. The process begins by rating down the quality for imprecision if a recommendation would be altered if the lower versus the upper boundary of the CI represented the true underlying effect. If the CI does not cross this threshold, but the evidence fails to meet the OIS criterion, guideline authors should consider rating down the quality of evidence for imprecision. In this instance, judging the OIS criterion will require a sample size calculation for the continuous variable.

In the context of a guideline, the decision-making threshold for an acceptable estimate of treatment requires consideration of the full context of the recommendation, including other outcomes such as all potential benefits and important adverse effects (*see Example 7*).

Example 7: Considering the full context of a recommendation

A systematic review suggests that corticosteroid administration decreases the length of hospital stay in patients with exacerbations of chronic obstructive pulmonary disease (COPD) by 1.42 days (95% CI: 0.65, 2.2). The lower boundary of the CI is 0.65 days, a rather small effect size that may not be considered important to patients.

As it turns out, steroids also reduce the likelihood of treatment failure (variably defined) during inpatient or outpatient follow-up (RR: 0.54; 95% CI: 0.41, 0.71). The best estimate of likelihood of symptomatic deterioration in those not treated with steroids is approximately 30%. By administering steroids to these patients, the risk is reduced from 30% to 16% (30-[0.54x30]), a difference of 14%, and the effect is unlikely to be less than 9% (30-[0.71x30]).

Adverse effects were poorly reported in the studies. The only consistently reported problem was hyperglycemia, which was increased almost sixfold, representing an absolute increase of 15% to 20%. The extent to which this hyperglycemia had consequences important to patients is uncertain. One possible conclusion from this information is that, given the magnitude of reduction in deterioration and lack of evidence suggesting important adverse effects, a benefit of even 0.65 days of reduced average hospitalization would warrant steroid administration. If this were the conclusion, the CI (0.65, 2.2) would not cross the decision-making threshold and the guideline panel would proceed to consider whether the evidence meets the OIS criterion.

5.2.4.2 Imprecision in in systematic reviews

For authors of systematic reviews:

Quality of evidence refers to one's **confidence in the estimates of effect**. In systematic reviews **each outcome is considered separately**.

Authors of systematic reviews should not rate down quality due to imprecision on the basis of the trade-off between desirable and undesirable consequences; it is not their job to make value and preference judgments. Therefore, in judging precision, they should not focus on the threshold that represents the basis for a management decision. Rather, they should consider the optimal information size to make judgements.

For dichotomous outcomes

We suggest that authors of systematic reviews consider the following steps in deciding whether to rate down the quality of evidence for imprecision:

1. If the optimal information size criterion is **not met**, **rate down** for imprecision, unless the sample size is very large (at least 2000, and perhaps 4000 patients).

2. If the OIS criterion is met and the **95% CI excludes no effect** (i.e. CI around RR excludes 1.0), **do not rate down** for imprecision.

3. If OIS criterion is met, and the **95% CI overlaps no effect** (i.e. CI includes RR of 1.0) **rate down for imprecision** if the CI **fails to exclude important benefit or important harm**. (*see Example 8*)

Note:

To be of optimal use to guideline developers, a systematic review may still point out what thresholds of benefit would mandate rating down for imprecision.

Example 8: Meeting threshold OIS may not ensure precision

Although satisfying the OIS threshold in the presence of a CI excluding no effect indicates adequate precision, the same is not true when the point estimate fails to exclude no effect.

Consider the systematic review of β blockers in non-cardiac surgery previously introduced in Example 6 above. For total mortality, with 295 deaths and a total sample size of over 10000, the point estimate and 95% CI for the RR with β blockers were 1.24 (95% CI: 0.99, 1.56). Despite the large sample size and number of events, one might be reluctant to conclude precision is adequate when a small reduction in mortality with β blockers, as well as an increase of 56%, remain plausible. This suggests that when the OIS criteria are met, and the CI includes the null effect, systematic review authors should consider whether CIs include appreciable benefit or harm.

Authors should use their judgment in **deciding what constitutes appreciable benefit and harm** and provide a rationale for their choice. If reviewers fail to find a compelling rationale for a threshold, our suggested default threshold for appreciable benefit and harm that warrants rating down is an RRR or RR increase of 25% or more.

For continuous outcomes

Review authors can calculate the OIS for continuous variables in exactly the same way they can for binary variables by specifying the α and β error thresholds (we have suggested 0.05 and 0.2) and the Δ, and choosing an appropriate population standard deviation based on one of the relevant studies.

Whether you will rate down for imprecision is **dependent on the choice of the difference** (Δ) you wish to detect and the resulting sample size required. Again, the merit of the GRADE approach is not that it ensures agreement between reasonable individuals, but that the judgements being made are explicit.

Example 9: Judgements about imprecision depend on the choice of difference to detect

Consider the systematic review previously introduced in Example 7 above, which suggests that corticosteroid administration decreases the length of hospital stay in patients with exacerbations of chronic obstructive pulmonary disease (COPD) by 1.42 days (95% CI: 0.65, 2.2).

Choosing a Δ of 1.0 (implying a judgment that reductions in stay of more than a day are important) and using the standard deviation associated with hospital stay in the four relevant studies (3.4, 4.5, and 4.9) yields corresponding required total sample sizes of 364, 636, and 754. The 602 patients available for this analysis do not therefore meet the OIS criterion, and one would consider rating down for imprecision.

Had we chosen a smaller difference (e.g. 0.5 days) that we wished to detect, the sample size of the studies would have been unequivocally insufficient. Had we chosen a larger value (e.g. 1.5 days) the sample size of 602 would have met the OIS criterion.

Note: Outcomes reported as a standardized mean difference

A particular challenge in calculating the OIS for continuous variables arises when studies have used different instruments to measure a construct, and the pooled estimate is calculated using a standardized mean difference. Systematic review and guideline authors will most often face this situation when dealing with patient-reported outcomes, such as quality of life. In this context, we suggest authors choose one of the available instruments (ideally, one in which an estimate of the minimally important difference is available) and calculate an OIS using that instrument.

Because it may give false reassurance, we hesitate to offer a rule-of-thumb threshold for the absolute number of patients required for adequate precision for continuous variables. For example, using the usual standards of α (0.05) and β (0.20), and an effect size of 0.2 standard deviations, representing a small effect, requires a total sample size of approximately 400 (200 per group), sample size that may not be sufficient to ensure prognostic balance.

Nonetheless, whenever there are sample sizes that are less than 400, review authors and guideline developers should certainly consider rating down for imprecision. In future, statistical simulations may provide the basis for a robust rule of thumb for continuous outcomes. The limitations of an arbitrary threshold sample size suggest the advisability of addressing precision by calculation of the relevant OIS for each continuous variable.

5.2.4.3 Rating down two levels for imprecision

When there are very few events and CIs around both relative and absolute estimates of effect, that include both appreciable benefit and appreciable harm, systematic reviewers and guideline developers should consider rating down the quality of evidence by two levels.

Example 10: Rating down for imprecision by two levels

A systematic review of the use of probiotics for induction of remission in Crohn's disease found a single randomized trial that included 11 patients. Four of five patients in the treatment group achieved remission, and five of six patients in the control group achieved remission. The point estimate of the risk ratio (0.96) suggests no difference, but the CI includes a reduction in likelihood of remission of almost half, or an increase in the likelihood of over 50% (95% CI: 0.56, 1.69). As there are few events and the CI includes appreciable benefit and harm, one would rate down quality of evidence by two levels for imprecision.

5.2.5 Publication bias

Publication bias is a systematic under-estimation or an over-estimation of the underlying beneficial or harmful effect due to the **selective publication of studies**. Confidence in the combined estimates of effects from a systematic review can be reduced when publication bias is suspected, even when the included studies themselves have a low risk of bias.

Note:

Some systems for assessing the quality of the body of evidence use the term "reporting bias" with 2 subcategories: selective outcome reporting and publication bias. However, GRADE considers *selective outcome reporting* under *risk of bias* (study limitations) since it can be addressed in single studies. In contrast, when an entire study remains unpublished (unreported), one can assess the likelihood of *publication bias* only by looking at a group of studies. Currently, GRADE follows the Cochrane Collaboration's approach and consider *selective outcome reporting* as an issue in risk of bias in individual studies (Cochrane Handbook. Chapter 8.5 The Cochrane Collaboration's tool for assessing risk of bias).

Empirical evidence suggests that studies reporting statistically significant findings are more likely to be accepted for publication than those reporting statistically insignificant findings ("negative studies"). Publication bias arises when entire studies go unreported. Lack of success to identify studies is typically a result of studies either remaining unpublished or obscurely published (e.g. in journals with limited circulation not indexed by major databases, as conference abstracts or theses), thus, methodologists have labeled the phenomenon "publication bias." Authors of systematic reviews may fail to identify studies that are unpublished or that have been published in a non-indexed, limited-circulation journal or in the grey literature even if they employ most rigorous search techniques. If rigorous search techniques are not implemented it is difficult to make the judgement about publication bias since studies might remain unidentified both because of publication bias or because of insufficient effort to identify them.

The risk of publication bias may be higher for systematic reviews of observational studies than for reviews of RCTs. This can occur, especially if observational studies are conducted automatically from patient registries or medical records. In these instances, it is difficult for the reviewer to know if the observational studies that appear in the literature represent all or a fraction (usually those that showed "interesting" results) of the studies conducted.

Table 5.8: Possible sources of publication bias throughout the publication process

Phases of research publication	Actions contributing to or resulting in bias.
Preliminary and pilot studies	Small studies more likely to be "negative" (e.g. those with discarded or failed hypotheses) remain unpublished; companies classify some as proprietary information.
Report completion	Authors decide that reporting a "negative" study is uninteresting; and do not invest the time and effort required for submission.
Journal selection	Authors decide to submit the "negative" report to a nonindexed, non-English, or limited-circulation journal.
Editorial consideration	Editor decides that the "negative" study does not warrant peer review and rejects manuscript.
Peer review	Peer reviewers conclude that the "negative" study does not contribute to the field and recommend rejecting the manuscript. Author gives up or moves to lower impact journal. Publication delayed.
Author revision and resubmission	Author of rejected manuscript decides to forgo the submission of the "negative" study or to submit it again at a later time to another journal (see "journal selection" above).
Report publication	Journal delays the publication of the "negative" study. Proprietary interests lead to report getting submitted to, and accepted by, different journals.

Studies with **small sample sizes** are more likely to remain unpublished or ignored. Discrepancies between results of meta-analyses of small studies and subsequent large trials may occur as often as 20% of the time, and publication bias may be a major contributor to such discrepancies. Therefore, one should suspect publication bias when published evidence is limited to a small number of small trials. This is especially true if many of these small studies show benefits of certain intervention.

Methods to detect the possibility of publication bias in systematic reviews include visual inspection and tests for asymmetry of funnel plots (Cochrane Handbook. Chapter 10.4 Detecting reporting biases). Empirical examination of patterns of results may suggest publication bias if results are asymmetrical about the summary estimate of effect. This can be determined either through visual inspection of a funnel plot (shown below) or from a positive result for a statistical test for asymmetry. As a rule-of-thumb, funnel plot and statistical tests for asymmetry should be used to detect publication bias if there are at least 10 studies included in the meta-analysis (some say at lest 5 studies).

Another test used to detect publication bias is referred to as the "trim and fill" method is an extension of the funnel plot. This trim and fill technique begins by removing small "positive" studies that do not have a negative counterpart, leaving a symmetrical funnel plot. The new supposed true effect is then calculated using the effects of the studies included in the new funnel plot. The next step is to add hypothetical studies which mirror the results of the positive studies, but still retains the new pooled effect estimate. It is important to note that even if asymmetry is detected, it may not be the result of publication bias. For example, in smaller studies, over-estimates of effect may yield an asymmetric funnel plot that could be explained by limitations other than publication bias such as a restrictive study population. To strengthen conclusions regarding publication bias it is recommended that multiple tests be used.

Recursive cumulative meta-analysis, used to detect lag time bias, performs a meta-analysis at the end of each year, noting changes in effect estimates for each progressing year. If effects of an intervention continuously decrease, there is a strong indication of lag time bias.

Regardless of the test used, review authors and guideline developers should be aware such tests can be prone to error and their results should be interpreted with caution. It is extremely difficult to be confident that publication bias is absent and almost as difficult to place a threshold on when to rate down quality of evidence due to the strong suspicion of publication bias. For this reason GRADE suggests rating down quality of evidence for publication bias by a maximum of one level.

Example 1: Trials with positive findings (i.e. statistically significant differences) are more likely to be published than trials with negative or null findings

A systematic review assessed the extent to which publication of a cohort of clinical trials is influenced by the statistical significance, perceived importance, or direction of their results. It found five studies that investigated these associations in a cohort of registered clinical trials. Trials with positive findings were more likely to be published than trials with negative or null findings (odds ratio: 3.9; 95% CI: 2.7 to 5.7). This corresponds to a risk ratio of 1.8 (95% CI: 1.6 to 2.0), assuming that 41% of negative trials are published (the median among the included studies, range = 11% to 85%). In absolute terms, this means that if 41% of negative trials are published, we would expect that 73% of positive trials would be published. Two studies assessed time to publication and showed that trials with positive findings tended to be published after 4 to 5 years compared with those with negative findings, which were published after 6 to 8 years. Three studies found no statistically significant association between sample size and publication. One study found no statistically significant association between either funding mechanism, investigator rank, or sex and publication.

Systematic reviews **performed early** in the development of a body of research may be biased due to the tendency for positive results to be published sooner and for negative results to be published later or withheld. This is referred to as "lag bias" and especially true of industry funded studies.

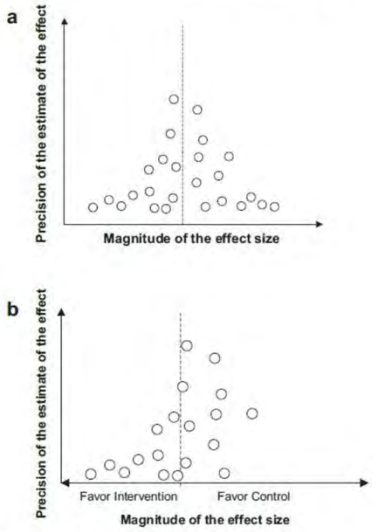
Example 3: Reduced effect estimate in a systematic review as a result of negative studies not being published

An investigation of 74 antidepressant trials with a mean sample size of fewer than 200 patients was submitted to the FDA. Of the 38 studies viewed as positive by the FDA, 37 were published. Of the 36 studies viewed as negative by the FDA, only 14 were published. Publication bias of this magnitude can seriously bias effect estimates.

Example 5: Funnel plots to detect publication bias

In A, the circles represent the point estimates of the trials. The pattern of distribution resembles an inverted funnel. Larger studies tend to be closer to the pooled estimate (the dashed line). In this case, the effect sizes of the smaller studies are more or less symmetrically distributed around the pooled estimate.

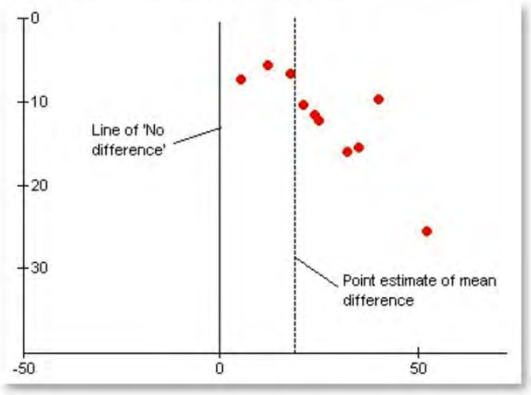
In B, publication bias is detected. This funnel plot shows that the smaller studies are not symmetrically distributed around either the point estimate (dominated by the larger trials) or the results of the larger trials themselves. The trials expected in the bottom right quadrant are missing. One possible explanation for this set of results is publication bias - an overestimate of the treatment effect relative to the underlying truth.



Example 6: Publication bias detected

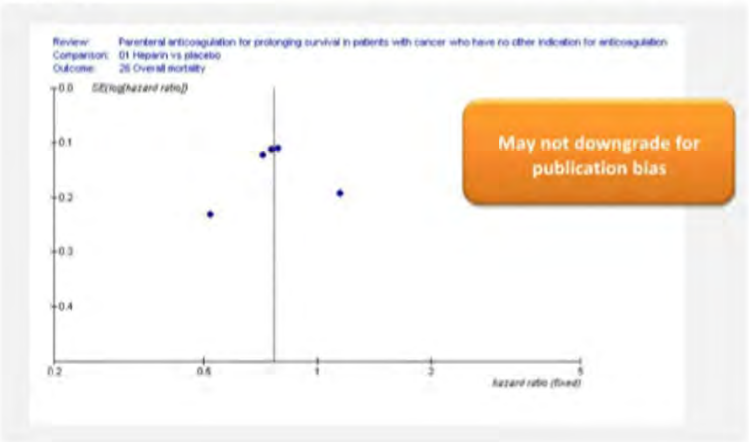
A number of small trials from a systematic review of oxygen therapy in patients with chronic obstructive pulmonary disease showed that the intervention improved exercise capacity, but evaluation of the data suggested publication bias.

The funnel plot of exercise distance shows distance on the x-axis and variance on the y-axis. The red dots represent the mean differences of individual trial estimates and the dotted line the point estimate of the mean effect indicating benefit from oxygen treatment. The distribution of these dots to the right of the dotted line suggests that there may be the equivalent number of 'negative' trials that have not been included in this analysis. Thus, one may downgrade the quality of evidence in this case due to uncertainty resulting from asymmetry in the pattern of results.



Example 8: Publication bias undetected

A systematic review of parenteral anticoagulation for prolonged survival in patients with cancer who had no other indication for anticoagulation shows five RCTs which are symmetrically distributed around the best estimate of effect. Publication bias is undetected in this scenario and thus the evidence should not be downgraded.



When to downgrade the quality of evidence because of suspicion of publication bias

Guideline panels and authors of systematic reviews should consider the extent to which they are uncertain about the magnitude of the effect due to selective publication of studies and they may downgrade the quality of evidence by one level. Consider:

- study design (experimental vs. observational)
- study size (small studies vs. large studies)
- lag bias (early publication of positive results)
- search strategy (was it comprehensive?)
- asymmetry in funnel plot.

5.3. Factors that can increase the quality of the evidence

Consideration of factors reducing quality of evidence must precede consideration of reasons for rating it up. Thus, consideration of all our previously presented criteria for rating down certainty of evidence (risk of bias, imprecision, inconsistency, indirectness, and publication bias) must precede consideration of reasons for rating it up. The decision to rate up should only rarely be made if serious limitations are present in any of these areas. In particular, decisions to rate up because of large or very large effects should consider not only the point estimate but also the width of the CI around that estimate of an effect: one should rarely rate up for large effects if the CI overlaps substantially with effects smaller than the chosen threshold. The following sections discuss in detail the 3 factors that permit rating up the quality of evidence, i.e. increase confidence in an estimate of an effect. Using the GRADE framework, body of evidence from observational studies is initially classified as low quality evidence (i.e. permitting low confidence in the estimated effect). There are times, however, when we have high confidence in the estimate of effect from observational studies (including cohort, case-control, before-after, time series studies, etc.) and to non-randomized experimental studies (e.g. quasi-randomized and non-randomized controlled trials). The circumstances under which the body of evidence from observational studies may provide higher than low confidence in the estimated effects will likely occur infrequently.

Note: Although it is theoretically possible to rate up results from randomized control trials, we have yet to find a compelling example of such an instance.

5.3.1 Large magnitude of an effect

When body of evidence from observational studies not downgraded for any of the 5 factors yield large or very large estimates of the magnitude of an intervention effect, then we may be more confident about the results. In those situations, even though observational studies are likely to provide an overestimate of the true effect, the study design that is more prone to bias is unlikely to explain all of the apparent benefit (or harm). Decisions to rate up quality of evidence because of large or very large effects (Table 5.9) should consider not only the point estimate but also the precision (width of the CI) around that effect: one should rarely and very cautiously rate up quality of evidence because of apparent large effects, if the CI overlaps substantially with effects smaller than the chosen threshold of clinical importance.

Table 5.9. Definitions of large and very large effect

Magnitude of Effect	Definition	Quality of Evidence
Large	RR* >2 or <0.5 (based on direct evidence, with no plausible confounders)	may increase 1 level
Very large	RR* >5 or <0.2 (based on direct evidence with no serious problems with risk of bias or precision, i.e. with (sufficiently narrow confidence intervals)	may increase 2 levels

* Note: these rules apply when effect measure is expressed as relative risk (RR) or hazard ratio (HR). They cannot always be applied when the effect measure is expressed as odds ratio (OR). We suggest converting OR to RR and only then assessing the magnitude of an effect.

One may be more likely to rate up the quality of evidence because of large or very large magnitude of an effect, when:

- effect is rapid
- effect is consistent across subjects
- previous trajectory of disease is reversed
- large magnitude of an effect is supported by indirect evidence

Note: When outcomes are subjective it is important to be cautious when considering upgrading because of observed large effects. This is especially true when outcome assessors were aware which group study subjects belonged to (i.e. were not blinded).

Examples

A systematic review of observational studies examining the relationship between infant sleeping position and sudden infant death syndrome (SIDS) found an odds ratio of 4.1 (95% CI: 3.1, 5.5) of SIDS occurring with front vs. back sleeping positions. Furthermore, “back to sleep” campaigns that were started in the 1980s to encourage back sleeping position were associated with a relative decline in the incidence of SIDS by 50-70% in numerous countries.

5.3.2. Dose-response gradient

The presence of a dose-response gradient has long been recognized as an important criterion for believing a putative cause-effect relationship. The presence of a **dose-response gradient** may increase our confidence in the findings of observational studies and thereby increase the quality of evidence.

Example 1: Dose-response gradient (Upgraded by One Level)

The observation that, in patients receiving anticoagulation with warfarin, there is a dose response gradient between higher levels of the international normalized ratio (INR), an indicator of the degree of anticoagulation, and an increased risk of bleeding increases our confidence that supratherapeutic anticoagulation levels increase bleeding risk.

Example 2: Dose-response gradient (Upgraded by One Level)

The dose-response gradient associated with the rapidity of antibiotic administration in patients presenting with sepsis and hypotension may also be a reason to upgrade the quality of evidence for such a study. There is a large absolute increase in mortality with each hour’s delay of antibiotic administration. This dose-response relationship increases our confidence that the effect on mortality is real and substantial leading to upgrading the quality of the evidence.

5.3.3. Effect of plausible residual confounding

On occasion, **all plausible residual confounding** from observational studies may be working to **reduce the demonstrated effect** or **increase the effect, if no effect was observed**.

Rigorous observational studies will accurately measure prognostic factors associated with the outcome of interest and will conduct an adjusted analysis that accounts for differences in the distribution of these factors between intervention and control groups. The reason that in most instances we consider observational studies as providing only low-quality evidence is that **unmeasured or unknown determinants of outcome** unaccounted for in the adjusted analysis are **likely to be distributed unequally** between intervention and control groups, referred to as “residual confounding” or “residual biases.”

On occasion, all plausible confounders (biases) from observational studies unaccounted for in the adjusted analysis (i.e. residual confounders) of a rigorous observational study would result in an underestimate of an apparent treatment effect. If, for instance, only sicker patients receive an experimental intervention or exposure, yet they still fare better, it is likely that the actual intervention or exposure effect is even larger than the data suggest. A parallel situation exists when observational studies have failed to demonstrate an association.

Example 1: When confounding is expected to reduce a demonstrated effect (Upgraded by One Level)

A rigorous systematic review of observational studies including a total of 38 million patients demonstrated higher death rates in private for-profit versus private not-for-profit hospitals. It is likely, however, that patients in the not-for-profit hospitals were sicker than those in the for-profit hospitals. This would bias results against the not-for-profit hospitals. The second likely bias was the possibility that higher numbers of patients with excellent private insurance coverage could lead to a hospital having more resources and a spill-over effect that would benefit those without such coverage. Since for-profit hospitals are likely to admit a larger proportion of such well-insured patients than not-for-profit hospitals, the bias is once again against the not-for-profit hospitals. Because the plausible biases would all diminish the demonstrated intervention effect, one might consider the evidence from these observational studies as moderate rather than low quality.

Example 2: When confounding is expected to reduce a demonstrated effect (Upgraded by One Level)

In a systematic review investigating the use of condoms in homosexual male relationships as a way of preventing the spread of HIV, five observational studies were identified. The pooled estimate was a relative risk of 0.34 (95%, 0.21 – 0.54) in favour of condom use. The authors failed to adjust in the analysis for the fact that condom users are more likely to have more partners than non-condom users. One would expect that more partners would have increased the risk of acquiring HIV and therefore reduced the resulting relative risk of HIV infection. Therefore, the confidence in this effect, which is still large, would lead to upgrading by one level.

Example 3: When confounding is expected to increase the effect but no effect was observed (Upgraded by One Level)

The hypoglycaemic drug phenformin causes lactic acidosis, and the related agent metformin is under suspicion for the same toxicity. Very large observational studies have failed to demonstrate an association between metformin and lactic acidosis. Given the likelihood that clinicians would have been more alert to lactic acidosis with metformin and would have therefore over-reported its occurrence, and that no association was found, one could upgrade this evidence.

Example 4: When confounding is expected to increase the effect but no effect was observed (Upgraded by One Level)

Consider the early reports associating MMR vaccination with autism. One would think that there would be over-reporting of autism in children given MMR vaccines. However, systematic reviews failed to prove any association between the two. Due to the negative results, despite the potential presence of

confounders which would increase the likelihood of reporting of autism, no association was found. Therefore, we may upgrade the level of evidence by one level.

5.4 Overall quality of evidence

The overall quality of evidence is a combined rating of the quality of evidence across all outcomes considered critical for answering a health care question (i.e. making a decision or a recommendation).

We caution against a mechanistic approach toward the application of the criteria for rating the quality of the evidence up or down. Although GRADE suggests the initial separate consideration of five categories of reasons for rating down the quality of evidence, and three categories for rating it up, with a yes/no decision regarding rating up or down in each case, the final rating of overall evidence quality occurs in a continuum of confidence in the estimates of effects.

For authors of systematic reviews:

Authors of systematic reviews **do not grade the overall quality of evidence** across outcomes. Because systematic reviews do not – or at least should not – make recommendations, authors of systematic reviews rate the quality of evidence only for each outcome separately.

For guideline panels and others making recommendations:

Guideline panels **have to determine the overall quality of evidence** across all the critical outcomes essential to a recommendation they make. Guideline panels provide a single grade of quality of evidence for every recommendation, but the strength of a recommendation usually depends on evidence regarding not just one, but a number of patient-important outcomes and on the quality of evidence for each of these outcomes.

Because the GRADE approach rates quality of evidence separately for each outcome, it is frequently the case that quality differs across outcomes. When determining the overall quality of evidence across outcomes:

1. Consider **only** those outcomes that have been deemed **critical**.

2. If the quality od evidence is the **same** for all critical outcomes, then this becomes the overall quality of the evidence supporting the answer to the question.

3. If the quality of evidence **differs** across critical outcomes, it is logical that the overall confidence in effect estimates cannot be higher than the lowest confidence in effect estimates for any outcome that is critical for a decision. Therefore, the **lowest quality of evidence** for any of the critical outcomes determines the overall quality of evidence.

Example 1: Rating overall quality of evidence based on the importance of outcomes

Several systematic reviews of high-quality randomised trials suggest a decrease in the incidence of infections and, likely, the mortality of ventilated patients in intensive care units receiving selective digestive decontamination (SDD). The quality of evidence on the effect of SDD on the emergence of bacterial antibiotic resistance and its clinical relevance is much less clear. One might reasonably grade the evidence about this feared potential adverse effect as low quality. If those making a recommendation felt that these downsides of therapy were critical, the overall grade of the quality of evidence for SDD would be low. If guideline panel felt that the emergence of bacterial antibiotic resistance was important but not critical, the grade for an overall quality of evidence would be high.

However, which outcomes are critical may depend on the evidence. On occasion, the overall confidence in effect estimates may not come from the outcomes judged critical at the beginning of the guideline development process – judgments about which outcomes are critical to the decision (recommendation) may change when considering the results. Note that such judgments require careful consideration and are probably rare.

There are 2 prototypical situations in which an outcome initially considered critical may cease to be critical once the evidence is summarized:

1. An outcome turns out to be **not relevant** (e.g. a particular adverse event may be considered critical at the outset of the guideline process but, if it turns out that the event occurs very infrequently, the final decision may be that this adverse effect is important but not critical to the recommendation).

2. An outcome turns out to be **not necessary** if, across the range of possible effects of the intervention on that outcome, the recommendation and its strength would remain unchanged. If there is higher quality of evidence for some critical outcomes to support a decision, then one need not rate down quality of evidence because of lower confidence in estimates of effects on other critical outcomes that support the same recommendation.

For instance, consider the following question: should statins vs. no statins be used in individuals without documented coronary heart disease but at high risk of cardiovascular events? Guideline developers are likely to start the process by considering outcomes: death from cardiovascular causes, myocardial infarction, stroke, and adverse effects, as critical to the decision.

A systematic review or randomized trials demonstrated consistent reductions in myocardial infarctions and stroke but nonsignificant reductions in coronary deaths. Serious adverse effects were unusual and readily reversible with drug discontinuation. The guideline authors found that for three of the four outcomes (myocardial infarction, stroke, and adverse effects) there was high quality evidence. For coronary deaths evidence was of moderate quality because of imprecision.

Should the overall quality of evidence across outcomes be high or moderate? The judgments made at the beginning of the process suggest that the answer is "moderate". However, once it is established that the risk of myocardial infarction and stroke decreases with statins, most people would find compelling reason to use statins. Knowing whether coronary mortality also decreases is no longer

necessary for the decision (as long as it is very unlikely that it increases). Considering this, the overall rating of quality of evidence is most appropriately designated as "high".

6. Going from evidence to recommendations

6.1 Recommendations and their strength

The **strength of a recommendation** reflects the extent to which a guideline panel is **confident that desirable effects of an intervention outweigh undesirable effects**, or vice versa, across the range of patients for whom the recommendation is intended.

GRADE specifies **two categories** of the strength of a recommendation. While GRADE suggests using the terms **strong** and **weak** recommendations, those making recommendations may choose different wording to characterize the two categories of strength.

In special cases, guideline panels may recommend an intervention be used **only in research** until more data is generated, which would allow for a more comprehensive recommendation, or not make a recommendation at all.

There are limitations to formal grading of recommendations. Like the quality of evidence, the balance between desirable and undesirable effects reflects a continuum. Some arbitrariness will therefore be associated with placing particular recommendations in categories such as “strong” and “weak.” Most organisations producing guidelines have decided that the merits of an explicit grade of recommendation outweigh the disadvantages.

Strength of recommendation on a continuum: categorical terminology

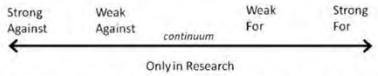


Fig. 1. Strength of recommendation: a continuum divided into categories.

For a guideline panel or others making recommendations to offer a strong recommendation they have to be **certain** about the various factors that influence the strength of a recommendation. The panel also should have the relevant information at hand that supports a clear balance towards either the desirable effects of an intervention (to recommend an action) or undesirable effects (to recommend against an action).

When a guideline panel is **uncertain** whether the balance is clear or when the relevant information about the various factors that influence the strength of a recommendation is not available, a guideline panel should be more cautious and in most instances it would opt to make a weak recommendation.

Figure 3: Balance scales to depict strong vs. weak recommendations.

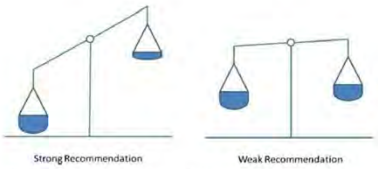


Fig. 2. Balance scales to depict strong vs. weak recommendations.

To aid interpretation GRADE suggests implications of strong or weak recommendations that follow from the recommendations. The advantage of two categories of strength of recommendations is that they provide clear direction to patients, clinicians, and policy-makers.

Table 6.1. Implications of strong and weak recommendations for different users of guidelines

	Strong Recommendation	Weak Recommendation
For patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions	Recognize that different choices will be appropriate for different patients, and that you must help each patient arrive at a management decision consistent with her or his values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should

	consistent with their values and preferences.	expect to spend more time with patients when working towards a decision.
For policy makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policy making will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

Individualization of clinical decision-making in weak recommendations remains a challenge. Although clinicians always should consider patients' preferences and values, when they face weak recommendations they may have more detailed conversations with patients than for strong recommendations to ensure that the ultimate decision is consistent with the patient's preferences and values.

Important Note:

Clinicians, patients, third-party payers, institutional review committees, other stakeholders, or the courts should **never view recommendations as dictates**. Even strong recommendations based on high-quality evidence will not apply to all circumstances and all patients.

Users of guidelines may reasonably conclude that following some strong recommendations based on the high quality evidence will be a mistake for some patients. No clinical practice guideline or recommendation can take into account all of the often compelling unique features of individual patients and clinical circumstances. Thus, nobody charged with evaluating clinician's actions, should attempt to apply recommendations by rote or in a blanket fashion.

6.1.1 Strong recommendation

A strong recommendation is one for which guideline panel is confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention).

Note: Strong recommendations are not necessarily high priority recommendations.

A strong recommendation implies that most or all individuals will be best served by the recommended course of action.

Example 1: Sample strong recommendations

- Early anticoagulation in patients with deep venous thrombosis for the prevention of pulmonary embolism;
- Antibiotics for the treatment of community acquired pneumonia;
- Quitting smoking to prevent adverse consequences of tobacco smoke exposure;
- Use of bronchodilators in patients with known COPD

6.1.2 Weak recommendation

A weak recommendation is one for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists.

A weak recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values. When there are weak recommendations caregivers need to allocate more time to shared decision making, making sure that they clearly and comprehensively explain the potential benefits and harms to a patient.

Alternative names for weak recommendations

Some have been concerned with the term "weak recommendation" experiencing an unintended negative connotation with the word "weak", often also confusing it with "weak" evidence. To avoid confusion, weak recommendations can instead be described using the terms:

- **conditional** (depending on patient values, resources available or setting)
- **discretionary** (based on opinion of patient or practitioner)
- **qualified** (by an explanation regarding the issues which would lead to different decisions).

If any variations are used it is essential that authors exercise consistency across all recommendation in a guideline and across all guidelines they produce.

6.1.3 Recommendations to use interventions only in research

Promising interventions (usually new ones) with thus far insufficient evidence of benefit to support their use may be associated with appreciable harms or costs. Decision makers may worry about providing premature favorable recommendations for their use, encouraging the rapid diffusion of potentially ineffective or harmful interventions, and preventing recruitment to research already under way. They may be equally reluctant to recommend against such interventions out of fear that they will inhibit further investigation. By making recommendations for use of an intervention only in the context of research they may provide an important stimulus to efforts to answer important research questions, thus resolving uncertainty about optimal management.

Recommendations for using interventions only in research are appropriate when three conditions are met:

1. There is thus far insufficient evidence to support a decision for or against an intervention
2. Further research has large potential for reducing uncertainty about the effects of the intervention
3. Further research is thought to be of good value for the anticipated costs.

Recommendations for using interventions only in research should be accompanied by detailed suggestions about the specific research questions that should be addressed, particularly which patient-important outcomes they should measure. The recommendation for research may be accompanied by an explicit strong recommendation not to use the experimental intervention outside of the research context.

6.1.4 No recommendation

There are 3 reasons for which those making recommendations may be reluctant to make a recommendation for or against a particular management strategy, and also conclude that a recommendation to use the intervention only in research is not appropriate.

1. The confidence in effect estimates is so low that the panels feel a recommendation is too speculative (see the US Preventative Services Task Force discussion on the topic [Petitti 2009; PMID: 19189910].
2. Irrespective of the confidence in effect estimates, the trade-offs are so closely balanced, and the values and preferences and resource implications not known or too variable, that the panel has great difficulty deciding on the direction of a recommendation.
3. Two management options have very different undesirable consequences, and individual patients' reactions to these consequences are likely to be so different that it makes little sense to think about typical values and preferences.

The third reason requires an explanation. Consider adult patients with thalassemia major considering hematopoietic cell transplantation (possibility of cure but an early mortality risk of 33%) vs. continued medical treatment with transfusion and iron chelation (continued morbidity and an uncertain prognosis). A guideline panel may consider that in such situations the only sensible recommendation is a discussion between patient and physician to ascertain the patient's preferences.

Users of guidelines, however, may be frustrated with the lack of guidance when the guideline panel fails to make a recommendation. The USPSTF states: "Decision makers do not have the luxury of waiting for certain evidence. Even though evidence is insufficient, the clinician must still provide advice, patients must make choices, and policy makers must establish policies" [Petitti 2009; PMID: 19189910].

Clinicians themselves will rarely explore the evidence as thoroughly as a guideline panel, nor will they devote as much thought to the trade-offs, or the possible underlying values and preferences in the population. GRADE encourages panels to deal with their discomfort and to make recommendations even when confidence in effect estimate is low and/or desirable and undesirable consequences are closely balanced. Such recommendations will inevitably be weak, and may be accompanied by qualifications.

In the unusual circumstances in which panels may choose not to make a recommendation, they should specify the reason for this decision (see above).

6.2 Factors determining direction and strength of recommendations

Four key factors influence the direction and the strength of a recommendation (Table 6.2)

Table 6.2. Domains that contribute to the strength of a recommendation

Domain	Comment
Balance between desirable and undesirable outcomes (trade-offs) taking into account: - best estimates of the magnitude of effects on desirable and undesirable outcomes - importance of outcomes (estimated typical values and preferences)	The larger the differences between the desirable and undesirable consequences, the more likely a strong recommendation is warranted. The smaller the net benefit and the lower certainty for that benefit, the more likely a weak recommendation is warranted
Confidence in the magnitude of estimates of effect of the interventions on important outcomes (overall quality of evidence for outcomes)	The higher the quality of evidence, the more likely a strong recommendation is warranted
Confidence in values and preferences and their variability	The greater the variability in values and preferences, or uncertainty about typical values and preferences, the more likely a weak recommendation is warranted

Resource use	The higher the costs of an intervention (the more resources consumed), the less likely a strong recommendation is warranted

6.2.1 Balance of desirable and undesirable consequences

Deciding about the balance between desirable and undesirable outcomes ("trade-offs") one considers two domains:

1. best estimates of the magnitude of desirable effects and the undesirable effects (summarized in evidence profiles)

2. importance of outcomes – typical values that patients or a population apply to those outcomes ("weight" of outcomes).

6.2.1.1 Estimates of the magnitude of the desirable and undesirable effects

Large relative effects of an intervention consistently pointing in the **same direction** - towards desirable or towards undesirable effects are more likely to warrant a **strong** recommendation. Conversely, large relative effects of an intervention pointing in **opposite directions** - large desirable effects accompanied by large undesirable ones will lead to **weak** recommendations.

Large absolute effects are also more likely to lead to a strong recommendation, than small absolute effects. Baseline risk (control event rate) can influence the balance of desirable and undesirable outcomes. Large baseline risk differences will result in large differences in absolute effects of interventions. The strength of recommendations and its direction, therefore, will likely differ in high- and low-risk groups.

Examples

Large gradient between the desirable and undesirable effects (higher likelihood of a strong recommendation)

1. The very large gradient between the benefits of low dose aspirin on reductions in death and recurrent myocardial infarction and the undesirable consequences of minimal side effects and costs make a strong recommendation very likely.

Small gradient between the desirable and undesirable effects (higher likelihood of a weak recommendation)

1. Consider the choice of immunomodulating agents, namely cyclosporine or tacrolimus, in kidney transplant recipients. Tacrolimus results in better graft survival (a highly valued outcome), but at the important cost of a higher incidence of diabetes (the long-term complications of which can be devastating).

2. Patients with atrial fibrillation typically are more stroke averse than bleeding averse. If, however, the risk of stroke is sufficiently low, the trade-off between stroke reduction and increase in bleeding risk with anticoagulants is closely balanced.

6.2.1.2 Best estimates of values and preferences

Without considering the associated values and preferences, assessing large vs. small magnitude of effects may be misleading. Balancing the magnitude of desirable and undesirable outcomes requires considering weight (importance) of those outcomes that is determined by values and preferences.

Ideally, to inform estimates of typical patient values and preferences, guideline panels will conduct or identify systematic reviews of relevant studies of patient values and preferences. There is, however, paucity of empirical examinations of patients' values and preferences.

Well resourced guideline panels will usually complement such studies with consultation with individual patients and patients' groups. The panel should discuss whose values these people represent, namely representative patients, a defined subset of patients, or representatives of the general population.

Less well-resourced panels, without systematic reviews of values and preferences or consultation with patients and patient groups, must rely on unsystematic reviews of the available literature and their experience of interactions with patients. How well such estimates correspond to true typical values and preferences is likely to be uncertain.

Whatever the source of estimates of typical values and preferences, explicit, transparent statements of the panel's choices are imperative (see 6.3.3 Providing transparent statements about assumed values and preferences).

6.3.2 Confidence in best estimates of magnitude of effects (quality of evidence)

For all outcomes considered, the GRADE process requires a rating describing the quality of evidence. Ultimately, guideline authors will form their recommendations based on their confidence in all effect estimates for each outcome considered critical to their recommendation and the quality of evidence.

Quality of evidence ratings are determined by the eight already discussed; the five criteria that result in rating down the quality of evidence (study limitations, inconsistency, indirectness, imprecision, and publication bias result in rating down the quality of evidence whereas the remaining three criteria, lead to an increase in evidence quality; large magnitude of effect, dose-response gradient and when all plausible biases or confounders increase our confidence in the estimated effect.

Typically, a strong recommendation is associated with high, or at least moderate, confidence in the effect estimates for critical outcomes. If one has high confidence in effects on some critical outcomes (typically benefits), but low confidence in effects on other outcomes considered critical (often long-term harms), then a weak recommendation is likely warranted. Even when an apparently large gradient exists in the balance of desirable vs. undesirable outcomes, panels will be appropriately reluctant to offer a strong recommendation if their confidence in effect estimates for some critical outcomes is low.

For some questions, direct evidence about the effects on some critical outcomes may be lacking (e.g. quality of life has not been measured in any study). In such instances, even if well measured **surrogates** are available, confidence in estimates of effects on patient-important outcomes is very likely to be low.

Low confidence in effect estimates may, rarely, be tied to strong recommendations. In general, **GRADE discourages guideline panels from making strong recommendations when their confidence in estimates of effect for critical outcomes is low or very low**. GRADE has identified five paradigmatic situations in which strong recommendations may be warranted despite low or very low quality of evidence (Table 6.3). These situations can be conceptualized as ones in which a panel would have a low level of regret if subsequent evidence showed that their recommendation was misguided.

Table 6.3. Paradigmatic situations in which a strong recommendation may be warranted despite low or very low confidence in effect estimates

	Condition	Example
1	When low quality evidence suggests benefit in a life threatening situation (evidence regarding harms can be low or high)	1. Fresh frozen plasma or vitamin K in a patient receiving warfarin with elevated INR and an intracranial bleed. Only low quality evidence supports the benefits of limiting the extent of the bleeding. 2. Amphotericin B vs. itraconazole in life threatening disseminated blastomycosis. High quality evidence suggests that amphotericin B is more toxic than itraconazole, and low quality evidence suggests that it reduces mortality in this context.
2	When low quality evidence suggests benefit and high quality evidence suggests harm or a very high cost	Head-to-toe CT/MRI screening for cancer. Low quality evidence of benefit of early detection but high quality evidence of possible harm and/or high cost (strong recommendation against this strategy)
3	When low quality evidence suggests equivalence of two alternatives, but high quality evidence of less harm for one of the competing alternatives	Helicobacter pylori eradication in patients with early stage gastric MALT lymphoma with H. pylori positive. Low quality evidence suggests that initial H. pylori eradication results in similar rates of complete response in comparison with the alternatives of radiation therapy or gastrectomy; high quality evidence suggests less harm/morbidity
4	When high quality evidence suggests equivalence of two alternatives and low quality evidence suggests harm in one alternative	Hypertension in women planning conception and in pregnancy. Strong recommendations for labetalol and nifedipine and strong recommendations against angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) all agents have high quality evidence of equivalent beneficial outcomes, with low quality evidence for greater adverse effects with ACE inhibitors and ARBs
5	When high quality evidence suggests modest benefits and low/very low quality evidence suggests possibility of catastrophic harm	Testosterone in males with or at risk of prostate cancer. High quality evidence for moderate benefits of testosterone treatment in men with symptomatic androgen deficiency to improve bone mineral density and muscle strength. Low quality evidence for harm in patients with or at risk of prostate cancer
INR – international normalized ratio; CT – computed tomography; MRI – magnetic resonance imaging; MALT – mucosa-associated lymphoid tissue.		

6.3.3 Confidence in values and preferences

Uncertainty concerning values and preferences or their **variability** among patients may lower the strength of a recommendation.

As noted above, systematic study of patients' values and preferences are very limited. Thus, panels will often be uncertain about typical values and preferences. The greater is the uncertainty, the more likely they will make a weak recommendation. Given the sparse systematic study of patients' values and preferences, one could argue that large uncertainty always exists about the patients' perspective. On the other hand, clinicians' experience with patients may provide considerable additional insight. Indeed, on occasion, panels will, on the basis of clinical experience, be confident regarding typical patient's values and preferences. Pregnant women's strong aversion to even a small risk of important fetal abnormalities may be one such situation.

Large variability in values and preferences may also make a weak recommendation more likely. In such situations, it is less likely that a single recommendation would apply uniformly across all patients, and the right course of action is likely to differ between patients. Again, systematic research about variability in values and preferences is sparse. On the other hand, clinical experience may leave a panel confident that values and preferences differ widely among patients.

Example

1. A hopeful patient may place more emphasis on a small chance of benefit, whereas a pessimistic, risk-averse patient may place more emphasis on avoiding the risks associated with a potentially beneficial therapy. Some patients may have a belief that even if the risk of an adverse event is low, they will be the person who will suffer such an adverse effect. For instance, in patients with idiopathic pulmonary fibrosis, evidence for the benefit of steroids warrants only low confidence, whereas we can be very confident of a wide range of adverse effects associated with steroids. The hopeful patient with pulmonary fibrosis may be enthusiastic about use of steroids, whereas the risk-averse patient is likely to decline.

2. Thromboprophylaxis reduces the incidence of venous thromboembolism in immobile, hospitalized severely ill medical patients. Careful thromboprophylaxis has minimal side effects and relatively low cost while being very effective at preventing deep venous thrombosis and its sequelae. Peoples' values and preferences are such that virtually all patients admitted to a hospital would, if they understood the choice they were making, opt to receive some form of thromboprophylaxis. Those making recommendations can thus offer a strong recommendation for thromboprophylaxis for patients in this setting.

3. A systematic review and meta-analysis describes a relative risk reduction (RRR) of approximately 80% in recurrent DVT for prophylaxis beyond 3 months up to one year. This large effect supports a strong recommendation for warfarin. Furthermore, the relatively narrow 95% confidence interval (approximately 74 to 88%) suggests that warfarin provides a RRR of at least 74%, and further supports a strong recommendation. At the same time, warfarin is associated with an inevitable burden of keeping dietary intake of vitamin K relatively constant, monitoring the intensity of anticoagulation with blood tests, and living with the increased risk of both minor and major bleeding. It is likely, however, that most patients would prefer avoiding another DVT and accept the risk of a bleeding episode. As a result, almost all patients with high risk of recurrent DVT would choose taking warfarin for 3 to 12 months, suggesting the appropriateness of a strong recommendation. Thereafter, there may be an appreciable number of patients who would reject life-long anticoagulation.

6.3.4 Resource use (cost)

Panels may or may not consider resource use in their judgments about the direction and strength of recommendations. Reasons for not considering resource use include a lack of reliable data, the intervention is not useful and the effort of calculating resource use can be spared, the desirable effects so greatly outweigh any undesirable effects that resource considerations would not alter the final judgment, or they have elected (or been instructed) to leave resource considerations up to other decision makers. Panels should be explicit about the decision they made not to consider resource utilization and the reason for their decision.

If they elect to include resource utilization when making a recommendation, but have not included resource use as a consequence when preparing an evidence profile, they should be explicit about what types of resource use they considered when making the recommendation and whatever logic or evidence was used in their judgments.

Cost may be considered just another potentially important outcome – like mortality, morbidity, and quality of life – associated with alternative ways of managing patient problems. In addition to these clinical outcomes, however, an intervention may increase costs or decrease costs. The GRADE approach recommends that important or critical resource use be considered alongside other relevant outcomes in evidence profiles and summary of findings tables. It is important to use natural units when presenting resource use data as these can be applied in any setting.

Special considerations when incorporating resources use (cost) in recommendations:

- What are the differences between costs and other outcomes?
- Which perspective to take?
- Which resource implications to include?
- How to make judgments about the quality of the evidence?
- How to present these implications?
- What is potential usefulness of a formal economic model?
- How to consider resource use in formulating recommendations?

6.3.4.1 Differences between costs and other outcomes

There are several differences between costs and other outcomes:

1. With costs the issue of who pays and who gains is most prominent.
2. Attitudes about the extent to which costs should influence the decision differ depending on who bears the cost.
3. Costs tend to vary widely across jurisdictions and over time.
4. People have different perspectives on the envelope in which they are considering opportunity costs.
5. Resource allocation is a far more political issue than consideration of other outcomes.

1. **With costs the issue of who pays and who gains is most prominent.**

For most outcomes other than costs, it is clear that the patient and, secondarily, the patient's family gains the advantages, and has to live with the disadvantages (this is not true of all outcomes – with vaccinations the entire community benefits from the herd effect, or widespread use of antibiotics may have down-stream adverse consequences of drug resistance). Health care costs are often borne by the society as a whole. Even within a society, who bears the cost may differ depending on the patient's age or situation.

2. **Attitudes about the extent to which costs should influence the decision differ depending on who bears the cost.**

If costs are borne by the government, or a third party payer, some would argue that the physician's responsibility to the patient means that costs should not influence the decision. On the other hand, a clinicians' responsibility when caring for a patient is discharged in a broader context: resources that are used for an intervention cannot be used for something else and can affect the ability of the health system to best meet the needs of those it serves.

3. **Costs tend to vary widely across jurisdictions or even within jurisdictions, and over time.**

Costs of drugs are largely unrelated to the costs of production of those drugs, and more to marketing decisions and national policies. Hospitals or health maintenance organizations may, for instance, negotiate special arrangements with pharmaceutical companies for prices substantially lower than are available to patients or other providers. Even when resource use remains the same, the resource implications may vary widely across jurisdictions. Costs can also vary widely over time (e.g. when a drug comes off patent or a new, cheaper technology becomes available). The large variability in costs over time and jurisdictions requires that guideline panels formulate health care questions as specific as possible when bringing cost into the equation. The choice of comparator can be a particular problem in economic analyses. If the choice of the comparator is inappropriate (for instance, no treatment rather than an alternative though less effective intervention) conclusions may be misleading. Even when resource use remains the same, the resource implications may vary widely across jurisdictions. A year's supply of a very expensive drug may pay a nurse's salary in the United States, six nurses' salaries in Poland, and 30 nurses' salaries in China. Thus, what one can buy with the resources saved if one foregoes purchase of the drug (the "opportunity cost") – and the health benefits achieved with those expenditures - will differ to a large extent.

4. **People have different perspectives on the envelope in which they are considering opportunity costs.**

A hospital pharmacy with a fixed budget considering purchase of an expensive new drug will have a clear idea of what that purchase will mean in terms of other medications the pharmacy cannot afford. People often assume the envelope is public health spending – funding a new drug or program will constrain resources for other public health expenditures. However, one may not be sure that refraining from that purchase really means that equivalent resources will be available for the health care system. Further, one may ask if the public health care is spending the correct envelope.

5. **Resource allocation is a far more political issue than consideration of other outcomes.**

Whether the guideline panel does or does not explicitly consider resource allocation issues, those politics may bear on a guideline panel's function through conflict of interest.

Despite these differences, approaches to cost (resource use) are similar to other outcomes:

- guideline panels need to consider only important resource implications
- decision makers require an estimate of the difference between treatment and control
- guideline panels must make explicit judgments about the quality of evidence regarding incremental resource use.

6.3.4.2 Perspective

GRADE suggests that a broad perspective is desirable.

A recommendation could be intended for a very narrow audience, such as a single hospital pharmacy, an individual hospital or a health maintenance organization. Alternatively it could be intended for a health region, a country or an international audience.

Regardless of how narrow or broad the intended audience, guideline groups that choose to incorporate resource implications must be explicit about the perspective they are taking.

Alternatively a guideline may choose to take a societal perspective, and include all important resource implications, regardless of who bears the costs.

In a publicly funded health system the patient perspective would consider only resource implications that directly affect individual patients (e.g. out of pocket costs) and would ignore most of the costs generated (e.g. costs borne by the government). In European health care systems in which, for the most part, governments bear the cost of health care, expenses borne directly by patients will be minimal. A pharmacy perspective would ignore down-stream cost savings resulting for adverse events (e.g. stroke or

myocardial infarction) prevented by a drug. A hospital perspective would ignore out-patient costs either incurred, or prevented. In the private sector, where disenrollment and loss of insurance can shift the burden of costs from one system to another, estimates of resource use should include the down-stream costs of all treated patients, not just those who remain in a particular health plan.

An even broader perspective, that of society, would include indirect costs or savings (e.g. lost wages). These are difficult to estimate and controversial because they assume that lost productivity will not be replaced by an individual who otherwise would be unemployed or underemployed, and implicitly place lower value on individuals not working (e.g. the retired). Taking a health systems perspective has another advantage. A comprehensive display of the resource use associated with alternative management strategies allows an individual or group – a patient, a pharmacy, or a hospital – to examine the relative merits of the alternatives from their particular perspective.

Clinicians seeing patients who are uncovered by either public or private insurance may need to help these individuals to make decisions taking into account their out of pocket costs. This is particularly true when clinical advantages and disadvantages are closely balanced, and there are substantial out of pocket costs. In these circumstances, if a guideline panel has used the GRADE approach and made evidence profiles available to the guideline users, clinicians can review evidence summaries and ensure that the patients' decision to accept the recommended management strategy is consistent with their values and preferences – either though communicating the information directly to the patient, or by finding out what the patients' situation and values and preferences are.

6.3.4.3 Resource implications considered

Evidence profiles and summary of findings tables should always present resource use, not just monetary values as monetary values for the same resource will vary depending on setting.

We suggest that guideline developers document best estimates of resource use, not best estimate of costs. Costs are a function of resources expended and the cost per unit of resource. Given the wide variability in costs per unit, reporting only total costs across broad categories of resource expenditure leaves users without the information required to judge whether estimates of unit costs apply to their setting. It is therefore recommended that natural units be used to estimate resource use. For example, required number of days stayed in hospital, the cost per night will vary depending on the setting.

Users of guidelines will be best informed if the guideline developers specify resources consumed by alternate management strategies, because they can:

- judge whether the resource use reflects practice patterns in their setting
- focus on the items of most relevance to them
- ascertain whether the unit costs apply in their setting.

Unless resource use is specified, users in settings other than that on which the analysts focus cannot estimate the associated incremental costs of the intervention.

6.3.4.4 Confidence in the estimates of resource use (quality of the evidence about cost)

Evidence of resource use may come from different sources than evidence of health benefits. This may be the case both because trials of interventions do not fully report resource use, because the trial situation may not fully reflect the circumstances (thus the resource use) that we would expect in clinical practice, because the relevant resource use may extend beyond the duration of trial, and because resource use may vary substantially across settings.

For resource use that is reported in the context of trials, criteria for quality assessment are identical to that of other outcomes. Just as for other outcomes of a trial, the quality of evidence may differ across different resources. For example, drug use may be relatively easy to estimate, whereas use of health professionals' time may be more difficult, and the estimate of drug use may therefore be of higher quality.

6.3.4.5 Presentation of resource use

A balance sheet (e.g. evidence profile) should inform judgments about whether the net benefits are worth the incremental costs. Balance sheets efficiently present the raw information required to make informed explicit judgments concerning resource use in guideline recommendations. However, when complex trade-off decisions involving several outcomes need to be made judgments may remain implicit or qualitatively described.

Pooling resource estimates from different studies is seldom as it can be quite controversial and should be carefully considered. However, authors can consider presenting pooled estimates of resource use when they are confident that the outcome in question has a common meaning (i.e. number of nights stayed in hospital) across the studies involved in analysis. Even in this case, it is recommended that authors adjust for geographical and temporal differences in cost.

6.3.4.6 Economic model

Formal economic modeling may – or may not - be helpful.

Formal economic modeling results in cost per unit benefit achieved: cost per natural unit, such as cost per stroke prevented (cost-effectiveness analysis) cost per quality-adjusted life year gained (cost-utility analysis) cost and benefits valued in monetary values (cost-benefit analysis). These summaries can be helpful for informing judgments. Unfortunately, many published cost-effectiveness analyses have a high probability of being flawed or biased, and are setting-specific. When estimates of harms, benefits and resources used are based on low quality evidence, transparency of the economic model will be reduced and the model may be misleading.

Should guideline panels consider developing their own formal economic model?

Creating an economic model may be advisable if:

- guideline groups have the necessary expertise and resources
- difference in resources consumed by the alternative management strategies is large and therefore there is substantial uncertainty about whether the net benefits of an intervention are worth the incremental costs
- quality of available evidence regarding resource consumption is high and it is likely that a full economic model would help inform a decision
- implementing an intervention requires large capital investments, such as building new facilities or purchasing new, expensive equipment.

Modeling – while necessary for taking into account complexities and uncertainties in calculating cost per unit benefit – reduces transparency. Any model is only as good as the data on which it is based. When estimates of benefits, harms, or resources used come from low quality evidence, results of any economic modeling will be highly speculative.

Although criteria to assess the credence to give to results from statistical models of cost-effectiveness or cost-utility are available, these models generally include a large number of assumptions and varying quality evidence for the estimates that are included in the model. For these reasons, GRADE working group recommends not including cost-effectiveness or cost-utility models in evidence profiles. These models may, however, inform judgments of a guideline panel, or those of governments, or third part payers considering whether to include an intervention among their programs' benefits.

6.3.4.7 Consideration of resource use in recommendations

Guideline panel may choose to explicitly consider or not to consider resource use in recommendations.

A guideline panel may legitimately choose to leave considerations of resource use aside, and offer a recommendation solely on the basis of other advantages and disadvantages of the alternatives being considered. Resource allocation must then be considered at the level of the ultimate decision-maker – be it the patient and healthcare professional, an organization (e.g. hospital pharmacy or a health maintenance organization), a third party payer, or a government. Guideline panels should be explicit about the decision to consider or not to consider resource utilization.

If guideline panel considers resource use it should, prior to bringing cost into the equation, first decide on the quality of evidence regarding other outcomes, and weigh up the advantages and disadvantages. Decisions regarding the importance of resource use issues will flow from this first step. For example, resource implications may be irrelevant if evidence of net health benefits is lacking. If advantages of an intervention far outweigh disadvantages, resource use is less likely to be important. Resource use usually becomes important when advantages and disadvantages are closely balanced.

GRADE approach suggests that panels considering resource use should offer only a single recommendation taking resource use into account. Panels should refrain from issuing two recommendations – one not taking resource use into account and a second doing so. Although this would have the advantage of explicitness on which GRADE places a very high value, GRADE working group is concerned that those with interests in dissemination of an intervention would effectively use only the recommendation ignoring resource implications as a weapon in their battle for funds (public funds, in particular).

6.4 Presentation of recommendations

6.4.1 Wording of recommandations

Wording of a recommendation should offer clinicians as many indicators as possible for **understanding and interpretation**.

Recommendations should always answer the initial clinical question. Therefore, they should specify **patients or population** (characterized by the disease and other identifying factors) for whom the recommendation is intended and a recommended **intervention** as specifically and detailed as needed. Unless it is obvious, they should also specify the comparator. Sometimes, the recommendation may include a reference to the setting (e.g. primary or tertiary care, high- or low-income countries, etc.).

In general, it seems preferable to present recommendations in favor of a particular management approach rather than against an alternative. For instance, in considering the addition of aspirin to clopidogrel in patients who have had a stroke, it would be preferable to state: "In patients who have had a stroke, we suggest clopidogrel alone vs. adding aspirin to clopidogrel" rather than: "In patients who have had a stroke and are using clopidogrel, we suggest not adding aspirin". However, when a useless or harmful therapy is in wide use, recommendations against a management approach are appropriate. For instance, "In patients undergoing cardiac surgery who were not previously receiving beta blockers, we suggest not initiating perioperative beta blocker therapy".

Recommendations in the passive voice may lack clarity, therefore, GRADE suggest that guideline developers present recommendations in the active voice.

For **strong recommendations**, the GRADE working group has suggested adopting terminology, such as "**we recommend**..." or "**clinicians should**...", "clinicians should not…" or "Do…", "Don't…"

For **weak recommendations**, the GRADE working group has suggested less definitive wording, such as "**we suggest**..." or "**clinicians might**..." or "We conditionally recommend…" or "We make a qualified recommendation that…".

Wording strong and weak recommendations is particularly important when guidelines are developed by international organizations and/or are intended for patients and clinicians in different regions, cultures, traditions, and usage of language. It is also crucial to explicitly and precisely consider wording when translating recommendations into different languages. Whatever terminology guideline panels choose to

use to communicate the dichotomous nature of a recommendation, it is essential that they inform their users what the terms imply by providing the explanations as in Table 5.9.

Misinterpretation is possible however strength of recommendations is expressed. We suggest guideline developers consider using both words and symbols (which may be less confusing than numbers or letters) to express strength of recommendations.

6.3.2 Symbolic representation

A variety of presentations of quality of evidence and strength of recommendations may be appropriate. Most guideline panels have used letters and numbers to summarize their recommendations. Because of highly variable use of numbers and letters by different organizations this presentation may be confusing. Symbolic representations of the quality of evidence and strength of recommendations are appealing in that they are not burdened with this historical confusion. On the other hand, clinicians seem to be very comfortable with numbers and letters, which are particularly suitable for verbal communication, so there may be good reasons why organizations have chosen to use them.

The GRADE working group has decided to offer preferred symbolic representations, but users of guidelines based on the GRADE approach will often see numbers and letters being used to express the quality of evidence and strength of a recommendation.

Table 6.4. Suggested representations of quality of evidence and strength of recommendations

Quality of Evidence	**Symbol**	**Letter** (varies)
High	⊕⊕⊕⊕	A
Moderate	⊕⊕⊕◯	B
Low	⊕⊕◯◯	C
Very low	⊕◯◯◯	D
Strength of Recommendation	Symbol	Number
Strong for an intervention	↑↑	1
Weak for an intervention	↑?	2
Weak against an intervention	↓?	2
Strong against an intervention	↓↓	1

6.4.3 Providing transparent statements about assumed values and preferences

Ideally, **recommendations should be accompanied by a statement presenting assumptions about the values and preferences** that underlie recommendations. For instance, a guideline addressing issues of thrombosis prevention and treatment in pregnancy noted: "Our recommendations reflect a belief that most women will place a low value on avoiding the pain, cost, and inconvenience of heparin therapy to avoid the small risk of even a minor abnormality in their child associated with warfarin prophylaxis".

In addition to, or in place of, making such general statements, guideline panels may provide **statements associated with individual recommendations**, especially those that are particularly sensitive to values and preferences. In such cases authors should place statements about underlying values and preferences with the recommendation statement rather than in the accompanying text. This prominent positioning of the statements will make it less likely that users of guidelines miss the importance of the values and preference judgments.

Consider, for instance, two groups that were part of a broader guideline effort made apparently contradictory recommendations regarding aspirin vs. clopidogrel in patients with atherosclerotic vascular disease, despite using the same underlying evidence from a trial that enrolled both patients with threatened stroke and those with peripheral vascular disease. One group focusing on stroke prevention recommended clopidogrel over aspirin stating: "This recommendation places a relatively high value on a small absolute risk reduction in stroke rates, and a relatively low value on minimizing drug expenditures". The other group focusing on the peripheral vascular disease recommended aspirin over clopidogrel, stating: "This recommendation places a relatively high value on avoiding large resource expenditures to achieve small reductions in vascular events". These recommendations suggest opposite courses of action. Both are appropriate given the stated values and preferences, which were made explicit in qualifying statements accompanying each recommendation.

Another way to frame values and preferences statements that panels may want to consider is in terms of patients who do not share the values and preferences underlying the recommendation. For instance, one may say: "For most healthy patients with achalasia undergoing an invasive procedure, we suggest minimally invasive surgical myotomy rather than pneumatic dilatation. Patients who prefer to avoid surgery and the high rates of gastroesophageal reflux disease seen after surgery, and who are willing to accept a higher initial failure rate and long-term recurrence rate, can reasonably choose pneumatic dilatation".

6.5 The Evidence-to-Decision framework

Ultimately, guideline panels must integrate these determinants of direction and strength to make a strong or weak recommendation for or against an intervention. Table 6.2 presents the generic Evidence-to-Decision (EtD) table that groups making recommendations may use to facilitate decision making, record judgements, and document the process of going from evidence to the decision. Table 6.3 presents an

example of EtD framework used in development of recommendations about the use of ASA in patients with atrial fibrillation (PDF version).

Table 6.5. The Evidence-to-Decision framework

<table>
<tr><th></th><th>Criteria</th><th>Judgements</th><th>Research evidence</th><th>Additional considerations</th></tr>
<tr><td>Problem</td><td>Is there a problem priority?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td rowspan="5">Benefits & harms of the options</td><td>What is the overall certainty of this evidence?</td><td>○ No included studies
○ Very low
○ Low
○ Moderate
○ High</td><td>The relative importance or values of the main outcomes of interest:
<table><tr><th>Outcome</th><th>Relative importance</th><th>Certainty of the evidence (GRADE)</th></tr><tr><td>Outcome 1</td><td>CRITICAL</td><td>⊕⊕⊕⊕ HIGH</td></tr><tr><td>Outcome 2</td><td>CRITICAL</td><td>⊕⊕⊕◯ MODERATE</td></tr></table>Summary of findings: intervention C
<table><tr><th>Outcome</th><th>Without intervention I</th><th>With intervention I</th><th>Difference (95% CI)</th><th>Relative effect (RR) (95% CI)</th></tr><tr><td>Outcome 1</td><td>61 per 1000</td><td>37 per 1000 (25 to 49)</td><td>25 fewer per 1000(from 12 fewer to 37 fewer)</td><td>RR 0.6 (0.4 to 0.8)</td></tr><tr><td>Outcome 2</td><td>108 per 1000</td><td>99 per 1000 (80 to 134)</td><td>9 fewer per 1000(from 26 more to 28 fewer)</td><td>RR 0.92 (0.74 to 1.24)</td></tr></table></td><td></td></tr>
<tr><td>Is there important uncertainty about how much people value the main outcomes?</td><td>○ Important uncertainty or variability
○ Possibly important uncertainty or variability
○ Probably no important uncertainty of variability
○ No important uncertainty of variability
○ No known undesirable</td><td></td><td></td></tr>
<tr><td>Are the desirable anticipated effects large?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td>Are the undesirable anticipated effects small?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td>Are the desirable effects large relative to undesirable effects?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td rowspan="2">Resource use</td><td>Are the resources required small?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td>Is the incremental cost small relative to the net benefits?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td>Equity</td><td>What would be the impact on health inequities?</td><td>○ Increased
○ Probably increased
○ Uncertain
○ Probably reduced
○ Reduced
○ Varies</td><td></td><td></td></tr>
<tr><td>Acceptability</td><td>Is the option acceptable to key stakeholders?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
<tr><td>Feasibility</td><td>Is the option feasible to implement?</td><td>○ No
○ Probably no
○ Uncertain
○ Probably yes
○ Yes
○ Varies</td><td></td><td></td></tr>
</table>

Evidence to Decisions Framework: explanations

Purpose of the framework
The purpose of this framework is to help panels developing guidelines move from evidence to recommendations. It is intended to:

- Inform panel members' judgements about the pros and cons of each option (intervention) that is considered
- Ensure that important factors that determine a recommendation (criteria) are considered
- Provide a concise summary of the best available research evidence to inform judgements about each criterion
- Help structure discussion and identify reasons for disagreements
- Make the basis for recommendations transparent to guideline users

Development of the framework
The framework is being developed as part of the DECIDE project using an iterative process informed by the GRADE approach for going from evidence to clinical recommendations, a review of relevant literature, brainstorming, feedback from stakeholders, application of the framework to examples, a survey of policymakers, user testing, and trials. DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) is a 5-year project (running from January 2011 to 2015) co-funded by the European Commission under the Seventh Framework Programme. DECIDE's primary objective is to improve the dissemination of evidence-based recommendations by building on the work of the GRADE Working Group to develop and evaluate methods that address the targeted dissemination of guidelines.

Description of the framework
The framework includes a ***table*** with the following columns:

- ***Criteria*** (factors that should be considered) for health system or public health recommendations
- ***Judgements*** that the panel members must make in relation to each criterion, which may include draft judgements suggested by the people who have prepared the framework
- ***Research evidence*** to inform each of those judgements, which may include links to more detailed summaries of the evidence
- ***Additional considerations*** to inform or justify each judgement

The framework also includes the following ***conclusions*** that the panel members must reach, which may include draft conclusions suggested by the people who have prepared the framework:

- The ***balance of consequences*** of the option being considered in relation to the alternative (comparison)
- The ***type of recommendation*** (against the option, for considering the option under specified conditions, or for the option)
- The ***recommendation*** in concise, clear and actionable text
- The ***justification*** for the recommendation, flowing from the judgements in relation to the criteria
- Any important ***subgroups considerations*** that may be relevant to guideline users
- Key ***implementation considerations*** (in addition to any that are specified in the recommendation), including strategies to address any concerns about the acceptability and feasibility of the option
- Suggestions for ***monitoring and evaluation*** if the option is implemented, including any important indicators that should be monitored and any needs for a pilot study or impact evaluation
- Any key ***research priorities*** to address important uncertainties in relation to any of the criteria

Flexibility
The framework is flexible. Organisations may elect to modify the terminology (and language) that is used, the criteria, the response options and guidance for using the framework to ensure that the framework is fit for purpose.

Use of the framework
Suggestions for how to use the framework are provided in: Framework for going from evidence to a recommendation – Guidance for health system and public health recommendations, including suggestions for preparing frameworks, supporting use of the framework by guideline panels, and using the framework to support well-informed decisions by guideline users.

The final recommendation made by the guideline panel is a consensus based on the judgements of the panel members, informed by the evidence presented in the framework and the panel members' expertise and experience.

Explanations of the criteria in the framework
Why these criteria?
The criteria included in the framework are ones that have emerged from our literature review, brainstorming, feedback from stakeholders, application of the framework to examples, a survey of policymakers and user testing. It is possible that we will make further modifications based on continuing feedback, applications of the framework and user testing. Guideline developers may also want to make modifications, such as adding or removing criteria that are or are not important for them to consider. However, there is clear and consistent support for routinely including all of these criteria and, up to now, a lack of clear and consistent support for including other potential criteria.

Detailed judgements
The judgements that need to be made are sometimes complex. Guideline panels are likely to find it helpful to make and record detailed judgements for some criteria using ***tables for detailed judgements***. This includes, for example, detailed judgements about the size of the effect for each outcome, the certainty of the evidence of the relative importance of the outcomes and resource use, and important subgroup considerations. Some criteria could be split into two or more separate criteria and some panels may elect to do this in order to highlight key considerations that are of particular importance for their guidelines. For example, there are several reasons why an option may not be acceptable to key stakeholders and these could potentially be considered as separate criteria.

From whose perspective?
Guideline panels should explicitly state the perspective that they are taking when making recommendations. This is especially important for determining which costs (resource use) to consider. It can also influence which outcomes and whose values are considered. For example, out-of-pocket costs are important from the perspective of an individual patient, whereas costs to the government are important from the perspective of the government. Health system and public health decisions are made on behalf of a population and a broad perspective is required. However, because of their mandate, some panels might take the perspective of the ministry of health or health department, whereas other panels might take a societal perspective (including all costs, regardless of who pays). Other perspectives (the distribution of the benefits, harms and costs) should be taken when considering the acceptability of the option to key stakeholders.

Large or small compared to what?

Some of the criteria imply a comparison; for example, the size of effects or resource requirements ***compared to what***? The comparisons or standards that are used are likely to be different for different organisations, guideline panels and jurisdictions. Some organisations or guideline panels may elect to specify the comparisons or standards that they will use. In the absence of such specified comparisons, guideline panel members should consider what their comparisons or standards are when they disagree, for example, about whether resource requirements are large. When the comparison being used is the source of their disagreement, they should agree on an appropriate comparison and include this as an additional consideration in the framework when it is relevant.

Guidance for making judgements
Suggestions for how to make judgements in relation to each criterion are provided in Framework for going from evidence to a recommendation – Guidance for health system and public health recommendations.

For each criterion there are four or five response options, from those that favour a recommendation against the option on the left to ones that favour a recommendation for the option on the right. In addition, most of the options include *varies* as a response option for situations when there is important variation across different settings for which the guidelines are intended and those differences are **substantial enough that they might lead to different recommendations for different settings.**

Questions to consider for each criterion and their relationship to a recommendation
For each criterion we suggest one or more detailed questions to consider when making a judgement and explain the relationship between the criterion and the recommendation.

Criteria	Questions	Explanations
Is the problem a priority?	*Are the consequences of the problem serious (i.e. severe or important in terms of the potential benefits or savings)? Is the problem urgent? Is it a recognised priority (e.g. based on a national health plan)? Are a large number of people affected by the problem?*	The more serious a problem is, the more likely it is that an option that addresses the problem should be a priority (e.g., diseases that are fatal or disabling are likely to be a higher priority than diseases that only cause minor distress). The more people who are affected, the more likely it is that an option that addresses the problem should be a priority.
Is there important uncertainty about how much people value the main outcomes?	*How much do those affected by the option value each of the outcomes in relation to the other outcomes (i.e. what is the relative importance of the outcomes)? Is there evidence to support those value judgements, or is there evidence of variability in those values that is large enough to lead to different decisions?*	The more likely it is that differences in values would lead to different decisions, the less likely it is that there will be a consensus that an option is a priority (or the more important it is likely to be to obtain evidence of the values of those affected by the option). Values in this context refer to the relative importance of the outcomes of interest (how much people value each of those outcomes). These values are sometimes called 'utility values'.
What is the overall certainty[1] of the evidence of effectiveness?	*What is the overall certainty of this evidence of effects, across all of the outcomes that are critical to making a decision?*	The less certain the evidence is for critical outcomes (those that are driving a recommendation), the less likely that an option should be recommended (or the more important it is likely to be to conduct a pilot study or impact evaluation, if it is recommended).
How substantial are the desirable anticipated effects?	*How substantial (large)are the desirable anticipated effects (including health and other benefits) of the option (taking into account the severity or importance of the desirable consequences and the number of people affected)?*	The larger the benefit, the more likely it is that an option should be recommended.
How substantial are the undesirable anticipated effects?	*How substantial (large) are the undesirable anticipated effects (including harms to health and other harms) of the option (taking into account the severity or importance of the adverse effects and the number of people affected)?*	The greater the harm, the less likely it is that an option should be recommended.
Do the desirable effects outweigh the undesirable effects?	*Are the desirable effects large relative to the undesirable effects?*	The larger the desirable effects in relation to the undesirable effects, taking into account the values of those affected (i.e. the relative value they attach to the desirable and undesirable outcomes) the more likely it is that an option should be recommended.
How large are the resource requirements?	*How large an investment of resources would the option require or save?*	The greater the cost, the less likely it is that an option should be a priority. Conversely, the greater the savings, the more likely it is that an option should be a priority.
How large is the incremental cost relative to the net benefit?	*Is the cost small relative to the net benefits (benefits minus harms)?*	The greater the cost per unit of benefit, the less likely it is that an option should be a priority.
What would be the impact on health inequities?	*Would the option reduce or increase health inequities?*	Policies or programmes that reduce inequities are more likely to be a priority than ones that do not (or ones that increase inequities).
Is the option acceptable to key stakeholders?	*Are key stakeholders likely to find the option acceptable (given the relative importance they attach to the desirable and undesirable consequences of the option; the timing of the benefits, harms and costs; and their moral values)?*	The less acceptable an option is to key stakeholders, the less likely it is that it should be recommended, or if it is recommended, the more likely it is that the recommendation should include an implementation strategy to address concerns about acceptability. Acceptability might reflect who benefits (or is harmed) and who pays (or saves); and when the benefits, adverse effects, and costs occur (and the discount rates of key stakeholders; e.g. politicians may have a high discount rate for anything that occurs beyond the next election). Unacceptability may be due to some stakeholders: ● Not accepting the distribution of the benefits, harms and costs ● Not accepting costs or undesirable effects in the short term for desirable effects (benefits) in the future ● Attaching more value (relative importance) to the undesirable consequences than to the desirable consequences or costs of an option (because of how they might be affected personally or because of their perceptions of the relative importance of consequences for others) ● Morally disapproving (i.e. in relationship to ethical principles such as autonomy, nonmaleficence, beneficence or justice)
Is the option feasible to implement?	*Can the option be accomplished or brought about?*	The less feasible (capable of being accomplished or brought about) an option is, the less likely it is that it should be recommended (i.e. the more barriers there are that would be difficult to overcome).

[1] The "certainty of the evidence" is an assessment the likelihood that the effect will be substantially different from what the research found.

Explanations of the conclusions in the framework

Suggestions for how to make judgements in relation to each conclusion are provided in: *Framework for going from evidence to a recommendation – Guidance for health system and public health recommendations*. For each conclusion, we suggest one or more questions to consider when making a judgement and explain what is needed.

Term	Question	Explanation
Overall judgement across all criteria	*What is the overall balance between all the desirable and undesirable consequences?*	An overall judgement whether the desirable consequences outweigh the undesirable consequences, or vice versa (based on all the research evidence and additional information considered in relation to all the criteria). Consequences include health and other benefits, adverse effects and other harms, resource use, and impacts on equity
Type of recommendation	*Based on the balance of the consequences in relation to all of the criteria in the framework, what is your recommendation?*	A recommendation based on the balance of consequences and your judgements in relation to all of the criteria, for example: ● Not to implement the option ● To consider the option only in the context of rigorous research ● To consider the option only with specified monitoring and evaluation ● To consider the option only in specified contexts ● To implement the option
Recommendation (text)	*What is your recommendation in plain language?*	A concise, clear and actionable recommendation
Justification	*What is the justification for the recommendation, based on the criteria in the framework that drove the recommendation?*	A concise summary of the reasoning underlying the recommendation
Subgroup considerations	*What, if any, subgroups were considered and what, if any, specific factors (based on the criteria in the framework) should be considered in relation to those subgroups when implementing the option?*	A concise summary of the subgroups that were considered and any modifications of the recommendation in relation to any of those subgroups
Implementation considerations	*What should be considered when implementing the option, including strategies to address concerns about acceptability and feasibility?*	Key considerations, including strategies to address concerns about acceptability and feasibility, when implementing the option
Monitoring and evaluation considerations	*What indicators should be monitored? Is there a need to evaluate the impacts of the option, either in a pilot study or an impact evaluation carried out alongside or before full implementation of the option?*	Any important indicators that should be monitored if the option is implemented
Research priorities	*Are there any important uncertainties in relation to any of the criteria that are a priority for further research?*	Any research priorities

Explanations of terms used in summaries of findings

Term	Explanation
Outcomes	These are all the ***outcomes*** (potential benefits or harms) that are considered to be ***important*** to those affected by the intervention, and which are important to making a recommendation or decision. Consultation with those affected by an intervention (such as patients and their carers) or other members of the public may be used to select the ***important outcomes***. A review of the literature may also be carried out to inform the selection of the important outcomes. The importance (or value) of each outcome in relation to the other outcomes should also be considered. This is the ***relative importance of the outcome.***
95% Confidence Interval (CI)	A ***confidence interval*** is a range around an estimate that conveys how precise the estimate is. The confidence interval is a guide to how sure we can be about the quantity we are interested in. The narrower the range between the two numbers, the more confident we can be about what the true value is; the wider the range, the less sure we can be. The width of the confidence interval reflects the extent to which chance may be responsible for the observed estimate (with a wider interval reflecting more chance). ***95% Confidence Interval (CI)*** means that we can be 95 percent confident that the true size of effect is between the lower and upper confidence limit. Conversely, there is a 5 percent chance that the true effect is outside of this range.
Relative Effect or RR (Risk Ratio)	Here the ***relative effect*** is expressed as a ***risk ratio (RR).*** Risk is the probability of an outcome occurring. A ***risk ratio*** is the *ratio* between the risk in the intervention group and the risk in the control group. For example, if the risk in the intervention group is 1% (10 per 1000) and the risk in the control group is 10% (100 per 1000), the relative effect is 10/100 or 0.10. If the RR is exactly 1.0, this means that there is no difference between the occurrence of the outcome in the intervention and the control group. If the RR is greater than 1.0, the intervention increases the risk of the outcome. If it is a good outcome (for example, the birth of a healthy baby), a RR greater than 1.0 indicates a desirable effect for the intervention. Whereas, if the outcome is bad (for example, death) a RR greater than 1.0 would indicate an undesirable effect. If the RR is less than 1.0, the intervention decreases the risk of the outcome. This indicates a desirable effect, if it is a bad outcome (for example, death) and an undesirable effect if it is a good outcome (for example, birth of a healthy baby).
Certainty of the evidence (GRADE)2	The ***certainty of the evidence*** is an assessment of how good an indication the research provides of the likely effect; i.e. the likelihood that the effect will be substantially different from what the research found. By ***substantially different*** we mean a large enough difference that it might affect a decision. This assessment is based on an overall assessment of reasons for there being more or less certainty using the ***GRADE*** approach. In the context of decisions, these considerations include the applicability of the evidence in a specific context. Other terms may be used synonymously with *certainty of the evidence*, including ***quality of the evidence***, ***confidence in the estimate***, and ***strength of the evidence***. Definitions of the categories used to rate the certainty of the evidence (***high***, ***moderate***, ***low***, and ***very low***) are provided in the table below.

Definitions for ratings of the certainty of the evidence

Ratings	Definitions
⊕⊕⊕⊕ High	This research provides a very good indication of the likely effect. The likelihood that the effect will be ***substantially different is low.***
⊕⊕⊕◯ Moderate	This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different is moderate.
⊕⊕◯◯ Low	This research provides some indication of the likely effect. However, the likelihood that it will be substantially different (a large enough difference that it might have an effect on a decision) is high.
⊕◯◯◯ Very Low	This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different (a large enough difference that it might have an effect on a decision) is very high.

7. The GRADE approach for diagnostic tests and strategies

Recommendations concerning diagnostic testing share the fundamental logic of recommendations for therapeutic and other interventions, such as screening. However, diagnostic questions also present unique challenges.

While some tests naturally report positive and negative results (e.g., pregnancy, HIV infection), other tests report their results as ordinal (e.g., Glasgow coma scale or mini-mental status examination) or continuous variable (e.g., metabolic measures), usually with increasing likelihood of disease or adverse events as the test results become more extreme. For simplicity, in this discussion we generally assume a diagnostic approach that ultimately categorizes test results as positive or negative. This also recognizes that many tests ultimately lead to dichotomized decisions to treat or not to treat.

Clinicians and researchers often administer diagnostic tests as a package or strategy composed of several tests. Thus, one can often think of evaluating or recommending a diagnostic strategy rather than a single test.

Examples
1. In managing patients with a diagnosis of cervical intraepithelial neoplasia, a precursor of prevent cervical cancer, based on visual inspection with acetic acid (VIA) clinicians may proceed to treatment directly or apply a strategy of testing for human papilloma virus and VIA.

2. Testing strategy may use an initial sensitive but non-specific test which, if positive, is followed by a more specific test (e.g., testing for HIV includes the use of an ELISA test followed by quantitative HIV RNA determination for those with positive results of the ELISA test; but one could ask the question why quantitative HIV RNA determination alone would not be appropriate).

7.1. Questions about diagnostic tests

The format of the question asked by authors of systematic reviews or guideline developers follows the same principles as the format for management questions:
- Should TEST A vs. TEST B be used in SOME PATIENTS/POPULATION?
- Should TEST A vs. TEST B be used for SOME PURPOSE?

7.1.1. Establishing the purpose of a test

Guideline panels should be explicit about the purpose of the test in question. Researchers and clinicians apply medical tests that are usually referred to as "diagnostic" – including signs and symptoms, imaging, biochemistry, pathology, and psychological testing – for a number of purposes. These applications include identifying physiological derangements, establishing prognosis, monitoring illness and treatment response, screening and diagnosis.

7.1.2. Establishing the role of a test

Guideline panels and authors of systematic reviews should also clearly establish the role of a diagnostic test or strategy. This process should begin with determining the standard diagnostic pathway – or pathways – for the target patient presentation and identify the associated limitations. Knowing those limitations one can identify particular shortcomings for which the alternative diagnostic test or strategy offers a putative remedy. The purpose of a test under consideration may be for (i) **replacement** (e.g., of tests with greater burden, invasiveness, cost, or inferior accuracy), (ii), **triage** (e.g., to minimize use of an invasive or expensive test) or (iii) **add-on** (e.g., to further enhance diagnostic accuracy beyond the existing diagnostic pathway) (Table 7.1) [Bossuyt 2006; PMID: 16675820].

Table 7.1. Possible roles of new diagnostic tests

Replacement	A new test might substitute an old one, because it is more accurate, less invasive, less risky or uncomfortable for patients, organizationally or technically less challenging, quicker to yield results or more easily interpreted, or less costly.
Triage	A new test is added before the existing diagnostic pathway and only patients with a particular result on the triage test continue the testing pathway; triage tests are not necessarily more accurate but usually simpler and less costly.
Add-on	A new test is added after the existing diagnostic pathway and may be used to limit the number of either false positive or false negative results after the existing diagnostic pathway; add-on tests are usually more accurate but otherwise less attractive than existing tests.

7.1.3. Clear clinical questions

Clearly establishing the role or purpose of a test or test strategy will lead to the identification of sensible clinical questions that, similar to other management problems, have four components: patients, diagnostic intervention (strategy), comparison diagnostic intervention (strategy), and the outcomes of interest.

Examples
1: In patients suspected of coronary artery disease (patients) should multi-slice spiral computed tomography (CT) of coronary arteries (intervention) be used as replacement for conventional invasive coronary angiography (comparison) to lower complications with acceptable rates of false negatives associated with coronary events and false positives leading to unnecessary treatment and complications (outcomes)?
This example illustrates one common rationale for a new test – test replacement (coronary CT instead of conventional angiography) to avoid complications associated with a more invasive and expensive alternative for a condition that can effectively be treated. In this situation, the new test would only need to replicate the results of the existing test to demonstrate greater patient net benefit. This assumes that the new test similarly categorizes patients at the same stage of the disease and that the consequences of the test result, i.e. management decisions and outcomes, are similar.

2: In patients suspected of cow's milk allergy (CMA), should skin prick tests rather than an oral food challenge with cow's milk be used for the diagnosis and management of IgE-mediated CMA.
3: In adults cared for in a non-specialized clinical setting, should serum or plasma cystatin C rather than serum creatinine concentration be used for the diagnosis and management of renal impairment.

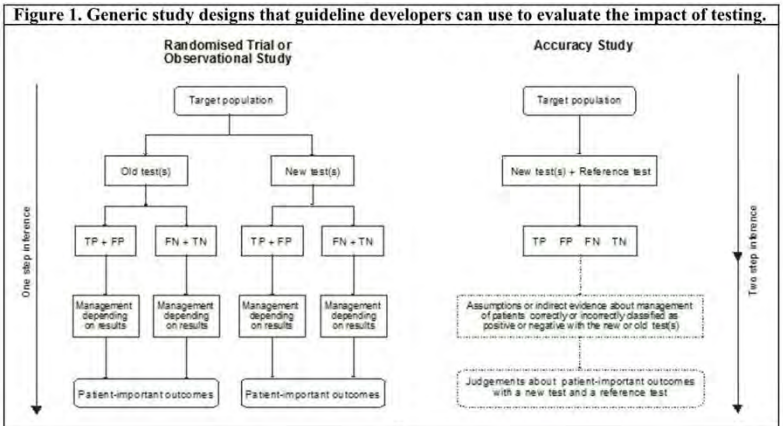
7.2. Gold standard and reference test

The concept of diagnostic accuracy relies on the presence of a so-called **"gold standard"**, i.e. a clearly stated definition of the target disease (i.e. construct of a disease). However, the term "gold standard" is ambiguous and not consistently defined. Moreover, constructs of diseases are constantly changing with progress in understanding biology (e.g. in oncology, with a more molecular understanding of the underlying pathologies or Alzheimer's dementia). We will use the term "gold standard" here as representing the "perfect" approach to defining or diagnosing the disease or condition of interest, even if the approach is theoretical and based on convention. Following from this definition, diagnostic test accuracy (e.g. sensitivity and specificity) as a measurement property is not associated with a "gold standard". We will use the term **"reference standard"** or reference test for the test or test strategy that is the current best and accepted approach to making a diagnosis against which a comparison (with an index test) may be made.

7.3. Estimating impact on patients

It follows that recommendations regarding the use of medical tests require inferences about the **consequences** of falsely identifying patients as having or not having the disease. If a test fails to improve patient-important outcomes there is no reason to use it, whatever its accuracy. Given the uncertainties about both reference and gold standards and the relation between diagnosis and patient or population consequences, the best way to assess a diagnostic test or strategy would be a test-treat randomized controlled trial in which investigators allocate patients to experimental or control diagnostic approaches and measure patient-important outcomes (mortality, morbidity, symptoms, quality of life and resource use).

Figure 1. Generic study designs that guideline developers can use to evaluate the impact of testing.



Example Randomized controlled trials (RCTs) that explored a diagnostic strategy guided by the use of B-type natriuretic peptide (BNP) – designed to aid diagnosis of heart failure – compared with no use of BNP in patients presenting to the emergency department with acute dyspnea. As it turned out, the group randomized to receive BNP spent a shorter time in the hospital at lower cost with no increased mortality or morbidity.	**Example** Consistent evidence from well designed studies demonstrates fewer false negative results with non-contrast helical CT than with intravenous pyelography (IVP) in the diagnosis of suspected acute urolithiasis. However, the stones in the ureter that CT detects but IVP "misses" are smaller, and hence are likely to pass more easily. Since RCTs evaluating the outcomes in patients treated for smaller stones are not available, the extent to which reduction in cases that are missed (false negatives) and follow-up of incidental findings unrelated to renal calculi with CT have important health benefits remains uncertain.
Two generic ways in which one can evaluate a test or diagnostic strategy: a) Patients are randomized to a new test or strategy or, alternatively, to an old test or strategy. Those with a positive test (cases detected) are randomized (or were previously randomized) to receive the best available management (second step of randomization for management not shown in this figure). Investigators evaluate and compare patient-important outcomes in all patients in both groups. b) Patients receive **both** a new test and a reference test (it often, however, is the old or comparator test or strategy). Investigators can then calculate the accuracy of the test compared to the reference test (first step). To make judgments about patient-importance of this information, patients with a positive test (or strategy) in either group are (or have been in previous studies) submitted to treatment or no treatment; investigators then evaluate and compare patient-important outcomes in all patients in both groups (second step).	

When diagnostic intervention studies (RCTs or observational studies) comparing alternative diagnostic strategies with assessment of direct patient-important outcomes are available, guideline panels can use the GRADE approach for other interventions.

If studies measuring the impact of testing on patient-important or population-important outcomes are not available, guideline panels must focus on other studies, such as diagnostic test accuracy studies, and make inferences about the likely impact of using alternative tests on patient-important outcomes. In the latter situation, diagnostic accuracy can be considered a surrogate outcome for patient-important benefits and harms.

Key questions when using test accuracy as a surrogate are:

- what outcomes can those labeled as cases and those labeled as not having a disease expect based on the knowledge about the best available management?
- will there be a reduction in false negatives (cases missed) or false positives and corresponding increases in true positives and true negatives?
- how similar (or different) are people to whom the test is applied and classified accurately by the alternative testing strategies to those evaluated in studies?

7.4. Indirect evidence and impact on patient-important outcomes

A recommendation associated with a diagnostic question follows from an evaluation of the balance between the desirable and undesirable consequences of the diagnostic test or strategy. It should be based on a systematic review addressing the clinical question as well as information about management after applying the diagnostic test.

Inferring from accuracy data that a diagnostic test or strategy improves patient-important outcome usually requires access to effective management. Alternatively, even with no effective treatment being available, using an accurate test may be beneficial, if it reduces adverse effects, cost or the anxiety through excluding an ominous diagnosis, or if confirming a diagnosis improves patient well-being from the prognostic information it imparts. Before drawing such inferences judgments about the confidence in diagnostic accuracy information is required.

7.5. Judgment about the quality of the underlying evidence

As described above, when studies as described in Figure 1a are available, the approach to assessing the confidence in effect estimates (quality of evidence) described for other interventions in prior articles in this series should be used. The rest of the current article focuses on the situation when such direct data on patient-important outcomes are lacking and the body of evidence is derived from DTA studies. Thus, in this article, we will provide guidance for assessing the confidence in estimates for those synthesizing information from DTA studies, e.g. authors of systematic reviews. Summary of findings (SoF) tables and GRADE evidence profiles provide transparent accounts of this information by summarizing numerical information and ratings of the confidence in these estimates.

7.5.1. Initial study design

In a typical test accuracy study, a consecutive series of patients suspected for a particular condition are subjected to the index test (the test being evaluated) and then all patients receive a reference or gold standard (the best available method to establish the presence of the target condition). While in the GRADE approach appropriate accuracy studies (see below) start as high quality evidence about diagnostic accuracy, these studies are vulnerable to limitations and often lead to low quality evidence to support guideline recommendations, mostly owing to indirectness of evidence associated with diagnostic accuracy being only a surrogate for patient outcomes.

7.5.2. Factors that determine and can decrease the quality of evidence

Table 7.2. Factors that decrease the quality of evidence for studies of diagnostic accuracy and how they differ from evidence for other interventions

Factors that determine and can decrease the quality of evidence	Explanations and how the factor may differ from the quality of evidence for other interventions
Study design	Different criteria for accuracy studies Cross-sectional or cohort studies in patients with diagnostic uncertainty and direct comparison of test results with an appropriate reference standard (best possible alternative test strategy) are considered high quality and can move to moderate, low or very low depending on other factors.
Risk of bias (limitations in study design and execution)	Different criteria for accuracy studies 6. Representativeness of the population that was intended to be sampled. 7. Independent comparison with the best alternative test strategy. 8. All enrolled patients should receive the new test and the best alternative test strategy. 9. Diagnostic uncertainty should be given. 10. Is the reference standard likely to correctly classify the target condition?
Indirectness Patient population, diagnostic test, comparison test and indirect comparisons of tests	Similar criteria The quality of evidence can be lowered if there are important differences between the populations studied and those for whom the recommendation is intended (in prior testing, the spectrum of disease or co-morbidity); if there are important differences in the tests studied and the diagnostic expertise of those applying them in the studies compared to the settings for which the recommendations are intended; or if the tests being compared are each compared to a reference (gold) standard in different studies and not directly compared in the same studies. Similar criteria Panels assessing diagnostic tests often face an absence of direct evidence about impact on patient-important outcomes. They must make deductions from diagnostic test studies about the balance

	between the presumed influences on patient-important outcomes of any differences in true and false positives and true and false negatives in relationship to test complications and costs. Therefore, accuracy studies typically provide low quality evidence for making recommendations due to indirectness of the outcomes, similar to surrogate outcomes for treatments.
Important Inconsistency in study results	Similar criteria For accuracy studies unexplained inconsistency in sensitivity, specificity or likelihood ratios (rather than relative risks or mean differences) can lower the quality of evidence.
Imprecise evidence	Similar criteria For accuracy studies wide confidence intervals for estimates of test accuracy, or true and false positive and negative rates can lower the quality of evidence.
High probability of Publication bias	Similar criteria A high risk of publication bias (e.g., evidence only from small studies supporting a new test, or asymmetry in a funnel plot) can lower the quality of evidence.
Upgrading for dose effect, large effects residual plausible bias and confounding	Similar criteria For all of these factors, methods have not been properly developed. However, determining a dose effect (e.g., increasing levels of anticoagulation measured by INR increase the likelihood for vitamin K deficiency or vitamin K antagonists). A very large likelihood of disease (not of patient-important outcomes) associated with test results may increase the quality evidence. However, there is some disagreement if and how dose effects play a role in assessing the quality of evidence in DTA studies.

7.5.2.1. Risk of bias

Several instruments for the evaluation of risk of bias in DTA studies are available. Cochrane Collaboration suggests a selection of the items from the QUADAS [Whiting 2003; PMID 14606960] and QUADAS-2 [Whiting 2011; PMID 22007046] instruments. Authors of systematic reviews and guideline panels can use the criteria from the QUADAS list (Table 7.3) to assess the risk of bias within and across studies.

Serious limitations in a body of evidence that indicate risk of bias, if found, will likely lead to downgrading the quality of evidence by one or two levels.

Table 7.3. Quality criteria of diagnostic accuracy studies derived from QUADAS (Reitsma 2009; http://srdta.cochrane.org/)	
1.	Was the spectrum of patients representative of the patients who will receive the test in practice? (representative spectrum)
2.	Is the reference standard likely to classify the target condition correctly? (acceptable reference standard)
3.	Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests? (acceptable delay between tests)
4.	Did the whole sample or a random selection of the sample, receive verification using the intended reference standard? (partial verification avoided)
5.	Did patients receive the same reference standard irrespective of the index test result? (differential verification avoided)
6.	Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)? (incorporation avoided)
7.	Were the reference standard results interpreted without knowledge of the results of the index test? (index test results blinded)
8.	Were the index test results interpreted without knowledge of the results of the reference standard? (reference standard results blinded)
9.	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? (relevant clinical information)
10.	Were uninterpretable/intermediate test results reported? (uninterpretable results reported)
11.	Were withdrawals from the study explained? (withdrawals explained)

Table 7.4. Quality criteria of diagnostic accuracy studies derived from QUADAS-2				
Domain	**Patient Selection**	**Index Test**	**Reference Standard**	**Flow and Timing**
Description	Describe methods of patient selection Describe included patients (previous testing, presentation, intended use of index test, and setting)	Describe the index test and how it was conducted and interpreted	Describe the reference standard and how it was conducted and interpreted	Describe any patients who did not receive the index tests or reference standard or who were excluded from the 2 X 2 table (refer to flow diagram) Describe the interval and any interventions between index tests and the reference standard
Signaling questions (yes, no, or unclear)	Was a consecutive or random sample of patients enrolled? Was a case–control design avoided? Did the study avoid inappropriate	Were the index test results interpreted without know- ledge of the results of the reference standard? If a threshold was used, was it pre-	Is the reference standard likely to correctly classify the target condition? Were the reference standard results interpreted without	Was there an appropriate interval between index tests and reference standard? Did all patients receive a reference

	exclusions?	specified?	knowledge of the results of the index test?	standard? Did all patients receive the same reference standard? Were all patients included in the analysis?
Risk of bias (high, low, or unclear)	Could the selection of patients have introduced bias?	Could the conduct or interpretation of the index test have introduced bias?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Could the patient flow have introduced bias?

7.5.2.2. Indirectness of the evidence

Judging indirectness of the evidence presents additional and probably greater challenges for authors of systematic reviews of diagnostic test accuracy and for guideline panels making recommendations about diagnostic tests. First, as with therapeutic interventions, indirectness must be assessed in relation to the population, setting, the intervention (the new or index test) and the comparator (another investigated test or the reference standard). For instance, a judgment of indirectness of the population can result from using a different test setting such as the patients seen in an emergency department may differ from patients seen in a general practitioner office, the patients included in the studies of interest may differ or the target condition of the population is not the same in the studies compared to the question asked.

If the clinical question is about the choice between two tests, neither of which is a reference standard, one needs to assess whether the two tests were compared directly against each other and the reference test in the same study, or in separate studies in which each test was compared separately against the reference standard. For example, a systematic review comparing the diagnostic accuracy of two tests for renal insufficiency – serum creatinine and serum cystatin C – identified a number of studies that performed serum tests for both creatinine and cystatin C and the reference standard in the same patients (Table 7.5).

Table 7.5. Diagnostic accuracy SoF table: cystatin vs. creatinine in diagnosis of renal failure

Population / Setting: Adults and children who were healthy, now suspected to have or had impaired renal function in a non-specialized clinical setting
New Test / Cut-off value: Serum or plasma Cystatin C (Cys C) / 0.82 to 1.64 mg/L [1]
Comparison Test / Cut-off value: Serum Creatinine concentration (S Creat) / 70.7 to 130.74 µmol/L [1]
Reference Test: Glomerular Filtration Rate measured by exogenous inulin, Cr-EDTA, Tc-DTPA, iohexol or I-lothalamate

Test Important Outcome	Results per 1000 patients tested (95% CI)						Number of participants (Studies)	Quality of Evidence	Comment
	Pre-test probability 10%		Pre-test probability 50%		Pre-test probability 90%				
	Cys C	S Creat	Cys C	S Creat	Cys C	S Creat			
True Positive (TP)	81 (76-85)	69 (61-76)	405 (380-425)	345 (305-380)	648 (608-680)	552 (488-608)	2007 (27)	⊕⊕OO Low [3]	Detection of TPs will likely improve mortality and slow progression to ESRD. TPs will have further testing which will increase anxiety, complications and resources use.
TP absolute difference[2]	12 more (9-15 more)		60 more (44-75 more)		96 more (72-120 more)				
False Positive (FP)	108 (81-144)	315 (286-342)	60 (45-80)	175 (160-190)	24 (18-32)	70 (64-76)	2007 (27)	⊕⊕OO Low [3]	FPs will likely have further testing which will increase anxiety, complications and resources use.
FP absolute difference[2]	207 fewer (196-217 fewer)		115 fewer (80-120 fewer)		46 fewer (44-48 fewer)				
True Negative (TN)	792 (756-819)	585 (558-612)	440 (420-455)	325 (310-340)	176 (168-182)	130 (124-136)	2007 (27)	⊕⊕OO Low [3]	TNs will likely be reassured, but will still be retested every year to detect new cases that develop.
TN absolute difference[2]	207 more (196-217 more)		115 more (110-120 more)		46 more (44-48 more)				
False Negative (FN)	19 (15-24)	31 (24-39)	95 (75-120)	155 (120-195)	152 (120-192)	248 (192-312)	2007 (27)	⊕⊕OO Low [3]	FN will likely have progression to ESRD and increased mortality due to delayed diagnosis.
FN absolute difference[2]	12 fewer (9-15 fewer)		60 fewer (45-75 fewer)		96 fewer (70-120 fewer)				

Footnotes:
**Roos et al. Diagnostic accuracy of cystatin C compared to serum creatinine for the estimation of renal dysfunction in adult and children-A meta analysis. Clinical Biochemistry 40 (2007) 383-391
(1) In these studies, cystatin C was measured using particle-enhanced immunoturbidimetry (PETIA) and particle-enhanced immunonephelometry (PENIA) and creatinine using the standard and modified Jaffe assay, and the enzymatic assay. Studies included in the meta-analysis directly compared Cys C versus S Creat.
(2) Differences calculated as an absolute difference with when cystatin C is done compared to serum creatinine
(3) Low quality evidence is due to very serious indirectness of outcomes in a wide spectrum of patients and indirect comparison of tests and serious imprecision.
(4) Low quality evidence is due to some limitation in the design and very few events noted that affected imprecision.

Unlike for management questions, **if only diagnostic accuracy information is available, the assessment of indirectness requires additional judgments about how the correct and incorrect classification of subjects as having or not having a target condition relates to patient important outcomes.** While authors of systematic reviews will frequently skip this assessment because their interest may relate only to the review of the diagnostic accuracy, guideline panels must always make this judgment – either implicitly or, better, explicitly and transparently.

7.5.2.3. Inconsistency, imprecision, publication bias and upgrading for dose effect, large estimates of accuracy and residual plausible confounding

Although these criteria are applicable to a body of evidence from studies of diagnostic test accuracy, the methods to determine whether a particular criterion is met are less well established compared with the evidence about the effects of therapeutic interventions. Further theoretical and empirical work is required to provide guidance how to assess those criteria.

7.5.3. Overall confidence in estimates of effects

Tables 7.6 and 7.7 show the assessment of the confidence in the estimates and the SoF table of all critical outcomes for the comparison of computed tomography (CT) angiography with an invasive angiography (the reference standard) in patients suspected of coronary artery disease.

Table 7.6. . Quality assessment of diagnostic accuracy studies – example: should multi-slice spiral computed tomography instead of conventional coronary angiography be used for diagnosis of coronary artery disease?

No. of studies	Design	Limitations (RoB)	Indirectness of patients, intervention and comparator	Inconsistency	Imprecision	Other considerations	Quality of evidence
True positives (Patients with coronary artery disease) and False negatives (Patients incorrectly classified as not having coronary artery disease)							
21 studies (1570 patients)	Cross sectional studies[2]	None	None[3]	Serious inconsistency[3]	None	None[4]	⊕⊕⊕◯ Moderate
True negatives (Patients without coronary artery disease) and False Positives (Patients incorrectly classified as having coronary artery disease)							
21 studies (1570 patients)	Cross sectional studies[2]	None	None[3]	Serious inconsistency[3]	None	None [4]	⊕⊕⊕◯ Moderate

[1] A full quality assessment would include a row for each of the patient-important outcomes associated with each possible test result (TP, TN, FP, FN and inconclusive results) as well as test complications and costs (see table 3). We have presented a simplified summary of the quality of evidence for the critical outcomes here.
[2] All patients were selected to undergo conventional coronary angiography and were, therefore, generally presenting with high probability of coronary artery disease (median prevalence in the included studies: 63.5%, Range 6.6% to 100%).
[3] There was statistically significant, unexplained heterogeneity of results for sensitivity (the proportion of patients with positive coronary angiography with a positive CT scan), specificity (the proportion of patients with negative coronary angiography with a negative CT scan), likelihood ratios and diagnostic odds ratios, lowering the quality of evidence for the consequences of TP, TN and FP from high to moderate and for FN test results from moderate to low.[39]
[4] The possibility of publication bias is not excluded but it was not considered sufficient to downgrade the quality of evidence.

Table 7.7. . Summary of findings of all critical outcomes for the comparison of computed tomography (CT) angiography with an invasive angiography (the reference standard) in patients suspected of coronary artery disease.

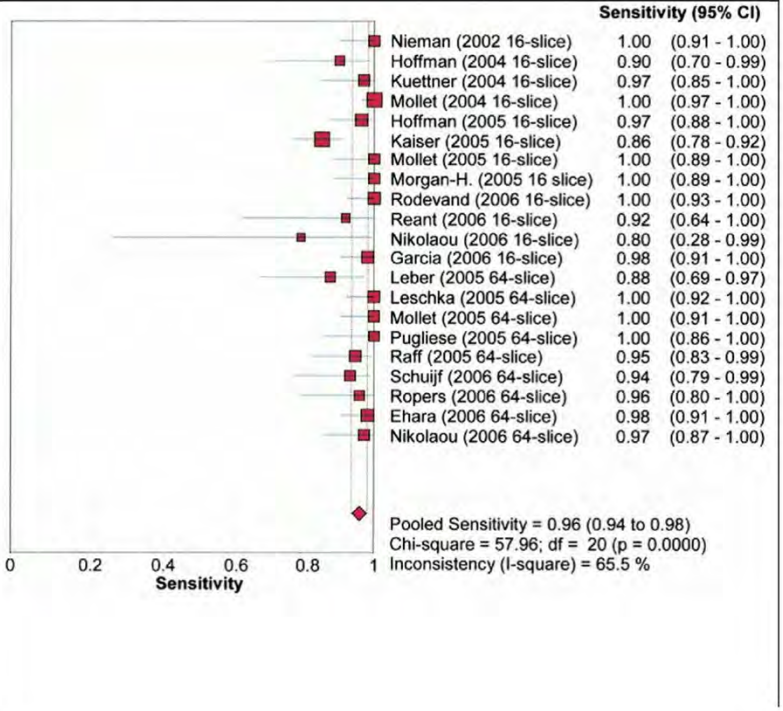
Summary of findings – example. Assumed pre-test probability (prevalence) was 20%.

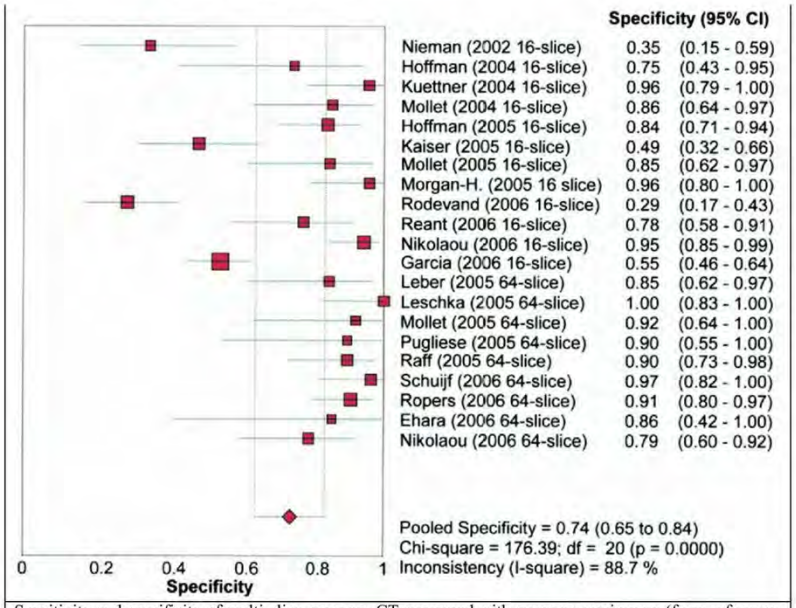
	Test findings		
Pooled sensitivity	0.96 (95% CI: 0.94 to 0.98)		
Pooled specificity	0.74 (95% CI: 0.65 to 0.84)		
	Consequences		
	Number per 1000[1]		Importance
TP[2]	192		8
TN[3]	592		8
FP[4]	208		7
FN[5]	8		9
Inconclusive results[6,7]	–		5
Cost[7]	–		5

[1] all results are given per 1000 patients tested based on the prevalence of 20% and pooled sensitivity and specificity.
[6] inconclusive results are either uninterpretable, indeterminate or intermediate test results
[2] Important because mandates drugs, angioplasty and stents, bypass surgery.
[3] Important because spares patients unnecessary interventions associated with adverse effects.
[4] Important because patients are exposed to unnecessary potential adverse effects from drugs and invasive procedures.
[5] Important because increase risk of coronary events as a result of patients not receiving efficacious treatment.
[6] Uninterpretable, indeterminate, or intermediate test results; important because generate anxiety, uncertainty as to how to proceed, further testing, and possible negative consequences of either treating or not treating.
[7] Although the results for these consequences are not reported because they are not exactly known on the basis of the available data, they are important.

The original accuracy studies were well planned and executed, the results are precise, and one does not suspect relevant publication bias. However, there are problems with inconsistency. Reviewers addressing the relative merits of CT versus invasive angiography for diagnosis of coronary disease found important heterogeneity in the results for the proportion of invasive angiography-negative patients with a positive CT test result (specificity) and in the results for the proportion of angiography-positive patients with a negative CT test result (sensitivity) that they could not explain (Figure 2). This heterogeneity was also present for other measures of diagnostic test accuracy (i.e. positive and negative likelihood ratios and diagnostic odds ratios). Unexplained heterogeneity in the results across studies reduced the quality of evidence for all outcomes.

Figure 2. Example for heterogeneity in diagnostic test results





Sensitivity and specificity of multi-slice coronary CT compared with coronary angiogram (from reference 4). This heterogeneity also existed for likelihood ratios and diagnostic odds ratios.

One of the aims of the GRADE Working Group is to reduce unnecessary confusion arising from multiple systems for grading quality of evidence and strength of recommendations. To avoid adding to this confusion by having multiple variations of the GRADE system we suggest that the criteria below should be met when saying that the GRADE approach was used. Also, while users may believe there are good reasons for modifying the GRADE system, we discourage the use of "modified" GRADE approaches that differ substantially from the approach described by the GRADE Working Group.

However, we encourage and welcome constructive criticism of the GRADE approach, suggestions for improvements, and involvement in the GRADE Working Group. As most scientific approaches to advancing healthcare, the GRADE approach will continue to evolve in response to new research and to meet the needs of authors of systematic reviews, guideline developers and other users.

Checklist: Suggested criteria for stating that the GRADE system was used

1. **Definition of quality of evidence:** The quality of evidence (confidence in the estimated effects) should be defined consistently with the definitions (for guidelines or for systematic reviews) used by the GRADE Working Group.

2. **Criteria for assessing the quality of evidence:** Explicit consideration should be given to each of the eight GRADE criteria for assessing the quality of evidence (risk of bias, directness of evidence, consistency and precision of results, risk of publication bias, magnitude of the effect, dose-response gradient, and influence of residual plausible confounding) although different terminology may be used.

3. **Quality of evidence for each outcome:** The quality of evidence (confidence in the estimated effects) should be assessed for each important outcome and expressed using four categories (e.g. *high, moderate, low, very low*) or, if justified, three categories (e.g. *high, moderate, and low* [*low* and *very low* being reduced to one category]) based on consideration of the above factors (see point 2) with suggested interpretation of each category that is consistent with the interpretation used by the GRADE Working Group.

4. **Summaries of evidence:** Evidence tables or detailed narrative summaries of evidence, transparently describing judgements about the factors in point 2 above, should be used as the basis for judgements about the quality of evidence and the strength of recommendations. Ideally, full evidence profiles suggested by the GRADE Working Group should be used and these should be based on systematic reviews. At a minimum, the evidence that was assessed and the methods that were used to identify and appraise that evidence should be clearly described. In particular, reasons for downgrading and upgrading the quality of evidence should be described transparently.

5. **Criteria for determining the strength of a recommendation:** Explicit consideration should be given to each of the four GRADE criteria for determining the strength of a recommendation (the balance of desirable and undesirable consequences, quality of evidence, values and preferences of those affected, and resource use) and a general approach should be reported (e.g. if and how costs were considered, whose values and preferences were assumed, etc.).

6. **Strength of recommendation terminology:** The strength of recommendation for or against a specific management option should be expressed using two categories (*weak* and *strong*) and the definitions/interpretation for each category should be consistent with those used by the GRADE Working Group. Different terminology to express *weak* and *strong* recommendations may be used (e.g. alternative wording for *weak* recommendations is *conditional*), although the interpretation and implications should be preserved.

7. **Reporting of judgements:** Ideally, decisions about the strength of the recommendations should be transparently reported.

8. Criteria for determining whether the GRADE approach was used

One of the aims of the GRADE Working Group is to reduce unnecessary confusion arising from multiple systems for grading quality of evidence and strength of recommendations. To avoid adding to this confusion by having multiple variations of the GRADE system we suggest that the criteria below should be met when saying that the GRADE approach was used. Also, while users may believe there are good reasons for modifying the GRADE system, we discourage the use of "modified" GRADE approaches that differ substantially from the approach described by the GRADE Working Group.
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9. Glossary of terms and concepts

This glossary is partially based on the glossary of the Cochrane Collaboration and the Users' Guides to the Medical Literature with permission.

Absolute risk reduction (ARR): Synonym of the **risk difference** (RD). The difference in the risk between two groups. For example, if one group has a 15% risk of contracting a particular disease, and the other has a 10% risk of getting the disease, the risk difference is 5 percentage points.

Baseline risk: synonym of control group risk.

Bias: A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (**selection bias**), the care that is provided, exposure to other factors apart from the intervention of interest (**performance bias**), withdrawals or exclusions of people entered into a study (**attrition bias**) or how outcomes are assessed (**detection bias**). Systematic reviews of studies may also be particularly affected by **reporting bias**, where a biased subset of all the relevant data is available.

Burden: ;Burdens are the demands that patients or caregivers (e.g. family) may dislike, such as having to take medication or the inconvenience of going to the doctor's office.

Case series: A study reporting observations on a series of individuals, usually all receiving the same intervention, with no control group.

Case report: A study reporting observations on a single individual. Also called: anecdote, case history, or case study.

Case-control study: An observational study that compares people with a specific disease or outcome of interest (cases) to people from the same population without that disease or outcome (controls), and which seeks to find associations between the outcome and prior exposure to particular risk factors. This design is particularly useful where the outcome is rare and past exposure can be reliably measured. Case-control studies are usually retrospective, but not always.

Categorical data: Data that are classified into two or more non-overlapping categories. Gender and type of drug (aspirin, paracetamol, etc.) are examples of categorical variables.

Clinical practice guideline (CPG): A systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

Cohort study: An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A **prospective** cohort study assembles participants and follows them into the future.
A **retrospective** (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present.

Comparison: intervention against which new intervention is compared, control group.

Confidence interval (CI): A measure of the uncertainty around the main finding of a statistical analysis. Estimates of unknown quantities, such as the RR comparing an experimental intervention with a control, are usually presented as a point estimate and a 95% confidence interval. This means that if someone were to keep repeating a study in other samples from the same population, 95% of the calculated confidence intervals from those studies would include the true underlying value. Conceptually easier than this definition is to think of the CI as the range in which the truth plausibly lies. Wider intervals indicate less precision; narrow intervals, greater precision. Alternatives to 95%, such as 90% and 99% confidence intervals, are sometimes used.

Confounder: A factor that is associated with both an intervention (or exposure) and the outcome of interest. For example, if people in the experimental group of a controlled trial are younger than those in the control group, it will be difficult to decide whether a lower risk of death in one group is due to the intervention or the difference in ages. Age is then said to be a confounder, or a confounding variable. Randomisation is used to minimise imbalances in confounding variables between experimental and control groups. Confounding is a major concern in non-randomised studies.

Consumer (healthcare consumer): Someone who uses, is affected by, or who is entitled to use a health related service.

Context: The conditions and circumstances that are relevant to the application of an intervention, for example the setting (in hospital, at home, in the air); the time (working day, holiday, night-time); type of practice (primary, secondary, tertiary care; private practice, insurance practice, charity); whether routine or emergency. Also called **clinical situation**.

Continuous data: Data with a potentially infinite number of possible values within a given range. Height, weight and blood pressure are examples of continuous variables.

Control: In a controlled trial a control is a participant in the arm that acts as a comparator for one or more experimental interventions. Controls may receive placebo, no treatment, standard treatment, or an active intervention, such as a standard drug. In an observational study a control is a person in the group without the disease or outcome of interest.

Control Group Risk: observed risk of the event in the control group. Synonym of baseline risk. The control group risk for an outcome is calculated by dividing the number of people with an outcome in control group by the total number of participants in the control group.

Critical appraisal: The process of assessing and interpreting evidence by systematically considering its validity, results, and relevance.

Desirable effect: A desirable effect of adherence to a recommendation can include beneficial health outcomes, less burden and savings.

Dose response gradient: The relationship between the quantity of treatment given and its effect on outcome.

Effect size (ES): A generic term for the estimate of effect of treatment for a study. Sometimes the term is used to refer to the standardized mean difference.

To facilitate understanding we suggest interpretation of the effect size offered by Cohen (Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed; 1988). According to this interpretation, an effect size or standardized mean difference of around:

- **0.2** is considered a **small** effect
- **0.5** is considered a **moderate** effect
- **0.8** or higher is considered a **large** effect.

Effectiveness: The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess effectiveness are sometimes called pragmatic or management trials.

Efficacy: The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials.

Estimate of effect: The observed relationship between an intervention and an outcome expressed as, for example, a number needed to treat, odds ratio, risk difference, risk ratio, relative risk reduction, standardised mean difference, or weighted mean difference.

External validity: The extent to which results provide a correct basis for generalisations to other circumstances. For instance, a meta-analysis of trials of elderly patients may not be generalizable to children. Also called**generalizability** or **applicability**.

Follow-up: The observation over a period of time of study/trial participants to measure outcomes under investigation.

Hazard ratio (HR): A measure of effect produced by a survival analysis and representing the increased risk with which one group is likely to experience the outcome of interest. For example, if the hazard ratio for death for a treatment is 0.5, then we can say that treated patients are likely to die at half the rate of untreated patients.

Intention to treat analysis (ITT): A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may

reflect non-adherence to the protocol. The term is often misused in trial publications when some participants were excluded.

Internal validity: The extent to which the design and conduct of a study are likely to have prevented bias. Variation in methodological quality can explain variation in the results of studies. More rigorously designed (better quality) trials are more likely to yield results that are closer to the truth.

Intervention: The process of intervening on people, groups, entities, or objects in an experimental study. In controlled trials, the word is sometimes used to describe the regimens in all comparison groups, including placebo and no-treatment arms.

Mean difference (MD): the 'difference in means' is a standard statistic that measures the absolute difference between the mean value in the two groups in a clinical trial. It estimates the amount by which the treatment changes the outcome on average. It can be used as a summary statistic in meta-analysis when outcome measurements in all trials are made on the same scale. Previously referred to as weighted mean difference (WMD).

Meta-analysis: The statistical combination of results from two or more separate studies.

Minimally important difference (MID): The smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management.

Number needed to treat (NNT): An estimate of how many people need to receive a treatment before one person would experience a beneficial outcome. For example, if you need to give a stroke prevention drug to 20 people before one stroke is prevented, then the number needed to treat to benefit for that stroke prevention drug is 20. It is estimated as the reciprocal of the risk difference.

Number needed to harm (NNH): A number needed to treat to benefit associated with a harmful effect. It is an estimate of how many people need to receive a treatment before one more person would experience a harmful outcome or one fewer person would experience a beneficial outcome.

Observational study: A study in which the investigators do not seek to intervene, and simply observe the course of events. Changes or differences in one characteristic (e.g. whether or not people received the intervention of interest) are studied in relation to changes or differences in other characteristic(s) (e.g. whether or not they died), without action by the investigator. There is a greater risk of selection bias than in experimental studies.

Odds ratio (OR): The ratio of the odds of an event in one group to the odds of an event in another group. In studies of treatment effect, the odds in the treatment group are usually divided by the odds in the control group. An odds ratio of one indicates no difference between comparison groups. For undesirable outcomes an OR that is less than one indicates that the intervention was effective in reducing the risk of that outcome. When the risk is small, the value of odds ratio is similar to risk ratio. When the events in the control group are not frequent, OR and HR can be assumed to be equal to the RR for the application of this criterion.

Optimal information size (OIS): number of patients generated by a conventional sample size calculation for a single trial.

Outcome: A component of a participant's clinical and functional status after an intervention has been applied, that is used to assess the effectiveness of an intervention.

Point estimate: The results (e.g. mean, weighted mean difference, odds ratio, risk ratio or risk difference) obtained in a sample (a study or a meta-analysis) which are used as the best estimate of what is true for the relevant population from which the sample is taken.

Population: The group of people being studied, usually by taking samples from that population. Populations may be defined by any characteristics e.g. geography, age group, certain diseases.

Precision: A measure of the likelihood of random errors in the results of a study, meta-analysis or measurement. The less random error the greater the precision. Confidence intervals around the estimate of effect from each study are one way of expressing precision, with a narrower confidence interval meaning more precision.

Quality of evidence: The extent to which one can be confident that an estimate of effect is correct.

Randomised controlled trial (RCT): An experimental study in which two or more interventions are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or interventions are assigned within individuals (for example, in different orders or to different parts of the body).

Relative risk (RR): Synonym of risk ratio. The ratio of risks in two groups. In intervention studies, it is the ratio of the risk in the intervention group to the risk in the control group. A risk ratio of one indicates no difference between comparison groups. For undesirable outcomes, a risk ratio that is less than one indicates that the intervention was effective in reducing the risk of that outcome.

Relative risk reduction (RRR): The proportional reduction in risk in one treatment group compared to another. It is one minus the risk ratio. If the risk ratio is 0.25, then the relative risk reduction is 1-0.25=0.75, or 75%.

Review Manager (RevMan): Software used for preparing and maintaining Cochrane systematic reviews. RevMan allows you to write ad manage systematic review protocols, as well as complete reviews, including text, tables, and study data. It can perform meta-analysis of the data entered, and present the results graphically.

Risk: The proportion of participants experiencing the event of interest. Thus, if out of 100 participants the event (e.g. a stroke) is observed in 32, the risk is 0.32. The control group risk is the risk amongst the control group. The risk may sometimes be referred to as the event rate.

Standardised mean difference (SMD): The difference between two estimated means divided by an estimate of the standard deviation. It is used to combine results from studies using different ways of measuring the same continuous variable, e.g. pain. By expressing the effects as a standardised value, the results can be combined since they have no units. Standardised mean differences are sometimes referred to as a d index.

Statistically significant: A result that is unlikely to have happened by chance. The usual threshold for this judgement is that the results, or more extreme results, would occur by chance with a probability of less

than 0.05 if the null hypothesis was true. Statistical tests produce a p-value used to assess this.

Strength of a recommendation: The degree of confidence that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

Surrogate outcome: Outcome measure that is not of direct practical importance but is believed to reflect an outcome that is important; for example, blood pressure is not directly important to patients but it is often used as an outcome in clinical trials because it is a risk factor for stroke and heart attacks. Surrogate outcomes are often physiological or biochemical markers that can be relatively quickly and easily measured, and that are taken as being predictive of important clinical outcomes. They are often used when observation of clinical outcomes requires long follow-up. Also called: intermediary outcomes or surrogate endpoints.

Systematic review: A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Undesirable effect: An undesirable effect of adherence to a recommendation can include harms, more burden, and costs.

10. Articles about GRADE

The following is a collection of published documents about the GRADE approach.

Introductory series published in the BMJ (2008)

1. GRADE: an emerging consensus | LINK | PDF | PubMed
2. What is "quality of evidence" and why is it important to clinicians? | LINK | PDF | PubMed
3. Going from evidence to recommendations | LINK | PDF | PubMed
4. Grading quality of evidence and strength of recommendations for diagnostic tests and strategies | LINK | PDF | PubMed
5. Incorporating considerations of resources use into grading recommendations | LINK | PDF | PubMed
6. Use of GRADE grid to reach decisions when consensus is elusive | LINK | PDF | PubMed

Series of articles with examples from the field of allergy published in Allergy (2010)

1. Overview of the GRADE approach and grading quality of evidence about interventions | LINK | PDF | PubMed
2. GRADE approach to grading quality of evidence about diagnostic tests and strategies | LINK | PDF | PubMed
3. GRADE approach to developing recommendations | LINK | PDF | PubMed

Series of detailed articles for authors of guidelines and systematic reviews published in JCE (2011-2014)

1. Introduction: GRADE evidence profiles and summary of findings tables | LINK | PDF | PubMed
2. Framing the question and deciding on important outcomes | LINK | PDF | PubMed
3. Rating the quality of evidence | LINK | PDF | PubMed
4. Rating the quality of evidence: study limitations (risk of bias) | LINK | PDF | PubMed
5. Rating the quality of evidence: publication bias | LINK | PDF | PubMed
6. Rating the quality of evidence: imprecision | LINK | PDF | PubMed
7. Rating the quality of evidence: inconsistency | LINK | PDF | PubMed
8. Rating the quality of evidence: indirectness | LINK | PDF | PubMed
9. Rating up the quality of evidence | LINK | PDF | PubMed
10. Considering resource use and rating the quality of economic evidence | LINK | PDF | PubMed
11. Making an overall rating of confidence in effect estimates for a single outcome and for all outcomes | LINK | PDF | PubMed
12. Preparing Summary of Findings tables for binary outcomes | LINK | PDF | PubMed
13. Preparing Summary of Findings tables for continuous outcomes | LINK | PDF | PubMed
14. Going from evidence to recommendations: the significance and presentation of recommendations | LINK | PDF | PubMed
15. Going from evidence to recommendations: determinants of a recommendation's direction and strength | LINK | PDF | PubMed
16.
17.
18.
19.
20.

Reproducibility of the GRADE approach (2013)
The GRADE approach is reproducible in assessing the quality of evidence of quantitative evidence syntheses | PDF | PubMed

11. Additional resources

Resources for authors of systematic reviews

The Cochrane Handbook

The Cochrane Handbook includes two principle chapters which provide information on how to create Summary of Findings tables using the information from Cochrane systematic reviews and GRADEing the evidence.

Part 2 Chapter 11: Presenting results and 'Summary of findings' tables

Part 2 Chapter 12: Interpreting results and drawing conclusions

General evidence-based medicine resources

The Cochrane Library

The Cochrane Library contains high-quality, independent evidence to inform healthcare decision-making. It includes reliable evidence from Cochrane and other systematic reviews, clinical trials, and more. Cochrane reviews bring you the combined results of the world's best medical research studies, and are recognised as the gold standard in evidence-based health care.

The Cochrane Handbook

The Cochrane Handbook for Systematic Reviews of Interventions (the Handbook) provides guidance to authors for the preparation of Cochrane Intervention reviews (including Cochrane Overviews of reviews). The Handbook is updated regularly to reflect advances in systematic review methodology and in response to feedback from users.

Users' Guides to the Medical Literature

A complete set of Users' Guides to find, evaluate and use medical literature which were originally published as a series in the Journal of the American Medical Association (JAMA).

Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice (Interactive) presents the sophisticated concepts of evidence-based medicine (EBM) in unique ways that can be used to determine diagnosis, decide optimal therapy, and predict prognosis. It also offers in-depth expansion of methodology, statistics, and cost issues that emerge in medical research.

Guideline specific resources

Improving the use of research evidence in guideline development (SERIES)

A series of 16 papers published in Health Research Policy and Systems in 2006, Volume 4, Issues 12 to 28 about guideline development. Topics are Guidelines for guidelines, Priority setting, Group composition and consultation process, Managing conflicts of interest, Group processes, Determining which outcomes are important, Deciding what evidence to include, Synthesis and presentation of evidence, Grading evidence and recommendations, Integrating values and consumer involvement, Incorporating considerations of cost-effectiveness, affordability and resource implications, Incorporating considerations of equity, Adaptation, applicability and transferability, Reporting guidelines, Disseminating and implementing guidelines, and Evaluation.

The AGREE instrument

The purpose of the Appraisal of Guidelines Research & Evaluation (AGREE) Instrument is to provide a framework for assessing the quality of clinical practice guidelines.

GRADE Working Group

The Grading of Recommendations Assessment, Development and Evaluation (short GRADE) Working Group began in the year 2000 as an informal collaboration of people with an interest in addressing the shortcomings of present grading systems in health care. Our aim is to develop a common, sensible approach to grading quality of evidence and strength of recommendation.

Guidelines Advisory Committee

The Guidelines Advisory Committee (GAC) is an independent partnership of the Ontario Medical Association and the Ontario Ministry of Health and Long Term Care (MOHLTC). The GACs mission is to promote better health for the people of Ontario by encouraging physicians and other practitioners to use evidence-based clinical practice guidelines and clinical practices based on best available evidence. We identify, evaluate, endorse and summarize guidelines for use in Ontario.

National Guideline Clearing House

The National Guideline Clearinghouse (NGC) is a comprehensive database of evidence-based clinical practice guidelines and related documents. NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

National Library of Guidelines

The National Library of Guidelines is a collection of guidelines for the NHS. It is based on the guidelines produced by NICE and other national agencies. The main focus of the Library is on guidelines produced in the UK, but where no UK guideline is available, guidelines from other countries are included in the collection.

12. The GRADE Working Group

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group began in the year 2000 as an informal collaboration of more than 60 methodologists, clinicians, systematic reviewers, and guideline developers representing various organizations with the goal to address shortcomings of present grading systems in health care. The aim was to develop a common, sensible approach to grading quality of evidence and strength of recommendations. Based on shared experience, a critical review of other systems, and working through examples and applying the system in guidelines, the Working Group has developed the GRADE approach as a common, transparent and sensible method to grading quality of evidence and strength of recommendations.

Several organizations that are now using or endorsing the GRADE approach in its original format or with minor modifications:

[INSERT LIST OF ORGANIZATIONS]

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[1]

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

USPATH
UNITED STATES PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

April 21, 2022

WPATH/USPATH Denounce Florida Department of Health for Harmful Guidelines Targeting Trans Youth

The World Professional Association for Transgender Health (WPATH) and United States Professional Association for Transgender Health (USPATH) denounce guidance from the Florida Department of Health aimed at stopping medically necessary health care for transgender youth. The Florida guidelines were issued in response to a fact sheet on gender-affirming care put forth by the U.S. Department of Health and Human Services.

“Florida’s Health Department should be looking out for the interests of trans youth instead of misrepresenting the science on how to care for them. This so-called guidance is dangerous and will contribute to putting Florida’s trans youth population, their families, and their care providers in harm’s way. It is shameful to see yet another attack from a state that is laser-focused on targeting trans and LGBQ people for political gain.”

##

Visit https://www.wpath.org/policies to view our public documents.

Visit https://www.tandfonline.com/loi/wijt20 to view the International Journal of Transgender Health with open access to our editorials.

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World Professional Association for Transgender Health (WPATH) Board of Directors and Ethics Committee Statement Opposing Legislation that Endangers Health

The members of the WPATH Ethics Committee applaud the June 15, 2020 ruling issued from the United States Supreme Court that rejects discrimination based on gender identity or sexual orientation in the workplace. The rationale for this ruling put forth by the majority articulates plainly that a person's gender identity and sexual orientation cannot be parsed from personhood.

We strongly condemn the current **United States Department of Health and Human Services (HHS)** new rule that eliminates protections from discrimination based on gender identity and sexual orientation in the healthcare setting afforded by Section 1557 of the 2010 Affordable Care Act (ACA).

Section 1557 is a civil rights provision in the ACA that prohibits discrimination by covered health programs and activities on the basis of race, color, national origin, sex, age, and disability. The current U.S. Administration's pointed attempt to narrow the definition of sex discrimination to exclude discrimination based on a person's gender identity signals that the HHS Office for Civil Rights will not enforce the ACA to protect transgender people. The elimination of protections from discrimination in healthcare for a vulnerable population is a clear violation of ethical tenets in the medical profession and civil and human rights laws. This HHS rule also eliminates from healthcare the very same civil rights protections recently affirmed by the U.S. Supreme Court in the workplace.

Like this HHS rule, efforts to deny recognition for transgender people are occurring in other countries as well. **The State Duma of Russia** is now considering three bills aimed at preventing transgender people from obtaining consistent documentation of legal gender recognition and preventing them from marrying or adopting children, as well as explicitly forbidding same sex marriage (see https://meduza.io/en/cards/russia-has-a-new-draft-law-with-major-consequences-for-transgender-people).

The Hungarian Parliament recently passed a regressive law defining gender as fixed at birth and dictated by genital structure and chromosomes, which is a belief not supported by science. The law also forbids any change of birth documentation, which denies trans people accurate identification in the healthcare setting and in society at large.

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(see https://www.nytimes.com/2020/05/28/world/europe/hungary-transgender-law.html).

In Brazil, pronouncements by President Jair Bolsonaro that invalidate transgender identity and LGBTQ rights and have encouraged parliamentary debate of the already passed Brazilian Federal Council of Medicine's Resolution (CFM-2.265/19), which supports transgender healthcare services for transgender youth ages 16-18. Reversal of this resolution would create extreme suffering for many trans youth. Brazil already has the largest annual murder toll of trans people worldwide. These legislative efforts are clear violations of human rights principles and existing laws, constitutions, and medical guidelines. Further information on global human rights conditions for LGBTQ people can be found at https://www.hrw.org/topic/lgbt-rights# and https://www.amnesty.org/en/what-we-do/discrimination/lgbt-rights/

Just as the global COVID-19 pandemic of 2020 has shown us that our health and wellbeing are intertwined locally, nationally, and globally, so too do the negative healthcare and social impacts of gender- and sexual orientation-based discrimination ultimately affect all of humanity.

The WPATH Board of Directors and the Ethics Committee firmly protests the new U.S. HHS rule which, by pointedly denying civil rights protections to LGBTQ people, openly permits hostile health care providers, institutions, and insurance companies to discriminate on the basis of sexual orientation or gender identity. We also oppose oppressive legislative efforts anywhere in the world. We urge healthcare providers, administrators, government officials, and concerned individuals everywhere to protest the measures highlighted here and *all* discrimination that promotes inequitable treatment and exacerbates health disparities wherever they exist.

Approved August 3, 2020

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Takashi Yamashita
Minister of Justice, Government of Japan
1-1-1 Kasumigaseki,Chiyoda-ku,Tokyo 100-8977,Japan

Takumi Nemoto
Minister of Health, Labour and Welfare, Government of Japan
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo, 100-8916 Japan

May 28, 2019

Your Excellencies:

The World Professional Association for Transgender Health (WPATH) is the only international, interdisciplinary professional association dedicated to the scientific study of gender dysphoria and the evidence-based best practices in transgender health. We are a non-profit association with over 2200 members in the fields of medicine, mental health, law and ethics, and scientific research. Formed in 1979 for the purpose of bringing scientists and medical providers together to exchange knowledge about the field, we are the creators of the internationally accepted Standards of Care for the Health of Transsexual, Transgender, and Gender-nonconforming People, now in its 7th edition (SOC v7), and available in a Japanese translation[1] on our website: www.wpath.org. We have also advised governments around the world with respect to transgender health and human and civil rights. Our mission is to encourage education and research to ensure that the highest possible standards of health, social services, and justice are available to transgender people around the world.

We, WPATH's leadership, write to encourage Japan to urgently amend the "Gender Identity Disorder Special Cases Act"[2] as it contains some harmful and unscientific elements, and is not in line with international consensus on protecting and promoting the health of transgender people.

In writing this letter, we use the term *transgender* as an adjective to describe all those who identify in a gender other than the one that matches the sex they were assigned at birth. The term, used in this simple way, includes persons who seek gender affirming medical services,

[1] https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_Japanese.pdf
[2] Act on Special Cases in Handling Gender Status for Persons with Gender Identity Disorder, Act No. 111 of July 16, 2003. 性同一性障害者の性別の取扱いの特例に関する法律. http://www.japaneselawtranslation.go.jp/law/detail/?id=2542&vm=04&re=02

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as well as those who do not. It includes persons who identify using labels other than transgender, and who are described by others by way of other terms (for example, by way of the term transsexual or gender-diverse). It includes persons who identify as male or female, as well as those who identify as both or neither, and who therefore find male and female gender markers inadequate in describing who they are.

As you are aware, Japan's law regulating legal recognition for transgender people requires a diagnosis of "Gender Identity Disorder" (GID) before any transgender person can apply to secure legal recognition of their appropriate gender. "GID" is defined in the law as: *A person, despite his/her biological sex being clear, who continually maintains a psychological identity with an alternative gender, who holds the intention to physically and socially conform to an alternative gender.* In addition to providing a certificate attesting to the fact that the individual has been diagnosed with GID, an applicant to the court must meet the following qualifications:

- Be 20-years-old or older;
- Be presently unmarried;
- Not presently have any underage children;
- Not have gonads or permanently lack functioning gonads; and
- Have a physical form that is "endowed with genitalia that closely resemble the physical form of an alternative gender."

All of the above provisions require revision—most urgently, WPATH encourages the government of Japan to eliminate the sterilization requirement and update the diagnosis requirement in line with APA and WHO standards. The GID Special Cases Act, while serving to acknowledge the existence of a population and allowing for their legal recognition, is a formidable barrier for transgender people in Japan. The requirement of a "GID" diagnosis is unscientific and is no longer in use in the medical or mental health care fields in either clinical or research settings. The requirement of single marital status and not having minor children amounts to discrimination; and the requirement of surgeries that sterilize amounts to coerced sterilization—a widely-recognized human rights violation, including in Japan.

As the world's peak professional organization concerned with transgender health, WPATH is aware of the importance that gender recognition can play in facilitating the health and wellbeing of transgender people. We share here the official WPATH Identity Recognition Statement.

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WPATH Identity Recognition Statement:

The World Professional Association for Transgender Health (WPATH) recognizes that, for optimal physical and mental health, persons must be able to freely express their gender identity, whether or not that identity conforms to the expectations of others. WPATH further recognizes the right of all people to identity documents consistent with their gender identity, including those documents which confer legal gender status. Such documents are essential to the ability of all people to enjoy rights and opportunities equal to those available to others; to access accommodation, education, employment, and health care; to travel; to navigate everyday transactions; and to enjoy safety. Transgender people, regardless of how they identify or appear, should enjoy the gender recognition all persons expect and deserve. Medical and other barriers to gender recognition for transgender individuals may harm physical and mental health.

WPATH opposes all medical requirements that act as barriers to those wishing to change legal sex or gender markers on documents. These include requirements for diagnosis, counseling or therapy, puberty blockers, hormones, any form of surgery (including that which involves sterilization), or any other requirements for any form of clinical treatment or letters from doctors. WPATH argues that marital and parental status should not be barriers to recognition of gender change, and opposes requirements for persons to undergo periods living in their affirmed gender, or for enforced waiting or 'cooling off' periods after applying for a change in documents. Further, court and judicial hearings can produce psychological, as well as financial and logistical barriers to legal gender change, and may also violate personal privacy rights or needs.

WPATH advocates that appropriate gender recognition should be available to transgender youth, including those who are under the age of majority, as well as to individuals who are incarcerated or institutionalized. WPATH recognizes that there is a spectrum of gender identities, and that choices of identity limited to Male or Female may be inadequate to reflect all gender identities. An option of X, NB (non-binary), or Other (as examples) should be available for individuals who so choose. WPATH urges governments to eliminate barriers to gender recognition, and to institute transparent, affordable and otherwise accessible administrative procedures affirming self-determination, when

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gender markers on identity documents are considered necessary. These procedures should be based in law and protect privacy.

We are aware that in January 2019, the Supreme Court of Japan issued its judgment in the case of Takakito Usui, a 43-year-old transgender man who had brought a case to the court challenging the GID Special Cases Act on the grounds that the requirement of surgery violated Japan's constitution. While the court upheld the GID Special Cases act as constitutional at this time, the justices also stated that, "It cannot be denied that [this law] impinges on freedom from invasion of bodily [integrity]."

Two of the justices in a concurring opinion wrote of the urgency of Usui's case, and the need to reform Japan's law: "The suffering that [transgender people] face in terms of gender is also of concern to society that is supposed to embrace diversity in gender identity." They concluded that for transgender people, being "able to receive rulings of changes in recognition of gender status…is an important, perhaps even urgent, legal benefit."[3]

WPATH recognizes that, for optimal physical and mental health, persons must be able to freely express their gender identity, whether or not that identity conforms to the expectations of others.

WPATH further recognizes the right of all people to identity documents consistent with their gender identity, including those documents which confer legal gender status. Such documents are essential to the ability of all people to enjoy rights and opportunities equal to those available to others; to access accommodation, education, employment, and health care; to travel; to navigate everyday transactions; and to enjoy safety. Transgender people, regardless of how they identify or appear, should enjoy the gender recognition all persons expect and deserve.

Some transgender people want to undergo hormonal treatment, surgical procedures, or other medical interventions as part of their transition. Others do not. Access to gender-affirming healthcare is important;

[3] Heisei 30 nen (2018)(ku) No. 269 Tokubetsu-koukoku Appeal Case Against the Koukoku Dismissal Decision Against the Decision to Dismiss the Application to Change the Treatment of Sex, Heisei 31 nen (2019) Decision by the Second Petty Bench of the Supreme Court, http://www.courts.go.jp/app/files/hanrei_jp/274/088274_hanrei.pdf; See Appendix 4

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however mandatory use of medical services as part of the legal recognition process is not recommended on the basis of science or human rights. The decision to undergo invasive medical or surgical procedures of any kind should remain with the individual in consultation with their physician(s).

Medical and other barriers to gender recognition for transgender individuals may harm physical and mental health. WPATH opposes all medical requirements that act as barriers to those wishing to change legal sex or gender markers on documents. These include requirements for diagnosis, counseling or therapy, puberty blockers, hormones, any form of surgery (including that which involves sterilization), or any other requirements for any form of clinical treatment or letters from doctors. People experience their lives under many different circumstances and may lack the means or the opportunity to overcome these barriers, yet their gender identity is an innate characteristic that they deserve to have recognized.

Although WPATH acknowledges that age restrictions are subject to local jurisdiction, we wish to point out that many countries do allow individuals younger than age 20 to transition and to receive identity documents that support their gender identity. Also, most countries that do acknowledge transgender individuals also do not restrict marriage or enforce divorce, nor do they demand that any children of a transgender person must reach the age of majority before a transgender parent may be legally recognized. Clinical and practical experience has shown that requirements such as these imposed by Japan's current law do not serve to protect parties who may be in relationship with a transgender person, but instead interfere with the rights of all parties to enjoy the support of their family members. Further, the physical form of an individual's genitalia in no way describes or defines the individual's gender. Variation in human bodies, whether congenital, accidental, or deliberately achieved should not limit any individual's integrity with respect to their gender identity or their humanity.

Japan has taken some important steps in recent years to respect the rights and protect the health of sexual and gender minorities, including by the Tokyo Metropolitan Government passing a non-discrimination law

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with protections for gender identity.[4] The 2020 Olympic Games in Tokyo will be an important moment for the government of Japan to demonstrate to the world that it respects the rights of all people, and WPATH encourages urgent reform of the GID Special Cases act in order to do so. These are complex components of human experience, and we urge Your Excellencies to consider them with due diligence.
Please contact us if we may be of assistance in the process of reforming this law.

Sincerely and respectfully,

Vin Tangpricha, MD
President
on behalf of the WPATH Board of Directors

[4] Human Rights Watch, "Tokyo: New Law Bars LGBT Discrimination," October 5, 2018, https://www.hrw.org/news/2018/10/05/tokyo-new-law-bars-lgbt-discrimination.

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

USPATH
UNITED STATES PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

November 22, 2022

USPATH and WPATH Respond to NY Times Article "They Paused Puberty, But Is There a Cost?" published on November 14, 2022

The recent *New York Times* article, "They Paused Puberty, But Is There a Cost?", furthers the atmosphere of misinformation and subjectivity that has grown to surround the area of gender affirming medical interventions for transgender youth. The methods of the authors of this piece come up short in their interpretation and application of available data; the article supports inaccurate narratives that puberty blocking medicines are conclusively harmful to long-term bone density or other health outcomes, and that transition reversal/regret is a common outcome for these treatments. Additionally lacking in the article is an explicit statement that any harms which may exist are outweighed by the substantial benefits these treatments confer to transgender youth, and we wish to respond below to certain specific statements and references made in this article.

The cited bone expert from Mayo Clinic, Dr. Sundeep Khosla, MD, is an adult endocrinologist who does not work clinically with transgender youth and has only a single publication on transgender health. This publication is not a research study, but a brief review commentary on the issue of bone density in adult transgender people. Transgender youth are not addressed in the commentary. In this paper, data are reviewed and discussed, and it is concluded that in the context of hormone therapy, "bone mineral density is generally preserved in both trans women and trans men".

The anecdote provided of an adolescent who began, and then stopped pubertal suppression due to bone density loss lacks important details, including age and pubertal stage at initiation of puberty blockers, length of time on blockers, baseline bone density ("Z-score"), and whether the bone density comparison was made to identified gender or birth-assigned sex. Additional important information not provided includes calcium intake, and vitamin D intake and level, as well as level of physical activity, all of which play a substantial role in maintenance of bone mineral density.

The single expert who performed the literature review, Dr. Farid Foroutan, PhD, is an epidemiologist with no experience in clinical medicine, child and identity development, bone density, or any aspect of the field of transgender health. Nearly the entirety of his professional experience lies in population health studies of heart disease. The interpretation of clinical studies, especially those with findings that are nuanced, inconclusive, or have a small effect size, require interpretation through a clinical lens, with clinician-scientists experienced in the

translation of research data into clinical practice. In fact, Dr. Foroutan recently co-authored a paper which highlighted this very concern, so it is unclear why he did not advocate for a more nuanced and clinically grounded analysis, and an expanded roster of expertise on the review team.

We were surprised to see reference to a subjective statement from Dr. Catherine Gordon, MD regarding "getting behind" on bone density, and we question whether this comment was taken out of context. Dr. Gordon is a long-standing advocate for trans youth care, and in her June 2022 single-author commentary published in *Pediatrics*, she stated that, "The duration of pubertal suppression with gonadotropin hormone releasing hormone agonists varies, but can extend up to 4 years for younger patients who are not able to provide consent until age 16 for receipt of gender-affirming therapy. Puberty blockers represent an invaluable intervention for these children and adolescents, to reduce anxiety and 'buy time' until final decisions can be made about gender assignment." A subsequent commentary co-authored by Dr. Gordon and published in November 2022 in JAMA Open Access stated, "Concerns about skeletal losses become less significant in an adolescent with active suicidal ideations. Although the significance of the risks may be unclear, there is strong evidence regarding the benefits of GnRHa in transgender youth: it can be a life-changing and lifesaving treatment for a vulnerable population who is at high risk for anxiety, depression, and suicide."

Anecdotes are provided about two teens who were found to have severe osteoporosis after 1 and 3 years of blocker treatment. In both cases, a baseline bone density test was not done. It is unlikely that such a degree of severe osteoporosis would develop after these short courses of treatment, and there were likely other pre-existing factors at play. The 2017 Endocrine Society Guidelines, co-sponsored by WPATH, as well as the SOC8 recommend baseline bone density assessment prior to initiating blocker therapy, as well as ongoing reassessments, and optimization of calcium and vitamin D.

The blockers themselves do not impact bone density. Bone density is impacted by the fact that sex steroid production is temporarily halted when puberty blockers are initiated. The adolescent in this anecdote was already using estrogen, which promotes bone health. Therefore, the point about stopping blockers due to bone density loss is moot. Many types of blockers are routinely used in combination with estrogen well through adulthood without deleterious effects on bone density. This has been the common practice for treatment of adult transgender individuals for decades. Bone density loss is generally not a concern once hormone therapy has begun. In fact, Dr. Khosla's paper states that, "the skeleton should be relatively well protected, assuming adequate compliance with hormone therapy".

Experts in the field are indeed concerned regarding bone density among youth using puberty blockers. The WPATH SOC8 cautions that, "for adolescents older than 14 years, there are currently no data to inform HCPs whether GnRHas (puberty blocking medication) can be administered as monotherapy (and for what duration) without posing a significant risk to skeletal health." The SOC8 also states that, "When deciding on the duration of GnRHa monotherapy, all contributing factors should be considered, including factors such as pretreatment bone mass..." and, "The clinical course of the treatment, e.g., the development of bone mass during GnRHa treatment and the adolescent's response to treatment, can help to determine the length of GnRHa monotherapy."

The spotlighting of three youth, one of whom continues on treatment, one of whom stopped due to bone density loss under unclear circumstances, and one of whom reversed their transition, is

not a proportionate representation of the actual population. Transition reversal, especially when unrelated to external factors such as discrimination or rejection by family, is rare. In fact, more study is needed on the reasons youth are kept on blockers for extended reasons; what percentage of cases are due to the youth continuing to explore goals, and what percentage involves parental hesitance to support moving forward with hormone therapy?

The findings of the seven citations provided at the end of the paper require a nuanced interpretation by clinician-scientists familiar with this population and subject matter. Many of the studies used sex assigned at birth, rather than identified gender, as the comparitor. Many of the differences found failed to reach statistical significance, and of those that did, many are of questionable clinical significance. Any such risk must also be taken into context with the substantial benefits of treatment, and harms of not accessing such treatment, including high rates of mental health disorders and suicidality.

Finally, the authors of this article suggest that “England’s National Health Service last month proposed restricting use of the drugs for trans youths to research settings.” In fact, the pivot that the National Health Service took was to enroll ALL youth initiating puberty blockers for treatment of gender dysphoria into a prospective research protocol so that more comprehensive data might be collected.

We agree that “less vitriol, more science”, as stated in conclusion by the authors, is needed in this area. This includes responsible reporting that takes into consideration realistic estimates of the prevalence of transition reversal, a nuanced and transparent discussion of all bone health factors, and an overall risk-benefit analysis that includes the substantial risks of delayed or denied treatment. Misinformation about the science behind the care of trans youth, such as presented in this article, can be and has been used to justify political actions or even violence against the trans and gender diverse community. With growing efforts to ban medically necessary gender affirming care for trans youth, and attacks rise such as was recently seen in the mass murder at Club Q in Colorado Springs, CO, measured and responsible journalism is ever the more essential. With the recent release of the WPATH SOC8, USPATH is working to explore quality assurance and fidelity in the provision of this life-saving care in the US, and will report the findings and recommendations of our group once the process is completed.

Signed:

USPATH Board
WPATH Executive Committee

25 November 2022

WPATH, ASIAPATH, EPATH, PATHA, and USPATH Response to NHS England in the United Kingdom (UK)

Statement regarding the Interim Service Specification for the Specialist Service for Children and Young People with Gender Dysphoria (Phase 1 Providers) by NHS England*

Following the publication of the interim report of the Cass Review of gender identity services for children and young people in England in March 2022 NHS England has now issued an interim service specification for "Phase 1" services pending establishment of new regional services in England.
See https://www.engage.england.nhs.uk/specialised-commissioning/gender-dysphoria-services/

WPATH, ASIAPATH, EPATH, PATHA, and USPATH have major reservations about this interim service specification.

1. The document fails to state that gender diversity is a normal and healthy aspect of human diversity (Coleman et al., 2022), and that many transgender people experience gender incongruence from childhood or adolescence (James et al., 2016). Transgender and gender diverse (TGD) people have a human right to access the highest achievable standard of health care, including gender-affirming care (World Health Organization, (2017; Yogyakarta Principles.org., 2007). WPATH, ASIAPATH, EPATH, PATHA, and USPATH are concerned that rather than emphasising the importance of equitable access to medically necessary support and treatment for children, adolescents and young adults experiencing

gender incongruence, the service specification appears designed to place unnecessary barriers in their way. Additionally, we state that when gender affirming medical treatment is provided with a standardised multidisciplinary assessment and treatment process, thorough informed consent, and ongoing monitoring and psychosocial support, the rate of regret of gender-affirming medical treatment commenced in adolescence has been observed to be very low and the benefits of treatment in adolescence are potentially greater than the benefits of gender-affirming treatment commenced in adulthood (Coleman et al., 2022). Hence, the harms associated with obstructing or delaying access to wished-for and indicated treatment for the majority, appear greater than the risks of regret for the few (Coleman et al., 2022), when transgender and cisgender people are correctly regarded as equal.

2. The document makes assumptions about transgender children and adolescents which are outdated and untrue, which then form the basis of harmful interventions. Amongst these is the supposition that gender incongruence is transient in pre-pubertal children. This document quotes selectively and ignores newer evidence about the persistence of gender incongruence in children (Olson et al., 2022). Many older studies regarding the stability of gender identity enlisted children who did not have gender incongruence or gender dysphoria, but rather, had culturally non-conforming gender expression. The findings of these older studies should only carefully be applied to children and young people who are presenting to gender identity clinics seeking gender-affirming treatment: it may be a different population (Temple Newhook et al., 2018). The document also makes unsupported statements about the influence of family, social, and mental health factors on the formation of gender identity. WPATH, ASIAPATH, EPATH, PATHA, and USPATH believe that children and young people can have agency and can express their gender identity, and that the best course of action is to work collaboratively with the child or young person and family to support the TGD person (Coleman et al., 2022).
3. The document highlights that there have been approximately 5000 referrals to the NHS GIDS in 2021/2022, an increase from previous years. It states that referrals are currently 8.7 young people per 100,000 population. These figures are not put in context. The referrals to GIDS range between age 3 and 17. There are 10,752,647 young people aged between 3 and 17 in England and Wales, making up 18% of the total population (Office of National Statistics, 2021). Hence, referrals to GIDS are 8.7 young people per 18,000 same age population. This is a rate of 0.048% of this population, or fewer than 5 in 10,000 young people. Population estimates of the proportion of people who are transgender range from 0.3% to 0.5% in adults, and 1.2% to 2.7% in adolescents (Coleman et al., 2022). Hence, referrals to GIDS represent a very tiny fraction of the total population of

young people, and only a small proportion of those who self-identify as transgender. These referrals are likely to be made up of those young people who have the most severe gender incongruence. WPATH, ASIAPATH, EPATH, PATHA, and USPATH strongly recommend that services should be designed that welcome these appropriate referrals, providing expedited access to expert assessment, and treatment where appropriate (Coleman et al., 2022).

4. The document underscores the expectations of the family and parent/carer around the child/young person's gender incongruence. WPATH, ASIAPATH, EPATH, PATHA, and USPATH's position is that while it is important for health professionals to work inclusively with the family and parent/carer to assist children and young people on their gender journey, the needs of the child/young person must be paramount (Coleman et al., 2022). Family acceptance and support is essential for wellbeing (Pariseau et al., 2019; Russell et al., 2018; Simons et al., 2013).
5. This document seems to triage treatment based on an ability of the child or young person to prove the severity of their gender dysphoria. There is a reference to "the clarity, persistence and consistency of gender incongruence…". WPATH, ASIAPATH, EPATH, PATHA, and USPATH believe that each person has a unique gender journey. There can be many reasons why children and young people may have trouble expressing or understanding their own gender incongruence. WPATH, ASIAPATH, EPATH, PATHA, and USPATH believe that all healthcare should be patient-centered and individually tailored (Coleman et al., 2022).
6. This document discourages social transition in pre-pubertal children. This is despite recent evidence pointing to positive mental health and social well-being outcomes in children who are allowed to socially transition in supportive environments before puberty (Durwood et al., 2017; Gibson et al., 2021). The document refers to the so-called "risks of an inappropriate gender transition" but does not name these risks or provide a reference for this statement. There is a section with criteria to support social transition in adolescents; this seems to suggest that adolescents will only be supported to socially transition if they meet the criteria set by the service. This represents an unconscionable degree of medical and State intrusion into personal and family decision-making about simple everyday matters such as clothing, name, pronouns, and school arrangements. Ultimately, social transition in practice is a personal and family decision, led by the young person, and should not require medical permission. WPATH, ASIAPATH, EPATH, PATHA, and USPATH do not support a gatekeeping approach to social transition (Coleman et al., 2022).
7. This document severely limits access to puberty suppression by only allowing treatment in the context of a formal research protocol. The eligibility criteria for

enrolment in this formal research protocol are not specified, but the concern is that they will be restrictive. WPATH, ASIAPATH, EPATH, PATHA, and USPATH disagree with this approach, and emphasise the increasing evidence that access to reversible puberty blockers, and later gender-affirming hormone treatment if wished, is associated with positive mental health and social well-being in adolescents with gender incongruence, and that adolescents are satisfied with these treatments and perceive them as essential and lifesaving (Coleman et al., 2022). We are deeply concerned that the NHS is taking inappropriate approaches to evaluating the established body of evidence and is therefore drawing erroneous conclusions underestimating the effectiveness of puberty suppression. It is ethically problematic to compel adolescents to participate in a research study to access medically necessary treatment; research participation should be voluntary and should not occur under coercive conditions and in clinical research "the safety and wellbeing of the individual prevail over the interests of science and society" (National Health Service Health Research Authority, 2022). It is also deeply concerning that the document does not describe any process for provision of estrogen or testosterone therapies for older adolescents.

8. At several points in the document, there is an emphasis on "careful exploration" of a child or young person's co-existing mental health, neuro-developmental and/or family or social complexities. There is also a suggestion that a "care plan should be tailored to the specific needs of the individual following careful therapeutic exploration…" WPATH, ASIAPATH, EPATH, PATHA, and USPATH are concerned that this appears to imply that young people who have coexisting autism, other developmental differences, or mental health problems may be disqualified, or have unnecessary delay, in their access to gender-affirming treatment. This would be inequitable, discriminatory, and misguided (Coleman et al., 2022). WPATH, ASIAPATH, EPATH, PATHA, and USPATH recommend that puberty suppression, where urgently indicated, can be commenced promptly, and proceed alongside and at the same time as any necessary diagnostic clarification of other conditions, or treatment of other conditions. Whilst careful assessment is imperative, undue delay inherent within a model of care is not a neutral option and may cause significant harm to those accessing services (Coleman et al., 2022).
9. There is an alarming statement in the summary that "the primary intervention for children and young people… is psychosocial (including psychoeducation) and psychological support and intervention." In another section, the document goes on to state that one outcome from the screening process would be "discharge with psychoeducation…" Disturbingly, this decision might be made without speaking directly with the young person or family. Taking No 8 and 9 together, this

document seems to view gender incongruence largely as a mental health disorder or a state of confusion and withholds gender-affirming treatments on this basis. WPATH, ASIAPATH, EPATH, PATHA, and USPATH call attention to the fact that this "psychotherapeutic" approach, which was used for decades before being superseded by evidence-based gender-affirming care, has not been shown to be effective (AUSPATH, 2021; Coleman et al., 2022). Indeed, the denial of gender-affirming treatment under the guise of "exploratory therapy" has caused enormous harm to the transgender and gender diverse community and is tantamount to "conversion" or "reparative" therapy under another name.

10. This document reasserts the outdated "gatekeeping model" of access to gender affirming care. There are many references within the document to patients only being able to access care and be referred to the next intervention down the line if they can meet criteria set by the service. There are clear statements that if adolescents are taking puberty suppression or gender-affirming hormones obtained elsewhere, the service will not provide any care. The purpose of this section seems to be about empowering the service to withhold treatment and health monitoring from children or young people who have obtained medication without the permission of the service. WPATH, ASIAPATH, EPATH, PATHA, and USPATH affirm the human right of self-determination in health care (World Health Organization, 2017). Moreover, such action contravenes the core aspects of the NHS Constitution (Department of Health and Social Care, 2021). Children and adolescents can contribute substantially to their health care decision making, with age-appropriate capacity to weigh the risks and benefits according to their own judgement (Amnesty International, 2020; Steinberg, 2013; Vrouenraets et al., 2021; Weithorn & Campbell, 1982). Furthermore, WPATH, ASIAPATH, EPATH, PATHA, and USPATH recommend a harm-minimisation approach, and encourages doctors to work with people who access treatment from other sources in a non-judgmental manner to help them to maximise their health status (Coleman et al., 2022).
11. The document states that general practitioners would be advised to "initiate local safeguarding protocols" if a child or young person obtains puberty blockers or hormones from another source. This recommendation, which would see families reported to child protection services, is gravely concerning. The draft service specification makes it clear that it will be difficult to obtain prompt access to puberty suppression. Families who are in the position of seeing their young adolescent descend into suicidal distress as they continue to experience incongruent pubertal changes, whilst being unable to access appropriate care from the NHS service, may make the difficult decision to obtain puberty suppression through non-NHS sources, as caring parents affirming their child's identity and supporting health care according to international treatment standards. These

> parents would then be at risk of being reported to child protection services, a ludicrous and dangerous situation; or a general practitioner with a better understanding of gender incongruence might be put at risk of censure for refusing to make such an inappropriate child protection referral, against the recommendations of the specialist service. WPATH, ASIAPATH, EPATH, PATHA, and USPATH believe that the appropriate interim service specification should instead be supporting GPs and families to provide the best evidence-based and compassionate care for children and young people with gender incongruence, including access to puberty suppression and gender-affirming hormones where indicated (Coleman et al., 2022; de Vries et al., 2021).

Overall, WPATH, ASIAPATH, EPATH, PATHA, and USPATH find serious flaws in this document, which sets out a plan for a service for gender diverse children and young people in England that is likely to cause enormous harm and exacerbate the higher rates of suicidality experienced by these young people in the context of ongoing pathologisation and discrimination. WPATH, ASIAPATH, EPATH, PATHA, and USPATH urge NHS England and Wales to reconsider its approach, which is now contrary to the progress being made in many countries around the world and incongruent with statements from the World Health Organization (2017) and the Yogyakarta Principles (2007) relating to the right to the highest attainable standard of health.

WPATH thanks AUSPATH for allowing the use of the content of their Statement issued on 16 November 2022 about the Interim Service Specification for the Specialist Service for Children and Young People with Gender Dysphoria (Phase 1 Providers) by NHS England.

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August Dekker

vs.

Jason Weida

CONFIDENTIAL - ATTORNEY'S EYES ONLY

Deposition of:

E. Kale Edmiston, Ph.D

March 23, 2023

Vol 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION
CASE NO. 4:22-CV-00325-RH-MAF

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.
_____/

VIDEO-RECORDED DEPOSITION OF E. KALE EDMISTON, Ph.D.

Thursday, March 23, 2023
10:07 a.m. - 11:43 a.m.

VIA ZOOM

Stenographically Reported By:
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ALSO PRESENT:
Zack Bennington, paralegal
Randy Wright, videographer

INDEX OF PROCEEDINGS

Thereupon,
the following proceedings began at 10:07 a.m.:

* * *

THE VIDEOGRAPHER: We are now on the record. The time is 10:07 a.m. This is the video-recorded deposition of Dr. Kale Edmiston in the matter of August Dekker et al. versus Jason Weida, et al.

This deposition is being held remotely via Zoom meetings on March 23rd, 2023. The videographer is Randy Wright, and the stenographer is Barbie Gallo, both in association with Lexitas.

Will counsel please announce their appearance for the record.

MR. BEATO: Good morning. This is Michael Beato on behalf of the defense.

MS. RIVAUX: Good morning. This is Shani Rivaux with Pillsbury, Winthrop, Shaw, Pittman on behalf of the plaintiffs, and with me is Gary Shaw.

MR. GONZALEZ: This is Omar Gonzalez on behalf of the plaintiffs. I'm with Lamda Legal.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

THE STENOGRAPHER: Do we need an appearance from Mr. Bennington?

If you would, Doctor --

MR. BENNINGTON: I'm --

THE STENOGRAPHER: I'm sorry.

MR. BENNINGTON: That's okay.

Good morning. I'm a paralegal appearing here from Holtzman Vogel.

THE STENOGRAPHER: Dr. Edmiston, do you consent to my administering the oath to you remotely this morning since we are not all in person?

THE WITNESS: Yes.

THE STENOGRAPHER: If you would raise your right hand, I'll swear you in. Do you swear the testimony you're about to give in this matter will be the truth, the whole truth and nothing but the truth so help you God.

THE WITNESS: Yes.

THE STENOGRAPHER: Thank you.

THEREUPON,
E. KALE EDMISTON, Ph.D.,
Being by me first duly sworn to tell the whole truth, as hereinafter certified, testified as follows:

DIRECT EXAMINATION

BY MR. BEATO:

Q. All right. Perfect.

Good morning, Doctor. Again, my name is Michael Beato, and I represent the defendants in this case. Before we begin, let me ask you, have you ever been deposed before?

A. No.

Q. Okay. So let me go over some ground rules. So, number one, for the benefit of the court reporter when answering a question, please verbally state "yes" or "no" if the question so desires instead of nodding "yes" or "no."

A. (Nodding head).

Q. Also, a deposition is not an endurance contest. If you need a break at any time, please let me know, and I think we can accommodate that.

Moreover, for the benefit of the court reporter, we can endeavor to limit crosstalk, so I will not speak when you're speaking and vice versa. And if you don't understand any of my questions, please let me know. I'm more than happy to clarify or restate the question.

With that said, let me ask you some preliminary questions. Are there any notes or

documents in front of you right now?

A. I have my -- my report in front of me right now.

Q. Perfect. Any other documents?

A. I have a tablet, but I can put it away.

Q. I'm just curious.

Have you talked to anyone about this deposition?

MS. RIVAUX: I'm going to object to form.

Go ahead, you can answer.

A. I -- my -- my partner is aware that I'm doing it.

BY MR. BEATO:

Q. Okay. What is your current occupation?

A. I am an associate professor.

Q. At what university?

A. UMass Chan School of Medicine.

Q. When did you start this job?

A. September.

Q. And you are a professor of what area?

A. Psychiatry.

Q. What does your job entail?

A. My job entails conducting research and mentoring students.

Q. What specific research?

A. I conduct research in anxiety and depression.

Q. Where do you currently live?

A. I live in Worcester, Massachusetts.

Q. And could you describe to me your educational background.

A. Yeah, I completed a bachelor's degree at Hampshire College, and from there I worked at a neuroscience or psychiatry lab at the Yale School of Medicine.

Then I went on to earn a Ph.D. in neuroscience from Vanderbilt University. And then after that, I did two post docs, one at China Medical University and the other at university of Pittsburgh.

Q. Thank you, Doctor.

And this is a standard deposition question. Are you taking any medications that would affect your memory today?

A. No.

Q. Perfect. So for the purposes of this deposition I'm going to define the firm "gender-affirming care" as puberty blockers, cross-sex hormones, surgeries and treatments to alter primary or secondary sex characteristics for gender dysphoria. Does that work for you, Doctor?

A. I think those are all very different things, so I would actually appreciate specificity.

Q. Okay. Fair enough. But in terms of the blanket term, it's our understanding that it would incorporate those four different treatments. When greater specificity is warranted, I can clarify.

A. Okay.

Q. Are you a psychiatrist?

A. No.

Q. Are you a neurologist?

A. No.

Q. Are you an endocrinologist?

A. No.

Q. Are you a surgeon?

A. No.

Q. In your medical opinion, what is your definition of gender dysphoria?

A. Well, I don't have a medical opinion because I'm trained as a scientist, not a medical provider.

Q. All right. So what is your going definition of gender dysphoria?

A. I would probably -- probably lean on the language that's used in the DSM-5.

Q. And what is your definition of gender identity?

A. A sense of one's self as being a particular gender.

Q. Can one change one's gender identity throughout one's life?

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. You can answer.

A. I don't really feel that it's my place to determine that for another person.

Q. Fair enough.

So based on your previous answers you haven't diagnosed anyone with gender dysphoria?

A. No.

Q. Never prescribed puberty blockers for an individual with gender dysphoria?

A. No. I have a Ph.D., not an M.D.

Q. So cross-sex hormone surgeries, haven't prescribed or performed that for an individual with gender dysphoria?

A. No.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So now I'm going to pull up a document. Hopefully this works. I am not good with technology, so please bear with me, Doctor.

Tell me if you see this document.

A. Yes.

Q. Okay. Perfect. What is this document?

A. That is my rebuttal report.

MR. BEATO: So, court reporter, I'm going to mark this as Exhibit 1.

(Defendants' Exhibit Number 1 for i.d.)

BY MR. BEATO:

Q. So, Doctor, does this document fairly and accurately state your expert opinions in this case?

A. Yes.

Q. Are all of the studies and evidence you relied on contained in the bibliography in this report?

A. Yes.

Q. So I'm scrolling down on page 1. The title says "corrected." Why is this a corrected copy?

MS. RIVAUX: Objection. You can answer.

A. Can you sort of -- can you restate that?

BY MR. BEATO:

Q. Oh, sure. What does the title of this document say?

A. Corrected Expert Rebuttal Report of E. Kale Edmiston, Ph.D.

Q. Thank you, Doctor. And why does it say "corrected"?

A. Because it was corrected.

Q. Did you submit an earlier version of an expert rebuttal report in this case?

A. Yes.

Q. What is the difference between Exhibit 1, the corrected one, and the previous one?

A. The previous one cited a Soleman 2013 study where I should have cited a Soleman 2016 study, and there are two instances where that's the case.

Q. Thank you, Doctor.

Could you just quickly specify, do you recall which paragraphs?

A. Paragraphs 26 and 29.

Q. Okay. Excellent memory, by the way. It's impressive.

So here's another question. Have you conducted any empirical research on gender dysphoria?

A. Can you define what you mean by "empirical"?

Q. What does empirical research mean to you?

A. All -- if you mean by empirical, original research with data than I've collected, I have. But I have not -- my publications have been reviews of the extant literature.

Q. So to clarify, you have original research with data; is that correct?

A. I'm sorry?

Q. I apologize, Doctor. So am I correct so for empirical research on gender dysphoria you have original research with data?

MS. RIVAUX: Objection. Form.

You can answer.

A. I have done studies related to gender dysphoria, but those studies haven't been published to date.

BY MR. BEATO:

Q. So could you -- oh, I apologize, Doctor.

A. I've also -- but I have published studies that have reviewed the literature on specific topics related to gender dysphoria.

Q. Thank you for the clarification. Could you describe those for us?

MS. RIVAUX: Objection. Form.

You can answer.

A. Yeah. What do you mean by "describe"?

BY MR. BEATO:

Q. Can you explain what you are studying in those studies you referenced?

A. So there is review study that I published some years ago that reviews the primary care literature among transgender people. There is a review paper that

is currently in press that reviews the neuro -- the sort of biological basis for a trans identity. And then I have another paper that has been submitted related to adolescent decision making and brain development as it pertains to gender dysphoria.

Q. Thank you. Are those documents mentioned in your bibliography?

A. They are. There's also another paper that I'm revising that's in the bibliography as well that is about development and mental health in trans adolescents.

Q. In your opinion, what makes a treatment experimental?

MS. RIVAUX: Objection. Form.

A. I would say that that designation is outside of -- that's not my responsibility to determine, but I would say that -- I'll leave it at that.

BY MR. BEATO:

Q. Okay. And you collect research, Professor?

A. Yes.

Q. And you deal with -- do you deal with studies that are high quality and low quality?

A. Yes.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So what is -- so what makes evidence low quality?

A. There are a lot of different reasons why a study might be low quality. However, all studies have limitations, and so as a scientist my job is to review all of the literature and look at it as a whole because any one study will necessarily have limitations, so you can't look at any one study to sort of draw a definitive conclusion.

Q. So in your answer, Doctor, you mentioned limitations. What are the limitations that you're thinking of?

A. I mean, I think any study can have limitations, and there are so many different sorts of limitations. It can be related to study design or available data. No one study can do everything, so, you know, resources are always finite.

Q. Understood. Could you think of any other limitations besides those two?

A. It -- there are -- I mean, there are numerous possible limitations. That's sort of the nature of science, so I couldn't possibly begin to list every limitation or every possible limitation of a scientific study.

Q. Okay. And, Doctor, how did you learn about this case?

A. I was aware of the law from the news, and I assumed that there would be a challenge to it. And then I was approached by Lambda Legal, and that's how I learned about this specific case.

Q. And in preparing your expert rebuttal report, what defendants' reports did you read?

A. I read Dr. Scott's and Biggs', Dr. Levine's, several others. I don't recall all of them at this time.

Q. So I'm going down on Exhibit 1 to page 3, paragraph 7 which I'm highlighting. Doctor, could you read the highlighting. Don't read the highlight, but can you see the highlighting? It doesn't make the text darker?

A. Yes.

Q. Perfect.

Is that an accurate statement, Doctor?

A. Yes.

Q. Did you rely on the WPATH Standards of Care 8 in making conclusions in your expert report?

MS. RIVAUX: Objection. Form.

A. I relied on my expertise on the topic.

BY MR. BEATO:

Q. Is it your opinion that WPATH sets the professional standards of care for treatments for gender dysphoria?

MS. RIVAUX: Objection. Form.

You can answer.

A. They are one organization. There are other medical organizations that also have standards of care.

BY MR. BEATO:

Q. And what are those medical organizations?

A. Well, the Endocrine Society comes to mind.

Q. Did you review any Endocrine Society documents in making this expert report?

A. No.

Q. In paragraph 7, it states that you were a chapter author for the Assessment chapter; is that correct?

A. Yes.

Q. Does the Assessment chapter involve treatments for adults?

MS. RIVAUX: Objection. Form.

A. The Assessment chapter outlines the assessment process for adults.

BY MR. BEATO:

Q. Does your expert report concern treatment

for adults?
A. No.
MS. RIVAUX: Objection. Form.
BY MR. BEATO:
Q. Do your conclusions reached in the Assessment chapter fairly and accurately describe your opinions and conclusions about gender-affirming care?
MS. RIVAUX: Objection. Form.
A. The Assessment chapter is a consensus document of many experts.
BY MR. BEATO:
Q. Is that a "yes"?
MS. RIVAUX: Objection. Form.
A. I -- you know, my -- I stand by the standards of care as the gold standard for treatment guidelines.
BY MR. BEATO:
Q. Why do you say that?
MS. RIVAUX: Objection. Form.
You can answer.
A. Yeah, because it -- because of the process through which it was created.
BY MR. BEATO:
Q. And what was the process in which it was created?

MS. RIVAUX: Objection. Form.
I'm also going to object to the extent that it would address any issues that are covered by the stay that you -- in this case that you do not go into any of that.
So I'm assuming, Michael, that you're not asking anything that's privileged information as it relates to that.
MR. BEATO: So let me ask you -- let me ask you, Shani, is it plaintiffs' position that I cannot ask any WPATH-specific question to the doctor?
MS. RIVAUX: No, I'm not suggesting you can't ask WPATH questions, but just you can't go into the issues that are currently addressed in the order that stays the discovery relating to internal processes of WPATH. So as long as it's not going into that, it's fine just depending on the question, but I guess that's the concern that I have is just not to violate that court order or to violate any nondisclosure agreement. You can ask anything that's about public information but nothing internal or private to WPATH that would violate that court order or require Dr. Edmiston to violate his

confidentiality agreement.
MR. BEATO: So, for example, asking about how the doctor went about and revised the assessment chapter to Standard of Care 8 I cannot, according to plaintiffs, I cannot ask questions relating to that?
MS. RIVAUX: Ask -- say that again. I'm not sure I understood.
MR. BEATO: Sure. I'll break it down. So in paragraph 7 the doctor states that the doctor was an author for the Assessment chapter for Standards of Care 8. And in revising the standards of care, specifically the Assessment chapter, I cannot ask any questions as to what was the consensus; how did you come up with revisions; what was the process like, I cannot --
MS. RIVAUX: I -- so I think it's going to be tough to -- I'm not giving you any blanket prohibition or objection, so it may be easier just to go question by question.
But I think to the extent it doesn't reveal information that seeks confidential information, then that's fine. So I think the limitation and the instruction is just not to reveal

confidential information.
MR. BEATO: Okay. I'm a little --
MS. RIVAUX: If you want to ask -- ask the question, and then we can, you know -- to the extent it doesn't seek information, my instruction is going to be to the extent it doesn't reveal confidential information or information that would otherwise be barred by the current stay and order, then Dr. -- then Dr. Edmiston can certainly answer the question.
MR. BEATO: Sure. And I'm happy to seek additional court guidance on this particular issue too.
MS. RIVAUX: I'm sorry?
MR. BEATO: I'm happy to seek additional court guidance on this issue too because we believe it goes to credibility.
MS. RIVAUX: Right. Well, I think here really the issue is he's here to take about his expert report, not WPATH. And if there's specific questions that you want to ask about it, you know, we could go about it individually. But, as I mentioned, there's a stay in place as it relates to specific areas relating to WPATH that you're aware of, and, you know, there's a

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confidentiality agreement. So to the extent that it doesn't violate those, you can ask the questions. And if we need to seek additional guidance from the court, we certainly can do that.

MR. BEATO: Okay. How about -- okay. How about this? I ask my questions. You can instruct the witness not to answer any questions you believe he should not answer.

MS. RIVAUX: Okay.

MR. BEATO: Okay. Perfect.

BY MR. BEATO:

Q. So, Doctor, how does the -- well, let me take a step back before I take a step forward.

Does WPATH standards of care have a process in which those standards of care are revised?

MS. RIVAUX: Objection. Form.

You can answer.

A. What do you mean by "revised"?

BY MR. BEATO:

Q. So in terms of making a new version.

A. Oh. So the shift -- the drafting of version 8?

Q. Precisely. Perfectly.

A. All right. Yes.

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Q. What is that process?

MS. RIVAUX: Objection. Form.

You can answer to the extent it doesn't violate your confidentiality agreement or the stay entered by the Appellate Court relating to the subpoenas to WPATH.

A. I would refer you to the WPATH SOC8 website which outlines that process.

(Defendant's Exhibit Number 2 for i.d.)

BY MR. BEATO:

Q. So I'm going to pull up another document. I'm mark this as Exhibit 2. So I will scroll down. It's six pages. And I will ask if this document looks familiar to you.

A. No, I have not seen it before.

Q. Could you read the title for me?

A. "Establishing the SOC8 Revision Committee and Meet the Chairs and Lead Evidence Team."

Q. And I can represent that this was on the website.

So I'm going to page 3. Doctor, were you a chapter lead when the Assessment chapter was being revised or reviewed?

MS. RIVAUX: Objection. Form.

A. I was a chapter co-author.

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BY MR. BEATO:

Q. What's the difference between the two?

A. A chapter lead, I don't believe I can answer a specific question about roles.

Q. Okay. Based on what counsel said?

A. Yes.

Q. Who was the chapter lead during the revision process for the Assessment chapter?

A. Christina. I'm sure she's listed on the website.

(Defendant's Exhibit Number 3 for i.d.)

BY MR. BEATO:

Q. I'm going to pull up another document. This is Exhibit 3. It's a little bit longer than the other one, but I'm going to scroll down. I will also represent that this is from the WPATH website.

Does this document look familiar to you, Doctor?

A. No.

Q. So I'm scrolling down to page 12, and I'll represent that there are individuals under the Assessment Of Adults With Gender Diversity/Dysphoria.

Doctor, do these individuals look familiar to you?

A. Yes.

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MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. How do you know these individuals?

MS. RIVAUX: Objection. Form.

You can answer.

A. I worked with them to write the chapter.

BY MR. BEATO:

Q. Are there any individuals who worked with you who are not listed here?

MS. RIVAUX: Objection. Form. And objection to the extent you can't answer without violating a confidentiality agreement or any stay in this case.

A. The authors list for SOC8 is very long. Many different people were involved in it, and the document was written collaboratively.

BY MR. BEATO:

Q. And earlier in the deposition you said that the standards of care is a consensus document. What does that mean?

A. I would refer you to the process, the consensus process that is outlined on the website.

Q. Can you describe the process just generally?

A. There --

MS. RIVAUX: I'm going to object, again,

only to the extent that you can answer the question -- I mean to the extent the question is asking generalities and not asking specifics into the process or things that would be violated, then that's fine, you can answer.

BY MR. BEATO:

Q. Let me clarify. Generally speaking.

A. Yes, there was a lit review that was conducted externally, and then there were grievance statements, and then the authors all had to build a consensus around the statements.

Q. Understood.

Doctor, are you a member of WPATH?

A. I was. I believe my membership -- I might be overdue on my dues, but, yes, I was at one time.

Q. When did you start being a member of WPATH?

A. I don't recall at this time exactly.

Q. Ballpark range?

A. Probably around probably 2017, I would guess.

Q. And so this is another general question. Looking at Exhibit Number 3 for the individuals listed here -- and, again, you recall working with these individuals?

A. Yes.

Q. Are any of them endocrinologists, to your memory?

MS. RIVAUX: Objection. Form.

A. No.

BY MR. BEATO:

Q. Are any of them surgeons?

MS. RIVAUX: Objection. Form.

A. There are endocrinologists and surgeons involved in SOC8 for the hormone and surgery chapters of SOC8.

BY MR. BEATO:

Q. And how would you describe each of these individual's areas of expertise?

MS. RIVAUX: Objection. Form.

A. I think that the document describes their areas of expertise.

BY MR. BEATO:

Q. Fair enough. So I'm going back to Exhibit Number 2, and I'm scrolling down to page 4, chapter stakeholder members. Again, this is on the public website. Does WPATH when it's revising its standards of care, to your knowledge, employ the help of nonmedical professionals in that process?

MS. RIVAUX: Objection. I'm going to give the same instruction. And also just to the extent that Dr. Edmiston is also not here, doesn't speak on behalf of WPATH. But to the extent that Dr. Edmiston has personal knowledge that doesn't violate any confidentiality agreement or the order, then you may answer.

A. Can you define "medical professional"?

BY MR. BEATO:

Q. Sure. So, for example, an M.D., an endocrinologist, psychiatrist, someone who's gone to medical school.

A. There are certainly people involved in drafting the standards of care who have expertise who did not go to medical school because obviously there are lots of different manners to become educated and gain expertise on this topic.

Q. And this topic is?

A. Transgender healthcare.

Q. And you mentioned or counsel mentioned a confidentiality agreement.

A. Yes.

Q. As a member of WPATH you signed a confidentiality agreement?

A. No, as a --

MS. RIVAUX: Objection. Form. Sorry.

BY MR. BEATO:

Q. I'm sorry.

MS. RIVAUX: I'm raising an objection only to the extent you're not going to violate any agreement.

BY MR. BEATO:

Q. No, do not violate anything. I'm just asking what's with the confidentiality?

A. The chapter authors all signed it.

Q. I see.

A. We were asked to. I don't know what anyone else did.

Q. Understood. So WPATH asked you to sign that confidentiality agreement?

MS. RIVAUX: Objection to form.

A. I signed a confidentiality statement.

BY MR. BEATO:

Q. Understood. And, again, Doctor, we're just building the record. I don't want you to violate anything or make you feel uncomfortable in answering any questions.

So let me scroll up on Exhibit 2. I know, Doctor, you said you weren't a chapter lead. But looking at the criteria for chapter leads, WPATH full member in good standing. What do you think that means?

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MS. RIVAUX: Objection. Form.
A. I assume it means that you're a member of WPATH.
BY MR. BEATO:
Q. A well-recognized advocate for WPATH and the standards of care?
MS. RIVAUX: Objection. Form.
A. I'm not sure what you're asking me. Are you asking me what a -- like what the word "recognized" means? I'm not sure what you're asking.
BY MR. BEATO:
Q. Sure, what does recognize mean in this context, in your opinion?
MS. RIVAUX: Objection to form.
A. That -- that you are known to people in this area.
BY MR. BEATO:
Q. Understood.
So, Doctor, we're going to move away from the process questions.
So now let me see if I can move this.
(Defendant's Exhibit Number 4 for i.d.)
BY MR. BEATO:
Q. I'm now going to introduce this as Exhibit 4. Doctor, does this look familiar?

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A. Yes.
Q. What is this document?
A. This is the Standards of Care 8.
Q. Excellent.
So -- well, let me ask you this.
Do you think WPATH is an advocacy organization?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. Why?
MS. RIVAUX: Objection, form.
You can answer.
A. The purpose of WPATH is to gather the scientific evidence and expertise of scientists and clinicians to -- to develop the standards of care and to disseminate research.
BY MR. BEATO:
Q. And what kind of evidence does WPATH collect?
MS. RIVAUX: Objection. Form.
A. So, again, I would refer you to the website which outlines the process for drafting the standards of care.

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BY MR. BEATO:
Q. And in terms of the chapter that you assisted with authoring, which chapter is that?
MS. RIVAUX: Objection. Form.
A. I am co-author of the Assessment of Adults chapter.
BY MR. BEATO:
Q. And that is Chapter 5?
A. Yes.
Q. I am now going on Exhibit 4 to page 33. I'm scrolling to the -- now I'm on page 34. I'm scrolling to the bottom of page 34. Doctor, I just have a few questions.
If you look at 5.4, it says, "We suggest..." and 5.5, "We recommend..."
A. Um-hum.
Q. Is there a difference between "suggest" and "recommend" here?
A. Yes.
Q. What is that difference?
A. They are different words.
Q. Okay. Do they convey anything differently? So there is -- strike that.
So they're used synonymously?
A. No.

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Q. So what are their differences?
A. The WPATH document has graded evidence, so the language there is specific to the strength of evidence.
Q. And what kind of evidence grading systems does WPATH use?
A. I'm sorry. Can you repeat the question?
Q. Sure. So what kind of evidence grading system does WPATH use?
So, for example, I believe the Endocrine Society uses the GRADE system.
A. I would refer you to the website for that information.
Q. Understood. So now I'm going to go back to page 33, Doctor. One moment, Doctor.
33, I'm highlighting a section. It begins, "For TGD..." and goes all the way to "... required."
So, Doctor, I highlighted this sentence. Just so the record is clear, what does TGD mean in this chapter?
A. I would suggest that you scroll up to the top. It will be defined there.
Q. Right up here (indicating)?
A. Yes.
Q. Transgender and gender diverse?

Page 34

A. Yes.
Q. So in this highlighted section can you elaborate on that sentence?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. It says what it says?
A. If you have a specific question, I'm happy to, you know -- if you have a specific question. But I -- I don't know what you -- you'll have to ask me a specific question.
BY MR. BEATO:
Q. Sure. So when it says "...less common treatments..." what does less common treatments mean?
MS. RIVAUX: Objection. Form. You can answer.
A. I think if an adult was to ask for an intervention that was nonstandard.
BY MR. BEATO:
Q. As an example, what would that be?
A. I wouldn't really want to speculate.
Q. Can you provide an example, though?
MS. RIVAUX: I'm going to object on the grounds of scope, but you can go ahead and answer.

Page 35

A. Yeah, I mean, it's a -- it is a bit outside of the scope of, you know, my rebuttal. Sometimes people ask for -- they might ask for a surgical intervention that's nonstandard for as an example.
BY MR. BEATO:
Q. And limited research evidence, what does that mean?
MS. RIVAUX: Objection. I'm going to object on both form and scope here, but you can answer.
A. I mean, somebody -- it's -- there's always a possibility that someone might request an intervention that hasn't been researched before or has been researched very little.
BY MR. BEATO:
Q. Can you provide an example, Doctor?
MS. RIVAUX: Objection. Form and scope. You can answer.
A. I think the same -- the same answer. So if someone were to ask -- if an adult were to ask for a nonstandard surgical intervention, for example.
BY MR. BEATO:
Q. Scrolling to page 34, I'm highlighting another sentence beginning with, "The statements below..." and ending with "...consensus of professional best practice."

Page 36

Doctor, what does the phrase "consensus of best" -- strike that -- "consensus of professional best practice" mean?
MS. RIVAUX: Objection. Form and scope. You can answer.
A. Yeah, I mean, again, I would refer you to the WPATH website where they outline a lot of sort of the process and the specific terminology that they use in this document.
BY MR. BEATO:
Q. With that in mind, could you today provide me with what your opinion as an author of this section, what consensus of professional best practice means?
MS. RIVAUX: Objection to both form and scope. You can answer.
A. The consensus of ex -- people with expertise on the topic.
BY MR. BEATO:
Q. And how would you define expertise on the topic?
MS. RIVAUX: Objection. Form and scope. But you can answer.
A. I would, again, refer you to the WPATH website where they talk about the -- they outline the

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sort of selection process for authors and how they determine expertise.
BY MR. BEATO:
Q. Okay. So I'm going back to Exhibit -- bear with me. This is now Exhibit 3. Again, we're still on page 12 and 13. Do all of these individuals support gender-affirming care?
MS. RIVAUX: Objection. Form; scope. And to the extent it doesn't violate your confidentiality agreement or the stay, you can answer and if you know.
A. These individuals support the care that is -- has an evidence -- that -- you know, your question is very broad because gender-affirming care is very broad.
BY MR. BEATO:
Q. It is.
A. And the SOC8 guidelines recommend an individualized approach to care. So I think everyone involved in -- for those individuals they support quality healthcare.
Q. Going back to Exhibit 4, this sentence, Doctor, "The empirical evidence base for the," scrolling to page 35 -- "assessment of TGD adults is limited."

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My question is, in the sentence, what does "empirical evidence base" mean?

MS. RIVAUX: Objection. Form and scope. You can answer.

A. So I would have to re-read the chapter in context. I do not want to define what a specific word means in a specific sentence without reading the context in which it occurs.

BY MR. BEATO:

Q. Fair enough. And would that same answer be true for "limited" in this sentence?

A. Yes.

MS. RIVAUX: Objection. Form; scope.

BY MR. BEATO:

Q. Doctor, I apologize. I did not hear an answer.

A. Oh. Yes.

Q. Let's go to the next page. This sentence, Doctor, "Some TGD individuals will have the capacity to grant consent immediately during the assessment."

What does that mean?

MS. RIVAUX: Objection. Form and scope.

A. This is about the assessment of adults and is about the assessment process being individualized.

Page 39

BY MR. BEATO:

Q. So in an individualized scenario, can an individual be given puberty blockers for gender dysphoria after one medical treatment?

MS. RIVAUX: Objection. Form.

A. I would ask you to restate the question with a little bit more specificity.

BY MR. BEATO:

Q. Fair question, Doctor. Fair question.

Let me -- let me go back to these questions.

Scrolling down to the next page, statement 5.3A, Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. So this is a sentence from the adult chapter that says "To access GAMSTs, a TGD person's gender incongruence must be marked and sustained."

So that means that part of the assessment process is to determine sort of the duration of the feelings of gender incongruence and the degree to which they are distracting or upsetting or troubling.

BY MR. BEATO:

Q. Scrolling a little bit further down, while marked and sustained gender incongruence is present, going all the way down to access gender-affirming care, Doctor, what does that sentence mean?

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MS. RIVAUX: I'm going to object to form and scope.

A. That if a person -- it just means that -- it's not -- there's not some threshold of suffering that someone -- you know, that someone needs to suffer a certain amount before they're allowed to access healthcare.

BY MR. BEATO:

Q. Okay. Moving to page --

Well, actually, Doctor, we've been going for about an hour. Would you like a five-minute break?

A. No, I'm okay.

Q. Okay. Okay. And, once again, if you'd like a break at any time, please let me know. More than happy to accommodate.

A. Sure.

Q. So this is on Page 38 highlighting the sentence -- oops, no -- I -- I apologize.

Page 39, "in rare cases..." Doctor, in this sentence what does "rare cases" mean?

MS. RIVAUX: Objection. Form and scope.

A. So in rare cases would mean a nontypical instance.

BY MR. BEATO:

Q. And in the context of this sentence what would that nontypical instance be?

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MS. RIVAUX: Objection. Form and scope.

A. So I would have to review the Hembree citation there. I mean, one example could be if someone had an estrogen receptor positive cancer.

BY MR. BEATO:

Q. And generally speaking, Doctor, when you were authoring this section, did you read all of these cases that are mentioned in this chapter?

MS. RIVAUX: Objection. Form; scope.

And to the extent it doesn't violate any of the stay order that we discussed or the confidentiality order, you may answer.

A. I have reviewed much of this literature. If you have a specific question about a specific paper, then I would request that you give me a break to review the specific paper.

BY MR. BEATO:

Q. Understood. And perfectly reasonable. I just had a broad general question.

And within the literature that you have reviewed when authoring this chapter, do you know if any of those studies were low evidence?

MS. RIVAUX: Objection. Form; scope.

You can answer.

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A. I think that you would have to describe what you mean by "low evidence." I recall you asked me that question before, and I answered that all studies have limitations, and that's why we look at the literature as a whole to draw conclusions.

I'm sure you're aware, there's quite a bit of evidence cited in SOC8. I'm not sure off the top of my head how many citations there are, but it's quite a few.

BY MR. BEATO:

Q. So earlier in the deposition I think you provided examples of low-quality evidence or limitations. Do you recall saying study design could lead to evidence being low quality?

MS. RIVAUX: Objection. Form.

A. I believe I said that that is an example of a limitation. I didn't -- I do not think I said that it was an example of low quality.

BY MR. BEATO:

Q. Okay. And -- okay. And as of right now, you do not recall if any of those citations mentioned in Chapter 5 have low-quality evidence?

MS. RIVAUX: Objection. Form; scope.

A. I -- I take -- I sort of -- I challenge the premise of the idea of low quality. I am instead

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talking about the limitations that occur with any scientific study, which is why we do lots of different studies to draw conclusions.

So I sort of -- or not sort of. I object to the premise of the question.

BY MR. BEATO:

Q. So still on page 39, sentence, "Because of the possible harm..." all the way down to "...is important," Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. Again, I would ask that if you want me to discuss specific sentences from a very large document that I would be given time to review the document in its entirety to ensure that I am fully representing the context of any particular sentence.

BY MR. BEATO:

Q. Fair enough. And, again, you authored this document, or at least this chapter in the Standards of Care 8?

MS. RIVAUX:

A. I --

MS. RIVAUX: Objection to form; scope and the other restrictions that we've talked about before relating to your confidentiality agreement and the stay order in place.

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A. Yes, I was a co-author of SOC8.

BY MR. BEATO:

Q. And this chapter?

A. Yes.

Q. Any other chapters, Doctor?

MS. RIVAUX: Objection. Form; scope; and same objections relating to the confidentiality agreement and the violation of -- and any -- and not to violate the stay in place.

A. I would, again, refer you to the WPATH website which outlines the process by which this document was drafted. It was written via consensus and was drafted collaboratively.

BY MR. BEATO:

Q. Okay. So I don't think you answered my question. Did you -- again, noting the objections, did you contribute in authoring any other chapters in WPATH?

MS. RIVAUX: I'm going to object to form; scope.

Again, do not violate your confidentiality agreement or the stay that's in place.

A. Yeah, that would -- that would -- discussing that would be in violation of the confidentiality agreement.

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BY MR. BEATO:

Q. All right. I'll move on.

Doctor, to the best of your knowledge in Chapter 5, does Chapter 5 discuss any negative health risks of gender-affirming care?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. The Assessment chapter discusses the types of assessments that are necessary to determine eligibility and readiness for gender-affirming care.

BY MR. BEATO:

Q. Does it also talk about risks involved?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. I would ask what you mean by "talk about." It outlines what assessments need to be or should be done to determine the readiness for care.

BY MR. BEATO:

Q. And if I understand this correctly, part of the assessments involve evaluating benefits and risks?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. Broadly, yes.

BY MR. BEATO:

Q. And in evaluating the risks, does that

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also -- in evaluating -- sorry.
In evaluating risks, do you also have to weigh irreversible potential medical consequences?
MS. RIVAUX: Objection. Form; scope.
You can answer.
A. This is very standard healthcare. All healthcare interventions have outcomes associated with them, and this is no different from any other type of health intervention.
BY MR. BEATO:
Q. So, Doctor, I would like to take a five-minute break if you don't mind.
A. Sure.
MR. BEATO: Would you mind if we reconvene, just because I like base-five numbers, how about 11:15?
THE WITNESS: Sounds good.
MR. BEATO: Thank you very much.
THE VIDEOGRAPHER: Stand by. We're going off video record. The time is 11:08 a.m.
(A recess was taken from 11:08 a.m. to 11:16 a.m.)
THE VIDEOGRAPHER: We are back on the video record. The time is 11:16 a.m.
BY MR. BEATO:
Q. All right. So, Doctor, let me ask you this.

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And let me pull up Exhibit 1, the expert rebuttal report. Did you base any of your expert opinions on the WPATH Standards of Care Version 8?
MS. RIVAUX: Objection. Form. You can answer.
MR. BEATO: Counsel, can I have the basis for the objection?
MS. RIVAUX: It was confusing the way you worded the question.
MR. BEATO: Okay. I could rephrase.
BY MR. BEATO:
Q. Doctor, did you use WPATH's Standard of Care Version 8 recommendations as a basis for your expert report opinions?
A. I suppose I would ask what you mean by "use." I have expertise and I reviewed the relevant literature.
Q. So I'm scrolling down to page 4, paragraph 13. I highlight, "My opinions are based..." and I go down to "...including my work as a contributing author of WPATH Standards of Care 8."
Doctor, is paragraph 13 a fair and accurate representation of your opinion?
A. Yes.
Q. Is the confidentiality from WPATH, is that

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preventing you from answering some of the WPATH questions in this case?
MS. RIVAUX: Objection. Form; scope; and, again, the same objections relating to the confidentiality agreement and the stay order.
A. I'm adhering to the confidentiality agreement that I signed.
BY MR. BEATO:
Q. Understood.
And, Doctor, again, in your expert report do you opine on adult treatment?
A. In the rebuttal.
Q. Right. Apologies. I can be clear. Let me rephrase.
Doctor, in your expert rebuttal report, do you discuss adult treatment?
A. It -- the primary point or one of the primary points of my report was related to adolescent brain development.
Q. Understood. So where specifically do you mention adults in your expert rebuttal report?
A. I would have to review, but I believe by and large the report is regarding adolescents because that is what is pertinent.
Q. And if you need time to review this report,

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let me know. So, again, your report concerns adolescent treatment; is that correct?
A. Yes.
Q. Now, Doctor, regarding adolescent treatment and gender-affirming care, is there a lot of literature out there on the treatment?
MS. RIVAUX: Objection. Form.
MR. BEATO: Basis for objection?
MS. RIVAUX: It's a really broad, ambiguous question. There's a lot of literature out there. It's just, you know, just a broad, ambiguous question.
BY MR. BEATO:
Q. Okay. Let me rephrase.
Doctor, is there a good, a great deal of evidence on the effects of gender-affirming care on adolescents?
MS. RIVAUX: Objection. Form.
MR. BEATO: Basis, Counsel.
MS. RIVAUX: Same thing. I think it's ambiguous to say whether there's a great deal. I think it's ambiguous. But he may answer.
BY MR. BEATO:
Q. I will scroll down to, we're still on Exhibit 1, page 21.

Doctor, could you read this sentence for me?

A. "In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Q. Doctor, is "great deal," is that vague?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: What's the relevance?

MR. BEATO: The doctor wrote it.

MS. RIVAUX: Okay. So you can ask him about what he means by it.

BY MR. BEATO:

Q. What do you mean by "a great deal"?

A. So in this instance I'm looking at the literature, the decades of use of GnRHa treatment and the expertise of, my own expertise, the expertise of my colleagues. There's a great deal -- again, there's a great deal of evidence to support this, right. So I'm thinking broadly about evidence from clinical experience of my colleagues as well as the research literature.

Q. Okay. When you say "research literature," what do you mean?

A. Publications like peer-reviewed publications.

Q. Can you provide me examples of those?

A. I would refer to you my bibliography. I think there's quite a few citations.

Q. Can you name one off the top of your head?

A. There's a de Vries paper.

Q. And, again, Doctor, if I'm reading this correctly, "In contrast, there's a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Again, that's accurate?

A. Yeah, so the sentence that that is -- so the sentence begins with the phrase, "In contrast." The sentence prior to it says, "There is little to support the defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain." So I stand by the sentence as written.

Q. Understood. I will scroll up to page 16, paragraph 31. I highlighted the first sentence. Doctor, could you please read that sentence?

A. Yes, "There is a small body of literature on the effects of gender-affirming hormone care on the brain in transgender adolescents."

So am I correct in assuming that you're trying to suggest that these two sentences are in conflict with each other?

Q. No.

A. Oh, okay. Great.

Q. Let's go to paragraph 5. I'm sorry. I misspoke. Page 5. Bear with me, Doctor. Sorry. So in chapter -- strike that. Sorry.

In paragraph 16, I believe you're responding to one of Dr. Scott's statements; is that correct?

A. Yes.

Q. I'm highlighting one sentence, I believe it's the second sentence, "That is, literature indicates that there are highly specific circumstances in which adolescents are more likely to engage in risky or impulsive behavior."

Doctor, my question is, did you provide a citation for that assertion?

A. I do later on.

Q. Where is that?

A. I believe it's -- yeah, paragraph 18.

Q. And all those cases stand for that proposition?

A. So those are references that describe the context -- the contextual nature of decision making and adolescents.

Q. And I'm scrolling back to page 5. Bear with me. The sentence, "However, none of these examples are

relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional."

Doctor, my question is, what does protracted mean here?

A. Drawn out.

Q. So in this context, what period of time are we talking about?

A. I'm sorry. They're doing some work outside of my office and it's a little loud. Can you repeat the question?

Q. No problem whatsoever. No problem. And, again, if there's like a -- something going on in the background, more than happy to do that.

So in the final sentence of paragraph 16, "However, none of these treatments are relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional," what does "protracted" mean? Like what kind of -- here's the question. What kind of period of time are we looking at?

A. So it could be -- you know, I think that it varies, which is why SOC8 recommends an individualized approach. It could be eight months or even years for some people.

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Q. Okay. Do you have a citation or a study or some basis for that proposition?

A. I believe in the next paragraph I cite the, I think it's a Bauer study. Yeah, the Bauer 2022 study which outlines the time between an adolescent realizing that they're trans and then them coming out to a healthcare provider.

Q. All right. So the this sentence -- okay. Understood. So that citation for that's -- okay. Thank you, Doctor. That's all I wanted.

A. Um-hum.

Q. Give me one second.

Let's go to Paragraph 25. I think this is on page 10, still on Exhibit 1. I'm highlighting the second sentence in Paragraph 25, "Case studies are the lowest quality of evidence." Could you elaborate on that, Doctor?

A. Yeah, a case study is a study of a single individual, so they are generally not regarded as the type of evidence that we would want to use to make -- to inform, you know, standards of care policy, you know, the -- because it's just regarding a single person, so generally, you know, we don't think of those as being generalizable.

Q. Understood. And what limitations come with case studies?

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A. Well, it's a study of a single person, so we don't know if we can extrapolate the findings to the broader population.

Q. Are there any other limitations inherent with case studies, or it's just the focus of an individual on one person, to your knowledge?

A. I would say that's probably the primary limitation of a case study is just the, you know, questionable generalized ability of them.

Q. Understood.

In your knowledge, do you know if WPATH references any case studies in its standards of care?

A. I don't know off the top of my head, but I do know that WPATH cites a large body of literature that includes empirical studies, longitudinal studies, cross-sectional studies, cohort studies, unlike Dr. Levine who did not cite any valid literature.

Q. And in terms of the literature, does it pertain to adolescent treatments with gender dysphoria?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: I didn't understand the question.

MR. BEATO: Sure, I'll back up. I can take a step back before taking a step forward.

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BY MR. BEATO:

Q. So, Doctor, you said that in the standards of care, in WPATH there's a lot of longitudinal peer-reviewed literature, correct?

A. I said that there is a variety of different types of evidence that are informing recommendations as a whole, so that could include longitudinal cohort, cross-sectional.

Q. Could that also include case studies?

A. It may, yes.

Q. And in terms of the longitudinal cohort literature that you mentioned, does that literature reference or relate to adolescent treatment concerning gender-affirming care?

A. There have been longitudinal adolescent studies. If you're asking me to speak to a specific one, I would want to take a break and review it.

Q. Understood. Without speaking in depth about it, could you identify them for me off the top of your head, or are they mentioned in your bibliography?

A. They are mentioned in my bibliography.

Q. To your mind, does your bibliography reference all of those longitudinal cohort adolescent related studies that you're thinking of right now?

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A. I cite the -- so I did a targeted literature review, and I cite the studies that I was -- that I identified that looked at mental health outcomes in transgender youth. I would hesitate to claim that I have cited every longitudinal study of transgender youth, but I did do a thorough literature review.

Q. Fair enough. Fair enough. Are there any additional reports that should be in your bibliography?

A. Not that I'm aware of.

Q. Let me go to paragraph 27 highlighting the first sentence, "Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both 'unknown' and 'likely negative.'"

Does WPATH comment on the effects of GnRH -- I'm going to get it wrong, Doctor. I apologize.

Does WPATH opine on the effects of GnRHa treatment on the brain?

A. Not that I recall, but I would want to review the entire document before making a definitive statement.

Q. Is there a great deal of evidence on the subject?

A. There is --

MS. RIVAUX: Objection.

THE WITNESS: Sorry.

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MS. RIVAUX: You can answer.
MR. BEATO: And what's the basis for the objection?
MS. RIVAUX: I'm not sure when you're saying "there's a great deal of evidence on the subject" what the subject in particular you were referring to.
MR. BEATO: The effects of GnRHa treatment on the brain.
MS. RIVAUX: Do you want to rephrase -- the way -- to me, the way it came out was a little -- is a little bit ambiguous. If you want to rephrase it that way, that's fine.
MR. BEATO: No problem whatsoever. I'm just asking for the basis of the objection so I can ask a better question.
MS. RIVAUX: Yeah, that's fine.
MR. BEATO: Perfect.
BY MR. BEATO:
Q. So, Doctor, is there a great deal of evidence on the effects of GnRHa treatment on the brain?
A. There is -- there is evidence. There are studies that look at GnRHa treatment on the brain.
Q. How many studies are you thinking of right now?
A. In humans -- well, also, I guess it would depend. If you mean in humans, in transgender adolescents, I believe there's three neuroimaging studies. There are also animal studies as well.
Q. With, for example, I think, sheep?
A. Yes, there are some studies of sheep.
Q. Sheep and mice?
A. And a primate study also.
Q. And for those -- if I remember this -- please correct me if I'm wrong. For those three human studies, what were the results of those studies?
A. I outlined those in the report. Those studies used different imaging modalities. They found differences in brain structure function that were associated with sex assigned at birth; others that were associated with gender identity.
But when they ran correlations to determine associations between GnRHa treatment and brain structure function, they did not find any -- there were no significant findings.
Q. Okay. So no significant findings of benefits in the treatments?
A. No significant findings of any association.
Q. Understood. And for the animal studies, the sheep, mice and primates, what were the results of those studies?
A. Well, as I outlined in my rebuttal as well as the paper, the review paper that I wrote that I cited, the problem with a lot of the animal literature is that they don't use the correct reference group for comparing. So a lot of those studies report differences with GnRH treatment, but really their difference is between natal sex, so we would expect a medication that delays puberty to have sex-specific effects. That is the desired outcome of the treatment.
Q. And I have no additional questions regarding the report. I do have additional follow-up questions, though.
Earlier in the deposition you stated that you were aware of the law in place in Florida.
A. (Nodding head).
Q. By the way, it's not a law; it's a regulation, but understood, understood.
A. All right.
Q. How did you hear about it, the at-issue regulation?
A. I don't recall.
Q. Understood. If you could think back, was it social media, the news or you don't remember?
A. I don't remember. I don't recall at this time.
Q. And for your expert report, did you review the at-issue regulations?
A. I reviewed, as I believe is stated at the beginning of the report, I reviewed the Florida Medicaid opinion.
Q. The so-called GAPMS report?
A. Yes.
Q. But not the at-issue regulation?
A. No, I did not review the text of it.
Q. But you were aware of the at-issue regulation through something?
A. (Nodding head).
Q. Okay. What is your opinion on the GAPMS report?
MS. RIVAUX: Objection. Scope.
A. I would ask that you just be a little bit more specific.
BY MR. BEATO:
Q. Sure. So in writing this expert report, you reviewed the GAPMS report with the accompanying attachments, correct?
A. Um-hum, yes.
Q. As a professor, as a scientist, what are

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your opinions of the GAPMS report?
MS. RIVAUX: Objection. Scope.
You can answer.
A. I was surprised that it didn't seem to cite a lot of relevant literature.
BY MR. BEATO:
Q. What literature would you have cited?
A. All the literature that I cited in my rebuttal.
Q. And in hearing about the at-issue regulation, how do you feel about the regulation?
MS. RIVAUX: Objection.
BY MR. BEATO:
Q. What is your opinion as to the regulation?
MS. RIVAUX: Objection. Scope.
A. I believe that healthcare decisions should be made between patients and providers and their families and based on expert medical evidence and standards of care.
MR. BEATO: Doctor, I have no further questions.
Counsel can ask some follow-up questions.
MS. RIVAUX: I don't have any follow-up questions.
MR. BEATO: All right. Doctor, you're done.

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THE WITNESS: All right. Thank you.
MR. BEATO: Thank you, Doctor. I know you're probably busy. And thank you for making yourself available and taking time to answer these questions. It's really appreciated.
MS. RIVAUX: Do you want to give him the instruction about reading or waiving?
MR. BEATO: Could you do that, Counsel?
MS. RIVAUX: Sure. So, Dr. Edmiston, you have the right to read your report and make any changes to the extent that there were any errors in the transcription or you can waive that. Otherwise, you'd get a copy. If you choose to read it, you'll have 30 days when you get it to review it to make any changes. There will be a form in which you can make any correction. And then that gets sent back and a corrected copy will get circulated to everybody.
THE WITNESS: Yeah, I'd like to read it.
MS. RIVAUX: Okay.
MR. BEATO: And, Doctor, just to be super cautious because I know you have a confidentiality agreement, I don't want to violate that at all. If you said something inadvertently that, you know, maybe you probably

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shouldn't have said, should this deposition be under seal? We can send the court reporter the protective order. I just want to make sure.
MS. RIVAUX: Yeah, you know what? Why don't we do it that way, and then if there's any reason to unseal it or to seal any specific portion, we can go ahead and do that. And then we can -- you know, if there's anything -- so until Dr. Edmiston has an opportunity to review it, and then we can mark things confidential as appropriate later on. I appreciate that. Thank you.
MR. BEATO: No problem. Doctor, I understand. You're put in a tough position, right. You have -- you got something signed. I respect that. I wasn't trying to make you feel uncomfortable or get around that, so I just want to make sure everything is good.
I will ask, though, for an expedited transcript.
And, Doctor, I want to make sure you have sufficient time to review it, but at the same time we want to get this finalized as soon as possible.
THE WITNESS: I appreciate that.

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MR. BEATO: So, Zack, are you on there? We can send over the court reporter the protective order.
THE STENOGRAPHER: I just want to remind you we're still on video record.
MR. BEATO: That's fine. This can all be on the record. That's fine.
Okay. I think we're -- I think we're good. Thank you for your time, Doctor.
THE WITNESS: You're welcome.
THE VIDEOGRAPHER: This is the videographer. Would anyone like to order a copy of the video?
MR. BEATO: A copy of the video, I don't need a copy of the video.
THE VIDEOGRAPHER: And Ms. Rivaux?
MS. RIVAUX: I don't -- I don't think we need a copy of the video at this time. But for the transcript, we'd like it at the same time, please.
MR. BEATO: Yes, expedited.
THE VIDEOGRAPHER: Is there a date for that? Just as soon as possible or --
MS. RIVAUX: As soon as possible.
THE VIDEOGRAPHER: Okay.
MR. BEATO: Thank you very much.

THE VIDEOGRAPHER: And then I'll go ahead and take us off the video record. We're going off the record in the video deposition of Dr. Kale Edmiston. We're going off the record on March 23rd, 2023 at 11:43 a.m.

(Thereupon, the proceedings concluded at 11:43 a.m.)

(The witness did not waive signature.)

CERTIFICATE OF OATH

THE STATE OF FLORIDA)

COUNTY OF PALM BEACH COUNTY)

I, the undersigned authority, certify that E. KALE EDMISTON, Ph.D. remotely appeared before me and was duly sworn on the 23rd day of March 2023.

Signed this 23rd day of March 2023.

Barbara Gallo

BARBIE GALLO, RMR-CRR

Notary Public - State of Florida

My Commission No. GG939757

My Commission Expires: December 15, 2023

CERTIFICATE OF REPORTER

THE STATE OF FLORIDA)

COUNTY OF PALM BEACH)

I, Barbie Gallo, RMR-CRR, Registered Merit Reporter-Certified Realtime Reporter, certify that I was authorized to and did stenographically report the deposition of E. KALE EDMISTON, Ph.D., pages 1 through 69; that a review of the transcript was requested; and that the transcript is a true and complete record of my stenographic notes.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 23rd day of March 2023.

Barbara Gallo

Barbie Gallo, RMR-CRR

Thursday, March 23rd, 2022
E. Kale Edmiston, Ph.D. c/o Shani Rivaux
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IN RE: DEKKER vs WEIDA
CASE NO.: CASE NO. 4:22-CV-00325-RH-MAF
Please take notice that on the 23rd day of March 2023, you gave your deposition in the above cause. At that time you did not waive your signature.
The above-addressed attorney has ordered a copy of this transcript and will make arrangements with you to read their copy. Please execute the Errata Sheet, which can be found at the back of the transcript, and have it returned to us for distribution to all parties.
If you do not read and sign the deposition within 30 days, the original, which has already been forwarded to the ordering attorney, may be filed with the Clerk of the Court.
If you wish to waive your signature now, please sign your name in the blank at the bottom of this letter and return it to the address listed below.
Very truly yours,
Barbie Gallo, RMR-CRR
Phipps Reporting, Inc.
1551 Forum Place, Suite 200-E
West Palm Beach, Florida 33401
I do hereby waive my signature.

E. KALE EDMISTON, Ph.D.

ERRATA SHEET

DO NOT WRITE ON TRANSCRIPT - ENTER CHANGES HERE

IN RE: DEKKER vs WEIDA

CASE NO.: CASE NO. 4:22-CV-00325-RH-MAF

WITNESS: E. KALE EDMISTON, PH.D.

TAKEN: 03/23/2023

PAGE	LINE	CHANGE	REASON FOR CHANGE

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____

Date E. KALE EDMISTON, Ph.D.

B

C

Q

R

S