Standards of Care Version 8 Update

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Disclosures

Co-Chair Standards of Care 8 Revision Committee, World Professional Association for Transgender Health
Learning Objectives

- Describe changes in trans health guidelines 1979 - present
- Explain the process of the WPATH SOC guideline review
  - Describe the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system in clinical practice guidelines
Case Presentation – Tim

- 34 year old white transgender man wishes to continue testosterone
- Metoidioplasty in Serbia (42)
- Top surgery in USA (22)
- Healthy, no medical issues
- Meds: transdermal testosterone
Clinical Questions

- What is the optimal dose of testosterone?
- Is breast cancer screening recommended?
- Does testosterone dosing need adjustment for older age?
- Is oophorectomy recommended?
- Should aromatase inhibitors be used?
Case Presentation - Rachel

- 54 year old transgender woman on hormones
- At what age should we decrease or stop hormones?
- What health screenings does she need?
What is a Guideline?

“Guidelines are recommendations intended to assist providers and recipients of health care and other stakeholders to make informed decisions”

*World Health Organization*
From Evidence to Recommendations

- Make judgements based on
  - Quality of evidence, but also
  - Weighing benefits and harms
  - Resources, costs

- Application
  - Who is intended to use the guideline?
  - What is the scope of the guideline?
  - Who is it relevant to?
  - What questions need to be answered?
STATE OF THE ART AND SCIENCE

What’s in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care

Madeline B. Deutsch, MD, MPH, Asa Radix, MD, MPH, and Sari Reisner, ScD
Timeline for WPATH Guidelines

1935 - Methyltestosterone
1938 - Di-Ethyl Stilbesterol (DES)
1939 - Testosterone use (Dillon)
1941 - Conjugated estrogens
1966 - The Transsexual Phenomenon
1979 - HBIGDA standards of care
2012 - WPATH SOC 7
2017 - Endocrine Society Ver 2
2019 - WPATH SOC8 (in progress)
Guideline Process

1. Identify scope
2. Convene group
3. Refine questions
4. Assess evidence
5. Recommendation Statements
6. Delphi Process*
7. Draft guideline
8. External review
9. Disseminate guideline

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WPATH Standards of Care: Guideline Development Methodology

9 July 2018

Objective

WPATH Mission
The World Professional Association for Transgender Health (WPATH) is an interdisciplinary professional and educational organization dedicated to transgender health. The mission of WPATH is to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health.

Purpose of the Standards of Care
The overall goal of the guidelines from WPATH, called “Standards of Care”, is to provide clinical guidance for health professionals to assist transgender, and gender nonconforming/ people with safe and effective pathways to achieve lasting personal comfort with their gendered selves, and to maximize their overall health, psychological well-being, and self-fulfillment. This assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments.

Target Audience
While this is primarily a document for health professionals, the Standards of Care may also be used by individuals, their families, and social institutions to promote optimal health for members of this diverse population.

Target Population
1. Identify Scope
What is Different about the Scope?

- This version of the Standards of Care is the first to be developed using an evidence-based approach.
- Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.
2. Convene Group
WPATH SOC 8 Team

- Medical/scholars
  - Surgery/internal medicine (endo)/primary care/behavioral health/voice/epidemiology/education/law etc., (composition important)
- Community
  - TGNB consumers, healthcare providers
- Methods
  - Evidence Based Team (Technical staff, epidemiologists)
- Administrative support
  - Veritas
- Technical writer
Guidelines Committee

Nomination of co-chairs
- Eli Coleman (chair)
- Jon Arcelis & Asa Radix (co-chairs)

Chapter leads
- 50 applications received
- 24 leads chosen

Working groups/stakeholders
- 164 applications received
- 18 counties
Chapter Leads

Sam Winter (AUSTRALIA)
Sari Reisner (USA)
Michael Goodman (USA)
Mick van trosenburg (Netherlands)
Madeline Deutsch (USA)
Amy Tishelman (USA)
Annelou de Vries (NETHERLANDS)
Scott Leibowitz (USA)
Walter Bouman (UK)
Joz Motman (Belgium)
Christina Richards (UK)
Gail Knudson (CANADA)

Dan Karasic (USA)
Vin Tangpricha (USA)
Timo Nieder (GERMANY)
Leena Nahata (USA)
Adrienne Hancock (USA)
Stan Monstrey (BELGIUM)
Loren Schechter (USA)
Randi Ettner (USA)
George Brown USA
Heino Meyer (USA)
Thomas Johnson USA
Lin Fraser (USA)
Chapter Members
What’s New for SOC8?

- Assessment, Support and Therapeutic Approaches for Children
- Assessment, Support and Therapeutic Approaches for Adolescents
- Assessment, Support and Therapeutic Approaches for Non-binary individuals
- Reproductive Health for Adolescents and Adults
- Applicability of the Standards of Care to Eunuchs
- Competency, Training, Education
- Ethics
How do we move from questions to guidelines creation?

3. Refine Questions
Examples of Areas of Consideration

- Social transition in children?
- Recommendations for adolescents accessing blockers, hormones, surgeries?
  - Age
  - Criteria
  - Number of letters
  - Qualifications of professionals providing letters
  - Hormones for surgery
  - Living in gender confirming role
Examples of Areas of Consideration

- Recommendations for adults accessing hormones and surgeries?
  - Criteria
  - Number of letters
  - Qualifications of professionals providing letters
  - Hormones prior to surgery
  - Living in gender confirming role

- Informed consent – this means something different to everyone
Formulate a Question

What is the impact of puberty blockers on transgender adolescents?

- Population: *Transgender adolescents (tanner 2)*
- Intervention: *Puberty blockers*
- Comparison: *No blockers*
- Outcomes:
  - *Psychological outcomes (depression, anxiety)*
  - *Bone mineral density*
  - *Cognitive issues*
  - *Fertility*

*Consider and balance both desirable and undesirable outcomes*
Examples of questions when no systematic review is needed (best practice)

- **Terminology**
  - What words should we use to describe transgender people?
  - What words should we use for professionals?
  - What should the document be called?

- **Global**
  - How can the SOC be inclusive of non-western, European/North American cultures and identities?
  - What are the differences in assessment, care, treatment?
Systematic Review

- Necessary to evaluate outcomes across studies
- Rate quality of evidence
- Leads to creation of recommendations
4. Assess Evidence
Methodology

- All chapters have to include methodology
  - Reviewing past SOC
  - Systematic reviews
  - Published & grey literature

- Where no data exist
  - Convening meetings
  - Special issues, e.g., nonbinary issue IJT
5. Recommendation Statements
Education Chapter Recommendation

- We advise that all members of the healthcare workforce, receive cultural-competency training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.
Examples of Recommendations

- **Reproductive Health**: In order to optimize long-term reproductive and psychosocial outcomes we advise that patients and families receive information and counseling from their health care team regarding the potential risks of hormonal interventions on future fertility prior to initiation of these therapies.
6. Delphi Process
Delphi Process

- Statements are loaded to a Survey Monkey and sent out to all members of the SOC8 Committee.
- Committee members have to either agree to the statement as is, or disagree and provide comments/suggestions.
- Statements that have 80% consensus were accepted, and those that do not reach 80% consensus have to be redrafted by the Chapters and go through the Delphi process again for a maximum of 3 rounds.
Q4 We advise that clinicians provide information to gender non-binary people about the effects of hormonal therapies/surgery on future fertility and options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

Answered: 76  Skipped: 0

<table>
<thead>
<tr>
<th>#</th>
<th>PLEASE PROVIDE COMMENTS, ESPECIALLY IF YOU RESPONDED 1-6</th>
<th>DATE</th>
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<tbody>
<tr>
<td>1</td>
<td>It is worthy to note that it is just &quot;surgery&quot; but what is this surgery or surgeries affirming? Notice to that gender affirming is found in questions #2 and #3.</td>
<td>9/4/2019 9:13 AM</td>
</tr>
<tr>
<td>2</td>
<td>Who do you mean with &quot;clinicians&quot;?</td>
<td>9/4/2019 5:06 AM</td>
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<td>3</td>
<td>Who is the clinician?</td>
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<td>4</td>
<td>Again, it would be important to double-check that the statement in the hormone chapter (for trans and gender diverse people) is consistent with the approach here.</td>
<td>9/3/2019 8:58 PM</td>
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7. Draft Guideline
Structure for Chapters

- Background – brief introduction outlining scope of chapter (1-2 pages maximum).
- Summary of Recommendations – each recommendation statement in a box.
- Within main text, with subheadings/sections of chapter as warranted, the recommendations with accompanying text. (maximum of approximately 3 paragraphs per recommendation statement)
GRADE

- Grading of Recommendations Assessment, Development and Evaluation
- 2000 - Working group to establish guidance
- Goal to develop a logical, transparent system for grading
  - the quality of evidence (high, moderate, low, or very low)
  - strength of recommendations (strong or weak)
- Many organizations now using GRADE: WHO, CDC-ACIP, ACP, IDSA

http://www.gradeworkinggroup.org/
GRADE

- Quality of evidence:
  - ⭐⭐⭐⭐ (High) *RCTs*
  - ⭐⭐⭐ (Moderate)
  - ⭐⭐ (Low) *Observational studies* ⭐ (Very low)

- Recommendation:
  - Weak
  - strong
8. External Review
Gathering Feedback

- 43 TGNB members of the guidelines committee
- Global Transgender Advisory Group (international organizations) to provide feedback
- Beta version to be posted on WPATH website (www.wpath.org) for comments
- External agencies such as the WHO, UN, Endocrine Society, etc., to review
9. Disseminate Guideline
- What questions do you want to see answered in SOC8?
- What areas/Chapters are missing?
What ideas do you have for disseminating guidelines?
Acknowledgments

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- Jon Arcelus, MD, MSc, FRCPsych, PhD
- Gail Knudson, MD, MEd, FRCPC