

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE
ANDERSON; individually and on behalf of all
others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

**PLAINTIFFS' MOTION TO EXCLUDE
EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.**

Now come, Plaintiffs, by and through their counsel, and respectfully move this Court to exclude the expert report, opinions, and testimony of Defendants' proposed expert, Stephen B. Levine, M.D., pursuant to Federal Rules of Civil Procedure 26 and 37, and Federal Rules of Evidence 104, 403, and 702. Dr. Levine is not a qualified expert on gender dysphoria or its treatment, and his opinions and testimony are neither relevant nor reliable pursuant to the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. His opinions and testimony are likewise inadmissible because any probative value they may have is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. *See* Fed. R. Evid. 403.

A memorandum of law is filed contemporaneously herewith.

Dated: May 31, 2022

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, and any attachments, were served
electronically on May 31, 2022 on the following counsel for Defendants in this case:

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Dated: May 31, 2022

Respectfully submitted,

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DECLARATION OF CARL S. CHARLES

Pursuant to 28 U.S.C. § 1746, I, Carl S. Charles, do hereby declare as follows:

1. I am over 18 years of age.
2. I am a Senior Attorney at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.
3. I have personal knowledge of the facts stated herein, except those stated upon information and belief, and if called upon, could and would testify competently to them.
4. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D. ("Dr. Levine.").
5. Attached as **Exhibit A** is a true and correct copy of the expert witness declaration of Dr. Levine (including a copy of his curriculum vitae) in the above-captioned matter, which is dated and was served on Plaintiffs on February 18, 2022, and was entered as Exhibits 1 and 2 to Dr. Levine's deposition in this matter on April 27, 2022.
6. Attached as **Exhibit B** is a true and correct copy of excerpts of the transcript of

the deposition of Dr. Levine on April 27, 2022, taken in relation to the above-captioned matter.

7. Attached as **Exhibit C** is a true and correct copy of excerpts from the transcript of the deposition of Dr. Levine taken on September 10, 2021, in relation to *Kadel v. N. C. State Health Plan for Tchrs. and State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021) which was entered as Exhibit 5 to Dr. Levine's deposition in this matter on April 27, 2022.

8. Attached as **Exhibit D** is a true and correct copy of excerpts from the transcript of the bench trial in *Soneeya v. Turco*, No. 07-12325-DPW (D. Mass 2019) where Dr. Levine testified on April 4, 2019.

9. Attached as **Exhibit E** is a true and correct copy of an excerpt of the transcript of the deposition of Commissioner Cynthia Beane taken on March 29, 2022, in relation to the above-captioned matter, which was entered as Exhibit 22 to Dr. Levine's deposition in this matter on April 27, 2022.

10. Attached as **Exhibit F** is a true and correct copy of excerpts of the zoomed deposition of Dr. Levine taken December 21, 2020, in relation to *Claire v. Florida Dept. of Management Services*, 504 F. Supp. 3d 1328 (N.D. Fla. 2020).

11. Attached as **Exhibit G** is a true and correct copy of the article "International Clinical Practice Guidelines For Gender Minority/Trans People: Systematic Review And Quality Assessment," published in April 2021, which was entered as Exhibit 10 to Dr. Levine's deposition in this matter on April 27, 2022.

12. Attached as **Exhibit H** is a true and correct copy of Marci Bowers. M.D.,'s statement entitled "Dear Colleagues and Friends," published on her website after October 4, 2021, which was entered as Exhibit 11 to Dr. Levine's deposition in this matter on April 27, 2022.

13. Attached as **Exhibit I** is a true and correct copy of a printout from the Cass

Review website “About The Review” page, which was accessed on April 26, 2022.

14. Attached as **Exhibit J** is a true and correct copy of an excerpt of the rebuttal report of Joanna Olson-Kennedy, M.D., signed on March 17, 2022, and served on Defendants March 18, 2022, in the above captioned matter.

15. Attached as **Exhibit K** is an excerpt from the published Ph.D. Thesis, “On Gender Dysphoria,” written by Cecilia Dhejne, Ph.D., in 2017.

16. Attached as **Exhibit L** is a true and correct copy of the article “Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden,” published in February 2011.

17. Attached as **Exhibit M** is a true and correct copy of the article “Long Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death,” published in March 2016.

18. Attached as **Exhibit N** is a true and correct copy of an excerpt from the Diagnostic and Statistical Manual of Mental Disorders, Version 5.

19. Attached as **Exhibit O** is a true and correct copy of an excerpt of the transcript of the deposition of Dan Karasic, M.D., taken on April 15, 2022, in relation to the above-captioned matter.

20. Attached as **Exhibit P** is a true and correct copy of Interqual Criteria Sheets for Gender-Confirming Surgeries (Hysterectomy and Phalloplasty) served on Plaintiffs on or about March 2022, in the above captioned matter.

21. Attached as **Exhibit Q** is a true and correct copy of the article “Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria,” published March 19, 2019.

22. Attached as **Exhibit R** is a true and correct copy of the article “Do Clinical Data

From Transgender Adolescents Support the Phenomenon of ‘Rapid-Onset Gender Dysphoria’?,” published in The Journal of Pediatrics in April 2022.

23. Attached as **Exhibit S** is Defendant’s Response to Plaintiff’s [sic] Second Set of Interrogatories to Defendants William Crouch, Cynthia Beane, and West Virginia Department of Health and Human Resources, Bureau For Medical Services, served on Plaintiffs on October 25, 2021, in the above captioned matter.

24. Attached as **Exhibit T** is a true and correct copy of an excerpt from the transcript of the deposition of Stephen Levine, M.D., on March 31, 2022, in relation to *B. P. J. v. W. Va. State Bd. of Educ.*, 550 F. Supp. 3d 347 (S.D.W. Va. 2021), which was entered as Exhibit 3 to Dr. Levine’s deposition in this matter on April 27, 2022.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 31st day of May 2022.



Carl S. Charles

Exhibit A

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EXPERT DISCLOSURE REPORT OF DR. STEPHEN B. LEVINE, M.D.

I. CREDENTIALS & SUMMARY OF OPINIONS

A. Academic and Clinical Activities

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 then became an Assistant Professor of Psychiatry at Case Western and became a Full Professor in 1985.

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' and couples' sexuality, 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. In 2021 I was placed in the Case Western Reserve University's Department of Psychiatry's Hall of Fame.

3. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of a gender 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 the World Professional Association for Transgender Health, or WPATH) and served as the Chairman of the committee that developed the 5th version of the *WPATH 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 continued to serve as Co-Director. It has subsequently been renamed the Gender Diversity Clinic.

4. I have been a visiting professor at Stanford University and St. Elizabeth's Hospital in Washington, D.C., as well a grand rounds presenter at various departments of psychiatry over many years. 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 other solo authored books, I authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender Revolution." I am a frequent reviewer of submitted papers to the *Archives Sexual Behavior*, *Journal of Sex & Marital Therapy*, and *Journal of Sexual Medicine*. I am an infrequent or occasional reviewer for 25 other journals in various medical specialties and psychological and sociologic journals on topics related to human sexuality. I have published 180 article and book chapters, nineteen of which focus on gender identity. A November 2021 publication, *Reflections on The Clinician's Role with Individuals Who Self-Identify as Transgender*, was published in the Archives of Sexual Behavior. Another publication, *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and*

Young Adults, which I am the lead author of, has been tentatively accepted for publication by the Journal of Sex & Marital Therapy awaiting minor changes.

5. I have received the following grants for scientific research and/or program development:

1. Twenty-three separate pharmaceutical company grants to study various pro-sexual medications;
2. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosus. Co-principal investigator; and
3. Five separate grants from the private Sihler Mental Health Foundation create the Program for Professionals which evaluated medical and religious leaders accused of sexual offenses; to establish a Center for Marital and Sexual Health; to create a placebo-controlled research study on Clomipramine for premature ejaculation; to create a follow-up study of clergy accused of sexual impropriety; and to establish a new clinical service for women with breast cancer.

6. Over the years I have lectured frequently to professional groups. During the previous two years, these lectures have included:

1. The Mental Health Professionals' Role with the Transgendered: Making the Controversies Clear, given to Grand Rounds at the University Hospitals of Cleveland on March 12, 2021;
2. Psychotherapeutic Approaches to Sexual Problems, an invited lecture to the American Psychiatric Association Annual Meeting on May 1, 2021 (similar lecture in May 2020);

3. Seven years of six-hour Continuing Education Courses at the American Psychiatric Association Meetings on Love and Sexuality;
4. Grand Rounds at Akron General Hospital on Clinical Considerations in Dealing with Transgender Identified Individuals October 28, 2021;
5. Grand Rounds at Cleveland Clinic Foundation on Sexuality Education of Psychiatric Residents on June 25, 2020;
6. Grand Rounds at Cleveland Clinic Foundation June 2019 Transgenderism: Beware! Repeated by invitation at Akron General Hospital and at National meeting of American Association of Behavioral Health in 2019 in Washington, DC;
7. Three-hour workshop at Society of Sex Therapy and Research in April 2020 on Therapy for Sexual Problems;
8. Workshop on “Let’s talk about sex!” at the American Association of Directors of Psychiatric Residency Training in March 2020 in Dallas, Texas;
9. Three-hour continuing education seminar with Massachusetts Department of Corrections Gender Identity Staff Fall 2019 in Foxboro, MA;
10. Four-hour workshop at Harvard Student Health Clinic in Boston on January 26, 2022;
11. Three one-hour lectures on Transgender Phenomena in June 2022 at Henry Ford Hospital Department of Psychiatry in Detroit; and
12. Semi-annual 2.5 hour lectures on the Ethical Prohibition against sex with patients at the Case Western Reserve University Department of Ethics seminars.

B. Expert Witness Testimony

7. 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”). In addition, I have given testimony in:

1. U.S. District Court for the Eastern District of Massachusetts, Judge Mark L. Wolf’s independent, court-appointed witness in *Michelle Kosilek vs. Massachusetts* of a transgender inmate within the Massachusetts prison system. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.
2. Deposition in the *Battista vs. Massachusetts Dept. of Corrections* case (transsexual issue) in Cleveland, October 2009;
3. Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in October 2018 in Cleveland and 2019 in Boston;
4. Witness for *State of Florida vs. Reyne Keohane*, July 2017;
5. Pennsylvania legislative testimony. Written submission and live testimony before a committee of the Pennsylvania legislature, March 2020 (Engaged by Pennsylvania Family Institute);
6. *In the Interests of the Younger Children*. Expert testimony by deposition and at trial in Dallas, TX. (Engaged by Texas counsel Odeneal & Odeneal) (Dallas Cty. Dist. Ct. 2019);

7. *Doe v. Madison Metropolitan School District*. Expert declaration submitted February 19, 2020, rebuttal declaration submitted August 14, 2020;
8. *Hecox v. Idaho*. Expert declaration submitted June 4, 2020. (D. Idaho);
9. *In the matter of Rhys & Lynn Crawford*. March 30, 2021, *Tingley v. Washington State* (W.D. Wa.);
10. *Bell v. The Tavistock & Portman NHS Foundation Trust* [2020] EWHC (Admin) 3274 [64] in High Court of London, Decision handed down on December 1, 2020. The High Court cited evidence I offered about how young people mature through adolescence.
11. In the High Court of Justice Queen's Bench Division administrative court. *The Queen (on the application of) L. and Hampshire County Council*;
12. *North Carolina, Kadal v. Folwell* (M.D.N.C)
13. *Hennessy-Waller v. Snyder*, Case No. CV-20-00335-TUC-SHR, 2021 WL 1192842, at *5-6 & n.10 (D. Ariz. Mar. 30, 2021). The District of Arizona relied on evidence I submitted regarding the guidelines for treating adolescents with gender dysphoria.

8. In addition to the above, I have been retained by the defense in this case to serve as an expert witness. My compensation is \$400 per hour. My compensation for depositions is \$500 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

9. 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**.

C. Summary of Opinions

10. Below is a key summary of my opinions in this case.

- The right to bodily autonomy via “gender-affirming” hormonal and surgical interventions should not be confused with medical necessity. An objective test for medical necessity of transgender interventions does not exist. The diagnosis is self-generated by the patient, and merely recorded by the clinician. The choice of interventions is granted based on a patient’s wish. In transgender healthcare, this is often wrongly equated with medical necessity.
- Medically necessary care should not be conflated with “gender-affirming” care. The latter has not been shown to result in significant lasting improvements in mental health or reduction in suicidality/suicide long-term. Multiple quality systematic reviews of evidence failed to show credible improvements. Claims that such care is highly effective come from studies that are methodologically weak and biased.
- There are significant risks of complications associated with gender-affirming hormonal and surgical interventions. The established risks include adverse effects on bone health, cardiovascular health, and fertility. There are many other risks that are just now emerging in the literature.
- There is a crisis of inadequate or absent mental health assessments prior to undergoing transition. Because of the unfortunate politicization of transgender healthcare, ethical mental health clinicians report intense pressure to confirm every gender-dysphoric patient as transgender, and to recommend gender-affirming treatments. There is also an entire industry of mental health clinicians, hormone prescribers, surgeons and even hospitals who have built lucrative lines of

business from scaling the costly “transgender healthcare” model. Females as young as 13 are treated with mastectomies based on perfunctory evaluations.

- The risks of providing on-demand “gender-affirming” interventions are going to be borne out disproportionately by youth and by vulnerable populations. While the Plaintiffs are mature adults, patients who most commonly seek gender-affirming interventions are teenagers and young adults, 2-10% of whom currently identify as transgender. The majority suffer from a heavy burden of mental illness. This marked epidemiologic shift occurred around 2014-2015 and remains poorly understood. The evidence of hormonal and surgical treatment regret among patients coming from this population is starting to mount.
- There is a range of treatments to ameliorate gender dysphoria, from non-invasive to highly invasive. Gender dysphoria has many causes, and many ways to ameliorate it. The narrative that “only hormones and surgeries work” dominating the US is both erroneous and motivated by considerations other than the long-term well-being of the patient. In contrast, a growing number of European nations are now prioritizing psychotherapy as the first line of treatment for gender-dysphoric young people.
- To determine whether West Virginia Medicaid and PEIA should be forced to categorically cover medical and surgical interventions for gender dysphoria, one will need to consider the balance of benefits and harms of such a decision. The potential benefits of reduced out-of-pocket burdens for mature adults must be carefully weighed against long-term health risks; risks of harming youth; and the significant cost implications to the already-strained system. It is my opinion that given

the current poor state of transgender healthcare, West Virginia should invest in a process that, at a minimum, assures safeguarding of vulnerable youth, before any change to the status quo is contemplated.

II. EXPERT TESTIMONY

A. My Assessment of the Plaintiff's Expert Witness Statements

11. I have reviewed the expert disclosure reports of the plaintiffs' experts that were submitted during discovery in this litigation. It is my educated opinion that these disclosures misrepresent the body of evidence regarding the safety and efficacy of hormonal and surgical interventions for gender dysphoria. The degree of misrepresentation varies from unduly focusing on weak unreliable studies that purport positive treatment results while ignoring problematic findings that come from more reliable high-quality studies, to outright misrepresenting the results of studies. Unfortunately, this type of biased promotion of the erroneous narrative of purportedly proven benefits of hormones and surgeries has become endemic in the field of transgender medicine.¹

12. I maintain that while well-meaning and sincere in their beliefs, their apparent clinical certainty simplifies the weighty issues involved. They do not know what happens to most of their patients over time; they do not know the error rates of their clinical decisions; they pay no

¹ Clayton A, Malone WJ, Clarke P, Mason J, D'Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adolesc Ment Health*. Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533

attention to the well-known medical, social, and psychological problems of adult trans communities as consistently reported in cross-sectional studies over the years.²

13. Medicine learns about the efficacy of its treatments by careful follow up of its patients. Long-term follow up, and quality studies demonstrating long-term efficacy of interventions in the area of transgender health are conspicuously lacking. Scientific commitment requires professionals to separate beliefs from what science has firmly established.

14. Unfortunately, the testimonies by the two expert witnesses for the Plaintiffs are guided by their individual and passionately-held beliefs regarding the benefits of hormones and surgeries, not by the best available evidence, which raises serious questions about the risk/benefit profile of these interventions.

15. The body of evidence shows a lack of long-term demonstrated efficacy, and points to a growing risk of harm and regret, especially among young patients who are now seeking these interventions in record numbers. It is with these vulnerable patients' long-term health and wellbeing in mind that I share the below.

B. Expert Witness Statement by Dr. Karasic.

16. In my review of the "Expert Disclosure Report of Dan H. Karasic, M.D.," dated January 14, 2022 ("Karasic"), I note that Dr. Karasic makes a variety of inaccurate and misleading statements. They range from inaccurate information about the nature of sex and gender dysphoria, to biased overviews of what is known about various therapies for gender dysphoria, to misrepresentations of outcomes of therapies—all with a strong bias toward pharmacological and

² Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

surgical interventions. In addition, Dr. Karasic makes a number of sweeping and purportedly scientific assertions without any references at all. Below are examples of Dr. Karasic's misinterpretations and misrepresentations of the state of evidence.

17. Dr. Karasic's testimony conflates sex and gender identity. Dr. Karasic states, "[a]side from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include...gender identity, and variations in brain structure and function."³ This directly contradicts a recent Scientific Statement by the Endocrine Society, which implores researchers to not conflate biological sex, which is binary and straightforward in over 99% of the cases, with the concept of gender identity, which can indeed represent a wide spectrum.⁴

18. Despite the increasing ability of hormones and various surgical procedures to re-configure 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 the assertions of certain members of the medical community, the aspiration of some trans individuals to become "a complete man" or "a complete woman" is not biologically attainable.^{5 6} It is possible for some individuals to "pass" unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks.

³ Karasic, p.5, para 20

⁴ Bhargava A, et al. Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. *Endocrine Reviews*, Volume 42, Issue 3, June 2021, Pages 219–258, <https://doi.org/10.1210/endrev/bnaa034>.

⁵ Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

⁶ Levine SB. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

19. The binary nature of sex (with extremely rare exceptions known as Differences of Sexual Development /DSD or “intersex disorders”⁷) in no way invalidates one’s subjective sense of a discordant gender identity. The push toward conflation of sex and gender identity is largely a politically-motivated move, which does a disservice to science, and which can cause direct medical harm to the patient.^{8 9}

20. Dr. Karasic misrepresents treatment recommendations from an advocacy organization as scientific facts. In his witness statement, Dr. Karasic regards treatment recommendations issued by the advocacy organization *The World Professional Association of Transgender Health* (WPATH) as “authoritative protocols.” WPATH’s core mission, since its inception, has been to destigmatize transgender identities and to advocate for easy access and broad insurance coverage for transgender-related procedures.¹⁰ WPATH guidelines, entitled “Standards of Care” (SOC), do favor medicalized approaches to the management of gender dysphoria. While these guidelines have been influential in years past, they are increasingly coming under scrutiny, with a growing list of countries abandoning their use.

21. A recently published systematic review found the current WPATH SOC7 guidelines to be of very low quality and unfit tools for clinical decision-making, noting “incoherence”

⁷ Lee PA, Houk CP, Ahmed SF, Hughes IA, in collaboration with the participants in the International Consensus Conference on Intersex organized by the Lawson Wilkins Pediatric Endocrine Society and the European Society for Paediatric Endocrinology. Consensus Statement on Management of Intersex Disorders. *PEDIATRICS*. 2006;118(2):e488-e500. doi:10.1542/peds.2006-0738

⁸ Stroumsa D, Roberts EFS, Kinnear H, Harris LH. The Power and Limits of Classification — A 32-Year-Old Man with Abdominal Pain. *N Engl J Med*. 2019;380(20):1885-1888. doi:10.1056/NEJMp1811491

⁹ Whitley CT, Greene DN. Transgender Man Being Evaluated for a Kidney Transplant. *Clinical Chemistry*. 2017;63(11):1680-1683. doi:10.1373/clinchem.2016.268839

¹⁰ Fraser L. Psychotherapy in the World Professional Association for Transgender Health’s *Standards of Care* : Background and Recommendations. *International Journal of Transgenderism*. 2009;11(2):110-126. doi:10.1080/15532730903008057

within the recommendations.¹¹ (A similar low-quality assessment was given to the Endocrine Society guidelines, which Dr. Karasic refers to, and which, incidentally, has been co-authored by many of the several of the same authors as SOC7).

22. A newly released draft of the upcoming SOC8 version of the guidelines appears to continue to suffer from a number of serious methodological problems that will limit its clinical use.¹² It is perhaps not surprising that a growing number of countries are deviating from WPATH and Endocrine Society guidelines and are developing their own treatment guidelines that prioritize psychological treatments for youth. They include such pioneers in gender-affirming care as Sweden, Finland, and the UK.^{13 14 15}

23. As the Co-Chair of WPATH SOC5 Committee, I have had first-hand experience with the organization and its evolution toward its current state of advocacy at the expense of rigorous science. I will detail my experiences in separate section of this document. My experience appears to be consistent with that of the incoming president of WPATH, a transgender woman and surgeon, Dr. Bowers, who recently admitted that activism within WPATH has taken over science, and that, within WPATH, any deviation from the hormonal and surgical “gender-affirming” treatment model is currently not tolerated: “There are definitely people [in WPATH] who are trying to keep out anyone who doesn’t absolutely buy the party line that everything should be

¹¹ Dahlen S, Connolly D, Arif I, Junejo MH, Bewley S, Meads C. International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment. *BMJOpen*. 2021;11(4):e048943. doi:10.1136/bmjopen-2021-048943

¹² Society for Evidence-Based Gender Medicine. *WPATH SOC8 Draft Guideline*, Jan. 16, 2022, https://segm.org/draft_SOC8_lacks_methodological_rigor

¹³ Society for Evidence-Based Gender Medicine. *One Year Since Finland Broke with WPATH “Standards of Care,”* July 2, 2021, https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors

¹⁴ Society for Evidence-Based Gender Medicine. *Sweden’s Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies*, May 5, 2021, https://segm.org/Sweden_ends_use_of_Dutch_protocol

¹⁵ Cass Review, Independent Review of Gender Identity Services for Children and Young People, *About the Review*, <https://cass.independent-review.uk/about-the-review/>

affirming, and that there's no room for dissent.”¹⁶ Can an organization with such a stance legitimately represent itself as a scientific organization, or be relied upon to issue unbiased, science-based information to inform the care of gender dysphoric individuals?

24. Of note, in 2016, Health and Human Services (HHS) came under significant pressure from activists to adopt the WPATH “Standards of Care” as the prevailing guideline for determining medical necessity considerations for gender-affirming surgeries. After conducting a thorough evaluation of the evidence, the HHS refused, explaining their opinions in this way: “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.”¹⁷ More generally, in that same Decision Memo, the HHS refused to mandate coverage for transgender surgeries, leaving it up to the individual states to decide, due to lack of evidence of long-term benefits.

25. Dr. Karasic incorrectly asserts that gender-affirming treatments for gender dysphoria are “highly effective.”¹⁸ In his expert witness testimony, Dr. Karasic states that hormonal and surgical treatments for gender dysphoria are “highly effective,” suggesting that an expected

¹⁶ Abigail Shrier, *Top Trans Doctors Blow the Whistle on ‘Sloppy’ Care*, Oct. 4, 2021, <https://bari-weiss.substack.com/p/top-trans-doctors-blow-the-whistle>

¹⁷ Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) :109. “WPATH Standards of Care” p. 41. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>

¹⁸ Karasic, p.9, para 31

outcome of such treatments is “significant or potentially complete relief.”¹⁹ However, the most generous way to describe the state of evidence regarding the efficacy of hormonal and surgical interventions is “mixed,” and more accurately, lacking any evidence of lasting long-term improvements in psychological functioning.

26. There are indeed a number of studies that show positive results, but such studies are typically short-term and suffer from significant methodological limitations. For example, several such studies that have made recent headlines in the US rely on the same large online panel of respondents recruited by politically active organizations promoting transgender rights.²⁰

²¹ ²² The problems with those studies have been widely recognized.²³ ²⁴ ²⁵

27. In contrast, long-term studies from quality samples, as well as independent systematic reviews that synthesize and evaluate the entire body of evidence, rather than being swayed by individual studies, nearly universally conclude that the benefits of hormonal and surgical interventions are of very low certainty. For example, two recent systematic reviews of evidence for hormonal interventions for youth conducted by the UK National Institute for Health

¹⁹ Karasic, p.1, para 39

²⁰ Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. 2020;145(2):e20191725. doi:10.1542/peds.2019-1725

²¹ Turban JL, Beckwith N, Reisner SL, Keuroghlian AS. Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults. *JAMA Psychiatry*. 2020;77(1):68. doi:10.1001/jamapsychiatry.2019.2285

²² James, S. E., Herman, J. L., 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

²³ Biggs M. Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Arch Sex Behav*. 2020;49(7):2227-2229. doi:10.1007/s10508-020-01743-6

²⁴ D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. Published online October 21, 2020. doi:10.1007/s10508-020-01844-2

²⁵ Biggs, Michael (2022): Comment on Turban et al. 2022: Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex. figshare. Journal contribution. <https://doi.org/10.6084/m9.figshare.19018868.v1>

and Care Quality (NICE), which is tasked with evaluating the efficacy of all treatments provided by UK's publicly-funded National Health Service (NHS), found both puberty blockers and cross-sex hormonal treatments for youth to be of questionable benefit. They concluded that the reported benefits come from "small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty."^{26 27} In this context, the "very low certainty" designation means that even when a study reports positive results, there is a high likelihood that patients will not experience the benefits of the proposed interventions outside of the study settings, in the real world.²⁸ Similar conclusions of very low certainty of benefits have been reached by a number of other independent systematic reviews of evidence both in the US and internationally.^{29 30 31}

28. The results of independent evidence reviews by agencies responsible for ensuring equitable access to high quality healthcare and prudent use of scarce healthcare resources, stand

²⁶ National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>

²⁷ National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, p. 14. 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>

²⁸ Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology*. 2011;64(4):401-406. doi:10.1016/j.jclinepi.2010.07.015

²⁹ Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

³⁰ Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>

³¹ Gender affirmation surgery for gender dysphoria - effects and risks: Health Technology Assessment review 2018. Swedish Health Authority. Published online 2018. https://alfresco-offentlig.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/441006af-62a7-4f19-be73-6d698bf635f5/2018_102%20Rapport%20K%C3%B6nsdysfori.pdf?a=false&guest=true&fbclid=IwAR2_BBIVfFBKok9XZ7JiTXfwOfT-gcCXIzAySkh6wIXUJK8s_L_8XZy-tdIA

in sharp contrast to systematic reviews of evidence commissioned and paid for by WPATH, which Dr. Karasic prefers to rely upon. These advocacy-driven reviews also accept that the quality of the evidence is low, but paradoxically conclude *with confidence* that hormonal and surgical treatments produce desired and lasting results.³² The problems with activism-driven research and conflicts of interest influencing research outcomes have become endemic in the field of gender medicine.³³

29. Dr. Karasic misrepresents what is known about the connection between gender-affirming treatments and suicide. Dr. Karasic makes a bold claim that failure to obtain gender-affirming medical and surgical interventions puts patients at heightened risk suicidality.³⁴ This assertion is directly contradicted by a key longitudinal study that examined this very question.³⁵
³⁶ The study, which utilized Sweden’s entire health registry, accounted for every patient ever treated, and followed patients over a 10-year time period, found that gender-dysphoric patients who took hormones and underwent surgeries did not fare any better in the long-term than similarly gender-dysphoric patients who did not obtain these interventions. Specifically, there was no difference in the rates of ongoing levels of mental illness and no difference in the rates of serious suicide attempts. In fact, the “surgery” group had nearly twice as many suicide attempts than the group that did not receive surgery, although the difference did not reach statistical significance.³⁷

³² Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. *Journal of the Endocrine Society*. 2021;5(4):bvab011. doi:10.1210/jendso/bvab011

³³ Society for Evidence-Based Gender Medicine, *The Signal—and the Noise—in the Field of Gender Medicine*, Jan. 31, 2022, https://segm.org/flawed_systematic_review_puberty_blockers

³⁴ Karasic, p.1; p.8, para 28.

³⁵ Bränström R, Pachankis JE. Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study. *AJP*. 2020;177(8):727-734. doi:10.1176/appi.ajp.2019.19010080

³⁶ Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction

³⁷ Society for Evidence-Based Gender Medicine, *Correction of a Key Study: No Evidence of “Gender-Affirming” Surgeries Improving Mental Health*, Aug. 30, 2020, https://segm.org/ajp_correction_2020

30. Instead of reflecting on the findings (or lack thereof) of this very prominent study, Dr. Karasic instead relies on a much lower quality study which did not include long-term follow-up, accounted for only 33% of the patients treated (compared to the 100% in the above-referenced study), and did not even attempt to evaluate suicidality.³⁸

31. It is of note that the suicidality argument has been extensively misused by the proponents of rapid medicalization of gender-dysphoric individuals, and particularly minors, with the dark and emotive narrative of a choice between a “dead son or a live daughter.” The rates of suicide attempts and completed suicide are significantly elevated in transgender-identifying patients compared to the general population. However, it is well-established that suicides are complex events and can rarely be attributed to a single cause.

32. The rate of death by suicide in gender dysphoric youth in the UK has recently been estimated to be 0.03% over a 10-year period.³⁹ The rate of suicides for transgender adults in Sweden is estimated to be 0.6% over a 20-year period.⁴⁰ A key longitudinal study from the Netherlands found that suicides occur at similar rates during all stages of transition, from the time the individual is placed on a wait list, and through decades following the final surgery.⁴¹ This latter fact is the key reason why mental health treatments should be applauded by psychiatrists such as Dr. Karasic, rather than dismissed as ineffective or even stigmatized as unethical.

³⁸ Owen-Smith AA, Gerth J, Sineath RC, et al. Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals. *The Journal of Sexual Medicine*. 2018;15(4):591-600. doi:10.1016/j.jsxm.2018.01.017

³⁹ Biggs M. Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Arch Sex Behav*. Published online January 18, 2022. doi:10.1007/s10508-022-02287-7

⁴⁰ Socialstyrelsen [National Board of Health and Welfare]. *Utvecklingen Av Diagnosen Könsdysfori [The Evolution of the Diagnosis of Gender Dysphoria]*. Socialstyrelsen [Swedish Health Authority]; 2020. Accessed October 29, 2020. <https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/vanligt-med-flera-psykiatriska-diagnoser-hos-personer-med-konsdysfori/>

⁴¹ Wiepjes CM, den Heijer M, Bremmer MA, et al. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017). *Acta Psychiatr Scand*. 2020;141(6):486-491. doi:10.1111/acps.13164

33. Dr. Karasic conflates “medically indicated care” with affirmation and misrepresents the role of mental health services in treatment gender-dysphoric individuals as ineffective and unethical. Dr. Karasic asserts that “medically-indicated care” is “aligning an individual patient’s body and presentation with their internal sense of self.”⁴² He asserts that other than gender-affirming hormones and surgeries, “no alternative treatments have been demonstrated to be effective.” He further goes on to state, “gender identity change efforts provide no benefit and instead do harm.”⁴³ Presumably, with these two statements, Dr. Karasic attempts to put to bed the vigorous ongoing debate in the scientific community about how to best care for the exponential and poorly understood rise in trans identifications in youth. Even the authors of the seminal study that gave rise to the practice of pediatric medical and surgical gender transition worldwide, known as the “Dutch Study,” recently conceded the difficulty in determining “who will benefit from medical gender affirmation and for whom ... mental health support might be more appropriate.”⁴⁴

34. It is a well-established fact that in both adult and pediatric populations of gender dysphoric individuals, the prevalence of co-occurring mental illness is extremely high.⁴⁵ According to a comprehensive data source from a major US-based health system, Kaiser Permanente, over 70% of gender-dysphoric youth suffer from comorbid mental health issues, and in the majority of these cases the mental health issues predated the onset of gender dysphoria.⁴⁶

⁴² Karasic, p.8., para 28.

⁴³ Karasic, para 29, p 9.

⁴⁴ de Vries ALC. Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents. *Pediatrics*. 2020;146(4):e2020010611. doi:10.1542/peds.2020-010611

⁴⁵ Hanna B, Desai R, Parekh T, Guirguis E, Kumar G, Sachdeva R. Psychiatric disorders in the U.S. transgender population. *Ann Epidemiol*. 2019;39:1-7.e1. doi:10.1016/j.annepidem.2019.09.009

⁴⁶ Becerra-Culqui TA, Liu Y, Nash R, et al. Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers. *Pediatrics*. 2018;141(5):e20173845. doi:10.1542/peds.2017-3845

35. While scientists may never fully agree to what extent the high burden of mental illness is the result versus the cause of one's transgender identification, there is little doubt that vulnerable individuals considering embarking on a life-long pursuit of medical interventions need extensive psychological evaluations and support, and their mental health conditions need to be appropriately treated.

36. Recently-released guidance from a professional psychiatry association adopted the position that extensive psychotherapeutic support should be the first line of treatment for gender-dysphoric individuals and especially minors, stating: "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people. It is important to understand the different factors, complexities, theories, and research relating to Gender Dysphoria."⁴⁷ A set of guidelines released by Finland, a key pioneer in pediatric gender transition, recently reversed course and now states that psychotherapy, rather than hormones and surgeries, should be the first line of treatment for gender-dysphoric youth.⁴⁸

⁴⁷ The Royal Australian & New Zealand College of Psychiatrists, *Recognising and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence*, Aug. 2021, <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria>

⁴⁸ Society for Evidence-Based Gender Medicine, *One Year Since Finland Broke with WPATH "Standards of Care,"* July 2, 2021, https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors

37. In a growing number of instances, especially among gender-dysphoric youth, proper therapeutic exploration has led to a resolution of gender dysphoria.^{49 50 51 52 53} It is true that quality evidence proving long-term effectiveness of psychotherapy interventions is missing—just as they are lacking for the hormonal and surgical interventions. However, Dr. Karasic’s attempts to stigmatize gender-exploratory psychotherapy as “gender identity change efforts,”⁵⁴ or to stigmatize as “unethical” appear to be politically motivated to maintain his beliefs with little concern for the patient’s long-term outcomes in mind. Such efforts will only serve to limit access to quality healthcare for the already struggling and vulnerable group of gender dysphoric patients.⁵⁵

38. Dr. Karasic inaccurately portrays what is known – and not known—about treatment regret. Dr. Karasic claims with certainty that regret for transgender-related procedures is extremely low. To support his assertion, he points to several sources, not the least of which is a

⁴⁹ Schwartz D. Clinical and Ethical Considerations in the Treatment of Gender Dysphoric Children and Adolescents: When Doing Less Is Helping More. *Journal of Infant, Child, and Adolescent Psychotherapy*. Published online November 22, 2021;1-11. doi:10.1080/15289168.2021.1997344

⁵⁰ Spiliadis A. Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development. *Metalogos Systemic Therapy Journal*. 2019;35:1-9.

https://www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI/Other/Rebekah_Murphy_TowardsGenderExploratoryModelslowingthingsdownopeningthingsupandexploringidentitydevelopment.pdf

⁵¹ Bonfatto M, Crasnow E. Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service. *Journal of Child Psychotherapy*. 2018;44(1):29-46. doi:10.1080/0075417X.2018.1443150

⁵² Churcher Clarke A, Spiliadis A. ‘Taking the lid off the box’: The value of extended clinical assessment for adolescents presenting with gender identity difficulties. *Clin Child Psychol Psychiatry*. 2019;24(2):338-352. doi:10.1177/1359104518825288

⁵³ Lemma A. Trans-itory identities: some psychoanalytic reflections on transgender identities. *The International Journal of Psychoanalysis*. 2018;99(5):1089-1106. doi:10.1080/00207578.2018.1489710

⁵⁴ Karasic, p.9, para 29

⁵⁵ D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav*. Published online October 21, 2020. doi:10.1007/s10508-020-01844-2

seminal study in the field of pediatric gender medicine, which is known as the “Dutch Study,” and which serves as the key pillar for the practice of pediatric gender transition.⁵⁶

39. In describing the outcomes of the Dutch study, Dr. Karasic states, “none of the youth who received puberty blockers, hormones, and surgery, and followed over an 8-year period expressed regret”.⁵⁷ What Dr. Karasic’s assessment fails to reveal is that this “low regret” statistic excludes 4 patients (6% of the initial sample of 70) who were severely harmed by the treatment; they were merely dropped from the study’s conclusions. This includes 1 death of a young person from surgical complications, and 3 cases of adolescents who developed new-onset obesity and diabetes in the course of being treated with hormones. Several more youths refused to engage with the researchers when they were contacted, leading to more questions.

40. Nor does Dr. Karasic accurately report the length of the study follow-up: rather than 8 years, these outcomes were assessed merely 1.5 years after the final phase of the treatment was completed. It is well-known in transgender research that regret takes approximately 10 years after the completion of procedures to materialize.⁵⁸

41. Dr. Karasic also fails to reflect on the extensive vetting that the patients in the study from the Netherlands received, and how different the process of gender transition in the US is conducted. Most of the cases of gender dysphoria presenting with a wish for sex reassignment today are adolescents, many of whom came to identify as transgender first time after puberty,

⁵⁶ de Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*. 2014;134(4):696-704. doi:10.1542/peds.2013-2958

⁵⁷ Karasic, para 42, p12.

⁵⁸ Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. *The Journal of Sexual Medicine*. 2018;15(4):582-590. doi:10.1016/j.jsxm.2018.01.016

with no history of childhood gender incongruence.^{59 60} Such cases were explicitly disqualified by the Dutch protocol as having high potential for being a “false positive” and leading to future regret.⁶¹

42. To assert low regret rates, Dr. Karasic also leans heavily on a “pooled review.” The profound limitations of this poor-quality, error-ridden review, conducted by a group of surgeons, rather than evidence evaluation experts, have been outlined in a recent publication.⁶² In addition to been plagued by significant errors, such is misstating sample sizes of the included studies, and inaccurately categorizing the interventions received by the patients, the review suffers from a number of other limitations.

43. For example, the definition of “regret” in the reviewed studies is very narrow. To be considered a “regretter,” an individual had to change legal sex markers, reverse surgeries, or start hormonal interventions to revert the body to the original state.^{63 64} However, few individuals know how to successfully navigate complex legal matters, and even fewer can afford to undergo reversal procedures, either due to financial limitations, or the physical impossibility to reverse surgeries. Regret in ordinary lives, let alone trans lives, is far more complicated, nuanced, conflictual, and often increases over time as the results of an experience is appreciated.

⁵⁹ Kaltiala-Heino R, Sumia M, Työläjäarvi M, Lindberg N. Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child Adolesc Psychiatry Ment Health*. 2015;9(1):9. doi:10.1186/s13034-015-0042-y

⁶⁰ Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

⁶¹ Levine et al., (in press). Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults. *Journal of Sex & Marital Therapy*.

⁶² Expósito-Campos P, D’Angelo R. Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and Reconstructive Surgery - Global Open*. 2021;9(11):e3951. doi:10.1097/GOX.0000000000003951

⁶³ Karasic, para 43, p12.

⁶⁴ Bustos VP, Bustos SS, Mascaro A, et al. Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and Reconstructive Surgery - Global Open*. 2021;9(3):e3477. doi:10.1097/GOX.0000000000003477

44. Additionally, the studies evaluated the outcomes of highly selected populations of patients who had to be approved for gender-transition following extensive psychiatric evaluations—a process that transgender rights advocates have decried as discriminatory, and which has been largely abandoned in the US. However, even these older studies likely significantly underestimate true rate of regret. They routinely lose to follow-up 30%-40% of individuals; those who drop out of care are more likely to be adversely affected.⁶⁵

45. More pertinent to the current situation at hand, the recent relaxation of criteria for eligibility for these interventions appears to have created a growing number of regretters in the last several years—or at the very least, individuals who wish to stop gender-affirming treatments and reverse their effects. Two recent studies from the UK, a country that still maintains that some psychological evaluations, albeit abbreviated ones, are necessary, estimated that the rate of de-transition is approximately 10% after a short period of time, and an even higher rate of dropping out of care for unknown reasons.^{66 67} Two other recent studies of detransitioners—individuals who underwent medical transition and later stopped or reversed transgender interventions—revealed that they felt rushed into transition, that their self-identification as transgender was a mistaken attribution of their generalized distress, same-sex attraction, or a myriad of other factors that were not properly explored.^{68 69}

⁶⁵ D’Angelo R. Psychiatry’s ethical involvement in gender-affirming care. *Australas Psychiatry*. 2018;26(5):460-463. doi:10.1177/1039856218775216

⁶⁶ Boyd I, Hackett T, Bewley S. Care of Transgender Patients: A General Practice Quality Improvement Approach. *Healthcare*. 2022;10(1):121. doi:10.3390/healthcare10010121

⁶⁷ Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: retrospective case-note review. *BJPsych open*. 2021;7(6):e184. doi:10.1192/bjo.2021.1022

⁶⁸ Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

⁶⁹ Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

46. Three-quarters of them did not return to the doctors who recommended or administered gender-affirmative interventions to tell them about detransition.⁷⁰ This highlights that individual clinician experiences of low regret, such as the ones reported by Dr. Karasic, need to be balanced with an objective and rigorous outcomes analysis, which is sorely lacking.

47. Dr. Karasic fails to acknowledge the ongoing vigorous scientific debate in the scientific community. It appears that Dr. Karasic believes that a widespread scientific consensus regarding the safety and efficacy of gender-affirming interventions exists. While it is true that many US-based medical societies either do not oppose or even endorse these interventions, this should not be mistaken for scientific consensus—nor should it be forgotten that US medical societies have quite a history of endorsing interventions at one point, only to retract their positions later. While the lobotomy example, with major medical societies endorsing the procedure, is often cited, a much more recent example with the opioid treatment guidelines is readily available. To quote the incoming president of WPATH who reflected on the state transgender care in the US, “This is typical of medicine. We zig and then we zag, and I think maybe we zigged a little too far to the left...”⁷¹

48. There have been over 50 recent publications in peer-reviewed journals questioning the approach to care for gender dysphoric youth.⁷² Key international pioneers of medical transition, from Sweden to Finland to the UK, in the last 48 months have recognized the profound lack of evidence that these interventions lead to long-term improvements and have also

⁷⁰ See Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

⁷¹ Abigail Shrier, *Top Trans Doctors Blow the Whistle on ‘Sloppy’ Care*, Oct. 4, 2021, <https://bari-weiss.substack.com/p/top-trans-doctors-blow-the-whistle>

⁷² Society for Evidence-Based Gender Medicine, *B. Scientists Debate Medical Affirmation of Minors*, <https://segm.org/studies> (literature listing)

noted growing evidence that they can result in harm. As a result, these health systems are now deviating from the gender-affirmative model and are prioritizing psychological interventions for young people presenting with gender dysphoria.

49. The Karolinska Hospital, which is the home of the Nobel Prize for Medicine, announced in May that they will cease all medical transitions for those under 18 in general medical practice, only allowing them in strictly controlled clinical trial settings.

50. The situation is starting to shift in the US as well, as concerned clinicians, and even the leaders of WPATH are calling into question the irresponsible promotion of the medicalization model for minors.^{73 74 75} Remarkably, WPATH issued a public statement reprimanding these professional for speaking out.⁷⁶

51. Improper analysis of financial impact. Finally, Dr. Karasic rushes to assure that the cost of providing transgender interventions is exceedingly low. However, these assertions seem questionable. For example, treatment with puberty blockers can cost \$6,000-\$40,000 per year per child.⁷⁷ The cost of cross-sex hormones is lower, but these costs are greatly amplified by the life-long nature of hormonal supplementation. The cost of surgeries, re-operations, and occa-

⁷³ Anderson, E., Edwards-Leeper, L. (2021, November 24). The mental health establishment is failing trans kids. *Washington Post*. Accessed December 20, 2021 <https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/>

⁷⁴ Anderson, E. (2022, January 3). Opinion: When it comes to trans youth, we're in danger of losing our way. *The San Francisco Examiner*. Accessed January 5th, 2022

<http://www.sfexaminer.com/opinion/are-we-seeing-a-phenomenon-of-trans-youth-social-contagion/>

⁷⁵ Malone, W. J., Hruz, P. W., Mason, J. W., & Beck, S. (2021). Letter to the Editor from William J. Malone et al: "Proper Care of Transgender and Gender-diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective." *Journal of Clinical Endocrinology and Metabolism*, 106(8), e3287–e3288. <https://doi.org/10.1210/clinem/dgab205>

⁷⁶ <https://www.wpath.org/media/cms/Documents/Public%20Policies/2021/Joint%20WPATH%20USPATH%20Letter%20Dated%20Oct%2012%202021.pdf>

⁷⁷ <https://www.legacyhealth.org/-/media/Files/PDF/Services/Children/Transgender-Services/Re-sources/PUBERTAL-SUPPRESSION-MEDICATION-COVERAGE.pdf>

sional requests to reverse the surgeries for those who regret the interventions, are in tens to hundreds of thousands of dollars, with some cases reaching into the millions.⁷⁸ The costs of treating side-effects of the treatments, such as the well-documented increase in cardiovascular complications, or the increasing evidence that bone health may be compromised long-term when such treatments are started in adolescence, also has to be factored in.^{79 80 81 82}

52. Last but not least, the costs of fertility preservations must be factored in. Adults undergoing cross-sex hormonal or surgical intervention have either diminished or lost fertility.⁸³ Children treated with puberty blockers followed by cross-sex-hormones are expected to be sterile.⁸⁴ This has given rise to an industry of fertility preservation for this population. Few children can comprehend the loss of future fertility, and as of today very few pursue these offers.⁸⁵ However, as these treatments continue to gain momentum, fertility preservation, including novel techniques of extracting immature eggs of young females and maturing them in vitro, are expected to

⁷⁸ <https://www.newsweek.com/we-need-balance-when-it-comes-gender-dysphoric-kids-i-would-know-opinion-1567277>

⁷⁹ Alzahrani T, Nguyen T, Ryan A, et al. Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population. *Circ: Cardiovascular Quality and Outcomes*. 2019;12(4). doi:10.1161/CIRCOUTCOMES.119.005597

⁸⁰ Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons. *Ann Intern Med*. 2018;169(4):205-213. doi:10.7326/M17-2785

⁸¹ 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*. 2015;100(2):E270-E275. doi:10.1210/jc.2014-2439

⁸² Biggs M. Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria. *J Pediatr Endocrinol Metab*. 2021;34(7):937-939. doi:10.1515/jpem-2021-0180

⁸³ Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. *Transl Androl Urol*. 2019;8(3):209-218. doi:10.21037/tau.2019.05.09

⁸⁴ 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.” *J Clin Endocrinol Metab*. 2019;104(3):686-687. doi:10.1210/jc.2018-01925

⁸⁵ Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility Preservation Utilization Among Transgender Youth. *J Adolesc Health*. 2017;61(1):40-44. doi:10.1016/j.jadohealth.2016.12.012

gain momentum.⁸⁶ In addition, requests for reversal of such procedures are expected to increase, and therefore must be factored into the final financial impact estimate.

53. These costs have to be considered in the context of the rapid rise in the rate of transgender identification, especially among youth. While Dr. Karasic estimates the prevalence of transgender identification to be 0.5%, recent studies of youth suggest it ranges from 2% to 9%.^{87 88} Although not all of trans-identifying individuals will choose to undergo medical interventions, the majority do, and this proportion will only increase when such interventions are provided at no cost to the patient, and when access to non-invasive treatments with psychotherapy is effectively curbed as “unethical.”

54. The data already show that the numbers of individuals seeking transgender interventions on West Virginia Medicaid increased from 30 individuals in 2016, to 686 individuals through the end of September in 2021, a 2,300% increase in less than 5 years. Applying the upper bound of the current estimate of 9% trans-identification, as many as 30,000 West Virginia youth could be identifying as transgender, and an unknown number of them could be pursuing hormonal and surgical interventions in the future.

55. A proper economic analysis associated with the cost of providing gender-affirming interventions by West Virginia Medicaid and PEIA needs to be conducted before the asser-

⁸⁶ Mattawanon N, Spencer JB, Schirmer DA, Tangpricha V. Fertility preservation options in transgender people: A review. *Rev Endocr Metab Disord*. 2018;19(3):231-242. doi:10.1007/s11154-018-9462-3

⁸⁷ Kidd KM, Sequeira GM, Douglas C, et al. Prevalence of Gender-Diverse Youth in an Urban School District. *Pediatrics*. 2021;147(6):e2020049823. doi:10.1542/peds.2020-049823

⁸⁸ 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(3):67-71. doi:10.15585/mmwr.mm6803a3

tions of negligible costs, which are boldly made by Dr. Karasic, are accepted. Whatever the impressive skills of individual physicians maybe, economic analysis is not one of them. This includes myself. Others must be relied upon to answer the question.

56. Dr. Karasic is neither neutral nor logical in his assertions, betraying the mindset of an activist, rather than a dispassionate clinician pursuing evidence. Dr. Karasic makes a number of sweeping statements that are self-contradictory. He acknowledges that “gender dysphoria [sic](uncapitalized) is distress related to the incongruence between one’s gender identity and attributes related to one’s sex...”⁸⁹ yet characterizes the role of mental health services to aid in the amelioration of gender dysphoria as conversion efforts that are unethical.⁹⁰ In all other areas of medicine treating distress with psychotherapy (alone or in conjunction with other interventions) is the standard treatment approach. He states that having gender dysphoria “is widely accepted as a variation in human development” and not a disorder,⁹¹ yet asserts that the state of West Virginia should provide extensive medical and surgical interventions to treat this condition.

57. Dr. Karasic must pick a side: is gender dysphoria an illness that needs treatments, or is it a normal variation of human diversity with no significant inherent disadvantages, which needs no intervention? If treatments are needed, then why would one set of treatments, namely, hormones and surgeries, which carries a heavy continuing medical burden, be widely offered and privileged by being excused from having to demonstrate long-term safety and efficacy as is required in all other areas of medicine. Why should another set of treatments, namely psychological, which are non-invasive and a commonly-accepted approach to treating all other forms of distress, be labeled as “unethical”? Such contradictions abound the highly politicized field of

⁸⁹ Karasic, para 22, p.6

⁹⁰ Karasic, para 21, p.6

⁹¹ Karasic, para 27, p.7

transgender medicine, where a mere acknowledgement that the majority of gender-dysphoric people suffer from mental illness is either positioned as transphobic or is dismissed as merely resulting from the stress of being a minority. The reality is much more complex.

58. I am also concerned by Dr. Karasic’s apparent attempts to silence scientific debate. For example, in 2017, Dr. Karasic⁹² attempted to suppress the presentation of a key research paper at a scientific conference.⁹³ The research paper in question noted a sharp rise in trans identification among adolescent females with no childhood history of gender dysphoria and urged more research.⁹⁴

59. The dramatic increase in the incidence of youths declaring a transgender identity in the last several years, and a marked demographic shift toward adolescent females seeking gender reassignment, described by the “offending” paper, has since been recognized by every pediatric gender clinic in the world.^{95 96 97} In fact, this profound epidemiologic shift, and the lack of understanding of its etiology and appropriate interventions, is one of the key reasons why leading pediatric gender clinics throughout the world are currently changing their treatment guidelines toward much more caution—an approach that Dr. Karasic equates to “opposing trans care.”

⁹² Alliance Health Project, University of California San Francisco. *Activist Psychiatrist Dan Karasic, MD Retiring*, June 11, 2020, <https://alliancehealthproject.ucsf.edu/blog/activist-psychiatrist-dan-karasic-md-retiring>

⁹³ Brie, J. 4thWaveNow, WPATH & The Advocate aim to suppress new research on adolescent gender dysphoria, Feb. 25, 2018, <https://4thwavenow.com/2018/02/25/wpath-the-advocate-aim-to-suppress-new-research-on-adolescent-gender-dysphoria/>

⁹⁴ Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. Romer D, ed. *PLoS ONE*. 2018;13(8):e0202330. doi:10.1371/journal.pone.0202330

⁹⁵ de Graaf NM, Giovanardi G, Zitz C, Carmichael P. Sex Ratio in Children and Adolescents Referred to the Gender Identity Development Service in the UK (2009–2016). *Arch Sex Behav*. 2018;47(5):1301-1304. doi:10.1007/s10508-018-1204-9

⁹⁶ Kaltiala-Heino R, Bergman H, Työlajärvi M, Frisen L. Gender dysphoria in adolescence: current perspectives. *AHMT*. 2018;Volume 9:31-41. doi:10.2147/AHMT.S135432

⁹⁷ Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

60. Dr. Karasic was not alone in attempting to suppress this research—pressured by other activists, the journal editors subjected the paper to a rarely conducted second peer review post-publication, following which the research was vindicated and republished with no substantive changes to its findings and conclusions.⁹⁸ Unfortunately, such politicization of research in the area of transgender medicine has become common. It is quite possible that such advocacy will hurt the very people these actions intend to protect—gender-dysphoric individuals in general, and vulnerable LGBT youth in particular.

61. Dr. Karasic’s former employer characterizes him as an “activist psychiatrist.”⁹⁹ While his activism for transgender rights is admirable, mixing politics and clinical matters creates a dangerous combination. I maintain that Dr. Karasic’s “expert opinion” submission should be viewed as that of an ardent advocate of transgender rights and body autonomy. However, the submitted opinion is demonstrably biased and lacks the scientific rigor and credibility to be used as an expert opinion in determining whether these interventions are safe, effective, and medically necessary.

C. Expert Witness Statement by Dr. Schechter.

62. I have also reviewed the “Expert Disclosure Report of Loren S. Schechter, M.D.,” dated January 14, 2022 (“Schechter”). Dr. Schechter appears to be highly qualified to perform various types of plastic surgery procedures (from Botox, to facelifts and “mommy makeover” surgeries, to gender confirmation surgeries).¹⁰⁰ He also claims to be an expert in the surgical and

⁹⁸ Littman L. The Use of Methodologies in Littman (2018) Is Consistent with the Use of Methodologies in Other Studies Contributing to the Field of Gender Dysphoria Research: Response to Restar (2019). *Arch Sex Behav.* 2020;49(1):67-77. doi:10.1007/s10508-020-01631-z

⁹⁹ Alliance Health Project, University of California San Francisco. *Activist Psychiatrist Dan Karasic, MD Retiring*, June 11, 2020, <https://alliancehealthproject.ucsf.edu/blog/activist-psychiatrist-dan-karasic-md-retiring>

¹⁰⁰ Loren S. Schechter, MD, “Body,” <https://drlschechter.com/body/>

post-operative care body of literature for gender-affirmative care, as evidenced by his work on WPATH's "Standards of Care" surgery and post-operative sections. However, Dr. Schechter seems to be unaware of the body of literature that shows that gender-affirming interventions fail to improve mental health or to reduce suicidality or suicide long-term^{101, 102}

63. In fact, he appears to be unaware of a key systematic review of surgeries for adults conducted by the HHS in 2016, which found no evidence of benefits of surgeries, and even posited that surgeries themselves may be contributing to the markedly elevated rate of morbidity and mortality found in the post-operative transgender populations.^{103, 104} Another systematic review of evidence by the Hayes Corporation, which reviews treatments for insurance payers for 84% of insured Americans,¹⁰⁵ reviewed evidence for gender reassignment surgery, rating the quality of evidence from "A" (strongest) to "D2" (weakest).¹⁰⁶ The evidence for gender reassignment surgery for minors earned the lowest "D2" rating: "insufficient published evidence to assess the safety and/or impact on health outcomes or patient management."¹⁰⁷ The rating of the same surgeries for adults was "C," indicating "[p]otential but unproven benefit." Hayes noted,

¹⁰¹ Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction

¹⁰² Wiepjes CM, den Heijer M, Bremmer MA, et al. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017). *Acta Psychiatr Scand*. 2020;141(6):486-491. doi:10.1111/acps.13164

¹⁰³ Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>

¹⁰⁴ Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

¹⁰⁵ Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

¹⁰⁶ Hayes, Inc., The Hayes Difference, <https://www.hayesinc.com/about-hayes/>.

¹⁰⁷ Hayes Inc., The Hayes Rating, <https://www.hayesinc.com/about-hayes/>.

“substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.”¹⁰⁸

64. Dr. Schechter’s lack of familiarity with quality systematic reviews and seminal studies in this area can be excused by the fact that his focus is on improving surgical care and on pursuing new frontiers, including Dr. Schechter’s pioneering work of uterine transplantation for biological males who identify as female.¹⁰⁹

65. It seems that Dr. Schechter’s expertise in providing gender-affirming surgeries and training others to do the same makes him a stellar choice for an expert witness in cases where these types of surgeries may have been inadequately performed (which is, unfortunately, a frequent occurrence ^{110 111}). However, he is a lesser-informed and, arguably, a problematically conflicted expert when it comes to elucidating the evidence on whether various types of transgender surgeries he performs should be viewed as medically necessary and qualifying for coverage with the Federal and State funds.

D. Understanding WPATH and its “Standards of Care”

66. Dr. Karasic and Dr. Schechter note that they are members of WPATH, invoke the guidelines that that organization publishes, and assert that those guidelines are “widely recognized” and “authoritative.” (Karasic 32, 34; Schechter 22.) Accordingly, I provide some context concerning that private organization and its guidelines.

¹⁰⁸ Id.

¹⁰⁹ Schechter, p.5

¹¹⁰ Dreher PC, Edwards D, Hager S, et al. Complications of the neovagina in male-to-female transgender surgery: A systematic review and meta-analysis with discussion of management: Systematic Review of Neovaginal Complications. *Clin Anat.* 2018;31(2):191-199. doi:10.1002/ca.23001

¹¹¹ Walt Heyer, *The Federalist*. 9 *Transgender Patients Complain Of Mutilation, Botched Sex-Change Surgeries In Oregon*, Dec. 6, 2018, <https://thefederalist.com/2018/12/06/9-transgender-patients-complain-mutilation-botched-sex-change-surgeries-oregon/>

67. 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 its guidelines in 1999. 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 Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health, or WPATH.

68. 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' values, sensibilities, and perceived needs into consideration, it limits the ability for honest, methodologically competent debate. It also means that WPATH can no longer be considered a purely professional organization.

69. WPATH takes a narrow and ideologically driven view on increasingly controversial 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, *Reflections*, at 240.) These are obviously incompatible goals. WPATH is supportive of those who want sex-reassignment surgery even though the purported benefits of such surgery is not borne out by the evidence. Skepticism as to the benefits of sex-reassignment surgery to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs (as its current president recently pointed out). 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. Skepticism is not welcomed by those whose careers are based on providing these "treatments."

70. A group of respected endocrinologists recently recognized that "despite the misleading name, WPATH Standards of Care 7 are . . . practice guidelines, not standards of care."¹¹² "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." WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations sometimes conflict. The limitations of its guidelines, 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 to hold sway.

71. In recent years, WPATH has fully adopted some mix of the medical and rights paradigms discussed above. 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, *Reflections*, at 240.) Two separate evaluations, one from Canada and one from the U.K. reviewed WPATH's guidelines and found them untrustworthy.¹¹³

¹¹² W. Malone, et al. (2021), Letter to the Editor from William J. Malone et al: "Proper Care of Transgender and Gender-diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective," *J. of Clin. Endocrinol. & Metab.* at 1, doi: 10.1210/clinem/dgab205.

¹¹³ S. Dahlen, et al. (2021) International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment. *BMJ Open* 11(4). doi: 10.1136/bmjopen-2021-048943. PMID: see also <https://genderreport.ca/bias-not-evidence-dominate-transgender-standard-of-care/>

72. Most psychiatrists and psychologists who treat patients suffering severe distress from gender dysphoria sufficiently 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-medical 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.

73. For example, 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.¹¹⁴ 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.

74. In my experience most current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by mental health professionals who are not deeply experienced with recognizing and treating frequently associated psychiatric comorbidities. Moreover, they have been educated in affirmative care without understanding the points I am making in this report. Because the 7th version of the WPATH guidelines deleted the requirement for therapy, trans care facilities that consider those guidelines sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with Master's degrees rather than medical or PhD psychology degrees.

¹¹⁴ WPATH De-Psychopathologisation Statement (May 26, 2010), available at wpath.org/policies

75. As a result of the downgrading of the role of the psychiatric assessment of patients, new “gender affirming” clinics have arisen in many urban settings that quickly (sometimes within an hour’s time) recommend transition. Indeed, Dr. Karasic recommends surgery for each of the named Plaintiffs following a single Zoom call with each. Patients and their families are not told they are entering an unproven, experimental, and potentially dangerous process.

76. Concerned parents who came wanting to know what is going on in their children are overwhelmed and feel disoriented, fearful for the health and safety of their children, and dependent on the professional. It has been ten years since the WPATH guidelines were last revised. Much has changed in that interval.

77. The increased incidence of post-pubertal gender dysphoria in biological females since the 7th edition of the WPATH guidelines is a cause for alarm among all knowledgeable professionals. As the Dahlen et al. study pointed out, standards of care throughout medicine have the ethical standard that no more than 30% of those formulating the recommendations should earn their income based on the guidelines offered. Experts in methodology are required, in addition, to be clinicians. But the majority of WPATH’s writers’ group were those whose income is derived from trans care. Their “inconsistent” recommendations did not flow from scientific evidence.

78. It is my understanding that the complex committee process that will generate the final version of SOC8 is at least two years delayed; this is most likely because of controversies with the organization about what is the best policy to govern children and adolescents. Voting on policy is the product of inadequate science, which ideally, speaks for itself in dictating treatment guidelines.

79. I have reviewed the draft SOC8 guidelines released by WPATH at the end of 2021. I, along with many other professionals, found it sorely lacking. While it purports to be evidence-based, none of the recommendations are linked to the evidence, as is done in a high-quality guideline. WPATH fails to acknowledge the well-documented phenomenon known as “rapid-onset gender dysphoria” now commonly occurring among adolescents, despite the fact that multiple clinicians report this is just what they are observing is happening.¹¹⁵ There is also no chapter on detransition, despite the evidence that a growing number of young people regret transition and wish to reverse it.^{116 117} Yet, WPATH contains a chapter on eunuchs and describes a “male-to-eunuch gender dysphoria,” and mentions the longevity benefits of pre-pubertal castration.

80. Thus, it is my opinion that WPATH is a problematically conflicted organization that misrepresents itself as credible scientific group.

E. Key Opinions

81. I would like to elucidate the key dilemmas in the area of transgender care. Some of the statements may be somewhat repetitive with the information presented in the rebuttals of the Plaintiffs’ witnesses above, so I will do my best to minimize such repetition.

1. The right to bodily autonomy via “gender-affirming” hormonal and surgical interventions should not be confused with medical necessity

¹¹⁵ Hutchinson A, Midgen M, Spiliadis A. In Support of Research Into Rapid-Onset Gender Dysphoria. *Arch Sex Behav.* 2020;49(1):79-80. doi:10.1007/s10508-019-01517-9

¹¹⁶ See Vandebussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality.* Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

¹¹⁷ See Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav.* Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

82. Individuals suffering from gender dysphoria who wish to re-align the body with their inner sense of self in some specific way have this right. Their desires interact with medical and surgical technologies such that, if patient wants it and we can attain it, why not? However, this should not be equated with medical necessity.

83. The list of gender-affirming interventions is ever-growing. It is not limited to puberty blockers, cross sex hormones, breast augmentation, and genital restructuring. Rather, it now commonly includes facial surgeries involving nose, chin, forehead, lips, eyes; vocal cord surgery; hair transplantation;¹¹⁸ and a growing list of procedures for patients who identify as non-binary, which include phallos-preserving vaginoplasty (the construction of a neovagina while preserving the penis) and nullification procedures (which obliterate all sex organs).¹¹⁹ As surgical techniques advance, so will the list of physical modification procedures, which will one day include advances such as uterine transplantation to allow trans women to gestate. The opportunities to modify a human body to match one's internally held sense of self are nearly limitless, with a willing surgeon and available financial compensation.

84. Advocates for affirmative care insist these are not cosmetic procedures when a person has gender dysphoria, and indeed growing numbers of states are compelled to cover such procedures under the umbrella of transgender healthcare.^{120 121} The advocates of the affirmative

¹¹⁸ Arocha Hair Restoration and Transplant Center, "Hair Transplants as a Part of Gender Reassignment Surgery," <https://arochahairrestoration.com/gender-reassignment/hair-transplants-gender-reassignment-surgery/>

¹¹⁹ Align Surgical Associates, Inc., "Phallus-Preserving Vaginoplasty," <https://www.alignsurgical.com/non-binary/phallus-preserving-vaginoplasty/>

¹²⁰ COLORADO BENEFITS FOR HEALTH CARE COVERAGE 38, <https://www.cms.gov/CCIIO/Resources/DataResources/ehb> (listing covered "Gender Affirming Care").

¹²¹ Washington State Senate Bill 5313-S2, amended by House Amendment 456, adopted Mar. 24, 2021, <https://lawfilesexternal.wa.gov/biennium/2021-22/Pdf/Amendments/House/5313-S2%20AMH%20CODY%20H1369.1.pdf>

approach agree that not all people who identify as transgender need medical treatments. However, they assert that such treatments *are* medically necessary for those who desire them. In fact, “patient desire” for transgender interventions has supplanted the traditional definition of medical necessity used in all other areas of medicine.¹²² The power of their rhetorical device—medically necessary—is considerable; it rests on the trusted reputation of the medical profession. Our noble profession tries hard but is not always correct.

85. West Virginia Medicaid defines medical necessity as “items or services furnished to a patient that are reasonable and necessary for the diagnosis or treatment of illness or injury, to improve the functioning of a malformed body member, to attain, maintain, or regain functional capacity, for the prevention of illness, or to achieve age appropriate growth and development.”¹²³ PEIA defines a service as medically necessary in a similar fashion.¹²⁴ Asserting medical necessity for transgender treatments is challenging for several reasons, starting with the fact that the very ***nature of the diagnosis is in flux.***

86. First, the two prevailing diagnostic systems sharply disagree on the very fundamental aspect of the diagnosis—patient distress.¹²⁵ According to DMS-5, the patient must experience significant distress to qualify for the diagnosis of “gender dysphoria.” To be considered

¹²² Turban JL, King D, Kobe J, Reisner SL, Keuroghlian AS. Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. Radix AE, ed. *PLoS ONE*. 2022;17(1):e0261039. doi:10.1371/journal.pone.0261039

¹²³ National Academy for State Health Policy, “State Definitions of Medical Necessity under the Medicaid EPSDT Benefit,” Apr. 23, 2021, <https://www.nashp.org/medical-necessity/>

¹²⁴ “A service is considered to be medically necessary if it is: consistent with the diagnosis and treatment of the injury or illness; in keeping with generally accepted medical practice standards; not solely for the convenience of the patient, family or health care provider; not for custodial, comfort or maintenance purposes; rendered in the most cost-efficient setting and level appropriate for the condition; and not otherwise excluded from coverage under the PEIA PPB Plans. See Summary Plan Description, PPB Plan A, B & D, Plan Year 2020, pg. 54. <https://peia.wv.gov/Forms-Downloads/Pages/Summary-Plan-Descriptions.aspx>

¹²⁵ See Levine et al., (in press). Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults. *Journal of Sex & Marital Therapy*.

for medical necessity, the contemplated treatments, therefore, must show that they can reduce the distress associated with “gender dysphoria.” However, according to ICD-11, a diagnostic category which has come into effect in January 2022, and which is expected to supersede DSM-5 in regards to determining eligibility for transgender interventions, having distress is no longer required to be diagnosed, and rather than “gender dysphoria,” the diagnosis is called “gender incongruence.” If ICD-11 is to be relied on for medical necessity determination, it stands to reason that the contemplated interventions should aim to resolve the said “incongruence” in order to achieve “congruence.” However, what “congruence” with one’s body means is a highly personal feeling not subject to objective medical criteria. Few individuals (transgender or not) feel entirely happy with their bodies, which is one of the reasons for the booming cosmetic surgery industry in the US. Having the diagnosis for gender dysphoria / gender incongruence does not imply medical necessity for hormone replacement therapy or surgical intervention. There are many patients with gender dysphoria who do not want hormones while they are exploring their evolving identities and social roles.

87. Second, while the DSM-5 diagnosis of “gender dysphoria” (DSM-5) and its ICD-11 counterpart “gender incongruence” are actual diagnoses (albeit contradictory), it is the term “transgender” that is widely used in the context of medical necessity of hormonal and surgical interventions. However, it is not clear how the term “transgender” interacts with the diagnoses in the DSM-5 and ICD-11. For example, it is well-known that gender dysphoria can be a manifestation of underlying mental health conditions and resolves once those conditions are treated.

¹²⁶ In this case, is the effected individual “transgender” while they experience gender dysphoria, but no longer “transgender” once it resolves?

¹²⁶ Urban-Kowalczyk M. Gender Dysphoria as a Clinical Manifestation of Schizophrenia – Case Series. *European Psychiatry*. 2015;30:1773. doi:10.1016/S0924-9338(15)31366-3

88. Third, there is no objective test to confirm that someone is “transgender” beyond an individual’s thoughts and feelings, which are subject to change. I and other clinicians have witnessed reinvestment in the patient’s biological sex in some individual patients following a period of time. There are now studies confirming that identifying as transgender for some period of time, and then re-identifying with one’s sex is not an infrequent phenomenon. Such processes appear to be increasing now that quality mental health assessments are bypassed in favor of vastly eased access hormones and surgeries.

89. In the gender clinic that I founded in 1974 and continue to co-direct, we have seen many instances of individuals who claimed a transgender identity for a time, but ultimately changed their minds and reclaimed the gender identity congruent with their sex. 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.¹²⁷ I have seen several Massachusetts inmates and trans individuals in the community abandon their trans female identity after several years.¹²⁸ A surgical group prominently active in the sex-reassignment surgery field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form.¹²⁹

90. Even more importantly, the majority (61-98%) of children who identify as transgender will reidentify with their sex before reaching maturity absent any interventions.¹³⁰

¹²⁷ Levine SB. Transitioning Back to Maleness. *Arch Sex Behav*. 2018;47(4):1295-1300. doi:10.1007/s10508-017-1136-9

¹²⁸ See Levine SB. Reflections on the Clinician’s Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

¹²⁹ Djordjevic et al. (2016), Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery, *J. Sex Med*. 13(6) 1000, DOI: 10.1016/j.jsxm.2016.02.173.

¹³⁰ Ristori J, Steensma TD. Gender dysphoria in childhood. *International Review of Psychiatry*. 2016;28(1):13-20. doi:10.3109/09540261.2015.1115754

¹³¹ Many professionals are unfamiliar with these eleven research studies indicating a high natural resolution rate of gender dysphoria children by late adolescence.¹³² I have personally seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. However, treating a child with gender-affirming interventions appears to solidify this identity in nearly 100% of the cases.^{133 134 135}

91. I noted an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years.¹³⁶ One such online community has over 20,000 members.¹³⁷ While it would be wrong to assert that each of the members have detransitioned, it is reasonable to assume that many are considering it and many have accomplished some degree of it. “Desisters” and “detransitioners” appear to come from a cohort of young adults who began to transition in high numbers as teens 5-7 years ago.

¹³¹ Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. *Front Psychiatry*. 2021;12. doi:10.3389/fpsy.2021.632784

¹³² Cantor J. M. (2020). Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy. *Journal of Sex & Marital Therapy*, 46(4), 307–313. <https://doi.org/10.1080/0092623X.2019.1698481>

¹³³ Zucker, *Myth of Persistence*, at 8 (citing H. Meyer-Bahlburg (2002), Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol, *Clinical Child Psychology & Psychiatry* 7, 360 at 362.).

¹³⁴ Brik T, Vrouenraets LJJJ, de Vries MC, Hannema SE. Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria. *Arch Sex Behav*. 2020;49(7):2611-2618. doi:10.1007/s10508-020-01660-8

¹³⁵ 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. Santana GL, ed. *PLoS ONE*. 2021;16(2):e0243894. doi:10.1371/journal.pone.0243894

¹³⁶ Entwistle K. Debate: Reality check – Detransitioners’ testimonies require us to rethink gender dysphoria. *Child Adolesc Ment Health*. Published online May 14, 2020:camh.12380. doi:10.1111/camh.12380

¹³⁷ Reddit, Detransition Subreddit, <https://www.reddit.com/r/detrans/>

This phenomenon is driven primarily by adolescent females, although adolescent males also present for care in much higher numbers than previously observed.¹³⁸ For example, at a London pediatric gender clinic in 2000-2001, 26 requests for services occurred; in 2019-2020, 2728 referrals were recorded—more than a 100-fold increase.^{139,140} The explosive growth of urban trans health centers in the US also reflects a similar trend.

92. Researchers are just starting to explore the phenomenon of rapid trans-identification followed by re-identification with their biological sex. Before this, neither advocates nor skeptics of hormonal and surgical interventions had any sense of the rate of these phenomena. One of the first studies to note the phenomenon of rapid trans-identification in teen years following a gender-normative childhood was by Littman.¹⁴¹ This is the research that Dr. Karasic worked hard to suppress, as discussed above. The phenomenon she described has now been confirmed by every major pediatric gender clinic in the world.^{142 143 144} Two very recent studies from several UK clinics that suggest the rate of detransition among patients who transitioned in recent years is as high as 10% in the first 18 months of treatment and could be much higher if the

¹³⁸ Zucker K. J. (2019), Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues, *Archives of Sexual Behavior*, 48(7), 1983-1992. <https://doi.org/10.1007/s10508-019-01518-8>

¹³⁹ de Graaf, N. M., Carmichael, P., Steensma, T. D., & Zucker, K. J. (2018). Evidence for a Change in the Sex Ratio of Children Referred for Gender Dysphoria: Data From the Gender Identity Development Service in London (2000-2017). *The Journal of Sexual Medicine*, 15(10), 1381–1383. <https://doi.org/10.1016/j.jsxm.2018.08.002>.

¹⁴⁰ Zucker K. J. (2017). Epidemiology of gender dysphoria and transgender identity. *Sexual Health*, 14(5), 404–411. <https://doi.org/10.1071/SH17067>

¹⁴¹ See L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, *PLoS ONE* 13(8): e0202330 at 13.

¹⁴² See de Graaf NM, Giovanardi G, Zitz C, Carmichael P. Sex Ratio in Children and Adolescents Referred to the Gender Identity Development Service in the UK (2009–2016). *Arch Sex Behav*. 2018;47(5):1301-1304. doi:10.1007/s10508-018-1204-9

¹⁴³ See Kaltiala-Heino R, Bergman H, Työlajärvi M, Frisen L. Gender dysphoria in adolescence: current perspectives. *AHMT*. 2018;Volume 9:31-41. doi:10.2147/AHMT.S135432

¹⁴⁴ Zucker KJ. Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues. *Arch Sex Behav*. 2019;48(7):1983-1992. doi:10.1007/s10508-019-01518-8

patients lost to follow-up are accounted for (20%+ dropped out of treatment). Two more studies that pursued in-depth exploration of the motivations that lead one to a trans identification and later desistance have been published, showing that social influence, uncontrolled mental illness, and other factors had led these individuals to an erroneous temporary conclusion that they were transgender.^{145 146 147 148}

93. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical “brain structure” associated with transgender identity, as of yet there is no credible scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria.^{149,150} More recent studies demonstrating diverse MRI patterns seem to be adding to the hypothesis that the brain may be different in these groups, but whether the differences are caused by the identity or themselves cause the identity is unclear. Most authorities in the field are clear such data are used to build an etiological hypothesis and do not justify statements suggesting gender dysphoria is a biological illness.¹⁵¹

¹⁴⁵ See Boyd I, Hackett T, Bewley S. Care of Transgender Patients: A General Practice Quality Improvement Approach. *Healthcare*. 2022;10(1):121. doi:10.3390/healthcare10010121

¹⁴⁶ See Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: retrospective case-note review. *BJPsych open*. 2021;7(6):e184. doi:10.1192/bjo.2021.1022

¹⁴⁷ See Vandenbussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

¹⁴⁸ See Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

¹⁴⁹ Mueller, De Cuypere & T’Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. *American Journal of Psychiatry* 174: 12, 2017.

¹⁵⁰ Frigerio et al (2021) Structural, functional, and metabolic brain differences as a function of gender identity or sexual orientation: A systematic review of the human neuroimaging literature. *Archives of Sexual Behavior*. 503329-3352. <https://doi.org/10.1007/s10508-021-02005-9>

¹⁵¹ See Mueller SC, et al The Neuroanatomy of Transgender Identity: Mega-Analytic Findings From the ENIGMA Transgender Persons Working Group. *J Sex Med*. 2021 Jun;18(6):1122-1129. doi: 10.1016/j.jsxm.2021.03.079. Epub 2021 May 22. PMID: 34030966

94. Thus, because the causal mechanisms of gender incongruence are not scientifically established, the available diagnoses are contradictory in terms of what the nature of the problem that is addressed is, it is challenging to even begin to establish the basis for medical necessity.

B. Medically-necessary care should not be conflated with “gender-affirming” care. The latter has not been shown to result in significant lasting improvements in mental health or reduction in suicidality/suicide long-term.

95. Further, to demonstrate medical necessity, one must be able to demonstrate that treatments “improve the functioning of a malformed body member, to attain, maintain, or regain functional capacity, for the prevention of illness, or to achieve age appropriate growth and development.”¹⁵² However, despite decades of research, no convincing evidence exists that either hormonal or surgical interventions result in *lasting improvements* to the individuals’ functioning, mental health, substance abuse, or suicidality. The research purporting to show these benefits comes from poor-quality, short-term studies, and is contradicted by longer-term, higher-quality studies and quality systematic reviews of evidence.^{153 154 155 156} I note that the Plaintiffs’ expert

¹⁵² See National Academy for State Health Policy, “State Definitions of Medical Necessity under the Medicaid EPSDT Benefit,” Apr. 23, 2021, <https://www.nashp.org/medical-necessity/>

¹⁵³ Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734. doi:10.1176/appi.ajp.2020.1778correction

¹⁵⁴ Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

¹⁵⁵ See National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>

¹⁵⁵ See National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>

¹⁵⁶ See Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). :109. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>

witnesses do not address the quality of evidence in favor of their opinions. But it is an ethical principle throughout medicine that treatment should be based on science.

96. In evaluating claims of scientific or medical knowledge, it is important 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. In order of increasing confidence, such “knowledge” may be based upon data comprising:

- a. Expert opinion—it is 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, and therefore does not garner as much respect from professionals as what follows:
- b. A single case or series of cases (what could be called anecdotal evidence),
- c. A series of cases with a control group,
- d. A cohort study,
- e. A randomized double-blind clinical trial,
- f. An overview of the multiple studies (e.g., narrative review, descriptive review, etc.),
- g. A systematic review of all available studies on a given topic. It may also include meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

97. Individual studies can suffer from methodological limitations that make them unreliable. As an experienced reviewer of submitted manuscripts to well respected scientific journals, I find myself frequently pointing out to authors that their conclusions are presented with too much confidence, certainty, or authority given the limitations that they have described in their

article. The danger of this is that when they or others quote their findings in a sentence or two, there is no hint of the studies known limitations. This phenomenon is one of the reasons why whenever possible, clinical and policy decision-makers more heavily rely on systematic reviews of evidence. Systematic reviews utilize reproducible methods to systematize and categorize all available knowledge. However, to be credible systematic reviews need to be conducted according to strict metrological standards. To date, every credible quality systematic review of evidence in the area of transgender medicine have found the evidence to be of low to very low quality, and the findings of benefits to be uncertain.

98. Cochrane reviews are generally considered the gold standard of systematic reviews in medicine.¹⁵⁷ Cochrane goes to great lengths to assure that researchers conducting the reviews of evidence are free from problematic conflicts of interest, and that they follow a strict and highly reproducible research methodology. A 2020 Cochrane review of hormonal treatment outcomes for male-to-female transitioners older than 16 years found “insufficient evidence to determine the efficacy or safety of hormonal treatment approaches.” It is remarkable that six decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking.¹⁵⁸

99. The National Institute of Health and Care Excellence (NICE) is another organization known for its excellence and expertise in evidence evaluation. They undertook two systematic evidence reviews of the use of GnRH agonists (“puberty blockers”) and cross-sex hormones as treatments for gender dysphoric patients <18 years old. These reviews were led by Dr. Hilary

¹⁵⁷ Deshpande S, Misso K, Westwood M, et al. Not All Cochrane Reviews Are Good Quality Systematic Reviews. *Value in Health*. 2016;19(7):A371. doi:10.1016/j.jval.2016.09.142

¹⁵⁸ 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. <https://doi.org/10.1002/14651858.CD013138.pub2>, at <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full>

Cass and published in March 2021. The reviews found the evidence of benefit of using puberty blocking drugs and cross sex hormones to treat young people struggling with gender identity as “very low certainty.” For puberty blockers, the review’s conclusions stated, “The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning), in children and adolescents with gender dysphoria are of very low certainty using modified GRADE. They suggest little change with GnRH [puberty blockers] analogues from baseline to follow-up.”¹⁵⁹ To state it plainly, the review found no credible evidence that puberty blockers improve functioning of children. A similar conclusion of very low certainty was drawn regarding the evidence of treatment with cross-sex hormones. The review noted a possibility of benefits, but stated, “[a]ny 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.”¹⁶⁰ NICE reviews did not address surgeries, but other systematic reviews did.

100. Another expert systematic review, conducted by the Hayes Corporation, which reviews treatments for insurance payers for 84% of insured Americans, reviewed evidence for gender reassignment surgery, rating the quality of evidence from “A” (strongest) to “D2” (weakest). The evidence of gender-affirming surgery for minors earned the lowest “D2” rating: “insuf-

¹⁵⁹ See National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, p. 13. 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>

¹⁶⁰ See National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, p. 14. 11 March 2021, at <https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01>

ficient published evidence to assess the safety and/or impact on health outcomes or patient management.” The rating for surgeries for adults was a higher grade of “C,” indicating “[p]otential but unproven benefit.” Hayes noted, “substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.”¹⁶¹

101. The Centers for Medicare & Medicaid Services, within the U.S. Department of Health and Human Services (HHS) conducted a systematic review of evidence of gender-affirming surgeries for adults. The HHS refused to mandate coverage for these services due to insufficient evidence of benefit. Remarkably, the HHS stated: “Further, we cannot exclude [gender-affirming] therapeutic interventions as a cause of the observed excess morbidity and mortality.”¹⁶²

102. The public health authorities in Sweden and Finland, countries that are among the pioneers of medical transition, have recently concluded their own systematic reviews of evidence of gender-affirming interventions, with a focus on youth. Both came to similar conclusions as the systematic reviews above: the evidence of benefit was found to be unconvincing.^{163 164} Consequently, both Finland, and Sweden’s leading Karolinksa Hospital (which grants the Nobel Prize

¹⁶¹ See Hayes, Inc., Sex Reassignment Surgery for the Treatment of Gender Dysphoria, Hayes Directory (Aug. 1, 2018).

¹⁶² Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). p. 46. :109. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>

¹⁶³ See Gender affirmation surgery for gender dysphoria - effects and risks: Health Technology Assessment review 2018. Swedish Health Authority. Published online 2018. https://alfresco-offentlig.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/441006af-62a7-4f19-be73-6d698bf635f5/2018_102%20Rapport%20K%C3%B6nsdysfori.pdf?a=false&guest=true&fbclid=IwAR2_BBIVfFBKok9XZ7JiTXfwOfT-gcCXIzAySkh6wLXUJK8s_L_8XZy-tdIA

¹⁶⁴ Pasternack I, Söderström I, Saijonkari M, Mäkelä M. Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa. Systemaattinen katsaus. [Appendix 1 Systematic Review]. Published online 2019:106. Accessed March 1, 2021. <https://app.box.com/s/y9u791np8v9gsunwgpr2kqn8swd9vdtx>

in Medicine) have either stopped or sharply curtailed the practice of pediatric gender transitions, and now prioritize psychotherapy instead.

103. A review by Professor Carl Heneghan, the editor of the British Medical Journal, and the Director of the Centre for Evidence-Based Medicine in Oxford University, also conducted a review of evidence with a focus on young people (although it was not a “systematic review”). His conclusion was that the evidence for the use of gender-affirming puberty blockers and hormones in youth was of very low quality, and there are substantial risks and unknowns involved. He stated, “The development of these interventions should, therefore, occur in the context of research, and treatments for under 18 gender dysphoric children and adolescents remain largely experimental. There are a large number of unanswered questions that include the age at start, reversibility; adverse events, long term effects on mental health, quality of life, bone mineral density, osteoporosis in later life and cognition. We wonder whether off label use is appropriate and justified for drugs such as spironolactone which can cause substantial harms and even death. We are also ignorant of the long-term safety profiles of the different GAH regimens. The current evidence base does not support informed decision making and safe practice in children.”

165

104. In 2017, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.¹⁶⁶ These guidelines were based on two systematic reviews, which also found the evidence for hormonal use to be of “very low” and “low” quality

¹⁶⁵ Heneghan C, Jefferson T. Gender-affirming hormone in children and adolescents. BMJ EBM Spotlight. Published February 25, 2019. Accessed October 9, 2020. <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>

¹⁶⁶ See Hembree, W. C. et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, doi: 10.1210/jc.2017-01658 (2017) p.3-4.

(i.e., which translates into low confidence in the balance of risk and benefits).” Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines. However, while the guidelines “recommended” hormonal interventions for gender dysphoric individuals, these recommendations were graded as “weak.” The guidelines’ authors had this to say about what differentiates a “weak” recommendation from a “strong” one: “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.” In other words, the Endocrine Society is saying: we cannot be sure that on average, the benefits of administering hormonal interventions will outweigh the harm—for either adults or children.” This indeed is a sobering notion.

105. There are, of course, “overviews” and “systematic reviews” that will claim just the opposite—that hormones and surgeries are a proven, safe, and effective treatment. Such reviews are often problematically conflicted. Rather than being conducted by independent experts in evidence evaluation with no conflicts of interest, they are often commissioned by activist clinicians and/or funded by organizations such as WPATH (the organization with a stated goal of creating broad access for hormones and surgeries for all those who wish to receive them) or one of its pharmaceutical company sponsors.

106. I am familiar with least two such recent reviews, which are problematically flawed, although I am certain there are others.¹⁶⁷ ¹⁶⁸ One of them was recently harshly critiqued by a group of researchers and exposed as deeply flawed.¹⁶⁹ The authors note that the review of the evidence for puberty blockers, “illustrates a concerning trend, that we have observed in the GD [gender dysphoria] literature, to overstate the evidence underpinning clinical practice recommendations for youth with GD. New publications reference prior ones with increasing and unwarranted confidence, and with the risk of misleading clinicians regarding the state of evidence. There is also a marked asymmetry in outcomes reporting: findings of positive outcomes of medical interventions are trumpeted in abstracts, while their profound limitations cannot be seen by busy clinicians unless they have a subscription to the journal. (Journals typically charge ~\$40 per article.) To the best of my knowledge, another group of researchers contacted the publishing journal of the other review, commissioned by WPATH, and which will serve as the basis for WPATH’s upcoming SOC8 recommendation, but the editor refused to publish the critique.

107. A discerning consumer of systematic reviews will note that reviews published by independent authorities with no conflict of interest universally find no compelling evidence that gender-affirming treatments lead to demonstrable lasting improvements in mental health, while reviews commissioned and / or led by transgender rights activists tend to find just the opposite.

¹⁶⁷ Rew L, Young CC, Monge M, Bogucka R. Review: Puberty blockers for transgender and gender diverse youth—a critical review of the literature. *Child Adolesc Ment Health*. 2021;26(1):3-14. doi:10.1111/camh.12437

¹⁶⁸ Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. *Journal of the Endocrine Society*. 2021;5(4):bvab011. doi:10.1210/jendso/bvab011

¹⁶⁹ See Clayton A, Malone WJ, Clarke P, Mason J, D’Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adolesc Ment Health*. Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533

108. The question of suicide and whether gender-affirming treatments reduce suicide deserves special consideration. Like many proponents of unfettered access to hormones and surgery, Dr. Karasic raises the specter of suicide and claims that “[t]he denial of medically indicated care to transgender people ... causes additional distress and poses other health risks, such as ... suicidality.”¹⁷⁰ Contrary to such assertions, no studies show that “affirmation” with hormones and surgeries reduces suicides in the long term.

109. Individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after gender-confirmation.

¹⁷¹ For example, 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 suicide rates.¹⁷² Similarly, researchers in Sweden have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period.¹⁷³ The Swedish follow-up study found a suicide rate in the post-surgery population 19.1 times greater than that of the controls after affirmation treatment. Decades later, the suicide rate was still 3.5 times greater among the trans identified Swedish population than other citizens.

¹⁷⁰ Karasic, p.8 para 28

¹⁷¹ See Levine SB. Reflections on the Clinician’s Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

¹⁷² Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482

¹⁷³ C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, *PLOS ONE* 6(2) e16885 (“Long Term”); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, *Nordic J. of Psychiatry* 70(4).

110. However, there is no evidence that transition reduces suicide rates. For example, a key study from the Netherlands found that suicide rates are similar across all stages of transition from pre-treatment assessment, to several post-surgery.¹⁷⁴

111. The most conclusive results, however, come from a key paper by Bränström and Panchankis published in 2019.¹⁷⁵ The original paper did not find that hormones improved long-term mental health or suicide attempted, but did find such an effect for surgeries, claiming “the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them.” They claimed their research provided the first empirical evidence that gender transition surgeries had long-term mental-health benefits.

112. Seven letters were submitted to the editor from MDs, PhDs, and other methodologists that clarified methodological blunders and/or misrepresentations of the data. These were published in August 2020 along with the original article. Following these letters, the journal editors commissioned independent statistical reviews, and following a re-analysis, the researchers had to admit that there was no evidence that surgeries improved mental health or suicidality either (in fact, suicide attempts were roughly double in the “surgery” compared to the “no surgery” group although the result was not statistically significant).

¹⁷⁴ C.M. Wiepjes, et al. (2020), Trends in Suicide Death Risk in Transgender People: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972–2017), *Acta Psychiatr Scand* 141(6). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7317390/>.

¹⁷⁵ See Bränström R, Pachankis JE: Reduction in Mental Health Treatment Utilization among Transgender Individuals after Gender-affirming Surgeries: A Total Population Study. *Am J Psychiatry* 2020; 177: 727–734.

113. The journal published a correction, along with the authors' statement that "more research" is needed.^{176 177} Remarkably, the journal allowed the original publication with its flawed title, which states that surgeries reduce risk of suicide, to stand uncorrected. The correction is instead residing along with the original article, unconscious, despite the fact that the correction entirely invalidated the study's main conclusion. This illustrates the bias that currently plagues transgender research literature, where studies with "positive" findings are quickly published and lauded, while correction of flawed data are either not undertaken, or if pursued, tend to be "buried." As pervasive and powerful a problem this is within trans medicine, I would like to again emphasize that the Bränström and Panchankis study was undertaken in order to investigate the long term psychological benefits of these increasingly common interventions.

114. Another example of the gross bias in the state of transgender treatment literature toward escalating poor quality "positive" findings while suppressing well-reasoned critique is the 2020 article by Turban, et al.¹⁷⁸ This publication, purporting that puberty blockers prevent suicidality, has been heavily promoted by the journal that published it, and has been widely covered by lay press. The study suffers from very serious limitations and cannot be used to justify such a sweeping claim. It has been rigorously criticized for a range of issues, not least among which was not emphasizing that both those treated and not treated with puberty blockers had high suicidal ideation rates and more patients on these drugs were hospitalized for suicidal plans than the untreated. However, the researchers who escalated these concerns to the journal editor were not permitted to publish their critique. Instead, they had to find other journals to make their critique

¹⁷⁶ See Correction to Bränström and Pachankis. *AJP*. 2020;177(8):734-734.

¹⁷⁷ See Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters, *Am J Psychiatry* 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

¹⁷⁸ See J. Turban et al., Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation, *Pediatrics* 145(2), DOI: 10.1542/peds.2019-1725

public.^{179 180 181} This is highly unusual for other areas of research, where debate is welcomed. Notably, a recent re-analysis of the same data used by Dr. Turban and his colleagues showed no effect of puberty blockers on mental health, invalidating the study’s headline findings.¹⁸²

115. It is important to note that in considering “suicide,” mental health professionals distinguish between suicidal thoughts (ideation), suicide gestures, suicide attempts with a lethal potential, and completed suicide. Numerous studies have found suicidal ideation to have been present at some time in life in at least ~40-50% of adolescents and adults before and after various forms of transition. This figure is approximately twice that in gay and lesbian communities. In the heteronormative communities it is approximately 4%.

116. While elevated, suicide in trans-identified individuals remains, thankfully, a relatively rare event. The estimated suicide rate of trans adolescents is similar to that of teenagers who are in treatment for serious mental illness.¹⁸³ What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers.¹⁸⁴ Recently, the UK data was used to estimate the suicide rate in trans-identified teens and found it to be 0.03% over a 10-

¹⁷⁹ See Biggs M. Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Arch Sex Behav.* 2020;49(7):2227-2229. doi:10.1007/s10508-020-01743-6

¹⁸⁰ See D’Angelo R, Syrulnik E, Ayad S, Marchiano L, Kenny DT, Clarke P. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav.* Published online October 21, 2020. doi:10.1007/s10508-020-01844-2

¹⁸¹ See Clayton A, Malone WJ, Clarke P, Mason J, D’Angelo R. Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021). *Child Adolesc Ment Health.* Published online December 22, 2021:camh.12533. doi:10.1111/camh.12533

¹⁸² See Biggs, Michael (2022): Comment on Turban et al. 2022: Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex. figshare. Journal contribution. <https://doi.org/10.6084/m9.figshare.19018868.v1>

¹⁸³ de Graaf NM, Steensma TD, Carmichael P, et al. Suicidality in clinic-referred transgender adolescents. *Adolescent Psychiatry.* Published online June 2020:17. doi:<https://doi.org/10.1007/s00787-020-01663-9>

¹⁸⁴ A. Perez-Brumer, J. K. Day et al. (2017), Prevalence & Correlates of Suicidal Ideation Among Transgender Youth in Cal.: Findings from a Representative, Population-Based Sample of High Sch. Students, *J. Am. Acad. Child Adolescent Psychiatry* 56(9), 739 at 739.

year period, while the adult rate was estimated to be 0.6% over a 20-year period in Sweden .¹⁸⁵

186

117. In sum, claims that affirmation will reduce the risk of suicide are not based on science. Such claims overlook the complexity of suicide as a phenomenon which is rarely driven by a single cause and the lack of long-term evidence that gender-affirmation reduces suicides. They also overlook the other tools that the profession does have for addressing depression and suicidal thoughts in a patient once that risk is identified, including cognitive behavioral therapy, medication, a new psychotherapy process. and other proven interventions. Psychiatry, of course, has a long history of striving to prevent suicide in those who seek our care.¹⁸⁷

C. There are significant risks of complications associated with gender-affirming hormonal and surgical interventions.

118. The risks associated with medical transition are significant. They tend to be underplayed in the literature promoting transgender medical and surgical interventions. The risks affect a range of domains.

¹⁸⁵ Biggs M. Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Arch Sex Behav*. Published online January 18, 2022. doi:10.1007/s10508-022-02287-7

¹⁸⁶ Socialstyrelsen [National Board of Health and Welfare]. *Utvecklingen Av Diagnosen Könsdysfori [The Evolution of the Diagnosis of Gender Dysphoria]*. Socialstyrelsen [Swedish Health Authority]; 2020. Accessed October 29, 2020. <https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/vanligt-med-flera-psykiatriska-diagnoser-hos-personer-med-konsdysfori/>

¹⁸⁷ See Levine S. B. (2021). Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Archives of Sexual Behavior*, 50(8), 3527–3536. <https://doi.org/10.1007/s10508-021-02142-1>

Disease and mortality generally

119. Hormonal interventions are associated with 3-5 fold increase in rates of heart attacks and strokes, with effects on bone health, and with generally elevated morbidity and mortality of adults.^{188 189 190 191 192}

120. Shortened life expectancy has been repeatedly documented in Sweden, the US, and Denmark..

121. Many of the long-term risks for young people are not yet known, as the practice of medically transitioning minors and young people is relatively new and no long-term data are available.

122. After puberty, the individual who wishes to live as the opposite sex will in most cases have to take cross-sex hormones for most of life. The long-term health risks of this major alteration of hormonal levels have not yet been quantified in terms of exact risk.¹⁹³ However, a recent study found greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals taking estrogen. Those authors concluded, “it is

¹⁸⁸ See Alzahrani T, Nguyen T, Ryan A, et al. Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population. *Circ: Cardiovascular Quality and Outcomes*. 2019;12(4). doi:10.1161/CIRCOUTCOMES.119.005597

¹⁸⁹ See Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons. *Ann Intern Med*. 2018;169(4):205-213. doi:10.7326/M17-2785

¹⁹⁰ 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*. 2015;100(2):E270-E275. doi:10.1210/jc.2014-2439

¹⁹¹ See Biggs M. Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria. *J Pediatr Endocrinol Metab*. 2021;34(7):937-939. doi:10.1515/jpem-2021-0180

¹⁹² See C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, *PLOS ONE* 6(2) e16885 (“Long Term”); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, *Nordic J. of Psychiatry* 70(4).

¹⁹³ See Tishelman et al., *Serving TG Youth* at 6-7 (Long-term effect of cross-sex hormones “is an area where we currently have little research to guide us.”).

critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone treatment.”¹⁹⁴

123. Another group of authors similarly noted that administration of cross-sex hormones creates “an additional risk of thromboembolic events”—blood clots which are associated with strokes, heart attacks, and lung and liver failure.¹⁹⁵ The reason medical follow up of lipid parameters, weight gain, smoking history, and red blood cell counts is recommended for patients on hormones is that these are known predisposing factors to cardiovascular disease in the future.

124. 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. Although 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 of such risks, including that of reduced life expectancy.¹⁹⁶

Health risks inherent in complex surgery

125. Complications of surgery exist for each procedure,¹⁹⁷ and complications in surgery affecting the reproductive organs and urinary tract can have significant anatomical and functional complications for the patient’s quality of life. In the famous “Dutch study,” one of 70 treated adolescents died as a result of surgery.¹⁹⁸

¹⁹⁴ D. Getahun et al. (2018), Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study, *Annals of Internal Medicine* at 8, DOI:10.7326/M17-2785.

¹⁹⁵ See C. Guss et al., *TGN Adolescent Care* at 5.

¹⁹⁶ See Blosnich, J. R., Brown, G. R., Wojcio, S., Jones, K. T., & Bossarte, R. M. (2014). Mortality among Veterans with Transgender-related Diagnoses in the Veterans Health Administration, FY2000–2009. *LGBT Health*, 1, 269–276. doi:10.1089/lgbt.2014.0050

¹⁹⁷ Levine, *Informed Consent*, at 5 (citing T. van de Grift, G. Pigot et al. (2017), A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen, *J. Sexual Medicine* 14(12) 1621.).

¹⁹⁸ See de Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*. 2014;134(4):696-704. doi:10.1542/peds.2013-2958

126. Non-fatal but serious surgical complications are common for all surgeries, from mastectomies, where a significant proportion of individuals permanently lose sensation, to genital surgeries, which can result in lasting problems with pain, urination, and a myriad of other issues.^{199 200 201} Re-operations are frequently performed.

Infertility and Sterility

127. Sex-reassignment surgery that removes testes, ovaries, or the uterus is inevitably sterilizing. While by no means all transgender adults elect sex-reassignment surgery, many patients do ultimately feel compelled to take this serious step in their effort to live fully as the opposite sex.

128. Treating children with puberty blockers followed by cross-sex hormones is expected to result in sterility.²⁰² Fertility preservation is often not possible with children whose gonads have not yet matured. Most children do not opt for fertility preservation when such options are offered.²⁰³ Children cannot adequately anticipate their future desires to be a biological parent. The future psychological burden of sterility for such youth is yet unknown, as no long-term follow-up exists on children who were treated in this manner.

¹⁹⁹ See Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr.* 2018;172(5):431. doi:10.1001/jamapediatrics.2017.5440

²⁰⁰ Dreher PC, Edwards D, Hager S, et al. Complications of the neovagina in male-to-female transgender surgery: A systematic review and meta-analysis with discussion of management: Systematic Review of Neovaginal Complications. *Clin Anat.* 2018;31(2):191-199. doi:10.1002/ca.23001

²⁰¹ Rashid M, Tamimy MS. Phalloplasty: The dream and the reality. *Indian J Plast Surg.* 2013;46(2):283-293. doi:10.4103/0970-0358.118606

²⁰² See 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." *J Clin Endocrinol Metab.* 2019;104(3):686-687. doi:10.1210/jc.2018-01925

²⁰³ See Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility Preservation Utilization Among Transgender Youth. *J Adolesc Health.* 2017;61(1):40-44. doi:10.1016/j.jadohealth.2016.12.012

²⁰³ Mattawanon N, Spencer JB, Schirmer DA, Tangpricha V. Fertility preservation optio

129. Practitioners must also recognize that the administration of cross-sex hormones creates a risk of infertility or irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner.^{204 205}

130. 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 transition for any patient. However, it is particularly difficult for parents of a young child to seriously contemplate that child's potential as a future parent and grandparent. This makes it even more critical that the mental health professional spend substantial and repeated time with parents to help them see the implications of what they are considering. The percentage of transitioned patients who will become increasingly suicidal as they fully realize the meaning of permanent sterility and the loss of the possibility of being a biological parent has never been studied and is thus unknown.

Loss of sexual function

131. Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. Dr. Karasic and Dr. Schechter do not acknowledge these physical effects of puberty blockers.

²⁰⁴ See Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. *Transl Androl Urol*. 2019;8(3):209-218. doi:10.21037/tau.2019.05.09

²⁰⁵ See C. Guss et al., *TGN Adolescent Care* at 4 (“a side effect [of cross-sex hormones] may be infertility”) and 5 (“cross-sex hormones . . . may have irreversible effects”); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are “irreversible interventions” with “significant ramifications for fertility”).

132. Additionally, youth will also experience the social, psychological, and interpersonal impact of not being in puberty for 2-5 years while their peers are challenged by the normative processes of maturing bodies and minds. To my knowledge, data quantifying these impacts have not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function.

133. More generally, sexual dysfunction is not an uncommon complication of genital surgery.²⁰⁶ Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgender population.²⁰⁷

Psychosocial and other effects

134. Besides puberty blockers' physical side effects like affecting height and bone density, the drugs also have irreversible psychosocial effects. That is because puberty blockers also halt the normal social and psychological process of maturation at that developmentally crucial stage, with lifelong effects.

135. The social and psychological impacts of remaining puerile for, e.g., two-to-five years while one's peers are undergoing pubertal transformations, and of undergoing puberty at a substantially older age, have not been systematically studied. However, clinical mental health professionals often hear of distress and social awkwardness in those who otherwise suffer delayed onset of puberty. In my opinion, individuals in whom puberty is delayed for multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand

²⁰⁶ Dunford C, Bell K, Rashid T. Genital Reconstructive Surgery in Male to Female Transgender Patients: A Systematic Review of Primary Surgical Techniques, Complication Profiles, and Functional Outcomes from 1950 to Present Day. *European Urology Focus*. 2021;7(2):464-471. doi:10.1016/j.euf.2020.01.004

²⁰⁷ Levine, *Informed Consent*, at 6; see Perelman and Watters, 2016, Delayed Ejaculation in *Handbook of Clinical Sexuality for Mental Health Professionals* 3rd edition, New York, Routledge.

on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence.

136. We should recall that puberty introduces sexual desire, changes socialization patterns, and enables teens to enter into early romantic relationships, all of which can lead to maturation, self-confidence, and an understanding of the complexity of partner relationship. Delaying puberty can reasonably be assumed to increase the adolescent's sense of isolation, otherness, and being an outsider.²⁰⁸ Please note that social anxiety is a very common symptom among candidates for puberty blocking hormones.

137. The Endocrine Society guidelines rightly recognize both “the sense of social isolation from having the timing of puberty to be so out of sync with peers” and the “potential harm to mental health (emotion and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age.”²⁰⁹

138. Just as medicine does not know what the long-term health effects on bone, brain, and other organs are from delaying puberty between ages 11-16, psychology likewise does not know the long-term effects on coping skills, interpersonal comfort, and sexual function comfort (intimate relationships) of blocking puberty in a young person while one's peers are undergoing their maturational gains in these vital arenas of future mental health. It is well known that many effects of cross-sex hormones cannot be reversed should the patient later regret his transition.

139. Claims that using puberty blockers for gender-transition procedures is “reversible” or that they merely “pause” puberty are also false, misleading, and naive. Based on concerns that virtually all adolescents who begin puberty blockers proceed to cross-sex hormones,

²⁰⁸ See Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

²⁰⁹ Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, p. 3885.

the UK National Health Service has officially recommended against such language, stating that “[r]esearchers and clinical staff working in gender identity development should consider carefully the terms that they use in describing treatments e.g. avoid referring to puberty suppression as providing a ‘breathing space,’ to avoid risk of misunderstanding.”²¹⁰ This is a wise recommendation, and it should be followed.

Family, friendship, and romantic relationships

140. 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.

141. Friendship in general is highly desirable, many trans teens and older individuals desire to interact more fully and extensively with those in the larger population. But, by adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals and the generally limited set of others who are most comfortable interacting with them.²¹¹ Among young adolescent trans-identified teens, friends are often virtual. For some these are their only friends, while for others conversations over the Internet dominate their connections with others.²¹²

²¹⁰ Investigation into the Study “Early Pubertal Suppression in a Carefully Selected Group of Adolescents with Gender Identity Disorders,” National Health Service Health Research Authority (October 14, 2019), <https://www.hra.nhs.uk/about-us/governance/feedback-raising-concerns/investigation-study-early-pubertal-suppression-carefully-selected-group-adolescents-gender-identity-disorders/>

²¹¹ See Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482

²¹² Shrier A. (2019) *The Transgender Craze Seducing Our Daughters*, Regnery Publishing, Washington, DC

142. There is also a sexual-romantic risk that needs to be considered. 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, he discovers that the pool of those interested consists largely of individuals looking for exotic sexual experiences rather than genuinely loving relationships.^{213, 214}

Potential for worsened mental health

143. One would expect the negative physical and social impacts reviewed above to adversely affect the mental health of individuals who have transitioned. In addition, adult-transitioned individuals find that living as the other sex (or, in a manner that is consistent with the stereotypes of the other sex as the individual perceives them) is a continual challenge and stressor, and many find that they continue to struggle with a sense of inauthenticity in their transgender identity and bear chronic uneasiness.²¹⁵

144. In addition, individuals often pin excessive hope in transition, believing that transition will solve mental health co-morbidities or what are in fact ordinary social stresses associated with maturation. Thus, transition can result in deflection from mastering personal challenges at the appropriate time or addressing conditions that require treatment. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a

²¹³ See Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *Journal of Sex & Marital Therapy*. 2018;44(1):29-44. doi:10.1080/0092623X.2017.1309482

²¹⁴ Anzani, A., Lindley, L., Tognasso, G., Galupo, M. P., & Prunas, A. (2021). "Being Talked to Like I Was a Sex Toy, Like Being Transgender Was Simply for the Enjoyment of Someone Else": Fetishization and Sexualization of Transgender and Nonbinary Individuals. *Archives of Sexual Behavior*, 50(3), 897–911. <https://doi.org/10.1007/s10508-021-01935-8>

²¹⁵ See Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2019;45(3):218-229. doi:10.1080/0092623X.2018.1518885

transgender identity. Indeed, Swedish researchers in a long-term study (up to 30 years since sex-reassignment surgery, with a median time since sex-reassignment surgery of > 10 years) concluded that individuals who have sex-reassignment surgery should have postoperative lifelong psychiatric care.²¹⁶ With respect to youths a cohort study found that transgender youth 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.²¹⁷

D. There is a crisis of inadequate or absent mental health assessments prior to undergoing transition.

145. Prominent mental health experts in the area of transgender health have recently gone public with their concerns about the state of mental health assessments of youth.

146. Dr. Edwards-Leeper, who claims to have brought the practice of pediatric gender transition from the Netherlands to the US, and Dr. Anderson, a transwoman and a former leader of the US Chapter of WPATH who recently stepped down amid the controversy of her whistleblowing, said this in a recent interview about the state of mental health care:

“Providers may also be afraid of being cast as transphobic bigots by their local colleagues and referral sources if they engage in gender exploring therapy with patients, as some have equated

²¹⁶ See Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. Scott J, ed. *PLoS ONE*. 2011;6(2):e16885. doi:10.1371/journal.pone.0016885

²¹⁷ Reisner et al. (2015), Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study, *J. of Adolescent Health* 56(3) at 6, DOI:10.1016/j.jadohealth.2014.10.264.

this with conversion therapy,” and continued, “the field has moved from a more nuanced, individualized and developmentally appropriate assessment process to one where every problem looks like a medical one that can be solved quickly with medication or, ultimately, surgery. As a result, we may be harming some of the young people we strive to support — people who may not be prepared for the gender transitions they are being rushed into.”^{218 219}

147. To properly assess medical necessity of various treatments, clinicians must carefully and thoroughly consider each individual patient’s clinical history, including mental health comorbidities, previous physical and psychological treatments, characteristic patterns, quality of relationships with each family member, and behavioral and verbal manifestations concerning gender nonconformity to determine the influences upon the patient’s gender incongruity.²²⁰ The history will undoubtedly be unique to each patient. So should be treatment recommendations.

148. Unfortunately, currently in the US, if therapists are involved at all, they are typically the “gender-affirming” therapists, who are expected to accept a patient’s self-diagnosis of gender dysphoria or gender incongruence based upon the patient’s report of a transgender identity. The result of such wide-spread, preconceived, unsupported motives not based in medical science is that the vast majority of patients who present for medical care reporting gender-related distress or with a self-diagnosis of gender dysphoria or gender incongruence based upon a transgender identity, will get rapid approval for hormonal and surgical interventions.

²¹⁸ Edwards-Leeper, Laura and Erica Anderson, “The mental health establishment is failing trans kids,” *The Washington Post*, <https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/>

²¹⁹ Anderson, E. (2022, January 3). Opinion: When it comes to trans youth, we’re in danger of losing our way. *The San Francisco Examiner*. Accessed January 5th, 2022

²²⁰ See Levine SB. Reflections on the Clinician’s Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav*. Published online September 15, 2021. doi:10.1007/s10508-021-02142-1

149. Yet according to WPATH, perfunctory mental health assessments, which the draft SOC8 describe as “brief assessment process,” are sufficient to approve 14-year-olds for treatment with irreversible cross-sex hormones, 15-year-olds with double mastectomies, and 17-year-olds with removal of their testes. Remarkably, the draft version of SOC8 claims that even if a patient is unable to provide informed consent, this should not be a barrier to surgery: “limits to capacity to consent to treatment should not be an impediment to individuals receiving appropriate GAMST [gender affirmative medical and surgical treatments].”²²¹

E. The risks of providing on-demand “gender-affirming” interventions are going to be borne out disproportionately by youth and by vulnerable populations.

150. There has been a recent sharp rise in trans-identification among youth, affecting 2% - 10% of the population, which remains poorly understood. Most are adolescent females with no history of childhood gender dysphoria, although the prevalence of males has also significantly increased. The majority suffer from significant mental health comorbidities.^{222 223}

151. The understanding of this phenomenon remains controversial. One group considers the Internet and rising status of trans persons to influence naïve youngsters to come out as trans while the other group thinks that the knowledge of treatment possibilities has allowed teens

²²¹ Society for Evidence-Based Gender Medicine, “WPATH SOC8 Draft Guideline,” Jan. 16, 2022, https://segm.org/draft_SOC8_lacks_methodological_rigor

²²² Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjäarvi, and Louise Frisen. “Gender Dysphoria in Adolescence: Current Perspectives.” *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41, <https://doi.org/10.2147/AHMT.S135432>

²²³ Zucker, Kenneth J. “Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues.” *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. <https://doi.org/10.1007/s10508-019-01518-8>

who always felt like the opposite gender to courageously reveal their status. The latter explanation rests on the assumption that trans identities are biologically dictated, which has not been demonstrated to be true.

152. Although research suggests there may be a biological influence, no studies have been able to identify a “transgender brain” once they have controlled for sexual orientation and cross-sex hormonal exposure.^{224 225} Such vital methodological confounds are rarely mentioned by those who present their hypothesis of a biogenic etiology as proven fact.

153. It is unknown how to best care for the rapidly growing group of trans-identified youth. A fundamental issue that is not being addressed is the adult fate of teens undergoing hormonal and surgical interventions. This glaring unanswered question is central for three reasons: first, multiple scientific reviews have pointed out a lack of convincing evidence of improved mental health during adolescence; second, every study of adult trans populations has indicated a high prevalence of various mental health problems; third, the age at which irreversible interventions are offered are getting progressively lower. For example, a key study reports that gender-dysphoric adolescents have had “top surgery” as young as 13.²²⁶

154. As pointed out earlier, in the absence of such early and aggressive interventions, the majority of children in eleven studies (typically, a large majority) who are diagnosed with

²²⁴ Skorska MN, Chavez S, Devenyi GA, et al. A Multi-Modal MRI Analysis of Cortical Structure in Relation to Gender Dysphoria, Sexual Orientation, and Age in Adolescents. Published online 2021:24.

²²⁵ Hoekzema E, Schagen SEE, Kreukels BPC, et al. Regional volumes and spatial volumetric distribution of gray matter in the gender dysphoric brain. *Psychoneuroendocrinology*. 2015;55:59-71. doi:10.1016/j.psyneuen.2015.01.016

²²⁶ See Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr*. 2018;172(5):431. doi:10.1001/jamapediatrics.2017.5440

gender dysphoria “desist”—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not.^{227 228} Nor is it known how many of the adolescents from the newly-presenting cohorts, who had no childhood history of gender incongruence, will persist versus desist, and how to best help them overcome their distress.

155. Detransitioners from the novel cohort of youth have begun to vocally voice regret, saying they were let down by the medical establishment.^{229 230}

156. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children and adolescents have an increased prevalence and incidence

²²⁷ See Ristori J, Steensma TD. Gender dysphoria in childhood. *International Review of Psychiatry*. 2016;28(1):13-20. doi:10.3109/09540261.2015.1115754

²²⁸ See Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. *Front Psychiatry*. 2021;12. doi:10.3389/fpsy.2021.632784

²²⁹ See Vandebussche E. Detransition-Related Needs and Support: A Cross-Sectional Online Survey. *Journal of Homosexuality*. Published online April 30, 2021:20. doi:10.1080/00918369.2021.1919479

²³⁰ See Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. Published online October 19, 2021. doi:10.1007/s10508-021-02163-w

of trans identities. These include: children of color,²³¹ children with mental developmental disabilities,²³² including children on the autistic spectrum (at a rate more than 7x the general population),²³³ children residing in foster care homes, adopted children (at a rate more than 3x the general population),²³⁴ children with a prior history of psychiatric illness,²³⁵ and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys).²³⁶ These data are consistent with Littman's research.²³⁷ Properly protecting vulnerable, marginalized patients from unproven, potentially dangerous treatments should be an essential concern. (G. Rider at 4.)

²³¹ 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. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-nonconforming identity, but only 29% of the set who had a gender identity consistent with their sex.)

²³² D. Shumer & A. Tishelman (2015), The Role of Assent in the Treatment of Transgender Adolescents, *Int'l J. of Transgenderism* at 1, DOI: 10.1080/15532739.2015.1075929.

²³³ D. Shumer et al. (2016), Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, *LGBT Health*, 3(5) 387 at 387.

²³⁴ D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, *Transgender Health* Vol. 2(1) 76 at 77.

²³⁵ L. Edwards-Leeper et al. (2017), 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 at 375 ("Psychological Profile"); R. Kaltiala-Heino et al. (2015), Two Years of Gender Identity Service for Minors: Overrepresentation of Natal Girls with Severe Problems in Adolescent Development, *Child & Adolescent Psychiatry & Mental Health* 9(9) 1 at 5 (In 2015 Finland gender identity service statistics, 75% of adolescents assessed "had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria."); L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, *PLoS ONE* 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that 62.5% of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability preceding the onset of gender dysphoria.")

²³⁶ G. Rider at 4; See 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. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-nonconforming identity, but only 29% of the set who had a gender identity consistent with their sex.); see D. Shumer & A. Tishelman (2015), The Role of Assent in the Treatment of Transgender Adolescents, *Int. J. Transgenderism* at 1, DOI: 10.1080/15532739.2015.1075929; D. Shumer et al. (2016), Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, *LGBT Health*, 3(5) 387 at 387; Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, *Transgender Health*, Vol. 2(1) 76 at 77; L. Edwards-Leeper et al. (2017), 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 at 375 ("Psychological Profile"); R. Kaltiala-Heino et al. (2015), Two Years of Gender Identity Service for Minors: Overrepresentation of

157. The lack of knowledge of etiology of the current presentations and future outcomes, combined with the lack of proper assessments, creates a very problematic situation for youth and vulnerable people, who are disproportionately affected by the lack of safeguards and wide accessibility of on-demand hormonal and surgical interventions.

F. There is a range of treatments to ameliorate gender dysphoria, from non-invasive to highly invasive.

158. Gender dysphoria has multiple causal influences and multiple resolutions.

159. As demonstrated above, hormones and surgeries have not been demonstrated to improve long-term outcomes of gender dysphoria sufferers.

Natal Girls with Severe Problems in Adolescent Development, *Child and Adolescent Psychiatry & Mental Health*, 9(9) 1 at 5 (in the 2015 Finland gender identity service statistics, 75% of adolescents assessed “had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria.”).

²³⁷ See L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, *PLoS ONE* 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that 62.5% of gender dysphoric adolescents had “a psychiatric disorder or neurodevelopmental disability preceding the onset of gender dysphoria.”).

160. The results of alternative approaches, such as watchful waiting for children, or gender-psychotherapy, are likewise lacking in long-term evidence. However, emerging evidence suggests that psychotherapy is a promising intervention for young people.^{238 239 240 241 242}

It should be noted that a key Finnish gender program recently announced that psychotherapy should be the first line of treatment for all gender dysphoric youth. A growing list of European countries appear to be moving in the same direction.

G. To determine whether West Virginia Medicaid and PEIA should be forced to categorically cover medical and surgical interventions for gender dysphoria, one will need to consider the balance of benefits and harms of such a decision.

161. Plaintiffs advocate for a lessened financial burden to achieve their desires for hormonal and various surgical procedures. These desires assume long lasting psychological benefits. Their personal economic benefits must be weighed against the harms to youth and other vulnerable individuals who include many transgender adults.

²³⁸ Schwartz D. Clinical and Ethical Considerations in the Treatment of Gender Dysphoric Children and Adolescents: When Doing Less Is Helping More. *Journal of Infant, Child, and Adolescent Psychotherapy*. Published online November 22, 2021;1-11. doi:10.1080/15289168.2021.1997344

²³⁹ Spiliadis A. Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development. *Metalogos Systemic Therapy Journal*. 2019;35:1-9.

https://www.ohchr.org/Documents/Issues/SexualOrientation/IESOGI/Other/Rebekah_Murphy_TowardsaGenderExploratoryModelslowingthingsdownopeningthingsupandexploringidentitydevelopment.pdf

²⁴⁰ Bonfatto M, Crasnow E. Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service. *Journal of Child Psychotherapy*. 2018;44(1):29-46. doi:10.1080/0075417X.2018.1443150

²⁴¹ Churcher Clarke A, Spiliadis A. ‘Taking the lid off the box’: The value of extended clinical assessment for adolescents presenting with gender identity difficulties. *Clin Child Psychol Psychiatry*. 2019;24(2):338-352. doi:10.1177/1359104518825288

²⁴² Lemma A. Trans-itory identities: some psychoanalytic reflections on transgender identities. *The International Journal of Psychoanalysis*. 2018;99(5):1089-1106. doi:10.1080/00207578.2018.1489710

162. Financial considerations must also be taken into account. The life-long costs of transgender interventions which are ever-growing in numbers and complexity, the cost of managing complications, fertility preservation, the costs of covering detransition procedures that will grow in numbers, and even the cost of potential future litigation over lack of safeguarding of youth and vulnerable populations must be accounted before any changes to the current laws are implemented.

163. It is my opinion that if West Virginia Medicaid and PEIA are forced to categorically cover medical and surgical treatments for patients with gender dysphoria without regard for traditional views of medical necessity and in contradiction to the unbiased, peer-reviewed, and high-quality literature cited herein, substantial harmful effects will occur. Vulnerable and impressionable youth will be disproportionately affected.

164. At this late half-century stage of surgical trans care, trans medicine is actually at an early scientific stage of hormonal and surgical trans care. What is glaringly necessary to advance the field is a social commitment to designing and implementing multiple site studies for each of the areas of uncertainty among children, young teens, older adolescents, and adults. It is most prudent and protective to support psychological services for trans-identified individuals, particularly for youth and their families. The least prudent approach would be to open the insurance gates so that all who think they want a medical or surgical intervention for themselves or their child should have it. I hope that I have made the reasons for this final statement abundantly clear.

*****SIGNATURE PAGE TO FOLLOW*****

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 18, 2022.



Stephen B. Levine, M.D.

Curriculum Vita
Stephen B. Levine, M.D.

Introduction:

Dr. Stephen B. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the solo author of four books, Sex Is Not Simple in 1989 (translated to German in 1992 and reissued in English in 1997 as Solving Common Sexual Problems); Sexual Life: A Clinician's Guide in 1992; Sexuality in Midlife in 1998 and Demystifying Love: Plain Talk For the Mental Health Professional in 2006; Barriers to Loving: A Clinician's Perspective in October 2013. He is the Senior Editor of the first (2003), second (2010) and third (2016) editions of the Handbook of Clinical Sexuality for Mental Health Professionals. He 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. From 1993 to 2017, he was co-director of the Center for Marital and Sexual Health/Levine, Risen & Associates, Inc. in Beachwood, Ohio. He and two colleagues received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005.

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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
- 1976 Board Certification American Board of Neurology and Psychiatry
- 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-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, 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

Professional Societies:

- 1971- American Psychiatric Association; fellow
- 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
 - President 1987-89
- 1983- International Academy of Sex Research
- 1983- Harry Benjamin International Gender Dysphoria Association
 - 1997-98 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:
 - Archives of Sexual Behavior
 - Annals of Internal Medicine
 - British Journal of Obstetrics and Gynecology

- JAMA
- Diabetes Care
- American Journal of Psychiatry
- Maturitas
- Psychosomatic Medicine
- Sexuality and Disability
- Journal of Nervous and Mental Diseases
- Journal of Neuropsychiatry and Clinical Neurosciences
- Neurology
- Journal Sex and Marital Therapy
- Journal Sex Education and Therapy
- Social Behavior and Personality: an international journal (New Zealand)
- International Journal of Psychoanalysis
- International Journal of Transgenderism
- Journal of Urology
- Journal of Sexual Medicine
- Current Psychiatry
- International Journal of Impotence Research
- Prospectus Reviewer for:
 - Guilford
 - Oxford University Press
 - Brunner/Routledge
 - Routledge

Expert Witness Appearances:

- US District Court, Judge Mark L. Wolf's witness in Michelle Kosilek vs. Massachusetts Dept of Corrections et al. case (transsexual issue) in Boston 2007
- Deposition in the Battista vs. Massachusetts Dept of Corrections case (transsexual issue) in Cleveland October 2009
- Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston
- Witness for Florida Department of Corrections in Keohone case, July, 2017

Consulting:

- 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

Grant Support/Research Studies;

- Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.
- 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 erythematosus and sexuality in women
- Sihler Mental Health Foundation
 - Program for Professionals
 - Setting up of Center for Marital and Sexual Health
 - Clomipramine and Premature ejaculation
 - Follow-up study of clergy accused of sexual impropriety
 - 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 of 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 FSDD-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:

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
 - (a) Translated into German as Angstfreie Sexualität: Glück und Erfüllung in der Liebe, Wilhelm Heyne Verlag, Muchen, 1992
 - (b) 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
 - (a) See review in Archives of Sexual Behavior 28(4): 361-363,1999
- 4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998
 - (a) See review in Am Journal of Psychiatry 156((9):1468, 1999
 - (b) See review in Contemporary Psychology APA Review of Books 44(4):293-295, 1999
 - (c) See review J Sex Education and Therapy January, 2000
 - (d) See review J Sex and Marital Therapy, Winter, 2000
- 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. see review American Journal of Psychiatry April, 2005
 2. 2006 SSTAR Book Award: Exceptional Merit
 3. see review in Archives of Sexual Behavior 35(6):757-758
 4. see two reviews in Journal of Sex and Marital Therapy 33(3):272-276
- 7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
 - (a) See review in Psychiatric Times, August 2008 by Leonore Tiefer
 - (b) See review in Journal of Sex and Marital Therapy 34(5)-459-460.
- 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. See review by Pega Ren, J Sex & Marital Therapy
- 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

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) Articles in *Medical Aspects of Human Sexuality*
 - (a) Treating the single impotent male. 1976; 10:123, 137
 - (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9
 - (c) Do men like women to be sexually assertive? 1977;11:44
 - (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31
 - (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.
 - (f) Commentary on sexual revenge.1979;13:19-21
 - (g) Prosthesis for psychogenic impotence? 1979;13:7
 - (h) Habits that infuriate mates. 1980;14:8-19
 - (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116
 - (j) Ford AB, Levine SB. *Sexual Behavior and the Chronically Ill*

- Patients. 1982; 16:138-150
- (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172
 - (l) Co-existing organic and psychological impotence. 1985;19:187-8
 - (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40
- 12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5
 - 13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92
 - 14) 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
 - 15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977
 - 16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597
 - 17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977;3:177-186
 - 18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15
 - 19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978;4:235-258
 - 20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978;113:958-962
 - 21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981;6:102-108
 - 22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113
 - 23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929
 - 24) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8
 - 25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983;12:247-61
 - 26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173
 - 27) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982;9:21-28
 - 28) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982;8:316-324
 - 29) Nymphomania. Female Patient 1982;7:47-54
 - 30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982;16:135-9
 - 31) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

- 32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.
- 33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine
- 34) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984;86:412-418
- 35) 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
- 36) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984;13:287-9
- 37) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96
- 38) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-
- 39) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985
 - (a) Translated into German
 - (b) Translated into Spanish
- 40) 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
- 41) 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
- 42) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987;13:35-44
- 43) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.
- 44) Lets talk about sex. National Hemophilia Foundation January, 1988
- 45) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988
- 46) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.
- 47) 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
- 48) 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.
- 49) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991

- 6(8):13-19
- 50) 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
- 51) 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
- 52) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injections in the management of diabetic impotence. *Journal of Sexual Education and Therapy* 16(2):126-36, 1989
- 53) Is it time for sexual mental health centers? *Journal of Sex & Marital Therapy* 1989;
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Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

Christopher Fain, individually and on behalf of all
others similarly situated, et al.,

Plaintiffs,

vs.

CIVIL ACTION NO. 3:20-cv-00740

William Crouch, et al.,

Defendants.

REMOTE VIDEOTAPED DEPOSITION OF DR. STEPHEN LEVINE

DATE: April 27, 2022

TIME: 8:00 a.m. CST

PLACE: Veritext Virtual Videoconference

REPORTED BY: KELLEY E. ZILLES, RPR (Via Videoconference)

JOB NUMBER: 5176996

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INDEX

WITNESS: DR. STEPHEN LEVINE PAGE

EXAMINATION BY MR. CHARLES..... 10
AFTERNOON SESSION..... 111
EXAMINATION BY MR. DAVID..... 229

OBJECTIONS... 14, 71, 73, 85, 86, 91, 92, 93, 94, 119,
133, 134, 163, 231, 232, 233, 235, 238, 239, 240

EXHIBITS MARKED AND REFERRED TO:

Exhibit 1 Expert Disclosure Report of Dr.
Stephen B. Levine, M.D..... 18

1	Exhibit 2	Curriculum Vitae.....	20
2			
3	Exhibit 3	BPJ vs. West Virginia State Board of	
4		Education, et al Deposition of	
5		Stephen Levine, Volume I, 3/30/22.....	53
6			
7	Exhibit 4	Special Programs.....	64
8			
9	Exhibit 5	Kadel vs. Folwell, et al Deposition of	
10		Stephen B. Levine, M.D., 9/10/21.....	76
11			
12	Exhibit 6	Case Western Health Care Coverage for	
13		Staff and Students.....	88
14			
15	Exhibit 7	Considering Sex as a Biological Variable	
16		in Basic and Clinical Studies: An	
17		Endocrine Society Scientific Statement.	97
18			
19	Exhibit 8	Reflections on the Clinician's Role with	
20		Individuals Who Self-identify as	
21		Transgender Paper.....	100
22			
23	Exhibit 9	One Year Since Finland Broke with WPATH	
24		Standards of Care, 7/2/21.....	105
25			

1	Exhibit 10	International Clinical Practice Guidelines	
2		for Gender Minority/Trans People:	
3		Systematic Review and Quality Assessment	
4		Article.....	113
5			
6	Exhibit 11	Dear Colleagues, Clients and Friends,	
7		by Marci Bowers, M.D.....	125
8			
9	Exhibit 12	Gender Dysphoria and Gender	
10		Reassignment Surgery Article.....	131
11			
12	Exhibit 13	Canadian Gender Report.....	140
13			
14	Exhibit 14	Detransition-Related Needs and Support: A	
15		Cross-Sectional Online Survey Article..	155
16			
17	Exhibit 15	Individuals Treated for Gender Dysphoria	
18		with Medical and/or Surgical Transition	
19		Who Subsequently Detransitioned: A	
20		Survey of 100 Detransitioners.....	161
21			
22	Exhibit 16	Endocrine Treatment of	
23		Gender-Dysphoric/Gender-Incongruent	
24		Persons: An Endocrine Society Clinical	
25		Practice Guideline.....	163

1	Exhibit 17	Pediatric Obesity–Assessment, Treatment,	
2		and Prevention: An Endocrine Society	
3		Clinical Practice Guideline.....	177
4			
5	Exhibit 18	26 Swedish Review Unavailable.....	189
6			
7	Exhibit 19	Finnish Article.....	189
8			
9	Exhibit 20	Gender-Affirming Hormone in Children	
10		and Adolescents Blog Screen Shot.....	193
11			
12	Exhibit 21	Gender-Affirming Hormone in Children	
13		and Adolescents Article, 2/25/19.....	194
14			
15	Exhibit 22	Fain vs. Crouch, et al Deposition	
16		Transcript of Cynthia Beane, 3/29/22...	217
17			
18	Exhibit 23	Transgender and Gender Diverse Children	
19		and Adolescents: Fact-Checking of AAP	
20		Policy.....	221
21			
22	Exhibit 24	A Follow-Up Study of Boys with Gender	
23		Identity Disorder Article.....	224
24			
25			

1 Exhibit 25 Gender Dysphoria in Childhood Article.. 227

2
3
4 (Original exhibits attached to original transcript.
5 Copies attached to transcript copies.)
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10
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1 of your career, right?

2 A. Yes.

3 Q. Okay. You listed 23 separate pharmaceutical
4 company grants to study various pro-sexual medications,
5 right?

6 A. Yes.

7 Q. Were any of these 23 grants related to the
8 treatment of gender dysphoria in transgender people?

9 A. No.

10 Q. And were any of the grants related to the
11 treatment, any kind of treatment of prepubertal children
12 with gender dysphoria?

13 A. No.

14 Q. Or adolescents with gender dysphoria?

15 A. No.

16 Q. You also list in that same section in your
17 report, Dr. Levine, that you received a U.S. National
18 Institute of Health grant for the study of sexual
19 consequences of systemic lupus erythematosus and that
20 you were a co-principle investigator. Does that ring a
21 bell, is that accurate?

22 A. It is accurate.

23 Q. Okay. And did this grant have to do with the
24 study of anything related to gender dysphoria?

25 A. No.

1 A. Only to the extent that the grant helped us to
2 set up the Center For Marital & Sexual Health. The
3 Center For Marital & Sexual Health had a program called
4 the Case Western Reserve Gender Identity Clinic, and so
5 this was, this was not a grant for research, this was a
6 grant for the establishment, the administrative
7 establishment of our center that dealt with many sexual,
8 all sexual things including trans phenomenon. We didn't
9 in those days call it so much trans phenomenon, but we
10 called it gender identity problems.

11 Q. Right. So one of the grants was used to start
12 the Center for Marital & Sexual Health, but those five
13 separate grants were not for the study or, or direct
14 treatment under the Sihler Mental Health Foundation?

15 A. That's correct.

16 Q. Okay. But the Center For Marital & Sexual
17 Health, as a clinician there you saw a wide range of
18 patients there, right?

19 A. Yes.

20 Q. With a variety of problems related to sexuality
21 or sexual well-being?

22 A. Yes.

23 Q. Okay. And did you treat any children with
24 gender dysphoria at the Center For Marital & Sexual
25 Health?

1 A. If I can clarify your question, by you do you
2 mean me personally or do you mean under me as the
3 supervisor of people who did that?

4 Q. Let's start with you personally.

5 A. Yes, I have only on a rare occasion personally
6 treated or directly or indirectly treated a child. My
7 center, however, over the years has, has seen children
8 and, and I've been involved in the, the treatment as a
9 supervisor of those children.

10 Q. Okay. So you've reviewed their cases by way of
11 your supervision of clinicians at the center, but not
12 individually?

13 A. That's right.

14 Q. Okay. And is that the same for any adolescents
15 with gender dysphoria who were seen at the center? In
16 the early years I'm talking about now, not in recent
17 times.

18 A. Well, in the early years I occasionally saw
19 personally an older teenager, older adolescent, but in
20 the early years you must understand most of the patients
21 were adults.

22 Q. Okay. So to your knowledge, Dr. Levine, have
23 you received any grants to study the treatment -- I'm
24 sorry, excuse me. Have you received any grants to study
25 treatment for adults with gender dysphoria?

1 April 27, 2022. We're going back on the record at
2 10:36 a.m.

3 BY MR. CHARLES:

4 Q. Okay. Dr. Levine, talking about your writing
5 credentials, you've testified previously that you were
6 involved in drafting portions of the WPATH standards of
7 care Version 5, right?

8 A. Yes, I was the chairman of that group.

9 Q. And besides that, have you developed -- let me
10 back up. Have you helped to develop treatment
11 guidelines for the treatment of children or adolescents
12 with gender identity issues?

13 A. If you mean have I been part of a national or
14 international group that tried to, to publish, that
15 published guidelines about the treatment of these
16 individuals, the answer is no. But in my November of
17 2021 article I gave, I offered my opinions about what
18 the evaluation of adolescents and children ought to
19 consist of. In that sense I'm hoping that would
20 influence the guidelines of those committees who might
21 function in the future.

22 Q. I see. When we spoke in September of 2021 for
23 the Kadel vs. Folwell deposition, you said that you were
24 working with SEGM to develop some treatment guidelines.
25 What, what happened to those?

1 Q. Yes, Exhibit 01.

2 A. Would you give me the pages again.

3 Q. Sure, Page 2, Paragraph 3, so that will be the
4 top of Page 2, the paragraph does begin on Page 1.

5 A. Yeah.

6 Q. Okay. So in that paragraph your report states
7 that, "During this era an occasional child was seen."
8 By this era do you mean from around 1974 to 1993?

9 A. Yes.

10 Q. Okay. And by occasional do you mean infrequent?

11 A. Infrequent is a good word.

12 Q. So is it fair to say during that period your
13 clinic did not see many children with gender dysphoria?

14 A. It's fair to say that.

15 Q. And in your deposition on March 30th you
16 estimated that over the course of your career you've
17 probably only seen regularly six prepubertal children,
18 right?

19 A. It's an estimate, yes.

20 Q. And around 50 adolescents, give or take?

21 A. Give or take an unknown number, yeah, ten, 12,
22 five.

23 Q. Sorry, so you --

24 A. I've had extensive experience talking to
25 adolescents over the course of my career, adolescents

1 should do about the whole problem of insuring people
2 with this condition, I think it's beyond my expertise.

3 Given my medical knowledge and given my, what I
4 would like to say my knowledge of the literature, given
5 my knowledge of the patient, I recognize that there are
6 lots of possibilities and I think it would be a shame
7 for some people not to have access to that care and I
8 think even though it's a shame, it poses new
9 developmental challenges for the patient which they may,
10 may very well rise to the occasion and find some other
11 solution to their dilemma.

12 Q. Okay. So, so you're not offering an expert
13 opinion about what insurance should or should not cover
14 here?

15 A. Yeah, I believe that that's the policy level
16 done at government level and insurance company level
17 having to do with all sorts of decisions that no doctor,
18 including Dr. Levine, has adequate background
19 information to make that determination.

20 Q. But generally would it be fair to say you want
21 what is best for your patients?

22 A. Yes, I do.

23 Q. Even if they're not wealthy or affluent, right?

24 A. Even if they're not wealthy or affluent or
25 insurance covered.

1 A. I got it.

2 Q. Oh, you can see it?

3 A. I got it now.

4 MR. CHARLES: So for the record, this is
5 Exhibit SL05, deposition of Stephen B. Levine on
6 September 10th, 2021 in the matter of Kadel, et al. vs.
7 Folwell.

8 Q. And you, you said earlier today, Dr. Levine, you
9 remember giving this deposition last year?

10 A. I did, I do.

11 Q. Okay. And if you'll just scroll to Page 2
12 there. Actually, no, that's okay, Doctor, just leave it
13 open for a minute for me, if you would. The page
14 numbers on this document are in the upper right-hand
15 corner.

16 A. I see.

17 Q. Okay. So if you could please scroll to Page 51.

18 A. Getting close, 50, 51, I'm there.

19 Q. Okay. So then down at line 14, it's about
20 halfway down the page, do you see that? The page, I'm
21 sorry, the line numbers are on the left-hand side of the
22 page.

23 A. I see it.

24 Q. Okay. So the question was, "And using that same
25 framing of regular, how many children, so under age 11?"

1 Answer, in the last year? Question, yes, yes, in the
2 last year. Answer, zero." So I just wanted to refresh
3 your recollection of your testimony there and ask, have
4 you seen, like has that number changed in the last seven
5 months since you provided this testimony?

6 A. No.

7 Q. Okay. Let's see. And then on that same page,
8 Dr. Levine, at line 19, it begins, "How many
9 adolescents," do you see that?

10 A. Yes.

11 Q. Okay. It says, "How many adolescents in regular
12 treatment for gender dysphoria would you approximate
13 you've seen in the last five years individually,
14 exclusive of your supervision of other clinicians?" At
15 line 24, "Answer, if you ask me the question in the last
16 year, I would have told you five or six, but since
17 you've asked it as a five-year period, I'm at a loss to
18 tell you whether it's 12 or 15." That's on the top of
19 Page 52, do you see that, Dr. Levine?

20 A. I see it.

21 Q. Okay. So then has that -- so let me start
22 first, in September of '21 you said in the last year you
23 had seen about five or six adolescents, would that, has
24 that number changed in the last seven months?

25 A. A little bit, yeah.

1 A. Page 51.

2 Q. Okay. Can you please scroll to Page 55.

3 A. I'm there.

4 Q. Okay. So at line 13 on Page 55, "Question,
5 okay, and I'm sorry, just by recent, when was the last
6 time you wrote a letter of authorization for a gender
7 affirming surgery for an adult? Answer, probably
8 12 months ago." So have you written a letter of
9 authorization for a gender affirming surgery in the last
10 seven months, Dr. Levine?

11 A. I think the last letter -- you, I need to, I
12 need to help you qualify your question. I have in the
13 last seven months given my, my approval to several
14 letters for bilateral mastectomies for members in Mass
15 at Framingham, the correctional institution in
16 Massachusetts. I don't know if that would number two or
17 three, but since September the 10th I believe at least
18 two and possibly three letters. I haven't personally
19 written the letter, but I am the consultant to a group
20 of team that approves such surgeries, and so the answer
21 to the question is yes.

22 Q. Okay. Thank you. And to your recollection,
23 any, any such letter outside the, outside of that
24 context?

25 A. Since September the 10th?

1 Q. That's correct, yes.

2 A. Yes, I think the answer is that, no, but I
3 believe at our center someone else has written one
4 letter for bilateral mastectomies.

5 Q. Okay. Thank you. Dr. Levine, are you familiar
6 with the, the exclusion for gender affirming surgical
7 care in the West Virginia Medicaid Program that's at
8 issue in this case?

9 MR. DAVID: Objection to form.

10 Q. You can answer.

11 A. I'm vaguely familiar that surgical care is
12 excluded currently, but endocrine care is not excluded.

13 Q. Have you reviewed any documents that, that show
14 that exclusion or was that information just communicated
15 to you by counsel?

16 A. Verbally communicated.

17 Q. Okay. And so you're aware that there are
18 categorical exclusions, which means that the exclusions
19 prohibit surgical care related to the treatment of
20 gender dysphoria regardless of a West Virginia Medicaid
21 member's need for it or appropriateness for such
22 intervention?

23 MR. DAVID: Objection to form.

24 Q. Let me simplify my question.

25 A. Thank you.

1 Q. The categorical, the exclusion does not
2 investigate or contemplate whether someone receiving
3 West Virginia Medicaid needs or is an appropriate
4 candidate for such intervention, it just prohibits it,
5 period?

6 MR. DAVID: Objection to form.

7 A. The categorical exclusion would include surgery
8 for teenagers and surgery for adults, so it would cover
9 removing the breasts or removing the scrotum of a
10 15-year-old who feels like --

11 Q. Not my question, Dr. Levine. Let me, let me
12 rephrase again. The, the West Virginia Medicaid Program
13 and the exclusion it maintains, which excludes surgical
14 care for members for whom it is appropriate, it, it just
15 excludes it, you're, you're aware it just excludes it,
16 there's no, there's no conditional considerations or any
17 investigation done into the member's health at all, it
18 just, there's no coverage for that care, you understand
19 that?

20 A. I, I --

21 MR. DAVID: Objection to form.

22 A. I think that's what categorical means, so I
23 think the answer is I understand that at the moment,
24 yes.

25 Q. Okay. But you don't view your testimony here in

1 your expert report as being in support of that exclusion
2 or whether it should exist, right?

3 A. Yeah, it's my understanding that, that the
4 lawyers who hired me wanted me to testify to the state
5 of science in this field, and, and so I have not been
6 involved with the legal questions, per se, or giving an
7 opinion about those matters. As I sort of indicated to
8 you before, I don't really feel that the, my expertise
9 extends to how the insurance industry works and how
10 governments and legislatives works and so forth. So I,
11 I think the answer to the question is that I'm not
12 considering myself to be expert on the question that
13 you're asking me.

14 Q. Right. So you're, you, you are an expert about
15 what your testimony is about though, right, and you're
16 saying your testimony is not about whether or not that
17 exclusion should exist?

18 A. Yes, I'm not offering an opinion about pro or
19 con about that question.

20 Q. I see. Because you're, you're, as you say,
21 you're not a politician or a law maker?

22 A. Or an insurance expert.

23 Q. Right. Or a public health expert, right?

24 A. Well, I'm a little more ambivalent about public
25 health matters, yeah. I'm not as, I'm not, I really

1 think that public health is the issue here and so I, I
2 don't want to say I'm not an expert. I'm not an expert
3 in public health, but I do have opinions about the
4 long-term public health of people who are prematurely
5 having their bodies changed because I do think this has
6 public health implications for the future of each of
7 these, these adolescence children and young adults.

8 Q. Understood.

9 A. And adults as well.

10 Q. And you, generally speaking, don't advocate to
11 deny all forms of medical intervention to people with
12 gender dysphoria though, right?

13 A. That's right.

14 Q. Okay. I'm going to introduce another exhibit,
15 Dr. Levine, give me just a moment.

16 (Exhibit 6 marked for identification.)

17 Q. Okay. It should be now or shortly visible, you
18 might need to refresh.

19 A. I now have Exhibit 6 here.

20 Q. Okay.

21 MR. CHARLES: So I'm showing Dr. Levine
22 what has been marked as SL06.

23 Q. Dr. Levine, this is a short document, please
24 just take a minute and scroll through it.

25 A. Okay, I, I've scrolled.

1 (A break was taken at 11:33 a.m.)

2 VIDEO TECHNICIAN: We're going back on the
3 record at 12:34 p.m.

4 MR. CHARLES: Okay. So I'm showing Dr.
5 Levine what has been marked as SL09, an article from
6 Society for Evidence Based Gender Medicine entitled,
7 "One year since Finland broke with WPATH standards of
8 care."

9 BY MR. CHARLES:

10 Q. Dr. Levine, do you see the date of publication
11 in the left corner of that first page?

12 A. July 2nd.

13 Q. And, and the year is 2021, right?

14 A. Yes.

15 Q. So looking at the first paragraph there, I'm
16 just going to read that, "A year ago the Finnish Health
17 Authority (PALKO/COHERE) deviated from WPATH standards
18 of care 7 by issuing new guidelines that state that
19 psychotherapy rather than puberty blockers and cross sex
20 hormones should be a first line treatment for gender
21 dysphoric youth. This change occurred following a
22 systematic evidence review which found a body of
23 evidence for pediatric transition inconclusive."

24 And then the next paragraph, the first sentence,
25 "Although pediatric medical transition is still allowed

1 in Finland, the guidelines urge caution given the
2 unclear nature of the benefits and the interventions,
3 largely reserving puberty blockers and cross sex
4 hormones for minors with early onset gender dysphoria
5 and no co-occurring mental health conditions." Did I
6 read that correctly?

7 A. Yes, you did.

8 Q. Okay. So as this article states, medical
9 interventions are still available in Finland for youth
10 experiencing gender dysphoria, right?

11 A. On a case-by-case basis I think.

12 Q. And --

13 A. I should say on a case-by-case basis and two
14 research centers as opposed to in any practitioner's
15 office throughout the country.

16 Q. Right. But it's, it's not been completely
17 prohibited is what I'm asking?

18 A. Oh, it's been, it's been, the brakes have been
19 put on.

20 Q. But it's not been completely prohibited is what
21 I'm asking?

22 A. That's what you and I have agreed on, yes.

23 Q. So it's not been completely prohibited, right?

24 A. Right.

25 Q. So then in the third paragraph beginning with,

1 "The qualifying criteria for gender reassignment of
2 youth articulated in the 2020 Finnish treatment
3 guidelines are consistent with the original Dutch
4 protocol, but represent a significant tightening of the
5 more recent practices promoted by WPATH." So the
6 article describes it as a tightening of the standards
7 which WPATH allows for, right?

8 A. Yes.

9 Q. So you, you've talked about in your report an
10 idea of rapid affirmation treatment where you allege
11 that diagnoses of gender dysphoria are being made in an
12 hour and then, and then prescriptions provided for
13 medical interventions, right?

14 A. Yes.

15 Q. Do you have, or I should say, your evidence for
16 that is anecdotal in nature, right?

17 A. My evidence for that is what has been told to me
18 by parents, what has been told to me by patients and
19 what this, what the third paragraph of this document
20 says.

21 Q. Right. So --

22 A. So I don't really think the answer is simply
23 anecdotal, it's based upon a considerable consistent
24 range of, of experiences, both of my personal
25 experiences, of my patient's personal experiences, and

1 paragraph -- actually, hang on a second. Dr. Levine,
2 let's go ahead and go to Page 26 of your report,
3 Exhibit 1.

4 A. Okay. Let me, I have to scroll back. Did you
5 say page or Paragraph 26?

6 Q. That would be Page 26.

7 A. Okay, I'm on Page 26.

8 Q. Okay. Okay. So, Dr. Levine, you've testified
9 previously that you generally provide care along some of
10 the same guidelines as WPATH, right?

11 A. In a general way, sure.

12 Q. And the difference from your view is that you
13 require psychotherapy for some not necessarily
14 predetermined length of time for patients that you see
15 before you will authorize any kind of like medical
16 intervention, right?

17 A. I don't want to answer that question right or
18 wrong because embedded in the question is the word
19 psychotherapy and I don't know what you understand by
20 psychotherapy, I mean, you're a lawyer and I'm a
21 practitioner of psychotherapy. And I think when a
22 lawyer uses psychotherapy it is a certain concept about
23 I'm trying to achieve a certain aim, you see. And in
24 the context of the question that you've asked, you could
25 substitute an extended period of time with the patient

1 working with patients.

2 Q. Okay. So back to my question. On some, on some
3 level that that is, that universe of care that you are
4 providing, which again, I think I'm still going to call
5 it psychotherapy, but I understand your explanation that
6 it is, that encompasses a lot that you do in your, in
7 your clinical practice, but again, the difference for
8 you between the Levine way, if we can shorthand, and
9 WPATH is that you cultivate, you engage in that process
10 as a requirement before you will authorize any kind of
11 medical intervention for a patient for the treatment of
12 gender dysphoria?

13 A. That's true.

14 Q. Okay. Thank you. But even still as a part of
15 your practice as we discussed earlier, you still
16 occasionally write letters of authorization for medical
17 interventions, like endocrine treatments or surgical
18 interventions?

19 A. Yes.

20 Q. Okay. Okay. Let's go back to your report,
21 please, to Page 35.

22 A. I am there.

23 Q. Okay. And looking at Paragraph 70, let's start
24 with Paragraph 70. I take that back, let's go with
25 Paragraph 71 at the bottom of the page, "In recent years

1 WPATH has fully adopted some mix of the medical and
2 rights paradigm discussed above. It has downgraded the
3 role of counseling or psychotherapy as a requirement for
4 these life-changing processes. WPATH no longer
5 considers pre-operative psychotherapy to be a
6 requirement. It is important to WPATH if the person has
7 gender dysphoria, the pathway to the true, the
8 development of this state is not. Cited Levine,
9 Reflections, at 240. Two separate evaluations, one from
10 Canada and one from the UK reviewed WPATH's guidelines
11 and found them untrustworthy."

12 So for that footnote 113 you've cited the Dahlen
13 study which we talked about and then there's also a
14 citation here that says, "See also," and then there's a,
15 a Web address, do you see that, the very last line?

16 A. Yeah, yeah, right.

17 Q. It says, "Gender report, CA"?

18 A. Yeah.

19 (Exhibit 13 marked for identification.)

20 Q. Okay. There should be another exhibit there for
21 you, Exhibit 13. Just let me know when you can see
22 that.

23 A. Okay. Okay.

24 Q. Okay.

25 A. Yeah, okay.

1 Q. Have you, have you seen this article before
2 either on the Internet or printed out perhaps?

3 A. The reason I cited it is that I had read it
4 before.

5 Q. Okay. And this is not a peer reviewed journal,
6 is it?

7 A. This is a journalist, but if you look very
8 carefully at the, its length and its content, it's very
9 impressive.

10 Q. Okay. Is this the review from Canada that you
11 were talking about in that sentence --

12 A. Yes, yes, it is.

13 Q. Okay. But it's, it's not a systematic review
14 like the one from the UK?

15 A. It's not systematic in that it wasn't done by a
16 community of scientists, a committee of scientists.

17 Q. Okay. And the --

18 A. It is systematic and it is a review, but it's
19 one person's review.

20 Q. Right. So it's more, we were discussing the
21 difference between systematic reviews earlier today,
22 it's a, it's, it's not a scientific committee that's
23 done in a, in a formal way that we were discussing, it's
24 more akin to that latter one person reviewing things
25 kind of --

1 A. It's an investigative report by a journalist.

2 Q. Right. And you see in the first page, Dr.
3 Levine, it says, "The following investigative report was
4 developed by @LisaMacRichards (a pseudonym)"?

5 A. Yeah, okay, right.

6 Q. Okay.

7 A. I see I'm wrong, she wasn't the journalist.

8 Q. So we, you don't know who this author is, right?

9 A. Well, her real identity?

10 Q. Correct, yeah.

11 A. No, I don't know who Lisa Mac Richards really
12 is.

13 Q. Okay. So it's hard to know if she's an actual
14 person?

15 A. If she's an actual person, is that what you
16 said?

17 Q. What I mean to say is, because she's using a
18 pseudonym, you can't confirm her identity is what she
19 represents it is, right?

20 A. Well, she says it's a pseudonym, so I presume
21 the rest of the paragraph is correct, that she works at
22 a Canadian hospital and holds a master's of science
23 degree and, yeah.

24 Q. But what I mean is there's no way to confirm
25 that because we don't know what her name is?

1 A. It could be written by a man, I don't know, it
2 could be written by a committee, I have no idea.

3 Q. Okay. Okay. So going back to what we were
4 talking about just a few minutes ago, Dr. Levine, about
5 your approach versus WPATH. You, you've said before,
6 not, not necessarily today, but you've testified in
7 other depositions that your approach has the limitation
8 that there's not any scientific evidence or long-term
9 studies to support it, right?

10 A. I think in particular what I said is that, that
11 the status of the outcome, the outcome status and the
12 methodologic status of psychotherapy as a first line
13 approach to the trans adolescent has, does not have a
14 firm evidence base just as trans affirmative care does
15 not have a firm evidence base.

16 So oftentimes that's, that's, I get a question
17 just like you ask, you just posed sort of implying that
18 there's no evidence that my, my recommendations have a
19 scientific proven basis to it. And that is correct,
20 except that all other psychiatric difficulties are
21 treated with, in our society both European and American
22 and Asian societies by a psychotherapeutic extended
23 evaluation and treatment approach before, with or
24 without psychiatric medications, you see.

25 And so we are trying to make a, you, some people

1 centers have cropped up that are providing affirming
2 care in one hour, again, we talked about the 35 parents
3 you had talked to, you've mentioned a couple of patients
4 you've talked to, but you don't have, or I should say
5 what evidence can you provide me today that is, is
6 scientific peer reviewed published data showing that
7 this is actually what's happening in these clinics?

8 A. Well, if I look at Exhibit 6. Do you know what
9 the, the first name for this center was and the name of
10 so many of the 50 or so centers are? And it has the
11 term gender affirming care, the clinic, you see. If you
12 look at all of the materials in Exhibit 6, it's about
13 support and affirmation, it's not about investigation,
14 it's not about psychotherapy. And, and you see, gender
15 affirming care has been taken over, it's been taking
16 over the world's sensibilities without any scientific,
17 first demonstrating its efficacy with scientifically
18 respectable methods.

19 Q. I understand that, Dr. Levine, but that's not my
20 question. My question is, what evidence can you point
21 to that these kinds of interactions are happening in
22 clinics? Is your basis that the, are you basing that on
23 the way these centers are named?

24 A. I'm basing it on what they're named and I'm
25 looking at the document that you are, are talking about.

1 friendly especially designed specialty clinic. Those
2 clinics exist to take care of trans people, to give them
3 hormones and to get them surgery, that exists.

4 Q. But what you're describing --

5 A. It exists to do psychotherapy.

6 Q. Okay. And what you described, Dr. Levine, is
7 the basis for your, for this opinion, right?

8 A. The basis for my opinion is my collective
9 experience of dealing, watching, participating in the
10 evolution of the study of transsexual care over, over
11 since 1974.

12 Q. Okay. So your report states that you were
13 involved with WPATH before it was called WPATH, when it
14 was called the Harry Benjamin --

15 A. Can I help you?

16 Q. Yes. Harry Benjamin?

17 A. International Gender Dysphoria Association.

18 Q. Thank you. And you were involved around 1999
19 when the 6th version of the standards of care was
20 released, right, we talked about that?

21 A. Yes.

22 Q. Okay. And it's, it's true that you helped to
23 draft portions of that version, right?

24 A. Actually, my report misstates me as the
25 co-chair. If I remember correctly, I was the chairman.

1 Q. The chairman of that committee, okay. Thank
2 you.

3 A. And most, with very little exception I had a
4 significant editorial role in creating every sentence in
5 that 21-page document.

6 Q. Okay. And you've testified in other depositions
7 that even though the, there have been changes made to
8 the standards of care in subsequent versions, you still
9 continue to see your work reflected in those versions,
10 right?

11 A. Yes, my language.

12 Q. Yes, mm-hmm.

13 A. Yeah, my language, right. In fact, the next
14 version which came out I think three years later or two
15 years later I think was pretty much word for word except
16 for a requirement for one letter for endocrine treatment
17 rather than two, which is what my committee of eight
18 people recommended.

19 Q. Okay. And you've testified before that even
20 Version 7, which is, you know, one more, obviously one
21 more removed from Version 6, that that, as you read it
22 much of the language you had actually still, it was
23 still reflecting your language in that version even,
24 even though it's a much longer document?

25 A. Well, yeah, I think the introduction section

1 about what guidelines were and, and the problems of
2 cross culture, cross country rules affecting the laws
3 are different and the, that we wanted this to be a
4 information guide for, for patients and parents and
5 wives and husbands and so forth.

6 I think, you know, once, once we got, I mean, I
7 don't have it in front of me and I'm not sure I could
8 recognize every sentence I wrote anyway, but, but they
9 did, they did continue to use some of my sentences, some
10 of my concepts. It was my concept that there is a
11 difference between readiness criteria and eligibility
12 criteria, that was one of my contributions

13 Q. Thank you. And, and I think also you testified
14 in the Soneeya trial that you had asked to be involved
15 in helping to write standards of care 8 but were told
16 that you, in order to do so you had to be a WPATH
17 member, right?

18 A. Yes.

19 Q. And looking back at your report -- actually,
20 give me just a minute here. Actually, Dr. Levine,
21 let's --

22 MR. CHARLES: Sorry, Kelley and Kraig, can
23 we go off the record real quick.

24 VIDEO TECHNICIAN: We're going off the
25 record at 2:26 p.m.

1 be trans boys or trans males.

2 The historic pattern throughout most of the
3 world was 3.5 to 4 biologic males who wanted to be women
4 to biologic females who wanted to be men dominated
5 dramatically for decades in the '70s and the '80s and
6 the '90s and the early 2000s. But since 2005 there's
7 been a growing incidence of request for services and
8 particularly request for services from girls assigned at
9 birth who wanted to be males.

10 Some of us have come to in recent years call
11 this delayed or pubertal or rapid onset of gender
12 dysphoria, meaning it's a pubertal phenomenon because
13 there was no evidence prior to that except in the
14 retrospective subjective histories given by these kids
15 that they had any indication, parents and themselves,
16 had no behavioral indications that they were trans
17 identified or even sort of leaning in that direction.

18 Q. I understand that, Dr. Levine, and I'm not
19 talking necessarily about the, the increase in
20 referrals, I'm talking about this phenomenon that you
21 referenced called rapid onset gender dysphoria. So not
22 just adolescent onset gender dysphoria, which I
23 understand you're saying has somewhat increased since
24 2005, but rapid onset gender dysphoria. And I'm
25 specifically asking what peer reviewed studies, what

1 papers and what research would you refer me to or is
2 referenced in your report as evidence that this
3 hypothesis actually exists or that there's any
4 scientific study to support it?

5 A. No. 1, this is not a hypothesis, this is a
6 demonstrated fact.

7 Q. Okay. Based on what, Dr. Levine, that's what
8 I'm asking, what are the peer reviewed studies?

9 A. If you look up the presentations of Kenneth
10 Zucker, if you look at papers, I can't give you the
11 authors at the moment from Europe, this has been
12 documented by DiAngelo I believe in Australia, by
13 Clayton in Australia.

14 It seems to me there is no disagreements about
15 this except I've heard the cynical response that what
16 rapid onset gender dysphoria really means is that the
17 parents have suddenly discovered that their kids have
18 been transgender, meaning to deny the parental reports
19 that the children were not cross gender identified prior
20 to that, even though the kids say, well, I was never
21 comfortable with being a boy or a girl.

22 Q. Okay. So you, for this contention in your
23 report you cite one thing and that is Midgen A.
24 Hutchinson and her study is entitled, "In support of
25 research into rapid onset gender dysphoria." So that

1 was published in 2020 and I don't, I'm not seeing here
2 any of the other --

3 A. One, one of the reasons you're not seeing it is
4 that I assume that everyone understands that this is
5 true.

6 Q. Well, Dr. Levine, this is an expert report and
7 you have to include all of your expert opinions, and
8 you're also required under Rule 26 to disclose all of
9 the data and research that you considered for those
10 opinions. That's the purpose of our deposition today is
11 for me to understand and to have you put on the record
12 what you relied on to establish your opinions, so that's
13 what I'm trying to get at. And, and I understand what
14 you're saying that from your vantage point as a
15 clinician outside of the legal sphere that there are
16 things you think are givens, but we can't operate like
17 that unfortunately. So I need to, I need to understand,
18 and all I see here is the Midgen A. Hutchinson study
19 that's asking for support of, that's offering that she
20 wants to support research into this phenomenon, not that
21 the phenomenon has been evidenced to exist. Does that
22 make sense?

23 A. Yes. May I comment on that?

24 Q. On Hutchinson, yeah. Let me pull it up
25 actually.

1 this care and then after they lived following the care
2 they decided that their problems have not been solved
3 and they decided to return to the gender expression --

4 Q. I understand that, Dr. Levine, and I'm not
5 actually contesting the assertion in your, in your
6 report that detransition exists at all.

7 A. All right.

8 Q. What I'm asking about is your assertion in the
9 latter half of that sentence that says that there is a
10 growing number of young people who regret transition and
11 wish to reverse it. Again, I'm just trying to
12 understand what you're saying here and on what basis you
13 are making those assertions.

14 So I'm not asserting whether or not
15 detransitioning exists, my question is, this study did
16 not look at how many detransitioners are there now as
17 opposed to any other time in history, it was not a
18 qualitative or quantitative analysis. It was a study
19 according to the abstract here, and I'm just asking you
20 to confirm that, about the specific needs of
21 detransitioners, both psychological, medical, other
22 kinds of support, right? So that's what I'm saying is
23 this study is not, the aim is not to quantify the number
24 of, whether the number of detransitioners is growing or
25 shrinking or staying the same, right?

1 A. Yes, I can answer to your question, correct.

2 Q. Okay.

3 A. But it doesn't mean that -- I think you're
4 missing the point. And, and by, by having me say yes,
5 that it doesn't quantify the incidents of detransition,
6 it's missing the point.

7 Q. I understand that, Dr. Levine. But if your
8 point was, if your point in your report was detransition
9 is a thing and here are the psychological supports that
10 these people need, that's what you should have written,
11 but that's not what you wrote. You wrote that a growing
12 number of young people regret transition and wish to
13 reverse it.

14 So my question to you about the article you rely
15 on for that contention is, this article doesn't say
16 that, this article is not a study of the growing numbers
17 or small or diminishing numbers or staying the same
18 numbers of people who detransitioned. That's what I'm
19 asking you to confirm.

20 A. What I am confirming is that this particular
21 paper talks about 237 people who have detransitioned and
22 that WPATH has no serious discussion of detransition,
23 there's no chapter on this, on this phenomenon which is
24 extremely relevant to the care of transgender people,
25 especially transgender young people.

1 The reason I cited this is 237, and the reason,
2 the next thing, Littman is another additional 100
3 people. And if you, if you read closely some of the
4 references in this particular article, there is
5 Exposito-Campos' article talking about subreddit and the
6 number of people who were discussing detransition.

7 So what I'm saying if WPATH is responsible for,
8 for providing a scientific basis for affirmative care,
9 they must talk about the error rate as represented by
10 detransitioned people. And four years ago we had no
11 idea about the, the rate of detransitioned people and
12 today we have two studies that have been published from
13 the UK that begin to give us a rate of detransition.

14 And so to me you are making the wrong point and
15 that I have not been in error. You just have
16 misunderstood the difference of why I cited these
17 particular papers. These particular papers just
18 demonstrate that detransition is a real problem and, and
19 it is a moral and ethical and scientific problem. And
20 that WPATH if it's going to deal with the science of
21 transition, it has to deal with the error rates and what
22 happens to people who detransition, you see. And so I
23 don't, I don't have nothing more to say about that, I
24 just think your point is quite irrelevant.

25 Q. Okay. Well, I'm going to continue to ask you

1 about evidence that you cite in your report that you use
2 as support for assertions you're making, so I'm just
3 going to flag that for you now. And again, this --
4 let's actually, let me, let me just ask one more time.
5 This study does not speak to the numbers of people who
6 have detransitioned now as opposed to any other time in
7 history, right?

8 A. As far as I remember this paper, the answer to
9 your question is right.

10 Q. Sorry, the answer to my question is -- okay,
11 right, okay. So let's actually now that you mention it,
12 let me just pull up really quickly the Littman study
13 that you mentioned.

14 (Exhibit 15 marked for identification.)

15 Q. This will be Exhibit 15.

16 A. Okay.

17 Q. Okay.

18 MR. CHARLES: So for the record, I'm
19 showing Dr. Levine what has been marked as SL15,
20 "Individuals treated for gender dysphoria with medical
21 and/or surgical transition who subsequently
22 detransitioned, a survey of 100 detransitioners by Lisa
23 Littman, received," well, published online 19 October
24 '21.

25 Q. Okay. So looking at the abstract again, the

1 whether or not the numbers of detransitioners are
2 growing, right?

3 MR. DAVID: Objection to form.

4 A. You know, I, I don't know if I should just
5 repeat what I said before. Detransition is a
6 phenomenon, science is only now beginning to get, we
7 have two studies that were published within the last I
8 think four months or five months.

9 Q. Okay. So, Dr. Levine, are you refusing to
10 answer my question because --

11 A. Not at all, I'm answering your question, I'm
12 answering.

13 Q. No, you're not.

14 A. Well, then ask me the question again. I'm
15 sorry, I apologize. You want to confine me to an answer
16 and so, so set me up for the answer you want, please.

17 Q. Okay. What I'm asking is, this sentence by the
18 admission of the author was not designed to assess the
19 prevalence of detransition?

20 A. That's true.

21 Q. Okay. Instead the purpose of this study was to
22 identify detransition reasons and narratives in order to
23 inform clinical care and future research, right?

24 A. Correct.

25 Q. Okay. Thank you. Okay. Let's, I'm going to

1 guidelines has confidence that persons who receive care
2 according to the strong recommendation will derive on
3 average more benefit than harm." The following sentence
4 says, "Weak recommendations require more careful
5 consideration of the person's circumstances, values and
6 preferences to determine the best course of action."
7 That sentence does not say weak recommendations mean
8 that we're, mean that so and so is going to derive more
9 harm than benefit or so and so, we're not sure if
10 they're going to derive more harm than benefit. It says
11 there, "Weak recommendations require more careful
12 consideration of the person's circumstances, values and
13 preferences to determine the best course of action." So
14 my question is, where are you getting that weak
15 recommendations mean what you are saying it means in the
16 second to last sentence of your report?

17 A. Because I interpret that sentence, which we
18 agree upon, you see. What, what that sentence really
19 means to me, Mr. Charles, is that science cannot answer
20 the question because we haven't done the appropriate
21 studies and there is this issue of the long-term
22 consequences. So reading our sentences, reading my
23 reports we should, we're not, we don't have, we don't
24 have to rest on science now, science can't help you,
25 what can help you is what the patient prefers, what the

1 doctor's values are and what the patient's values are.

2 Q. Okay. So, Dr. Levine, that's your
3 editorializing, it's not based on what the, what the,
4 what the actual words of the guidelines are saying.

5 A. Well, you know, every reader, especially every
6 professional reader integrates the scientific or these
7 consensus documents with his own values and personal
8 clinical experiences and what he knows in terms of other
9 data. And so even though you say it's my personal
10 interpretation, I, I don't want that to be demeaned.
11 Lots of people --

12 Q. I'm not, I'm not demeaning it at all, Dr.
13 Levine. I'm just making sure that you and I are reading
14 the same words from the guidelines and that you aren't
15 quoting something that I'm not seeing from the
16 guidelines, that's what I mean, I'm not demeaning your
17 professional experience at all.

18 A. Right. Well, thank you for that.

19 Q. So let me, let me ask one follow-up. You said
20 that you thought some people read these recommendations,
21 some, some clinicians read them and said, oh, the
22 Endocrine Society is recommending hormones and without
23 any, without any nuance or, or without really say
24 understanding the various, in my view, pretty, pretty
25 nuanced things that this guideline says. What evidence

1 A. This is --

2 Q. Well, let me just ask you, Dr. Levine, you don't
3 speak Finnish, do you?

4 A. I'm an American, which means I have one
5 language.

6 Q. Okay. Okay.

7 A. I only speak English.

8 Q. Okay. Are you saying you have read a
9 translation of this document at some point?

10 A. Yes.

11 Q. And do you know if it was an official
12 translation, a certified official translation?

13 A. I don't know if it was a certified one. I think
14 I, I accessed it through SEGM.

15 Q. Okay. All right. Let's go, let's go back to
16 your report, Exhibit 1.

17 A. God, I'm having the same damn problem again.
18 All right. Exhibit 1, I'm going to get there. All
19 right, here I am.

20 Q. Okay. And you, you said earlier that the UK was
21 also changing some of their guidelines with regard to
22 medical interventions for the treatment of gender
23 dysphoria, right?

24 A. Yes.

25 Q. Give me just a second here. But the UK has also

1 not completely banned all medical interventions, right,
2 they're just adjusting them?

3 A. That's correct, you're correct.

4 Q. And then are you aware of the Cass review?

5 A. Yes.

6 Q. That the UK is doing?

7 A. Yes.

8 Q. Okay. And, and as a part of that review you're
9 aware that the, that the national, what do they call it,
10 the National Health Service acknowledges that some
11 children do experience gender dysphoria and will need
12 clinical support and interventions?

13 A. Yes.

14 Q. Okay.

15 A. That's the clinical perception around many
16 people, yeah.

17 Q. Okay. All right. Let's take a look, hopefully
18 you still have it up, Page 51 of your report,
19 Paragraph 103.

20 A. Getting there. Okay, I'm here.

21 Q. Okay. So in Paragraph 103 you're talking about
22 a review by Professor, excuse me, Professor Carl
23 Heneghan, the editor of the British Medical Journal.
24 And the citation provided to that review is at the end
25 of the paragraph, do you see that, footnote 165?

1 list that those are between \$6,000 and \$4,000 per year
2 per child. Do you, do you know, Dr. Levine, how cost
3 sharing works between West Virginia Medicaid Program and
4 the federal government?

5 A. I presume that Medicaid patients who are insured
6 by Medicaid don't pay for their medications.

7 Q. Okay. But I guess what I'm asking is, do you
8 know what percentage or do you know what the cost is to
9 West Virginia Medicaid versus what the cost is to the
10 federal government, CMS, HHS that subsidizes the West
11 Virginia Medicaid Program?

12 A. Oh, no.

13 Q. Okay. So you're not offering an opinion about
14 the cost of puberty blockers under the West Virginia
15 cost sharing plans, right?

16 A. You mean to the insurance company?

17 Q. Correct, yeah.

18 A. Oh, yeah, no. This is, this kind of information
19 is very kept, very carefully kept from physicians.

20 Q. Okay. So not, no, making no representations in
21 this report about the ultimate cost to the program or
22 even to the patient, right?

23 A. No, we physicians don't know about things like
24 that.

25 Q. Okay. So then the, in the same paragraph at the

1 bottom of Page 26, going into Page 27 you say, "The cost
2 of surgeries, reoperations and occasional requests to
3 reverse the surgeries for those who request the
4 interventions are in the tens to hundreds of thousands
5 of dollars with some cases reaching into the millions."
6 But again, you're not offering an expert opinion here
7 about the cost of surgical care for the treatment of
8 gender dysphoria under the West Virginia Medicaid
9 Program, right?

10 A. No, I'm just saying that physicians like myself
11 have a hard time keeping up with our fields of expertise
12 and, and Dr. Karasic is probably no exception. And when
13 he assures the world that this is cost-effective care, I
14 don't really think he has any basis for knowing that,
15 for the same reasons that you are, you know, pointing to
16 my deficiencies of knowledge.

17 Q. Fair enough. And, and you also don't represent
18 that you know how much the federal government subsidizes
19 surgeries that West Virginia excludes or doesn't exclude
20 from its coverage under the Medicaid program?

21 A. I don't, I don't know at all.

22 Q. Okay. And you're not offering an opinion about
23 which members or how many West Virginia Medicaid
24 recipients might need surgery, right, for treatment of
25 gender dysphoria, let me be clear?

1 A. Well, I don't think West Virginia is an
2 exception to the international phenomenon of increasing
3 numbers of gender, cross gender identified adolescents.

4 Q. Oh, no, but I'm, Dr. Levine, I'm asking about
5 surgery specifically. You, you're not offering an
6 opinion about how many West Virginia Medicaid members
7 may need or be indicated for surgery for gender
8 dysphoria, that's not an opinion you're offering here?

9 A. I still want to say that West Virginia is
10 probably no exception and if we increase the number of
11 people getting treatment and given, you know, some
12 professionals' concepts about how to ideally treat these
13 individuals, I wouldn't be surprised if more West
14 Virginia citizens would be requesting surgery.

15 Q. But you don't know how many West Virginia
16 Medicaid member recipients may need surgery?

17 A. Oh, no, I don't know that.

18 Q. Okay. And you can't, you can't then also know
19 like what particular surgeries any of those people might
20 need?

21 A. Oh, yes, oh, yes, I do, I can.

22 Q. No, no, I'm saying the individual people, you
23 can't know what, what they need because you don't --

24 A. Oh, if I know if they're females --

25 Q. Dr. Levine, I'm talking about you're not

1 representing that you know what individual members might
2 need as per their specific individual treatment? I'm
3 not asking do you know the range of types of surgeries,
4 that's not my question. My question is, you are not
5 offering an opinion that you know what individual West
6 Virginia Medicaid members, what kinds of surgery they
7 may or may not need?

8 A. So if you tell me there's a person named Jane
9 Doe and John Doe in West Virginia and that they're
10 20 years old and they're persistent in their transgender
11 identity for eight years, I, you know, I can, as you
12 said, I could pretty much predict what the first surgery
13 would, that would be requested would be. But I would, I
14 couldn't guarantee that I would be right because someone
15 may want a rhinoplasty when I think they want, they
16 would want an orchiectomy. But, you know, but I don't
17 want to, you know, I mean, these, this is not rocket
18 science because there are only a limited range of
19 surgeries that could possibly be done.

20 Q. Okay. I guess what I mean is, treatment for
21 transgender people for the treatment of gender dysphoria
22 is individualized, so you're not saying I know what this
23 particular person needs because you haven't met with
24 them, right?

25 A. Well, that's right. But on the other hand --

Exhibit C



Deposition of:
Stephen B. Levine , MD

September 10, 2021

In the Matter of:
Kadel, et al vs. Folwell

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

3 ~~~~~

4 MAXWELL KADEL, et al.,

5 Plaintiffs,

6 vs. Case No. 1:19-cv-272-LCB-LPA

7
8 DALE FOLWELL, in his official
9 capacity as State Treasurer of
10 North Carolina, et al.,

11 Defendants.

12 ~~~~~

13 Video Deposition of
14 STEPHEN B. LEVINE, M.D.

15 September 10, 2021
16 9:05 a.m.

17 Taken at:
18 Veritext Legal Solutions
19 1100 Superior Avenue
20 Cleveland, Ohio

21 Tracy Morse, RPR
22
23
24
25

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TRANSCRIPT INDEX

APPEARANCES.....	2
INDEX OF EXHIBITS.....	4
EXAMINATION OF STEPHEN B. LEVINE, M.D.	
By MR. CHARLES.....	7
By MR. KNEPPER.....	227
By MR. CHARLES.....	244
REPORTER'S CERTIFICATE.....	249
EXHIBIT CUSTODY	
EXHIBITS RETAINED BY COURT REPORTER, 1-21	
(No Exhibit 16)	

1		INDEX OF EXHIBITS	
2	NUMBER	DESCRIPTION	MARKED
3	Exhibit 1	4/28/2021 Declaration....	14
4		of Stephen B. Levine,	
		M.D. With Attachment	
5	Exhibit 2	12/21/2020 Zoom.....	56
		Deposition of Stephen	
		Levine, M.D.	
6	Exhibit 3	Typewritten Three-Page...	62
		Document Entitled,	
7		"Special Programs,"	
8	Exhibit 4	1/1/2019-12/31/2019.....	78
		North Carolina State	
		Health Plan Benefits	
9		Booklet, Bates Numbers	
		PLAN DEF0001785-0001900	
10	Exhibit 5	Lesbian Gay Bisexual.....	89
		Transgender Center	
11		Document Entitled,	
		"Transgender Resources"	
12	Exhibit 6	4/8/19 Soneeya v. Turco..	104
		Trial Transcript, Day 1	
13	Exhibit 7	"Correction: Parent.....	116
		Reports of adolescents	
14		And young adults	
		Perceived to show signs	
15		Of a rapid onset of	
		Gender dysphoria,"	
16		Article	
	Exhibit 8	"Transgender Teens: Is...	122
17		The Tide Starting To	
		Turn?" Article	
18	Exhibit 9	"Finland Issues Strict...	139
		Guidelines for Treating	
19		Gender Dysphoria,"	
		Article	
20	Exhibit 10	"Recommendation of the...	140
		Council for Choices in	
21		Health Care in Finland	
		(PALKO/COHERE Finland),"	
22		Article	
	Exhibit 11	"Stod och utredning vid...	145
23		konsinkongruens hos barn	
		Och ungdomar," Article	
24			
25			

	INDEX OF EXHIBITS (Continued)	
	NUMBER	DESCRIPTION MARKED
1		
2		
3	Exhibit 12	"Long-Term Follow-Up of..154 Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," Article
4		
5		
6	Exhibit 13	2017 "On Gender.....156 Dysphoria," Booklet From Department of Clinical Neuroscience, Karolinska Institutet
7		
8	Exhibit 14	"Long-Term Follow-Up of..161 Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death," Article
9		
10		
11	Exhibit 15	5/15/2017 Telephonic.....170 Deposition of Stephen Levine, M.D.
12		
13	Exhibit 17	"A Typology of Gender....196 Detransition and Its Implications for Healthcare Providers," Article
14		
15	Exhibit 18	DSM-5: Frequently Asked..202 Questions
16	Exhibit 19	"Endocrine Treatment of..213 Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline," Article
17		
18		
19	Exhibit 20	"Pediatric Obesity.....217 Assessment, Treatment, And Prevention: An Endocrine Society Clinical Practice Guideline," Article
20		
21		
22	Exhibit 21	"Practice Parameter on...223 Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance In Children and Adolescents," Article
23		
24		
25		

1 Q. Okay. And so then were there any
2 external grants to research and publish about
3 the treatment of children or adolescents --

4 A. No.

5 Q. -- with gender dysphoria?

6 Okay. Is that a, "No," when I included
7 the, "Gender dysphoria," as well?

8 A. That is a, no.

9 Q. Okay. Thank you. Okay. So on
10 page 3 of your report -- actually, I'm sorry.
11 It's going to be the bottom of page 4 and to
12 the top of page 5. Your report lists your
13 experience as an expert witness, which we
14 talked about a little bit earlier. I just --
15 I'm wondering if you would confirm this is not
16 an exhaustive list of your experience as an
17 expert witness either via deposition or report.

18 A. I wouldn't want to testify that
19 this is absolutely complete, given the fact
20 that I don't keep a list compiled. This is
21 kind of compiled retrospectively from memory
22 and documents. And so this is the best I could
23 have done on April of 2021 --

24 Q. Understood. Thank you. So --

25 A. -- you might find something else.

1 Q. Was it --

2 A. -- in a commercial building where
3 our clinic was. It was just, you know, a
4 conference room in our clinic.

5 Q. And that was within -- was that
6 within a business --

7 A. It was --

8 Q. -- a psychiatric practice?

9 A. I'm sorry. I interrupted you.
10 It was within The Center For Marital
11 Health, which was a business that I and two
12 other people started and owned and ran. And in
13 that business, we continued the same kind of
14 work we did with the University minus the large
15 number of trainees.

16 Q. You mentioned that after '93, you
17 were not being paid by the University. Were
18 you providing your clinical psychiatric
19 professorship gratuitously?

20 A. Meaning without pay? Yes.

21 Q. Okay. Do you know if, after you
22 moved the clinic away from Case Western
23 Reserve, if Case Western Reserve University
24 Medical School created a separate gender
25 identity clinic?

1 A. Years later they did --

2 Q. Oh, sorry.

3 A. -- I would say, they created a
4 separate clinic perhaps in 2017, 2016.

5 Q. Do you know the name of that
6 clinic?

7 A. I don't think it's in the
8 department of psychiatry. I think it's in the
9 department of pediatrics. And the answer to
10 your question is, no.

11 Q. Does The LGBTQ and Gender Care
12 Program sound familiar?

13 A. No.

14 Q. But have you -- sorry. Have you
15 evaluated any patients through that separate
16 clinic that Case Western Reserve has?

17 A. No. Much to my dismay, that clinic
18 was formed and maintained without any input
19 from me, who I thought was one of the experts
20 in the field.

21 Q. Do you know if they have
22 psychiatrists, within that clinic?

23 A. I -- I'm not knowledgeable about
24 the composition of that clinic. There is a
25 very strong liaison between our department of

1 What do you mean by, "This era"?

2 A. Before 1993.

3 Q. Okay. And what do you mean by,
4 "Occasional"?

5 A. I would say that 95 percent of the
6 patients that we saw were 16 and 17, 18 and up.
7 We could debate what the word, "Child," means,
8 but to me an 11-year-old is a child, even
9 a 13-year-old is a child, especially when my
10 children were 13. And so we -- in the first
11 twenty years, transgender issues were primarily
12 an older teenager and adult, mostly adult
13 issues. In recent years, I would say, 12, 15
14 years, the number of adolescents appearing in
15 gender clinics at our place and everywhere as
16 far as I can see has increased exponentially,
17 especially the number of teenage girls who are
18 declaring themselves trans boys.

19 Q. So how many -- sorry. So the first
20 twenty or so years, you said approximately 5
21 percent of all patients were children.

22 A. Were younger -- on the younger end
23 of the spectrum --

24 Q. Right.

25 A. -- yes.

1 it, you see? But at this moment -- this week,
2 I have one patient that I see weekly, who is a
3 transgender teen. My staff -- if I can be
4 presumptuous to call them, "My staff" -- our
5 staff sees more.

6 Q. And thinking about the last year,
7 approximately how many adult patients did you
8 see -- and let's use your framing of,
9 "Regular." So that could be one, for one
10 followup visit or that could be for more -- how
11 many adult patients did you see for treatment
12 of gender dysphoria?

13 A. Approximately six.

14 Q. And using that same framing of,
15 "Regular," how many children, so under age 11?

16 A. In the last year?

17 Q. Yes, yes. In the last year.

18 A. Zero.

19 Q. How many adolescents in regular
20 treatment for gender dysphoria would you
21 approximate you've seen in the last five years
22 individually, exclusive of your supervision of
23 other clinicians?

24 A. If you ask me the question in the
25 last year, I would have told you five or six,

1 but since you ask it as a five-year period, I'm
2 at a loss to tell you whether it's twelve or
3 fifteen. I --

4 Q. An approximate is fine. Thank you.

5 A. -- let's just say a dozen with an
6 asterisk, very approximate.

7 Q. And jumping a little bit more in
8 terms of time. How about the last ten years?

9 A. Again, using the same asterisk, I
10 would say, double it.

11 Q. Okay. And you said zero people
12 under age 11, so children this last year. What
13 about in the last five years?

14 A. Oh, two years ago, we had this
15 charming little 6-year-old. One of my
16 colleagues specializes in children and I get to
17 hear about these cases. Occasionally I get to
18 meet the parents, but I personally have not
19 delivered a psychotherapeutic care or
20 evaluation directly of a child with the
21 exception of this one person that I was
22 involved with.

23 Q. And that was this last year, you
24 said?

25 A. That was -- I think it was probably

1 two, two and a half years ago.

2 Q. Oh, okay. And what kind of
3 treatment -- I should say, have you referred
4 any of those adolescent patients for additional
5 treatment, besides psychotherapy, for the
6 treatment of gender dysphoria?

7 A. Yes.

8 Q. And what kinds of treatment have
9 you referred them for?

10 A. For endocrine treatment.

11 Q. Okay. And approximately what
12 percentage of those adolescent patients have
13 you referred for endocrine treatment?

14 A. Give me the timeframe of that
15 question, please.

16 Q. Sure. So you said a few moments
17 ago, in the last five years, you saw maybe,
18 asterisk, 12 to 15 adolescent individually
19 yourself. Of those 12 to 15, what would be the
20 approximate percentage you referred for
21 endocrine treatment?

22 A. I'm hesitating to answer the
23 question, because some of those children have
24 been taking testosterone or estrogen
25 surreptitiously from their parents. And while

1 I didn't refer them for the treatment, I was
2 seeing them while they were taking the
3 treatment. So if we're only talking about
4 adolescent -- referrals of adolescents for
5 hormones, I would say a very small percentage
6 of those, say, I guess you would say 10
7 percent.

8 Q. Fair enough. Have you had yourself
9 individually as a clinician, have you had any
10 non-transgender children who you have made a
11 referral for endocrine treatments related to
12 other conditions?

13 A. No.

14 Q. Okay. So then zooming out 30,000
15 foot view of your 48-year career now, would you
16 say overall, you have provided treatment --
17 that is, psychiatric treatment -- to mostly
18 adults experiencing gender dysphoria, gender
19 identity issues?

20 MR. KNEPPER: Objection, form.

21 A. I would say that throughout my
22 career, we should divide my career into the
23 first twenty years where mostly adults were
24 seen by our team and myself. And then we ought
25 to talk about the last ten or fifteen years

1 where the number of adults has diminished and
2 the number of adolescents has increased
3 dramatically.

4 Q. Okay. Thank you. So as a part of
5 your private practice, do you write letters of
6 authorization for endocrine treatments?

7 A. Yes.

8 Q. And do you write letters of
9 authorization for gender affirming surgeries?

10 A. I have. I have not recently,
11 because most of my patients are 13 or 15 or 16,
12 you know.

13 Q. Okay. And I'm sorry. Just by,
14 "Recent," when was the last time you wrote a
15 letter of authorization for a gender affirming
16 surgery for an adult?

17 A. Probably twelve months ago.

18 Q. Okay. And over the course of your
19 career focusing on your treatment of adults
20 experiencing gender identity issues, for what
21 percentage of those patients would you estimate
22 you wrote a letter of authorization for gender
23 affirming surgery for?

24 MR. KNEPPER: Objection, form.

25 A. Again, I would like to put an

1 asterisk to whatever I answer this question as.
2 I have not kept track of those figures. I have
3 written -- I've written or cosigned letters for
4 hormone treatments and for gender confirming
5 surgeries for many people. There were more
6 people in the '70s and '80s than in recent
7 decades. In part as a reflection of my own
8 evolution of understanding of these problems
9 and in part it's a reflection of the demography
10 of patients who are coming to see me. I really
11 would not like to answer that question, only
12 because I don't know if the word, "Fifteen," or
13 the word, "Twenty-five," or the word,
14 "Thirty-five," is more accurate --

15 Q. Understood.

16 A. -- but I can tell you, I have
17 written letters, especially in the early years,
18 for the things that you're making reference to.

19 - - - - -

20 (Thereupon, Deposition Exhibit 2,
21 12/21/2020 Zoom Deposition of
22 Stephen B. Levine, M.D., was marked
23 for purposes of identification.)

24 - - - - -

25 Q. Okay. For the record, I'm showing

1 Q. Do you think as a general matter
2 that it's good for patients who come to DELR
3 for services related to gender dysphoria to be
4 able to have insurance coverage of that care?

5 MR. KNEPPER: Objection, form.
6 Beyond the scope.

7 A. Well, the people who come to DELR
8 are generally coming for evaluation and
9 psychotherapy services. And I believe it's
10 very important that people have access to
11 mental health care and that mental health care
12 for many of our patients are not wealthy,
13 affluent people. And the fees that even
14 masters prepared people charge can become
15 prohibitive. And so I think it's a very nice
16 idea, the psychiatric services, mental health
17 services evaluation and ongoing treatments,
18 with or without medication, it would be nice to
19 be able to cover those things, yes. I think
20 that's a long answer, yes.

21 Q. Understood. And thinking about the
22 treatment that you refer patients out for, the
23 endocrine treatments in particular, do you
24 think it is generally good if you provide
25 authorization for that treatment that the

1 patient be able to afford it?

2 MR. KNEPPER: Objection, form.

3 A. May I say, of course?

4 Q. You may. You may say anything you
5 would like.

6 A. Of course.

7 Q. Thank you. Well, anything you
8 would like within reason.

9 If you make a letter of authorization for
10 a patient for the treatment of gender dysphoria
11 specifically related to a surgical treatment,
12 do you think it is good that they be able to
13 access that treatment that you've authorized?

14 MR. KNEPPER: Objection, form.

15 A. Not to be cagey, I want to talk
16 about one word you just used in that sentence.
17 I need you to understand that historically in
18 our clinic for those 47 years, our clinics
19 for 47 years, we are not in the business and we
20 have never been in the business of recommending
21 surgery or recommending hormones. We recommend
22 a continued evaluation so that we -- the person
23 can make up their mind how to proceed.

24 It is not our knowledge base to know
25 who's going to do better and who's going to do

1 worse and who is not going to have any
2 difference at all with hormones or with
3 surgery. So what we do is we say, we will
4 write a letter of support for endocrine
5 treatment or for hormones if this is what you
6 want. And we say what our concerns are. We
7 tell the endocrinologist and we tell the
8 surgeon what our concerns are and that we
9 see -- we have reservations about this, and
10 these are our reservations, but the patient has
11 decided this is what he or she wants to do.

12 And so we write a letter of support, but
13 I don't -- every time you use the word,
14 "Recommendation," there's part of me that wants
15 to say, no, we do not recommend. We have never
16 recommended. We have not had the knowledge
17 base. We have not had the clinical experience
18 and the knowledge base to say, I'm a doctor. I
19 know this field. This is what I recommend to
20 make you better. We do not talk that way. We
21 do not think that way. And so I may want to
22 always put an asterisk to any sentence that you
23 use the word, "Recommend." I need you to
24 understand that that's where I'm coming from.

25 MR. CHARLES: Thank you,

1 Dr. Levine.

2 Excuse me just a moment. Can you read
3 back my question. I don't recall if I used,
4 "Recommend." I thought I used,
5 "Authorization." I just want to make sure.

6 (Record was read.)

7 MR. CHARLES: If we could just go
8 off the record for a second.

9 VIDEOGRAPHER: Off the record 10:52.

10 (Discussion held off the record.)

11 VIDEOGRAPHER: On the record 10:53.

12 BY MR. CHARLES:

13 Q. Okay. Thank you for that
14 clarification, Dr. Levine. I'll be more
15 careful about using terminology more close to,
16 "Authorization," rather than, "Recommendation,"
17 and I understand your distinction in your
18 practice. So do you, though, think it's good,
19 if you are authorizing a treatment, a patient
20 has said, This is the treatment I would like,
21 and you have done an evaluation and determined
22 that you will write, as you said, a letter of
23 support, do you then, as a practitioner, think
24 it's good that they can access it, that they
25 can afford it?

1 concept of agency and being a doctor, I think
2 is different than the implication of your
3 question.

4 Q. Is the worrisomeness for a
5 patient's future health, is that a reason to
6 deny all medical care for gender dysphoria?

7 A. Absolutely not.

8 Q. Dr. Levine, I'd like to return back
9 to, I believe it's Exhibit 2, the Claire
10 deposition. And please, if you would turn to
11 page 156.

12 A. I'm sorry. 150 what?

13 Q. Page 156. And beginning at line 10
14 on page 156, Dr. Levine, I'll read it, if
15 you'll just follow along, please.

16 Question: "Are you aware that this case
17 concerns an insurance exclusion that is
18 categorical at preventing" --

19 Skipping to line 15.

20 "-- hormones and surgery as a treatment
21 for gender dysphoria?"

22 Answer: "I am aware that your plaintiffs
23 are suing to get coverage for -- that is not
24 provided by their particular insurance. I am
25 aware of that."

1 demonstrate their efficacy. This is the
2 problem.

3 This is the essence of the problem. This
4 is, I think the essence of my testimony with
5 you today. It's not whether I personally as a
6 doctor would like this patient to have
7 insurance to cover their hormones. It's about,
8 is this the right thing to do for this person
9 and can I help the person see clearly what the
10 dangers are and what the benefits are. That's
11 the issue for a doctor, for Stephen Levine as a
12 doctor. I hope that's a cogent answer --

13 Q. It is --

14 A. -- to your question.

15 Q. -- it is cogent. Thank you.

16 Given all of that, is that -- so you just
17 explained, testified that there are
18 complications, some lack of -- and I'm
19 summarizing here, so I will confirm that this
20 is an accurate summary of what you just shared,
21 but I can't possibly repeat all of that. Given
22 all of those concerns that you have, is that a
23 reason to deny all medical interventions to
24 people with gender dysphoria?

25 MR. KNEPPER: Objection, form.

1 A. No, but that's not -- that's a
2 separate question about insurance.

3 Q. Yes, it is a separate question. So
4 now I'm asking: Are those concerns you raised
5 justifications in your mind for denying medical
6 interventions to all people with gender
7 dysphoria?

8 MR. KNEPPER: Objection, form.

9 A. You know, I'm not advocating
10 denying endocrine treatment or surgical
11 treatment. I'm just saying that we as a
12 medical profession need to walk the walk that
13 we talk. We say as a principle of ethics that
14 our interventions should be based upon the best
15 current knowledge, it should be based on
16 science. It should not be based on politics.
17 It should not be based on fashion. It should
18 not be based on civil rights considerations.
19 They should be based on the kinds of studies
20 that I just described to you with predetermined
21 outcome majors that are agreed upon --

22 Q. Sorry?

23 A. -- period.

24 Q. I was --

25 A. I forgot to put the period.

1 Q. That's okay. Did you just say,
2 Dr. Levine, you're not an expert in health
3 insurance?

4 A. I am not an expert in health
5 insurance.

6 Q. Okay. Or what insurance should or
7 should not cover?

8 A. Yes.

9 Q. Do you recall what the insurance
10 billing code typically is for psychotherapy for
11 gender dysphoria? I know it's been a long time
12 since you've accepted commercial insurance, so
13 I'm not sure if the billing codes are the same,
14 but do you recall --

15 A. The billing code is 90837.

16 Q. Okay. Is there a code that you're
17 familiar with that is F64.0?

18 A. That's not a billing -- that's
19 diagnostic code --

20 Q. Thank you.

21 A. -- there's a separate code for
22 diagnosis and a separate code for procedure.

23 Q. I see. So F64.0 is a diagnostic
24 code?

25 A. Yes.

1 VIDEOGRAPHER: Off the record 11:26.

2 (Recess taken.)

3 VIDEOGRAPHER: On the record 11:31.

4 BY MR. CHARLES:

5 Q. Okay. Dr. Levine, in your report,
6 you stated that you had not met with any of the
7 plaintiffs in this case, correct?

8 A. Yes.

9 Q. Okay. And you have not interviewed
10 any of the plaintiffs in this case, correct?

11 A. Correct.

12 Q. And so you are not offering any
13 opinions about the plaintiffs in this case,
14 correct?

15 A. Correct.

16 Q. Okay. And that would include the
17 veracity of their experiences of gender
18 dysphoria, correct?

19 A. Yes, correct.

20 Q. And that would not include the
21 accuracy of their gender dysphoria diagnoses,
22 correct?

23 A. Correct.

24 Q. Okay. You're not offering any
25 opinions about their mental health histories?

1 A. Correct.

2 Q. Nor any of the affects of the
3 gender affirming treatment they may have
4 received?

5 A. Correct.

6 Q. Okay. Thank you. Let's return to
7 your report. I don't know if you have that --

8 A. My report?

9 Q. Yes. You can put away that
10 document in your hand.

11 So if you would, please, turn to page 6
12 of your report.

13 Okay. So on page 6, paragraph a. at the
14 bottom of the page there, Dr. Levine. The
15 report states that this is one of the opinions
16 you're offering, which is, "Sex as defined by
17 biology and reproductive function cannot be
18 changed. While hormonal and surgical
19 procedures may enable some individuals to
20 'pass' as the opposite gender during some or
21 all of their lives, such procedures carry with
22 them physical, psychological, and social risks,
23 and no procedures can enable an individual to
24 perform the reproductive role of the opposite
25 sex." Did I read that correctly?

1 methodology and are capable of critically
2 reviewing the literature. So your statement is
3 true on the most superficial level, but is
4 totally incorrect when it comes to scientific
5 standards of care for issuing guidelines for
6 the medical profession. So I don't know how to
7 answer the question. On the surface, the
8 answer is, yes. And underneath the surface,
9 the answer is, no.

10 Q. So the International Journal For
11 Transgender Health is still a peer-reviewed
12 source, though, right?

13 A. It's peer reviewed by people who
14 make their living supporting transgender care.

15 Q. But it's still peer reviewed,
16 right?

17 A. It's peer reviewed --

18 Q. And as for your --

19 A. -- I think it's peer reviewed.

20 Q. Okay. Understood. And as for your
21 more conservative approach, can you cite to any
22 studies or research that resulted in better
23 outcomes than people who adhere strictly to the
24 WPATH standards of care version 7?

25 A. No. This is part of the problem in

1 evaluation leading to a therapeutic process, it
2 seems prudent, given the fact that we are
3 changing people's bodies, especially teenagers'
4 bodies, and they are not of developmental
5 sophistication yet that court systems or at
6 least one court system thinks they're certainly
7 too young to make these life-altering
8 decisions. So people in SEGM are biased in the
9 direction of being conservative and providing
10 psychotherapeutic evaluations of the child, of
11 the teenager and of their parents, of their
12 family systems to see if we can find a way to
13 help them be informed about what is going --
14 what they think they want to do in their
15 future.

16 Q. And so when you provide letters of
17 authorization for hormones or for surgery, do
18 you do so in accordance with the WPATH
19 standards of care?

20 A. Yes. That is the standard, to
21 provide a letter of recommendation.

22 Q. Okay. So turning back to your
23 report, Dr. Levine. You can go ahead and put
24 away the trial transcript there.

25 A. I'm sorry. Did you say, "Turning

1 Q. Okay. So is a, "Hypothesis," an
2 idea about why something happens, but doesn't
3 provide evidence for why something is
4 happening?

5 MR. KNEPPER: Objection, form.

6 A. A, "Hypothesis," generates the
7 pursuit of evidence.

8 Q. Has social contagion as an
9 explanation for increased cases of gender
10 dysphoria been scientifically proven yet?

11 A. No. But when you seek -- when you
12 see -- actually see patients and talk to them
13 about their friends and hear about the
14 influence of the Internet and the gurus on the
15 Internet who tell 13 and 12-year-old children
16 who are concerned about menses or concerned
17 about breast development or concerned about
18 their bodies changing and then they're told
19 that they're transsexual by somebody that
20 they've never met that they talked to on the
21 Internet, that would be social contagion or
22 social education.

23 Or when you hear about a friend who
24 declares themselves trans and then your patient
25 six months later declares themselves trans, you

1 wonder about the -- the interpersonal,
2 psychological link between best friends in
3 young puberty, young years of puberty and how
4 one can identify with one's friends and that
5 would be a social contagion. Those are 3the
6 kinds of ideas that people like me get when we
7 sit with people week after week talking about
8 their lives. You see, that's not science.

9 But that is clinician and this is the
10 kind of thing that leads to intuition, clinical
11 intuition and that's the source of the
12 generation of the hypothesis. But we think as
13 clinicians, when we hear -- I mean, I don't
14 think I've ever seen a teenager trans person
15 who hasn't been heavily involved and influenced
16 by the Internet, for example, but I have not
17 done studies to document that in a way that
18 would be scientifically acceptable. There are
19 other people who have.

20 And I doubt very much if you'll ever find
21 a clinician on any side of this issue, you see,
22 who would say, oh, no most of my patients have
23 never talked to anyone on the Internet about
24 transgender. The Internet is just part of life
25 today and -- but transgender teenagers spend

1 hours and hours of their time getting counseled
2 or participating with the virtual trans
3 community. That's a hypothesis.

4 Q. So no scientific citation?

5 A. When we use the word, "Scientific,"
6 in the best sense, yes, the answer to your
7 question is, no scientific.

8 Q. Okay. No studies of citations you
9 can point to today to support that hypothesis?

10 A. Oh, I think Lisa Littman's studies
11 are in the literature and/or in press that
12 documents this.

13 - - - - -

14 (Thereupon, Deposition Exhibit 7,
15 "Correction: Parent reports of
16 adolescents and young adults
17 perceived to show signs of a rapid
18 onset of gender dysphoria," Article,
19 was marked for purposes of
20 identification.)

21 - - - - -

22 Q. Okay. For the record, please note
23 I'm showing to Dr. Levine what has been marked
24 as Exhibit 7. "Correction: Parent reports of
25 adolescents and young adults perceived to show

1 signs of a rapid onset of gender dysphoria," by
2 Lisa Littman published March 19, 2019. Have
3 you seen this material before, Dr. Levine?

4 A. I've seen of it. I don't think
5 I've read it.

6 Q. Okay. Were you aware that the Lisa
7 Littman article had to be withdrawn, corrected
8 and republished?

9 A. Yes.

10 Q. Okay. And were you aware that the
11 initial article was based on a survey of
12 parents --

13 A. Yes.

14 Q. -- of purportedly transgender
15 children and the parents were recorded -- I'm
16 sorry. Let me start over. Were you aware that
17 the Littman article was based on a survey of
18 parents who were recruited through some parent
19 groups?

20 MR. KNEPPER: Objection, form.

21 A. I knew it was a survey of parents.

22 Q. Okay. And did you know there were
23 no report-outs from the young adults of those
24 parents in the article?

25 A. It was a report of parents'

1 transitioning. However, it is...important to
2 note that there are other survey items where
3 the parent would have direct access to
4 information about their child and that those
5 answers reflect items that can be directly
6 observed." Did I read that correctly?

7 A. Yes, you did.

8 Q. All right. Your report also cites
9 as support for the social contagion hypothesis
10 to an article from Medscape.com written by
11 Becky McCall and Lisa Nainggolan as support for
12 the social contagion theory. Is that correct?
13 I'm sorry. It's not going to be on this
14 article, Doctor.

15 A. I don't know that article.

16 Q. Okay.

17 A. You haven't asked me a question
18 about this. Did I misunderstand something?

19 Q. No, no. Sorry. We're just --

20 A. You haven't asked my opinions about
21 that, yeah.

22 - - - - -

23 (Thereupon, Deposition Exhibit 8,
24 "Transgender Teens: Is the Tide
25 Starting To Turn?" Article, was

1 marked for purposes of
2 identification.)

3 - - - - -

4 Q. Yeah. So, for the record, I'm
5 showing Dr. Levine what has been marked as
6 Exhibit 8. "Transgender Teens: Is the Tide
7 Starting To Turn?" by Becky McCall and Lisa
8 Nainggolan, April 26, 2021. Dr. Levine, you
9 said you have not reviewed this article before?

10 A. Which one are you referring to?

11 Q. I'm sorry. That one to your left.

12 A. This?

13 Q. Yes. Take your time.

14 A. Have I reviewed it, no. You know,
15 I've seen the picture of Keira Bell. I've seen
16 news reports of this in the past, but they were
17 just news reports, yeah.

18 Q. Do you know if either of the
19 authors of this article is a scientist?

20 A. I have no idea.

21 Q. Okay. Or a psychiatrist?

22 A. (Indicating.)

23 Q. I'm sorry. Could you make your
24 responses verbal? I'm forgetting.

25 A. I have no idea.

1 Q. Okay. Thank you. Have either of
2 them ever treated transgender children or
3 adolescents?

4 A. I would have no idea.

5 Q. Okay. To your knowledge, is the
6 information provided on Medscape.CA subject to
7 peer review?

8 A. I don't know how Medscape works.
9 I've heard there have been retractions, but I
10 don't know how their peer reviewed is made.
11 Perhaps people write in that, This is
12 ridiculous what you've been teaching or what
13 you've been saying, but whether they're peer
14 reviewed or not, I have no idea.

15 Q. So you probably -- I'm sorry. So
16 do you know if this article has been published
17 in a peer-reviewed journal to your knowledge?

18 A. "Transgender teens: Is the
19 Tides" -- that article?

20 Q. Yes.

21 A. I don't know. I don't know this
22 article. I don't know where it's from.

23 Q. Okay. So your report includes a
24 quotation from this article. "The vast
25 majority of youth now presenting with gender

1 multi-continental set of observations from
2 Europe, from Australia, from North America --

3 Q. Okay.

4 A. -- it almost doesn't even need
5 citations it's so clinically apparent.

6 Q. Okay. But there's no citation in
7 your report?

8 A. In my report, yes.

9 Q. Okay. So on page 18, going back to
10 your report, at the bottom of page 18, you use
11 a term, "Transgender Treatment Industry." Is
12 this the first time you have used this term?

13 A. In this report?

14 Q. No.

15 A. You mean, did I ever use it in
16 another report?

17 Q. Yeah, yeah.

18 A. I'm not sure. If this is -- if
19 it's not the first, it might be the second.

20 Q. And where did the term originate?

21 A. I think it -- the term originated
22 from Dwight Eisenhower at the end of his --
23 when he was leaving the presidency in 1952, he
24 warned the people about the military industrial
25 complex and that there was a very comfortable

1 the methods we made reference to before, the
2 efficacy of the treatment and the downsides of
3 the treatment. But because WPATH is an
4 advocacy organization and the scientific
5 establishment of the efficacy of their
6 treatments are not important to them, what they
7 are doing is teaching young mental health
8 professionals and medical professionals as a
9 whole what their ideology is. They say it's
10 scientifically established.

11 I'm here to tell you to the extent that I
12 understand science, it is not scientifically
13 established. In a sense, there is an industry
14 that has different elements that feed each
15 other; that's the transgender treatment
16 industry. I think if we put our heads
17 together, we could find another term.

18 Q. So did you coin that phrase then?

19 A. No --

20 Q. Okay.

21 A. -- no.

22 Q. Have you seen it used before in any
23 peer-reviewed articles?

24 A. Not in a peer-reviewed article.
25 I've seen it used in these kind of expert

1 opinion -- (Indicating.)

2 Q. Okay.

3 A. -- I would -- you know, if I had
4 time and I had a committee of people, I -- I
5 would probably find a different term for it.
6 But I don't mean it in a disparaging way. I
7 mean that this is a group of compassionate
8 people trying to help other people who actually
9 believe that the science has established the
10 best practices when in fact they're not well
11 informed.

12 Q. Do you need a sip of water after
13 that?

14 A. No. I'm just a long-winded guy.

15 I want to add, if I may, that we should
16 make a distinction between education and
17 indoctrination. Education can be based on
18 science. Indoctrination is based on preferred
19 beliefs that, if you allow me to use this term
20 again. The transgender treatment industry is
21 heavy on indoctrination and has declared, if
22 you look at the standards of care, if you don't
23 believe these systems, you're not a
24 competent -- you're not competent to take care
25 of people. That of course is the height of

1 A. No. Their gender dysphoria may be
2 a product, you see, of these other things. For
3 example, if you have someone who has been
4 sexually abused by her stepfather and becomes a
5 trans person in adolescents, we want to talk
6 about the sexual abuse and the process between
7 that person and what fears for the present and
8 the future that has caused the child. And
9 we're not attacking their trans identity.
10 We're trying to help them understand where they
11 came from and what they're coping with and why
12 they're so fearful or so distressed by their
13 body changing.

14 Q. And their gender dysphoria could be
15 separate and apart from that traumatic
16 experience?

17 A. Theoretically it could be, yes.

18 Q. And if it persisted sufficiently
19 enough, you would consider a letter of
20 authorization for --

21 A. Yes.

22 Q. -- hormones?

23 A. Yes.

24 MR. KNEPPER: Objection, form.

25 Q. Okay. If you would, please, turn

1 A. That is correct. And may I add
2 that it's very, very difficult to understand.
3 The natural question would be, how do you
4 compare the general population with the trans
5 people who did not have surgery with the trans
6 people who did have surgery.

7 Q. Thank you, Dr. Levine. That's not
8 my question, though. I just wanted to confirm
9 that was not the control group. You mentioned
10 this study later in your report, page 66
11 beginning at paragraph 74. Do you see that?

12 A. Um-hum.

13 Q. Okay. And basically that -- well,
14 here, let me point you exactly. The sentence
15 starts with, "Similarly," about halfway down
16 the page, third sentence of that paragraph.

17 A. Um-hum.

18 Q. And, as you mentioned, you cite the
19 Dhejne study and I believe -- or I should ask:
20 Is the Denmark study you're referencing the
21 study directly after it --

22 A. The Simonsen study.

23 Q. -- the Simonsen study?

24 A. Yes.

25 Q. Okay. So beginning with the Dhejne

1 study, do you think because that study showed
2 that some people committed suicide after gender
3 affirming surgery that no patient should be
4 able to access gender affirming surgery?

5 MR. KNEPPER: Objection, form.

6 A. That would be illogical.

7 Q. Okay. Dr. Levine, I understand you
8 said that would be illogical, but just to be
9 clear. You're not recommending -- sorry. I'm
10 not using that word. You're not saying that
11 the fact that some people commit suicide
12 following gender affirming surgery means that
13 there should be a ban on access to that
14 surgery. Is that right?

15 A. Not for that reason, no.

16 MR. KNEPPER: Objection, form.

17 Q. Not for that reason. Okay. Are
18 you recommending that there would be bans on
19 gender affirming surgery for any reason?

20 A. I think there are -- you know, I
21 think most prudent people in this field, just
22 to use the example of what you read out loud
23 about the Finland study, a case-by-case basis.
24 That's how doctor need to decide things, but
25 there are many, many reasons to be cautious

1 fashion and to be very hesitant about going
2 forward.

3 Q. But you're not recommending total
4 bans on gender affirming surgery?

5 A. I'm not recommending total bans.
6 I'm aware of the individual circumstances of
7 individual people's lives and their commitment
8 to transgender living. And I don't want to be
9 draconian about this. I want to be
10 compassionate about this.

11 Q. I understand. I appreciate that.
12 I just want to make sure I'm understanding you
13 correctly.

14 - - - - -

15 (Thereupon, Deposition Exhibit 12,
16 "Long-Term Follow-Up of Transsexual
17 Persons Undergoing Sex Reassignment
18 Surgery: Cohort Study in Sweden,"
19 Article, was marked for purposes of
20 identification.)

21 - - - - -

22 Q. So for the record, I'm presenting
23 to Dr. Levine what has been marked as
24 Exhibit 12. "Long-Term Follow-Up of
25 Transsexual Persons Undergoing Sex Reassignment

1 For the 22nd time today, did I read that
2 correctly?

3 A. It's the 23rd time.

4 Q. Oh, okay.

5 A. Yes.

6 Q. I was hoping you weren't counting,
7 but, okay. Did you testify earlier today that
8 the limitation of the Dhejne study is that the
9 controls were not transgender persons who had
10 not undergone gender affirming surgery?

11 A. Yes.

12 MR. KNEPPER: Objection, form.

13 Q. Okay. You can set that aside,
14 Dr. Levine.

15 - - - - -

16 (Thereupon, Deposition Exhibit 13,
17 2017 "On Gender Dysphoria," Booklet
18 From Department of Clinical
19 Neuroscience, Karolinska Institutet,
20 Stockholm, Sweden, was marked for
21 purposes of identification.)

22 - - - - -

23 Q. For the record, Dr. Levine has an
24 exhibit that has been marked as Exhibit 13.
25 "On Gender Dysphoria," by Cecilia Dhejne from

1 ideation in transgender people.

2 A. Well, you know about the
3 Branstrom-Pachankis study and the criticism of
4 the study --

5 Q. But I'm not talking about the
6 study.

7 A. -- and part of the study
8 demonstrated that it increased suicidal
9 ideation and attempts in the first two and a
10 half years after surgery, especially in the
11 first year --

12 Q. Right. Is your testimony --

13 A. -- so I'm not testifying that. I
14 thought you were asking me about this, which I
15 need to comment on, because this is not an
16 accurate depiction of my statement in the
17 reference. (Indicating.)

18 Q. Well, that's not what I'm asking
19 about, Dr. Levine.

20 A. Well, you're reading this and I'm
21 misquoted here. So I don't want you to imply
22 that she is accurately representing my views,
23 because I did not say that gender affirming
24 treatment in general should be stopped. I've
25 never said that. This is an article about

1 at different times have reported that in the
2 large majority of patients, absent a
3 substantial intervention such as social
4 transition and/or hormone therapy, gender
5 dysphoria does not," continue, "through
6 puberty."

7 So there are some children who persist in
8 their asserted gender identity through puberty,
9 correct?

10 MR. KNEPPER: Objection, form.

11 A. Correct.

12 Q. And some who persist in wanting to
13 transition via medical treatments?

14 MR. KNEPPER: Objection, form.

15 A. Yes. Some of the children have
16 learned about medical treatments somewhere
17 along the line and they feel instantly that
18 this is for them.

19 Q. And then looking at paragraph 56,
20 which is on page 41, so just the very next page
21 on the bottom, the second sentence in that
22 paragraph. "I observe an increasingly vocal
23 online community of young women who have
24 reclaimed a female identity after claiming a
25 male...identity at some point during their teen

1 transgender people is individual based, right?

2 A. Well, it's both --

3 MR. KNEPPER: Objection, form.

4 A. -- yes, that's partially true. And
5 ideally that's true, but it's obviously not
6 entirely true. It's why we're here, is it's
7 categorically based.

8 Q. Let me rephrase that. You design
9 treatment for your patients based on what that
10 patient in front of you, what they need, what
11 they want, what you determine -- sorry. Not
12 what you determine, but what you might
13 authorize?

14 MR. KNEPPER: Objection, form.

15 A. What the patient and I discern
16 together.

17 Q. Thank you. Okay. Let's jump to,
18 again, still in your report, page 68.

19 A. We've left 40 and 41? 68.

20 Q. Okay. Looking at the bottom of
21 page 68, Dr. Levine, paragraph 78. It states,
22 "Similarly, the American Psychological
23 Association has stated because approach" --

24 A. Sorry.

25 Q. I apologize.

1 Gender Nonconforming People (2015)."

2 So is that lack of consensus that you
3 discuss a justification to categorically ban
4 social transition for children as a treatment
5 for gender dysphoria?

6 MR. KNEPPER: Objection, form.

7 A. By, "Children," you mean 6 and 7
8 year olds?

9 Q. Those for whom medical intervention
10 is not indicated.

11 A. Is that a reason to ban it?

12 Q. Correct, social transition.

13 MR. KNEPPER: Objection, form.

14 A. The reason to -- so let me qualify
15 that. There's a, yes, answer, there's a reason
16 to ban it. And the reason to ban it is both a
17 developmental and an ethical reason. There
18 have been eleven studies of these cross-gender
19 identity children who are not socially
20 transitioned and the vast majority of them
21 de-transition by the time they're mid
22 adolescents or older adolescents. They become
23 homosexual individuals usually or bisexual
24 individuals, but they are cis gender.

25 So if we take a 6-year-old child and

1 A. -- nor you didn't ask me to comment
2 on that.

3 Q. It was related to what you had said
4 before. So this is related but not related to
5 what we just read. So you can put that aside.

6 A. Okay. But your next question was
7 about puberty blocking hormones, which are not
8 being used for 6-year-old's and 7-year-old's --

9 Q. Correct, yes, a separate group of
10 people.

11 A. -- so we're on a different
12 category.

13 Q. Yes.

14 A. Okay. So you asked me if I think
15 puberty blocking hormones should be used on a
16 case-by-case basis?

17 Q. Correct, yes.

18 A. I don't think so.

19 Q. So that is to say, there are no
20 circumstances you would advocate for a total
21 ban on that intervention?

22 MR. KNEPPER: Objection, form.

23 A. Number one, I've never seen a child
24 where that has come up where I thought it was a
25 good idea. In the cases I've seen, it was like

1 a treatment for the mother's pathology, not for
2 the child. And it's like a warning sign, boy,
3 be careful. You see, if you see one case like
4 that, you wonder -- and it's so conspicuous,
5 you wonder in the next case, if the same thing
6 is going on in a more subtle way.

7 Is the child acting out the ambitions of
8 the mother or the father? I just think
9 prudence -- I think considering the child has
10 not gone through puberty or has not gone far
11 into puberty and puberty brings all kind of
12 psychological, physical and social changes to a
13 child and those changes lead to desistance in
14 many, many children, to put them into a state
15 where all their peers are developing physically
16 and they're going to be poirot (phonetic).

17 And then most of those children have
18 social anxiety problems and they avoid -- they
19 don't have friends, right. And this is going
20 to make them even more different than their
21 peers and it's gone to deprive them of the
22 sexualization of their mind and the discovery
23 of masturbation and the discovery of sexual
24 desire for partners, you see. This is only
25 going to increase the child's difference from

1 her peers or his peers and I don't think this
2 is a prudent idea.

3 And if you wanted me to suggest a ban on
4 anything, it would be a ban on using puberty
5 blocking hormones, especially when the
6 evaluation of those children are focused on the
7 gender dysphoria of the child and not on the
8 background of the child and not on what's going
9 on. So I think that's an answer to your
10 question.

11 If we're going to use these drugs, if
12 we're going to use social transformation of
13 children, if we're going to use puberty
14 blocking hormones, it should only be used in a
15 carefully designed protocol. And follow up has
16 to be guaranteed so in one year and in two
17 years and in three years and before we start
18 giving cross-gender hormones we have data --

19 Q. Sorry.

20 A. -- so the answer to your question
21 is, I would consider banning puberty blocking
22 hormones even for children who have been
23 cross-gender identified for four years to give
24 them a chance to desist, which is exactly what
25 the Dutch protocol did, by the way.

1 Q. Sorry. So you just said you would
2 ban -- you would recommend a ban on --

3 A. If --

4 MR. KNEPPER: Objection, form.

5 A. -- look, I'm a doctor. I'm not a
6 policy maker --

7 Q. I understand, yes.

8 A. -- if you ask me my political
9 opinion about, should we ban this, is that a
10 reasonable thing, I think there's a very strong
11 argument for banning puberty blocking hormones.

12 Q. Okay. And, right. So you're here
13 as an expert offering an expert opinion. So
14 are you separating that from -- like are you
15 saying your political views that you would
16 advocate for bans or are you saying your expert
17 opinion you're offering in this case is you
18 would recommend ban?

19 MR. KNEPPER: Objection, form.

20 A. I would recommend ban. To what
21 extent it's from my politics or from my being a
22 parent or from my being a doctor, I don't know.
23 I would recommend we not use puberty blocking
24 hormones.

25 Q. In Claire, in this case that we

1 Answer: "Where we had a healthy mother
2 and father, an intact family who was
3 psychologically informed and who has -- where a
4 child has come out of toddlerhood acting
5 consistently in a gender atypical fashion, and
6 where the parents are not homophobic..."

7 Question: "The parents are not what kind
8 of people?"

9 Answer: "Homophobic."

10 For the 27th time, did I read that
11 correctly? Did I read that correctly?

12 A. Yes.

13 MR. CHARLES: Okay. All right.
14 Let's go ahead and take a break for a few
15 minutes.

16 VIDEOGRAPHER: Off the record 3:20.

17 (Recess taken.)

18 VIDEOGRAPHER: On the record 3:38.

19 BY MR. CHARLES:

20 Q. So, Dr. Levine, before the break,
21 you were talking about 6 and 7 year olds and
22 you mentioned there were eleven studies. Can
23 you identify which eleven studies from your
24 report you're referring to?

25 A. Cantor, the reference Cantor lists

1 the eleven studies and these eleven studies
2 have been done over probably thirty years.

3 Q. Okay. So Cantor was one review of
4 eleven studies?

5 A. Cantor was a review of the eleven
6 studies. I can't list to you the eleven
7 individual studies. The latest one is written
8 by Singh, S-i-n-g-h. It was published in April
9 of 2021, in the Frontiers of Psychiatry. And
10 that perhaps is the most comprehensive of them.
11 And that's the one that confirms -- that's a
12 study of boys and it confirmed that 12.2, I
13 think percentage of them persisted over a
14 thirteen-year period.

15 Q. So that was one -- that was the
16 Singh study that came out. Is that same study
17 mentioned in the Cantor review?

18 A. (Nodding.)

19 Q. Okay. And you said that
20 established that 12.2 percent of prepubertal
21 boys persisted into adolescents? Okay.

22 A. Yes. This harkens back to the
23 ethical issue that I talked about before. You
24 know, if you know that 88 percent of them are
25 going to persist -- desist, why in the world

1 identified 60,000 case reports world wide on
2 the Internet. See Exposito-Campos..." --

3 A. That is an error, by the way.

4 Q. Sorry. Which part of that is an
5 error?

6 A. That, "60,000," is my error. It
7 should say, "16,000."

8 - - - - -

9 (Thereupon, Deposition Exhibit 17,
10 "A Typology of Gender Detransition
11 and Its Implications for Healthcare
12 Providers," Article, was marked for
13 purposes of identification.)

14 - - - - -

15 Q. Okay. So for the record, I'm
16 showing Dr. Levine what has been marked as
17 Exhibit 17. "A Typology of Gender Detransition
18 and Its Implications for Healthcare Providers,"
19 Pablo Exposito-Campos, 2021. Okay. Have you
20 seen this study before, Dr. Levine?

21 A. Yes.

22 Q. Okay. So on page 1 of this report,
23 about halfway through the very first paragraph
24 in the introduction beginning with, "As a
25 consequence." Do you see that there?

1 important to note that this typology does not
2 suggest two clear-cut categories, for a
3 secondary detransition can lead to a primary
4 detransition" -- oh, sorry. Let me start over.
5 Sorry.

6 Okay. Let me start from a different
7 place, Dr. Levine. The second sentence.
8 "In r/detrans" --

9 And there's an HTTP address --

10 A. Okay.

11 Q. Okay. You see that.

12 -- "a subreddit for detransitioners to
13 share their experiences with more than 16,000
14 members, one can find several stories of people
15 who call their transgender status into question
16 after stopping transitioning due to medical
17 complications or feeling dissatisfied with
18 their treatment results"?

19 Do you know what a, "Subreddit," is,
20 Dr. Levine?

21 A. I believe it's just a division of a
22 larger website where people, you know, with
23 similar interests.

24 Q. Okay. Do you understand this
25 sentence to be suggesting that all 16,000 of

1 those members have offered a story of
2 detransition?

3 MR. KNEPPER: Objection, form.

4 A. I think -- I think it may be true
5 that either they have offered a personal story
6 or they're fascinated because of their own
7 considerations of that story. They're thinking
8 about it themselves, which would be in keeping
9 with the idea that even people who have
10 transitioned begin to doubt whether they made a
11 wise decision and they're considering
12 detransition. I'm not so sure it means that
13 all 16,000. I would have no way of
14 ascertaining that. You know, in my worry, I
15 would lean towards most of them are seriously
16 considering or have detransitioned. And in my
17 skepticism, I would say I'm not sure whether
18 it's 15,000 or 12,000 or 8,000.

19 Q. But you have no way to confirm
20 that --

21 A. I have no way.

22 Q. -- if it's all of them or a few of
23 them or three of them?

24 A. You're absolutely right. I have no
25 way of confirming that.

1 where hormones are safe and surgery is a good
2 thing to do. If a person said that, you know,
3 skeptically, I think that would disappoint
4 certain patients, but how it was said and when
5 it was said in response to what would either
6 determine whether the person is engaged with
7 the mental health professional or leaves the
8 mental health professional. You know, all
9 mental health professionals are not created
10 equal.

11 Q. So it sounds like you're saying it
12 could do harm to that patient?

13 MR. KNEPPER: Objection, form.

14 A. No, I'm not saying that. I'm
15 saying it could be disappointing to that
16 person. What that person did with the
17 disappointment may prove harmful just because
18 of that person or it may prove in fact
19 beneficial.

20 Q. Are you satisfied -- let's orient
21 this question around the patients you've seen
22 in the last 12 months. Are you satisfied that
23 those patients -- actually, sorry. Let me
24 start over. Are you satisfied that the
25 patients you have seen historically for whom

1 you provide letters of authorization for
2 hormones give sufficiently informed consent?

3 MR. KNEPPER: Objection, form.

4 A. From my point of view, I did what I
5 could to reach the standard of having the
6 person internalize and think about, digest,
7 dream about and come back and talk to me about
8 it. That's all I can do. I can't guarantee
9 that if I do what I do that it's going to
10 change your mind or help you steer your ship in
11 a slightly different angle --

12 Q. So --

13 A. -- so I would not write a letter of
14 recommendation if I didn't feel like I did my
15 part. And if the person indicated that they
16 couldn't pay attention to me, I wouldn't write
17 the letter.

18 MR. CHARLES: Understood.

19 Okay. John, finished.

20 MR. KNEPPER: You're finished?

21 MR. CHARLES: I mean, barring --

22 MR. KNEPPER: Barring --

23 MR. CHARLES: We can't tell the
24 future.

25 MR. KNEPPER: I wasn't ready for

1 history and current psychiatric diagnosis, it's
2 more complicated than just the internet.

3 But we need to understand who these
4 children are and how they're different from
5 their peers and what we could possibly do to
6 help them to have a better life. I know some
7 of the conversation today was, we'll help them
8 have a better life by giving them puberty
9 blocking hormones, but that doesn't address --
10 I think it has a risk of harming them further.
11 And it doesn't address the comorbid
12 developmental challenges that these children
13 face.

14 And I'm afraid -- and it's controversial,
15 because I don't have the answer. I'm afraid
16 there's a possibility we're making these
17 children have a worse outcome. And until you
18 can demonstrate to me in a very careful
19 controlled study that separates the autistic
20 from the non-autistic, you see? That separates
21 the kids who come from a family that's intact
22 from a family where there's a single parent.
23 Where you can separate the kids who were
24 sexually abused from the kids who were not
25 sexually abused. I'm not sure puberty blocking

Exhibit D

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KATHEENA SONEEYA,

Plaintiff,

Civil Action
No. 07-12325-DPW

V.

April 8, 2019

THOMAS A. TURCO III, in his official
capacity as Commissioner of the
Massachusetts Department of Correction, 10:23 a.m.

Defendant.

TRANSCRIPT OF BENCH TRIAL DAY 1

BEFORE THE HONORABLE DOUGLAS P. WOODLOCK

UNITED STATES DISTRICT COURT

JOHN J. MOAKLEY U.S. COURTHOUSE

1 COURTHOUSE WAY

BOSTON, MA 02210

DEBRA M. JOYCE, RMR, CRR, FCRR

KELLY MORTELLITE, RMR, CRR

Official Court Reporters

John J. Moakley U.S. Courthouse

1 Courthouse Way, Room 5204

Boston, MA 02210

joycedebra@gmail.com

1 witness, ask me.

2 MS. HANCOCK: Okay. Apologies, your Honor.

3 BY MS. HANCOCK:

4 Q. So two versions were released since 1999, correct?

5 A. Correct.

6 Q. And one in 2001, as you just testified, right?

7 A. Right.

8 Q. And another one in 2011; is that right?

9 A. Yes.

10 Q. And as you understand it, there's going to be an eighth
11 version coming out soon, correct?

12 A. Yes.

13 Q. And you're not involved in drafting that version, correct?

14 A. I am not.

15 Q. And you requested to participate in drafting that version,
16 correct?

17 A. I'm not sure that's correct.

18 Q. You did not ask to be involved in drafting that version?

19 A. I think -- I think I actually might have, now that you
20 bring it up, but I was told I had to be a member of WPATH.

21 Q. Now, you've worked as a consultant for the DOC since
22 around 2007 or 2008. Does that sound right?

23 A. That sounds right.

24 Q. And you're not technically engaged by the DOC, though,
25 right?

Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

Christopher Fain, individually and on behalf of all
others similarly situated, et al.,

Plaintiffs,

vs.

CIVIL ACTION NO. 3:20-cv-00740

William Crouch, et al.,

Defendants.

REMOTE DEPOSITION OF COMMISSIONER CYNTHIA BEANE

DATE: March 29, 2022

TIME: 8:00 a.m. CST

PLACE: Veritext Virtual Videoconference

REPORTED BY: KELLEY E. ZILLES, RPR (Via Videoconference)

JOB NUMBER: 5096149

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21
22
23 NOTE: The original deposition transcript will be
24 delivered to Tara Borelli, Esq., as the taking attorney.
25

1 occurred in West Virginia and we put a modifier on so we
2 can get those claims paid.

3 Q. Does BMS track a gender marker for its members?

4 A. Meaning male, female?

5 Q. Correct, including male and female. Does BMS
6 have a gender marker of male or female or any other kind
7 of gender marker on each member?

8 A. Yes, when you apply for Medicaid you say whether
9 you're male or female, that's in the system.

10 Q. And just to go back to our questions a moment
11 ago about that modifier. So the modifier doesn't,
12 there's no modifier that's attached to transgender
13 members generally, it sounds like that modifier that we
14 were discussing uses one kind to refer access to
15 pregnancy care of a transgender man, is that correct?

16 A. You are correct.

17 Q. So back to gender markers. You testified that
18 each Medicaid member has to designate a marker of male
19 or female when they apply for Medicaid, is that correct?

20 A. Correct.

21 Q. And can members change that gender marker at any
22 time after they have originally designated it?

23 A. I would assume so. I don't think we have
24 anything stopping that, but I would, I honestly don't
25 know if that's occurring or if that's happening. I

1 works with that does research for Dr. Becker, and I know
2 that Dr. Becker was on the call.

3 Q. So on a slightly different topic, are you
4 familiar with what social transition refers to?

5 A. I'm sorry, did you say -- I can't hear you.

6 Q. Are you familiar with what social transition
7 refers to?

8 A. I am not.

9 Q. So that would mean BMS does not have a position
10 on whether transgender children should be prevented from
11 socially transitioning, correct?

12 A. I don't believe we have a position. I'm not
13 even sure what it is.

14 Q. And are you familiar with what is sometimes
15 referred to as conversion therapy?

16 A. For someone who is gay, like pray the gay away?

17 Q. Yes, it can be referred to that. And for
18 purposes of this question, assume that it's applying
19 that principle to be transgender, so assume --

20 A. Yes, I have heard of that.

21 Q. Does BMS have a position on whether transgender
22 children should be subjected to conversion therapy?

23 A. No one should be subjected to that therapy.

24 Q. Thank you. All right. If you are good to keep
25 going for a little while, then I think I'll turn to our

Exhibit F

Stephen Levine
December 21, 2020

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

CASE NO. 4:20-cv-00020-MW/MAF

JAMI CLAIRE, KATHRYN LANE and
AHMIR MURPHY,

Plaintiffs,

vs.

FLORIDA DEPARTMENT OF
MANAGEMENT SERVICES, et al,

Defendants.

ZOOMED DEPOSITION OF STEPHEN B. LEVINE, M.D.

Monday, December 21, 2020

9:30 a.m. - 2:51 p.m.

Via Zoom

Tallahassee, Florida 32308

STENOGRAPHICALLY REPORTED BY:

SANDRA L. NARGIZ
RPR, CM, CRR, CRC, FPR, CCR-GA

Job No. 166551

Stephen Levine
December 21, 2020

Page 2

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Samantha Howell

24

25

Stephen Levine
December 21, 2020

Page 3

I N D E X

2	WITNESS	PAGE
3	STEPHEN B. LEVINE, M.D.	5
4	Direct Examination by Mr. Tilley	5
5	Cross Examination by Ms. Coles	171

5

6

7

8 (STENOGRAPHER'S NOTE: Exhibits were received
9 premarked electronically; only Exhibits 1, 2, 3, 7,
10 10, 11 and 13 were referred to in deposition.)

10

11

INDEX OF EXHIBITS

12

13	NO.	DESCRIPTION	ID
14	1	Levine expert report	70
15	2	Psychotherapeutic Approaches to Sexual Problems: An Essential Guide for Mental Health Professionals	109
16	3	Dhejne study	165
17	7	Standards of Care, V7	48
18	10	Kosilek report	83
19	11	Soneeya 2011 report	94
20	13	Soneeya case trial transcript	167

19

20

21

22

23	CERTIFICATE OF OATH	181
24	CERTIFICATE OF REPORTER	182
25	READ AND SIGN LETTER	183
26	ERRATA SHEET	184

25

Stephen Levine
December 21, 2020

Page 29

1 **right?**

2 A No, that is. I think -- we'll quibble
3 over the word only. If you use the word
4 predominantly, I would say they are predominantly
5 taking care of. They are a specialty clinic for the
6 transgender.

7 Q So predominantly treating transgender
8 people, but not 100 percent?

9 A That's my guess.

10 Q Okay. What sorts of treatments do you
11 provide for your patients with gender dysphoria?

12 A Psychiatric evaluation of the patient and
13 the family, the parents and the other siblings;
14 psychotherapy to further the process of
15 understanding this whole phenomenon; recommendations
16 for hormones and occasionally recommendations for --
17 depending on the biologic sex of the patient, for
18 genital or breast surgery.

19 Q How many patients have you recommended
20 hormone therapy for?

21 A You mean over 47 years?

22 Q Let's start with the 47 years, yeah.

23 A I don't know. Can I give you a gross
24 estimate?

25 Q Sure.

Stephen Levine
December 21, 2020

Page 37

1 to be directed to the surgeon.

2 Q Okay. If a surgeon told you I require a
3 letter for this facial feminization surgery, are
4 there circumstances under which you could see
5 yourself providing a letter, not of recommendation
6 but of authorization, for a person to receive this
7 surgery from the surgeon?

8 A I could see myself under certain
9 circumstances, if I understood the patient's motives
10 and had a lot of time to discover and discuss this,
11 the history and alternative approaches and wondering
12 about the psychology of wanting this, I could see
13 theoretically.

14 That's what I do, you know, as a
15 psychiatrist; I am trying to investigate the meaning
16 of the wish and the solution that the patient is
17 hoping for, the problem the patient is hoping this
18 would be a solution for.

19 And so I want to be able to consider this
20 and have a respectful, mutual, slow dialogue that is
21 slow, meaning multiple sessions, to consider the
22 nuances of this because, you know, all of us have a
23 self-concept of how handsome we are or pretty we
24 are, and most everyone wants to get a little more
25 handsome and a little more pretty and we are -- we

Stephen Levine
December 21, 2020

Page 47

1 Q Okay.

2 A I believe that if a surgeon is going to do
3 this, he ought to know what I think -- what I know
4 about the person's history and the person's
5 intellectual capacities and the prices they paid for
6 their gender dysphoria already.

7 For example, the loss of a family and no
8 relations to children, or the inability to have a
9 relationship, an intimate relationship with other
10 people. I believe the surgeon needs to have an
11 understanding of the person.

12 I don't have an understanding whatsoever
13 of the techniques of surgery. You see? I am just a
14 psychiatrist. And the psychiatrist -- and the
15 surgeon has very little understanding of how a
16 person got to be in his office. And I believe that
17 the letters of recommendation should capture the
18 humanness of this person and the desperation of this
19 person and the justification that the person uses
20 and the hopes they have for this surgery. But
21 that's Levine, you know.

22 Q I want to show you the WPATH Centers of
23 Care section that discusses letters. This is
24 Exhibit 7 which we are going to put on the screen.
25

Stephen Levine
December 21, 2020

Page 48

1 (Exhibit 7 was marked for identification.)

2 BY MR. TILLEY:

3 Q Let's go to page 27. It looks like the
4 document page 27, it's .pdf page 33, Bates stamp
5 PL 0450524.

6 You see, Dr. Levine --

7 MS. COLES: Can you read that, Dr. Levine?
8 It looks a little small on my computer.

9 THE WITNESS: I can read it. It says
10 referral for surgery.

11 MS. COLES: Okay. Just making sure.

12 BY MR. TILLEY:

13 Q At the bottom, I am going to start there
14 and then we'll go on to the following page. At the
15 bottom it says, The recommended content of the
16 referral letters for surgery is as follows: 1, the
17 client's general identifying characteristics -- now
18 we are continuing on to the next page -- number 2,
19 results of the client's psychosocial assessment,
20 including any diagnoses.

21 And then it goes on to 3, 4, 5, and 6.

22 Dr. Levine, can you just review those if
23 you can read it and then let me know if you agree
24 with those statements.

25 (Short pause.)

Stephen Levine
December 21, 2020

Page 49

1 A I don't disagree with the statements, but
2 each of those statements, of course, need to be
3 operationalized by the letter writer. For example,
4 the first one, identifying characteristics,
5 oftentimes identifying characteristics would be like
6 this is a 63-year-old Caucasian veterinarian. But
7 there are many other identifying characteristics
8 that might be included.

9 So you can interpret these things with
10 terse statements or elaborate statements. I favor
11 elaborate statements. For example, I would like to
12 say a divorced father of four, or a roller derby
13 official. I would like to identify him as much as a
14 person as possible. But in the history of medicine,
15 race, age, and nourishment passes for identifying
16 information.

17 So the results of the psychosocial
18 assessment, including any diagnosis. Psychosocial
19 assessment would be the processes in his life
20 history, including any current or past diagnoses,
21 you see. So substance abuse might be a very
22 important part of number 2.; and the duration. So
23 if I am writing a letter, if I am one of two people
24 who have been hired to write a letter for genital
25 surgery, and I might have had three visits with the

Stephen Levine
December 21, 2020

Page 103

1 not inquiring about your medical history and your
2 psychiatric history. But it may be psychologically
3 beneficial to you and an M.D. may recommend that you
4 do that. And that recommendation would be based on
5 his or her knowledge that you are likely to suffer
6 from seasonal affective disorder, and the treatment
7 is bright lights and sunshine. And sunshine would
8 be far superior because of its luminescence, the
9 number of lumens exposed, than bright lights.

10 BY MR. TILLEY:

11 Q Let's go back just briefly to WPATH. And
12 I know you mentioned you have a more conservative
13 approach. So let me ask you this.

14 Is it fair to say that if you personally
15 believed that you would authorize hormones or
16 surgery for someone with gender dysphoria, someone
17 following the WPATH Standards of Care would also
18 believe that?

19 A Yes.

20 Q Okay. Let's talk about insurance for a
21 little bit. If you recommended that -- if you
22 authorized some form of treatment for gender
23 dysphoria, whether it be hormones or some form of
24 surgery, would you expect that that treatment would
25 be covered by your patient's insurance?

Stephen Levine
December 21, 2020

Page 145

1 offering an opinion on transgender people accessing
2 sex-specific public places; is that right?

3 A No.

4 Q It's correct that that's not right?

5 A You mean like bathrooms, and so forth?

6 Q Right. You are not making an expert
7 opinion in this case concerning sex-specific spaces;
8 is that correct?

9 A That's right.

10 Q Okay. Let's go to page 13. You say that
11 plaintiffs assert that the WPATH Standards of Care
12 are widely accepted. Do you see that statement?

13 A Please tell me what paragraph it's in.

14 Q Under heading number 4.

15 A Yes. Okay.

16 Q Do you disagree that the WPATH Standards
17 of Care are widely accepted by the major medical and
18 mental health associations?

19 A No.

20 Q Okay. You just think that they are wrong;
21 is that correct?

22 A Yes, and widely accepted doesn't tell you
23 60 percent or 40 percent. It just says widely
24 accepted.

25 Q Okay. Is it -- how would -- how would you

Stephen Levine
December 21, 2020

Page 156

1 You see?

2 So I am saying, please, let me talk to you
3 about human beings here and how important having
4 ongoing lifelong relations with one's children are
5 and being a grandfather or grandmother, and being
6 connected to a family of origin. I am not talking
7 about categorical bans. I am talking about being
8 smart.

9 BY MR. TILLEY:

10 Q Are you aware that this case concerns an
11 insurance exclusion that is categorical at
12 preventing --

13 MS. COLES: Form.

14 BY MR. TILLEY:

15 Q -- hormones and surgery as a treatment for
16 gender dysphoria?

17 MS. COLES: Form.

18 A I am aware that your plaintiffs are suing
19 to get coverage for -- that is not provided by their
20 particular insurance. I am aware of that.

21 BY MR. TILLEY:

22 Q Do you think that exclusion is
23 appropriate?

24 MS. COLES: Form.

25 A I've already answered that question, I

Stephen Levine
December 21, 2020

Page 157

1 believe.

2 BY MR. TILLEY:

3 Q What is the answer?

4 A That it's a political decision that varies
5 from state to state, and it belongs to the process
6 of political science and the courts and not doctors.

7 Q And if you yourself were treating them and
8 determined that they understood the risks and you
9 thought the treatment would be psychologically
10 beneficial and provided letters of authorization to
11 them, you would want that treatment to be covered by
12 insurance; is that correct?

13 MS. COLES: Form.

14 A I am an agent of the patient, I want
15 what's best for the patient, and especially if the
16 patient couldn't otherwise afford it, I would wish
17 for my patient to have it, yes.

18 BY MR. TILLEY:

19 Q I know you said you are not about
20 categorical bans, but let me ask you about minors
21 again.

22 Would you support a categorical ban on
23 access to puberty blockers to treat gender
24 dysphoria?

25 MS. COLES: Form.

Exhibit G

BMJ Open International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment

Sara Dahlen ¹, Dean Connolly ^{2,3}, Isra Arif ⁴,
Muhammad Hyder Junejo ^{5,6}, Susan Bewley ⁷, Catherine Meads ⁸

To cite: Dahlen S, Connolly D, Arif I, *et al.* International clinical practice guidelines for gender minority/trans people: systematic review and quality assessment. *BMJ Open* 2021;**11**:e048943. doi:10.1136/bmjopen-2021-048943

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Received 15 January 2021

Revised 22 March 2021

Accepted 12 April 2021

Abstract

Objectives To identify and critically appraise published clinical practice guidelines (CPGs) regarding healthcare of gender minority/trans people.

Design Systematic review and quality appraisal using AGREE II (Appraisal of Guidelines for Research and Evaluation tool), including stakeholder domain prioritisation.

Setting Six databases and six CPG websites were searched, and international key opinion leaders approached.

Participants CPGs relating to adults and/or children who are gender minority/trans with no exclusions due to comorbidities, except differences in sex development.

Intervention Any health-related intervention connected to the care of gender minority/trans people.

Main outcome measures Number and quality of international CPGs addressing the health of gender minority/trans people, information on estimated changes in mortality or quality of life (QoL), consistency of recommended interventions across CPGs, and appraisal of key messages for patients.

Results Twelve international CPGs address gender minority/trans people's healthcare as complete (n=5), partial (n=4) or marginal (n=3) focus of guidance. The quality scores have a wide range and heterogeneity whichever AGREE II domain is prioritised. Five higher-quality CPGs focus on HIV and other blood-borne infections (overall assessment scores 69%–94%). Six lower-quality CPGs concern transition-specific interventions (overall assessment scores 11%–56%). None deal with primary care, mental health or longer-term medical issues. Sparse information on estimated changes in mortality and QoL is conflicting. Consistency between CPGs could not be examined due to unclear recommendations within the World Professional Association for Transgender Health Standards of Care Version 7 and a lack of overlap between other CPGs. None provide key messages for patients.

Conclusions A paucity of high-quality guidance for gender minority/trans people exists, largely limited to HIV and transition, but not wider aspects of healthcare, mortality or QoL. Reference to AGREE II, use of systematic reviews, independent external review, stakeholder participation and patient facing material might improve future CPG quality.

PROSPERO registration number CRD42019154361.

Strengths and limitations of this study

- First systematic review to identify and use a validated quality appraisal instrument to assess all international clinical practice guidelines (CPGs) addressing gender minority/trans health.
- International CPGs were studied due to their influential status in gender minority/trans health, though further research is needed on national and local CPGs.
- An innovative prioritisation exercise was performed to elicit stakeholders' priorities and inform the setting of AGREE II (Appraisal of Guidelines for Research and Evaluation tool) quality thresholds, however these stakeholder priorities may not be applicable outside the UK.
- An inclusive approach using wide criteria, extensive searches and approaching key opinion leaders should have allowed the study to identify all relevant international CPGs, however it is possible some may have been missed.

INTRODUCTION

Assessing the quality of clinical practice guidelines

Evidence-based practice integrates best available research with clinical expertise and the patient's unique values and circumstances. High-quality clinical practice guidelines (CPGs) support high-quality healthcare delivery. They can guide clinicians and policymakers to improve care, reduce variation in clinical practice, thereby affecting patient safety and outcomes. The Institute of Medicine defines CPGs as: 'statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options',¹ although other definitions exist.² Recommendations are used alongside professional judgement, directly or within decision aids, in training and practice. CPGs are important but have limitations depending on evidence selection and



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development processes.³ Grading of Recommendations, Assessment, Development and Evaluation (GRADE) was developed to address the evidence that is selected and appraised during CPG development.⁴⁻⁶ Using a systematic approach and transparent framework for developing and presenting summaries of evidence, GRADE is the most widely adopted tool worldwide for grading the quality of evidence and making recommendations,⁷ but does not alone ensure a CPG is high quality. Strength of evidence is only one component of what makes a 'good' CPG; factors such as transparency, rigour, independence, multidisciplinary input, patient and public involvement, avoidance of commercial influences and rapidity^{8,9} should also be considered. Broader domains of CPG quality are included in the Appraisal of Guidelines for Research and Evaluation instrument AGREE II.¹⁰⁻¹² Despite widely recognised principles and methods for developing sound CPGs, current research shows that guidelines on various topics lack appropriate uptake of systematic review methodologies in their development,¹³ give recommendations that conflict with scientific evidence¹⁴ or do not adequately take into account existing CPG quality and reporting assessment tools.¹⁵ This emphasises the ongoing need to appraise guidelines to ensure evidence-informed care.

Healthcare for gender minority/trans people

'Trans' is an umbrella term for individuals whose inner sense of self (gender identity) or how they present themselves using visual or behavioural cues (gender expression) differs from the expected stereotypes (gender) culturally assigned to their biological sex.¹⁶ 'Gender minority' is an often-used alternative population description. Some gender minority/trans people may seek medical transition, which involves interventions such as hormones or surgery that alter physical characteristics and align appearance with gender identity. Patient numbers referred to UK gender identity clinics and length of waiting lists have increased in the last decade, particularly for adolescents,¹⁷ a phenomenon seen elsewhere.¹⁸ Gender minority/trans people may have continuing, sometimes complex, life-long healthcare needs whether they undergo medical transition or not. Gender minority/trans people may experience more mental health issues such as mood and anxiety disorders,¹⁹ substance use²⁰ and higher rates of suicidal ideation.²¹ They may seek assistance with sexual health, mental health,²² substance use disorders,²³ prevention and/or management of HIV²⁴ as well as usual general health enquiries. However, they may encounter difficulties in accessing healthcare,²⁵ reporting negative healthcare experiences,²⁶ discrimination and stigma.^{27,28} Like all individuals, gender minority/trans people require high-quality evidence-based healthcare^{25,29} addressing general and specific needs.

Guidelines used internationally and in the UK

The quality of current guidelines on gender minority/trans health is unclear. The World Professional Association for Transgender Health (WPATH) Standards of

Care Version 7 (SOCv7)³⁰ represent normative standards for clinical care, acting as a benchmark in this field.³¹ Globally, many national and local guidelines³²⁻³⁵ are adaptations of, acknowledge being influenced by, or are intended to complement WPATH SOCv7,³⁰ despite expressed reservations that WPATH SOCv7³⁰ is based on lower-quality primary research, the opinions of experts and lacks grading of evidence.³⁶

In the UK, an advocacy group worked to incorporate WPATH SOCv7³⁰ into national practice.³⁷ WPATH SOCv7³⁰ informs National Health Service (NHS) gender identity clinics³⁸ and guidelines produced by the Royal College of Psychiatrists (without use of GRADE).³⁹ No CPGs were available from the National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), British Association of Gender Identity Specialists, or medical Royal Colleges, although the Royal College of General Practitioners issued a position statement on gender minority/trans healthcare in 2019.⁴⁰ Assessing quality of international CPGs such as WPATH SOCv7³⁰ has practice implications for the NHS³⁸ and private sector. CPGs with international scope may present additional challenges (eg, the implementability of key recommendations might not be easily translated among different contexts) but they seem to influence discourse around gender minority/trans health.³⁶ No prior study has investigated the number and quality of guidelines to support the care and well-being of gender minority/trans people. The purpose of this research was to identify and critically appraise all published international CPGs relating to the healthcare of gender minority/trans people.

METHODS

Approach/research design

The rationale was to identify the key CPGs available to healthcare practitioners in this field of clinical practice. Following preliminary searches, we chose international CPGs in view of WPATH's influence within the UK and elsewhere, and to avoid 'double-counting'. We considered AGREE II¹⁰⁻¹² the most appropriate tool; it is the most comprehensively validated and evaluated instrument available for assessing CPGs,^{41,42} designed for use by non-expert stakeholders¹⁰ such as healthcare providers, practicing clinicians and educators.¹¹ It benefits from clear instructions and prompts regarding scoring and several people applying the criteria independently (a minimum of two reviewers, but four are recommended). AGREE II synthesis calculates quality scores from 23 appraisal criteria organised into six key domains (scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, editorial independence) and an overall assessment of 'Recommend for use?' (answer options; yes, no, yes if modified). This systematic review was conducted according to a pre-specified PROSPERO protocol https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=154361

uploaded 19 December 2019. The MEDLINE strategy was straightforward; although not formally processed,⁴³ it was peer-reviewed by an information specialist.

Inclusion and exclusion criteria

We defined a CPG as a systematically developed set of recommendations that assist practitioners and patients in the provision of healthcare in specific circumstances, produced after review and assessment of available clinical evidence.^{12 44–46} CPGs published after 1 January 2010 were eligible if they (or part thereof) specifically targeted patients/population with gender minority/trans status and/or gender dysphoria, were evidence-based, with some documentation of development methodology, had international scope (more than one country, defined as a Member State of the United Nations) and were an original source. We chose the time frame to focus on the most recent guidelines, currently applicable to practice and to include WPATH SOCv7.³⁰ CPGs were eligible if they met the following inclusion criteria: participants/population was adults and/or children who are gender minority/trans with no exclusion due to comorbidities or age although differences/disorders in sex development (intersex) were excluded; exposure/intervention was any health intervention related to gender dysphoria or gender affirmation, or health concerns of gender minority/trans people, including screening, assessment, referral, diagnosis and interventions. We excluded previous versions of the same CPG. We used broad criteria because terminology has been in flux with changes made in both International Classification of Diseases and Diagnostic and Statistical Manual of Mental Disorders diagnostic criteria.¹⁶ There were no restrictions on setting or language.

Search strategy and guideline selection

We conducted the searches up to 11 June 2020 (CM), using search terms and appropriate synonyms (as Medical Subject Heading (MeSH) terms and text words) that we developed based on population and exposures (online supplemental table 1). We searched six databases (Embase, MEDLINE, Web of Science, PsycINFO, CINAHL, LILACS) and six CPG websites (Agency for Healthcare Research and Quality National Guideline Clearinghouse (NGC), eGuidelines and Guidelines, NICE National Library for Health, SIGN, EBSCO DynaMed Plus, Guidelines International Network Library) and the World Health Organization (WHO). The NGC closed in 2017 but CM hand-searched the archive. In addition to protocol, individual reviewers (IA, DC and MHJ) hand-searched four specialty journals (International Journal of Transgender Health, Transgender Health, LGBT Health, Journal of Homosexuality) to ensure key subject-relevant sources of abstracts were thoroughly checked. In order to find potential grey literature CPGs outwith the scholarly literature, two reviewers (IA and SD) independently performed four separate Google searches (not Google Scholar as misstated in the protocol) by

using one generic (clinical practice guidelines) plus one specific term (transgender, gender dysphoria, trans health or gender minority) and examining the first 100 hits. We identified International Key Opinion Leaders (n=24) via publications known to reviewers (DC and SD) and contacted them via email, with one reminder, to identify further guidelines. Reference lists of relevant reviews and all full-text studies were hand-searched to identify any relevant papers or CPGs not found by database searching. Two reviewers (SB and SD) independently read all titles and abstracts and assessed for inclusion. If there was uncertainty or disagreement, or reasonable suspicion that the full-text might lead to another relevant CPG, the full-text was obtained. Non-English abstracts were Google-translated but if a possible CPG could not be reliably excluded, the full-text paper was obtained and translated. Where full-text publications could not be accessed, we contacted authors directly. Two reviewers (SB and either DC/MHJ) independently carried out full-text assessment to determine inclusion or exclusion from the systematic review based on the above criteria, and noted reasons for excluding full-texts. The whole team discussed uncertainties and disagreements to achieve consensus, with voting and final adjudication by the senior author (CM).

Data extraction

Two reviewers (SB and SD) independently collected formal descriptive data of included CPGs. All ambiguities or discrepancies were referred to the team for discussion and to re-examine original texts and extract data. Information collected was title, author, year of publication, number of countries covered, originating organisation, audience, methods used, page and reference numbers (excluding accompanying materials) and funding. Key recommendations were extracted for comparison between CPGs. We searched for all text mentions of mortality or any measures of quality of life (QoL), and noted if accompanied by a citation. All patient facing material was extracted. In addition, we extracted data about publication outlet (journal/website), and whether the quantity of information pertaining to the health of gender minority/trans people represented a complete, partial or marginal proportion of recommendations in the CPG.

Outcomes

Outcomes were: the number and quality assessment scores (using AGREE II) of international CPGs addressing the health of gender minority/trans people; analysis and comparison of the presence or absence of information on estimated changes in mortality or QoL (any measure) following any specific recommended intervention, over any time interval; the consistency (or lack thereof) of recommendations across the CPGs; and the presence (or absence) of key messages for patients.

Quality assessment

All authors completed AGREE II video training, a practice assessment and two pilots whose results were discussed. The six reviewers (IA, SB, DC, SD, MHJ and CM) independently and anonymously completed quality scoring on every CPG by rating each of the items using the standard proforma on the My AGREE PLUS online platform (AGREE enterprise website),¹¹ which also calculated group appraisal scores.

Patient and public involvement

The AGREE II instrument generates quality scores but does not set specific parameters for what constitutes high quality, recommending that decisions about defining such thresholds should be made prior to performing appraisals, considering relevant stakeholders and the context in which the CPG is used.¹¹ To help set quality thresholds, we conducted an AGREE II domain prioritisation exercise in January 2020 via email, with one reminder. It was considered impossible to ensure comprehensive representation of international stakeholders. We chose the UK for feasibility, although validity might be limited to UK-based clinicians. Fifty-two UK service-user stakeholder groups and gender minority/trans advocacy organisations, identified via reviewer knowledge and internet searches (IA, SB, DC, SD, MHJ and CM), were informed about the study. They were invited to participate in a stakeholder prioritisation of the AGREE II domains, created using SurveyMonkey and with an option to remain anonymous (<https://www.surveymonkey.co.uk/r/WLZ55NQ> gives invitation wording, links to resources and protocol). The reviewer team performed an anonymous prioritisation for comparison.

Strategy for data and statistical analyses

Simple frequencies were used to present the stakeholder and reviewer priorities, and outcomes. Following team discussion of the prioritisation exercise results, no prespecified quality threshold score was used to define high or low quality, although colour was superimposed ($\leq 30\%$, 31% – 69% and $\geq 70\%$) on the final scores table to aid visual comparisons and interpretation.

RESULTS

Search results

Figure 1 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart⁴⁷) shows that 1815 citations were identified, of which 134 full-text publications were read (all available, three supplied by authors) and 122 excluded (online supplemental table W2 with reasons).

Data extraction

Table 1 shows the characteristics of the CPGs. Online supplemental tables W3 and W4 show raw data of key recommendations and mortality and QoL evidence.

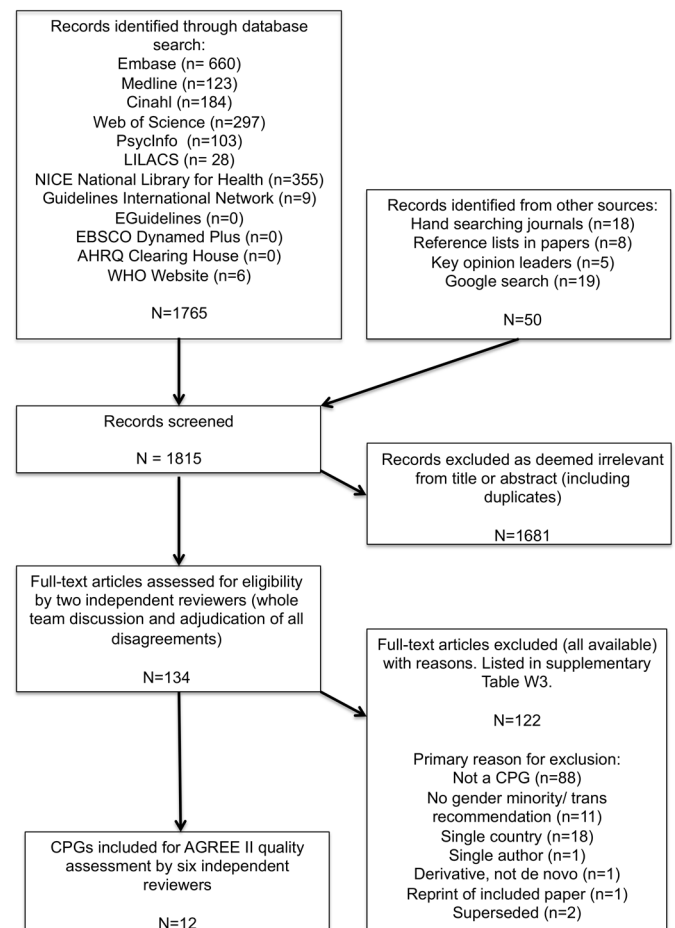


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. AGREE II, Appraisal of Guidelines for Research and Evaluation tool; CPG, clinical practice guideline; NICE, National Institute for Health and Care Excellence.

Number and characteristics of clinical practice guidelines

Twelve CPGs (table 1) originated from: WHO (n=3),^{48–50} WPATH (n=2),^{30 51} professional specialist/special-interest societies (n=4),^{52–55} small groups of experts (n=2)^{56 57} and one consortium.⁵⁸ All were published in English, in journals,^{51–57} the organisation's website^{48–50 58} or both.³⁰ Guideline development methodology was variable, including use of systematic reviews (table 1). Ten CPGs had no external review, eight had no update plans. Gender minority/trans health recommendations made up complete (n=5),^{30 51 53 55 57} partial (n=4)^{48–50 56} or marginal (n=3)^{52 54 58} focus of content. CPGs contained 10 to 155 pages, and 20 to 505 references. Funding sources were wide-ranging and sometimes multiple, from government agencies, professional societies, charities and private donations. Two CPGs provided no funding details.^{52 56}

A 13th CPG was excluded post-scoring as it had been superseded by a 2020 version without recommendations for gender minority/trans people.⁵⁹ It was arguable if four included CPGs did meet criteria: one had not been withdrawn⁴⁸; one contained minimal relevant content⁵²; one might not have been intended as a CPG³⁰ (although

Table 1 General characteristics of included clinical practice guidelines (n=12)

Number	Author (year)	Full title	Countries covered	Origin	Primary audience	Design (systematic review, SR, used and methods thereafter)	Planned update given	Funding
1	Coleman <i>et al</i> (2012) ³⁰	Standards of care for the health of transsexual, transgender and gender non-conforming people V.7	Global	WPATH	Health professionals	Work groups submit manuscripts based on prior literature reviews, no explicit links of recommendations to evidence, expert consensus. No independent external review	No	Tawani Foundation and gift from anonymous donor
2	Davies <i>et al</i> (2015) ⁵¹	Voice and communication change for gender non-conforming individuals: giving voice to the person inside	Global	WPATH	Speech-language therapists	Review of evidence. Expert consensus. No independent external review	No	Transgender Health Information Program of British Columbia Canada
3	ECDC (2018) ⁵⁸	Public health guidance on HIV, hepatitis B and C testing in the EU/EEA	EU/EEA	ECDC consortium CHIP, PHE, SSAT and EATG	Member states' public health professionals who coordinate the development of national guidelines or programmes for HBV, HCV and HIV testing	Four SRs, SIGN, NICE and AXIS checklists. Ad hoc internal and external expert panel, independent chair, expert consensus. No independent external review	No	Commissioned by ECDC, contractor Rigshospitalet CHIP
4	Gilligan <i>et al</i> (2017) ⁵²	Patient-clinician communication: American Society of Clinical Oncology consensus guideline	USA and others	ASCO	Clinicians who care for adults with cancer	Nine questions (one SR), expert consensus and a Delphi exercise. No independent external review	Regular review 3-year check	None declared
5	Hembree <i>et al</i> (2017) ⁵³	Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline	Global	Endocrine Society	Endocrinologists, trained mental health professionals and trained physicians	Two SRs and GRADE, rest expert consensus. No independent external review	No	Endocrine Society
6	IAPHCCO (2015) ⁵⁴	IAPAC guidelines for optimising the HIV care continuum for adults and adolescents	Global	IAPAC	Care providers, programme managers, policymakers, affected communities, organisations, and health systems involved with implementing HIV programmes and/or delivering HIV care	A systematic search of CDC database, expert consensus. No independent external review	No	IAPAC, US NIH and Office of AIDS Research
7	Ralph <i>et al</i> (2010) ⁵⁶	Trauma, gender reassignment and penile augmentation	Not specified (international publication)	Author group	Not stated (urological surgeons)	No SR. Unclear if literature review. Leading experts' consensus opinion. No independent external review	No	None declared
8	Strang <i>et al</i> (2018) ⁵⁷	Initial clinical guidelines for co-occurring autism spectrum disorder and gender dysphoria or incongruence in adolescents	Not specified (international publication)	Author group	Clinicians	No SR or literature review. Two-stage Delphi consensus. No independent external review	No	Isadore and Bertha Gudelsky Family Foundation
9	T'Sjoen <i>et al</i> (2020) ⁵⁵	ESSM Position Statement 'Assessment and hormonal management in adolescent and adult trans people, with attention for sexual function and satisfaction'	Europe	ESSM	European clinicians working in transgender health, sexologists and other healthcare professionals	No SR. Leading experts' consensus opinion. No independent external review	No	ESSM
10	WHO (2011) ⁴⁸	Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people. Recommendations for a public health approach	Global	WHO	National public health officials and managers of HIV/AIDS and STI programmes, NGOs including community and civil society organisations, and health workers	13 SRs for PICO and GRADE, external GDG, and independent external review	Yes in 2015	BMZ and PEPFAR through CDC and USAID
11	WHO (2012) ⁴⁹	Guidance on oral pre-exposure prophylaxis for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV. Recommendations for use in the context of demonstration projects	Global	WHO	Countries/member states	Four SRs (including values and preferences reviews) and GRADE, external GDG and independent external review group	Yes in 2015	Bill & Melinda Gates Foundation

Continued

Table 1 Continued

Number	Author (year)	Full title	Countries covered	Origin	Primary audience	Design (systematic review, SR, used and methods thereafter)	Planned update given	Funding
12	WHO (2016) ⁵⁰	Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. 2016 update	Global	WHO	National HIV programme managers and other decision-makers within ministries of health and those responsible for health policies, programmes and services in prisons	Two new SRs in revised guidance, GRADE, external GDGs and 79 independent external peer reviewers	Regular updates; no detail	UNAIDS, PEPFAR, Global Fund

AACE, American Association of Clinical Endocrinologists; ASA, American Society of Andrology; ASCO, American Society of Clinical Oncology; ASD, autism spectrum disorder; AXIS, Appraisal Tool for Cross-Sectional Studies; BMZ, German Federal Ministry for Economic Cooperation and Development; CDC, the Centers for Disease Control and Prevention; CHIP, CHIP/Region H, Rigshospitalet, University of Copenhagen; CPG, clinical practice guideline; EATG, European AIDS Treatment Group; EAU, European Association of Urology; ECDC, European Centre for Disease Prevention and Control; ESE, European Society for Endocrinology; ESPE, European Society for Pediatric Endocrinology; ESSM, European Society for Sexual Medicine; EU/EEA, European Union/European Economic Area; GDG, guideline development group; Global Fund, Global Fund to Fight AIDS, Tuberculosis and Malaria; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; HBV, hepatitis B virus; HCV, hepatitis C virus; IAPAC, International Association of Providers of AIDS Care; IAPHCCO, International Advisory Panel on HIV Care Continuum Optimization; NGO, non-governmental organisations; NICE, National Institute of Health and Care Excellence; NIH, National Institutes of Health; PEPFAR, US President's Emergency Plan for AIDS Relief; PES, Pediatric Endocrine Society; PHE, Public Health England; PICO, Participants/patients, Intervention, Comparators, Outcomes; SIGN, Scottish Intercollegiate Guidelines Network; SR, systematic review; SSAT, St Stephen's AIDS Trust; STI, sexually transmitted infection; UNAIDS, The United Budget, Results and Accountability Framework of the Joint United Nations Programme on HIV/AIDS; USAID, US Agency for International Development; WPATH, World Professional Association for Transgender Health.

WPATH SOCv7's stated overall goal is 'to provide clinical guidance for health professionals'³⁰ it contains no list of key recommendations nor auditable quality standards, yet is widely used to compare procedures covered by US providers^{60 61}; one variously described itself as 'position statement' and 'position study' (stating it did 'not aim to provide detailed clinical guidelines for professionals such as... [named]^{30 53}, but evidence was obviously linked to key recommendations for clinicians⁵⁵). After discussion it was decided not to exclude these borderline CPGs, as the definition of CPG in the protocol was intended to favour an inclusive approach.

Quality prioritisation and assessment

Results of the domain prioritisation by stakeholders (n=19 replies, response rate 39% excluding 3 'undeliverable') and reviewers (n=6) showed that stakeholders prioritised stakeholder involvement, whereas the reviewer team prioritised methodological rigour (online supplementary table W5). No stakeholder asked for clarification or more information.

Table 2 shows AGREE II scores by domain (8%–94%), and overall (11%–94%). The quality scores have a wide range and heterogeneity. Five CPGs focused on trans people as a key population for HIV and other blood-borne infections (overall assessment scores 69%–94%). Six CPGs concerned transition-specific interventions (overall assessment scores 11%–56%). Transition-related CPGs tended to lack methodological rigour and rely on patchier, lower-quality primary research. The two prioritised domain scores were usually comparable with the overall AGREE II quality assessment (ranges; stakeholder involvement 14%–93%, methodological rigour 17%–87%). Four CPGs obtained a majority opinion 'recommend for use',^{48–50 58} five CPGs had unanimous 'do not recommend',^{30 51 55–57} and three had minority support with division about the extent of 'yes, if modified',^{52–54} (table 2). Despite wide variation there was a pattern; HIV and blood-borne infection guidelines^{48–50 54 58} were higher quality, and those focusing on transition were lower quality.^{30 53 55–57}

Content

Four CPGs concerning HIV prevention, transmission and care^{48–50 54} and one public health guideline on population screening for blood-borne viruses,⁵⁸ contained recommendations for gender minority/trans people as a 'key population'. Three CPGs were devoted to overall transition care for all gender minority/trans people,^{30 53 55} two to an aspect of transition^{51 56} and one to transition in a specific group.⁵⁷ One oncology communication guideline contained a single recommendation relating to gender minority/trans people.⁵² No international guidelines were found that addressed primary care, psychological support/mental health interventions, or general medical/chronic disease care (such as cardiovascular, cancer or elderly care).

Table 2 AGREE II (Appraisal of Guidelines for Research and Evaluation tool) domain percentages and overall assessment of included guidelines, and summary of mortality/quality of life measures (n=12)

Number	Author (year)	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity and presentation	Applicability	Editorial independence	Overall assessment	Recommendation to use	Mortality	Quality of life	Mortality (any comment) and quality of life (any formal measure)
1	Coleman <i>et al</i> (2012) ⁵⁰	63%	47%	20%	37%	16%	15%	31%	Yes 0 No 5 If modified 1	Y	Y	M: Higher in post SRS vs matched no SRS, and both pre and post SRS vs gen popn. QoL: FtM<gen popn, FtM post breast/chest surgery >not surgery, mixed results at 15 years.
2	Davies <i>et al</i> (2015) ⁵¹	62%	38%	17%	61%	28%	14%	28%	Yes 0 No 3 If modified 3	N	Y	QoL: A voice-related TG QoL measure correlated with own and others' perception.
3	ECDC (2018) ⁵⁸	94%	56%	55%	76%	68%	38%	69%	Yes 4 No 0 If modified 2	Y	Y	M: Reduced by early diagnosis. QoL: Cost/QALY in anti-HCV birth cohort screening is acceptable. Universal offer HIV testing in hospital settings is highly cost effective.
4	Gilligan <i>et al</i> (2017) ⁵²	84%	67%	66%	81%	47%	61%	78%	Yes 2 No 0 If modified 4	N	N	
5	Hembree <i>et al</i> (2017) ⁵³	65%	40%	41%	73%	29%	65%	56%	Yes 1 No 2 If modified 3	Y	Y	M: TW/TM's CV mortality same ('insufficient very low quality data' for TM) and younger age at death after SRS. QoL: long-term psychological and psychiatric issues post SRS.
6	IAPHCCO (2015) ⁵⁴	85%	56%	61%	87%	40%	63%	81%	Yes 3 No 0 If modified 3	Y	Y	M: Lower if early ART, easy access, immediate ART, and community distribution. QoL: ART preserves QoL, and stigma and mental health impact on QoL.
7	Ralph <i>et al</i> (2010) ⁵⁶	45%	14%	19%	64%	5%	32%	28%	Yes 0 No 5 If modified 1	N	N	
8	Strang <i>et al</i> ⁵⁷ (2018) ⁵⁷	57%	33%	19%	39%	8%	25%	11%	Yes 0 No 6 If modified 0	N	N	
9	T'Sjoen <i>et al</i> (2020) ⁵⁵	59%	37%	35%	58%	15%	33%	42%	Yes 0 No 4 If modified 2	N	Y	QoL: Sexual life improves after GAMI, but not to non-TG levels.
10	WHO (2011) ⁴⁸	94%	89%	87%	86%	64%	82%	83%	Yes 5 No 0 If modified 1	Y	Y	M: Looked for mortality evidence but none found. QoL: Positive QALYs if HIV averted.
11	WHO (2012) ⁴⁹	85%	60%	81%	76%	41%	72%	72%	Yes 4 No 0 If modified 2	N	Y	QoL: Positive QALYs modelled if PrEP.
12	WHO (2016) ⁵⁰	94%	93%	81%	89%	84%	65%	94%	Yes 5 No 0 If modified 1	Y	N	M: Better if access and if adhere to OST, and at prison release; if early ART and completed TB Rx, HBV/ HCV managed; and access to post-abortion care. Worse if food insecure, poor nutrition, low body mass index.

Colours to aid interpretation (not thresholds) ≤30% RED, 31–69% AMBER, ≥70% GREEN.

ART, antiretroviral therapy; CV, cardiovascular; ECDC, European Centre for Disease Prevention and Control; FtM, female-to-male; GAMI, gender affirming medical intervention; gen popn, general population; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IAPHCCO, International advisory panel on HIV care continuum optimization; M, mortality; OST, opiate substitute therapy; PrEP, pre-exposure prophylaxis; QALY, quality adjusted life year; QoL, Quality of life; Rx, treatment; SR, systematic review; SRS, sex reassignment surgery; TB, tuberculosis; TG, trans people/gender-minority; TM, trans man; TW, trans woman.

Mortality and quality of life

Six CPGs referred to mortality^{30 48 50 53 54 58} and eight to QoL^{30 48 49 51 53–55 58} (table 2). Online supplemental table W4 shows all extractions of sentences relating to mortality or morbidity, associated references and which CPGs included no such data. More robust evidence was linked to the recommendations in the HIV and blood-borne virus CPGs whereas there was little, inconsistent data and poorer linking to evidence in transition-related CPGs.

Consistency of recommendations across the CPGs

Online supplemental table W5 contains all extracted key recommendations where these could be distinguished. It shows little overlap of topic content across the CPGs. Many recommendations in WHO 2011⁴⁸ and 2016⁵⁰ were similar, but not identical, the former not being stood down after the latter was published. No statements were highlighted by the WPATH SOCv7³⁰ authors as key recommendations, and it proved impossible for all six reviewers independently performing data extraction to identify them. The total number of extracted recommendations ranged between 0 and 168 with little consistency or agreement on what passages were selected. Some extracted statements might have been intended as recommendations or standards, but many were flexible, disconnected from evidence and could not be used by individuals or services to benchmark practice. After discussion of this incoherence within WPATH SOCv7³⁰ and our inability therefore to compare recommendations across all CPGs, it was decided not to revisit inclusions post hoc but to abandon this protocol aim.

Patient facing material

No patient-facing material was found in any guideline.

DISCUSSION

Statement of principal findings

Variable quality international CPGs regarding gender minority/trans people's healthcare contain little, conflicting information on mortality and QoL, no patient facing messages and inconsistent use of systematic reviews in generating recommendations. A major finding is that the scope of the guidelines is confined to HIV/STI prevention or management of transition with an absence of guidelines relating to other medical issues. WPATH SOCv7³⁰ cannot be considered 'gold standard'.

Strengths and weaknesses of this study

Strengths include protocol preregistration, stakeholder involvement, piloting all stages, an extensive systematic search without language restriction for any relevant current guidelines, wide inclusion criteria including grey literature, use of key opinion leaders, close attention to avoidance of bias, double full-text reading and data entry and careful presentation of results. Six trained reviewers, exceeding AGREE II recommendations,¹¹ compensated for expected variation in scoring. Extensive searches

should have mitigated loss of CPGs. Limitations include some uncertainty about stakeholder understanding despite a good response rate, and generalisability of the prioritisation only to the UK; stakeholders elsewhere might have different priorities. Focusing only on international CPGs might have missed higher quality national and local CPGs derived from them or written de novo. The social acceptance and consequent healthcare system coverage of gender minority/trans health related interventions vary among different countries, which may limit the space for international and multinational guidelines. While the search strategy yielded an oncology communication CPG with a single recommendation for gender minority/trans people,⁵² other general health CPGs with similar solo statements might have been missed.

Comparison with other studies, discussing important differences in results

This is the first systematic review using a validated quality appraisal instrument of international CPGs addressing gender minority/trans health. It may act as a benchmark to monitor and improve population healthcare. CPG quality results correspond with, and quantitatively confirm, previously noted concerns about the evidence-base^{36 62 63} and variable use of quality assessment in systematic reviews,^{64–66} in a healthcare field with unknown or unclear longitudinal outcomes.¹⁷ AGREE II has been applied to CPGs in other medical areas, including cancer,⁶⁷ diabetes,⁶⁸ pregnancy⁶⁹ and depression.⁷⁰ These exercises tend to show room for improvement. Developers have been criticised for not using methodological rigour when writing reliable evidence-based guidelines,⁷¹ as well as not implementing high-quality CPGs.⁷² Thus, finding poor quality CPGs is not confined to this area of healthcare.⁷³ Improvement messages are generalisable to other specialties.

Meaning of the study: possible explanations

The finding of higher-quality, but narrow, focus on gender minority/trans people's healthcare for blood-borne infections may relate to the global HIV pandemic and the WHO applying twin lenses of public health and human rights (ie, the population as 'means' and 'ends'). The lower-quality CPGs focus on transition. WPATH SOCv7³⁰ originated nearly a decade ago from a special-interest association; diagnostic criteria and CPG methodology have since changed. Although HIV and transition are important, it is puzzling to have found so little else, maybe suggesting CPGs for gender minority/trans people have been driven by provider-interests rather than healthcare needs. Including gender minority/trans people in guidelines can be considered a matter of health equity, where CPGs have a role to play.⁷⁴ GRADE suggests CPG developers may consider equity at various stages in creating guidelines, such as deciding guideline questions, evidence searching and assembly of the guideline group.⁷⁵ How CPGs may impact more vulnerable members of

society should be reflected-upon during guideline development,⁷⁶ and implementation.⁷⁷

Implications for clinicians, UK and international policymakers and patients

Clinicians should be made aware that gender minority/trans health CPGs outside of HIV-related topics are linked to a weak evidence base, with variations in methodological rigour and lack of stakeholder involvement. While patient care plans ought to take into account the individual needs of each gender minority/trans person, a gap appears to exist between clinical practice and research in this field.⁷⁸ Clinicians should proceed with caution, explain uncertainties to patients and recruit to research.

Policymakers ought to invest in both primary research and high-quality systematic reviews in areas relevant for CPG and service development. Organisations producing guidelines and aspiring to higher-level quality could use more robust methods, handling of competing interests^{79 80} and quality assessment. CPG developers should label key recommendations clearly. Although editorial independence was lowest priority for stakeholders, independent external review is important to avoid biases and bad practices, examine use of resources, resist commercial interests and gain widespread credibility outside the field.

The UK is fortunate in being familiar with developing priority-setting partnerships (eg, James Lind Initiative⁸¹) and generating suites of clinical questions that might cover all steps in patient pathways (eg, in partnership with Cochrane Collaboration⁸²). These could underpin multidisciplinary and funded research priorities whose results feed into future better evidence-based CPGs. Implications for UK education and curricular content (eg, new gender identity healthcare credentials⁸³), should be carefully scrutinised.

Internationally, CPG development and implementation will vary depending on local country contexts and available resources. Those countries with quality assurance agencies might use them for external assurance. Countries might reconsider the wisdom of adapting low-quality 'off the shelf' international CPGs without due assessment of the evidence for recommendations (eg, using the GRADE-ADOLOPMENT framework⁸⁴). WHO demonstrates how CPGs can achieve high quality.

Patients should be positively encouraged to engage with CPG development as stakeholders. The lack of patient-facing material should be addressed, especially as medical and non-medical online material contains jargon, is unreliable and potentially misleading.⁸⁵ Future CPGs should be populated with patient-facing decision aids (eg, fact boxes⁸⁶ and icon arrays⁸⁷) that explain sizes of benefits and harms to support informed patient choice. Patients and carers will benefit from a more focused approach to throughout-life healthcare. As the figures for gender minority/trans patients increase within the NHS and internationally, so does the need for consistent guidance to clinicians across specialisms on specific risks to, and means of treating, this population. Current patients should be welcomed to contribute, where they are

comfortable, to any research being undertaken by their clinicians, in order to improve data and future practice for gender minority/trans health.

Unanswered questions and future research

This study should be replicated as new iterations of international CPGs become available. It can be applied to national guidelines and countries should perform their own stakeholder prioritisation. When 'best available evidence' is poor, quality improvement can be driven both from inside and outside the field. International guideline developers require more primary research for this population, and impetus from clinicians and scientists to build a better evidence base using robust data from randomised controlled trials and long-term observational cohort studies, especially regarding chronic diseases, health behaviours, substance use, screening and how interventions (eg, hormones) might impact on long-term health (eg, risk of cardiovascular and thromboembolic disease). Mortality and QoL data are required to address questions of clinical and cost-effectiveness.

CONCLUSION

Gender minority/trans health in current international CPGs seems limited to a focus on HIV or transition-related interventions. WPATH SOCv7³⁰ is due for updating and this study should be used positively to accelerate improvement. Future guideline developers might better address the holistic healthcare needs of gender minority/trans people by enhancing the evidence-base, upgrading the quality of CPGs and increasing the breadth of health topics wherein this population is considered.

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Exhibit H



Marci L. Bowers, M.D.

(650) 570-2270

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Dear colleagues, clients and friends,



Regarding the 10/4/21 article by Abigail Shrier, I remain disappointed by the tone and intent of the article. My comments were taken out of context and used to cast doubt upon trans care, particularly the use of puberty blockers. Worse, Jazz

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Jennings was disrespectfully and erroneously portrayed as a puberty blockade failure, based solely upon her television portrayal. That said, the author conveyed to me that she is *not against* the use of puberty blockade but rather, interested in better informed consent, a principle upon which we both agreed. I did believe that my comments would be conveyed fairly.

My comments were limited to transfeminine persons, not transmasculine, a point not made.

My concerns regarding consent included long term sexual function, data that we currently do not know, although patients retain sensation including clitoris and G-spot. Sexual naivete is a potential concern but not central to my argument and it is far from certain that patients will sustain permanent sexual dysfunction. It is still possible that adults with a history of puberty blockade will go on to have satisfying sexual lives, but these patients need to be tracked and this measure documented.

My concerns regarding fertility are secondary, a potential that many transfeminine persons are willing to forego.

My concerns regarding puberty blockade and its negative impact upon later genital surgery remain and are not allayed by new techniques of vaginoplasty including peritoneal pull through. Complications and challenges for these patients are without a doubt, increased.

My hope is that colleagues, onlookers and members of the transgender community at large will recognize my long-term contributions to the field, my unwavering advocacy for patients, the 'one off' regarding this article—wrong time, wrong venue. Although my comments were my own professional opinions, I do recognize that, as President-elect, I now speak for WPATH as well. I have learned from this experience and will be better. I also hope that my comments will help future clinicians, families and patients make more certain, informed choices. I believe that this moment will spur studies, will inspire surgeons to seek better results, and encourage families to consider a bit of puberty when weighing treatment options.

What I hope for, most of all, is that my out-of-context comments will not be excerpted to weaponize ongoing attacks upon transgender persons. We have been here since the beginning of time and will be here in the future. We must not allow the critics and skeptics to undo our legitimacy. Rather than attack one another, we are best served by our support of WPATH and its goal of establishing evidence-based care that affirms gender identity as another important aspect of global diversity.

For patients and families seeking guidance going forward, I will say this based upon my own professional experience:

- consider consultation with a gender surgeon prior to blockers. Not all puberty blocked individuals will have insufficient growth going into blockers though puberty may be deemed beneficial for some
- If you can possibly stand a bit of puberty, the extra genital skin growth, likely orgasm and potential fertility may be attractive enough to consider the option. Early post-pubertal kids in their early teens still transition extremely well

For doubters, conservatives, naysayers and haters who continue to misgender, mischaracterize and malign trans persons around the globe, you've lost credibility with me, and likely, with God above.

Marci L. Bowers, MD

← *60 Minutes Overtime Interview*

*Detransition, Baby: Examining Factors Leading to ‘Detransitioning’
and Regret in the Transgender Community* →

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Exhibit I

About the Review



An Introduction to the Cass Review



Hear from Hilary about why she got involved in the Review

Children and young people accessing the NHS deserve timely and supportive services, and clinical staff with the training and expertise to meet their healthcare needs.

Not all children and young people who are exploring their gender identity require clinical support from the NHS. However, some young people whose gender identity differs from their gender assigned at birth can experience extreme distress; this is referred to by clinicians as gender dysphoria. These children and young people need clinical support to help them understand the options available to them and to provide appropriate treatment.

The aim of the Cass Review is to ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria, and who need support from the NHS, receive a high standard of care that meets their needs and is safe, holistic and effective.

About the Review (<https://cass.independent-review.uk/about-the-review/>)

Terms of Reference (<https://cass.independent-review.uk/about-the-review/terms-of-reference/>).

Approach (<https://cass.independent-review.uk/about-the-review/approach/>).

The Chair (<https://cass.independent-review.uk/about-the-review/the-chair/>).

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Cass Review

Independent Review of Gender Identity
Services for Children and Young People

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Exhibit J

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and
on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740

HON. ROBERT C. CHAMBERS, JUDGE

EXPERT REBUTTAL REPORT OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., declare as follows:

1. My name is Johanna Olson-Kennedy. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have been asked by Plaintiffs' counsel to provide my expert opinion on gender identity, the treatment and diagnosis of gender dysphoria, particularly as it pertains to children and adolescents, and to respond to, rebut, and provide my expert opinion regarding the report by Dr. Stephen B. Levine in this case ("Levine Report").

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.

I. BACKGROUND AND QUALIFICATIONS

4. 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

which demonstrate the safety and positive impact of gender affirming medical interventions. Additionally, larger longitudinal studies are currently underway to help substantiate the significant existing data we have. (de Vries, et al, 2021; Weinand, 2015).

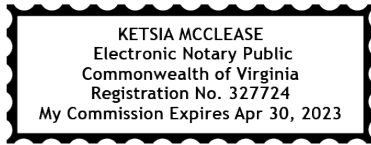
55. Additionally, although it is not possible to ethically conduct randomized control trials for gender-affirming care, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care. Clinicians 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 analogs. (Kuper, et al., 2020; Chew, et al., 2018; Colton-Meier, et al., 2011). The same is true with regards to surgery. (Marano, et al., 2021; Olson-Kennedy, et al., 2018; Murad, et al., 2010; Smith, et al., 2005; Pfafflin & Junge, 1998).

56. Dr. Levine inaccurately suggests that diagnosis of gender dysphoria is done solely through a patient’s self-diagnosis. Levine Report ¶ 148. His critique demonstrates a fundamental misunderstanding of how gender affirming care is provided. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not “self-diagnose,” as Dr. Levine suggests. 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

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 17 day of March, 2022.


Johanna Olson-Kennedy (Mar 17, 2022 10:26 PDT)
Johanna Olson-Kennedy, M.D., M.S.

Subscribed and sworn before me, a Notary Public in and for the County of Norfolk, State of
Virginia, this 17 day of March, 2022.





Signature of Notary

This notarial act was performed online by way of
two-way audio/video communication technology.

1647520704-olson-kennedy-rebuttal-report_final

Final Audit Report

2022-03-17

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Exhibit K

From DEPARTMENT OF CLINICAL NEUROSCIENCE
Karolinska Institutet, Stockholm, Sweden

ON GENDER DYSPHORIA

Cecilia Dhejne



**Karolinska
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Stockholm 2017

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On Gender Dysphoria

THESIS FOR DOCTORAL DEGREE (Ph.D.)

at Karolinska Institutet, to be publicly defended in lecture hall Nanna Svartz,
Karolinska University Hospital Solna.

Friday, March 31, 2017 at 9:00 a.m.

By

Cecilia Dhejne

Principal Supervisor:

Professor Mikael Landén
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Biostatistics, and Sahlgrenska Academy at
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6 ON THE IMPACT OF RESEARCH FINDINGS

Researchers are happy if their findings are recognized and have an impact. However, once published, the researcher loses control of how results are used. Study III is the first long-term cohort study of mortality and psychiatric inpatient care following gender transition (Dhejne et al., 2011). This paper has also had an impact outside the scientific world. Our findings have been used to argue that gender-affirming treatment should be stopped since it could be dangerous (Levine, 2016). But the results have also been used to show the vulnerability of the group and that better transgender health care is needed (Arcelus & Bouman, 2015; Zeluf et al., 2016). Despite the paper clearly stating that the study is not designed to evaluate whether or not gender-affirming is beneficial, it has been interpreted as such. But we do not know what would have happened without gender-affirming treatment; the situation may have been even worse. As an analogy, similar studies have found increased somatic morbidity, suicide rates, and overall mortality for patients treated for depression and bipolar disorder (Ösby, Brandt, Correia, Ekbom, & Sparen, 2001). This is important information, but it does not follow that antidepressant or mood stabilizing treatment cause the mortality. Most of the articles that use the study to argue against gender-affirming health care are published in non-peer reviewed papers and the public media in general. These non-scientific publications are difficult to keep track of. I am grateful to friends, colleagues, patients, LGBT organizations, and journalists who have alerted me when the results of the study have been misinterpreted, giving me a possibility to respond to the authors. One could argue that the results should never have been published due to the hurt caused to transgender persons. However, not publishing the results would also hurt the transgender group and take away an opportunity to receive better health care.

Exhibit L

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

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Abstract

Context: The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

Objective: To estimate mortality, morbidity, and criminal rate after surgical sex reassignment of transsexual persons.

Design: A population-based matched cohort study.

Setting: Sweden, 1973–2003.

Participants: All 324 sex-reassigned persons (191 male-to-females, 133 female-to-males) in Sweden, 1973–2003. Random population controls (10:1) were matched by birth year and birth sex or reassigned (final) sex, respectively.

Main Outcome Measures: Hazard ratios (HR) with 95% confidence intervals (CI) for mortality and psychiatric morbidity were obtained with Cox regression models, which were adjusted for immigrant status and psychiatric morbidity prior to sex reassignment (adjusted HR [aHR]).

Results: The overall mortality for sex-reassigned persons was higher during follow-up (aHR 2.8; 95% CI 1.8–4.3) than for controls of the same birth sex, particularly death from suicide (aHR 19.1; 95% CI 5.8–62.9). Sex-reassigned persons also had an increased risk for suicide attempts (aHR 4.9; 95% CI 2.9–8.5) and psychiatric inpatient care (aHR 2.8; 95% CI 2.0–3.9). Comparisons with controls matched on reassigned sex yielded similar results. Female-to-males, but not male-to-females, had a higher risk for criminal convictions than their respective birth sex controls.

Conclusions: Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Our findings suggest that sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group.

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Introduction

Transsexualism (ICD-10),[1] or gender identity disorder (DSM-IV),[2] is a condition in which a person's gender identity - the sense of being a man or a woman - contradicts his or her bodily sex characteristics. The individual experiences gender dysphoria and desires to live and be accepted as a member of the opposite sex.

The treatment for transsexualism includes removal of body hair, vocal training, and cross-sex hormonal treatment aimed at making the person's body as congruent with the opposite sex as possible to alleviate the gender dysphoria. Sex reassignment also involves the surgical removal of body parts to make external sexual characteristics resemble those of the opposite sex, so called sex reassignment/confirmation surgery (SRS). This is a unique

intervention not only in psychiatry but in all of medicine. The present form of sex reassignment has been practised for more than half a century and is the internationally recognized treatment to ease gender dysphoria in transsexual persons.[3,4]

Despite the long history of this treatment, however, outcome data regarding mortality and psychiatric morbidity are scant. With respect to suicide and deaths from other causes after sex reassignment, an early Swedish study followed 24 transsexual persons for an average of six years and reported one suicide.[5] A subsequent Swedish study recorded three suicides after sex reassignment surgery of 175 patients.[6] A recent Swedish follow-up study reported no suicides in 60 transsexual patients, but one death due to complications after the sex reassignment surgery.[7] A Danish study reported death by suicide in 3 out of 29 operated male-to-female transsexual persons followed for an average of six years.[8] By contrast, a Belgian study of 107 transsexual persons followed for 4–6 years found no suicides or deaths from other causes.[9] A large Dutch single-centre study (N=1,109), focusing on adverse events following hormonal treatment, compared the outcome after cross-sex hormone treatment with national Dutch standardized mortality and morbidity rates and found no increased mortality, with the exception of death from suicide and AIDS in male-to-females 25–39 years of age.[10] The same research group concluded in a recent report that treatment with cross-sex hormones seems acceptably safe, but with the reservation that solid clinical data are missing.[11] A limitation with respect to the Dutch cohort is that the proportion of patients treated with cross-sex hormones who also had surgical sex-reassignment is not accounted for.[10]

Data is inconsistent with respect to psychiatric morbidity post sex reassignment. Although many studies have reported psychiatric and psychological improvement after hormonal and/or surgical treatment,[7,12,13,14,15,16] other have reported on regrets,[17] psychiatric morbidity, and suicide attempts after SRS.[9,18] A recent systematic review and meta-analysis concluded that approximately 80% reported subjective improvement in terms of gender dysphoria, quality of life, and psychological symptoms, but also that there are studies reporting high psychiatric morbidity and suicide rates after sex reassignment.[19] The authors concluded though that the evidence base for sex reassignment “is of very low quality due to the serious methodological limitations of included studies.”

The methodological shortcomings have many reasons. First, the nature of sex reassignment precludes double blind randomized controlled studies of the result. Second, transsexualism is rare [20] and many follow-ups are hampered by small numbers of subjects.[5,8,21,22,23,24,25,26,27,28] Third, many sex reassigned persons decline to participate in follow-up studies, or relocate after surgery, resulting in high drop-out rates and consequent selection bias.[6,9,12,21,24,28,29,30] Forth, several follow-up studies are hampered by limited follow-up periods.[7,9,21,22,26,30] Taken together, these limitations preclude solid and generalisable conclusions. A long-term population-based controlled study is one way to address these methodological shortcomings.

Here, we assessed mortality, psychiatric morbidity, and psychosocial integration expressed in criminal behaviour after sex reassignment in transsexual persons, in a total population cohort study with long-term follow-up information obtained from Swedish registers. The cohort was compared with randomly selected population controls matched for age and gender. We adjusted for premorbid differences regarding psychiatric morbidity and immigrant status. This study design sheds new light on transsexual persons' health after sex reassignment. It does not, however, address whether sex reassignment is an effective treatment or not.

Methods

National registers

The study population was identified by the linkage of several Swedish national registers, which contained a total of 13.8 million unique individuals. The Hospital Discharge Register (HDR, held by the National Board of Health and Welfare) contains discharge diagnoses, up to seven contributory diagnoses, external causes of morbidity or mortality, surgical procedure codes, and discharge date. Discharge diagnoses are coded according to the 8th (1969–1986), 9th (1987–1996), and 10th editions (1997–) of the International Classification of Diseases (ICD). The register covers virtually all psychiatric inpatient episodes in Sweden since 1973. Discharges that occurred up to 31 December 2003 were included. Surgical procedure codes could not be used for this study due to the lack of a specific code for sex reassignment surgery. The Total Population Register (TPR, held by Statistics Sweden) is comprised of data about the entire Swedish population. Through linkage with the Total Population Register it was possible to identify birth date and birth gender for all study subjects. The register is updated every year and gender information was available up to 2004/2005. The Medical Birth Register (MBR) was established in 1973 and contains birth data, including gender of the child at birth. National censuses based on mandatory self-report questionnaires completed by all adult citizens in 1960, 1970, 1980, and 1990 provided information on individuals, households, and dwellings, including gender, living area, and highest educational level. Complete migration data, including country of birth for immigrants for 1969–2003, were obtained from the TPR. In addition to educational information from the censuses, we also obtained highest educational level data for 1990 and 2000 from the Register of Education. The Cause of Death Register (CDR, Statistics Sweden) records all deaths in Sweden since 1952 and provided information on date of death and causes of death. Death events occurring up to 31 December 2003 are included in the study. The Crime Register (held by the National Council of Crime Prevention) provided information regarding crime type and date on all criminal convictions in Sweden during the period 1973–2004. Attempted and aggravated forms of all offences were also included. All crimes in Sweden are registered regardless of insanity at the time of perpetration; for example, for individuals who suffered from psychosis at the time of the offence. Moreover, conviction data include individuals who received custodial or non-custodial sentences and cases where the prosecutor decided to caution or fine without court proceedings. Finally, Sweden does not differ considerably from other members of the European Union regarding rates of violent crime and their resolution.[31]

Study population, identification of sex-reassigned persons (exposure assessment)

The study was designed as a population-based matched cohort study. We used the individual national registration number, assigned to all Swedish residents, including immigrants on arrival, as the primary key through all linkages. The registration number consists of 10 digits; the first six provide information of the birth date, whereas the ninth digit indicates the gender. In Sweden, a person presenting with gender dysphoria is referred to one of six specialised gender teams that evaluate and treat patients principally according to international consensus guidelines: Standards of Care.[3] With a medical certificate, the person applies to the National Board of Health and Welfare to receive permission for sex reassignment surgery and a change of legal sex status. A new national registration number signifying the new gender is assigned after sex reassignment surgery. The National

Board of Health and Welfare maintains a link between old and new national registration numbers, making it possible to follow individuals undergoing sex reassignment across registers and over time. Hence, sex reassignment surgery in Sweden requires (i) a transsexualism diagnosis and (ii) permission from the National Board of Health and Welfare.

A person was defined as exposed to sex reassignment surgery if two criteria were met: (i) at least one inpatient diagnosis of gender identity disorder diagnosis without concomitant psychiatric diagnoses in the Hospital Discharge Register, and (ii) at least one discrepancy between gender variables in the Medical Birth Register (from 1973 and onwards) or the National Censuses from 1960, 1970, 1980, or 1990 and the latest gender designation in the Total Population Register. The first criterion was employed to capture the hospitalization for sex reassignment surgery that serves to secure the diagnosis and provide a time point for sex reassignment surgery; the plastic surgeons namely record the reason for sex reassignment surgery, i.e., transsexualism, but not any co-occurring psychiatric morbidity. The second criterion was used to ensure that the person went through all steps in sex-reassignment and also changed sex legally.

The date of sex reassignment (start of follow-up) was defined as the first occurrence of a gender identity disorder diagnosis, without any other concomitant psychiatric disorder, in the Hospital Discharge Register after the patient changed sex status (any discordance in sex designation across the Censuses, Medical Birth, and Total Population registers). If this information was missing, we used instead the closest date in the Hospital Discharge Register on which the patient was diagnosed with gender identity disorder without concomitant psychiatric disorder prior to change in sex status. The reason for prioritizing the use of a gender identity disorder diagnosis *after* changed sex status over *before* was to avoid overestimating person-years at risk of sex-reassigned person.

Using these criteria, a total of 804 patients with gender identity disorder were identified, whereof 324 displayed a shift in the gender variable during the period 1973–2003. The 480 persons that did not shift gender variable comprise persons who either did not apply, or were not approved, for sex reassignment surgery. Moreover, the ICD 9 code 302 is a non specific code for sexual disorders. Hence, this group might also comprise persons that were hospitalized for sexual disorders other than transsexualism. Therefore, they were omitted from further analyses. Of the remaining 324 persons, 288 were identified with the gender identity diagnosis *after* and 36 *before* change of sex status. Out of the 288 persons identified *after* changed sex status, 185 could also be identified *before* change in sex status. The median time lag between the hospitalization *before* and *after* sex change for these 185 persons was 0.96 years (mean 2.2 years, SD 3.3).

Gender identity disorder was coded according to ICD-8: 302.3 (transsexualism) and 302.9 (sexual deviation NOS); ICD-9: 302 (overall code for sexual deviations and disorders, more specific codes were not available in ICD-9); and ICD-10: F64.0 (transsexualism), F64.1 (dual-role transvestism), F64.8 (other gender identity disorder), and F64.9 (gender identity disorder NOS). Other psychiatric disorders were coded as ICD-8: 290-301 and 303-315; ICD-9: 290-301 and 303-319; and ICD-10: F00-F63 as well as F65-F99.

Identification of population-based controls (unexposed group)

For each exposed person ($N = 324$), we randomly selected 10 unexposed controls. A person was defined as unexposed if there were no discrepancies in sex designation across the Censuses, Medical Birth, and Total Population registers *and* no gender

identity disorder diagnosis according to the Hospital Discharge Register. Control persons were matched by sex and birth year and had to be alive and residing in Sweden at the estimated sex reassignment date of the case person. To study possible gender-specific effects on outcomes of interest, we used two different control groups: one with the same sex as the case individual at birth (birth sex matching) and the other with the sex that the case individual had been reassigned to (final sex matching).

Outcome measures

We studied mortality, psychiatric morbidity, accidents, and crime following sex reassignment. More specifically, we investigated: (1) all-cause mortality, (2) death by definite/uncertain suicide, (3) death by cardiovascular disease, and (4) death by tumour. Morbidity included (5) any psychiatric disorder (gender identity disorders excluded), (6) alcohol/drug misuse and dependence, (7) definite/uncertain suicide attempt, and (8) accidents. Finally, we addressed court convictions for (9) any criminal offence and (10) any violent offence. Each individual could contribute with several outcomes, but only one event per outcome. Causes of death (Cause of Death Registry from 1952 and onwards) were defined according to ICD as suicide (ICD-8 and ICD-9 codes E950-E959 and E980-E989, ICD-10 codes X60-X84 and Y10-Y34); cardiovascular disease (ICD-8 codes 390-458, ICD-9 codes 390-459, ICD-10 codes I00-I99); neoplasms (ICD-8 and ICD-9 codes 140-239, ICD-10 codes C00-D48), any psychiatric disorder (gender identity disorders excluded); (ICD-8 codes 290-301 and 303-315, ICD-9 codes 290-301 and 303-319, ICD-10 codes F00-F63 and F65-F99); alcohol/drug abuse and dependence (ICD-8 codes 303-304, ICD-9 codes 303-305 (tobacco use disorder excluded), ICD-10 codes F10-F16 and F18-F19 (x5 excluded); and accidents (ICD-8 and ICD-9 codes E800-E929, ICD-10 codes V01-X59).

Any criminal conviction during follow-up was counted; specifically, violent crime was defined as homicide and attempted homicide, aggravated assault and assault, robbery, threatening behaviour, harassment, arson, or any sexual offense.[32]

Covariates

Severe psychiatric morbidity was defined as inpatient care according to ICD-8 codes 291, 295-301, 303-304, and 307; ICD-9 codes 291-292, 295-298, 300-301, 303-305 (tobacco use disorder excluded), 307.1, 307.5, 308-309, and 311; ICD-10 codes F10-F16, F18-F25, F28-F45, F48, F50, and F60-F62. Immigrant status, defined as individuals born abroad, was obtained from the Total Population Register. All outcome/covariate variables were dichotomized (i.e., affected or unaffected) and without missing values.

Statistical analyses

Each individual contributed person-time from study entry (for exposed: date of sex reassignment; for unexposed: date of sex reassignment of matched case) until date of outcome event, death, emigration, or end of study period (31 December 2003), whichever came first. The association between exposure (sex reassignment) and outcome (mortality, morbidity, crime) was measured by hazard ratios (HR) with 95% CIs, taking follow-up time into account. HRs were estimated from Cox proportional hazard regression models, stratified on matched sets (1:10) to account for the matching by sex, age, and calendar time (birth year). We present crude HRs (though adjusted for sex and age through matching) and confounder-adjusted HRs [aHRs] for all outcomes. The two potential confounders, immigrant status (yes/no) and history of severe psychiatric morbidity (yes/no) prior to sex

reassignment, were chosen based on previous research[18,33] and different prevalence across cases and controls (Table 1).

Gender-separated analyses were performed and a Kaplan-Meier survival plot graphically illustrates the survival of the sex reassigned cohort and matched controls (all-cause mortality) over time. The significance level was set at 0.05 (all tests were two-sided). All outcome/covariate variables were without missing values, since they are generated from register data, which are either present (affected) or missing (unaffected). The data were analysed using SAS version 9.1 (SAS Institute Inc., Cary, NC, USA).

Ethics

The data linking of national registers required for this study was approved by the IRB at Karolinska Institutet, Stockholm. All data were analyzed anonymously; therefore, informed consent for each individual was neither necessary nor possible.

Results

We identified 324 transsexual persons (exposed cohort) who underwent sex reassignment surgery and were assigned a new legal sex between 1973 and 2003. These constituted the sex-reassigned (exposed) group. Fifty-nine percent (N = 191) of sex-reassigned persons were male-to-females and 41% (N = 133) female-to-males, yielding a sex ratio of 1.4:1 (Table 1).

The average follow-up time for all-cause mortality was 11.4 (median 9.1) years. The average follow-up time for the risk of being hospitalized for any psychiatric disorder was 10.4 (median 8.1).

Characteristics prior to sex reassignment

Table 1 displays demographic characteristics of sex-reassigned and control persons prior to study entry (sex reassignment). There were no substantial differences between female-to-males and male-to-females regarding measured baseline characteristics. Immigrant status was twice as common among transsexual individuals compared to controls, living in an urban area somewhat more common, and higher education about equally prevalent. Transsexual individuals had been hospitalized for psychiatric morbidity other than gender identity disorder prior to sex reassignment about four times more often than controls. To adjust for these baseline discrepancies, hazard ratios adjusted for immigrant status and psychiatric morbidity prior to baseline are presented for all outcomes [aHRs].

Mortality

Table 2 describes the risks for selected outcomes during follow-up among sex-reassigned persons, compared to same-age controls of the same birth sex. Sex-reassigned transsexual persons of both genders had approximately a three times higher risk of all-cause mortality than controls, also after adjustment for covariates. Table 2

Table 1. Baseline characteristics among sex-reassigned subjects in Sweden (N = 324) and population controls matched for birth year and sex.

Characteristic at baseline	Sex-reassigned subjects (N = 324)	Birth-sex matched controls (N = 3,240)	Final-sex matched controls (N = 3,240)
Gender			
Female at birth, male after sex change	133 (41%)	1,330 (41%)	1,330 (41%)
Male at birth, female after sex change	191 (59%)	1,910 (59%)	1,910 (59%)
Average age at study entry [years] (SD, min-max)			
Female at birth, male after sex change	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)
Male at birth, female after sex change	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)
Both genders	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)
Immigrant status			
Female at birth, male after sex change	28 (21%)	118 (9%)	100 (8%)
Male at birth, female after sex change	42 (22%)	176 (9%)	164 (9%)
Both genders	70 (22%)	294 (9%)	264 (8%)
Less than 10 years of schooling prior to entry vs. 10 years or more			
Females at birth, males after sex change	49 (44%); 62 (56%)	414 (37%); 714 (63%)	407 (36%); 713 (64%)
Males at birth, females after sex change	61 (41%); 89 (59%)	665 (40%); 1,011 (60%)	595 (35%); 1,091 (65%)
All individuals with data	110 (42%); 151 (58%)	1,079 (38%); 1,725 (62%)	1,002 (36%); 1,804 (64%)
Psychiatric morbidity* prior to study entry			
Female at birth, male after sex change	22 (17%)	47 (4%)	42 (3%)
Male at birth, female after sex change	36 (19%)	76 (4%)	72 (4%)
Both genders	58 (18%)	123 (4%)	114 (4%)
Rural [vs. urban] living area prior to entry			
Female at birth, male after sex change	13 (10%)	180 (14%)	195 (15%)
Male at birth, female after sex change	20 (10%)	319 (17%)	272 (14%)
Both genders	33 (10%)	499 (15%)	467 (14%)

Note:

*Hospitalizations for gender identity disorder were not included.

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Table 2. Risk of various outcomes among sex-reassigned subjects in Sweden (N = 324) compared to population controls matched for birth year and birth sex.

	Number of events cases/ controls 1973–2003	Outcome incidence rate per 1000 person-years 1973–2003 (95% CI)		Crude hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–1988	Adjusted* hazard ratio (95% CI) 1989–2003
		Cases	Controls				
Any death	27/99	7.3 (5.0–10.6)	2.5 (2.0–3.0)	2.9 (1.9–4.5)	2.8 (1.8–4.3)	3.1 (1.9–5.0)	1.9 (0.7–5.0)
Death by suicide	10/5	2.7 (1.5–5.0)	0.1 (0.1–0.3)	19.1 (6.5–55.9)	19.1 (5.8–62.9)	N/A	N/A
Death by cardiovascular disease	9/42	2.4 (1.3–4.7)	1.1 (0.8–1.4)	2.6 (1.2–5.4)	2.5 (1.2–5.3)	N/A	N/A
Death by neoplasm	8/38	2.2 (1.1–4.3)	1.0 (0.7–1.3)	2.1 (1.0–4.6)	2.1 (1.0–4.6)	N/A	N/A
Any psychiatric hospitalisation‡	64/173	19.0 (14.8–24.2)	4.2 (3.6–4.9)	4.2 (3.1–5.6)	2.8 (2.0–3.9)	3.0 (1.9–4.6)	2.5 (1.4–4.2)
Substance misuse	22/78	5.9 (3.9–8.9)	1.8 (1.5–2.3)	3.0 (1.9–4.9)	1.7 (1.0–3.1)	N/A	N/A
Suicide attempt	29/44	7.9 (5.5–11.4)	1.0 (0.8–1.4)	7.6 (4.7–12.4)	4.9 (2.9–8.5)	7.9 (4.1–15.3)	2.0 (0.7–5.3)
Any accident	32/233	9.0 (6.3–12.7)	5.7 (5.0–6.5)	1.6 (1.1–2.3)	1.4 (1.0–2.1)	1.6 (1.0–2.5)	1.1 (0.5–2.2)
Any crime	60/350	18.5 (14.3–23.8)	9.0 (8.1–10.0)	1.9 (1.4–2.5)	1.3 (1.0–1.8)	1.6 (1.1–2.4)	0.9 (0.6–1.5)
Violent crime	14/61	3.6 (2.1–6.1)	1.4 (1.1–1.8)	2.7 (1.5–4.9)	1.5 (0.8–3.0)	N/A	N/A

Notes:

*Adjusted for psychiatric morbidity prior to baseline and immigrant status.

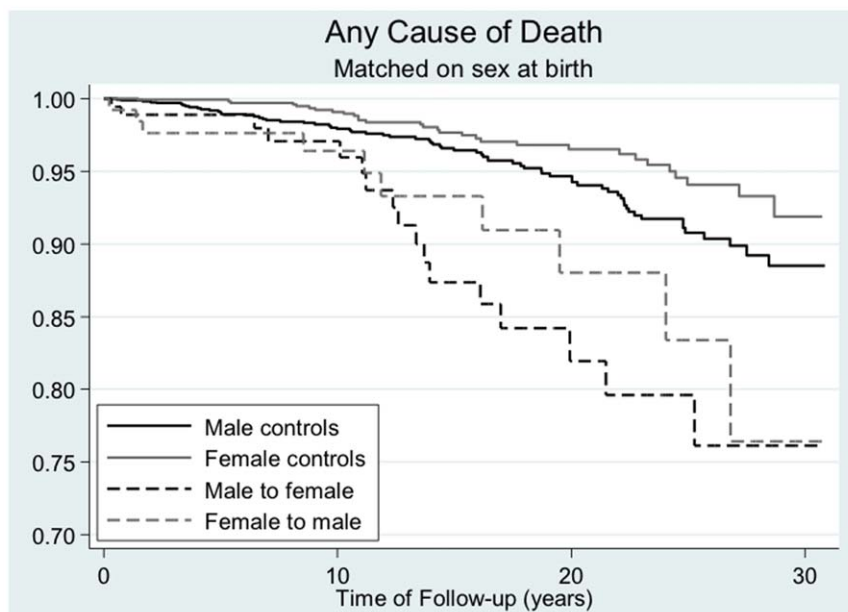
‡Hospitalisations for gender identity disorder were excluded.

N/A Not applicable due to sparse data.

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separately lists the outcomes depending on when sex reassignment was performed: during the period 1973–1988 or 1989–2003. Even though the overall mortality was increased across both time periods, it did not reach statistical significance for the period 1989–2003. The Kaplan-Meier curve (Figure 1) suggests that survival of transsexual persons started to diverge from that of matched controls after about 10 years of follow-up. The cause-specific mortality from

suicide was much higher in sex-reassigned persons, compared to matched controls. Mortality due to cardiovascular disease was moderately increased among the sex-reassigned, whereas the numerically increased risk for malignancies was borderline statistically significant. The malignancies were lung cancer (N = 3), tongue cancer (N = 1), pharyngeal cancer (N = 1), pancreas cancer (N = 1), liver cancer (N = 1), and unknown origin (N = 1).

**Figure 1.** Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.

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Psychiatric morbidity, substance misuse, and accidents

Sex-reassigned persons had a higher risk of inpatient care for a psychiatric disorder other than gender identity disorder than controls matched on birth year and birth sex (Table 2). This held after adjustment for prior psychiatric morbidity, and was true regardless of whether sex reassignment occurred before or after 1989. In line with the increased mortality from suicide, sex-reassigned individuals were also at a higher risk for suicide attempts, though this was not statistically significant for the time period 1989–2003. The risks of being hospitalised for substance misuse or accidents were not significantly increased after adjusting for covariates (Table 2).

Crime rate

Transsexual individuals were at increased risk of being convicted for any crime or violent crime after sex reassignment (Table 2); this was, however, only significant in the group who underwent sex reassignment before 1989.

Gender differences

Comparisons of female-to-males and male-to-females, although hampered by low statistical power and associated wide confidence intervals, suggested mostly similar risks for adverse outcomes (Tables S1 and S2). However, violence against self (suicidal behaviour) and others ([violent] crime) constituted important exceptions. First, male-to-females had significantly increased risks for suicide attempts compared to both female (aHR 9.3; 95% CI 4.4–19.9) and male (aHR 10.4; 95% CI 4.9–22.1) controls. By contrast, female-to-males had significantly increased risk of suicide attempts only compared to male controls (aHR 6.8; 95% CI 2.1–21.6) but not compared to female controls (aHR 1.9; 95% CI 0.7–4.8). This suggests that male-to-females are at higher risk for suicide attempts after sex reassignment, whereas female-to-males maintain a female pattern of suicide attempts after sex reassignment (Tables S1 and S2).

Second, regarding any crime, male-to-females had a significantly increased risk for crime compared to female controls (aHR 6.6; 95% CI 4.1–10.8) but not compared to males (aHR 0.8; 95% CI 0.5–1.2). This indicates that they retained a male pattern regarding criminality. The same was true regarding violent crime. By contrast, female-to-males had higher crime rates than female controls (aHR 4.1; 95% CI 2.5–6.9) but did not differ from male controls. This indicates a shift to a male pattern regarding criminality and that sex reassignment is coupled to increased crime rate in female-to-males. The same was true regarding violent crime.

Discussion

Principal findings and comparison with previous research

We report on the first nationwide population-based, long-term follow-up of sex-reassigned transsexual persons. We compared our cohort with randomly selected population controls matched for age and gender. The most striking result was the high mortality rate in both male-to-females and female-to-males, compared to the general population. This contrasts with previous reports (with one exception[8]) that did not find an increased mortality rate after sex reassignment, or only noted an increased risk in certain subgroups.[7,9,10,11] Previous clinical studies might have been biased since people who regard their sex reassignment as a failure are more likely to be lost to follow-up. Likewise, it is cumbersome to track deceased persons in clinical follow-up studies. Hence, population-based register studies like the present are needed to improve representativity.[19,34]

The poorer outcome in the present study might also be explained by longer follow-up period (median >10 years) compared to previous studies. In support of this notion, the survival curve (Figure 1) suggests increased mortality from ten years after sex reassignment and onwards. In accordance, the overall mortality rate was only significantly increased for the group operated before 1989. However, the latter might also be explained by improved health care for transsexual persons during 1990s, along with altered societal attitudes towards persons with different gender expressions.[35]

Mortality due to cardiovascular disease was significantly increased among sex reassigned individuals, albeit these results should be interpreted with caution due to the low number of events. This contrasts, however, a Dutch follow-up study that reported no increased risk for cardiovascular events.[10,11] A recent meta-analysis concluded, however, that data on cardiovascular outcome after cross-sex steroid use are sparse, inconclusive, and of very low quality.[34]

With respect to neoplasms, prolonged hormonal treatment might increase the risk for malignancies,[36] but no previous study has tested this possibility. Our data suggested that the cause-specific risk of death from neoplasms was increased about twice (borderline statistical significance). These malignancies (see Results), however, are unlikely to be related to cross-hormonal treatment.

There might be other explanations to increased cardiovascular death and malignancies. Smoking was in one study reported in almost 50% by the male-to-females and almost 20% by female-to-males.[9] It is also possible that transsexual persons avoid the health care system due to a presumed risk of being discriminated.

Mortality from suicide was strikingly high among sex-reassigned persons, also after adjustment for prior psychiatric morbidity. In line with this, sex-reassigned persons were at increased risk for suicide attempts. Previous reports [6,8,10,11] suggest that transsexualism is a strong risk factor for suicide, also after sex reassignment, and our long-term findings support the need for continued psychiatric follow-up for persons at risk to prevent this.

Inpatient care for psychiatric disorders was significantly more common among sex-reassigned persons than among matched controls, both before and after sex reassignment. It is generally accepted that transsexuals have more psychiatric ill-health than the general population prior to the sex reassignment.[18,21,22,33] It should therefore come as no surprise that studies have found high rates of depression,[9] and low quality of life[16,25] also after sex reassignment. Notably, however, in this study the increased risk for psychiatric hospitalisation persisted even after adjusting for psychiatric hospitalisation prior to sex reassignment. This suggests that even though sex reassignment alleviates gender dysphoria, there is a need to identify and treat co-occurring psychiatric morbidity in transsexual persons not only before but also after sex reassignment.

Criminal activity, particularly violent crime, is much more common among men than women in the general population. A previous study of all applications for sex reassignment in Sweden up to 1992 found that 9.7% of male-to-female and 6.1% of female-to-male applicants had been prosecuted for a crime.[33] Crime after sex reassignment, however, has not previously been studied. In this study, male-to-female individuals had a higher risk for criminal convictions compared to female controls but not compared to male controls. This suggests that the sex reassignment procedure neither increased nor decreased the risk for criminal offending in male-to-females. By contrast, female-to-males were at a higher risk for criminal convictions compared to female controls and did not differ from male controls, which suggests increased crime proneness in female-to-males after sex reassignment.

Strengths and limitations of the study

Strengths of this study include nationwide representativity over more than 30 years, extensive follow-up time, and minimal loss to follow-up. Many previous studies suffer from low outcome ascertainment,[6,9,21,29] whereas this study has captured almost the entire population of sex-reassigned transsexual individuals in Sweden from 1973–2003. Moreover, previous outcome studies have mixed pre-operative and post-operative transsexual persons,[22,37] while we included only post-operative transsexual persons that also legally changed sex. Finally, whereas previous studies either lack a control group or use standardised mortality rates or standardised incidence rates as comparisons,[9,10,11] we selected random population controls matched by birth year, and either birth or final sex.

Given the nature of sex reassignment, a double blind randomized controlled study of the result after sex reassignment is not feasible. We therefore have to rely on other study designs. For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively[7,12] or retrospectively,[5,6,9,22,25,26,29,38] and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria. The limitation is of course that the treatment has not been assigned randomly and has not been carried out blindly.

For the purpose of evaluating the safety of sex reassignment in terms of morbidity and mortality, however, it is reasonable to compare sex reassigned persons with matched population controls. The caveat with this design is that transsexual persons before sex reassignment might differ from healthy controls (although this bias can be statistically corrected for by adjusting for baseline differences). It is therefore important to note that the current study is only informative with respect to transsexuals persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism. In other words, the results should not be interpreted such as sex reassignment *per se* increases morbidity and mortality. Things might have been even worse without sex reassignment. As an analogy, similar studies have found increased somatic morbidity, suicide rate, and overall mortality for patients treated for bipolar disorder and schizophrenia.[39,40] This is important information, but it does not follow that mood stabilizing treatment or antipsychotic treatment is the culprit.

Other facets to consider are first that this study reflects the outcome of psychiatric and somatic treatment for transsexualism provided in Sweden during the 1970s and 1980s. Since then, treatment has evolved with improved sex reassignment surgery, refined hormonal treatment,[11,41] and more attention to psychosocial care that might have improved the outcome. Second, transsexualism is a rare condition and Sweden is a small country (9.2 million inhabitants in 2008). Hence, despite being based on a

comparatively large national cohort and long-term follow-up, the statistical power was limited. Third, regarding psychiatric morbidity after sex reassignment, we assessed inpatient psychiatric care. Since most psychiatric care is provided in outpatient settings (for which no reliable data were available), underestimation of the *absolute* prevalences was inevitable. However, there is no reason to believe that this would change the *relative risks* for psychiatric morbidity unless sex-reassigned transsexual individuals were more likely than matched controls to be admitted to hospital for any given psychiatric condition.

Finally, to estimate start of follow-up, we prioritized using the date of a gender identity disorder diagnosis *after* changed sex status over *before* changed sex status, in order to avoid overestimating person-years at risk after sex-reassignment. This means that adverse outcomes might have been underestimated. However, given that the median time lag between the hospitalization before and after change of sex status was less than a year (see Methods), this maneuver is unlikely to have influenced the results significantly. Moreover, all deaths will be recorded regardless of this exercise and mortality hence correctly estimated.

Conclusion

This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population. This highlights that post surgical transsexuals are a risk group that need long-term psychiatric and somatic follow-up. Even though surgery and hormonal therapy alleviates gender dysphoria, it is apparently not sufficient to remedy the high rates of morbidity and mortality found among transsexual persons. Improved care for the transsexual group after the sex reassignment should therefore be considered.

Supporting Information

Table S1 Risk of various outcomes in sex-reassigned persons in Sweden compared to population controls matched for birth year and birth sex.

(DOCX)

Table S2 Risk of various outcomes in sex-reassigned persons in Sweden compared to controls matched for birth year and final sex.

(DOCX)

Author Contributions

Conceived and designed the experiments: CD PL AJ NL ML. Performed the experiments: MB AJ. Analyzed the data: CD PL MB AJ NL ML. Contributed reagents/materials/analysis tools: PL NL AJ. Wrote the paper: CD PL MB AJ NL ML.

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Exhibit M

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Long-Term Follow-Up of Individuals Undergoing Sex-Reassignment Surgery: Somatic Morbidity and Cause of Death



Rikke Kildevæld Simonsen, MA,¹ Gert Martin Hald, PhD,² Ellids Kristensen, MD, FECSM,³ and Annamaria Giraldo, PhD, MD, FECSM³

ABSTRACT

Introduction: Studies of mortality and somatic well-being after sex-reassignment surgery (SRS) of transsexual individuals are equivocal. Accordingly, the present study investigated mortality and somatic morbidity using a sample of transsexual individuals who comprised 98% (n = 104) of all surgically reassigned transsexual individuals in Denmark.

Aims: To investigate somatic morbidity before and after SRS and cause of death and its relation to somatic morbidity after SRS in Danish individuals who underwent SRS from 1978 through 2010.

Methods: Somatic morbidity and mortality in 104 sex-reassigned individuals were identified retrospectively by data from the Danish National Health Register and the Cause of Death Register.

Main Outcome Measures: Somatic morbidity and cause of death.

Results: Overall, 19.2% of the sample were registered with somatic morbidity before SRS and 23.1% after SRS ($P =$ not significant). In total, 8.6% had somatic morbidity before and after SRS. The most common diagnostic category was cardiovascular disease, affecting 18 individuals, 9 before and 14 after SRS, and 5 of those 14 who were affected after SRS had cardiovascular disease before and after SRS. Ten individuals died after SRS at an average age of 53.5 ± 7.9 years (male to female) and 53.5 ± 7.3 years (female to male).

Conclusion: Of 98% of all Danish transsexuals who officially underwent SRS from 1978 through 2010, one in three had somatic morbidity and approximately 1 in 10 had died. No significant differences in somatic morbidity or mortality were found between male-to-female and female-to-male individuals. Despite the young average age at death and the relatively larger number of individuals with somatic morbidity, the present study design does not allow for determination of casual relations between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality.

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Key Words: Follow-Up; Gender Identity Disorder; Somatic Morbidity; Sex-Reassignment Surgery; Transsexualism

INTRODUCTION

Transsexualism refers to a condition in which the core characteristic is an individual's experience of profound incongruence between assigned sex at birth and the experienced gender.¹ According to the *International Statistical Classification of*

Diseases and Related Health Problems, 10th Edition (ICD-10),² the diagnostic criteria of transsexualism are (i) the desire to live and be accepted as the opposite sex, (ii) usually a sense of discomfort with or inappropriateness of one's anatomic sex, and (iii) a wish to have surgery and/or hormonal treatment (HT) to make the body as congruent as possible with the preferred sex. To develop characteristics of the opposite sex, treatment with cross-sex hormones (HT), castration, and genital reconstructive surgery (sex-reassignment surgery [SRS]) might be conducted.

The parent category of transsexualism in the *ICD-10* is gender identity disorder (GID).² In Denmark, individuals with GID are referred to the Gender Identity Unit, University of Copenhagen (GIUUC) under *ICD-8*³ code 302.39 and 1993 *ICD-10*² codes DF64.0 to DF64.9 by a general practitioner or psychiatrist. Assessment, in accordance with Danish Health Authority

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guidelines,⁴ includes blood sample analyses for chromosomal and hormonal abnormalities, screening for psychiatric and somatic morbidities, psychological testing, and sessions with a psychologist or psychiatrist.

If SRS is desired by the individual diagnosed with transsexualism, an observational period of at least 1 year 6 months (in the study period, 2 years), including 1 year of HT and living in the gender role as the opposite sex, is obligatory before applying for SRS to the Danish Health Authority. The Danish legal criteria for SRS and castration are an *ICD-10* diagnosis of transsexualism (F64.0), persistent wish for and understanding of the consequences of castration, and a minimum age of 18 years (during the study period, ie, 1978–2010, the minimum age was 21 years).⁵ All treatment is paid for by the public Danish medical system. Treatment with cross-sex hormones and genital reconstructive surgery has existed for more than 60 years, but findings on mortality and somatic well-being after SRS in long-term follow-up studies are equivocal.⁶ For possible somatic consequences of HT, the following outcomes have been studied the most: cardiovascular disease (CVD), bone growth, and hormone-sensitive cancer malignancies.

A review and meta-analysis of 16 studies, including 1,471 male-to-female (MtF) and 651 female-to-male (FtM) individuals, found no overall significant effect of HT on CVD.⁷ However, the type of HT (ethinyl estradiol) and the manner in which HT (oral estrogens) was administered in MtF patients were significantly associated with CVD.^{8,9} Further, in a Swedish study, increased CVD mortality in FtM and MtF individuals at least 10 years after HT was found,⁶ indicating a possible delay of adverse somatic consequences from HT on cardiovascular pathology.¹⁰

Studies of muscle and musculoskeletal diseases, bone growth, and bone deficiencies overall did not show an increased risk of osteoporosis in FtM individuals.^{11–16} However, in MtF individuals, lower bone mass density, possibly from androgen deprivation, was found after treatment compared with before treatment with HT.^{17–19} However, because of increased bone density before treatment and no loss of bone density from menopause, MtF individuals maintain a lower risk of osteoporosis than assigned women.²⁰

In cancer studies involving transsexuals receptive of SRS and/or HT, the focus has been on breast cancer, although the overall number of studies in relation to this issue is limited. The conclusions emerging from these studies suggest that for MtF individuals^{20–23} the risk of breast cancer is lower than the expected risk of breast cancer in assigned women but similar to that expected in assigned men. For FtM individuals, male sex hormones might have an antiproliferative effect on breast cancer cell lines.^{24,25} Thus, few cases of breast cancer in FtM individuals have been reported,^{26,27} indicating FtM individuals have similar risk as expected for male breast cancer.

Concerning cancer malignancies, a Belgian study, in which the average time of HT was 6 years (FtM) or 7 years (MtF), found

no increase in cancer malignancies among included transsexuals compared with controls randomly selected from the population.²⁸ In contrast, a Swedish study found borderline significant risk of death from neoplasms compared with controls.⁶ Lifestyle habits such as smoking and avoidance of the health care system were suggested as possible mediating mechanisms.

When studying increased and decreased risks of cancer in transsexuals receiving HT, it is important to note that HT has been used for 60 years in some transsexual individuals. Accordingly, the duration of exposure to HT might not be long enough for tumors to manifest and the number of individuals exposed is small.²⁹ Further, it has been suggested that inconsistency in reporting cancer incidents among transsexuals might lead to an underreporting of cancer in this cohort,^{21,30} likely affecting prevalence and incidence rates.

Studies of mortality in transsexuals have suggested an increased mortality risk compared with controls.^{6,10} For example, a Swedish study of 324 MtF and FtM individuals after SRS (follow-up = 11.4 years) found that the all-cause mortality rate was three times higher in this cohort compared with controls.⁶ Similarly, in a Dutch long-term follow-up study of 966 MtF and 365 FtM individuals (follow-up = 18.5 years), a 51% higher mortality rate was found in MtF subjects compared with the general population.¹⁰ For FtM subjects, no increased mortality was found compared with the general population. A Dutch study of 1,109 individuals receiving HT found no increased mortality overall, but in MtF subjects 25 to 39 years old, mortality was significantly increased because of suicide, acquired immune deficiency syndrome, CVD, drug abuse, and unknown causes.³¹ The only Danish study on transsexualism conducted thus far, which included 37 individuals, reported three deaths of 29 reassigned MtF individuals and no deaths of 8 FtM individuals studied from 1956 through 1978.³²

Somatic morbidity after alcohol abuse has not been investigated previously, although studies of substance abuse in individuals with transsexualism have been conducted. A Belgian study (N = 35) conducted at the University Hospital of Gent found alcohol and drug abuse in 50% of MtF and 61.5% of FtM individuals.³³ A Spanish study (N = 230) of individuals with complaints of GID seen at the Hospital Clinic (Barcelona, Spain) found current alcohol- and substance-related disorders in 11% MtF and 1.4% of FtM subjects.³⁴ A Swiss study found that 45% of 31 GID individuals diagnosed by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*³⁵ had lifetime substance abuse (MtF = 50%, FtM = 36.4%).³⁶ A Swedish study of 233 individuals found substance abuse in 18.2% of FtM and 11.9% MtF individuals.³⁷ However, in a different Swedish study of 324 MtF and FtM transsexual individuals, no significant risk of being hospitalized for substance abuse was found compared with the general Swedish population.⁶ Lung diseases related to or caused by smoking have not been investigated previously in persons with transsexualism, although lesbian, gay, bisexual, and transgender persons have a higher incidence of smoking.^{38,39} Accordingly, this was included as an outcome in the present study.

For many of the studies that have focused on somatic morbidity and mortality, including those reviewed earlier, the following methodologic shortcomings apply: small sample, recruitment and diagnostic biases and inconsistencies (eg, place of participant recruitment and differences in diagnostic criteria), heterogeneity of treatment regimens, and varied duration of follow-up periods.⁶

The aim of the present study was to (re)investigate somatic morbidity and mortality using registry data in a cohort including 98% of all Danish individuals referred to a public GID clinic in Denmark who underwent SRS from 1978 through 2010 after a diagnosis of transsexualism.

AIMS

The specific aims of the study were to investigate (i) somatic morbidity before and after SRS and (ii) cause of death and its relation to somatic morbidity.

METHODS

Procedure

The study was approved by the Danish Data Protection Agency and the Danish Health Authority. Permission was obtained from the Civil Law Board to identify names and social security numbers of individuals who underwent SRS from 1978 through 2010 and who were treated at the GIUUC.

National Registers

The Danish National Health Register (LPR) was used to draw data on somatic morbidity. The LPR contains diagnoses and dates of onset and end of treatment of all somatic episodes at hospitals from 1977 (inpatients) and from 1995 (outpatients). In the LPR, diagnoses are coded according to the *ICD-8* (1969–1993) or *ICD-10* (1994–).^{2,3} Data from the LPR from 1977 to January 2013 were included in the study.

The Cause of Death Register has recorded all deaths and causes of death in Denmark since 1970. Death events occurring up to April 2014 were included in the study.

Study Population

Included in the study were 104 individuals (56 MtF and 48 FtM) diagnosed with transsexualism according to the *ICD-8*³ or *ICD-10*² at the GIUUC. All participants underwent castration with permission from the Danish Health Authority from 1978 through 2010. Verification that an individual had undergone SRS was accomplished using social security numbers (ie, Danish Cause of Death Register numbers); numbers ending in even numbers indicate female-assigned sex and those ending with odd numbers indicate male-assigned sex. Accordingly, changes in this number from even to odd or vice versa indicate the official change of assigned sex (ie, successful completion of SRS). Baseline data (Table 1) were obtained from medical records.

Table 1. Baseline Data

Variables	Male to female (n = 56)	Female to male (n = 48)
Mean age at referral (y), mean (SD)	30.3 (9.8)	27.0 (8.7)
Mean age at permission for SRS (y), mean (SD)	37.1 (9.7)	32.6 (8.0)
Mean age at initiating cross-sex hormones (y), mean (SD)	32.0 (9.9)	29.8 (8.4)
Mean length of follow-up (y), mean (SD)	16.38 (7.1)	10.21 (6.1)

SRS = sex-reassignment surgery.

Sociodemographic data (Table 2) were obtained from medical records and are further described by Simonsen et al.⁴⁰

Because of the lack of a specific code for SRS, the date of start of follow-up was defined as the date of permission to undergo SRS.

Measures

Baseline data (Table 1) were obtained from medical records based on interviews performed by specialized psychiatrists, psychologists, and medical doctors at the GIUUC during the treatment period.

Using the LPR and death registers, we obtained information pertaining to somatic morbidity before and after permission to undergo SRS and time and cause of death after obtaining this permission. More specifically, somatic diagnoses given to the patient from 1977 to January 2013 were investigated. Accordingly, each individual could present with different diagnoses, but multiple contacts with the somatic care system with the same diagnosis only had one outcome before SRS and one outcome after SRS. In addition, data on time and cause of death after permission to undergo SRS were drawn from the death registers until April 2014.

For each diagnosis, specifically chronic heart disease (*ICD-10* diagnoses F400–490), chronic lung disease (*ICD-10* diagnoses J40–47, *ICD-8* diagnoses 490–493), cancer (*ICD-10* diagnoses C00–C97.9, D00–D10.9, *ICD-8* diagnoses 140–209), alcohol-related liver morbidity (*ICD-10* K70–77, *ICD-8* 303–304), or muscle and musculoskeletal diseases (*ICD-10* M80–85, *ICD-8* 720–729), individuals were stratified by diagnostic group membership (ie, had received the diagnosis or had not received the diagnosis) and assigned sex (ie, MtF or FtM).

Mortality was determined by the cause-of-death certificate. Hence, each individual was dead or alive. For death, data related to cause of death were drawn from the death certificate.

Statistics

Statistical analyses were conducted in SPSS 19.0 (SPSS, Inc, Chicago, IL, USA). Clinical variables were analyzed using descriptive statistics. Means and SDs were calculated for

Table 2. Sociodemographics by Male to Female and Female to Male*

	Male to female (n = 58)	Female to male (n = 50)
Primary and secondary education (y), n (%)		
≤11	40 (69.0)	38 (76.0)
12–13 (completion of high school)	16 (27.6)	12 (24.0)
Missing information	2 (3.4)	0
Education beyond primary and secondary school at time of referral, n (%)		
None	29 (50.0)	30 (60.0)
≤3 y or apprenticeship	21 (36.2)	8 (16.0)
≥4 y	5 (8.6)	10 (20.0)
Unknown	3 (5.2)	2 (4.0)
Education beyond primary and secondary school when permission for SRS was granted, n (%)		
None	25 (43.1)	25 (50.0)
≤3 y or apprenticeship	21 (36.2)	13 (26.0)
≥4 y	8 (13.8)	10 (20.0)
Unknown	4 (6.9)	2 (4.0)
Employment at time of referral, n (%)		
Employed	36 (62.1)	31 (62.0)
Unemployed		
Sickness or unemployment benefits	12 (20.7)	7 (14.0)
Social welfare or pension	10 (17.3)	12 (24.0)
Employment when permission for SRS was granted, n (%)		
Employed	32 (55.2)	27 (54.0)
Unemployed		
Sickness or unemployment benefits	5 (8.6)	11 (22.0)
Social welfare or pension	20 (34.5)	11 (22.0)
Unknown	1 (1.7)	1 (2.0)

From Simonsen et al.⁴⁰

SRS = sex-reassignment surgery.

*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

continuous variables. Frequencies and percentages were generated for nominal and categorical variables. Between-group differences were analyzed using χ^2 test, t-test, and Fisher exact test.

No missing values were found for somatic outcome variables because they were obtained from the register data, where values are present (affected) or absent (unaffected).

RESULTS

Baseline data related to age at referral, permission for SRS, cross-sex hormonal initiation, and years of follow-up after SRS are presented in Table 1.

To investigate the first study aim concerning somatic morbidity before and after SRS, the total number of included

individuals who received a somatic diagnosis was identified (Table 3). As presented in Table 3, 20 FtM and MtF individuals (19.2%) before SRS and 24 FtM and MtF individuals (23.1%) after SRS had somatic morbidity, with no significant difference. Nine individuals (eight MtF and one FtM) had somatic morbidity before and after SRS, resulting in 35 individuals (33.7%) overall who had somatic morbidity. Table 4 lists the specific diagnoses of somatic morbidity.

As presented in Table 4, 25 somatic diagnoses were reported before SRS and 27 diagnoses after SRS from a total of 20 individuals before SRS and 24 individuals after SRS. Nine of the 24 individuals had somatic morbidity before and after SRS. The most common diagnostic category was CVD, affecting a total of 18 individuals, 9 before and 14 after (23 diagnoses) SRS, and 5 of the 14 individuals had CVD before and after SRS. The second most common diagnostic category was muscle and musculoskeletal diseases, with 12 diagnoses, six before and six after SRS, affecting a total of 11 individuals, with only one individual having muscle and musculoskeletal disease before and after SRS.

To investigate differences in somatic morbidity between MtF and FtM individuals, χ^2 test, Fisher exact, and t-test were used. Across diagnostic categories, no significant differences in somatic morbidity between MtF and FtM individuals were found. When comparing somatic diagnoses using χ^2 test, no significant differences between the number of somatic diagnoses given before and after SRS were found.

Concerning the second study aim, cause of death and its relation to somatic morbidity was investigated from after SRS until April 2014. Ten individuals (9.6%; six MtF [10.7%] and four FtM [8.3%]) died from after SRS to April 2014. Mean age at death was 53.5 ± 7.9 years (median = 55.5) for MtF individuals and 53.5 ± 7.3 years (median = 52.5) for FtM individuals ($P > .05$ by t-test). Somatic morbidity (ie, official cause of death) included two suicides (19 and 26 years after SRS, respectively), heart disease ($n = 2$), cancer ($n = 1$), ulcer ($n = 1$), and smoking- and alcohol-related diseases ($n = 4$).

Because the results might be influenced by changes in clinical procedures and guidelines over time and the cultural acceptance of transsexualism, data were checked for systematic differences in permission to undergo SRS from the first 16 years (1978–1994) to the next 16 years (1994–2010). Significantly ($P < .05$) more individuals with transsexualism received permission to undergo SRS from 1995 through 2010 (28 individuals in 1978–1994 and 76 individuals in 1995–2010).

DISCUSSION

We report the first nationwide register-based SRS follow-up study in Denmark of 98% of individuals who officially underwent SRS from 1978 through 2010.

For the first study aim (ie, investigation of somatic morbidity before and after SRS), we found that 19.2% of the cohort had a somatic diagnosis before and 23.1% after SRS. This difference

Table 3. Individuals with Somatic Morbidity Before and After SRS*

Diagnosis, n (%)	Before SRS		After SRS		Before and after SRS	
	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Cancer	0	3	2	1	0	1
CVD	5	4	6	8	5	0
Musculoskeletal	3	3	3	3	1	0
Lung	2	1	3	1	2	0
Alcoholic liver	1	3	0	0	0	0
Individuals with somatic diagnosis						
Yes	8 (14.3)	12 (25.0)	12 (21.4)	12 (25.0)	8 (14.3)	1 (2.1)
No	48 (85.7)	36 (75.0)	44 (78.6)	36 (75.0)	48 (85.7)	47 (97.9)

CVD = cardiovascular disease; SRS = sex-reassignment surgery.

*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

was found not to be statically significant. Further, no significant difference in somatic morbidity between FtM and MtF cohorts was found. For the second study aim (ie, investigation of mortality), no significant difference in mortality between MtF and FtM cohorts was found. Average age at death was 53.5 years, and 10 individuals died after SRS.

For somatic morbidity, CVD was found in 6 MtF individuals (10.7%) and 12 FtM individuals (25.0%). In comparison, 4.4% of assigned men and 3.6% of assigned women older than 35 years in the general Danish population were found to have CVD.⁴¹ In the present study, CVD might have been due to long-term follow-up after HT (16.3 years for MtF cohort, 10.8 years for FtM cohort) as reported by other studies,^{6,10} or the

observed prevalence of CVD might be explained by a correlation between depression and anxiety and CVD as suggested by previous research.^{42,43} Socioeconomic status and CVD are related,^{44,45} and the present study group was characterized not only by anxiety and depression⁴⁶ but also by social marginalization⁴⁷ and difficulties in school, education, and employment.⁴⁰ Hence, these factors could be important underlying mediating and/or moderating mechanisms driving or affecting prevalence rates of CVD in transsexuals, although the design of this study did not enable us to explore this further.

Muscle and musculoskeletal morbidity was found in 11 individuals (10.5%). From 1997 through 2002, 13.9% of the general Danish population was diagnosed with muscle and

Table 4. Number of Somatic Diagnoses*

Diagnosis, n (%)	Before SRS		After SRS	
	Male to female (n = 56)	Female to male (n = 48)	Male to female (n = 56)	Female to male (n = 48)
Alcohol related				
Yes	1 (1.8)	3 (6.2)	0	0
No	55 (98.2)	45 (93.8)	56 (100.0)	48 (100.0)
Cancer				
Yes	0	3 (6.3)	2 (3.8)	1 (2.0)
No	56 (100.0)	45 (93.8)	55 (98.2)	47 (97.9)
Heart				
Yes	5 (8.9)	4 (8.3)	6 (10.7)	8 (16.7)
No	51 (91.1)	44 (91.7)	50 (89.3)	40 (83.3)
Lung				
Yes	2 (1.8)	1 (2.1)	3 (5.4)	1 (2.1)
No	54 (96.4)	47 (97.9)	53 (94.6)	47 (97.9)
Musculoskeletal				
Yes	3 (5.4)	3 (6.3)	3 (5.4)	3 (6.3)
No	53 (94.6)	45 (93.8)	53 (94.6)	45 (93.7)
Positive somatic diagnosis	11	14	14	13

SRS = sex-reassignment surgery.

*The χ^2 and Fisher exact tests were conducted but showed no significance ($P < 0.05$).

musculoskeletal disease by hospital care.⁴⁸ Smoking and excessive alcohol consumption have been linked to low bone mass and increased fracture risk in MtF and FtM individuals,^{49,50} and such lifestyle issues might characterize the present cohort.^{6,46,51,52} However, given the limited number of individuals presenting with skeletal morbidity in this study, more comparable studies are needed to confirm the possible increased risk of skeletal morbidity in this cohort.

Concerning cancer malignancies, five individuals (6.2% of FtM and 3.6% of MtF) were found to have a diagnosis of cancer compared with 2.4% of assigned women and 1.56% of assigned men older than 15 years in the Danish general population.⁵³ Previous studies involving transsexual individuals have found hormone-sensitive tumors.^{16,20,54} Further, in the present study, two deaths were caused by cancer and by leukemia and lung cancer, respectively. However, as in the present study, small samples and the sample design preclude causal inferences regarding relations between treatment of SRS individuals and cancer or cancer-related deaths.

In Denmark, alcohol-related diseases cause 5% of the total number of deaths,⁵⁵ with more alcohol and substance abuse in sexual minority groups.^{51,52,56–58} Four individuals had a diagnosis of alcohol-related diseases before SRS with none after SRS. Further, in the present cohort, two individuals died of the effects of alcohol abuse after SRS. In a previous study on psychiatric morbidity of the present cohort, four diagnoses indicative of alcohol abuse after SRS were found.⁴⁶ Alcohol-related diseases are often the consequence of long-lasting alcohol abuse. Therefore, the actual number of individuals in the present cohort with alcohol abuse could be larger.

Four individuals had a diagnosis indicative of chronic lung disease (3.8%). In comparison, 1.3% of individuals older than 35 years in the in the general Danish population had a diagnosis of severe chronic lung disease.⁵⁹ Lung diseases have, to our knowledge, not been investigated previously in individuals with transsexualism, and therefore we lack and call for comparable studies in which to situate our findings.

Somatic morbidity in the present study group could be due to long-term HT and/or, as suggested by numerous previous studies, influenced by poor mental health, low economic status, social exclusion,⁶⁰ harassment, negative experiences with school⁶¹ and the employment system,^{34,37,62} and discrimination in the health care system.^{46,63,64} Thus, previous studies of the present group have found that 50% of the cohort did not complete further education beyond primary and secondary school. Also, at the time of SRS, only 55% were employed⁴⁰ and 25% presented with psychiatric morbidity before and after SRS.⁴⁶

For the second study aim (ie, cause of death and its relation to somatic morbidity), the study found that 9.6% of the cohort had died at an average age of 53.5 years, with the main cause of death related to smoking and alcohol abuse. The life expectancy of assigned women and men in Denmark is 81.9 and 78.0 years,

respectively. Previous studies of mortality in transsexual individuals in countries comparable to Denmark^{6,10} have found an increased risk of death in transsexual individuals. The present study had a lack of statistical power, and further long-term studies are needed to draw firm conclusions about transsexualism and increased risk of death.

Two individuals in the study group committed suicide 19 and 26 years after SRS, respectively. A Swedish study of SRS individuals (N = 324) found significantly increased mortality from suicide and significantly higher risk for suicide attempts compared with the general Swedish population.⁶ A Dutch study (N = 1,109) of SRS and non-SRS individuals found a high incidence of attempted suicide and completed suicide in the study cohort compared with the general Dutch population.³¹ An Italian study of 163 SRS MtF individuals found that four had attempted suicide before SRS and one had attempted suicide 12 to 18 months after SRS.⁶⁵ A Danish study reported death from suicide in 3 of 29 SRS MtF individuals (follow-up = 6 years).³² Many explanations can be considered for suicide and attempted suicide. One might be regret for undergoing SRS,³² but in the present study suicide occurred more than 19 years after SRS and therefore does not seem to be an immediate consequence of SRS. Because reasons for suicide attempts and manifest suicide often are multifactorial and because of the low incidence in the present study, further research is needed to contextualize these results further.

Limitations

The strength of this study is the unique cohort studied. Thus, on a national basis and over a 30-year period, 98% of all SRS individuals were included. This provides a unique opportunity to assess differences between MtF and FtM individuals on variables for somatic morbidity and mortality. The cohort included only individuals who received permission to undergo SRS during a period with strict criteria for obtaining permission to undergo SRS. Accordingly, the group is highly selected and might not reflect transsexuals per se in Denmark. Although we had a very large cohort for this type of study, some of our statistics had small cell sizes, limited numbers, and thus low statistical power, increasing the chances for type II errors. Because most somatic care in Denmark is provided by general practitioners, an underestimation of the prevalence of somatic morbidity in the study is plausible. Thus, somatic morbidity as presented in this study might be substantially higher.

CONCLUSION

Using a sample comprised of 98% of all individuals who underwent SRS in Denmark from 1978 through 2010, this study found somatic morbidity in 19.1% of the study group before and 23.2% after SRS. Mortality rates were 9.6%, with an average age at death of 53.5 years. No significant differences in somatic morbidity or mortality were found between MtF and FtM individuals. No firm conclusions can be drawn from the

present study, because the present study design does not allow for determination of causal relations between HT or SRS and somatic morbidity or mortality. One can speculate as to whether the increased risk of psychiatric problems and lifestyle issues in sexual minority groups influenced the risk of mortality and CVD in the present study. The findings underline the importance of supporting individuals with transsexualism to contact and be treated in the public health care system and to pay more attention to lifestyle issues in general.

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Exhibit N

Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English “sex” connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in this area. In this chapter, *sex* and *sexual* refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development denote conditions of inborn somatic deviations of the reproductive tract from the norm and/or discrepancies among the biological indicators of male and female. *Cross-sex* hormone treatment denotes the use of feminizing hormones in an individual assigned male at birth based on traditional biological indicators or the use of masculinizing hormones in an individual assigned female at birth.

The need to introduce the term *gender* arose with the realization that for individuals with conflicting or ambiguous biological indicators of sex (i.e., “intersex”), the lived role in society and/or the identification as male or female could not be uniformly associated with or predicted from the biological indicators and, later, that some individuals develop an identity as female or male at variance with their uniform set of classical biological indicators. Thus, *gender* is used to denote the public (and usually legally recognized) lived role as boy or girl, man or woman, but, in contrast to certain social constructionist theories, biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. *Gender assignment* refers to the initial assignment as male or female. This occurs usually at birth and, thereby, yields the “natal gender.” *Gender-atypical* refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; for behavior, *gender-nonconforming* is an alternative descriptive term. *Gender reassignment* denotes an official (and usually legal) change of gender. *Gender identity* is a category of social identity and refers to an individual’s identification as male, female, or, occasionally, some category other than male or female. *Gender dysphoria* as a general descriptive term refers to an individual’s affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category. *Transgender* refers to the broad spectrum of individuals who transiently or persistently identify with a gender different from their natal gender. *Transsexual* 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 involves a somatic transition by cross-sex hormone treatment and genital surgery (*sex reassignment surgery*).

Gender dysphoria refers to the distress that may accompany the incongruence between one’s experienced or expressed gender and one’s assigned gender. Although not all individuals will experience distress as a result of such incongruence, many are distressed if the desired physical interventions by means of hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children

302.6 (F64.2)

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
1. 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).
 2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
 3. A strong preference for cross-gender roles in make-believe play or fantasy play.
 4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
 5. A strong preference for playmates of the other gender.
 6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
 7. A strong dislike of one's sexual anatomy.
 8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults

302.85 (F64.1)

- 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:
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 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.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Specify if:

Posttransition: 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 cross-sex medical procedure or treatment regimen—namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

Specifiers

The posttransition specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender they have been assigned to (usually at birth, referred to as *natal gender*) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, the distress is not limited to a desire to simply be of the other gender, but may include a desire to be of an alternative gender, provided that it differs from the individual's assigned gender.

Gender dysphoria manifests itself differently in different age groups. Prepubertal natal girls with gender dysphoria may express the wish to be a boy, assert they are a boy, or assert they will grow up to be a man. They prefer boys' clothing and hairstyles, are often perceived by strangers as boys, and may ask to be called by a boy's name. Usually, they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These girls may demonstrate marked cross-gender identification in role-playing, dreams, and fantasies. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some natal girls may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal natal boys with gender dysphoria may express the wish to be a girl or assert they are a girl or that they will grow up to be a woman. They have a preference for dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may role-play female figures (e.g., playing "mother") and often are intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) are most often preferred. Stereotypical female-type dolls (e.g., Barbie) are often favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and competitive sports and have little interest in stereotypically masculine toys (e.g., cars, trucks). Some may pretend not to have a penis and insist on sitting to urinate. More

rarely, they may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

In young adolescents with gender dysphoria, clinical features may resemble those of children or adults with the condition, depending on developmental level. As secondary sex characteristics of young adolescents are not yet fully developed, these individuals may not state dislike of them, but they are concerned about imminent physical changes.

In adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of the other gender. To varying degrees, adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of the experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as the experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features Supporting Diagnosis

When visible signs of puberty develop, natal boys may shave their legs at the first signs of hair growth. They sometimes bind their genitals to make erections less visible. Girls may bind their breasts, walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, hormonal suppressors ("blockers") of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] analog, spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender reassignment surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as the experienced gender and dress partly or completely as the experienced gender, have a hairstyle typical of the experienced gender, preferentially seek friendships with peers of the other gender, and/or adopt a new first name consistent with the experienced gender. Older adolescents, when sexually active, usually do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Some adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender reassignment surgery. Others are satisfied with either hormone treatment or surgery alone.

Adolescents and adults with gender dysphoria before gender reassignment are at increased risk for suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk may persist.

Prevalence

For natal adult males, prevalence ranges from 0.005% to 0.014%, and for natal females, from 0.002% to 0.003%. Since not all adults seeking hormone treatment and surgical reassignment attend specialty clinics, these rates are likely modest underestimates. Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of natal boys to girls range from 2:1 to 4.5:1. In adolescents, the sex ratio is close to parity; in adults, the sex ratio favors natal males, with ratios ranging from 1:1 to 6.1:1. In two countries, the sex ratio appears to favor natal females (Japan: 2.2:1; Poland: 3.4:1).

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus adolescents and adults. Criteria for children are defined in a more con-

crete, behavioral manner than those for adolescents and adults. Many of the core criteria draw on well-documented behavioral gender differences between typically developing boys and girls. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and somatic sex is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is “really” not a member of the other gender but only “desires” to be. Distress may not be manifest in social environments supportive of the child’s desire to live in the role of the other gender and may emerge only if the desire is interfered with. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and somatic sex. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, and substance abuse) may be a consequence of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children, onset of cross-gender behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most typically developing children begin expressing gendered behaviors and interests. For some preschool-age children, both pervasive cross-gender behaviors and the expressed desire to be the other gender may be present, or, more rarely, labeling oneself as a member of the other gender may occur. In some cases, the expressed desire to be the other gender appears later, usually at entry into elementary school. A small minority of children express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to the experienced gender (“anatomic dysphoria”). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

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%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. In one sample of natal males, lower socioeconomic background was also modestly correlated with persistence. It is unclear if particular therapeutic approaches to gender dysphoria in children are related to rates of long-term persistence. Extant follow-up samples consisted of children receiving no formal therapeutic intervention or receiving therapeutic interventions of various types, ranging from active efforts to reduce gender dysphoria to a more neutral, “watchful waiting” approach. It is unclear if children “encouraged” or supported to live socially in the desired gender will show higher rates of persistence, since such children have not yet been followed longitudinally in a systematic manner. For both natal male and female children showing persistence, almost all are sexually attracted to individuals of their natal sex. For natal male children whose gender dysphoria does not persist, the majority are *androphilic* (sexually attracted to males) and often self-identify as gay or homosexual (ranging from 63% to 100%). In natal female children whose gender dysphoria does not persist, the percentage who are *gynephilic* (sexually attracted to females) and self-identify as lesbian is lower (ranging from 32% to 50%).

In both adolescent and adult natal males, there are two broad trajectories for development of gender dysphoria: early onset and late onset. *Early-onset gender dysphoria* starts in childhood and continues into adolescence and adulthood; or, there is an intermittent period in which the gender dysphoria desists and these individuals self-identify as gay or homosexual, followed by recurrence of gender dysphoria. *Late-onset gender dysphoria* occurs around puberty or much later in life. Some of these individuals report having had a desire to be of the other gender in childhood that was not expressed verbally to others. Others do not recall any signs of childhood gender dysphoria. For adolescent males with late-onset gender dysphoria, parents often report surprise because they did not see signs of gender

dysphoria during childhood. Expressions of anatomic dysphoria are more common and salient in adolescents and adults once secondary sex characteristics have developed.

Adolescent and adult natal males with early-onset gender dysphoria are almost always sexually attracted to men (androphilic). Adolescents and adults with late-onset gender dysphoria frequently engage in transvestic behavior with sexual excitement. The majority of these individuals are gynephilic or sexually attracted to other posttransition natal males with late-onset gender dysphoria. A substantial percentage of adult males with late-onset gender dysphoria cohabit with or are married to natal females. After gender transition, many self-identify as lesbian. Among adult natal males with gender dysphoria, the early-onset group seeks out clinical care for hormone treatment and reassignment surgery at an earlier age than does the late-onset group. The late-onset group may have more fluctuations in the degree of gender dysphoria and be more ambivalent about and less likely satisfied after gender reassignment surgery.

In both adolescent and adult natal females, the most common course is the early-onset form of gender dysphoria. The late-onset form is much less common in natal females compared with natal males. As in natal males with gender dysphoria, there may have been a period in which the gender dysphoria desisted and these individuals self-identified as lesbian; however, with recurrence of gender dysphoria, clinical consultation is sought, often with the desire for hormone treatment and reassignment surgery. Parents of natal adolescent females with the late-onset form also report surprise, as no signs of childhood gender dysphoria were evident. Expressions of anatomic dysphoria are much more common and salient in adolescents and adults than in children.

Adolescent and adult natal females with early-onset gender dysphoria are almost always gynephilic. Adolescents and adults with the late-onset form of gender dysphoria are usually androphilic and after gender transition self-identify as gay men. Natal females with the late-onset form do not have co-occurring transvestic behavior with sexual excitement.

Gender dysphoria in association with a disorder of sex development. Most individuals with a disorder of sex development who develop gender dysphoria have already come to medical attention at an early age. For many, starting at birth, issues of gender assignment were raised by physicians and parents. Moreover, as infertility is quite common for this group, physicians are more willing to perform cross-sex hormone treatments and genital surgery before adulthood.

Disorders of sex development in general are frequently associated with gender-atypical behavior starting in early childhood. However, in the majority of cases, this does not lead to gender dysphoria. As individuals with a disorder of sex development become aware of their medical history and condition, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are another gender. However, most do not progress to gender transition. Gender dysphoria and gender transition may vary considerably as a function of a disorder of sex development, its severity, and assigned gender.

Risk and Prognostic Factors

Temperamental. For individuals with gender dysphoria without a disorder of sex development, atypical gender behavior among individuals with early-onset gender dysphoria develops in early preschool age, and it is possible that a high degree of atypicality makes the development of gender dysphoria and its persistence into adolescence and adulthood more likely.

Environmental. Among individuals with gender dysphoria without a disorder of sex development, males with gender dysphoria (in both childhood and adolescence) more commonly have older brothers than do males without the condition. Additional predisposing

factors under consideration, especially in individuals with late-onset gender dysphoria (adulthood), include habitual fetishistic transvestism developing into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman) and other forms of more general social, psychological, or developmental problems.

Genetic and physiological. For individuals with gender dysphoria without a disorder of sex development, some genetic contribution is suggested by evidence for (weak) familiality of transsexualism among nontwin siblings, increased concordance for transsexualism in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. As to endocrine findings, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a disorder of sex development as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a disorder of sex development, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly atypical relative to what is usually seen in individuals with the same assigned gender. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-atypical postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of non-adherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with disorders of sex development and markedly gender-atypical behavior do not develop gender dysphoria. Thus, gender-atypical behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in 46,XY individuals with a disorder of sex development.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultures. The equivalent of gender dysphoria has also been reported in individuals living in cultures with institutionalized gender categories other than male or female. It is unclear whether with these individuals the diagnostic criteria for gender dysphoria would be met.

Diagnostic Markers

Individuals with a somatic disorder of sex development show some correlation of final gender identity outcome with the degree of prenatal androgen production and utilization. However, the correlation is not robust enough for the biological factor, where ascertainable, to replace a detailed and comprehensive diagnostic interview evaluation for gender dysphoria.

Functional Consequences of Gender Dysphoria

Preoccupation with cross-gender wishes may develop at all ages after the first 2–3 years of childhood and often interfere with daily activities. In older children, failure to develop age-typical same-sex peer relationships and skills may lead to isolation from peer groups and to distress. Some children may refuse to attend school because of teasing and harass-

ment or pressure to dress in attire associated with their assigned sex. Also in adolescents and adults, preoccupation with cross-gender wishes often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria, along with atypical gender expression, is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals from resource-poor family backgrounds. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort or inexperience in working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of atypical gender expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder occurs in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom cross-dressing behavior generates sexual excitement and causes distress and/or impairment without drawing their primary gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In many cases of late-onset gender dysphoria in gynephilic natal males, transvestic behavior with sexual excitement is a precursor.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is of some other gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur.

Other clinical presentations. Some individuals with an emasculation desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek castration and/or penectomy for aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of emotional and behavioral problems—most commonly, anxiety, disruptive and impulse-control, and de-

pressive disorders. In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing non-acceptance of gender-variant behavior by others. In older children, gender-variant behavior often leads to peer ostracism, which may lead to more behavioral problems. The prevalence of mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender variance in children. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior. Autism spectrum disorder is more prevalent in clinically referred children with gender dysphoria than in the general population. Clinically referred adolescents with gender dysphoria appear to have comorbid mental disorders, with anxiety and depressive disorders being the most common. As in children, autism spectrum disorder is more prevalent in clinically referred adolescents with gender dysphoria than in the general population. Clinically referred adults with gender dysphoria may have coexisting mental health problems, most commonly anxiety and depressive disorders.

Other Specified Gender Dysphoria

302.6 (F64.8)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording "other specified gender dysphoria" followed by the specific reason (e.g., "brief gender dysphoria").

An example of a presentation that can be specified using the "other specified" designation is the following:

The current disturbance meets symptom criteria for gender dysphoria, but the duration is less than 6 months.

Unspecified Gender Dysphoria

302.6 (F64.9)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

Exhibit O

In the Matter of:
CHRISTOPHER FAIN
vs
WILLIAM CROUCH, et al.

DR. DAN KARASIC

April 15, 2022



5010 Dempsey Drive
Cross Lanes WV 25313
304-415-1122

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY
MARTELL; BRIAN McNEMAR, SHAWN
ANDERSON a/k/a SHAUNTAE ANDERSON;
and LEANNE JAMES, individually and on
behalf of all others similarly situated,

Plaintiffs,

vs. Civil Action No. 3:20-cv-00740

WILLIAM CROUCH, in his official capacity as
Cabinet Secretary of the West Virginia
Department of Health and Human Resources;
CYNTHIA BEANE, in her official capacity as
Commissioner for the West Virginia Bureau for
Medical Services; WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN
RESOURCES, BUREAU FOR MEDICAL
SERVICES; JASON HAUGHT, in his official
capacity as Director of the West Virginia
Public Employees Insurance Agency; and
THE HEALTH PLAN OF WEST VIRGINIA, INC.,

Defendants.

"CONFIDENTIAL"

VIDEOTAPED DEPOSITION OF DR. DAN KARASIC
BY VIDEO CONFERENCE

The videotaped deposition of Dr. Dan
Karasic was taken on April 15, 2022,
at 12:02 p.m., at 5010 Dempsey Drive,
Cross Lanes, West Virginia.

ELITE COURT REPORTING, LLC
5010 Dempsey Drive
Cross Lanes, West Virginia 25313
(304) 415-1122

Martha Fourney, CSR

Confidential

Page 2

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Page 3

1 I N D E X

2

Witness

3

Dr. Dan Karasic

4

5

Examination

6

by Mr. David

Page 05

7

Exhibits

8

Number 1

Page 17

9

Number 2

Page 17

Number 3

Page 27

10

Number 4

Page 54

Number 5

Page 79

11

Number 6

Page 138

Number 7

Page 149

12

Number 8

Page 156

Number 9

Page 163

13

14

15

16

17

18

19

20

Reporter's Certification

Page 182

21

Errata Sheet/Signature Page

Enclosed

22

23

24

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Page 108

1 A. Yes. I'm familiar with the process to
2 get to gender incongruence by the World Health
3 Organization for ICD. But the United States,
4 in terms of ICD adoption, is way behind the
5 rest of the world. So we only -- we were using
6 ICD-9 which was adopted by -- you know, was
7 created around 1975, up until just a few years
8 ago. And then we moved to ICD-10 while they
9 were already working on its replacement.

10 So just our CMS - Center for Medicare
11 and Medicaid Services - it is just very slow in
12 new adoption of -- and so they have their own
13 ICD CM, which is the American -- it's the
14 ICD-10-CM, which is the American version of the
15 ICD that's in use here. I don't know whether
16 I'll still be in practice when ICD-11 is
17 adopted -- or alive, when the ICD-11 is adopted
18 in the United States.

19 Q. Okay. So it sounds like it might not
20 matter for practical purposes in the United
21 States anytime soon. But under ICD-11, for
22 gender incongruence -- if I'm understanding
23 that diagnostic code correctly, there is no
24 requirement of clinically significant distress

Exhibit P

InterQual®

2021, Apr. 2021 Release CP:Procedures**Subject:** 2, 3, 4, 5, 6, 7, 8 Gender Affirmation Surgery**Requested Service:** Hysterectomy for Gender Affirmation Surgery**Age:** Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:	Phone #:		
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

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ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions☐ 10. Primary gender affirmation surgery

☒ Strong and persistent cross-gender identification ≥ 6 months

☐ A) Yes

☐ B) No

- If option Yes selected, then go to question 2
- No other options lead to the requested service

☒ Choose all that apply:

- ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
- ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
- ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
- ☐ D) Strong desire to be the other gender or an alternative gender
- ☐ E) Strong desire to be treated as the other gender
- ☐ F) Strong confidence that typical feelings and reactions are of the other gender
- ☐ G) Other clinical information (add comment)

- If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
- No other options lead to the requested service

Gender Affirmation Surgery Hysterectomy for Gender Affirmation Surgery

Primary gender affirmation surgery (continued...)

3. Choose all that apply:

- ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
- ☐ B) Clinically significant increased risk of suffering
- ☐ C) Other clinical information (add comment)

- If 1 or more options A or B selected and option C not selected, then go to question 4
- No other options lead to the requested service

4. Gender affirmation surgery, Choose one:

- ☐ ~~A) Female-to-male surgery, genital~~
- ☐ ~~B) Female-to-male surgery, other~~
- ☐ ~~C) Male-to-female surgery, genital~~
- ☐ ~~D) Male-to-female surgery, other~~
- ☐ E) Other clinical information (add comment)

- If option A selected, then go to question 5
- No other options lead to the requested service

5. Choose all that apply:

- ☐ ~~A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery~~
- ☐ ~~B) Persistent and well-documented gender dysphoria~~
- ☐ ~~C) Capacity to make fully informed decisions and to consent~~
- ☐ ~~D) No psychiatric disorder by history or psychiatric disorder controlled~~
- ☐ E) Other clinical information (add comment)

- If the number of options selected is 4 and option E not selected, then go to question 6
- No other options lead to the requested service

6. Choose all that apply:

- ☐ ~~A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated~~
- ☐ ~~B) Lived ≥ 12 months in gender role congruent with gender identity~~
- ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here
- No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

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**Gender Affirmation Surgery
 Hysterectomy for Gender Affirmation Surgery**

Notes:

- 1:**
 InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.
- 2:**
 Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).
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 Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).
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 Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013). GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Gender Affirmation Surgery
Hysterectomy for Gender Affirmation Surgery

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Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

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6:

These criteria include the following procedures:

- Bilateral Mastectomy
- Breast Augmentation
- Clitoroplasty
- Gender Confirmation Surgery
- Gender Reassignment Surgery
- Hysterectomy
- Intersex Surgery
- Labiaplasty
- Male Chest Contouring
- Metoidioplasty
- Orchiectomy
- Ovariectomy
- Penectomy
- Penile Prosthesis
- Permanent Hair Removal
- Phalloplasty
- Salpingo-oophorectomy
- Scrotoplasty
- Sex Reassignment Surgery
- Transgender Surgery
- Transsexual Surgery
- Urethroplasty
- Vaginoplasty
- Vulvoplasty

7:

InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

Gender Affirmation Surgery
Hysterectomy for Gender Affirmation Surgery

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:

Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:

The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:

Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:

The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:

Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:

Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Gender Affirmation Surgery
Hysterectomy for Gender Affirmation Surgery

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:

It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Counselor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:

A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:

Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:

Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

Gender Affirmation Surgery
Hysterectomy for Gender Affirmation Surgery

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:

I/O Setting:

Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

All others - Outpatient

Gender Affirmation Surgery
Hysterectomy for Gender Affirmation Surgery

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58180, 58260, 58262, 58275, 58290, 58291, 58541, 58542, 58543, 58544, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures**Subject:** Gender Affirmation Surgery**Requested Service:** Phalloplasty for Gender Affirmation Surgery**Age:** Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:	Phone #:		
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

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ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions☐ 10. Primary gender affirmation surgery

☒ Strong and persistent cross-gender identification ≥ 6 months

☐ A) Yes

☐ B) No

- If option Yes selected, then go to question 2
- No other options lead to the requested service

☒ Choose all that apply:

- ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
- ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
- ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
- ☐ D) Strong desire to be the other gender or an alternative gender
- ☐ E) Strong desire to be treated as the other gender
- ☐ F) Strong confidence that typical feelings and reactions are of the other gender
- ☐ G) Other clinical information (add comment)

- If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
- No other options lead to the requested service

Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

Primary gender affirmation surgery (continued...)

3. Choose all that apply:

- ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
- ☐ B) Clinically significant increased risk of suffering
- ☐ C) Other clinical information (add comment)

- If 1 or more options A or B selected and option C not selected, then go to question 4
- No other options lead to the requested service

4. Gender affirmation surgery, Choose one:

- ☐ ~~A) Female-to-male surgery, genital~~
- ☐ ~~B) Female-to-male surgery, other~~
- ☐ ~~C) Male-to-female surgery, genital~~
- ☐ ~~D) Male-to-female surgery, other~~
- ☐ E) Other clinical information (add comment)

- If option A selected, then go to question 5
- No other options lead to the requested service

5. Choose all that apply:

- ☐ ~~A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery~~
- ☐ ~~B) Persistent and well-documented gender dysphoria~~
- ☐ ~~C) Capacity to make fully informed decisions and to consent~~
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6. Choose all that apply:

- ☐ ~~A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated~~
- ☐ ~~B) Lived ≥ 12 months in gender role congruent with gender identity~~
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**Gender Affirmation Surgery
 Phalloplasty for Gender Affirmation Surgery**

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Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

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Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:

Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:

The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:

Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:

The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:

Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:

Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:

It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Counselor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:

A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:

Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:

Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, *Neuropsychiatr Dis Treat* 2016, 12: 1953-66).

19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, *Good practice guidelines for the assessment and treatment of adults with gender dysphoria*. 2013; Coleman, *The World Professional Association for Transgender Health*. 2011, 7: 1-112).

20:

I/O Setting:

Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

All others - Outpatient

Gender Affirmation Surgery
Phalloplasty for Gender Affirmation Surgery

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 55899, Other _____

Exhibit Q

Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria

Lisa Littman

Published: March 19, 2019 • <https://doi.org/10.1371/journal.pone.0214157>

Notice of republication

After publication of this article [1], questions were raised that prompted the journal to conduct a post-publication reassessment of the article, involving senior members of the journal's editorial team, two Academic Editors, a statistics reviewer, and an external expert reviewer. The post-publication review identified issues that needed to be addressed to ensure the article meets *PLOS ONE*'s publication criteria. Given the nature of the issues in this case, the *PLOS ONE* Editors decided to republish the article, replacing the original version of record with a revised version in which the author has updated the Title, Abstract, Introduction, Discussion, and Conclusion sections, to address the concerns raised in the editorial reassessment. The Materials and methods section was updated to include new information and more detailed descriptions about recruitment sites and to remove two figures due to copyright restrictions. Other than the addition of a few missing values in Table 13, the Results section is unchanged in the updated version of the article. The Competing Interests statement and the Data Availability statement have also been updated in the revised version. The original version of the published article is appended to this Correction as [S1 File](#).

This Correction Notice serves to provide additional clarifications and context for the article in response to questions raised during the post-publication review of this work.

Emphasis that this is a study of parental observations which serves to develop hypotheses

This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term 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. This article has been revised to better reflect that these parent reports provide information that can be used to develop hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria among this demographic group.

Because this is a study of parent reports, there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives. Examples where parent answers reflect their perspective of the AYA include answers concerning the child's mental well-being, the parent-child relationship, and whether the child has high expectations about transitioning. However, it is also important to note that there are other survey items where the parent would have direct access to information about their child and that those answers reflect items that can be directly observed. Examples of this type include age, natal sex, diagnoses given by medical providers in the presence of the parent, directly observed behaviors of the child and the child's friend group, school performance, whether the child has dropped out or required a leave of absence from school, has been unable to hold a job, whether the child went to a clinic, or received treatment. Readers are reminded to keep in mind that this is a study of parent report and consideration of what information parents may or may not have access to is an important element of the findings.

Questions on whether the article describes adolescent-onset gender dysphoria or if it describes something new

There is some controversy over whether what is described as rapid onset of gender dysphoria, particularly in natal females, falls under the existing definition of late-onset or adolescent-onset gender dysphoria or whether it represents a new kind of development or presentation. This controversy might be a false dichotomy because both might be true. Although recent observations of adolescents and young adults who are predominantly natal female having a sudden onset of gender dysphoria symptoms beginning during or after puberty might technically fall under the existing definitions and criteria for adolescent and adult gender dysphoria [2], the substantial change in the demographics of patients presenting for care, the inversion of the sex ratio with disproportionate increase in adolescent natal females [3–5], and the new phenomenon of natal females exhibiting adolescent-onset and late-onset gender dysphoria [6–8] signal that something new may be happening as well. These changes may indicate that there are new etiologies leading to gender dysphoria and it is unclear, particularly without research about these new populations, whether gender dysphoria in this context has the same outcomes, desistance and persistence rates, and response to treatment as the gender dysphorias that have been previously studied.

Expanded discussion of qualitative analyses

Because this is a descriptive, exploratory study into a new topic with very little existing data, the addition of the qualitative analysis of two questions in addition to the quantitative analysis allowed for a greater depth of information to be used in the development of hypotheses. A grounded theory approach was selected as the strategy of choice for handling the qualitative data. There were two reviewers consisting of a professor with a PhD degree and expertise in qualitative methods (MM) [9] and the author (LL) who holds an MD and MPH degree, and has published both qualitative and quantitative research papers [10–11]. Each reviewer independently read and re-read the open-text responses in an iterative process to identify major themes arising from the data. Once each reviewer independently listed major themes and coded the open-text responses according to those themes, both reviewers compared notes to collaboratively revise and refine the major themes identified. Once an agreed-upon final list of themes was developed, attention was turned back to the data to code the open-text response with the final list of themes. After this task was completed, LL selected salient quotes to reflect each major theme, shared the quotes with MM, and both discussed collaboratively until agreement for the final list of major themes and associated quotes was reached. The incorporation of both the qualitative and quantitative analysis allowed for a more vivid picture of parent perspectives about the friendship group dynamics and behaviors and clinician interactions than could have been obtained from just one type of analysis.

Clarification of study design, methods, and related limitations

As mentioned in the article, the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing [12]. Descriptive studies often represent a first inquiry into an area of research and the findings of descriptive studies are used to generate new hypotheses that can be tested in subsequent research [12–13]. Because of the known limitations of descriptive studies, claims about causal associations cannot be made [12], and there were none made in the article. The conclusions of the current study are that the findings raise certain hypotheses and that more research is needed. Simple descriptive metrics to describe the quantitative characteristics of a sample in a descriptive study are the appropriate measures to use in this study. Additionally, because the data were collected at one point in time, no claims of cause and effect can be made.

All research methods have advantages and limitations. Obtaining information from parents (and guardians) about the health and well-being of children and adolescents is an established method of research [14]. Parental report, used elsewhere and in this study, offers the advantages of collecting data from adults who are knowledgeable about the child, who are able and willing to complete research activities such as detailed surveys, and who can provide details that are not available by other methods. Limitations of parental report include information that parents may not be aware of and parental biases. Anonymous surveys, used elsewhere and in this study, are advantageous for topics that might be stigmatized and can allow participants to be more honest in their responses but introduce the limitation that the researcher cannot verify the identity and experiences of the participants. The use of targeted recruitment and convenience samples, used elsewhere and in this study, offers the benefit of connecting with hard-to-reach populations but introduces limitations associated with selection bias that can subsequently be addressed by further studies. For the current study, selection bias may have resulted in findings that are more positive or more negative than would be found in a larger and less self-selected population. Subsequent studies should address these issues.

Updated Information about recruitment

Concerns were raised that this study only posted links to the recruitment information on selected sites that are viewed as being unsupportive of transition. However, announcements about the study included requests to distribute the recruitment information and link, and because information about where the participants encountered the announcement was not collected, it is not known which populations were ultimately reached. It has come to light that a link to the recruitment information and research survey was posted on a private Facebook group perceived to have a pro-gender-affirming perspective during the first week of the recruitment period (via snowball sampling). This private Facebook group is called "Parents of Transgender Children" and has more than 8,000 members. This means that parents participating in this research may have viewed the recruitment information from one of at least four sites with varied perspectives. Specifically, 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 and cautious or negative views about categorizing gender dysphoric youth as transgender. And, one of the sites that posted recruitment information is perceived to be pro-gender-affirming. The rest of the Correction notice will refer to recruitment from the four sites that are known to have posted the survey in the first week of recruitment: 4thwavenow, transgendertrend, Youth Trans Critical Professionals, and Parents of Transgender Children.

Parental approaches to gender dysphoria and views on medical interventions

To oversimplify parental approaches as simply "accepting" or "rejecting" misrepresents the range of responses and complexity of approaches that parents take when addressing the needs of their gender dysphoric children. Parental approaches are complex and cover many variables. For example, one parental approach might be to affirm the child as a person, support gender nonconformity, support gender exploration, support mental health evaluation and treatment as needed, support the exploration of potential underlying causes for the dysphoria while expressing caution about medical interventions. Another approach might be to affirm the child's newly declared gender identity, support gender nonconformity, support a liberal approach to medical intervention while expressing caution about mental health evaluation and caution about the exploration of potential underlying causes for the dysphoria. To categorize the former as "rejecting" and the latter as "accepting" would be inaccurate.

This study recruited participants based on whether participants thought their child exhibited a sudden or rapid onset of gender dysphoria beginning during or after puberty and did not recruit based on parental beliefs about what types of approaches toward gender dysphoric AYAs are best. Although one of the sites posting recruitment information might be considered to hold a pro-gender affirming perspective and three sites might be considered to hold a cautious or even negative perspective about medical or surgical interventions, the site where a participant first heard about the study may not be an accurate reflection of their beliefs and whether they endorse or disagree with the content of the websites. Data about where participants first heard about this study were not collected. Future studies should seek a wider array of websites to post recruitment information, recruit from clinicians with varied approaches to gender dysphoria, and ask specific questions about parental beliefs regarding their approach to their child's gender dysphoria, including: whether parents support or don't support gender exploration, gender nonconformity, mental health

evaluation and treatment, exploration of potential underlying causes for dysphoria, non-heterosexual sexual identity, and whether they hold a liberal, cautious or negative view about the use of medical and surgical interventions for gender dysphoric youth. Exploration about what types of affirmation are endorsed by parents including affirmation of the child as a person and affirmation of the child's gender identity would also be valuable.

Expanded discussion about limitations and biases

Regarding the reporting of gender dysphoria, an absence of childhood gender dysphoria and whether the AYA was gender dysphoric at the time of survey completion were based on parent report of whether certain indicators of gender dysphoria were observed prior to puberty or at the time of the survey. These determinations were not diagnoses made by clinicians. Three of the indicators listed in the DSM-5 include information that a parent might not have access to (unless the child told them directly) [2], and therefore answers based on parent perceptions may not accurately reflect the experiences or traits of the AYAs themselves. However, the other five indicators include readily observable behaviors and preferences that would seem difficult for a parent not to notice such as: strong preference or strong resistance to wearing certain kinds of clothing; strong preference or strong rejection of specific toys, games and activities; and strong preference for playmates of the other gender [2]. It is possible that a parent could have ignored some of these indicators, though other people in the child's life may have observed them. To improve the reliability of this measure, future studies should include evaluation from clinicians with input from parents, AYAs and from third party informants such as teachers, pediatricians, mental health professionals, babysitters, and other family members who knew the youth during childhood to verify the whether the readily observable behaviors and preferences were present or absent during childhood.

For a clinician to make a diagnosis of gender dysphoria in childhood, a child would need to exhibit at least six of the eight indicators. Given that 97.6% of the participants reported 2 or fewer readily observable indicators, even if hypothetically all participants incorrectly under-reported all three of the subtler indicators, 97.6% would still have fewer than six indicators. So, although no clinical evaluation was performed and a clear presence or absence of a diagnosis cannot be verified, given the reports of the easily observed behaviors and preferences, it can be said that it would be very unlikely for these AYAs to have met criteria for childhood gender dysphoria if they had seen a clinician for an evaluation.

There is expected variation in how objective parents can be about their own children. Some individual biases may limit the objectivity of parents. This descriptive study was not designed to explore or measure the objectivity of participants. Participants may have first learned about this study from one of four (or more) sites described previously where recruitment information was posted. It is possible that exposure to websites that take a cautious or negative approach to transition during adolescence and young adulthood and exposure to websites that take a pro-gender-affirming approach might influence how parents report about their children's experiences. There have not been any studies to determine if parents who seek information from online sites in general, don't seek information from online sites, or seek information from specific online sites, including the four sites noted for this study, differ in their ability to provide objective assessments of their children. However, if there were an excess of participants who, compared to other parents who take surveys reporting on their children, were less able to be objective about their children, it could limit some of the findings of the study, particularly for findings that are more interpretive rather than the findings that are more concrete.

The research survey did not specifically ask whether parents supported their AYAs' exploration of gender identity, so whether and what numbers of participants supported their child's exploration of gender identity is unknown. However, if there were an excess of parents who did not support the exploration of gender identity, it could potentially result in higher reports of declining mental health. The parents' perception that their child's mental health and the parent-child relationship were worse after the child announced a transgender-identification could be due to several variables such as conflict between parent and child, maladaptive coping mechanisms, or worsening psychiatric issues unrelated to gender. The trajectories for adolescent-onset gender dysphoria are not well understood and additional research is desperately needed.

There are many ways that parents can provide support for their child which include: affirming them as a unique and valuable person and as a loved member of the family; supporting their emotional and financial needs; supporting them in pursuing their interests; supporting them to develop the skills needed for self-sufficiency; supporting their choices of gender nonconforming clothing and interests; supporting their exploration of their identity; and supporting them in their critical thinking skills. Parental support is multifaceted and should not be oversimplified into a binary of whether a parent agrees or disagrees with a specific medical course. This study was not designed to measure different types of support provided by parents or levels of support. If there were an excess of parents who were unsupportive of their children, it might affect some of these initial findings. The nature and extent of parental support—including the many different ways that parents can support their children in becoming healthy, self-sufficient adults—is well worth further study.

Clarification of Fig 1

The purpose of Fig 1 was to provide the reader with a quick sense of what kinds of advice can be found and shared on Reddit and Tumblr. One example includes an excerpt from a publicly available Tumblr blog that posted a list of purported indirect signs of gender dysphoria. This excerpt is indeed an example of advice that can be found on Tumblr. Note, however, that the excerpted Tumblr post itself does not reflect the full content of the original blog it refers to, nor does the excerpt in Fig 1. The original blog is titled, "That was dysphoria? 8 signs and symptoms of indirect gender dysphoria" [15].

Discussion of the ICD-11 change from "gender dysphoria" to "gender incongruence"

The ICD-11 will go into effect in January 2022, and, with this change, the new diagnosis of "gender incongruence" will replace "gender dysphoria." Because the current descriptive, exploratory study raises hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria and concludes that more research is needed, it is unlikely that the change in diagnostic criteria will appreciably change the conclusion of the study, although the terminology may become outdated.

Supporting information

S1 File. PDF of the original article version that was published on August 16, 2018 (two figures removed due to copyright restrictions).
<https://doi.org/10.1371/journal.pone.0214157.s001>
 (PDF)

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Exhibit R



Do Clinical Data from Transgender Adolescents Support the Phenomenon of “Rapid Onset Gender Dysphoria”?

Greta R. Bauer, PhD, MPH¹, Margaret L. Lawson, MD, MSc, FRCPC², and Daniel L. Metzger, MD, FAAP, FRCPC³,
for the Trans Youth CAN! Research Team*

Although emergence of gender dysphoria at puberty is long established, a distinct pathway of rapid onset gender dysphoria was recently hypothesized based on parental data. Using adolescent clinical data, we tested a series of associations that would be consistent with this pathway, however, our results did not support the rapid onset gender dysphoria hypothesis. (*J Pediatr* 2022;243:224-7).

Puberty has long been understood as one period when gender dysphoria often first emerges.¹ Although most transgender (trans) older adolescents and adults report needing gender-affirming medical care (hormones and/or surgeries), and also report having been aware of their gender at young ages,² only a small proportion receive gender-affirming care as adolescents. Use of hormonal suppression with a gonadotropin-releasing hormone agonist, and hormones such as estrogen and testosterone therapies in trans and gender-diverse adolescents is supported by the American Academy of Pediatrics, the Pediatric Endocrine Society, the Endocrine Society, and the World Professional Association for Transgender Health.^{1,3-5} Referrals to adolescent gender clinics have increased internationally, particularly among those assigned female at birth.⁶⁻⁹

In 2018, a phenomenon of rapid onset gender dysphoria was hypothesized as a distinct pathway involving social contagion among youth vulnerable due to mental or neurodevelopmental disorders,¹⁰⁻¹² raising public concerns regarding potential for later regret following gender-affirming medical care. This discussion has occurred primarily in the context of data from a single online parental survey.^{10,11} Although this parental study has generated controversy,¹³ methodologic and social critique,^{12,14,15} and calls for additional research,^{16,17} its hypotheses have not yet been tested on data from youth themselves. Specifically, rapid onset gender dysphoria is hypothesized as a phenomenon in youth with gender dysphoria emerging at or after puberty, socially influenced through peer contagion, and with contributing factors including poor mental health, neurodevelopmental disabilities, parent-child conflict, and maladaptive coping strategies.^{10,11}

If the rapid onset gender dysphoria hypothesis indeed characterizes a distinct clinical phenomenon, and these youth access referrals for hormone suppression or gender-affirming hormones, then we would expect to see differentiation within clinical samples between those with more-recent (ie, rapid-onset) vs more-remote knowledge regarding their gender. Based on the published hypothesis,¹⁰ we would expect more recent gender knowledge to be associated with self-reported mental health measures, mental health and neurodevelopmental disability diagnoses, behaviors consistent with maladaptive coping (eg, self-harm), support from

online and/or transgender friends but not parents, and lesser gender dysphoria. We aim to test these hypotheses.

Methods

Baseline data (2017-2019) from the Trans Youth CAN! Cohort included pubertal/postpubertal adolescents age <16 years attending a first referral visit for hormone suppression or gender-affirming hormones at 10 Canadian medical clinics that provide specialized gender-affirming care to adolescents through a range of different care models. Ethics approval was received from all study sites. Years gender was known was missing for 1 participant (excluded), for a final sample of $n = 173$. Methods and measures are described in detail elsewhere.¹⁸

Self-reported measures were obtained from baseline interviewer-administered adolescent surveys,¹⁹ and diagnoses from baseline clinical records.²⁰ Recent gender knowledge was coded by subtracting age in years from age adolescents self-reported they “realized your gender was different from what other people called you.” As ages were whole numbers, a difference of 1 could indicate <1 year to just under 2 years. Values ≤ 1 were coded as recent gender knowledge, with an alternate definition (values ≤ 2) for sensitivity analysis. Mental health symptoms were assessed with the Overall Anxiety Severity and Impairment Scale,²¹ the Modified Depression Scale,²² and the Kessler-6 scale for psychological distress.²³ Mental health diagnoses extracted from chart included anxiety, depression, personality disorder, eating disorder, and neurodevelopmental disorder diagnoses

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*List of additional members of the Trans Youth CAN! Study Group is available at www.jpeds.com (Appendix).

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included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. Gender dysphoria symptoms were assessed using the Trans Youth CAN! Gender Distress Scale.²⁴ Self-reported mental health behaviors included self-harm, substance use, and suicidal behavior. Three measures captured social connections to online and trans communities: having gender-supportive online friends was coded if adolescents reported online friends who knew their gender and were “very supportive,” and having online or trans friends as general sources of support was indicated in checklist items. Parental support was coded if youth indicated all biological/step/foster parents were “very supportive” of their gender identity or expression.

Statistical analyses were conducted using SAS v 9.4.1 (SAS Institute, Inc), weighted to account for clinics’ different recruitment periods due to staggered start dates, to improve generalizability.¹⁸ For analyses of associations between recency of gender knowledge and hypothesized correlates, a series of multiple regressions was conducted, with recency as the independent variable of interest, controlling for age and sex assigned at birth. Linear regressions were used for continuous dependent variables (eg, psychometric scales). For dichotomous dependent variables, modified Poisson regression with robust variance estimation was used.²⁵ As “rapid-onset” has not been precisely defined, we conducted a sensitivity analysis repeating these analyses using the alternate (value ≤ 2) definition of recent gender knowledge.

Results

Recency of gender knowledge is presented in the [Figure](#), results of hypothesized associations (recency value ≤ 1) in [Table I](#), and

variable means and frequencies in [Table II](#) (available at www.jpeds.com). Controlling for age and sex assigned at birth, recent gender knowledge was not significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, gender dysphoria symptoms, self-harm, past-year suicide attempt, having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents. Recent gender knowledge was associated with lower scores on anxiety severity/impairment ($b = -3.272$; 95% CI $-5.172, -1.373$), and lower prevalence of marijuana use (prevalence ratio = 0.11; 95% CI 0.02, 0.82), counter to hypothesized directions of effect. For sensitivity analysis using the alternate (value ≤ 2) definition of recent gender knowledge, we found all results substantively the same in statistical significance and direction of effect, except past-year marijuana use, which now only approached statistical significance ($P = .0677$).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of rapid onset gender dysphoria during adolescence. Among adolescents under age 16 years seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in rapid onset gender dysphoria were either not statistically significant, or were in the opposite direction to what would be hypothesized. This putative phenomenon was posited based on survey data from a convenience sample of parents recruited from websites,¹⁰ and may represent the perceptions or experiences of those parents, rather than of

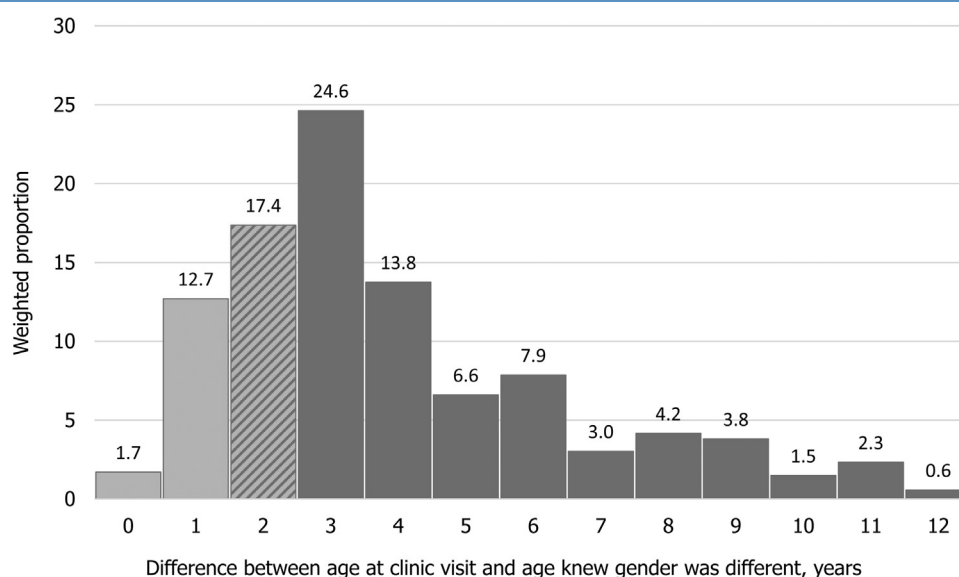


Figure. Recency of gender knowledge among adolescents age <16 years referred to Canadian clinics for hormone suppression or gender-affirming hormones ($n = 173$). Age at which knew gender was different was subtracted from current age in years; thus, “2 years” could range from more than 1 year to less than 3 years. Lighter gray represents recent gender knowledge in this analysis, with a sensitivity analysis also including the patterned bar.

Table I. Associations between short-term awareness of gender and variables hypothesized to be associated with rapid-onset gender dysphoria, controlling for age and sex assigned at birth

Dependent variables	B*	SE	P	PR*	95% CI†
Mental health scales					
Anxiety severity/impairment (OASIS)	−3.272	0.961	.0008		(−5.172, −1.373)
Depressive symptoms (MDS)	−1.276	0.845	.1328		(−2.944, 0.392)
Psychological distress (K6)	−1.156	1.060	.2771		(−3.248, 0.936)
Record of diagnosis with mental health disorder‡	−0.509	0.315	.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder§	0.066	0.362	.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	−0.193	0.122	.1139		(−0.434, 0.047)
Mental health related behaviors					
Self-harm, past year	−0.052	0.191	.7833	0.95	(0.65, 1.38)
Marijuana use, past year	−2.178	1.010	.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	−0.592	0.785	.4505	0.55	(0.12, 2.58)
Social connection indicators¶					
Reports having online friends supportive of gender	−0.050	0.157	.7505	0.95	(0.70, 1.29)
Indicates online friends as source of general support	−0.223	0.286	.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	−0.049	0.298	.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	−0.004	0.202	.9836	1.00	(0.67, 1.48)

B, beta regression; K6, Kessler-6 Scale; MDS, Modified Depression Scale; OASIS, Overall Anxiety Severity and Impairment Scale; PR, prevalence ratio; TYC-GDS, Trans Youth CAN! Gender Distress Scale.

*Estimates adjusted for age in years and sex assigned at birth.

†95% CIs for betas (for linear regressions) or PRs (for modified Poisson regressions).

‡Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.

§Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.

¶Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.¹⁰

adolescents, particularly those who may enter into clinical care. Similar analyses should be replicated using additional clinical and community data sources. Our finding of lower anxiety severity/impairment scores in adolescents with more recent gender knowledge suggests the potential for longstanding experiences of gender dysphoria (or their social complications) playing a role in development of anxiety, which could also be explored in future research. ■

The Trans Youth CAN! Study Team thank the trans youth and their families who have generously shared their time and experience with us. We acknowledge the contribution of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

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50 Years Ago in *THE JOURNAL OF PEDIATRICS*

What Changed the Prognosis of Juvenile Dermatomyositis?

Sullivan DB, Cassidy JT, Petty RE, Burt A. Prognosis in childhood dermatomyositis. *J Pediatr* 1972;80:555-63.

The addition of systemic corticosteroids to the treatment of juvenile dermatomyositis played a pivotal role in changing the outcome of this disease. This commentary published 50 years ago summarized the demographic, clinical, laboratory, pathology, treatment, and outcome of 18 children with dermatomyositis seen between 1960 and 1969 in a single center. The medical treatment consisted of systemic corticosteroids with tapering over 2 years. In a previous classic report from 1964,¹ on which we wrote a commentary in 2014,² only 33% were treated with corticosteroids. The outcomes were grim: one-third died, another one-third remained crippled, and only one-third recovered completely. However, in this study merely 8 years later, no deaths from dermatomyositis were recorded. Seventeen of the 18 children were functionally independent after treatment, but 8 of 18 developed calcinosis. Four patients had residual skin scarring, 4 developed mild joint contractures, and 6 had muscle atrophy. It is important to note that most of the cases in this series (13/18) were mild and monophasic, and only 5 patients had dyspnea or dysphagia indicative of a more severe disease, thus contributing to the good prognosis.

Modern aggressive therapy includes corticosteroid-sparing medications. Methotrexate is given as first-line treatment together with corticosteroids. Other medications for severe or chronic disease include intravenous immunoglobulin, calcineurin inhibitors, cyclophosphamide, and biologic modifiers (rituximab and tumor necrosis factor inhibitors). Janus kinase inhibitors have shown promise. Overall, mortality has decreased to 2.5%. However, even today, between 30% and 40% of the patients manifest a chronic disease course with functional impairments and develop calcinosis, and they require long-term immunosuppressive therapy with many potential complications.³ Thus, despite the improvement in prognosis, there is still a long way to optimize treatment of this rare disease. Precision medicine, using specific myositis autoantibodies and analysis of immune pathways in individual patients, may further improve the outcome of our patients.³ In addition, early diagnosis and treatment are key!

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Appendix

Additional members of the Trans Youth CAN! Study Group Members

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Table II. Weighted frequencies or means for sociodemographic and study variables (n = 173)

Variables	Value
Age, n (% _{weighted})	
10-11 y	17 (8.5)
12-13 y	37 (22.6)
14-15 y	119 (68.9)
Ethnoracial background,* n (% _{weighted})	
Indigenous	33 (18.4)
Nonindigenous visible minority [†]	10 (6.6)
Nonindigenous white	128 (75.0)
Immigration background, n (% _{weighted})	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n (% _{weighted})	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n (% _{weighted})	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Nonbinary [‡]	14 (8.3)
Mental health scales, mean _{weighted} (SD)	
Anxiety severity/impairment (OASIS)	8.842 (4.548)
Depressive symptoms (MDS)	15.077 (4.030)
Psychological distress (K6)	10.746 (5.100)
Record of diagnosis with mental health disorder, [§] n (% _{weighted})	92 (51.6)
Record of diagnosis with neurodevelopmental disorder, [¶] n (% _{weighted})	44 (25.9)
Gender dysphoria/distress (TYC-GDS), mean _w (SD)	4.048 (0.557)
Mental health related behaviors, n (% _{weighted})	
Self-harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,** n (% _{weighted})	
Reports having online friends supportive of gender	109 (69.9)
Indicates online friends as source of general support	79 (49.3)
Indicates trans friends as source of general support	92 (55.8)
All parents supportive of gender identity/expression	109 (61.8)

K6, Kessler-6 Scale; MDS, Modified Depression Scale; OASIS, Overall Anxiety Severity and Impairment Scale; TYC-GDS, Trans Youth CAN! Gender Distress Scale.

*Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Nonwhite, nonindigenous ethnoracial backgrounds were indicated by the following numbers of participants: 6 Black Canadian or African American, 2 Black African, 4 Latin American, 4 East Asian, 1 Indo-Caribbean, 3 Black Caribbean, 1 Middle Eastern, and 1 Southeast Asian (participants could indicate more than 1).

[†]The Canadian government defines visible minorities as "persons, other than Aboriginal peoples, who are non-Caucasian in race or nonwhite in color."²⁶

[‡]Response option was "nonbinary or something other than male or female."

[§]Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.

[¶]Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.

**Hypothesized by other authors based on a survey of parents.¹⁰

Exhibit S

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

**CHRISTOPHER FAIN; ZACHARY
MARTELL; and BRIAN MCNEMAR,**
Individually and on behalf of all others
similarly situated,

Plaintiffs,

**Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge**

v.

WILLIAM CROUCH, in his official capacity as
Cabinet Secretary of the West Virginia
Department of Health and Human Resources;
CYNTHIA BEANE, in her official capacity as
Commissioner for the West Virginia Bureau for
Medical Services; **WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN
RESOURCES, BUREAU FOR MEDICAL
SERVICES; TED CHEATHAM**, in his official
Capacity as Director of the West Virginia Public
Employees Insurance Agency; and **THE
HEALTH PLAN OF WEST VIRGINIA, INC.,**

Defendants.

**DEFENDANTS' RESPONSE TO PLAINTIFF'S SECOND SET OF
INTERROGATORIES TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE,
AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES,
BUREAU FOR MEDICAL SERVICES**

INTERROGATORIES

8. Identify all conditions, diagnostic codes, or instances where coverage for hysterectomy and/or oophorectomy surgical procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:

- a. Diagnostic code(s);
- b. Procedure code(s);
- c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis. In addition, we have requested documents which are used as part of the review process and these will be supplemented upon receipt.

9. Identify all conditions, diagnostic codes, or instances where coverage for vaginoplasty procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:
- a. Diagnostic code(s);
 - b. Procedure code(s);
 - c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis.

10. Identify all conditions, diagnostic codes, or instances where coverage for orchiectomy, penectomy, and/or phalloplasty procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:
- a. Diagnostic code(s);
 - b. Procedure code(s);
 - c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis.

11. Taking necessary steps to comply with applicable privacy laws, for each year since 2016 through the present identify the number of Health Plan participants who have submitted one or more claims with a diagnosis code for Gender Dysphoria or Gender Incongruence. This includes, but is not limited to, the following diagnosis: F64.0, Transsexualism (ICD-10-CM); F64.2, Gender identity disorder of childhood (ICD-10-CM); F64.8, Other gender identity disorders (ICD-10-CM); F64.9, Gender identity disorder, unspecified (ICD-10-CM); HA60, Gender incongruence of adolescence or adulthood (ICD-11); and HA61, Gender incongruence of childhood (ICD-11).

RESPONSE: Upon information and belief:

2016 30 members
2017 50 members
2018 243 members
2019 439 members
2020 602 members
2021 (through 9/30) 686 members.

**WILLIAM CROUCH,
CYNTHIA BEANE, and
WEST VIRGINIA DEPARTMENT OF
HEALTH AND HUMAN RESOURCES,
BUREAU FOR MEDICAL SERVICES,
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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

**CHRISTOPHER FAIN; ZACHARY
MARTELL; and BRIAN MCNEMAR,**
Individually and on behalf of all others
similarly situated,

Plaintiffs,

**Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge**

v.

WILLIAM CROUCH, in his official capacity as
Cabinet Secretary of the West Virginia
Department Of Health and Human Resources;
CYNTHIA BEANE, in her official capacity as
Commissioner for the West Virginia Bureau for
Medical Services; **WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN
RESOURCES, BUREAU FOR MEDICAL
SERVICES; TED CHEATHAM**, in his official
Capacity as Director of the West Virginia Public
Employees Insurance Agency; and **THE
HEALTH PLAN OF WEST VIRGINIA, INC.**

Defendants.

CERTIFICATE OF SERVICE

Now come Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources, by counsel, and do hereby certify that on the 25th day of October, 2021, a true and exact copy of **DEFENDANTS' RESPONSE TO PLAINTIFF'S SECOND SET OF INTERROGATORIES TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES** was served on counsel via electronic means as follows:

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Exhibit T

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and)
mother, HEATHER JACKSON,)

Plaintiff,)

vs.)

No. 2:21-cv-00316

WEST VIRGINIA STATE BOARD OF)
EDUCATION, HARRISON COUNTY)
BOARD OF EDUCATION, WEST)
VIRGINIA SECONDARY SCHOOL)
ACTIVITIES COMMISSION, W.)
CLAYTON BURCH in his official)
capacity as State)
Superintendent, DORA STUTLER,)
in her official capacity as)
Harrison County)
Superintendent, and THE STATE)
OF WEST VIRGINIA,)

Defendants,)

LAINIEY ARMISTEAD,)

Defendant-Intervenor.)
-----)

VIDEOTAPED DEPOSITION OF
STEPHEN LEVINE
Wednesday, March 30, 2022
Volume I

Reported by:
ALEXIS KAGAY
CSR No. 13795
Job No. 5122884
PAGES 1 - 289

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

)
B.P.J. by her next friend and)
mother, HEATHER JACKSON,)

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Plaintiff,)

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vs.)

) No. 2:21-cv-00316

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WEST VIRGINIA STATE BOARD OF)
EDUCATION, HARRISON COUNTY)
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CLAYTON BURCH in his official)
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Harrison County)
Superintendent, and THE STATE)
OF WEST VIRGINIA,)

)
Defendants,)

)
LAINEY ARMISTEAD,)

)
Defendant-Intervenor.)
_____)

Remote videotaped deposition of
STEPHEN LEVINE, Volume I, taken on behalf of Plaintiff,
with all participants appearing remotely, beginning at
9:09 a.m. and ending at 5:46 p.m. on Wednesday,
March 30, 2022, before ALEXIS KAGAY, Certified
Shorthand Reporter No. 13795.

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15 Also Present:

16 MITCH REISBORD - VERITEXT CONCIERGE

17

18 Videographer:

19 KIMBERLEE DECKER

20

21

22

23

24

25

1 Q Why don't you give me your estimate of how
2 many prepubertal children you've ever seen as patients,
3 and then we can ask more questions.

4 A I would say a handful. Six.

5 Q And how many of those -- of those 11:15:35
6 approximately six did you see more than one time?

7 A I can't recall one.

8 Q And then I'll ask the same question about
9 adolescents, which I'll mean minors from puberty
10 through being a minor. 11:16:00

11 How many adolescent patients have you had in
12 your career, approximately?

13 A 50.

14 Q And how many of those have you seen more than
15 once? 11:16:14

16 A Most.

17 Q And were most of those, of the adolescent
18 patients you've seen, late adolescence?

19 A No.

20 Q Turning back to your CV, you list yourself -- 11:16:27
21 you're listed as a clinical professor at Case Western
22 Reserve University School of Medicine; correct?

23 A Yes.

24 Q Do you work at Case Western Reserve University
25 School of Medicine full-time? 11:16:51

1 three months because I'm part of a committee to plan
2 the curriculum on sexuality and gender.

3 Speaking of education, the university --
4 other -- other institutions also asked me to teach
5 about this subject. And on August -- on April 7th, I'm 12:07:39
6 going to Akron to teach -- or virtually I'm going to
7 teach a three -- a two-and-a-half-hour seminar.

8 And I forgot to mention to you before, and I'd
9 like you to hear this, that when you were questioning
10 me about my credentials or not having a certificate 12:07:57
11 about -- in child psychiatry, you should know, I forgot
12 to tell you that Cleveland Clinic, department of child
13 psychiatry, and the University Hospitals, the
14 department of child psychiatry, sends residents to be
15 with me as part of their training in child development 12:08:18
16 and child clinical issues, child and adolescent
17 clinical issues.

18 So I think -- I just forgot to mention that.

19 Q Are you familiar with the University
20 Hospitals' LGBTQ and gender care program? 12:08:48

21 A I'm aware that it exists, yes.

22 Q Have you ever talked to any clinicians in that
23 practice?

24 A No one has ever talked to me in that practice.

25 The only time I have interaction with them is when -- 12:09:00

1 if I present grand rounds, some of those people ask me
2 a question. But they've never consulted me whatsoever
3 in the formation of their clinic and in the ongoing
4 work of their clinic.

5 Although, Cleveland Clinic has a very similar 12:09:20
6 program, and they have called me up and -- for some
7 advice sometimes.

8 But my -- my, quote, own University Hospitals'
9 place I don't really think has any people from child
10 psychiatry in it, but I'm not sure because they have 12:09:38
11 kept me away.

12 Q What do you mean they have kept you away?

13 A Just what I explained. They have never
14 communicated with me. It is -- you know, other people
15 know me as being published in this area. You know, I 12:09:54
16 think I've written 20 articles on this -- you know, I
17 have 20 or so publications in this area. You would
18 think that they would invite me or consult with me or
19 ask me questions, but I think they recognized that they
20 are part of what is called affirmative care and what I 12:10:18
21 would say, rapidly affirmative care, and -- and they
22 sense that I'm not so interested in rapid, that -- that
23 I believe that -- that I have long believed that people
24 who have this kind of dilemma need some patient time in
25 talking about this matter. 12:10:45

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE
ANDERSON; individually and on behalf of all
others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

**ORDER GRANTING PLAINTIFFS' MOTION
TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.**

This matter comes before the Court on the motion of Plaintiffs Christopher Fain and Shauntae Anderson to exclude the testimony of Stephen B. Levine, M.D., a disclosed expert of Defendants William Crouch, Cynthia Beane, and the West Virginia Department of Health and Human Resources, Bureau for Medical Services.

Having considered Plaintiffs' Motion and Memorandum in Support, and for good cause shown, IT IS HEREBY ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D. is GRANTED.

This ____ day of _____, 2022.

The Honorable Robert C. Chambers
United States District Judge