Exhibit GG

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PFLAG, INC.; *et al.*, *Plaintiff*, v. DONALD J. TRUMP, in his official capacity as President of the United States; *et al.*, *Defendants*.	Civil Action No. 8:25-cv-00337-BAH

REPLY EXPERT DECLARATION OF DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

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.

4. My background, qualifications, and the bases for my opinions are set forth my initial declaration.

5. I provide this reply expert declaration to respond to the amicus briefs filed by the State of Alabama et al. ("Alabama brief") and Do No Harm, Inc. ("DNH brief").

6. In preparing this reply expert declaration, I relied on my training and years of research and clinical experience, as set out in my curriculum vitae attached to my initial expert report as **Exhibit A**, and on the materials listed therein; and the materials referenced in my initial declaration and listed in the bibliography attached thereto as **Exhibit B;** and the materials

referenced herein and listed in the supplemental bibliography attached hereto as **Exhibit C**. The sources cited in each of these are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject, which include authoritative, scientific peer-reviewed publications.

7. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

OPINIONS

The Attempts to Discredit the WPATH Standards of Care, Version 8 Are Baseless.

8. The Alabama brief characterizes WPATH SOC 8 as a political and legal document. It is not. It cites to materials that represent an anonymized, cherry-picked subset of communications to and from members of WPATH, including those not in leadership roles, as well an email thread and related documents obtained from the U.S. Department of Health and Human Services, in order to weave a false narrative that the WPATH Standards of Care was unduly influenced by outside forces or reflects a particular point of view other than that contained in the published and peer-reviewed WPATH SOC 8 document. However, their assertions are not reflective of the process that led to WPATH SOC 8 nor of its substance.

9. WPATH SOC 8 the is the most recent version of practice guidelines that were first published as the Standards of Care in 1979 and updated periodically since then.

10. The process of developing the WPATH Standards of Care, Version 8 was a multistep, several years long effort that started in 2017. This process is outlined in great detail in Appendix A to SOC 8, a copy of which is attached hereto as **Exhibit D**.

11. The process for the development of SOC 8 involved the following stages:

a. Establishing Guideline Steering Committee including Chair, and Co-Chairs (July 19, 2017);

b. Based on SOC 7, the topics for SOC 8 were reviewed, main questions were developed, and chapters (scope of guidelines) were determined;

c. Selecting Chapter Members based upon expertise (March 2018);

d. Selecting the Evidence Review Team: John Hopkins University (May 2018);

e. Refining topics included in the SOC 8 and review questions for systematic reviews;

f. Conducting systematic reviews (March 2019);

g. Drafting the recommendation statements;

h. Voting on the recommendation statements using a Delphi process (September 2019–February 2022);

i. Grading of the recommendations statements;

j. Writing the text supporting the statements;

k. Independently validating the references used in the supportive text;

l. Finalizing a draft SOC 8 (December 1, 2021);

m. Feedback on the statements by International Advisory Committee;

n. Feedback on the entire draft of the SOC 8 during a public comment period (November 2021–January 2022);

o. Revision of final draft based on comments (January 2022- May 2022);

p. Approval of final draft by Chair and Co-Chairs (June 10, 2022);

q. Approval by the WPATH Board of Directors;

r. Publication of the SOC 8; and

s. Dissemination and translation of the SOC 8.

12. As I noted in my initial declaration, this "process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." Karasic Declaration ¶ 56 (quoting Coleman, et al., 2022, at S247).

13. By 2018 (over six years ago), chapter authors were invited to discuss their chapter drafts in meetings with the SOC editors at the WPATH conference in Buenos Aires. And, by 2019, chapter authors were asked to submit their committee's recommendations to the Delphi process. This process is described in paragraphs 58-59 of my initial declaration and in Appendix A to SOC 8.

14. With regards to SOC 8, every member of the SOC revision committee was instructed to vote for each statement. Response rates for each statement ranged from 74.8%-95.0%. Most statements were approved in 2019. Some statements from the various SOC 8 chapters that did not receive 75% approval on Delphi were revised, using the feedback from a form that accompanied each vote. Most of these votes on the revised statements happened in 2020. Throughout this process members of each chapter committee only saw the statements of other chapters that went to Delphi vote and had an opportunity to vote there and express opinions of each statement with their vote.

15. Following the aforementioned process, every recommendation contained in SOC 8, as published in 2022, was approved by 75% or more of the revision committee.

16. In late 2021, a draft of the statements and supportive text comprising each chapter was released for public comment. It was at this point that members of the public, members of WPATH, as well as members of SOC 8 committees could provide feedback on each chapter.

17. A public comment process with an attempt to address concerns raised through that process is a standard part of guideline development, not evidence of undue political influence. Indeed, "[s]takeholder engagement, of all those potentially affected by the recommendations included in a guideline, is critical … [and] helps to ensure guideline acceptability and feasibility, support for its uptake and the practices recommended, and possible effects on adherence to any treatments and practices recommended." (Petkovic, et al., 2022).

18. The Alabama brief alleges that SOC 8 was crafted to advance political and legal goals. This is false.

19. The first lawsuit against a ban on gender affirming care for minors was *Brandt v Rutledge*, which was filed in May 2021, long after most of SOC 8 had been written. It is common when developing clinical practice guidelines to make revisions based on public feedback. For SOC 8, the plan to engage in that feedback and revision process based on stakeholder input preceded the recent legal cases, and it is common for stakeholders in clinical practice guidelines to include organizations of healthcare providers such as the American Academy of Pediatrics and governmental bodies such as the Department of Health and Human Services.

20. The Alabama brief also suggests that Admiral Rachel Levine, the then-Assistant Secretary for Health for the U.S. Department of Health and Human Services, inappropriately influenced the timing and/or content of SOC 8. This is not true. As stated above, stakeholder involvement is an important aspect of the development of any clinical practice guideline. As such, Admiral Levine, as an openly transgender woman, physician, and the nation's Assistant Secretary

of Health, was a relevant stakeholder who shared her opinions about the development of SOC 8. Every stakeholder had the opportunity to provide feedback on the draft of SOC 8 as publicly released in 2021. Any input from Admiral Levine was simply stakeholder input, and in fact, there was significant stakeholder input regarding SOC 8 following the public comment process.

21. SOC 8 included one substantive change based on public feedback, which was the elimination of suggested age thresholds for the initiation of certain gender affirming medical interventions for adolescents. But the removal of these thresholds from the *draft* of SOC 8 following public comment and stakeholder input is in keeping with the process outlined for the development of SOC 8. What's more, removing those suggestions actually continued the philosophy of care from Standards of Care, Version 7, which made clear that clinical judgment is paramount. SOC 7, released in 2011, also did not have a minimum age requirement for chest surgery for transgender boys. When suggested ages were placed in the SOC 8 draft, each suggested age was followed by the text, "unless there are significant, compelling reasons to take an individualized approach." And SOC 8 as published states that "an individualized approach to clinical care is considered both ethical and necessary." (Coleman, et al., 2022, at S45). the Frequently Asked Questions (FAQs) associated with SOC 8 provide an explanation:

> Minimum ages for providing gender-affirming medical care were removed from the SOC-8 and replaced by strengthened criteria to help codify the framework that enables every [transgender and gender diverse] adolescent the opportunity to get their appropriate medical needs met at the appropriate time; these changes to the SOC-8 reflect the fact that one-size-fits-all health care models, especially transgender care, are not accurate or appropriate for every individual person.
>
> Prior to its September 2022 release, WPATH announced a public open comment period to the draft SOC-8 in December 2021 through January 2022. This comment period allowed input and feedback from professionals in the field from around the world who were concerned that the listing of ages would lead to further limitations to care by creating or reinforcing arbitrary boundaries to care and/or by ignoring possible contributing health factors including mental health, family support, or other individual health needs. After comments were reviewed and discussed by

> chapter authors and co-chairs, it was determined that the specific ages would be removed to ensure greater access to care for more people.

(WPATH, SOC 8 FAQs).

22. It should be noted that surgery is rare for minors with gender dysphoria, and usually it is just limited to chest surgery for those who need it. As SOC 8 states, "Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined by a multidisciplinary team experienced in adolescent and gender development." (Coleman, et al., 2022, at S66). Genital surgery continues to be incredibly rare for minors. SOC 8 recommends about non-chest surgeries that "an assessment of the adolescent's ability to adhere to postsurgical care recommendations and to comprehend the long-term impacts of these procedures on reproductive and sexual function is crucial." (Coleman, et al., 2022, at S66). It further specifically states that phalloplasty "is not recommended …[to] be considered in youth under 18 at this time." *Id.*

23. The Alabama brief further claims that WPATH SOC 8's statement of the medical necessity of transgender care was crafted in response to recent legal actions. This is, again, false. In fact, the medical necessity of transgender care has long been WPATH's position. WPATH's position statement on the medical necessity of transgender care dates back to 2008, which based on the Standards of Care Version 6, states in part:

> Medically necessary sex reassignment procedures also include complete hysterectomy, bilateral mastectomy, chest reconstruction or augmentation as appropriate to each patient, (including breast prostheses if necessary), genital reconstruction (by various techniques which must be appropriate to each patient, including, for example, skin flap hair removal, penile and testicular prostheses, as necessary), facial hair removal, and certain facial plastic reconstruction as appropriate to the patient. Furthermore, not every patient will have a medical need for identical procedures; clinically appropriate treatments must be determined on an individualized basis with the patient's physician. These procedures are not "cosmetic" or "elective" or for the mere convenience of the patient, but are understood to be medically necessary for the treatment of the diagnosed condition.

(Whittle, et al., 2009).

24. A very similar statement on medical necessity was released by WPATH in 2016, updated based on Standards of Care Version 7 (WPATH, 2016). The WPATH Board in 2016 upon releasing this update medical necessity determined that the next version of the medical necessity statement would be based on and included in the WPATH SOC 8, and therefore this was among the last text written for SOC 8, as an update of the 2008 and 2016 statements.

25. The Alabama brief states that practice guidelines should be written by those "sufficiently familiar with the topic, but not professionally engaged in performing, researching, or advocating for the practices under review." But in fact, the Institute of Medicine, the Agency for Healthcare Quality and Research in the United States and Canada, and the UK National Institute for Health and Clinical Excellence, among others, all recommend the inclusion and involvement of individuals with expertise in the pertinent content areas as essential to practice guideline development. This includes clinicians and researchers in the appropriate field. The diverse group of authors of SOC 8 came from many fields, with expertise in their disciplines as well as in transgender care. It would be atypical for clinical practice guidelines not to include content experts, including clinicians and researchers in the appropriate field, and undermine both the rigor and relevance of the clinical practice guidelines to exclude those actually involved in researching and delivering the care in question. Indeed, I am unaware of a single well-established and accepted clinical practice guideline in any other field of medicine that excluded experienced clinical practitioners in the relevant field from the guideline development process.

The Cass Review

26. The Alabama and DNH briefs criticize the omission of the Cass Review's Report in the declarations in support of plaintiffs. The Cass Review has been broadly criticized for, among other things, not following established standards for evaluating evidence and evidence quality;

failing to properly account for the balance between benefits and harms, patient values and preferences, and resource utilization in this context; misrepresenting data; and engaging in improper speculation and unfounded assertions. (McNamara, et al., 2024). Similarly, an analysis of the systematic reviews commissioned by the Cass Review using the ROBIS tool to assess risk of bias "resulted in all of the systematic reviews being judged as at a high risk of bias due to both methodological limitations and failure to adequately address these limitations in their conclusions and interpretations." (Noone, et al., 2024). In addition, the primary research commissioned by the Cass Review had several methodological limitations that it failed to disclose, "in stark contrast to the exclusion of research with far fewer limitations from the systematic reviews." *Id.* Thus, the Cass Review has been criticized for applying a "seeming double standard," which "calls into question" its claims that it was systematically reviewing and evaluating the evidence. *Id.* Ultimately, "the Cass Report's application of evidence-based medicine (EBM) to Gender-Affirming Care (GAC) is flawed" and "the Review's understanding of transgender identities and experiences deploys a paternalistic lens that disregards the competence of transgender young people." *Id.*

27. Because of concerns of its members, the British Medical Association has commissioned a task force to evaluate the Cass Review and its methodology and recommended "a pause to the implementation of the Cass Review's recommendations" and that "transgender and gender-diverse patients [be able to] continue to receive specialist healthcare, regardless of their age." (BMA, 2024). The British Medical Association also expressed concern about the Cass Review's Report's "impact on transgender healthcare provision because of its unsubstantiated recommendations driven by unexplained study protocol deviations, ambiguous eligibility criteria, and exclusion of trans-affirming evidence." *Id.*

28. While the Cass Review has been firmly criticized for its misapprehension of gender-affirming care and transgender identity, its methodological flaws, and the double standard it applied to gender-affirming care, it is worth noting that it nonetheless concurs with the WPATH Standards of Care and the Endocrine Society Clinical Practice Guidelines that: (1) medical care is appropriate for some transgender youth, (2) a holistic, comprehensive, and individualized assessment is needed, and (3) co-occurring mental health conditions should be properly treated before medically affirming interventions. (McNamara, et al., 2024).

29. The Cass Review's systematic reviews did show benefits from gender affirming medical interventions. For example, with regards to puberty blockers, the review found "*no change* before and after" receiving such treatment in measurements of gender dysphoria and body satisfaction. (Taylor, et al., 2024a). This is the desired and expected outcome of this treatment for those measures. And with regards to hormone therapy, the review found that the studies showed "*reduction in dysphoria*," "*lower dissatisfaction* in those receiving hormone treatment compared with those who had not," and that "evidence from mainly pre-post studies suggests hormones are associated with *improvements in depression, anxiety and other mental health difficulties after 12 months of treatment*," noting that "[m]oderate-quality evidence suggests mental health may be improved during treatment…." (Taylor, et al. 2024b).

30. Ultimately, NHS England decided to not make puberty blockers available as "a routine commissioning treatment option" for treating gender dysphoria and the Cass Review has recommended their continued availability through a research programme. (NHS, 2024a; Cass, 2024). In addition, gender-affirming hormones continue to be available to minors. (NHS England, 2024b; Cass, 2024).

Gender Dysphoria

31. The DNH brief dismisses Gender Dysphoria as a "psychological condition," as if it does not require medical treatment. Gender Dysphoria is a serious medical condition that warrants medical treatment when appropriate. It is characterized by the distress resulting from the misalignment between a person's gender identity, which has biological bases, and their body (i.e., physical characteristics). Gender Dysphoria is listed as a mental disorder in the Diagnostic and Statistical Manual of Mental Disorders, the DSM-5-TR, because the diagnosis focuses on the significant distress resulting between the incongruence between one's gender identity and body.

GRADE and Systematic Reviews

32. As an initial matter, systematic reviews do not report new research findings but are conducted to assess existing research. The DNH brief refers to some purported systematic reviews of the literature examining gender-affirming care for minors to argue that there is not sufficient evidence supporting the provision of this care.[1]

33. Further, it is important to put GRADE scores of systematic reviews in context. Chong, et al. (2023) found that only 36% of national guidelines for care were based on strong or moderate GRADE scores. Recommendations were often based on a comparison with alternatives; there is no evidence base to support conversion therapy or other psychotherapeutic interventions as an alternative for those who need gender-affirming medical treatment.

[1] Some of the reviews upon which the DNH brief relies, like the Finland and Florida commissioned reviews, are reports largely authored or commissioned by government committees that have not been published in any medical or scientific journals and have not been subjected to the peer-review process.

34. In one large study of systematic reviews, only 5.6% of all medical interventions, and 0.0% of all endocrine interventions had a high GRADE score. Most medical interventions had low or very low GRADE scores. (Howick, et al 2022).

35. In other studies, including one of all systematic reviews in the Cochrane database published over an 18-month period, only a small percentage of systematic reviews of medical interventions have a high GRADE score; for a majority of systematic reviews of medical interventions, GRADE scores are low or very low. (Fleming et al., 2016, Howick, et al., 2020). In a study of systematic reviews of interventions in anesthesiology, critical care medicine, and emergency medicine, only 10% had high GRADE scores, but banning the practice of anesthesiology, critical care medicine, and emergency medicine has not been contemplated. (Conway, et al, 2017). For complex interventions, for which gender affirming care certainly qualifies, no high GRADE scores were found for systematic reviews of any complex intervention. (Movsisyan, et al., 2016).

36. It is also worth noting that many of the systematic reviews upon which the DNH brief relies did not involve subject-matter experts in the field of gender medicine. For example, as the draft guideline "Gender incongruence and gender dysphoria in childhood and adolescence - diagnosis and treatment (S2k)" published by the Association of Scientific Medical Societies in Germany (AWMF) in 2024 noted, the Cass Review and the review from Finland purposefully excluded subject-matter experts from participating in the review, at most merely consulted with some externally, and in formulating the recommendations. (DGKJP, 2024). However, this is contrary to recommended practice when conducting systematic reviews. Both the Institute of Medicine (now the National Academy of Medicine) and Cochrane recommend that individuals with subject matter expertise be included in the performance of systematic reviews. (Lasserson, et

al., 2023; IOM, 2011). More specifically, the IOM states that a systematic review team "should include individuals with appropriate expertise and perspectives" and specifically recommends as a requirement that they "include expertise in the pertinent clinical content areas." (IOM, 2011). As Cochrane explains,

> Review teams must include expertise in the topic area under review. Topic expertise should not be overly narrow, to ensure that all relevant perspectives are considered. Perspectives from different disciplines can help to avoid assumptions or terminology stemming from an over-reliance on a single discipline. Review teams should also include expertise in systematic review methodology, including statistical expertise.
>
> Arguments have been made that methodological expertise is sufficient to perform a review, and that content expertise should be avoided because of the risk of preconceptions about the effects of interventions (Gøtzsche and Ioannidis 2012). However, it is important that both topic and methodological expertise is present to ensure a good mix of skills, knowledge and objectivity, because topic expertise provides important insight into the implementation of the intervention(s), the nature of the condition being treated or prevented, the relationships between outcomes measured, and other factors that may have an impact on decision making.

(Lasserson, et al., 2023).

37. In short, the DNH brief uses systematic reviews in ways they are not intended to be used. If only medical interventions with high GRADE scores were permitted by law, most medical interventions and all complex interventions would be banned. In a study of systematic reviews of interventions in anesthesiology, critical care medicine, and emergency medicine, only 10% had high GRADE scores, but banning the practice of anesthesiology, critical care medicine, and emergency medicine has not been contemplated. (Conway, et al, 2017).

Clinical Practice Guidelines

38. In developing guidelines that provide recommendations on clinical care, panels of experts do consider the evidence of a treatment's efficacy. But "[m]any factors play a role in making recommendations." (Djulbegovic, et al., 2009). They also consider the benefits and harms of both treatment and no treatment, patients' values and preferences, and the resources required to

offer treatment. (IOM, 2011; Guyatt, et al., 2008). As such, "evidence quality is not synonymous with clinical recommendations." (McNamara, et al., 2024; see also Platz, 2021 ("While evidence is a fundamental aspect for decision-making in evidence-based practice, it is in itself not a recommendation.")).

39. Many treatments for other conditions are widely accepted and in use without having been studied through randomized, controlled clinical trials. And many drugs for cancer and hematologic disorders have been FDA approved without a randomized controlled trial. (Hatswell, et al., 2016). Other drugs have been FDA approved with randomized controlled trials for one indication but are commonly used for another condition or in a different population than the one for which it was approved. (Wittich, et al., 2012).

40. Indeed, recommendations are based on a comparison with alternatives (Platz, 2021); there is no evidence base to support conversion therapy or other psychotherapeutic interventions as an alternative for those who need gender-affirming medical treatment.

41. Adopting policies prohibiting gender affirming medical interventions is not an alternative, rather it causes harms. Indeed, the introduction and passage of anti-transgender laws and policies like the Executive Orders have been shown to negatively affect the mental health and wellbeing of transgender youth, including increases in suicidality. For example, one study has documented that suicide attempts by transgender youth rose, often dramatically, in states which passed laws limiting transgender rights. (Lee, et al., 2024).

42. The harm of providing no treatment for gender dysphoria is not discussed by either the DNH or Alabama briefs. As discussed in my initial declaration (Section H), the denial of medically indicated care to transgender people not only results in the prolonging of their gender

dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality.

Additional Reponses

43. The DNH brief ignores the many studies documenting decreased suicidality following gender affirming treatment (discussed in the initial declaration) to focus on the lack of data on the impact of care on completed suicides. Measuring impact on completed suicide in youth is difficult even with larger populations, such as youth with depression. However, gender affirming treatment is first a treatment of gender dysphoria itself; it also has the secondary benefit of reducing depression, anxiety, suicidal thoughts and attempts, and overall quality of life.

44. The DNH brief attempts to draw a distinction between chest masculinization surgery for gender dysphoria in transgender male youth and chest masculinization surgery for gynecomastia in cisgender male youth. Like transgender youth, this surgery in cisgender youth is usually performed only when the youth is distressed by the feminine aspects of his chest. The quality of evidence per a systematic review for gynecomastia treatment in cisgender males is very low. (Fagerlund, et al., 2015). Satisfaction rates for gynecomastia surgery for cisgender males are much lower (Ridha, et al., 2008) than for chest masculinization surgery in transgender males (Bruce, et al., 2023). Nonetheless, of all the breast reduction chest surgeries performed among minors, both cisgender male minors and transgender minors, in 2019, 97% were performed on cisgender male minors (Dai, et al., 2024).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 26th day of February 2025.

Dan H. Karasic, M.D.

Exhibit C

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Exhibit D

Appendix A METHODOLOGY

1. Introduction

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Evidence-based research provides the basis for sound clinical practice guidelines and recommendations but must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

The SOC-8 revision committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers and stakeholders with diverse perspectives and geographic representation. All committee members completed conflict of interest declarations.*

A guideline methodologist assisted with the planning and development of questions, and an independent team undertook systematic reviews that were used to inform some of the statements for recommendations. Additional input to the guidelines was provided by an international advisory committee, legal experts, and feedback received during a public comment period. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus of the final recommendations was attained using a Delphi process that included all members of the Standards of Care Revision committee and required that recommendation statements were approved by 75% of members. Supportive and explanatory text of the evidence for the statements were written by chapter members. Drafts of the chapters were reviewed by the Chair and the Co-Chairs of the SOC Revision Committee to ensure the format was consistent, evidence was properly provided, and recommendations were consistent across chapters. An independent team checked the references used in the SOC-8 before the guidelines were fully edited by a single professional. A detailed overview of the SOC-8 Methodology is described below.

2. Difference between the methodology of the SOC-8 and previous editions

The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are:

- The involvement of a larger group of professionals from around the globe;
- A transparent selection process to develop the guidelines steering committee as well as to select chapter leads and members;
- The inclusion of diverse stakeholders in the development of the SOC-8
- Management of conflicts of interest
- The use of a Delphi process to reach agreement on the recommendations among SOC-8 committee members
- The involvement of an independent body from a reputable university to help develop the methodology and undertake independent systematic literature reviews where possible
- Recommendations were graded as either "recommend" or "suggest" based upon the strength of the recommendations.
- The involvement of an independent group of clinical academics to review citations.
- The involvement of international organizations working with the transgender and gender diverse (TGD) community, members of WPATH and other professional organizations as well as the general public who provided feedback through a public comment period regarding the whole SOC-8.

3. Overview of SOC-8 development Process

The steps for updating the Standards of Care are summarized below:

1. Establishing Guideline Steering Committee including Chair, and Co-Chairs (July 19, 2017)
2. Determining chapters (scope of guidelines)
3. Selecting Chapter Members based upon expertise (March 2018)
4. Selecting the Evidence Review Team: John Hopkins University (May 2018)
5. Refining topics included in the SOC-8 and review questions for systematic reviews
6. Conducting systematic reviews (March 2019)
7. Drafting the recommendation statements
8. Voting on the recommendation statements using a Delphi process (September 2019–February 2022)
9. Grading of the recommendations statements
10. Writing the text supporting the statements
11. Independently validating the references used in the supportive text
12. Finalizing a draft SOC-8 (December 1, 2021)
13. Feedback on the statements by International Advisory Committee
14. Feedback on the entire draft of the SOC-8 during a public comment period (November 2021–January 2022)
15. Revision of Final Draft based on comments (January 2022- May 2022)
16. Approval of final Draft by Chair and Co-Chairs (June 10, 2022)
17. Approval by the WPATH Board of Directors
18. Publication of the SOC-8
19. Dissemination and translation of the SOC-8

3.1. Establishment of Guideline Steering Committee

The WPATH Guideline Steering Committee oversaw the guideline development process for all chapters of the Standards of Care. Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board from WPATH members applying for these positions. Job descriptions were developed for the positions of Co-Chairs, Chapter Leads, Chapter Members and Stakeholder. WPATH members were eligible to apply by completing an application form and submitting their CV. The Board of WPATH voted for the position of co-chair (one member of the board did not participate in view of conflict of interest). The chairs and co-chairs selected the chapter leads and members (as well as stakeholders) based on the application form and CVs.

The Guideline Steering Committee for Standards of Care 8th Version are:

- Eli Coleman, PhD (Chair) Professor, Director and Academic Chair, Institute for Sexual and Gender Health, Department of Family Medicine and Community Health, University of Minnesota Medical School (USA)
- Asa Radix, MD, PhD, MPH (Co-chair) Senior Director, Research and Education Callen-Lorde Community Health Center Clinical Associate Professor of Medicine New York University, USA
- Jon Arcelus, MD, PhD (Co-chair) Professor of Mental Health and Well-being Honorary Consultant in Transgender Health University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

3.2. Determination of topics for chapters

The Guideline Steering Committee determined the chapters for inclusion in the Standards of Care by reviewing the literature and by reviewing the previous edition of the SOC. The chapters in the Standards of Care 8th Version:

1. Terminology
2. Global Applicability
3. Population estimates
4. Education*
5. Assessment of Adults
6. Adolescent
7. Children
8. Nonbinary
9. Eunuch
10. Intersex
11. Institutional environments
12. Hormone Therapy
13. Surgery and Postoperative Care
14. Voice and communication
15. Primary care
16. Reproductive Health
17. Sexual Health
18. Mental Health

* The Education Chapter was originally intended to cover both education and ethics. A decision was made to create a separate committee to write a chapter on ethics. In the course of writing the chapter, it was later determined topic of ethics was best placed external to the SOC8 and required further in-depth examination of ethical considerations relevant to transgender health.

3.3. Selection of chapter members

A call for applications to be part of the SOC-8 review committee (chapter lead or member) was sent to the WPATH membership. The Chairs of the Guideline Steering Committee appointed the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members were required to be WPATH Full Members in good standing and content experts in transgender health, including in at least one chapter topic. Chapter Leads reported to the Guideline Steering Committee and were responsible for coordinating the participation of Chapter Members. Chapter members reported directly to the Chapter Lead.

Each chapter also included stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that included a transgender child, sibling, partner, parent, etc. Stakeholders were not required to be full members of WPATH.

The Chapter Members were expected to:

- Participate in the development refinement of review questions
- Read and provide comments on all materials from the Evidence Review Team
- Critically review draft documents, including the draft evidence report
- Review and assess evidence and draft recommendations
- Participate in the Delphi consensus process
- Develop the text to back up the recommendation statements
- Grade each statement to describe the strength of the recommendation
- Review and address the comments from the Chairs during the whole process
- Develop the content of the chapters
- Review comments from public comments and assist in the development of a revision of guidelines
- Provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members was provided, as needed. Training content included formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation state-

ments, grading the evidence and the recommendations, and information about the guideline development program and process.

A total of 26 chapter-leads were appointed (some chapters required co-leads), 77 chapter members and 16 stakeholders. A total of 127 were selected. During the SOC process, 8 people left, due to personal or work-related issues. Therefore, there were 119 final authors of the SOC-8.

3.4. Selection of the evidence review team

The WPATH Board issued a request for applications to become the Evidence Review Team. For Standards of Care 8th Version the WPATH Board engaged the Evidence Review Team at Johns Hopkins University under the leadership of Karen Robinson.

- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

Dr Robinson also guided the steering committee in the development of the SOC-8 by providing advice and training in the development of PICO questions, statements, and the Delphi process as well as undertaking a very rigorous systematic literature review where direct evidence was available.

Conflict of interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team were asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, are personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

3.5. Refinement of topics and review of questions

The Evidence Review Team abstracted the recommendation statements from the prior version of the Standards of Care. With input from the Evidence Review Team, the Guideline Steering Committee and Chapter Leads determined:

- Recommendation statements that needed to be updated
- New areas requiring recommendation statements

3.6. Conduct the systematic reviews

Chapter Members developed questions to help develop recommendation statements. For the questions eligible for systematic review, the Evidence Review Team drafted review questions, specifying the Population, Interventions, Comparisons, and Outcomes (PICO elements). The Evidence Review Team undertook the systematic reviews. The Evidence Review Team presented evidence tables and other results of the systematic reviews to the members of the relevant chapter for feedback.

Protocol

A separate detailed systematic review protocol was developed for each review question or topic, as appropriate. Each protocol was registered on PROSPERO.

Literature search

The Evidence Review Team developed a search strategy appropriate for each research question including MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team searched additional databases as deemed appropriate for the research question. The search strategy included MeSH and text terms and was not limited by language of publication or date.

The Evidence Review Team hand searched the reference lists of all included articles and recent, relevant systematic reviews. The Evidence Review Team searched ClinicalTrials.gov for any additional relevant studies.

Searches were updated during the peer review process.

The literature included in the systematic review was mostly based on quantitative studies conducted in Europe, the US or Australia. We acknowledge a bias towards perspectives from the global north that does not pay sufficient attention to the diversity of lived experiences and perspectives within transgender and gender diverse (TGD) communities across the world. This imbalance of visibility in the literature points to a research and practice gap that needs to be addressed by researchers and practitioners in the future in order to do justice to the support needs of all TGD people independent of gender identification.

Study selection

The Evidence Review Team, with input from the Chapter Workgroup Leads, defined the eligibility criteria for each research question *a priori*.

Two reviewers from the Evidence Review Team independently screened titles and abstracts and full-text articles for eligibility. To be excluded, both reviewers needed to agree that the study met at least one exclusion criteria. Reviewers resolved differences regarding eligibility through discussion.

Data extraction

The Evidence Review Team used standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer abstracted the data, and a second reviewer confirmed the abstracted data.

Assessment of risk of bias

Two reviewers from the Evidence Review Team independently assessed the risk of bias for each included study. For

randomized controlled trials, the Cochrane Risk of Bias Tool was used. For observational studies, the Risk of Bias in Non-Randomized Studies—of Interventions (ROBINS-I) tool was used. Where deemed appropriate, existing recent systematic reviews were considered and evaluated using ROBIS.

Data synthesis and analysis

The Evidence Review Team created evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups reviewed and provided comments on the evidence tables.

Grading of the evidence

The Evidence Review Team assigned evidence grades using the GRADE methodology. The strength of the evidence was obtained using predefined critical outcomes for each question and by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

3.7. Drafting of the Recommendation Statements

Chapter Leads and Members drafted recommendation statements. The statements were crafted to be feasible, actionable, and measurable.

Evidence-based recommendation statements were based on the results of the systematic, and background literature reviews plus consensus-based expert opinions.

The Chair and Co-Chairs and Chapter Leads reviewed and approved all recommendation statements for clarity and consistency in wording. During this review and throughout the process any overlap between chapters was also addressed.

Many chapters had to work closely together to ensure consistency of their recommendations. For example, as there are now separate chapters for childhood and adolescence, to ensure consistency between both chapters, some authors were part of both chapters. For a similar reason, when applicable, a workgroup collaborated with other Chapter Workgroups on topics shared between the chapters (i.e., Assessment of Children, Assessment of Adults, Hormone Therapy, Surgery and Postoperative Care and Reproductive Health).

3.8. Approval of the recommendations using the Delphi process

Formal consensus for all statements was obtained using the Delphi process (a structured solicitation of expert judgements in three rounds). For a recommendation to be approved, a minimum of 75% of the voters had to approve the statement. A minimum of 65% of the SOC-8 members had to take part in the Delphi process for each statement. People who did not approve the statement had to provide information as to the reasons for their disapproval, so the statement could be modified (or removed) according to this feedback. Once modified, the statement was put through the Delphi process again. If after 3 rounds the statement was not approved, the statement was removed from the SOC. Every member of the SOC voted for each statement. There was a response rate between (74.79% and 94.96%) for the statements.

3.9. Grading criteria for statements

Once the statements passed the Delphi process, chapter members graded each statement using a process adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. This a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations (Guyatt et al., 2011). The statements were graded based on factors such as:

- The balance of potential benefits and harms
- Confidence in that balance or quality of evidence
- Values and preferences of providers and patients
- Resource use and feasibility

The statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
  - the evidence is of high quality
  - estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice)
  - there are few downsides of therapy/intervention/strategy
  - there is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
- Weak recommendations ("we suggest") are for those interventions/therapy/strategies where:
  - there are weaknesses in the evidence base
  - there is a degree of doubt about the size of the effect that can be expected in practice
  - there is a need to balance the potential upsides and downsides of interventions/therapy/strategies
  - there are likely to be varying degrees of acceptance among providers and patients or those for whom the recommendation applies.

3.10. Writing of the text supporting the statements

Following the grading of the statements, the Chapter Workgroups wrote the text providing the rationale or reasoning for the recommendation. This included providing the available evidence, providing details about potential benefits and harms, describing uncertainties, and information about implementation of the recommendation, including expected barriers or challenges among others. References use APA-7 style, to support the information in the text. Links to resources are also provided, as appropriate. The text, including whether a recommendation has been described as strong or weak, was reviewed and approved by the Chair and Co-Chairs.

3.11. External validation of references used to support the statements

A group of independent clinical academics working in the field of transgender health reviewed the references used in every chapter in order to validate that the references were appropriately used to support the text. Any queries regarding the references were sent back to the chapters for review.

3.12. Finalizing a draft SOC-8

A final SOC-8 draft was made available for comments.

3.13. Distribute Standards of Care for review by international advisors

The statements of the recommendations of Standards of Care 8th were circulated among the broader Standards of Care Revision Committee and the WPATH International Advisory Group, which included the Asia Pacific Transgender Network (APTN), the Global Action for Transgender Equality (GATE), the International Lesbian, Gay, Bisexual, Transgender, Intersex Association (ILGA), and Transgender Europe (TGEU).

3.14. Public comment period

The revised draft version of the Standards of Care document was posted online for comment from the public, including WPATH members, on the WPATH website. A 6-week period was allocated for comments. A total of 1,279 people made comments on the draft with a total of 2,688 comments.

3.15. Revision of final draft based on comments

The Chapter Leads and Guideline Steering Committee considered the feedback and made any necessary revisions. All public comments were read and, where appropriate, integrated into the background text.

As part of this process, 3 new Delphi statements were developed and 2 were modified enough to require a new vote by the SOC-8 committee. This meant a new Delphi process was initiated in January 2022. The results of this Delphi process were accepted by the chapters, and the new statements were added or modified accordingly. The new supportive text was added.

All the new versions of the chapters were reviewed again by the Chair and Co-Chairs and changes or modifications were suggested. Finally, once the Chairs and the Chapter Members were satisfied with the draft, the chapter was finalized.

All new references were double checked by an independent member.

3.16. Approval of final draft by Chair and Co-Chairs

Modifications were reviewed by the Chairs and were accepted by them.

3.17. Approval by the WPATH Board of Directors

The final document was presented to the WPATH Board of Directors for approval and it was approved on the 20th of June 2022.

3.18. Publication of the SOC-8 and dissemination of the Standards of Care

The Standards of Care was disseminated in a number of venues and in a number of formats including publication in the International Journal of Transgender Health (the official scientific journal of WPATH).

4. Plan to Update

A new edition of the SOC (SOC-9) will be developed in the future, when new evidence and/or significant changes in the field necessitating a new edition is substantial.

*The development of SOC-8 was a complex process at a time of COVID-19 and political uncertainties in many parts of the world. Members of the SOC-8 worked on the SOC-8 on top of their day-to-day job, and most of the meetings took place out of their working time and during their weekends via Zoom. There were very few face-to-face meetings, most of them linked to WPATH, USPATH or EPATH conferences. Committee members of the SOC-8 were not paid as part of this process.