EXHIBIT 168

From: Karen Robinson
To: adolescentsoc8@wpath.org
Subject: documents mentioned during call today
Date: Wednesday, June 6, 2018 10:20:00 AM
Attachments: Notes_IdentifyingStatements.pdf
SOC7 Statements and Possible Research Questions 08May18.doc
WPATH Guideline Development Methodology_Draft_4May2018.docx
WPATH_SOC8_Timeline_DRAFT_3May18.docx

All –
Nice to speak with you today.
I have attached documents mentioned to be sure you all have them on hand. Also pasted below is the email sent to the chapter leads.
Thanks,
Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
1830 E. Monument St., Suite 8068
REDACTED

Email to Chapter Leads:
All –
As discussed during our initial phone calls, a first task is to identify the specific statements to be considered for SOC8. We therefore would ask that you (Chapter Leads initially, and then Chapter Members) do following:

- Consider the end product. Think explicitly about the decisions for which you would like to make recommendation statements. What are the areas of uncertainty in practice? Where is guidance needed?
- Consider whether recommendations from other organizations may be adopted. For instance, for decisions around hormone therapy the recommendations from the Endocrine Society may be considered. For relevant statements, the Evidence Review Team would conduct a limited search to identify any studies published since development of recommendation(s) being considered for adoption.
- Review statements from SOC7 (for those chapters included in SOC7). The Evidence Review Team extracted statements from SOC7. I have attached a document that lists these statements by chapter. We have also made an initial classification as to whether the statement may be evidence-based (for which a systematic review will be conducted) or a good practice statement (see attached notes for definitions and examples).
    - Any statements missing?
    - Any statements to add?
    - Finalize classification as to evidence-based or good practice statement

As noted on the call, we know that this process will take time to fully complete. However, please let Chairs and me know of statements you think will be evidence-based by end of this month so that we

can begin the systematic reviews.
I am happy to respond to questions individually and/or to join calls with Chapter members if that would be useful.
This is a very important stage and we appreciate your guidance!
As promised, here are links to some of the resources/tools referenced in the methods document (we will add references to the document as it continues to be revised):
GRADE www.gradeworkinggroup.org
Cochrane Risk of Bias, ROBINS: Cochrane Handbook training.cochrane.org/handbook
ROBIS http://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/
Thanks,
Karen
Evidence Review Team
Attachments:
SOC7 Statements - as Word doc
Notes about recommendation statements – as PDF

From: Karen Robinson
To: soc8chapterleads@wpath.org
Subject: Examples from hormone chapter
Date: Tuesday, July 31, 2018 1:52:00 PM
Attachments: WPATH SOC8 Recommendations.docx
WPATH_SOC8_ChapterStructureTemplate.docx
Proposed Systematic Reviews to Karen.docx

All –

Please find below and attached example documents from the hormone chapter (thanks, Vin, for agreeing to share!). We (the chairs and I) thought that it might be helpful to see examples from your colleagues in other chapters. The specific wording of some of the recommendations needs refinement, but that is to be expected at this point. Please don't worry about the specific wording, or if you agree with these particular recommendations and questions. We are forwarding these simply as examples so you that can see something about their process, as well as the type of content and format of the recommendations and questions.

Please let us know if you have any questions.

Thanks,

Karen

From: vin.tangpricha@gmail.com [mailto:vin.tangpricha@gmail.com] **On Behalf Of** Vin Tangpricha
Sent: Tuesday, July 31, 2018 8:57 AM
To: Endocrinology SOC8 <endocrinologysoc8@wpath.org>
Subject: Update on Chapter

Dear Endo Chapter Members,

Thank you for participating on the recent calls. I just wanted to update everyone to our status. I think we are in good shape for now. We have sent over the requested systematic reviews over to Karen's team. We have edited and reaffirmed some of the Endocrine Society guideline recommendations and those that we did not want to handle, we have sent to other chapters. I think we can meet again in September to plan the writing of the guidelines while we are waiting the outcome of the systematic reviews. Please see attached the list of recommendations we kept for our chapter from the Endo guidelines, the systematic reviews in PICO format sent to Karen and instructions for the next step in the process of writing the chapter.

If you have time and would like to start on the next step, please let me know. Otherwise, we will plan a call sometime in September when most people are back from vacations.

Sincerely,

Vin

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Vin Tangpricha, M.D., Ph.D.

Professor of Medicine
Program Director, Endocrinology & Metabolism Fellowship
Program Director, ABIM Physician Scientist Pathway, Internal Medicine Residency
Division of Endocrinology, Metabolism & Lipids
Department of Medicine
Emory University School of Medicine

Staff Physician, Section of Endocrinology, Atlanta VA Medical Center
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Clinic appointments, 404-778-3280
Fellowship program inquires, Ms. Marcela Santamaria-Appling, 404-727-1549

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Editor in Chief, Journal of Clinical and Translational Endocrinology (JCTE), www.jctejournal.com

Potential Systematic Reviews to Discuss (These reviews are linked to the Questions on pages 2-6)
1. A systematic review on the best androgen lowering medication in terms of safety and efficacy. GnRH sub-groups
2. A systematic review on GnRH agonists on long term effects in children
3. A systematic review on risk of prolactinomas and hyperprolactinemia. Gender affirming hormone therapy.
4. A systematic review about the use of progesterones.(cyproterone)
5. A systematic review on thrombosis and associated risks with gender affirming hormone therapy (remove ethinyl from consideration) (route of admin)
6. Systematic review on polycythemia in transgender men
7.Systematic review of the uterine and ovarian (morphology) safety of testosterone in transgender men who have not had hysterectomy
8.Systematic review of the safety and efficacy of different routes of administration for estrogen (pill, skin, shots)
9.Systematic review on the psychological effects (including quality of life) associated with pubertal suppression
10. Systematic review on the psychological effects(including quality of life) associated with hormone therapy
11. Systematic review on metabolic syndrome in patients undergoing hormone therapy (both transgender men and women): BMI, weight, lipids, dm.
12. Systematic review on fertility.

From: Karen Robinson
To: Eli Coleman; Jon Arcelus; Asa Radix
Subject: FW: Chapter template
Date: Friday, July 20, 2018 8:41:00 AM
Attachments: WPATH_Mockup_ChapterTemplate.docx

Please review and confirm ok with suggestions. Also, please see questions in first paragraph in email below..

From: Karen Robinson
Sent: Monday, July 16, 2018 9:00 AM
To: Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>
Cc: 'Blaine Vella' <blaine@wpath.org>
Subject: Chapter template

Please review description below and mockup attached. Please include specific feedback on structure of statements (e.g., should it be 'we' or 'WPATH'?) and order of text and statements. Also, consider length suggestions. I think text length for rationale should be suggested at about 1 page (versus 3 paragraphs).

Template 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)
    - Text should precede each statement providing the rationale or reasoning for the recommendation. This should include outlining the available evidence, providing details about benefits and harms, a description of uncertainty, role of values and experience in developing the recommendation, and information about implementation of the recommendation, including expected barriers or challenges. Links to resources should also be provided, as appropriate.
    - Following the text the recommendation statement is provided in a standard, consistent format (see below)

Recommendation statements

- Evidence-based statements (wording followed by grading information in parentheses):
    - Strong recommendation: We recommend
    - Weak recommendation: We suggest

Example: We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

- Best practice statements (wording followed by 'ungraded best practice statement')
    - We advise

Example: We advise that people with X be referred to Y (ungraded best practice statement)

Background

This is where the scope of the chapter is described in 1-2 pages.

Summary of Recommendations

List all recommendations from this chapter here.

Subheading for Chapter Topic A

Brief paragraph about what is included in this topic.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum).

Here is the text for the recommendation statement.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum).

Here is the text for the recommendation statement.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum).

Here is the text for the recommendation statement.

From: Karen Robinson
To: Eli Coleman; Jon Arcelus; Asa Radix
Subject: FW: Notes on consensus process.
Date: Friday, July 20, 2018 8:40:00 AM
Attachments: Notes_IdentifyingStatements.pdf

Please confirm ok with process as outlined below…

From: Karen Robinson
Sent: Monday, July 16, 2018 8:27 AM
To: Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>
Cc: 'Blaine Vella' <blaine@wpath.org>
Subject: Notes on consensus process.

For your review:

We need the draft recommendation statements from each Chapter. Recall that recommendation statements should be explicit and actionable (please see attached notes).

The following is the consensus process for recommendation statements. This will be used for the best practice statements and for the evidence-based recommendation statements:

1. Chapter members draft and reach consensus within chapter on recommendations statements.
2. All recommendation statements are sent to the Guideline Steering Committee for review and revision.
3. An online Delphi will be set up to be used by all SOC8 members to vote on recommendation statements. Members will be able to opt out of voting on statements they feel are outside of their expertise or experience, and will also have opportunity to provide feedback on each statement. Consensus will be considered reach if recommendation statement is agreed to by 80% or more of votes. Those statements not reaching consensus will be sent back to all for another round of voting. These statements may be, as appropriate, revised based on feedback received. Three rounds will be held. Recommendation statements reaching consensus will be included in SOC8.

WPATH SOC8: Notes regarding initial identification of recommendation statements

Clinical Practice Guidelines: Systematically developed statements that include recommendations, strategies, or information that assist physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.

"Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options." IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.

Evidence-based Recommendation Statements:

- Based on systematic review with clear link to evidence
- Will be graded

Good Practice or Consensus-based Statements:

- Common sense or reminders of obvious
- Not appropriate for a systematic review or formal assessment of evidence

All recommendation statements should be:

- Clear and actionable
- Define all elements needed to implement (under what circumstances do something; exactly what to do under defined circumstances)
- Easily identifiable (i.e., typed in bold, summarized in a box, etc.)

Examples of Evidence-based Recommendation Statement (note different grading systems used):

> Antibiotics should be prescribed in children two years or older with a diagnosis of acute otitis media if the pain lasts longer than three days or if the pain increases after the consultation despite adequate treatment with painkillers; in these cases, amoxicillin should be given for 7 days (supplied with a dosage scheme). (Strong)
>
> The USPSTF recommends against the use of combined estrogen and progestin for the primary prevention of chronic conditions in postmenopausal women. (D recommendation)

Examples of Good Practice or Consensus-based Statements:

> In patients presenting with heart failure, clinicians should make an initial assessment of the patient's ability to perform routine/desired activities of daily living (ungraded good practice statement).
>
> Health services should be made available, accessible, and acceptable to sex workers based on the principles of avoidance of stigma, nondiscrimination, and the right to health (ungraded good practice statement).

Evidence-based Recommendation statements will be translated into questions for systematic review. These questions drive the entire process: what is identified, eligibility criteria, what is extracted and presented, and what analyses are completed. Questions are specified using the PICO format:

P	**Patient, population**
I	**Intervention**
C	**Comparison**
O	**Outcome**
T	**Timing**
S	**Setting**
D	**Study design**

From: Karen Robinson
To: Eli Coleman; Jon Arcelus; Asa Radix
Subject: FW: updated tracking document
Date: Friday, July 20, 2018 8:13:00 AM
Attachments: WPATH Tracking Sheet_12July18.docx

Eli asked for summary from last meeting.
I also sent draft consensus process and draft notes regarding structure of chapters. Let me know if you would like me to send these again.
Thanks,
Karen

From: Karen Robinson
Sent: Thursday, July 12, 2018 12:12 PM
To: 'Eli Coleman' <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>
Cc: 'Blaine Vella' <blaine@wpath.org>
Subject: updated tracking document

Thanks for the call today!
I have attached an updated tracking document.
Here are tasks based on call:

- KR will ask Blaine to set up call with Chapter Leads (start with existing SOC Chair calls for schedule)
- KR will ask Blaine re collection of COI/DOI from Chapter Leads and Members
- KR will flesh out the process for statements (item 2 on agenda) for review by Chairs. This will be provided to the Chapter Leads closer to date of call(s).
- KR will flesh out template for chapters, including guidance on length and a mockup (item #3 on agenda). This will be reviewed by Chairs but not yet provided to the Chapter Leads.
- Chairs will send KR the dates/info for SOC Chair calls and KR will join those, as possible.

Let me know if I have forgotten or misremembered anything.
I found the call very useful – thanks!
Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED

WPATH Tracking Sheet
12 July 2018

Chapter	Chair Coordinator	Chapter Lead	Likely to include Rec Statements?	Likely to include a systematic review?	Received statements?	KR Notes
I. Global Applicability of the Standards of Care	Asa		?	No		
II. Terminology – Diagnostic criteria	Asa	Sari	?	No		
III. Epidemiologic Considerations	Eli		No	No		Will provide additional references as check for completeness
IV. Overview of Therapeutic Approaches for Gender Health	Eli		No	No		Summary
V. The Role of Primary Care in Gender Health	Asa	Maddie	Yes	Yes		Reviewed questions - screening Two or more from hormone chapter re screening
VI. Assessment, Support and Therapeutic Approaches for Children	Jon	Amy	Yes	Yes		Not seen statements
VII. NEW: Assessment, Support and Therapeutic Approaches for Adolescents with Gender Diversity/Dysphoria	Jon	Scott	Yes	Yes?		Saw initial comments on SOC7 statements
VIII. Assessment and Therapeutic Approaches for Non-Binary	Asa	Walter Joz	No?	No		Haven't seen
IX. Assessment of Adults with Gender Diversity/Dysphoria	Jon	Christina	Yes	No?		Received extensive "questions" in May. Most recently email suggesting not understanding process.
X. Managing Mental and Behavioral Health Conditions in Adults	Jon	Dan	Yes	Yes		Received "questions"
XI. Hormone Therapy for Adolescents and Adults	Jon	Vin	Yes	Yes		SRs: 1. QoL 2. Prolactin 3. One or two others
XII. New: Sexual Health Across The Lifespan	Eli	Timo	Yes	Yes?		Asked regarding numbers. Nothing seen
XIII. Reproductive Health for Adolescents and Adults	Asa	Lina	Yes	No?		Haven't seen
XIV. Voice and Communication Therapy	Eli	Adrienne	Yes	Yes		Received "statements" and "questions"

XV.	Surgery Chapter for Adolescents and Adults; Postoperative Care and Follow-Up	Jon	Loren	Yes	Yes		Haven't received statements (techniques?)
XVI.	Applicability of the Standards of Care to People Living in Institutional Environments	Eli	Randi	Yes	No		Haven't seen anything
XVII.	Applicability of the Standards of Care to People with Intersex Conditions	Eli	Heino	Yes	No		Haven't received
XVIII.	NEW: Applicability of the Standards of Care to Eunuchs	Eli	Tom	Yes	No		Reviewed statements
XIX.	NEW: Competency, Training, Education, Ethics	Asa	Gail	Yes	No		Haven't received

From: Karen Robinson
To: Mazur, Tom
Subject: FW: WPATH SOC8: Identification of statements
Date: Tuesday, May 29, 2018 10:06:00 AM
Attachments: SOC7 Statements and Possible Research Questions 08May18.doc
Notes_IdentifyingStatements.pdf

Forwarding per request.
I am down at AHRQ for meeting on Monday so unfortunately will miss you.
Let me know if you have any questions,
Karen

From: Karen Robinson
Sent: Friday, May 11, 2018 11:17 AM
To: 'soc8chapterleads@wpath.org' <soc8chapterleads@wpath.org>
Subject: WPATH SOC8: Identification of statements

All –

As discussed during our initial phone calls, a first task is to identify the specific statements to be considered for SOC8. We therefore would ask that you (Chapter Leads initially, and then Chapter Members) do following:

- Consider the end product. Think explicitly about the decisions for which you would like to make recommendation statements. What are the areas of uncertainty in practice? Where is guidance needed?
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Cochrane Risk of Bias, ROBINS: Cochrane Handbook training.cochrane.org/handbook
ROBIS http://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/

Thanks,
Karen
Evidence Review Team
Attachments:
SOC7 Statements - as Word doc
Notes about recommendation statements – as PDF

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED

WPATH SOC8: Notes regarding initial identification of recommendation statements

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S	**Setting**
D	**Study design**

Identification of statements within chapters for which systematic reviews will be conducted, and which will be 'best practice statements' based on consensus expert opinion

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
Chapter V - Overview of Therapeutic Approaches for Gender Dysphoria				
9	Options for Psychological and Medical Treatment for Gender Dysphoria	For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person. Treatment options include: • Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity); • Hormone therapy to feminize or masculinize the body; • Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring); • Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience.		Systematic Review
10	Options for Social Support and Changes in Gender Expression	In addition (or as an alternative) to the psychological and medical treatment options described above, other options can be considered to help alleviate gender dysphoria, for example: • Offline and online peer support resources, groups, or community organizations that provide avenues for social support and advocacy; • Offline and online support resources for families and friends; • Voice and communication therapy to help individuals develop verbal and non-verbal communication skills that facilitate comfort with their gender identity; • Hair removal through electrolysis, laser treatment, or waxing; • Breast binding or padding, genital tucking or penile prostheses, padding of hips or buttocks; • Changes in name and gender marker on identity documents.		Systematic Review
Chapter VI - Assessment and Treatment of Children and Adolescents with Gender Dysphoria				
13	Competency of Mental Health Professionals Working with Children or Adolescents with Gender Dysphoria	The following are recommended minimum credentials for mental health professionals who assess, refer, and offer therapy to children and adolescents presenting with gender dysphoria: 1. Meet the competency requirements for mental health professionals working with adults, as outlined in section VII; 2. Trained in childhood and adolescent developmental psychopathology; 3. Competent in diagnosing and treating the ordinary problems of children and adolescents.		Good Clinical Practice Statement
14	Roles of Mental Health Professional Working with Children and Adolescents with Gender Dysphoria	The roles of mental health professionals working with gender dysphoric children and adolescents may include the following: 1. Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below). 2. Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		3. Assess and treat any co-existing mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan. 4. Refer adolescents for additional physical interventions (such as puberty suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments. 5. Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, & Salter, 2006; Grossman, D'Augelli, Howell, & Hubbard, 2006; Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010). 6. Provide children, youth, and their families with information and referral for peer support, such as support groups for parents of gender nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).		
14		Assessment and psychosocial interventions for children and adolescents are often provided within a multi-disciplinary gender identity specialty service. If such a multidisciplinary service is not available, a mental health professional should provide consultation and liaison arrangements with a pediatric endocrinologist for the purpose of assessment, education, and involvement in any decisions about physical interventions.		Good Clinical Practice Statement
15	Psychological Assessments of Children and Adolescents	Mental health professionals should not dismiss or express a negative attitude towards nonconforming gender identities or indications of gender dysphoria. Rather, they should acknowledge the presenting concerns of children, adolescents, and their families; offer a thorough assessment for gender dysphoria and any co-existing mental health concerns; and educate clients and their families about therapeutic options, if needed. Acceptance and removal of secrecy can bring considerable relief to gender dysphoric children/adolescents and their families.		Good Clinical Practice Statement
15		Assessment of gender dysphoria and mental health should explore the nature and characteristics of a child's or adolescent's gender identity. A psychodiagnostic and psychiatric assessment – covering the areas of emotional functioning, peer and other social relationships, and intellectual functioning/school achievement – should be performed. Assessment should include an evaluation of the strengths and weaknesses of family functioning. Emotional and behavioral problems are relatively common, and unresolved issues in a child's or youth's environment may be		Good Clinical Practice Statement
15		For adolescents, the assessment phase should also be used to inform youth and their families about the possibilities and limitations of different treatments. This is necessary for informed consent, but also important for assessment. The way that adolescents respond to information about the reality of sex reassignment can be diagnostically informative. Correct information may alter a youth's desire for certain treatment, if the desire was based on unrealistic expectations of its possibilities.		Good Clinical Practice Statement
15	Psychological and	Mental health professionals should help families to have an accepting and nurturing	• What are the benefits and harms	Systematic

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
	Social Interventions for Children and Adolescents	response to the concerns of their gender dysphoric child or adolescent. Families play an important role in the psychological health and well-being of youth. This also applies to peers and mentors from the community, who can be another source of social support.	of different types of psychotherapy?	Review
16		Psychotherapy should focus on reducing a child's or adolescent's distress related to the gender dysphoria and on ameliorating any other psychosocial difficulties. For youth pursuing sex reassignment, psychotherapy may focus on supporting them before, during, and after reassignment. Formal evaluations of different psychotherapeutic approaches for this situation have not been published, but several counseling methods have been described.	• What are the benefits and harms of different types of psychotherapy?	Systematic Review
16		Treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been attempted in the past without success. Such treatment is no longer considered ethical.		Good Clinical Practice Statement
16		Families should be supported in managing uncertainty and anxiety about their child's or adolescent's psychosexual outcomes and in helping youth to develop a positive self-concept.		Good Clinical Practice Statement
16		Mental health professionals should not impose a binary view of gender. They should give ample room for clients to explore different options for gender expression. Hormonal or surgical interventions are appropriate for some adolescents, but not for others.		Good Clinical Practice Statement
16		Clients and their families should be supported in making difficult decisions regarding the extent to which clients are allowed to express a gender role that is consistent with their gender identity, as well as the timing of changes in gender role and possible social transition. For example, a client might attend school while undergoing social transition only partly (e.g., by wearing clothing and having a hairstyle that reflects gender identity) or completely (e.g., by also using a name and pronouns congruent with gender identity). Difficult issues include whether and when to inform other people of the client's situation, and how others in their lives should respond.		Good Clinical Practice Statement
16		Health professionals should support clients and their families as educators and advocates in their interactions with community members and authorities such as teachers, school boards, and courts.		Good Clinical Practice Statement
16		Mental health professionals should strive to maintain a therapeutic relationship with gender nonconforming children/adolescents and their families throughout any subsequent social changes or physical interventions. This ensures that decisions about gender expression and the treatment of gender dysphoria are thoughtfully and recurrently considered. The same reasoning applies if a child or adolescent has already socially changed gender role prior to being seen by a mental health professional.		Good Clinical Practice Statement
17	Social Transition in Early Childhood	The current evidence base is insufficient to predict the long-term outcomes of completing a gender role transition during early childhood. Outcomes research with children who completed early social transitions would greatly inform future clinical recommendations.	• What are the benefits and harms of social transition? • At what age should social transition be stated?	Systematic Review
17		Regardless of a family's decisions regarding transition (timing, extent), professionals should counsel and support them as they work through the options and implications. If		Good Clinical

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		parents do not allow their young child to make a gender role transition, they may need counseling to assist them with meeting their child's needs in a sensitive and nurturing way, ensuring that the child has ample possibilities to explore gender feelings and behavior in a safe environment. If parents do allow their young child to make a gender role transition, they may need counseling to facilitate a positive experience for their child.		Practice Statement
18	Physical Interventions for Adolescents	Before any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken, as outlined above. The duration of this exploration may vary considerably depending on the complexity of the situation.		Good Clinical Practice Statement
18		A staged process is recommended to keep options open through the first two stages. Moving from one stage to another should not occur until there has been adequate time for adolescents and their parents to assimilate fully the effects of earlier interventions.		Good Clinical Practice Statement
18	Fully Reversible Interventions	Adolescents may be eligible for puberty suppressing hormones as soon as pubertal changes have begun. In order for adolescents and their parents to make an informed decision about pubertal delay, it is recommended that adolescents experience the onset of puberty to at least Tanner Stage 2.	• What are the benefits and harms of puberty-suppressing hormones? • At what age or stage of development should puberty-suppressing hormones be started?	Systematic Review
19		Puberty suppression may continue for a few years, at which time a decision is made to either discontinue all hormone therapy or transition to a feminizing/masculinizing hormone regimen. Pubertal suppression does not inevitably lead to social transition or to sex reassignment.	• How long should an individual continue taking puberty-suppressing hormones?	Systematic Review
19	Criteria for puberty suppressing hormones	In order for adolescents to receive puberty suppressing hormones, the following minimum criteria must be met: 1. The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); 2. Gender dysphoria emerged or worsened with the onset of puberty; 3. Any co-existing psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; 4. The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.		Good Clinical Practice Statement
19	Regimens, monitoring, and risks for puberty suppression	For puberty suppression, adolescents with male genitalia should be treated with GnRH analogues, which stop luteinizing hormone secretion and therefore testosterone secretion. Alternatively, they may be treated with progestins (such as medroxyprogesterone) or with other medications that block testosterone secretion and/or neutralize testosterone action.	• For adolescents assigned male at birth, what are the benefits and harms of puberty- suppressing hormones?	Systematic Review
19		Adolescents with female genitalia should be treated with GnRH analogues, which stop the production of estrogens and progesterone. Alternatively, they may be treated with progestins (such as medroxyprogesterone). Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses. In both groups of adolescents, use of GnRH analogues is the preferred treatment (Hembree et al., 2009), but their high cost is prohibitive for some patients	• For adolescents assigned female at birth, what are the benefits and harms of puberty-suppressing hormones?	Systematic Review

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
20		During pubertal suppression, an adolescent's physical development should be carefully monitored – preferably by a pediatric endocrinologist – so that any necessary interventions can occur (e.g., to establish an adequate gender appropriate height, to improve iatrogenic low bone marrow density) (Hembree et al., 2009).	• What is the optimal timing of monitoring? • What are the appropriate tests for monitoring?	Systematic Review
21	Partially Reversible Interventions	Adolescents may be eligible to begin feminizing/masculinizing hormone therapy, preferably with parental consent. In many countries, 16-year-olds are legal adults for medical decision-making and do not require parental consent. Ideally, treatment decisions should be made among the adolescent, the family, and the treatment team.		Good Clinical Practice Statement
21		Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009).	• At what age or stage of development should gender-affirming hormones be initiated? • For adolescents with male genitalia, what are the benefits and harms of feminizing hormone therapy? • For adolescents with female genitalia, what are the benefits and harms of masculinizing hormone therapy?	Systematic Review
21	Irreversible Interventions	Genital surgery should not be carried out until (i) patients reach the legal age of majority in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention.		Good Clinical Practice Statement
21		Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression.		Good Clinical Practice Statement
21	Risks of Withholding Treatment for Adolescents	Refusing timely medical interventions for adolescents might prolong gender dysphoria and contribute to an appearance that could provoke abuse and stigmatization. As the level of gender-related abuse is strongly associated with the degree of psychiatric distress during adolescence (Nuttbrock et al., 2010), withholding puberty suppression and subsequent feminizing or masculinizing hormone therapy is not a neutral option for adolescents.		Good Clinical Practice Statement
NEW: Assessment, Support, and Therapeutic Approaches for Adolescents with Gender Diversity/Dysphoria				
Chapter VII - Mental Health				
22	Competency of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria	The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria: 1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country. 2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria. 4. Documented supervised training and competence in psychotherapy or counseling. 5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria. 6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.		
23	Tasks of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria	Mental health professionals should determine a client's reasons for seeking professional assistance.		Good Clinical Practice Statement
24-25	Tasks Related to Assessment and Referral 3. Assess, diagnose, and discuss treatment options for co-existing mental health concerns	Some clients may benefit from psychotropic medications to alleviate symptoms or treat coexisting mental health concerns. Mental health professionals are expected to recognize this and either provide pharmacotherapy or refer to a colleague who is qualified to do so. The presence of co-existing mental health concerns does not necessarily preclude possible changes in gender role or access to feminizing/masculinizing hormones or surgery; rather, these concerns need to be optimally managed prior to or concurrent with treatment of gender dysphoria. In addition, clients should be assessed for their ability to provide educated and informed consent for medical treatments.		Good Clinical Practice Statement
28	Tasks Related to Psychotherapy	A mental health screening and/or assessment as outlined above is needed for referral to hormonal and surgical treatments for gender dysphoria. In contrast, psychotherapy – although highly recommended – is not a requirement.		Good Clinical Practice Statement
28		The SOC do not recommend a minimum number of psychotherapy sessions prior to hormone therapy or surgery.		Good Clinical Practice Statement
29		Therapy may consist of individual, couple, family, or group psychotherapy, the latter being particularly important to foster peer support.	• What are the benefits and harms of different types of counseling for adults with gender dysphoria?	Systematic Review
30		**Family therapy or support for family members** Family therapy might be offered as part of the client's individual therapy and, if clinically appropriate, by the same provider. Alternatively, referrals can be made to other therapists with relevant expertise to work with family members, or to sources of peer support (e.g., online or offline support networks of partners or families).	• What are the benefits and harms of different types of counseling for adults with gender dysphoria?	Systematic Review
31		**Follow-up care throughout life** Mental health professionals may work with clients and their families at many stages of their lives. Psychotherapy may be helpful at different times and for various issues throughout the life cycle.	• What are the benefits and harms of different types of counseling for adults with gender dysphoria?	Systematic Review
31		**Etherapy, online counseling, or distance counseling** Online or etherapy has been shown to be particularly useful for people who have	• What are the benefits and harms	Systematic Review

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		difficulty accessing competent psychotherapeutic treatment and who may experience isolation and stigma. By extrapolation, etherapy may be a useful modality for psychotherapy with transsexual, transgender, and gender nonconforming people.	of different types of counseling for adults with gender dysphoria?	
32	Other Tasks of the Mental Health Professional	**2. Provide information and referral for peer support** For some transsexual, transgender, and gender nonconforming people, an experience in peer support groups may be more instructive regarding options for gender expression than anything individual psychotherapy could offer (Rachlin, 2002). Both experiences are potentially valuable, and all people exploring gender issues should be encouraged to participate in community activities, if possible. Resources for peer support and information should be made available.	• What are the benefits and harms of different types of counseling for adults with gender dysphoria?	Systematic Review
32	Ethical Guidelines Related to Mental Health Care	Professionals must adhere to the ethical codes of their professional licensing or certifying organizations in all of their work with transsexual, transgender, and gender nonconforming clients.		Good Clinical Practice Statement
32		Treatment aimed at trying to change a person's gender identity and lived gender expression to become more congruent with sex assigned at birth has been attempted in the past (Gelder & Marks, 1969; Greenson, 1964), yet without success, particularly in the long term (Cohen-Kettenis & Kuiper, 1984; Pauly, 1965). Such treatment is no longer considered ethical.		Good Clinical Practice Statement
32		If mental health professionals are uncomfortable with or inexperienced in working with transsexual, transgender, and gender nonconforming individuals and their families, they should refer clients to a competent provider or, at minimum, consult with an expert peer. If no local practitioners are available, consultation may be done via telehealth methods, assuming local requirements for distance consultation are met.		Good Clinical Practice Statement
33	Issues of Access to Care	When faced with a client who is unable to access services, referral to available peer support resources (offline and online) is recommended. Finally, harm reduction approaches might be indicated to assist clients with making healthy decisions to improve their lives.		Good Clinical Practice Statement
Chapter VIII - Hormone Therapy				
33	Medical Necessity of Hormone Therapy	Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Hormone therapy can provide significant comfort to patients who do not wish to make a social gender role transition or undergo surgery, or who are unable to do so (Meyer III, 2009).		Good Clinical Practice Statement
34		Hormone therapy is a recommended criterion for some, but not all, surgical treatments for gender dysphoria (see section XI and Appendix C).		Good Clinical Practice Statement
34	Criteria for Hormone Therapy	The criteria for hormone therapy are as follows: 1. Persistent, well-documented gender dysphoria; 2. Capacity to make a fully informed decision and to consent for treatment; 3. Age of majority in a given country (if younger, follow the Standards of Care outlined in section VI); 4. If significant medical or mental health concerns are present, they must be reasonably well-controlled.		Good Clinical Practice Statement
36	Physical Effects of	Feminizing/masculinizing hormone therapy will induce physical changes that are more	• At what age or stage of	Systematic

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
	Hormone Therapy	congruent with a patient's gender identity.	development should gender-affirming hormones be initiated? • For adolescents with male genitalia, what are the benefits and harms of feminizing hormone therapy? • For adolescents with female genitalia, what are the benefits and harms of masculinizing hormone therapy?	Review
38		All other factors being equal, there is no evidence to suggest that any medically approved type or method of administering hormones is more effective than any other in producing the desired physical changes.	• At what age or stage of development should gender-affirming hormones be initiated? • For adolescents with male genitalia, what are the benefits and harms of feminizing hormone therapy? • For adolescents with female genitalia, what are the benefits and harms of masculinizing hormone therapy?	Systematic Review
39	Risks of Hormone Therapy	The risks associated with feminizing/masculinizing hormone therapy for the transsexual, transgender, and gender nonconforming population as a whole are summarized in Table 2.	• At what age or stage of development should gender-affirming hormones be initiated? • For adolescents with male genitalia, what are the benefits and harms of feminizing hormone therapy? • For adolescents with female genitalia, what are the benefits and harms of masculinizing hormone therapy?	Systematic Review
41	Competency of Hormone-Prescribing Physicians, Relationship with Other Health Professionals	Feminizing/masculinizing hormone therapy is best undertaken in the context of a complete approach to health care that includes comprehensive primary care and a coordinated approach to psychosocial issues (Feldman & Safer, 2009). While psychotherapy or ongoing counseling is not required for the initiation of hormone therapy, if a therapist is involved, then regular communication among health professionals is advised (with the patient's consent) to ensure that the transition process is going well, both physically and psychosocially.		Good Clinical Practice Statement
41		Given the multidisciplinary needs of transsexual, transgender, and gender nonconforming people seeking hormone therapy, as well as the difficulties associated with fragmentation of care in general (World Health Organization, 2008), WPATH strongly encourages the increased training and involvement of primary care providers in the area of feminizing/masculinizing hormone therapy.		Good Clinical Practice Statement
42	Responsibilities of Hormone-Prescribing	In general, clinicians who prescribe hormone therapy should engage in the following tasks:		Good Clinical

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
	Physicians	1. Perform an initial evaluation that includes discussion of a patient's physical transition goals, health history, physical examination, risk assessment, and relevant laboratory tests. 2. Discuss with patients the expected effects of feminizing/masculinizing medications and the possible adverse health effects. These effects can include a reduction in fertility (Feldman & Safer, 2009; Hembree et al., 2009). Therefore, reproductive options should be discussed with patients before starting hormone therapy (see section IX). 3. Confirm that patients have the capacity to understand the risks and benefits of treatment and are capable of making an informed decision about medical care. 4. Provide ongoing medical monitoring, including regular physical and laboratory examination to monitor hormone effectiveness and side effects. 5. Communicate as needed with a patient's primary care provider, mental health professional, and surgeon. 6. If needed, provide patients with a brief written statement indicating that they are under medical supervision and care that includes feminizing/masculinizing hormone therapy. Particularly during the early phases of hormone treatment, a patient may wish to carry this statement at all times to help prevent difficulties with the police and other authorities.		Practice Statement
42	Clinical Situations for Hormone Therapy	There are circumstances in which clinicians may be called upon to provide hormones without necessarily initiating or maintaining long-term feminizing/masculinizing hormone therapy. By acknowledging these different clinical situations (see below, from least to highest level of complexity), it may be possible to involve clinicians in feminizing/masculinizing hormone therapy who might not otherwise feel able to offer this treatment.		Good Clinical Practice Statement
44	Risk Assessment and Modification for Initiating Hormone Therapy	The initial evaluation for hormone therapy assesses a patient's clinical goals and risk factors for hormone-related adverse events. During the risk assessment, the patient and clinician should develop a plan for reducing risks wherever possible, either prior to initiating therapy or as part of ongoing harm reduction. All assessments should include a thorough physical exam, including weight, height, and blood pressure. The need for breast, genital, and rectal exams, which are sensitive issues for most transsexual, transgender, and gender nonconforming patients, should be based on individual risks and preventive health care needs		Good Clinical Practice Statement
44	Preventive Care	Hormone providers should address preventive health care with patients, particularly if a patient does not have a primary care provider. Depending on a patient's age and risk profile, there may be appropriate screening tests or exams for conditions affected by hormone therapy. Ideally, these screening tests should be carried out prior to the start of hormone therapy.		Good Clinical Practice Statement
46	Efficacy and risk monitoring during feminizing hormone therapy (MtF)	The best assessment of hormone efficacy is clinical response: Is a patient developing a feminized body while minimizing masculine characteristics, consistent with that patient's gender goals? In order to more rapidly predict the hormone dosages that will achieve clinical response, one can measure testosterone levels for suppression below the upper limit of the normal female range, and estradiol levels within a premenopausal female range but well below supraphysiologic levels.	• What is the optimal timing of monitoring? • What are the appropriate tests for monitoring?	Systematic Review
46		Monitoring for adverse events should include both clinical and laboratory evaluation. Followup should include careful assessment for signs of cardiovascular impairment and venous thromboembolism (VTE) through measurement of blood pressure, weight, and	• What is the optimal timing of monitoring? • What are the appropriate tests for	Systematic Review

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		pulse; heart and lung exams; and examination of the extremities for peripheral edema, localized swelling, or pain. Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual co-morbidities and risk factors, and the specific hormone regimen itself. Specific lab monitoring protocols have been published	monitoring?	
46	Efficacy and risk monitoring during masculinizing hormone therapy (FtM)	The best assessment of hormone efficacy is clinical response: Is a patient developing a masculinized body while minimizing feminine characteristics, consistent with that patient's gender goals? Clinicians can achieve a good clinical response with the least likelihood of adverse events by maintaining testosterone levels within the normal male range while avoiding supraphysiological levels. For patients using intramuscular (IM) testosterone cypionate or enanthate, some clinicians check trough levels while others prefer midcycle levels	• What is the optimal timing of monitoring? • What are the appropriate tests for monitoring?	Systematic Review
47		Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs and symptoms of excessive weight gain, acne, uterine break-through bleeding, and cardiovascular impairment, as well as psychiatric symptoms in at-risk patients. Physical examinations should include measurement of pressure, weight, pulse, and skin; and heart and lung exams. Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual co-morbidities and risk factors, and the specific hormone regimen itself. Specific lab monitoring protocols have been published.	• What is the optimal timing of monitoring? • What are the appropriate tests for monitoring?	Systematic Review
NEW: Sexual health across the Lifespan				
Chapter IX - Reproductive Health				
50	Reproductive Health	Many transgender, transsexual, and gender nonconforming people will want to have children. Because feminizing/masculinizing hormone therapy limits fertility (Darney, 2008; Zhang, Gu, Wang, Cui, & Bremner, 1999), it is desirable for patients to make decisions concerning fertility before starting hormone therapy or undergoing surgery to remove/alter their reproductive organs. ... Health care professionals – including mental health professionals recommending hormone therapy or surgery, hormone-prescribing physicians, and surgeons – should discuss reproductive options with patients prior to initiation of these medical treatments for gender dysphoria. ... MtF patients, especially those who have not already reproduced, should be informed about sperm preservation options and encouraged to consider banking their sperm prior to hormone therapy. ... Reproductive options for FtM patients might include oocyte (egg) or embryo freezing.		Good Clinical Practice Statement
51	Reproductive Health	A special group of individuals are prepubertal or pubertal adolescents who will never develop reproductive function in their natal sex due to blockers or cross gender hormones. At this time there is no technique for preserving function from the gonads of these individuals.		Good Clinical Practice Statement
Chapter X - Voice and Communication Therapy				
52	Competency of Voice and Communication Specialists	The following are recommended minimum credentials for voice and communication specialists working with transsexual, transgender, and gender nonconforming clients: 1. Specialized training and competence in the assessment and development of communication skills in transsexual, transgender, and gender nonconforming clients. 2. A basic understanding of transgender health, including hormonal and surgical treatments for feminization/masculinization and trans-specific psychosocial issues as outlined in the *SOC*; and familiarity with basic sensitivity protocols such as the use of preferred gender pronoun and name (Canadian		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		Association of Speech-Language Pathologists and Audiologists; Royal College of Speech Therapists, United Kingdom; Speech Pathology Australia). 3. Continuing education in the assessment and development of communication skills in transsexual, transgender, and gender nonconforming clients. This may include attendance at professional meetings, workshops, or seminars; participation in research related to gender identity issues; independent study; or mentoring from an experienced, certified clinician.		
53	Assessment and Treatment Considerations	Voice and communication treatment plans are developed by considering the available research evidence, the clinical knowledge and experience of the specialist, and the client's own goals and values.	• What are the benefits and harms of surgery to change one's voice? • What are the benefits and harms of speech therapy?	Systematic Review
Chapter XI - Surgery				
59	Criteria for breast/chest surgery (one referral)	Criteria for mastectomy and creation of a male chest in FtM patients: 1. Persistent, well-documented gender dysphoria; 2. Capacity to make a fully informed decision and to consent for treatment; 3. Age of majority in a given country (if younger, follow the SOC for children and adolescents); 4. If significant medical or mental health concerns are present, they must be reasonably well controlled. Hormone therapy is not a pre-requisite.		Good Clinical Practice Statement
59	Criteria for breast/chest surgery (one referral)	Criteria for breast augmentation (implants/lipofilling) in MtF patients: 1. Persistent, well-documented gender dysphoria; 2. Capacity to make a fully informed decision and to consent for treatment; 3. Age of majority in a given country (if younger, follow the SOC for children and adolescents); 4. If significant medical or mental health concerns are present, they must be reasonably well controlled. Although not an explicit criterion, it is recommended that MtF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.		Good Clinical Practice Statement
60	Criteria for genital surgery (two referrals)	Criteria for hysterectomy and ovariectomy in FtM patients and for orchiectomy in MtF patients: 1. Persistent, well documented gender dysphoria; 2. Capacity to make a fully informed decision and to consent for treatment; 3. Age of majority in a given country; 4. If significant medical or mental health concerns are present, they must be well controlled. 5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).		Good Clinical Practice Statement
60	Criteria for genital surgery (two referrals)	Criteria for metoidioplasty or phalloplasty in FtM patients and for vaginoplasty in MtF patients: 1. Persistent, well documented gender dysphoria; 2. Capacity to make a fully informed decision and to consent for treatment; 3. Age of majority in a given country; 4. If significant medical or mental health concerns are present, they must be well		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		controlled; 5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones). 6. 12 continuous months of living in a gender role that is congruent with their gender identity;		
61	Surgery for Persons with Psychotic Conditions and Other Serious Mental Illnesses	When patients with gender dysphoria are also diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated.		Good Clinical Practice Statement
62	Breast/Chest Surgery Techniques and Complications	For the MtF patient, a breast augmentation (sometimes called "chest reconstruction") is not different from the procedure in a natal female patient. It is usually performed through implantation of breast prostheses and occasionally with the lipofilling technique. Infections and capsular fibrosis are rare complications of augmentation mammoplasty in MtF patients (Kanhai, Hage, Karim, & Mulder, 1999).	• What are the benefits and harms of breast augmentation?	Systematic Review
63	Breast/Chest Surgery Techniques and Complications	For the FtM patient, a mastectomy or "male chest contouring" procedure is available. For many FtM patients, this is the only surgery undertaken. When the amount of breast tissue removed requires skin removal, a scar will result and the patient should be so informed. Complications of subcutaneous mastectomy can include nipple necrosis, contour irregularities, and unsightly scarring (Monstrey et al., 2008).	• What are the benefits and harms of a mastectomy?	Systematic Review
63	Genital Surgery Techniques and Complications	Genital surgical procedures for the MtF patient may include orchiectomy, penectomy, vaginoplasty, clitoroplasty, and labiaplasty. Techniques include penile skin inversion, pedicled colosigmoid transplant, and free skin grafts to line the neovagina. Sexual sensation is an important objective in vaginoplasty, along with creation of a functional vagina and acceptable cosmesis.	• What are the benefits and harms of genital surgical procedures?	Systematic Review
63	Genital Surgery Techniques and Complications	Genital surgical procedures for the MtF patient may include orchiectomy, penectomy, vaginoplasty, clitoroplasty, and labiaplasty. Techniques include penile skin inversion, pedicled colosigmoid transplant, and free skin grafts to line the neovagina. Sexual sensation is an important objective in vaginoplasty, along with creation of a functional vagina and acceptable cosmesis. Patients without former abdominal surgery, the laparoscopic technique for hysterectomy and salpingo-oophorectomy is recommended to avoid a lowerabdominal scar.	• What are the benefits and harms of genital surgical procedures?	Systematic Review
64	Other Surgeries	Other surgeries for assisting in body feminization include reduction thyroid chondroplasty (reduction of the Adam's apple), voice modification surgery, suction-assisted lipoplasty (contour modeling) of the waist, rhinoplasty (nose correction), facial bone reduction, face-lift, and blepharoplasty (rejuvenation of the eyelid). Other surgeries for assisting in body masculinization include liposuction, lipofilling, and pectoral implants. Voice surgery to obtain a deeper voice is rare but may be recommended in some cases, such as when hormone therapy has been ineffective.	• What are the benefits and harms of other surgical procedures?	Systematic Review
Chapter XII - Postoperative Care and Follow-Up				
64	Postoperative Care and Follow-up	Long-term postoperative care and follow-up after surgical treatments for gender dysphoria are associated with good surgical and psychosocial outcomes (Monstrey et al., 2009). Follow-up is important to a patient's subsequent physical and mental health and to a surgeon's knowledge about the benefits and limitations of surgery.		Good Clinical Practice Statement
Chapter XIII - Lifelong Preventive and Primary Care				

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
65	Lifelong Preventive and Primary Care	Primary care and health maintenance issues should be addressed before, during, and after any possible changes in gender role and medical interventions to alleviate gender dysphoria. While hormone providers and surgeons play important roles in preventive care, every transsexual, transgender, and gender nonconforming person should partner with a primary care provider for overall health care needs (Feldman, 2007).	• What are the benefits and harms of screening in the transgender population for cardiovascular disease, cancer, sexually transmitted diseases, and urinary tract infections? o How does this differ for those who have had surgery?	Systematic Review
65	General Preventive Health Care	Screening guidelines developed for the general population are appropriate for organ systems that are unlikely to be affected by feminizing/masculinizing hormone therapy. However, in areas such as cardiovascular risk factors, osteoporosis, and some cancers (breast, cervical, ovarian, uterine, and prostate), such general guidelines may either over- or underestimate the cost-effectiveness of screening individuals who are receiving hormone therapy. Several resources provide detailed protocols for the primary care of patients undergoing feminizing/masculinizing hormone therapy, including therapy that is provided after sex reassignment surgeries (Center of Excellence for Transgender Health, UCSF, 2011; Feldman & Goldberg, 2006; Feldman, 2007; Gorton, Buth, & Spade, 2005). Clinicians should consult their national evidence-based guidelines and discuss screening with their patients in light of the effects of hormone therapy on their baseline risk.		Good Clinical Practice Statement
66	Cancer Screening	Cancer screening of organ systems that are associated with sex can present particular medical and psychosocial challenges for transsexual, transgender, and gender nonconforming patients and their health care providers.	• What are the benefits and harms of screening in the transgender population for cardiovascular disease, cancer, sexually transmitted diseases, and urinary tract infections? o How does this differ for those who have had surgery?	Systematic Review
66	Urogenital Care	All MtF patients should receive counseling regarding genital hygiene, sexuality, and prevention of sexually transmitted infections; those who have had genital surgery should also be counseled on the need for regular vaginal dilation or penetrative intercourse in order to maintain vaginal depth and width (van Trotsenburg, 2009)		Systematic Review
67	Urogenital Care	Lower urinary tract infections occur frequently in MtF patients who have had surgery because of the reconstructive requirements of the shortened urethra. In addition, these patients may suffer from functional disorders of the lower urinary tract; such disorders may be caused by damage of the autonomous nerve supply of the bladder floor during dissection between the rectum and the bladder, and by a change of the position of the bladder itself. A dysfunctional bladder (e.g., overactive bladder, stress or urge urinary incontinence) may occur after sex reassignment surgery.	• What are the benefits and harms of screening in the transgender population for cardiovascular disease, cancer, sexually transmitted diseases, and urinary tract infections? o How does this differ for those who have had surgery?	Systematic Review
67	Urogenital Care	Most FtM patients do not undergo vaginectomy (colpectomy). For patients who take masculinizing hormones, despite considerable conversion of testosterone to estrogens, atrophic changes of the vaginal lining can be observed regularly and may lead to pruritus or burning. Examination can be both physically and emotionally painful, but lack of treatment can seriously aggravate the situation. Gynecologists treating the genital complaints of FtM patients should be aware of the sensitivity that patients with a male	• What are the benefits and harms of screening in the transgender population for cardiovascular disease, cancer, sexually transmitted diseases, and urinary tract infections?	Systematic Review

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		gender identity and masculine gender expression might have around having genitals typically associated with the female sex.	o How does this differ for those who have had surgery?	
Chapter XIV - Applicability of the Standards of Care to People Living in Institutional Environments				
67	Applicability of the Standards of Care to People Living in Institutional Environments	All elements of assessment and treatment as described in the SOC can be provided to people living in institutions (Brown, 2009). Access to these medically necessary treatments should not be denied on the basis of institutionalization or housing arrangements.		Good Clinical Practice Statement
68	Applicability of the Standards of Care to People Living in Institutional Environments	People who enter an institution on an appropriate regimen of hormone therapy should be continued on the same, or similar, therapies and monitored according to the SOC. A "freeze frame" approach is not considered appropriate care in most. People with gender dysphoria who are deemed appropriate for hormone therapy (following the SOC) should be started on such therapy. The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a high likelihood of negative outcomes such as surgical self-treatment by autocastration, depressed mood, dysphoria, and/or suicidality (Brown, 2010).		Good Clinical Practice Statement
68	Applicability of the Standards of Care to People Living in Institutional Environments	Housing and shower/bathroom facilities for transsexual, transgender, and gender nonconforming people living in institutions should take into account their gender identity and role, physical status, dignity, and personal safety. Placement in a single-sex housing unit, ward, or pod on the sole basis of the appearance of the external genitalia may not be appropriate and may place the individual at risk for victimization (Brown, 2009).		Good Clinical Practice Statement
Chapter XV - Applicability of the Standards of Care to People With Disorders of Sex Development				
70	Health History Considerations	Health professionals assisting patients with both a DSD and gender dysphoria need to be aware that the medical context in which such patients have grown up is typically very different from that of people without a DSD.		Good Clinical Practice Statement
NEW: Applicability of the Standards of Care to Eunuchs				
NEW: Competency, Training, Education, Ethics				

From: Karen Robinson
To: soc8chapterleads@wpath.org
Subject: Materials for discussion: consensus process and chapter structure
Date: Friday, July 20, 2018 9:49:00 AM
Attachments: WPATH_SOC8_ChapterStructureTemplate.docx
WPATH_SOC8_ConsensusProcess.docx
Notes_IdentifyingStatements.pdf

All –

I look forward to speaking with you either today (20 July) or next week (25 July).

I have attached documents related to some of what we will be discussing.

As a reminder, my evidence review team needs the questions for the systematic reviews to be conducted. One way to ensure that the questions are specific and will inform a recommendation is for you to think about the end product or the recommendation statements. What are the decision points for which SOC8 should provide guidance? Recall that you do not need to know the specific details. For instance you may not know if CBT or group therapy is better. You could say: We recommend use of CBT/group therapy for addressing <condition>. I would then know that you would like a review on the potential benefits and harms for CBT and group. I would respond with any questions I may have and send back to you a proposed systematic review question.

You may send me any draft statements, whether you think they may be evidence-based or best practice statements. I can provide feedback on distinction and on wording. I have attached notes about identifying statements and specific PICO format questions.

Thanks,

Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED

WPATH SOC8: Notes regarding initial identification of recommendation statements

Clinical Practice Guidelines: Systematically developed statements that include recommendations, strategies, or information that assist physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.

"Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options." IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.

Evidence-based Recommendation Statements:

- Based on systematic review with clear link to evidence
- Will be graded

Good Practice or Consensus-based Statements:

- Common sense or reminders of obvious
- Not appropriate for a systematic review or formal assessment of evidence

All recommendation statements should be:

- Clear and actionable
- Define all elements needed to implement (under what circumstances do something; exactly what to do under defined circumstances)
- Easily identifiable (i.e., typed in bold, summarized in a box, etc.)

Examples of Evidence-based Recommendation Statement (note different grading systems used):

> Antibiotics should be prescribed in children two years or older with a diagnosis of acute otitis media if the pain lasts longer than three days or if the pain increases after the consultation despite adequate treatment with painkillers; in these cases, amoxicillin should be given for 7 days (supplied with a dosage scheme). (Strong)
>
> The USPSTF recommends against the use of combined estrogen and progestin for the primary prevention of chronic conditions in postmenopausal women. (D recommendation)

Examples of Good Practice or Consensus-based Statements:

> In patients presenting with heart failure, clinicians should make an initial assessment of the patient's ability to perform routine/desired activities of daily living (ungraded good practice statement).
>
> Health services should be made available, accessible, and acceptable to sex workers based on the principles of avoidance of stigma, nondiscrimination, and the right to health (ungraded good practice statement).

Evidence-based Recommendation statements will be translated into questions for systematic review. These questions drive the entire process: what is identified, eligibility criteria, what is extracted and presented, and what analyses are completed. Questions are specified using the PICO format:

P	**Patient, population**
I	**Intervention**
C	**Comparison**
O	**Outcome**
T	**Timing**
S	**Setting**
D	**Study design**

Structure for chapters

20 July 2018

The following is the general structure. See following pages for a template and a mockup using the template.

- 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)
    - Text should precede each statement providing the rationale or reasoning for the recommendation. This should include outlining the available evidence, providing details about benefits and harms, a description of uncertainty, role of values and experience in developing the recommendation, and information about implementation of the recommendation, including expected barriers or challenges. Links to resources should also be provided, as appropriate.
    - Following the text the recommendation statement is provided in a standard, consistent format (see below)

<u>Recommendation statements</u>

- Evidence-based statements (wording followed by grading information in parentheses):
    - Strong recommendation: We recommend
    - Weak recommendation: We suggest

Example: We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

- Best practice statements (wording followed by 'ungraded best practice statement')
    - We advise

Example: We advise that people with X be referred to Y (ungraded best practice statement)

Background

This is where the scope of the chapter is described in 1-2 pages. Provide background information from a general review, including any definitions, as needed.

Summary of Recommendations

List all recommendations from this chapter here.

We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

We advise that people with X be referred to Y (ungraded best practice statement)

Subheading for Chapter Topic A

Brief paragraph about what is included in this topic.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

EXAMPLE MOCKUP

Chapter(assessment of adults presenting with symptoms of eating disorders)

Background

This is where the scope of the chapter is described in 1-2 pages.

The following chapter will discuss the main assessment process when working with adults presenting symptoms of an eating disorder. The chapter will discuss the recommendations regarding the background of the professionals working with people presenting with symptoms of eating disorders first. This will be followed by the assessment process and will conclude by the tools recommended to be used with working with people with eating disorders. This chapter will discuss the complex process of assessing an individual with an eating disorders. Before discussing this topic it is important for the professional to be able to differentiate the difference between clinical and non-clinical eating disorders. A non clinical eating disorders…

Summary of Recommendations

List all recommendations from this chapter here.

- We advise that the assessment of an adult with possible eating disorders should take into consideration the age, gender and the culture background of the individual (ungraded best practice statement).
- We advise that adults with symptoms suggesting the presence of an eating disorder should be assessed by professionals trained in this specialty (ungraded best practice statement).
- We advise that the assessment process for an individual presenting with symptoms of eating disorders should include assessment of capacity, medical assessment and psychiatric assessment (ungraded best practice statement).
- We recommend that the eating disorders questionnaire (EDQ) and the SCOFF questionnaire should be used as part of the assessment process (moderate; strong).
- We suggest that the assessment process should take into consideration risk factors such as age, gender and the existence of high levels of compulsive exercise (low; weak).

Subheading for Chapter Topic A (<not relevant in this example>)

Brief paragraph about what is included in this topic.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum).

The assessment of people with symptoms suggesting the existence of eating disorders can be complex as the definition of eating disorders varies according to age, gender and culture (REF). For example,

Asian cultures present with lack of body fat consent and BMI which appear to be low for western cultures are found to be not abnormal for certain Asian countries (REF, REF, REF). In addition gender could affect the presentation of an eating disorders as male, particularly athletes, could present with a full eating disorders in spite of having a healthy BMI (18-25). However, studies have also found that opposite findings although those studies have been biased by the lack of controls. In view of this we suggest that

- **Here is the text for the recommendation statement. We advise that the assessment of an adult with possible eating disorders should take into consideration the age, gender and the culture background of the individual (ungraded best practice statement).**

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum).

We commissioned a systematic review on tools for the assessment of eating disorders. The review identify 12 studies evaluating the performance of tools. The studies were generally well-designed, but there were concerns about risk of bias in 3 of the studies due to reporting bias. Overall, the body of evidence was considerate moderate for two tools…

- **Here is the text for the recommendation statement. We recommend that the eating disorders questionnaire (EDQ) and the SCOFF questionnaire should be used as part of the assessment process (moderate; strong).**
-

Consensus Process

20 July 2018

We need the draft recommendation statements from each Chapter. Recall that recommendation statements should be explicit and actionable (please see notes on identifying recommendations).

<To be added to the WPATH Guideline Development Methods document>

The following is the consensus process for recommendation statements. This will be used for the best practice statements and for the evidence-based recommendation statements:

1. Chapter members draft and reach consensus within chapter on recommendations statements.
2. All recommendation statements are sent to the Guideline Steering Committee for review and revision.
3. An online Delphi will be set up to be used by all SOC8 members to vote on recommendation statements. Members will be able to opt out of voting on statements they feel are outside of their expertise or experience, and will also have opportunity to provide feedback on each statement. Consensus will be considered reached if recommendation statement is agreed to by 80% or more of votes. Those statements not reaching consensus will be sent back to all for another round of voting. These statements may be, as appropriate, revised based on feedback received. Three rounds will be held. Recommendation statements reaching consensus will be included in SOC8.

From: Karen Robinson
To: Scott Leibowitz; ALC de <alc. devries@vumc. nl> Vries
Cc: Jon Arcelus; Tangpricha Vin; Eli Coleman; Blaine Vella
Subject: RE: adolescent chapter
Date: Thursday, November 1, 2018 9:37:00 AM

Scott – my apologies, I had tried to access the file when you first sent the link but got sidetracked as I was unable to sign in. I just tried again with no luck so will create a new account and try to get to the file before I need to head to the airport.
Thanks
Karen

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Sunday, October 28, 2018 11:42 AM
To: ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>
Cc: Karen Robinson < REDACTED Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>; Tangpricha Vin <vin.tangpricha@emory.edu>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>
Subject: Re: adolescent chapter

Hi all-
Thanks for sending these out Annelou.
Karen, I did add you to that drop box right during our last call last week. There's a column in our document for your feedback regarding the actual literature review statement question you need for the literature reviews we are requesting. We know we are up on the deadline, and everyone is traveling to Buenos Aires in a few days. Let me know if you are able to find the document in the drop box folder. It starts with: "USE THIS DOCUMENT"
THanks,
Scott

Scott Leibowitz, MD
Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH
Medical Director of Behavioral Health | THRIVE (gender and sex development) program
Associate Clinical Professor | The Ohio State University College of Medicine
(614) 722-2427 (office) | (614) 722-3913 (fax)
Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

On Thu, Oct 25, 2018 at 2:23 AM Vries, A.L.C. de <alc.devries@vumc.nl> wrote:

> Dear Karen
> I promised you some articles on decision making in teens; these are review articles, but show that there is some evidence.
> I think we need this sort of evidence base on decision making capacity in adolescents, regarding medical affirming treatment.
> Hope this is of help and clarifies what we mean.
> Kind regards,
> Annelou
>
> **Van:** Karen Robinson < REDACTED
> **Verzonden:** woensdag 17 oktober 2018 19:43
> **Aan:** 'Jon Arcelus' <Jon.Arcelus@nottingham.ac.uk>; vin.tangpricha@emory.edu
> **CC:** Scott Leibowitz <scottleibowitzmd@gmail.com>; Vries, A.L.C. de <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>
> **Onderwerp:** RE: adolescent chapter
> Could someone send around the current version of the statements prior to the call? Thanks!
>
> **From:** Jon Arcelus [mailto:Jon.Arcelus@nottingham.ac.uk]
> **Sent:** Wednesday, October 17, 2018 1:23 PM

To: vin.tangpricha@emory.edu
Cc: Karen Robinson < REDACTED Scott Leibowitz <scottleibowitzmd@gmail.com>; Vries, ALC de <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>
Subject: Re: adolescent chapter

In order to make sure that we have one, shall we schedule a teleconference tomorrow Thursday at 9:00 am EST time which is 14:00 UK time? Blaine can you plan one, please? Eli, can you join us?

Prof. Jon Arcelus, MD, PhD
Professor of Mental Health and of Transgender Health
Academic address: Room B18, Institute of Mental Health, Jubilee Campus, University of Nottingham, Nottingham, NG7 2TU, UK
Tel: +44 (0)115 7484098
Clinical Address: Nottingham Centre for Transgender Health, 12 Broad street, Nottingham NG1 3AL
https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

On 17 Oct 2018, at 16:21, Vin Tangpricha <vin.tangpricha@emory.edu> wrote:

> Hi Jon,
> Sorry, I am just seeing this now. I am at the airport heading to Denver for a meeting. I might be able to meet in the afternoons on Thur or Friday.
> On Wed, Oct 17, 2018 at 8:57 AM Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:
>
> > Thanks karen and Scott,
> > Once we know whether vin, eli and annalou can do at 8:00 am 9:00 am or 10:00 am EST time, which is 13:00, 14:00 and 15:00 in UK and one hour later in Holland, maybe Blaine can help us organizing a teleconference.
> > thanks
> > Jon
> > Prof. Jon Arcelus, MD, PhD
> > *Professor of Mental Health and Transgender Health*
> >
> > **Academic address:** *Centre for Social Futures,* Room B18, Institute of Mental Health, Jubilee Campus, Triumph Road, University of Nottingham, Nottingham, NG7 2TU, UK
> >
> > **Clinical Address:** Nottingham Centre for Transgender Health, 12 Broad Street, Nottingham NG1 3AL UK
> >
> > TEL +44 (0)115 8760160 (clinical)
> >
> > https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus
> >
> > NEW BOOK: The Transgender Handbook: A Guide for Transgender People, Their Families and Professionals
> >
> > ---
> >
> > **From:** Karen Robinson < REDACTED
> > **Sent:** 17 October 2018 1:46 PM

To: 'Scott Leibowitz'; Jon Arcelus
Cc: ALC de <alc. devries@vumc. nl> Vries; Eli Coleman
Subject: RE: Re:

All –

I could do a call tomorrow (Thurs) between 8-10 or 1-3:00.

It would be good if the current version of the statements could be forwarded. Systematic reviews covering bullet point one below are already underway for the endocrine chapter.

Thanks,

Karen

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Wednesday, October 17, 2018 8:33 AM
To: Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>
Cc: ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>; Karen Robinson <[REDACTED] Eli Coleman <colem001@umn.edu>
Subject: Re:

Hi Jon-

Glad you went into your spam folder to see that we are committee that is actively working on this and haven't been sitting quiet ducks! I agree- a conference call with me, you, Annelou, and Karen would probably very helpful. The current document is in the drop box and starts with "USE THIS DOCUMENT" but I have not yet updated the statements themselves to reflect all the feedback and lively discussion that our chapter calls have yielded. The columns to the right are notes from our chapter phone calls. We realize some of the statements need to be split into two and need to be made more actionable, than the way they are currently written. I was planning on doing that in the next day or so- *after* I get Eli and you the two slides for Buenos Aires. If I could simply update that later on tonight and send if that would be helpful going into a conference call, depending on when we schedule a call for.

As you all know, the Adolescent chapter is going to be one of the most scrutinized chapters in the entire standards of care. We are a unique chapter when it comes to the evidence based review because we **do** feel that there is a justification to do a literature review on what we postulate will be evidence based statements about the interventions (even though we expect the evidence to be graded low). Essentially the literature reviews on some of our statements- as we plan on submitting once I edit them to incorporate the feedback from our workgroup- are important for the following reasons:

-

Studies that demonstrate the psychological effectiveness of some of the interventions (blockers, hormones) in adolescence all included cohorts who went through a rather rigorous psychological assessment. We would like to talk this through as a group because it's a very important point.

- There is also literature on adolescent decision making and capacity to make informed decisions that carry lifelong ramifications. Since our chapter is a new chapter for the standards of care, and it focuses in on a developmental age group/assessment, (as opposed to other chapters that are more intervention specific), we are going to want to justify certain statements with graded evidence in terms of looking at the literature *on decision making in the developmental cohort (adolescence)* in general.

I happen to have time tomorrow morning EST. Any time between 8-10 AM if that happens to work for you, Annelou and Karen. I also have time tomorrow between 1-3:30 PM. (I'm not in clinic tomorrow- but rather at a local regional conference so there is some flexibility for me). Next week I'm in Seattle all week at AACAP, so hoping to finish all of this in short order and get our statements submitted. So the sooner the better.

Thanks,

Scott

Scott Leibowitz, MD

Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH

Medical Director of Behavioral Health | THRIVE (gender and sex development) program

Associate Clinical Professor | The Ohio State University College of Medicine

(614) 722-2427 (office) | (614) 722-3913 (fax)

Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

On Wed, Oct 17, 2018 at 4:30 AM Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:

> Dear Scott and Annalou,
> I have just found a lot of emails from Scott in my spam box, so I am a bit lost as to where we are.
> will it help to plan a telephone conference?
> As far as I understand there is some confusion as to the fact that you both feel that some statements need a systematic literature review and the feedback you got from karen and myself was they were consensus statements, hence they did not.
> It is very confusing, I do agree with you.
> I wonder whether having a telephone conference between the 4 of us, may help to clarify things, so Karen can explain things a bit better. As I cant access

the last version of the document, it will be good so attach it too.
if you feel that this is a possibility, I am quite flexible tomorrow (except from 6:30-10 pm uk time), Friday and Saturday (I can move things around) , so send us some dates and times and see if we can have a chat.
regards
Jon

Prof. Jon Arcelus, MD, PhD
Professor of Mental Health and Transgender Health

Academic address: *Centre for Social Futures,* Room B18, Institute of Mental Health, Jubilee Campus, Triumph Road, University of Nottingham, Nottingham, NG7 2TU, UK

Clinical Address: Nottingham Centre for Transgender Health, 12 Broad Street, Nottingham NG1 3AL UK

TEL +44 (0)115 8760160 (clinical)

https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

NEW BOOK: The Transgender Handbook: A Guide for Transgender People, Their Families and Professionals

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--

Vin Tangpricha, M.D., Ph.D.

Professor of Medicine
Program Director, Endocrinology & Metabolism Fellowship
Program Director, ABIM Physician Scientist Pathway, Internal Medicine Residency
Division of Endocrinology, Metabolism & Lipids
Department of Medicine
Emory University School of Medicine

Staff Physician, Section of Endocrinology, Atlanta VA Medical Center
Distinguished Physician, Emory Healthcare
Clinic appointments, 404-778-3280
Fellowship program inquires, Ms. Marcela Santamaria-Appling, 404-727-1549

101 Woodruff Circle NE- WMRB1301
Atlanta GA 30322
Ph (404) 727-7254
Fax (404) 592-6257
Email vin.tangpricha@emory.edu
Twitter: @vtangpricha
Editor in Chief, Journal of Clinical and Translational Endocrinology (JCTE),
www.jctejournal.com

From: Karen Robinson
To: "Eli Coleman"
Cc: Jon Arcelus; Asa Radix; Blaine Vella; Donna Kelly
Subject: RE: Conference Call - SOC 8 Chapter Leads
Date: Tuesday, May 1, 2018 8:05:30 AM

Thanks, Eli. It is important that we are on same page on the overall guideline development methods. There remain several outstanding issues, as you noted below. I will ask someone on my team to work to get a call with the chairs.
Thanks,
Karen

From: Eli Coleman [mailto:colem001@umn.edu]
Sent: Monday, April 30, 2018 2:56 PM
To: Karen Robinson < REDACTED
Cc: Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <ARadix@callen-lorde.org>; Blaine Vella <blaine@wpath.org>; Donna Kelly <donna@veritasmeetingsolutions.com>
Subject: Re: Conference Call - SOC 8 Chapter Leads
This looks good
The devil is on the details
If we could highlight the specific tasks for the workgroups and at least initial time lines
We need a general time line of the project
I don't think the mechanism for community input and even membership has been thought through ases mostly in expert opinion. And would not like that these recommendation graded as insufficient or inadequate.
We also need a vehicle for arriving at this expert opinion
There are still so many areas that we make recommendations

Sent from my iPhone

On Apr 30, 2018, at 1:30 PM, Karen Robinson < REDACTED wrote:

> Forwarding document again.
> I look forward to responses and feedback. And, yes, I had requested that we meet again before meeting with the chapter leads but we will make it work.
> Thanks
> Karen
>
> **From:** Karen Robinson
> **Sent:** Wednesday, April 25, 2018 1:44 PM
> **To:** Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Asa Radix <ARadix@callen-lorde.org>
> **Cc:** 'Blaine Vella' <blaine@wpath.org>; Donna Kelly <donna@veritasmeetingsolutions.com>
> **Subject:** RE: Conference Call - SOC 8 Chapter Leads
> All –
> For second call, do you mean Monday May 7th or May 9th, which is Wednesday.
> Also, please find attached a draft overview of the methods for guideline development. I had hoped to discuss this with the chairs first but it looks like the chapter lead calls are already scheduled. I have some questions for you, some of which are noted in comment boxes.
> Please also clarify what role you would like me to take during the calls. I have penciled in both.
> Thanks
> Karen
>
> **From:** Blaine Vella [mailto:blaine@wpath.org]

Sent: Wednesday, April 25, 2018 12:49 PM
To: SOC 8 Chapter Leads <soc8chapterleads@wpath.org>
Cc: Karen Robinson < REDACTED
Subject: Conference Call - SOC 8 Chapter Leads
Importance: High

Hello SOC8 Chapter Leads

Listed below are the two scheduled calls for the next SOC8 call. If you cannot make one, I hope you can make the other. Eli & the co-chairs will follow up with agenda items, etc. I will also be sending out an Outlook calendar invite which should adjust to your time zone. If your time zone is not listed in the chart below, please let me know ASAP so I can access the number for you.

Have a great morning, evening, afternoon

Best

Blaine

Tuesday, May 1, 2018 10:00am – 11:00am (US, ET)

Location	Call Time	Call In Number	Call In Number 2	Passcode
North America (US & Canada)	7 am Pacific 9am Central 10am Eastern	REDACTED	REDACTED	REDACTED
Amsterdam	4pm	REDACTED	REDACTED	REDACTED
Ghent	4pm	REDACTED		REDACTED
London	3pm	REDACTED	REDACTED	REDACTED
Oslo	4pm	REDACTED	REDACTED	REDACTED
Perth	10pm	REDACTED		REDACTED
Venezuela	10am	REDACTED		REDACTED

Monday, May 9, 2018 3:00pm – 4:00pm (US, ET)

Location	Call Time	Call In Number	Call In Number 2	Passcode
North America (US & Canada)	7 am Pacific 9am Central 10am Eastern	REDACTED	REDACTED	REDACTED
Amsterdam	9pm	REDACTED	REDACTED	REDACTED
Ghent	9pm	REDACTED		REDACTED
London	8pm	REDACTED	REDACTED	REDACTED
Oslo	9pm	REDACTED	REDACTED	REDACTED
Perth	3am	REDACTED		REDACTED
Venezuela	3pm	REDACTED		REDACTED

<WPATH Guideline Development Methodology_Draft_24April2018.docx>

From: Karen Robinson
To: Vries, ALC de
Cc: Scott Leibowitz; ARCELUS Jon - Consultant Psychiatrist (Jon.Arcelus@nottshc.nhs.uk); Eli Coleman; Asa Radix
Subject: RE: documents mentioned during call today
Date: Monday, July 16, 2018 10:11:00 AM
Attachments: image001.png

Thanks, all!
In general, given that this is a chapter focused on a particular subpopulation, I would suggest the group think about what recommendations from the other chapters apply here. I don't think we want to duplicate recommendations made about surgery or hormone therapy, for instance. Instead, think about what is different for this group – either in terms of adapting recommendations for general trans population or in unique decisions needing guidance in this age group.
Also, for several of the questions, while they are interesting, it is not clear what recommendation statement a review would inform.
e.g., for "1. Evidence for improved outcome when mental health is involved ?"
Define 'mental health' and 'involved'
What is statement?
We advise that trans adolescents or those with gender dysphoria received assessment/treatment/? from a mental health professional
Also, some questions would be useful for background but not lead to a recommendation:
e.g., Is there evidence for making a strict distinction between prepubescent children and pubescent adolescents? Define adolescence transgender care.
- This is a definitional background question not one leading to a specific recommendation.
I will send detailed comments on your question document later. I'm happy to have or join a call to discuss.
Thanks,
Karen

From: Vries, ALC de [mailto:alc.devries@vumc.nl]
Sent: Monday, July 16, 2018 8:16 AM
To: Karen Robinson < REDACTED
Cc: Scott Leibowitz <scottleibowitzmd@gmail.com>; ARCELUS Jon - Consultant Psychiatrist (Jon.Arcelus@nottshc.nhs.uk) <Jon.Arcelus@nottshc.nhs.uk>
Subject: RE: documents mentioned during call today

Dear Karen
It's been awhile since our conference call. Since then chapter members have continued working with the documents that you sent around. We have selected the statements concerning adolescent care and asked every member whether they thought that it should remain, change or be deleted or that there should be statements added. From the replies of everyone Scott and I have merged one file with what we now think should be the research questions for the systematic reviews. There is one more round to go, everyone has the chance to comment on this document, but before finishing, we are interested if these are the questions you can work with? Please let us know what your thoughts are, or how you would suggest we proceed,
Best regards,
Annelou
-on behalf of Scott and Jon-

cid:image002.png@01D40E30.3E299A80

Dr. Annelou L.C. de Vries | Child and adolescent psychiatrist
Departments of Child and Adolescent Psychiatry, Pediatrics, Pediatric Psychology and Center of Expertise on Gender Dysphoria
Location VUmc | Room number 1Y130 | PO Box 7057, 1007MB Amsterdam
T: +31 20 4440861 / + 31 20 444 2550 | E: alc.devries@vumc.nl
www.amsterdamumc.nl | www.vumc.nl / www.amc.nl

Van: Karen Robinson < REDACTED
Verzonden: woensdag 6 juni 2018 16:20
Aan: adolescentsoc8@wpath.org
Onderwerp: documents mentioned during call today

All –

Nice to speak with you today.

I have attached documents mentioned to be sure you all have them on hand. Also pasted below is the email sent to the chapter leads.

Thanks,

Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED
REDACTED
REDACTED
REDACTED

Email to Chapter Leads:

All –

As discussed during our initial phone calls, a first task is to identify the specific statements to be considered for SOC8. We therefore would ask that you (Chapter Leads initially, and then Chapter Members) do following:

- Consider the end product. Think explicitly about the decisions for which you would like to make recommendation statements. What are the areas of uncertainty in practice? Where is guidance needed?
- Consider whether recommendations from other organizations may be adopted. For instance, for decisions around hormone therapy the recommendations from the Endocrine Society may be considered. For relevant statements, the Evidence Review Team would conduct a limited search to identify any studies published since development of recommendation(s) being considered for adoption.
- Review statements from SOC7 (for those chapters included in SOC7). The Evidence Review Team extracted statements from SOC7. I have attached a document that lists these statements by chapter. We have also made an initial classification as to whether the statement may be evidence-based (for which a systematic review will be conducted) or a good practice statement (see attached notes for definitions and examples).

- Any statements missing?
- Any statements to add?
- Finalize classification as to evidence-based or good practice statement

As noted on the call, we know that this process will take time to fully complete. However, please let Chairs and me know of statements you think will be evidence-based by end of this month so that we can begin the systematic reviews.

I am happy to respond to questions individually and/or to join calls with Chapter members if that would be useful.

This is a very important stage and we appreciate your guidance!

As promised, here are links to some of the resources/tools referenced in the methods document (we will add references to the document as it continues to be revised):

GRADE www.gradeworkinggroup.org

Cochrane Risk of Bias, ROBINS: Cochrane Handbook training.cochrane.org/handbook

ROBIS http://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/

Thanks,

Karen

Evidence Review Team

Attachments:

SOC7 Statements - as Word doc

Notes about recommendation statements – as PDF

From: Karen Robinson
To: Tishelman, Amy; Eli Coleman; Jon Arcelus (Jon.Arcelus@nottingham.ac.uk)
Cc: Blaine Vella (blaine@wpath.org)
Subject: RE: WPATH SOC8: Identification of statements [EXTERNAL]
Date: Monday, May 21, 2018 7:54:00 AM
Attachments: image001.jpg

You can think of them as questions if you like. Most people I work with find it easier to think of the statement that they want to make or the guidance needed. You don't need consensus around the draft statements, nor do they need to be directional at this point. I am looking for something like, we need a statement for whether to do X or Y for Z.
If you send questions, I will translate.
Thanks,
Karen

From: Tishelman, Amy [mailto:Amy.Tishelman@childrens.harvard.edu]
Sent: Friday, May 18, 2018 6:55 PM
To: Karen Robinson < REDACTED Eli Coleman <colem001@umn.edu>; Jon Arcelus (Jon.Arcelus@nottingham.ac.uk) <Jon.Arcelus@nottingham.ac.uk>
Cc: Blaine Vella (blaine@wpath.org) <blaine@wpath.org>
Subject: RE: WPATH SOC8: Identification of statements [EXTERNAL]

Some of the statements are very straightforward and I could generate them now and I don't think they would be controversial—many were included in the SOC7. However, I think that there are some controversies in my chapter and we have a group of people with a diversity of ideas (I believe) which is fine. A review of literature first may help us to develop consensus around statements, and be more empirically grounded when possible. I talked this over today with another chapter Lead. I am more familiar with this process: develop questions→conduct lit search->read literature-> interpret literature-> write statements/recommendations based on science and/or clinic expertise when science is unavailable.
I am already familiar with a lot of relevant literature but I anticipate we will want to review literature not examined before. Would it be okay if we took this path and send questions for you to review prior to making statements/recommendations in some areas?

_____

Amy C. Tishelman, Ph.D.
Senior Attending Psychologist
Director of Clinical Research
Disorders of Sex Development-
Gender Management Service (DSD-GeMS)
Assistant Professor of Psychology
Harvard Medical School

From: Karen Robinson [mailto: REDACTED
Sent: Friday, May 18, 2018 9:38 AM
To: Tishelman, Amy; Eli Coleman; Jon Arcelus (Jon.Arcelus@nottingham.ac.uk)
Cc: Blaine Vella (blaine@wpath.org)
Subject: RE: WPATH SOC8: Identification of statements [EXTERNAL]

Amy –
Think about the final chapter – what are the statements you will want included? You can think about what decision points or areas of uncertainty there are.. what are those points, regardless of whether

this is evidence for rationale or not?
I am happy to have a call with you to discuss. Let me know some times that might work for you.
Thanks
Karen

From: Tishelman, Amy [mailto:Amy.Tishelman@childrens.harvard.edu]
Sent: Thursday, May 17, 2018 3:48 PM
To: Eli Coleman <colem001@umn.edu>; Karen Robinson < REDACTED Jon Arcelus (Jon.Arcelus@nottingham.ac.uk) <Jon.Arcelus@nottingham.ac.uk>
Cc: Blaine Vella (blaine@wpath.org) <blaine@wpath.org>
Subject: RE: WPATH SOC8: Identification of statements [EXTERNAL]

Hi All,
I don't mean to belabor this conversation and I appreciate your email. I feel that it is hard to make recommendations prior to doing the literature review, and I think this has been confusing me a bit. Doesn't it make sense to pose the questions, do the literature review and then, based on the data, make recommendations? And when the data is lacking, then come up with recommendations based on clinical judgement?
Thanks for weighing in on this.
Amy

Amy C. Tishelman, Ph.D.
Senior Attending Psychologist
Director of Clinical Research
Disorders of Sex Development-
Gender Management Service (DSD-GeMS)
Assistant Professor of Psychology
Harvard Medical School

From: Eli Coleman [mailto:colem001@umn.edu]
Sent: Thursday, May 17, 2018 2:52 PM
To: Karen Robinson
Cc: soc8chapterleads@wpath.org
Subject: Re: WPATH SOC8: Identification of statements [EXTERNAL]

Dear Amazing Chapter Leads,

I know that there has been some confusion and challenges regarding next steps - and particularly setting up teleconferences with your committee members.

Jon, Asa and myself met today and we wanted to clarify some things:

- While we would like you to plan a teleconference with your committee as soon as possible, you do not have to wait for that meeting to get started with your work. If you can't get everyone on a call - they can catch up with minutes.
- You can start a lot of the process by email - and follow up with a conference call (allowing for more discussion time)
- You do not have to make sure that Karen, Jon, Asa, or myself are on your first teleconference. Most importantly you find out when your committee can best meet. We will try to be there - but you have enough information to get started. Just let Blaine and

all of us when you are going to set it up. Blaine will offer assistance in making the call happen - or use your own teleconferencing capability.

- We suggest that the chapter leads review the summarized recommendations (for existing chapters) and add any suggested recommendations for consideration by your committee for input. Drafting something for your committee will facilitate things moving along. For new chapters, we suggest that you start drafting some recommendations for your committee to consider as well.

- Keep in mind the main thing we are looking for is prioritized recommendations that need systematic reviews by JH. We need to get the obvious ones to JH to begin their work. Others can be considered as we work through this process.

- You decide how you are going to work with your committee keeping in mind the time line. There is no one right way of doing this. Regular calls,email correspondence, meetign in a coffee shop in Amsterdam is all up to you.
- Start thinking about using the Buenos Aires Meeting as a possible face-to-face - with teleconference input for committee work. We will have a meeting scheduled on November 3 with the chapter leads followed by a broad meeting of all committee members. November 3 is a good day to think about meetings (or before) - and there are also lunch times through the conference. Jon will be preparing some options for times that your committees will meet - but for sure we will have a committee chapter lead meeting followed by a broad meeting just prior to the opening ceremony on Nov 3. Please plan accordingly .
- We are available any time for consult to move things along.

Hope these suggestions are helpful to you.

Best,

Eli, Asa and Jon

On Fri, May 11, 2018 at 10:16 AM, Karen Robinson < REDACTED wrote:
All –
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evidence-based (for which a systematic review will be conducted) or a good practice statement (see attached notes for definitions and examples).

- Any statements missing?
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As noted on the call, we know that this process will take time to fully complete. However, please let Chairs and me know of statements you think will be evidence-based by end of this month so that we can begin the systematic reviews.
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This is a very important stage and we appreciate your guidance!
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ROBIS http://www.bristol.ac.uk/population-health-sciences/projects/robis/robis-tool/
Thanks,
Karen
Evidence Review Team
Attachments:
SOC7 Statements - as Word doc
Notes about recommendation statements – as PDF

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED
REDACTED
REDACTED
REDACTED

--
Eli Coleman, PhD
Academic Chair in Sexual Health
Professor and Director
Image removed by sender.

From: Karen Robinson
To: Tishelman, Amy; Eli Coleman (colem001@umn.edu); Jon Arcelus (Jon.Arcelus@nottingham.ac.uk)
Subject: RE: WPATH SOC8: Identification of statements [EXTERNAL]
Date: Tuesday, May 15, 2018 4:48:00 PM

Amy –
The quick answer is do not feel limited by the prior statements. I would have members think about decisions made by care providers, including parents, where guidance would be useful. What are the areas of uncertainty? I would think first about those decision points. The question of whether there might be evidence is secondary.
Does that help? I'm happy to have a chat with you and/or join a call with the chapter members.
Thanks
Karen

From: Tishelman, Amy [mailto:Amy.Tishelman@childrens.harvard.edu]
Sent: Tuesday, May 15, 2018 4:42 PM
To: Eli Coleman (colem001@umn.edu) <colem001@umn.edu>; Jon Arcelus (Jon.Arcelus@nottingham.ac.uk) <Jon.Arcelus@nottingham.ac.uk>
Cc: Karen Robinson < REDACTED
Subject: [ALERT: ATTACHMENT(S) MAY CONTAIN VIRUS]FW: WPATH SOC8: Identification of statements [EXTERNAL]
Hi,
I have a quick question. The SOC8 chapter I am working on is new, and I think it is likely we will have questions never posed before (e.g., how does general literature say that preschoolers, and school age children communicate and what factors impact their verbalizations; what does research say about validated measures of gender identity in young children, etc). We may not know our end statements until we get the research (but we can make up something). To what extent do you want us to be governed by the statements you have already sent?
Thanks,
Amy

Amy C. Tishelman, Ph.D.
Senior Attending Psychologist
Director of Clinical Research
Disorders of Sex Development-
Gender Management Service (DSD-GeMS)
Assistant Professor of Psychology
Harvard Medical School

From: Karen Robinson [mailto: REDACTED
Sent: Friday, May 11, 2018 11:17 AM
To: 'soc8chapterleads@wpath.org'
Subject: WPATH SOC8: Identification of statements [EXTERNAL]
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Thanks,

Karen

Evidence Review Team

Attachments:

SOC7 Statements - as Word doc

Notes about recommendation statements – as PDF

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED
REDACTED
REDACTED
REDACTED

From: Karen Robinson
To: Tangpricha, Vin
Subject: Re: [External] Hormone chapter reviews: KQ 4, 5, 6, 7, 8, 9
Date: Wednesday, November 6, 2019 8:16:51 PM

Hi Vin!
I can do between 10:15 and 12:30 ET on Friday. Would any of those times work?

Sent from my iPhone

On Nov 6, 2019, at 4:05 PM, Tangpricha, Vin <vtangpr@emory.edu> wrote:

> I think we agree more than disagree. Do you have anytime Friday? I am on a flight 1:30 to 3:30 but outside those windows I have good availability.
>
> Sent from my iPhone
>
> > On Nov 6, 2019, at 3:41 PM, Karen Robinson < REDACTED wrote:
> >
> > Vin –
> > In looking at the summary prompted by your question I noticed some text that could be clarified. Please see attached revised summary.
> > I'm happy to have a call.
> > In case helpful prior to call, please note a few things:
> > - Biological plausibility is not (currently) a domain in grading strength or certainty of evidence; we did not assess or consider this in the systematic reviews.
> > - I would expect the panel members to have some disagreements with how we assessed some studies and classified the strength of evidence. The benefit is that you should be able to see clearly how we came to our conclusions (transparency) and the request would be that the panel members be explicit about what they think needs to be reconsidered.
> > - Recommendations are based on more than the body of evidence. The panel can certainly, for instance, consider biologic basis, other types of evidence, as well as other issues like resource use, acceptability, etc. in drafting recommendation statements.
> > - Finally, as I am sure you know, it is unfortunately often the case that we are disappointed at end of review to find, despite finding additional studies, careful data extraction, risk of bias assessment, etc. that there is a lack of evidence upon which to draw conclusions. We actually talked about this challenge yesterday during our quarterly AHRQ EPC meeting – no one likes it when our

end product says that we can't draw conclusions because the evidence base is insufficient!

Let me know a few times that would work for you

Thanks

Karen

From: Tangpricha, Vin <vtangpr@emory.edu>
Sent: November 6, 2019 2:22 PM
To: Karen Robinson < REDACTED
Subject: Re: [External] Hormone chapter reviews: KQ 4, 5, 6, 7, 8, 9

Hi Karen,

I have looked over these reports. Could we have a quick call maybe Friday morning about these? I agree with some of these reports that you couldn't make a conclusion on some of the questions but I wonder about KQ #6 which has a solid biologic basis. Could we discuss these before I send out to the group. My worry is that the group will say that the evidence reviews did not provide any additional information (and thus not useful).

Sincerely,

Vin

Vin Tangpricha, M.D., Ph.D.

Professor of Medicine
Program Director, Endocrinology & Metabolism Fellowship
Division of Endocrinology, Metabolism & Lipids
Department of Medicine
Emory University School of Medicine

Staff Physician, Section of Endocrinology, Atlanta VA Medical Center
Distinguished Physician, Emory Healthcare
Clinic appointments, 404-778-3280
Fellowship program inquires, Ms. Marcela Santamaria-Long, 404-727-1549
Pronouns: He/Him/His

101 Woodruff Circle NE- WMRB1301
Atlanta GA 30322
Ph (404) 727-7254
Fax (404) 592-6257
Email vin.tangpricha@emory.edu
Twitter: @vtangpricha
Editor in Chief, Journal of Clinical and Translational Endocrinology (JCTE), www.jctejournal.com

---

From: Karen Robinson < REDACTED

Sent: Tuesday, November 5, 2019 23:20
To: Tangpricha, Vin <vtangpr@emory.edu>
Subject: [External] Hormone chapter reviews: KQ 4, 5, 6, 7, 8, 9

Vin –

Please find attached the reports for 7 key questions (key questions were defined in protocol). We are working to finalize the other questions and will send as soon as complete.

Thanks

Karen

<Hormone KQ6 Transgender Men 31Oct19 06Nov19.docx>

From: Karen Robinson
To: Asa Radix
Cc: Jon Arcelus; Eli Coleman
Subject: my slides from Saturday
Date: Sunday, November 4, 2018 7:16:00 PM
Attachments: WPATH_SOC8_ChapterLeadsMeeting_3Nov18.pptx

Asa – Per request, please find my slides from Saturday.
I will upload these, as well as the other documents I have previously distributed, to the DropBox folder when I get back to office.
Thanks,
Karen

Overview of Methods and Status

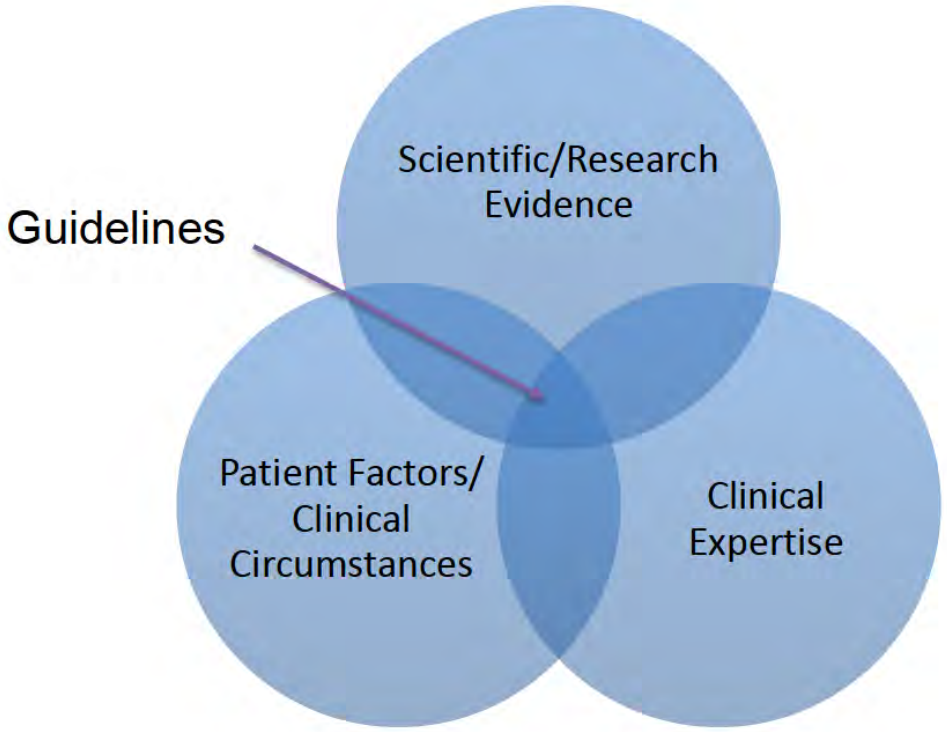
November 2018

WPATH SOC8 Chairs, Chapter Leads
and ERT (JHU)

JOHNS HOPKINS
SCHOOL OF MEDICINE

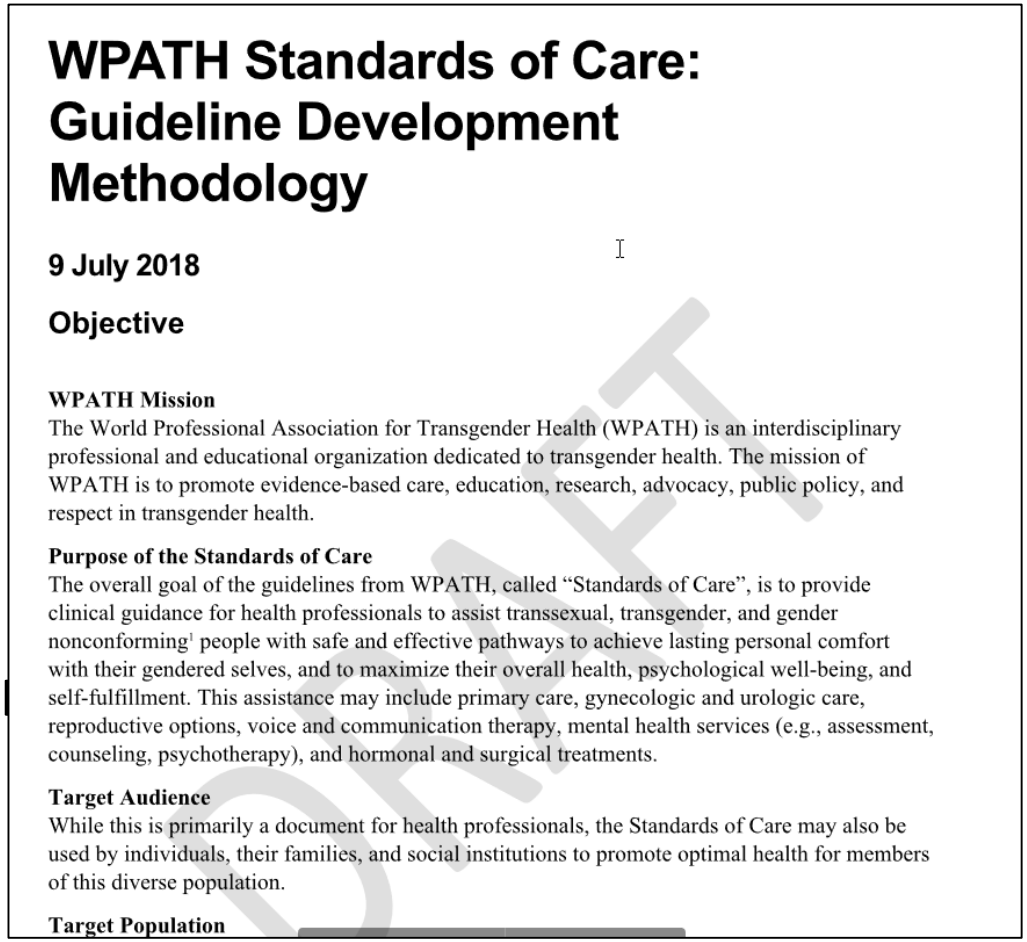
Clinical Practice Guidelines

Systematically developed statements that include recommendations, strategies, or information that assist physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.


Guidelines
Scientific/Research Evidence
Patient Factors/ Clinical Circumstances
Clinical Expertise

Guideline Process

1. Identify scope
2. Convene group
3. Refine questions
4. Assess evidence
5. Draft guideline
6. External review
7. Disseminate guideli



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 transsexual, transgender, and gender nonconforming[1] 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

JHU_000001615

What makes a good guideline?

Domains:

1. Scope & Purpose
2. Stakeholder Involvement
3. Rigour of Development
4. Clarity of Presentation
5. Applicability
6. Editorial Independence

JHU_000001616

1. Identify Scope

- Develop SOC8
  - Chapters, including new chapters identified

AGREE

- Scope and Purpose

2. Convene group

- Chairs
- Chapter Leads and Members
- Methodologist

AGREE

- Stakeholder involvement
- Editorial independence

AGREE Domain 6. Editorial Independence

Items:

- View of funding bod
  have not influenced
  content
- Competing interests
  development group
  members recorded a
  addressed

WPATH

WPATH Policy for Disclosures of Interests and Management of Conflicts
Standards of Care 8

The World Professional Association for Transgender Health (WPATH) develops the Standards of Care (SOC) for the health of Transsexual, Transgender and Gender Nonconforming People. Appointment to the SOC8 Committee as a Chair, Methodologist, Chapter Lead or Chapter Member is subject to approval of the WPATH Board.

Interests must be disclosed using the WPATH Disclosure Form. The Disclosure Form collects information about financial relationships with entities with direct interest in the SOC8 as well as any non-financial interests such as previously published opinions, institutional relationships, advocacy or policy positions, or specialty practice that may relate to the topics in SOC8.

Management of Conflicts of Interest
The WPATH Board reviews and assesses disclosure forms. Management of conflicts may include prohibiting membership in SOC8, open discussion with other chapter or SOC8 members, and/or recusal from decisions specific to disclosed interests.

Completed and signed forms should be submitted for review of the WPATH Board to blaine@wpath.org

Disclosure Form of Interests
Part 1. Identifying Information

Name:

Complete Mailing Address:

Email Address:

Telephone Number (Daytime):

Current Employer/Affiliation:

Chapter(s):

Part 2. Complete All Parts of the Disclosure Form.

- *Check "No" if no disclosure exists.*
- *Check "Yes" – please providing the requested information here to explicitly declare "Yes"*

JHU_000001619

3. Refine questions

Task discussed during initial calls:

To identify and refine questions for systematic reviews

- Review statements from SOC7
- Draft recommendations

AGREE

- Scope
- Rigour of development

SOC7 Statements
(May)

		adolescent's specific clinical situation and goals for gender identity expression.		
21	Risks of Withholding Treatment for Adolescents	Refusing timely medical interventions for adolescents might prolong gender dysphoria and contribute to an appearance that could provoke abuse and stigmatization. As the level of gender-related abuse is strongly associated with the degree of psychiatric distress during adolescence (Nuttbrock et al., 2010), withholding puberty suppression and subsequent feminizing or masculinizing hormone therapy is not a neutral option for adolescents.		Good Clinical Practice Statement
NEW: Assessment, Support, and Therapeutic Approaches for Adolescents with Gender Diversity/Dysphoria				
Chapter VII - Mental Health				
22	Competency of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria	The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria: 1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country. 2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria. 4. Documented supervised training and competence in psychotherapy or counseling. 5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria. 6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with		

From: Karen Robinson
Sent: Thursday, July 26, 2018 8:26 AM
To: soc8chapterleads@wpath.org
Cc: Eli Coleman <colem001@umn.edu>; Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>; Blaine Vella <blaine@wpath.org>
Subject: Register

Next Last

All –

Thanks for joining the calls last Friday and yesterday.

As a brief reminder, what we need now are questions that you think need to be addressed by systematic reviews. These should be very specific (such as in PICO format) and should clearly lead to one or more recommendations. To ensure both of those characteristics, I suggested that people think about the end product and draft recommendation statements – what is it that they need to say in the chapter? What are the decision points for which people need or could benefit from guidance from WPATH We do not expect the statements to be in final format and the statements may be stems without details (i.e., pending review to determine most appropriate intervention, assessment tool, timing, criteria, etc.).

In preparing protocols for the systematic reviews we have conducted some preliminary searching. The chapter members will need to describe the available evidence to provide the reasoning underlying best practice statements and for the background section of the chapter. We hope the attached might be helpful.

The file lists studies (broadly defined and not limited by design), systematic reviews, and guidelines. We have tagged each citation with the relevant chapter(s).

	A	S	T	U	V	
1						
2	**Bibliography**	**Chapter XVII. Applicability of the Standards of Care to People with Intersex**	**Chapter XVIII. NEW: Applicability of the Standards of Care to**	**Chapter XIX.NEW: Competency, Training, Education, Ethics**	**Other - Please enter the topic (e.g. HIV, sport etc.)**	**Oth spor**
1269	Clinics in plastic Surgery -Series				Journal Series	
1270	Practice parameter on gay, lesbian or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. American Academy of Child and Adolescent Psychiatry. NGC:009316				Guideline	
1271	Care of the HIV-infected transgender patient. New York State Department of Health. NGC:009206				Guideline	
1272	Kreukels BPC, Köhler B, Nordenström A, Roehle R, Thyen U, Bouvattier C, de Vries ALC, Cohen-Kettenis PT; dsd-LIFE group. Gender Dysphoria and Gender Change in Disorders of Sex Development/Intersex Conditions: Results From the dsd-LIFE Study. J Sex Med. 2018 May;15(5):777-785.	Study				
1273						

4. Assess Evidence

- ERT:
  - Conduct systematic reviews
  - Strength of evidence
- Chapter Members:
  - Provide guidance
  - Confirm summary and strength of evidence

AGREE

- Rigour of development

JHU_000001623

AGREE Domain 3. Rigour of Development

Items:

- Systematic search
- Clear selection criteria
- Strengths and limitations of body of evidence
- Methods for formulating recommendations
- Health benefits, side effects and risks considered
- Explicit link between recommendations and evidence
- Externally reviewed
- Procedure for updating

5. Draft guideline

- Chapter Members:
  - Write/Revise recommendation statements (informed by systematic review, as applicable)
  - Rate strength of each statement (as applicable)
  - Write accompanying text

AGREE

- Clarity of presentation

Structure for chapters

20 July 2018

The following is the general structure. See following pages for a template and a mockup using the template.

- 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)
    - Text should precede each statement providing the rationale or reasoning for the recommendation. This should include outlining the available evidence, providing details about benefits and harms, a description of uncertainty, role of values and experience in developing the recommendation, and information about implementation of the recommendation, including expected barriers or challenges. Links to resources should also be provided, as appropriate.
    - Following the text the recommendation statement is provided in a standard, consistent format (see below)

<u>Recommendation statements</u>

- Evidence-based statements (wording followed by grading information in parentheses):
    - Strong recommendation: We recommend
    - Weak recommendation: We suggest

Example: We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

- Best practice statements (wording followed by 'ungraded best practice statement')
    - We advise

Example: We advise that people with X be referred to Y (ungraded best practice statement)

Background

This is where the scope of the chapter is described in 1-2 pages. Provide background information from a general review, including any definitions, as needed.

Summary of Recommendations

List all recommendations from this chapter here.

We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

We advise that people with X be referred to Y (ungraded best practice statement)

Subheading for Chapter Topic A

Brief paragraph about what is included in this topic.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

6. External review

- External to SOC8 members:
  - Presentation to WPATH Board
  - Public review
- SOC8 members respond to comments and revise guideline

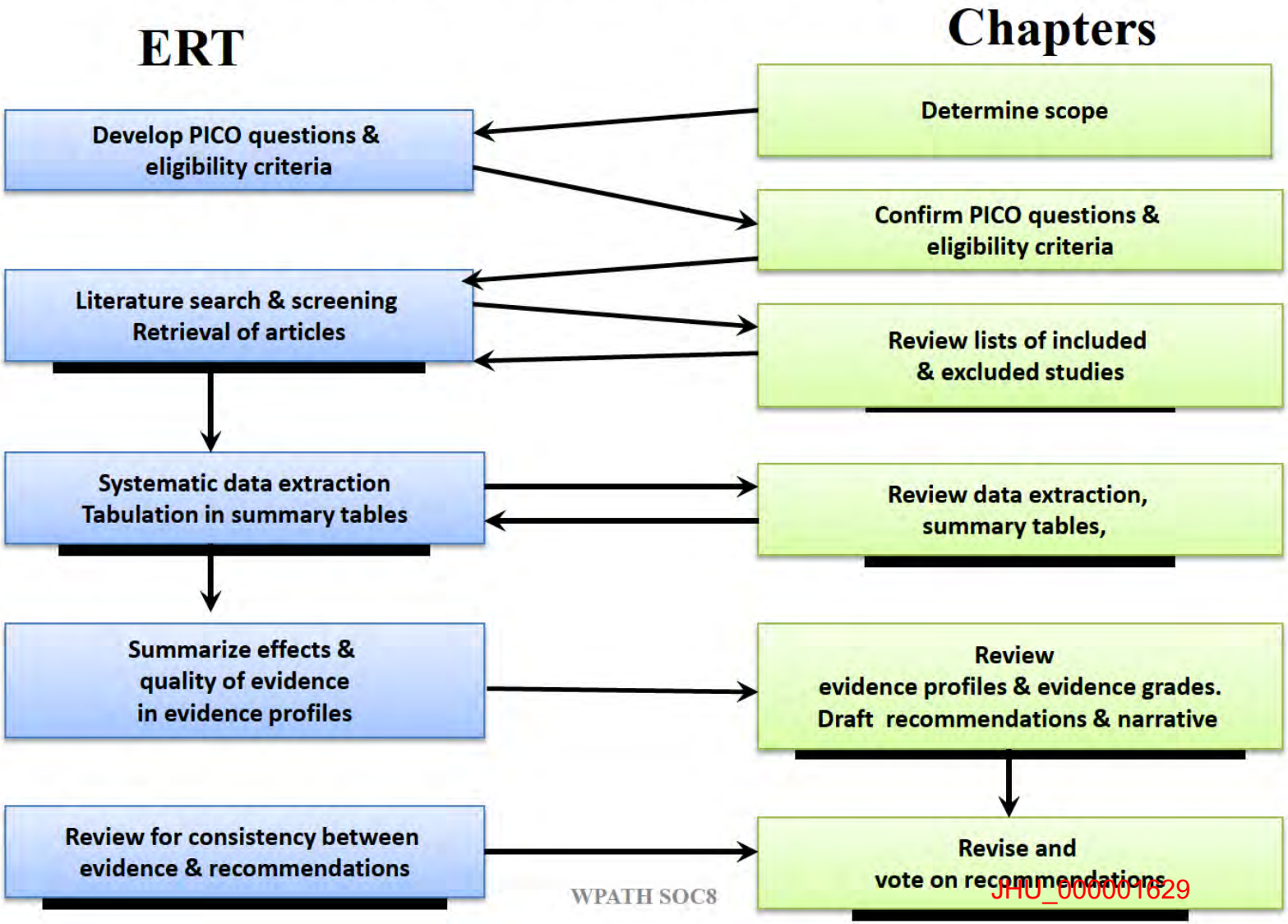
AGREE

- Rigour of development

7. Implementation

- Publication
- Other formats or method?

Chapter Members & ERT: Collaboration and Responsibilities



Systematic Reviews 101

Systematic Reviews

A review of existing evidence that uses explicit methods of identification, selection and validation of included information

- *Meta-analysis* uses statistical methods to quantitatively summarize results of similar but separate studies

Systematic Review Process

Definition of question(s)

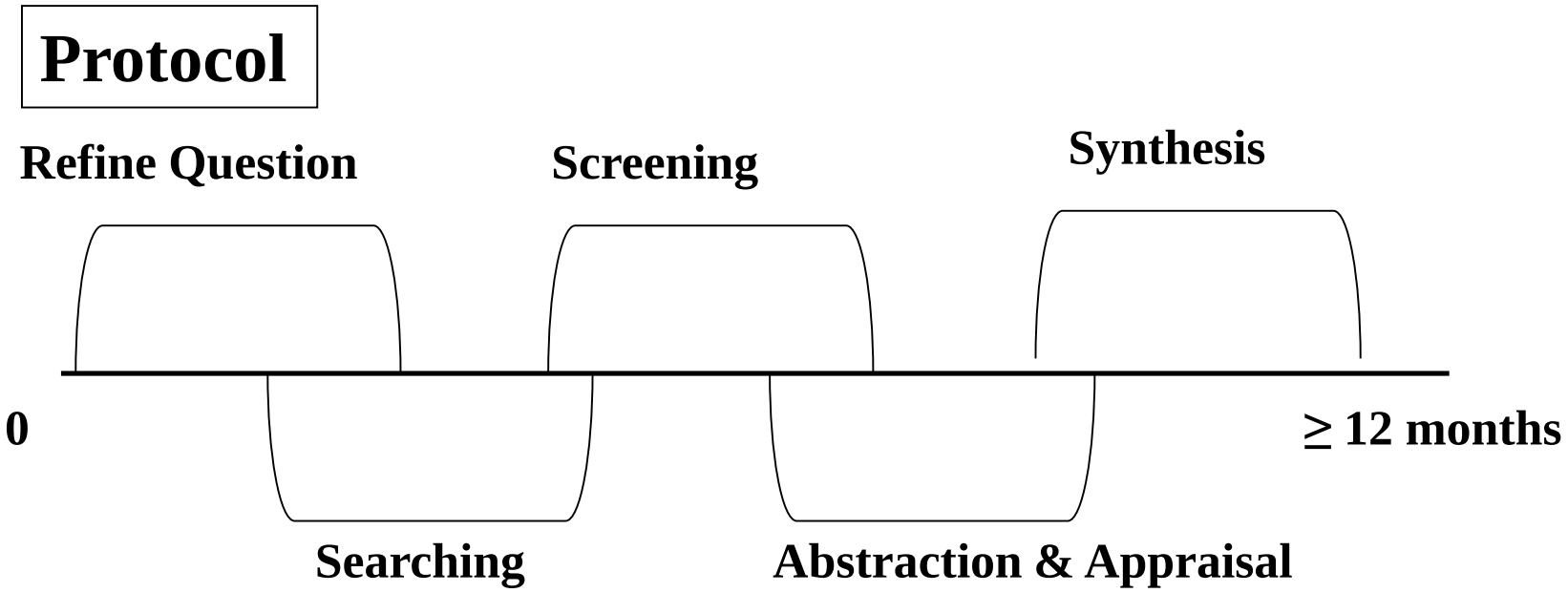
Identification of evidence

Selection of evidence

Evaluation of evidence

Synthesis of evidence

Timeline for Systematic Review



Definition of Questions

- Can it be answered?
  - uncertainty
  - availability of evidence
- Clear and specific
  - specify inclusion/exclusion criteria

 Drive ALL steps in process

Example of vague question:

What is the best strategy to prevent smoking in young people?

Well-Formulated Question

Patient (Population)	Intervention	Comparison	Outcome
• young people • under 25 • smoking frequency, consumption	Media: TV, radio, newspaper, booklets, posters, billboards…	No intervention	• objective (thiocyanate, alveolar CO) • self-reported behavior • intermediate • process

Well-Formulated Question

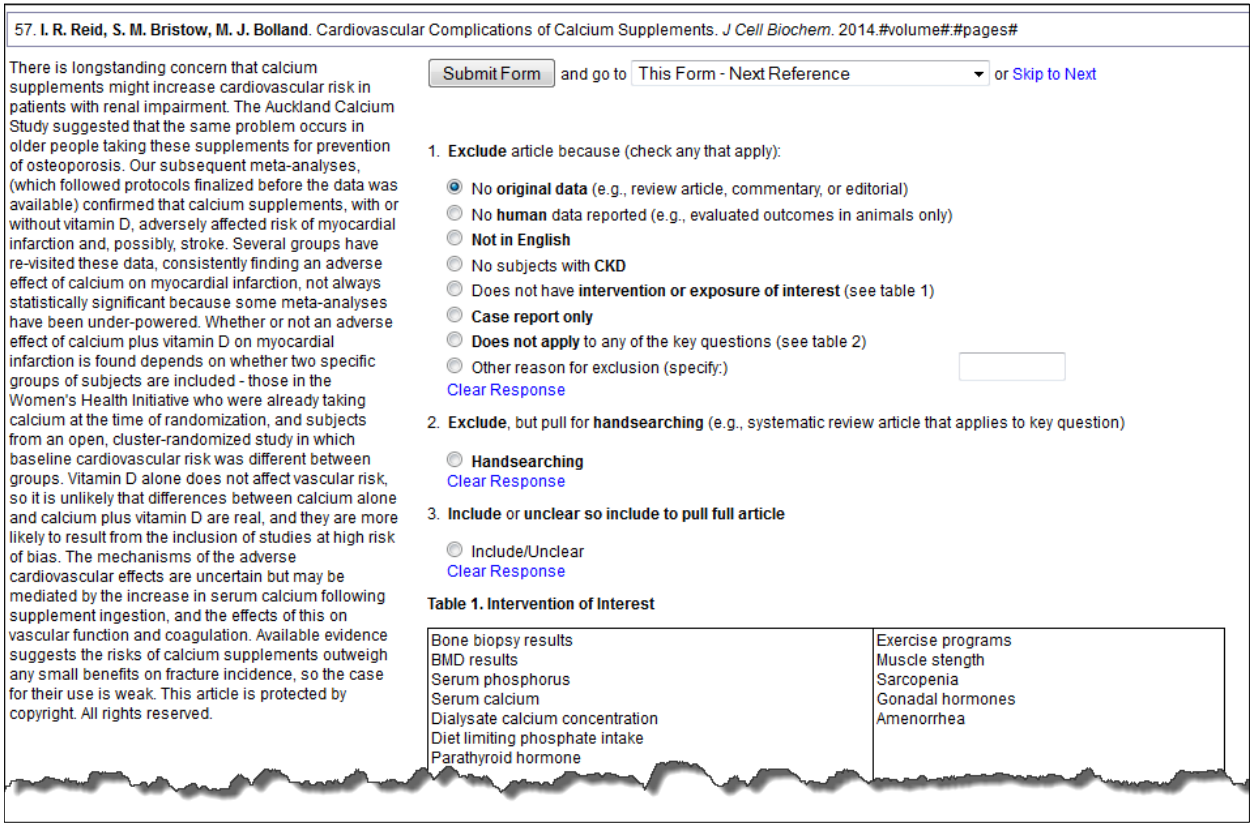
P	Patient, population
I	Intervention (Exposure)
C	Comparison
O	Outcome
T	Timing
S	Setting
D	Study design

Identification of Evidence

- Identify all possibly relevant studies
- Develop search protocol:
  - Sources: databases and hand searching
  - How searched
  - Dates
  - Strategies
  - Tracking
  - Documentation

Selection of Evidence

- Apply specific pre-defined inclusion/exclusion criteria
- Screen at two levels:
  - abstracts and titles
  - full-text
- Tracking



57. **I. R. Reid, S. M. Bristow, M. J. Bolland**. Cardiovascular Complications of Calcium Supplements. *J Cell Biochem*. 2014.#volume#:#pages#

There is longstanding concern that calcium supplements might increase cardiovascular risk in patients with renal impairment. The Auckland Calcium Study suggested that the same problem occurs in older people taking these supplements for prevention of osteoporosis. Our subsequent meta-analyses, (which followed protocols finalized before the data was available) confirmed that calcium supplements, with or without vitamin D, adversely affected risk of myocardial infarction and, possibly, stroke. Several groups have re-visited these data, consistently finding an adverse effect of calcium on myocardial infarction, not always statistically significant because some meta-analyses have been under-powered. Whether or not an adverse effect of calcium plus vitamin D on myocardial infarction is found depends on whether two specific groups of subjects are included - those in the Women's Health Initiative who were already taking calcium at the time of randomization, and subjects from an open, cluster-randomized study in which baseline cardiovascular risk was different between groups. Vitamin D alone does not affect vascular risk, so it is unlikely that differences between calcium alone and calcium plus vitamin D are real, and they are more likely to result from the inclusion of studies at high risk of bias. The mechanisms of the adverse cardiovascular effects are uncertain but may be mediated by the increase in serum calcium following supplement ingestion, and the effects of this on vascular function and coagulation. Available evidence suggests the risks of calcium supplements outweigh any small benefits on fracture incidence, so the case for their use is weak. This article is protected by copyright. All rights reserved.

Submit Form and go to This Form - Next Reference or Skip to Next

1. **Exclude** article because (check any that apply):
   - (●) No **original data** (e.g., review article, commentary, or editorial)
   - ( ) No **human** data reported (e.g., evaluated outcomes in animals only)
   - ( ) **Not in English**
   - ( ) No subjects with **CKD**
   - ( ) Does not have **intervention or exposure of interest** (see table 1)
   - ( ) **Case report only**
   - ( ) **Does not apply** to any of the key questions (see table 2)
   - ( ) Other reason for exclusion (specify:)

   Clear Response

2. **Exclude**, but pull for **handsearching** (e.g., systematic review article that applies to key question)
   - ( ) **Handsearching**

   Clear Response

3. **Include** or **unclear so include to pull full article**
   - ( ) Include/Unclear

   Clear Response

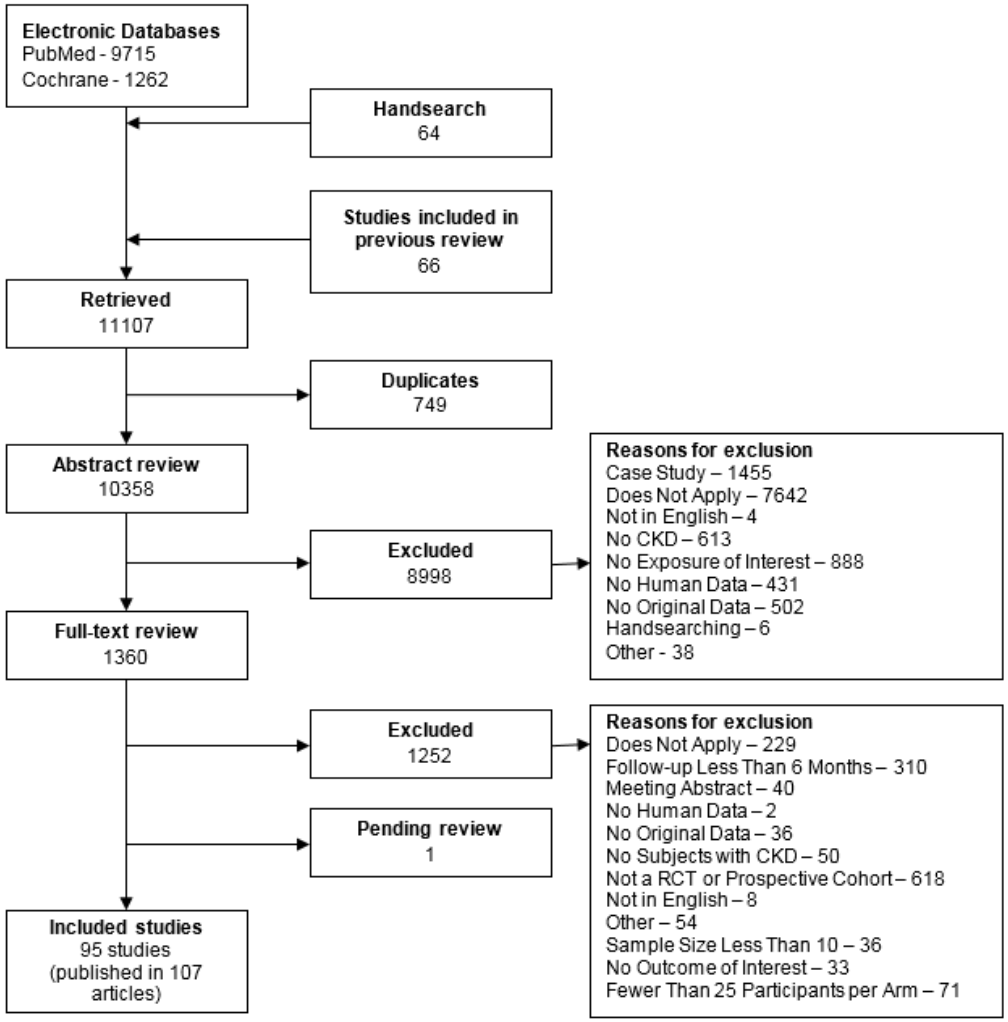
Table 1. Intervention of Interest

Bone biopsy results	Exercise programs
BMD results	Muscle stength
Serum phosphorus	Sarcopenia
Serum calcium	Gonadal hormones
Dialysate calcium concentration	Amenorrhea
Diet limiting phosphate intake	
Parathyroid hormone	

- **Two independent screeners**
- **All data entered into database**
- **Disagreements resolved by consensus or by third reviewer**

JHU_000001640

Summary of Search and Review Process



JHU_000001641

Listing of Excluded Articles

ID:1772
Cystic fibrosis and diabetes link. Podiatry Now 2008; 11 (10):20.
Unable to Retrieve

ID:1086
RCN Paediatric and Adolescent Diabetes Group 2002 Conference. Pract. Diabetes Int. 2003; 20 (2):77.
No original data (review, commentary, etc.)

ID:1893
Abbott, J., Conway, S. P., Etherington, C., Titzjohn, J., Gee, L., Morton, A., and et. al. Cystic Fibrosis related diabetes, eating behaviors and body satisfaction. Pediatric Pulmonology 98; Suppl 17:395.
Meeting abstract only

ID:80
Adler, A. I., Gunn, E., Haworth, C. S., and Bilton, D. Characteristics of adults with and without cystic fibrosis-related diabetes. Diabetic Medicine 2007; 24 (10):1143-8.
Pathophysiology and epidemiology

ID:611
Alagappan, V., Thiruvengadam, K. V., Deivanayagam, C. N., Mohan, V., Ramachandran, A., Viswanathan, M., Sreeram, D., and Doraiswamy, K. R. Secondary diabetes due to cystic fibrosis with multisystem involvement. Journal of the Association of Physicians of India 85; 33 (7):492-4.
Does not address any review questions

ID:600
Allen, J. L. Progressive nephropathy in a patient with cystic fibrosis and diabetes. New England Journal of Medicine 86; 315 (12):764.
No original data (review, commentary, etc.)

ID:16
Amadori, A., Antonelli, A., Balteri, I., Schreiber, A., Bugiani, M., and De Rose, V. Recurrent exacerbations affect FEV(1) decline in adult patients with cystic fibrosis. Respiratory Medicine 2009 ; 103 (3):407-13.
Unable to abstract data specifically for patients with CFRD / CF with IFG / CF with IGT

ID:673
Amendt, P. [Diabetes mellitus and mucoviscidosis]. Kinderarztliche Praxis 73; 41 (12):517-22.
Not in English

ID:236
Arrigo, T., De Luca, F., Lucanto, C., Lombardo, M., Rulli, I., Salzano, G., and Lombardo, F. Nutritional, glycometabolic and genetic factors affecting menarcheal age in cystic fibrosis. Diabetes Nutr Metab 2004; 17 (2):114-9.
Effect of CFRD on menarcheal age

ID:330
Augarten, A., Akons, H., Aviram, M., Bentur, L., Blau, H., Picard, E., Rivlin, J., Miller, M. S., Katznelson, D., Szeinberg, A., Shmilovich, H., Paret, G., Laufer, J., and Yahav, Y. Prediction of mortality and timing of referral for lung transplantation in cystic fibrosis patients. Pediatric Transplantation 2001; 5 (5):339-42.
Addresses CF but not AGM AND article does not address diagnosis / screening of CFRD

ID:375
Augarten, A., Dubenbaum, L., Yahav, Y., Katznelson, D., Szeinberg, A., Blank, A., and Sack, J. Lundh meal: a single non-invasive challenge test for evaluation of exocrine and endocrine pancreatic function in cystic fibrosis patients. International Journal of Clinical and Laboratory Research 99; 29 (3):114-6.
Does not address any review questions

ID:668
Banicevic, M., Joksimovic, I., Vulovic, D., Filipovic, D., and Sicevic, S. [Diabetes mellitus and cystic fibrosis]. Srpski Arhiv Za Celokupno Lekarstvo 75; 103 (7-8):681-6.
Not in English

ID:286
Banjar, H. The first case report in Saudi Arabia of diabetes mellitus and cystic fibrosis in two siblings. Annals of Tropical Paediatrics 2002; 22 (4):383-4.
No original data (review, commentary, etc.)

ID:228
Banjar, H. H. Cystic fibrosis: presentation with other diseases, the experience in Saudi Arabia. Journal of Cystic Fibrosis 2003; 2 (3):155-9.
Does not address any review questions

WPATH SOC8

- **Articles excluded at full-text level listed with reason(s) excluded**
- **Included in report**

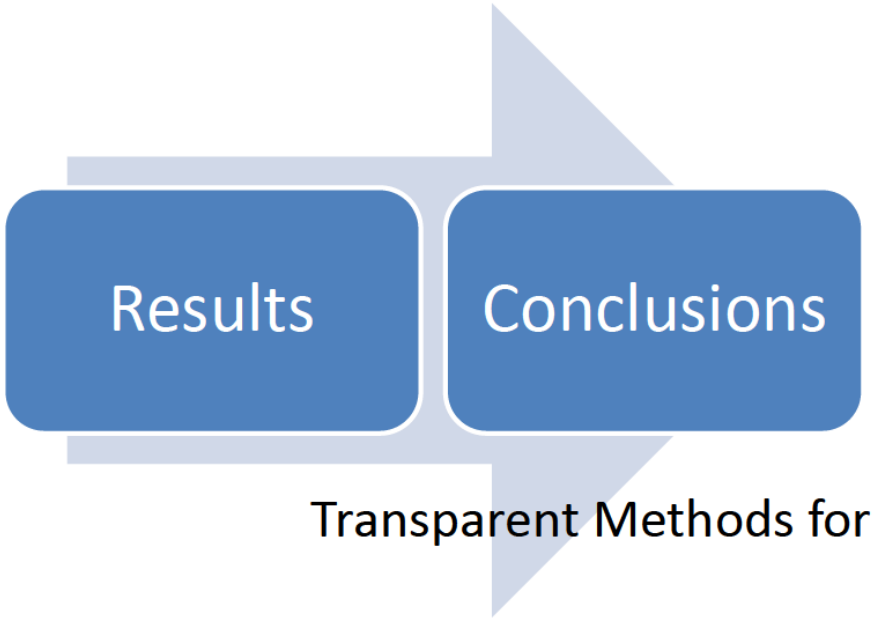
JHU_000001642

Evaluation of Evidence

- Assess risk of bias of individual studies:
  - Select tool based on study design
- Abstraction of relevant data
  - Including elements of PICO

Synthesis of Evidence

- Qualitative
- Quantitative



Transparent Methods for:

- Interpretation of results: Evaluate body of evidence addressing each question and outcome. We have stated in protocols we will use GRADE approach.

- Presentation of interpretation: Present results and interpretation to users. Suggest use Summary Tables.

WPATH SOC8

JHU_000001645

Evaluating Body of Evidence

Key element is to consider separately:

- Magnitude of Effect
- Certainty in the Evidence

Figure 1. Belief and confidence: a two-dimensional weather report. (Reprinted by permission from the Wall Street

Certainty in Evidence

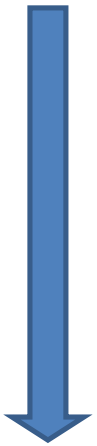
GRADE *Quality of the Evidence*

Four levels

A	High	We are very confident that the true effect lies close to that of the estimate of the effect
B	Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
C	Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
D	Very low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

GRADE System

HIGH	⨁⨁⨁⨁	A
MODERATE	⨁⨁⨁◯	B
LOW	⨁⨁◯◯	C
VERY LOW	⨁◯◯◯	D



Confidence

- Randomised controlled trials start as High
- Observational studies start as Low

FACTORS THAT CAN REDUCE THE QUALITY OF THE EVIDENCE

FACTOR	CONSEQUENCE
Limitations in study design or execution (risk of bias)	↓ 1 or 2 levels
Inconsistency of results	↓ 1 or 2 levels
Indirectness of evidence	↓ 1 or 2 levels
Imprecision	↓ 1 or 2 levels
Publication bias	↓ 1 or 2 levels

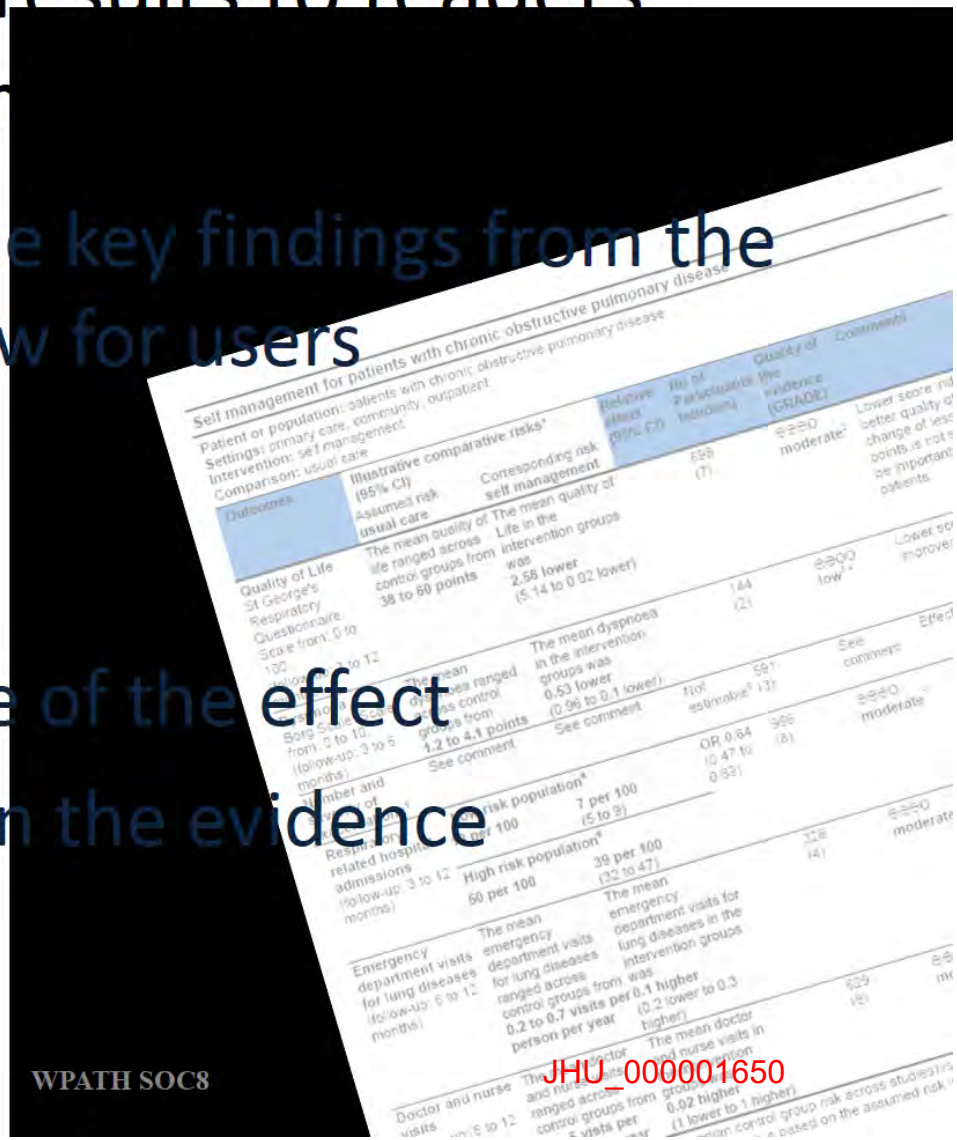
FACTORS THAT CAN INCREASE THE QUALITY OF THE EVIDENCE

FACTOR	CONSEQUENCE
Large magnitude of effect	↑ 1 or 2 levels
All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed	
Dose-response gradient	

Only use for observational studies not already downgraded

Presenting results to readers: Summ

- a summary of the key findings from the systematic review for users
- Presents
  - the magnitude of the effect
  - the certainty in the evidence



Current Status of SRs

Chapter	Number of SR questions	Protocol	Searching electronic databases	Citations screen at the title-abstract screening	Citations screen at the article screening	Data abstraction
Hormone Therapy	13	Completed	Completed (PubMed®, Embase®, and Pyscinfo)	N =1508 Completed	N =390 Ongoing	Not started yet
Voice	8	Completed	Completed (PubMed®, CINAHL, Embase®, and Pyscinfo)	N =631 Ongoing	Not started yet	Not started yet
Surgery	11	Drafted				

REDACTED

REDACTED

From: Strang, John [mailto:JStrang@childrensnational.org]
Sent: Wednesday, May 30, 2018 8:56 AM
To: Scott Leibowitz <scottleibowitzmd@gmail.com>; adolescentsoc8@wpath.org
Cc: Karen Robinson < REDACTED Blaine Vella <blaine@wpath.org>; Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>
Subject: RE: [EXTERNAL] SOC8- Adolescent- call and identification of statements

Thanks, Scott!

Might I jump in and ask about the research review team (Johns Hopkins) – would it make sense for us to meet with them at least once to provide some context? Do they deeply understand gender care and the broad gender spectrum? Do they understand limitations and challenges of research in this field including groups that are not yet represented in research?

I completely support an independent research review, but I would hope that those doing the review would be alerted to key aspects of care and challenges in this research to provide them some context for interpretations.

John

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Wednesday, May 30, 2018 8:44 AM
To: adolescentsoc8@wpath.org
Cc: REDACTED Blaine Vella; Eli Coleman; Jon Arcelus
Subject: [EXTERNAL] SOC8- Adolescent- call and identification of statements

ATTENTION: External Email! Do not click attachments/links unless sender is known.

Dear Adolescent SOC8 committee:

OK, thank you all for getting your doodle polls in. There are **two times** that had the most attendees participating which stand out as general possibilities. One had 7 responses (Laura and Jon cannot do, although perhaps we can get Laura to participate in a 7AM call if we send her a coffee gift certificate) and the other had 8 responses (everyone can do except for **me** which is during a time I usually see a patient, so I will have to move my patient around in order to accommodate this time).

The two general times are:

- Mondays: 7A PST/10A EST/3PM London/4PM Amsterdam
- Wednesdays: 7A PST/10A EST/3PM London/ 4 PM Amsterdam

Task 1: Identification of gaps and statements we would like to be able to include in SOC8.

PLEASE START DOING THIS OVER EMAIL. Our statements will be classified as either evidence-based or "good practice statement." I already sent this out to folks a few weeks back, but now we really need to start doing this. I'm copying Karen Robinson from the Johns Hopkins group who is leading the evidence review team. The more we discuss the statements and gaps over email in advance, the more productive our phone call will be.

Per the evidence review team at Johns Hopkins, think the following:

- Consider the end product. Think explicitly about the decisions for which you would like to make recommendation statements. What are the areas of uncertainty in practice? Where is guidance needed?

- Consider whether recommendations from other organizations may be adopted. For

instance, for decisions around hormone therapy the recommendations from the Endocrine Society may be considered. For relevant statements, the Evidence Review Team would conduct a limited search to identify any studies published since development of recommendation(s) being considered for adoption.

- Review SOC7 to see what is not included.

Task 2: Initial phone call date

Here are the four options at the above times. Mon June 4th, Weds June 6th, Mon June 11th, Weds June 13th.

Will set up another doodle poll right now. Please fill it out within the next **two days** so we can get this first call scheduled.

https://doodle.com/poll/a8mve2ryvigcab5w

Thanks everyone,

Scott

Scott Leibowitz, MD
Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH
Medical Director of Behavioral Health | THRIVE (gender and sex development) program
Associate Clinical Professor | The Ohio State University College of Medicine
(614) 722-2427 (office) | (614) 722-3913 (fax)
Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

From: Karen Robinson
To: Strang, John; Scott Leibowitz; adolescentsoc8@wpath.org
Cc: Blaine Vella; Eli Coleman; Jon Arcelus
Subject: RE: [EXTERNAL] SOC8- Adolescent- call and identification of statements
Date: Wednesday, May 30, 2018 9:52:00 AM

John –
To confirm as others have chimed in, I am trying to participate in all of the chapter calls. As the domain experts please share with me the specific challenges in the field for your chapter scope, including challenges in the research literature. It is also very important for us to have discussions at the start of the guideline process so that the questions are well-defined and 'right'. That is, that the questions lead to explicit recommendation statements, and are fully defined in terms of PICO (population, intervention, comparison, outcomes, plus timing, setting).
Please feel free to contact me directly with any questions or concerns. I look forward to working with you all.
Thanks,
Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
REDACTED

REDACTED

From: Strang, John [mailto:JStrang@childrensnational.org]
Sent: Wednesday, May 30, 2018 8:56 AM
To: Scott Leibowitz <scottleibowitzmd@gmail.com>; adolescentsoc8@wpath.org
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Will set up another doodle poll right now. Please fill it out within the next **two days** so we can get this first call scheduled.
https://doodle.com/poll/a8mve2ryvigcab5w
Thanks everyone,
Scott

Scott Leibowitz, MD
Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH
Medical Director of Behavioral Health | THRIVE (gender and sex development) program
Associate Clinical Professor | The Ohio State University College of Medicine
(614) 722-2427 (office) | (614) 722-3913 (fax)
Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

From: Karen Robinson
To: Vries, A.L.C. de; "Jon Arcelus"; vin.tangpricha@emory.edu
Cc: Scott Leibowitz; Eli Coleman; Blaine Vella
Subject: RE: adolescent chapter
Date: Thursday, November 1, 2018 9:19:00 AM

Thanks for forwarding these articles.
From our prior discussions, I understood the issue for this topic to be the age criteria for decision making, the capacity for informed consent. Here is the question I noted from our phone call: "At what age (by x, or range) does an individual have capacity for medical decision making?" Let me know if I have this wrong.
The articles forwarded provide limited indirect evidence for this question. Please let me know if I missed something:

- Quinn summarizes a variety of studies mostly focused on adolescent patients desires to be part of decision making. I didn't see any studies that assessed 'capacity' or age of such capacity.
- Byrnes is a narrative review of different aspects of decision making and I didn't see any specific studies cited.
- Grootens provides an overview of the components of decision making and, in particular, the brain or neurodevelopment aspects of competence. The conclusion of around 12 years of age as the threshold for competence seemed to be based on one study assessing the use of the MacArthur Tool. I did a quick search and found no such studies in transgender or any more generally in adolescents. Are there studies in transgender or other populations assessing age of decision making capacity? Is this the question you want assessed?

In general, I think you would be better served to cite these and related reviews as rationale for good practice statement(s). However, I am happy to discuss further and look forward to any clarifications.
Thanks
Karen

From: Vries, A.L.C. de [mailto:alc.devries@vumc.nl]
Sent: Thursday, October 25, 2018 2:23 AM
To: Karen Robinson < REDACTED 'Jon Arcelus' <Jon.Arcelus@nottingham.ac.uk>; vin.tangpricha@emory.edu
Cc: Scott Leibowitz <scottleibowitzmd@gmail.com>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>
Subject: RE: adolescent chapter
Dear Karen
I promised you some articles on decision making in teens; these are review articles, but show that there is some evidence.
I think we need this sort of evidence base on decision making capacity in adolescents, regarding medical affirming treatment.
Hope this is of help and clarifies what we mean.
Kind regards,
Annelou

Van: Karen Robinson < REDACTED
Verzonden: woensdag 17 oktober 2018 19:43
Aan: 'Jon Arcelus' <Jon.Arcelus@nottingham.ac.uk>; vin.tangpricha@emory.edu
CC: Scott Leibowitz <scottleibowitzmd@gmail.com>; Vries, A.L.C. de <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>

Onderwerp: RE: adolescent chapter

Could someone send around the current version of the statements prior to the call? Thanks!

From: Jon Arcelus [mailto:Jon.Arcelus@nottingham.ac.uk]
Sent: Wednesday, October 17, 2018 1:23 PM
To: vin.tangpricha@emory.edu
Cc: Karen Robinson < REDACTED Scott Leibowitz <scottleibowitzmd@gmail.com>; Vries, ALC de <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>
Subject: Re: adolescent chapter

In order to make sure that we have one, shall we schedule a teleconference tomorrow Thursday at 9:00 am EST time which is 14:00 UK time? Blaine can you plan one, please? Eli, can you join us?

Prof. Jon Arcelus, MD, PhD
Professor of Mental Health and of Transgender Health
Academic address: Room B18, Institute of Mental Health, Jubilee Campus, University of Nottingham, Nottingham, NG7 2TU, UK
Tel: +44 (0)115 7484098
Clinical Address: Nottingham Centre for Transgender Health, 12 Broad street, Nottingham NG1 3AL
https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

On 17 Oct 2018, at 16:21, Vin Tangpricha <vin.tangpricha@emory.edu> wrote:

> Hi Jon,
> Sorry, I am just seeing this now. I am at the airport heading to Denver for a meeting. I might be able to meet in the afternoons on Thur or Friday.
> On Wed, Oct 17, 2018 at 8:57 AM Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:
>
> > Thanks karen and Scott,
> > Once we know whether vin, eli and annalou can do at 8:00 am 9:00 am or 10:00 am EST time, which is 13:00, 14:00 and 15:00 in UK and one hour later in Holland, maybe Blaine can help us organizing a teleconference.
> > thanks
> > Jon
> > Prof. Jon Arcelus, MD, PhD
> > *Professor of Mental Health and Transgender Health*
> >
> > **Academic address:** *Centre for Social Futures,* Room B18, Institute of Mental Health, Jubilee Campus, Triumph Road, University of Nottingham, Nottingham, NG7 2TU, UK
> >
> > **Clinical Address:** Nottingham Centre for Transgender Health, 12 Broad Street, Nottingham NG1 3AL UK
> >
> > TEL +44 (0)115 8760160 (clinical)
> >
> > https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

NEW BOOK: The Transgender Handbook: A Guide for Transgender People, Their Families and Professionals

---

From: Karen Robinson < REDACTED
Sent: 17 October 2018 1:46 PM
To: 'Scott Leibowitz'; Jon Arcelus
Cc: ALC de <alc. devries@vumc. nl> Vries; Eli Coleman
Subject: RE: Re:

All –

I could do a call tomorrow (Thurs) between 8-10 or 1-3:00.

It would be good if the current version of the statements could be forwarded. Systematic reviews covering bullet point one below are already underway for the endocrine chapter.

Thanks,

Karen

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Wednesday, October 17, 2018 8:33 AM
To: Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>
Cc: ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>; Karen Robinson < REDACTED Eli Coleman <colem001@umn.edu>
Subject: Re:

Hi Jon-

Glad you went into your spam folder to see that we are committee that is actively working on this and haven't been sitting quiet ducks! I agree- a conference call with me, you, Annelou, and Karen would probably very helpful. The current document is in the drop box and starts with "USE THIS DOCUMENT" but I have not yet updated the statements themselves to reflect all the feedback and lively discussion that our chapter calls have yielded. The columns to the right are notes from our chapter phone calls. We realize some of the statements need to be split into two and need to be made more actionable, than the way they are currently written. I was planning on doing that in the next day or so- *after* I get Eli and you the two slides for Buenos Aires. If I could simply update that later on tonight and send if that would be helpful going into a conference call, depending on when we schedule a call for.

As you all know, the Adolescent chapter is going to be one of the most scrutinized chapters in the entire standards of care. We are a unique chapter when it comes to the evidence based review because we **do** feel that there is a justification to do

a literature review on what we postulate will be evidence based statements about the interventions (even though we expect the evidence to be graded low). Essentially the literature reviews on some of our statements- as we plan on submitting once I edit them to incorporate the feedback from our workgroup- are important for the following reasons:

- Studies that demonstrate the psychological effectiveness of some of the interventions (blockers, hormones) in adolescence all included cohorts who went through a rather rigorous psychological assessment. We would like to talk this through as a group because it's a very important point.
- There is also literature on adolescent decision making and capacity to make informed decisions that carry lifelong ramifications. Since our chapter is a new chapter for the standards of care, and it focuses in on a developmental age group/assessment, (as opposed to other chapters that are more intervention specific), we are going to want to justify certain statements with graded evidence in terms of looking at the literature *on decision making in the developmental cohort (adolescence)* in general.

I happen to have time tomorrow morning EST. Any time between 8-10 AM if that happens to work for you, Annelou and Karen. I also have time tomorrow between 1-3:30 PM. (I'm not in clinic tomorrow- but rather at a local regional conference so there is some flexibility for me). Next week I'm in Seattle all week at AACAP, so hoping to finish all of this in short order and get our statements submitted. So the sooner the better.

Thanks,

Scott

Scott Leibowitz, MD

Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH

Medical Director of Behavioral Health | THRIVE (gender and sex development) program

Associate Clinical Professor | The Ohio State University College of Medicine

(614) 722-2427 (office) | (614) 722-3913 (fax)

Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

On Wed, Oct 17, 2018 at 4:30 AM Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:

> Dear Scott and Annalou,
> I have just found a lot of emails from Scott in my spam box, so I am a bit lost as to where we are.
> will it help to plan a telephone conference?

As far as I understand there is some confusion as to the fact that you both feel that some statements need a systematic literature review and the feedback you got from karen and myself was they were consensus statements, hence they did not.
It is very confusing, I do agree with you.
I wonder whether having a telephone conference between the 4 of us, may help to clarify things, so Karen can explain things a bit better. As I cant access the last version of the document, it will be good so attach it too.
if you feel that this is a possibility, I am quite flexible tomorrow (except from 6:30-10 pm uk time), Friday and Saturday (I can move things around) , so send us some dates and times and see if we can have a chat.
regards
Jon

Prof. Jon Arcelus, MD, PhD
Professor of Mental Health and Transgender Health

Academic address: *Centre for Social Futures,* Room B18, Institute of Mental Health, Jubilee Campus, Triumph Road, University of Nottingham, Nottingham, NG7 2TU, UK

Clinical Address: Nottingham Centre for Transgender Health, 12 Broad Street, Nottingham NG1 3AL UK

TEL +44 (0)115 8760160 (clinical)

https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

NEW BOOK: The Transgender Handbook: A Guide for Transgender People, Their Families and Professionals

This message and any attachment are intended solely for the addressee

--
Vin Tangpricha, M.D., Ph.D.

Professor of Medicine
Program Director, Endocrinology & Metabolism Fellowship
Program Director, ABIM Physician Scientist Pathway, Internal Medicine Residency
Division of Endocrinology, Metabolism & Lipids
Department of Medicine
Emory University School of Medicine

Staff Physician, Section of Endocrinology, Atlanta VA Medical Center
Distinguished Physician, Emory Healthcare
Clinic appointments, 404-778-3280
Fellowship program inquires, Ms. Marcela Santamaria-Appling, 404-727-1549

101 Woodruff Circle NE- WMRB1301
Atlanta GA 30322
Ph (404) 727-7254
Fax (404) 592-6257
Email vin.tangpricha@emory.edu
Twitter: @vtangpricha
Editor in Chief, Journal of Clinical and Translational Endocrinology (JCTE), www.jctejournal.com

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Any views or opinions expressed by the author of this email do not necessarily reflect the views of the University of Nottingham. Email communications with the University of Nottingham may be monitored where permitted by law.

From: Karen Robinson
To: "Nahata, Leena"; Reproductive Health SOC8 (reproductivehealthsoc8@wpath.org)
Cc: blaine@wpath.org; "ARadix@callen-lorde.org"
Subject: RE: draft and next call
Date: Monday, June 25, 2018 9:48:33 AM

Leena –
Thanks for sending the draft.
I have copied section title "Preliminary Recommendations" and provide brief comments below. I hope this helps, Karen

PRELIMINARY RECOMMENDATIONS:

Research is needed to understand fertility related perspectives as TG youth age and mature – do they experience distress and regret in a similar way as we have seen in oncology?

KR: future research needs will be included in the SOC. I would suggest listing these separately from the recommendations.

Providers of TG care should be better trained to discuss infertility risk and FP.

KR: This is on right track but needs more detail to be a recommendation. What does 'better trained' mean? Which providers? Think about make explicit statements that are actionable.

From: Nahata, Leena [mailto:Leena.Nahata@nationwidechildrens.org]
Sent: Monday, June 25, 2018 9:24 AM
To: Reproductive Health SOC8 (reproductivehealthsoc8@wpath.org) <reproductivehealthsoc8@wpath.org>
Cc: blaine@wpath.org; 'ARadix@callen-lorde.org' <ARadix@callen-lorde.org>; Karen Robinson <REDACTED
Subject: draft and next call

Hi all,
To follow-up on our last call, I thought I'd get things going by sending a draft of my sections.
Blaine/Asa/Karen – please let us know if this seems to be on the right track so that others can use the feedback as they are working on their drafts.
I have included the minutes from the last call as a reminder of everyone's sections.
I'd like to have another group call in the next couple of weeks. Based on availability for the last call, I would propose the following options (all eastern standard time):

1. Friday July 6 11am-12pm
2. Friday July 13 10-11am
3. Friday July 13 11am-12pm

Please let me know if any of these DO NOT work for you and we will pick the one the majority of people can join. Thanks!
Leena

Leena Nahata, MD
Assistant Professor of Clinical Pediatrics
The Ohio State University College of Medicine

Division of Endocrinology
Medical Director, Program for Fertility and Reproductive Health
Principal Investigator, Center for Biobehavioral Health
The Research Institute at Nationwide Children's Hospital
Phone 614-722-4502

From: Karen Robinson
To: Jon Arcelus
Subject: Re: Just checking with you
Date: Thursday, September 27, 2018 6:19:06 AM
Attachments: image001.png

I agree, Jon. This is a best practice statement. (It is also too long and needs revision to be actionable.). I haven't seen the statements Would you like to send to me for review?
Karen

Sent from my iPhone

On Sep 27, 2018, at 4:47 AM, Jon Arcelus <Jon.Arcelus@nottingham.ac.uk> wrote:

> Dear Karen,
> I am trying to look at the statements from the adolescent chapter and they have indicated quite a few requiring literature review, but in my view they are practice statements, this is an example:
> **We recommend/suggest that for adolescents with gender dysphoria, the degree of reversibility of interventions should be based on the age, physical development and emotional maturity of the adolescent (e.g. most reversible medical treatment is with pubertal suppression which should be used before more definitive steps with sex hormones or surgical interventions).**
> What do you think?
> Regards
> Jon
> Prof. Jon Arcelus, MD, PhD
> Professor of Mental Health and Transgender Health
> **Academic address:** Room B18, Institute of Mental Health, Jubilee Campus, Triumph Road, University of Nottingham, Nottingham, NG7 2TU, UK
> **Clinical Address:** Nottingham Centre for Transgender Health, 12 Broad Street, Nottingham, NG1 3AL, UK
> TEL +44 (0)115 7484098
> https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus
> <image001.png>
>
>

From: Karen Robinson
To: Scott Leibowitz
Cc: Jon Arcelus; ALC de <alc. devries@vumc. nl> Vries; Eli Coleman; Blaine Vella
Subject: RE: next steps- Adolescent SOC8
Date: Sunday, November 25, 2018 4:35:00 PM

Sure, let me know some good times. I think that Blaine can help setting up a call so I have copied her here.
Thanks,
Karen

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Saturday, November 24, 2018 6:39 PM
To: Karen Robinson < REDACTED
Cc: Jon Arcelus <jon.arcelus@nottingham.ac.uk>; ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>
Subject: Re: next steps- Adolescent SOC8

I hope that for those of us who celebrated, your Thanksgiving was a nice one.
Karen, Annelou, Jon- I think maybe we should get a call set up soon so we can finalize the PICO structure for family acceptance.
Thanks,
Scott

Scott Leibowitz, MD
Child and Adolescent Psychiatrist | Nationwide Children's Hospital, Columbus, OH
Medical Director of Behavioral Health | THRIVE (gender and sex development) program
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Scott.Leibowitz@nationwidechildrens.org (hospital) | scottleibowitzmd@gmail.com (academic, non-hospital related)

On Tue, Nov 20, 2018 at 11:18 AM Karen Robinson < REDACTED wrote:

> Sorry for confusion, Scott. I was looking at the list you provided and thought it fell into same category as decision making. I have checked my notes and confirm that we will review 'family acceptance' looking at psychosocial outcomes. A couple of studies were mentioned as potentially eligible (NCT, US Trans Study, per my scribbles so might not be correct full names!).
> Let me know if you want to have a call. I think we have two things to clarify:
>
> 1. For adolescent decision making, which bodies of indirect evidence are to be considered.
>
> 2. Refinement of question for family acceptance (i.e., PICO).
>
> Thanks,
> Karen
>
> **From:** Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
> **Sent:** Tuesday, November 20, 2018 8:16 AM
> **To:** Karen Robinson < REDACTED
> **Cc:** Jon Arcelus <jon.arcelus@nottingham.ac.uk>; ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>
> **Subject:** Re: next steps- Adolescent SOC8
>
> Hi Karen,
> I apologize but I thought that the concept of family acceptance was something we discussed

has direct evidence and could be turned into a statement that has a systematic literature review done on it, with an actionable statement.
My interpretation from last we left it was that you were going to help us with formulating the statement so we can make it actionable and turn it into PICO format.
I know we're at the last and final step with this so we have to be quick. Thanks so much,
Scott

Scott Leibowitz, MD
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On Mon, Nov 19, 2018 at 9:07 PM Karen Robinson < REDACTED wrote:

> Thanks, Scott. It was nice to meet you and the rest of the chapter!
> As clarification, for those last two items you/your chapter are to identify the bodies of indirect evidence to be considered (for instance, for decision making we discussed several!). Also, we will help to identify evidence but will not be conducting systematic reviews and thus will not be grading the evidence.
> Thanks,
> Karen
> **From:** Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
> **Sent:** Monday, November 19, 2018 8:29 AM
> **To:** Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Karen Robinson < REDACTED
> **Cc:** ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>
> **Subject:** next steps- Adolescent SOC8
> Hi Jon and Karen,
> It was wonderful getting a chance to meet in person with both of you while in Buenos Aires. Annelou and I are ready to discuss our next steps. We realize we are so far behind on finalizing "the questions" for systematic review. We spoke this morning and are going to be touching base again later on this evening to strategize a timeline for our chapter and to discuss logistical aspects of what is needed. We thought it would be a good idea to reach out to you both and get a sense as to what we need to discuss for our own call that is happening later tonight (5PM my time/11PM Annelou time).
> Summarizing our understanding from the meeting:
>
> - Very little is happening in terms of systematic reviews for our chapter
> - We understand the difference between direct evidence and indirect evidence.
> - That what our committee has felt (and continues to feel) is evidence based (questions on stigma in community, family acceptance/rejection tied with outcomes, question on the role of mental health professional/assessment prior to medical interventions, gender identity change efforts/conversion therapies etc.) is thought of as *indirect* evidence.
> - Adolescent medical decision making literature *is something* that the Johns Hopkins team is able to help out in terms of a literature review and grading.
> - Family acceptance *is something* that the Johns Hopkins team is also willing to help out with in terms of a lit review and grading.
>
> We simply want to make sure we are now on the same page and have the correct to-do list/timeline in front of us.

Thanks,
Scott

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From: Karen Robinson
To: Scott Leibowitz; ALC de <alc. devries@vumc. nl> Vries
Cc: Eli Coleman; Jon Arcelus; Blaine Vella; Tangpricha Vin
Subject: RE: next steps- Adolescent SOC8
Date: Tuesday, December 4, 2018 7:30:00 AM

That is correct. We will send draft protocol to Scott and Annelou for review.
Thanks,
Karen

From: Scott Leibowitz [mailto:scottleibowitzmd@gmail.com]
Sent: Tuesday, December 4, 2018 7:10 AM
To: ALC de <alc. devries@vumc. nl> Vries <alc.devries@vumc.nl>
Cc: Eli Coleman <colem001@umn.edu>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Blaine Vella <blaine@wpath.org>; Tangpricha Vin <vin.tangpricha@emory.edu>; Karen Robinson <REDACTED
Subject: Re: next steps- Adolescent SOC8

Hi,
My understanding is that we discussed the PICO (which for us is actually PECO for this group because the E/Exposure replaces the I/Intervention) yesterday morning and so I want to clarify if that discussion was sufficient enough or not. Karen, do you need more from me on this?
THanks,
Scott

Scott Leibowitz, MD
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On Mon, Dec 3, 2018 at 10:05 AM Vries, A.L.C. de <alc.devries@vumc.nl> wrote:

> No Eli, that is not correct, sorry for the confusion, systematic review will be done on family acceptance/social acceptance and well-being; Scott will send the PICO out for that subject .
> Best
> Annelou
>
> **Van:** Eli Coleman <colem001@umn.edu>
> **Verzonden:** maandag 3 december 2018 15:23
> **Aan:** Vries, A.L.C. de <alc.devries@vumc.nl>
> **CC:** Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Blaine Vella <blaine@wpath.org>; Vin Tangpricha <vin.tangpricha@emory.edu>; Scott Liebowitz <scottleibowitzmd@gmail.com>; Karen Robinson <REDACTED
> **Onderwerp:** Re: next steps- Adolescent SOC8
>
> This is good to hear. If I understand correctly, you Karen will not be conducting any systematic reviews for your chapter correct?
> Best,
> Eli
>
> On Mon, Dec 3, 2018 at 8:03 AM Vries, A.L.C. de <alc.devries@vumc.nl> wrote:
>
> > Dear SOC steering committee,
> > Scott, Karen and I had a good call today on the adolescent chapter. Since all of you could not

participate, Scott will summarize the call later and send out the reformulated recommendation on the relevance of family and social acceptance and the PICO we distracted from that recommendation.
With regard to my questions below I have now understood from Karen that

1) After finalizing the recommendations within our chapter (we probably need 1-2 more conference calls in December and January), Scott and I will send them to Karen and you as the steering committee; with your help they will be reformulated them so that consistency within the SOC is guaranteed and necessary rewording is proposed to increase actionability and clarity etc.

2) After receiving the reformulated version of the recommendations, we as the adolescent chapter (leads , optionally with help of members) will work on writing the background information

3) Karen will support us in finding some of the 'indirect evidence literature' with regard to medical decision making in adolescence, adolescent (neurobiological) development and it's consequences for decision making, as well as providing evidence for appropriate ages for the different hormonal and surgical gender affirming interventions.

I felt we made good progress today and the process we should follow was clarified!
Best
Annelou

Van: Vries, A.L.C. de
Verzonden: maandag 26 november 2018 13:32
Aan: 'Scott Leibowitz' <scottleibowitzmd@gmail.com>; Karen Robinson < REDACTED
CC: Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>; vin.tangpricha@emory.edu
Onderwerp: RE: next steps- Adolescent SOC8
And if we make a call, I would like to clarify also what Karen's role will be in re-formulating the recommendations? In our chapter, many of the formulations at present were considered by Karen as

- not actionable

- not precise or clear enough, in need of rewording

- unsure how to implement them

- more background information than a recommendation

at present, our chapter group is not working yet on writing background information, but it seems that would only make sense at the moment that we have consensus about the recommendations? And will that be our task or will we get help for that?
Annelou

Van: Scott Leibowitz <scottleibowitzmd@gmail.com>
Verzonden: zondag 25 november 2018 22:38

Aan: Karen Robinson < REDACTED
CC: Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Vries, A.L.C. de <alc.devries@vumc.nl>; Eli Coleman <colem001@umn.edu>; Blaine Vella <blaine@wpath.org>; vin.tangpricha@emory.edu
Onderwerp: Re: next steps- Adolescent SOC8

And I like Eli's suggestion to include Vin, so I am copying him too.

Sent by my iPhone

On Nov 25, 2018, at 4:35 PM, Karen Robinson < REDACTED wrote:

Sure, let me know some good times. I think that Blaine can help setting up a call so I have copied her here.
Thanks,
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Subject: Re: next steps- Adolescent SOC8

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Thanks,
Scott

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--
Eli Coleman, PhD
Academic Chair in Sexual Health
Professor and Director
Program in Human Sexuality
Department of Family Medicine and Community Health
MEDICAL SCHOOL | UNIVERSITY OF MINNESOTA

From: Karen Robinson
To: Jon Arcelus; Eli Coleman; Asa Radix
Cc: Blaine Vella
Subject: RE: Notes on consensus process.
Date: Monday, July 16, 2018 9:50:00 AM

I agree that several are struggling. Part of this is due to lack of experience in guidelines and the very short orientation we provided over the phone. A few leads seem to think that they are writing a textbook or conducting research. There is an issue with the scope and purpose of chapters. Clarification that SOC8 are guidelines not a textbook would be helpful.
I'm happy to have separate discussions with people. I think we talked about having another call with the leads.
I have certainly heard the argument that they cannot make a statement without knowing the evidence. However, these are guidelines and not research papers. As guidelines we want to provide guidance for areas where the target audience needs guidance (areas of variation in practice, addressing needs, areas of decisional uncertainty). The 'results' of a review should not dictate the decisions for which statements are needed.
Some of the questions I just received from the adolescent chapter look ok. Many of the questions provided, including the one you note below, are not specific enough for systematic review (seem to be writing that textbook). That is one reason to ask back – what is the recommendation statement this will inform?
For instance:
"what models of care exist? What evidence these is for efficacy?" → We advise using X model of care in caring for transgender adolescents. I doubt there is evidence so I translated it to a best practice statement
"they want to have a review as to the most effective psychological care for young people with gender dysphoria" → Do they want to make a statement about a particular type of care? If so, then a review on the effect of this type of care is needed. 'Psychological support' is not a specific type of care – I would not use that in a recommendation statement as it is not actionable without definition.
I will copy you all in my response back to the adolescent group.
I am not sure what to suggest as way forward. Having the leads and chapters received consistent feedback would be good. To that end, I am happy to participate in calls or respond to emails. It seems that for many this is a scope/definitional issue – guidelines versus textbook.
Thanks,
Karen

From: Jon Arcelus [mailto:Jon.Arcelus@nottingham.ac.uk]
Sent: Monday, July 16, 2018 8:49 AM
To: Karen Robinson < REDACTED Eli Coleman <colem001@umn.edu>; Asa Radix <asa.radix@gmail.com>
Cc: Blaine Vella <blaine@wpath.org>
Subject: Re: Notes on consensus process.

Thanks Karen,
Yes, I have seen this document. I still think that chapter leads and members are having major problems understanding how to put together a statement, as most think of developing a question for a review.

I have explained this a lot of times and most have seen the document you sent but they still cant.
You must have received a list of questions from the adolescent chapter today which clearly shows this. The issue that most have is that if we dont know what evidence is there, how can we put together a statement to make a possible recommendation.
I think they have a point.
This is particularity the case for new chapters such as adolescent or assessments or the adapted ones such as child. as they cant follow what it was done before.
No matter how many times I have a conversation about it they still come with questions and no statements, I think we have a problem and not sure how to help them. I worry that people are starting to give up,
for example: they want to have a review as to the most effective psychological care for young people with gender dysphoria. This is usually a question for a literature review. and I think this is reasonable. how can they translate this into statement?
psychological support is as effective/less effective/ more effective as blockers or family work is as effective/less effective/more effective as ....and on and on...do you know what I mean?
The questions that they sent you, really shows the issues very clearly. I am starting to be concerned about this.
I include a review I did sometime ago where the question is: what are the mortality rates for people with eating disorders. as you can see , this is a question and cant be translated into a statement. I know this does not lead to a recommendation but it could be "what are the risk factors for mortality in people with eating disorders?"
I hope I am making sense.
Regards
Jon

Prof. Jon Arcelus, MD, PhD
Professor of Mental Health and Transgender Health

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TEL +44 (0)115 8760160 (clinical)

https://www.nottingham.ac.uk/medicine/about/psychiatryandappliedpsychology/people/jon.arcelus

NEW BOOK: The Transgender Handbook: A Guide for Transgender People, Their Families and Professionals

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From: Karen Robinson < REDACTED
Sent: 16 July 2018 13:27:24

To: Eli Coleman; Jon Arcelus; Asa Radix
Cc: Blaine Vella
Subject: Notes on consensus process.

For your review:

We need the draft recommendation statements from each Chapter. Recall that recommendation statements should be explicit and actionable (please see attached notes).

The following is the consensus process for recommendation statements. This will be used for the best practice statements and for the evidence-based recommendation statements:

1. Chapter members draft and reach consensus within chapter on recommendations statements.
2. All recommendation statements are sent to the Guideline Steering Committee for review and revision.
3. An online Delphi will be set up to be used by all SOC8 members to vote on recommendation statements. Members will be able to opt out of voting on statements they feel are outside of their expertise or experience, and will also have opportunity to provide feedback on each statement. Consensus will be considered reach if recommendation statement is agreed to by 80% or more of votes. Those statements not reaching consensus will be sent back to all for another round of voting. These statements may be, as appropriate, revised based on feedback received. Three rounds will be held. Recommendation statements reaching consensus will be included in SOC8.

From: Karen Robinson
To: Obedin-Maliver, Juno; Nahata, Leena
Subject: RE: question
Date: Sunday, November 25, 2018 5:00:00 PM
Attachments: SOC8_ReproductiveHealth_2018-11-05_KR.docx
Protocol_HormoneTherapy_17Oct18.docx

All –
Please see attached with suggestions and questions.
I am happy to discuss further.
Thanks,
Karen

From: Obedin-Maliver, Juno [mailto:Juno.Obedin-Maliver@ucsf.edu]
Sent: Tuesday, November 20, 2018 12:28 PM
To: Karen Robinson < REDACTED Nahata, Leena <Leena.Nahata@nationwidechildrens.org>
Subject: Re: question
Hi Leena and Karen,
Hope this finds you both well. I sent along questions on 11/5/18. I am re-attaching those questions we wrote for review here.
Hope this helps!
Cheers,
Juno
--
Juno Obedin-Maliver, MD, MPH, MAS
(Pronouns: she, her, hers)
Chief, Division of Gynecology
San Francisco VA Medical Center
Co-Director
The PRIDE Study
University of California, San Francisco
http://www.pridestudy.org/
Assistant Professor, Obstetrics, Gynecology & Reproductive Sciences
University of California, San Francisco
(e)ObedinMaliverJ(at)obgyn.ucsf.edu

From: Karen Robinson < REDACTED
Date: Tuesday, November 20, 2018 at 8:38 AM
To: "Nahata, Leena" <Leena.Nahata@nationwidechildrens.org>
Cc: "Obedin-Maliver, Juno" <Juno.Obedin-Maliver@ucsf.edu>
Subject: RE: question
Leena – First, I checked my notes but Juno should feel free to correct me! My understanding is that there are no systematic reviews to be conducted.
Thanks,
Karen

From: Nahata, Leena [mailto:Leena.Nahata@nationwidechildrens.org]
Sent: Tuesday, November 20, 2018 11:01 AM
To: Karen Robinson < REDACTED
Cc: 'Obedin-Maliver, Juno' <Juno.Obedin-Maliver@ucsf.edu>

Subject: question

Hi Karen,

Eli has asked the SOC chapter leads to complete a survey re: status of our chapters. The first question is:

"Our committee has submitted all potential systematic review questions to Karen Robinson – Yes, No, N/A (No systematic review needed)"

I know you and Juno had a discussion about this at WPATH and not sure if there was a decision about whether we should, in fact, submit questions to your team or if we should proceed with best practice recommendations only for the Reproductive Health chapter?

Thanks,

Leena

Systematic Review Protocol
Systematic Review Title: Effects of Hormone Therapy in Transgender People

17th October 2018

Objective: Update the Standards of Care recommendations/statements about the effects of hormone therapy treatment in transgender people. We will address the following key questions in this review:

KQ1. For transgender women, what are the safety and efficacy of androgen lowering medications compared to Spironolactone vs cyproterone vs GnRH agonists in terms of surrogate outcomes, clinical outcomes, and harms?

KQ2. For transgender adolescent, what are the long term effect of GnRH agonists compared to no treatment, in terms of surrogate outcomes, clinical outcomes, and harms?

KQ3. For transfeminine people on gender-affirming hormone therapy with estrogen, what are the comparative risks of prolactinomas and hyperprolactinemia between spironolactone, cyproterone, and GnRH agonists, in terms of prolactin levels and presence of prolactinomas confirmed by imaging?

KQ4. For transgender people, what are the effect of progesterones (cyproterone) compared to Medroxyprogesterone and other progesterones in terms of breast growth (adults), delay of puberty (children), and side effects?

KQ5. For transgender women, what are the comparative risks of different regimens of gender-affirming hormone therapy with estrogens (conjugated estrogen, estradiol, ethinyl estradiol) in terms of pulmonary embolism, deep-vein thrombosis, stroke, and myocardial infarction?

KQ6. For transgender men, what is the risk of polycythemia among transgender men on gender-affirming therapy with testosterone, as measured by hematocrit and hemoglobin levels?

KQ7. For transgender men, what is the effect of testosterone therapy on uterine, ovarian, cervical, vaginal, and breast pathology in transgender men who have not had a hysterectomy or oophorectomy?

KQ8. For transgender women what is the effect of estrogen therapy on breast, testicular, prostate and penile tissue in transgender women who have not had a gonedectomy?

KQ9. For transgender women, what is the safety of different routes of administration for estrogen (oral, cutaneous, intramuscular) in terms of myocardial infarction, stroke, deep-vein thrombosis, and pulmonary embolism?

KQ10. For transgender adolescent, what are the effects of suppressing puberty with GnRH agonists on quality of life?

KQ11. For transgender people, what are the psychological effects (including quality of life) associated with hormone therapy

KQ12. For transgender people, what are the effects of hormone therapy on metabolic syndrome?

KQ13. For transgender people, what are the effects of hormone therapy on fertility?

Methods

A. PICOT for each KQ in the Review

Inclusion and exclusion criteria are provided in Table 1

Table 1: List of Inclusion/Exclusion Criteria

	Inclusion	Exclusion
Population	• Transfeminine individuals (male-to-female [MTF], transsexual or transgender woman/female, assigned male at birth [AMAB]) • Transmasculine individuals (female-to-male [FTM], transsexual or transgender man/male, assigned female at birth [AFAB]) • Gender-nonconforming individuals	Animal studies
Interventions	All studies must evaluate an intervention of interest as defined by KQ1-13 (Table 2)	5-alpha reductase inhibitors (e.g., finasteride, dutasteride), Flutamide No intervention of interest as defined by KQ1-13 (Table 2) Type of hormone therapy not described (except qualitative studies)
Comparisons	No intervention, or one or more of the interventions of interest	
Outcomes	Outcome of interest as defined by KQ1-13 (Table 3)	We will exclude studies that do not report the outcomes of interest. Do not report separate outcomes for transgender population
Type of Study	Any study design except single case reports	Publications with no original data (e.g., editorials, letters, comments, reviews) Full text not presented or unavailable, abstracts Single case reports
Timing	Participants must have been treated for at least 3 months	Duration of treatment is less than 3 months
Setting	All settings	

Table 2: List of Hormone Therapy Drugs (Interventions)[1-5]

Hormone Therapy Drugs	Brand Name	Route
Children at Puberty		
Leuprorelin	Lupron	Injection
Goserelin	Zoladex	Injection
Buserelin	Suprefact	Injection
Triptorelin	Trelstar	Injection
Histrelin	Supprelin LA	Implant
Transmasculine Adolescents and Adults		
Testosterone undecanoate	Andriol	Oral
	Aveed	Injection
Testosterone enanthate	Delatestryl	Injection
	Primoteston	
Testosterone cypionate	Depo-Testosterone	Injection
Testosterone propionate	Generic	Injection
Testosterone caproate + isocaproate + phenylpropionate + propionate	Omnadren	Injection
Testosterone decanoate + isocaproate + phenylpropionate + propionate	Sustanon	Injection
Testosterone propionate + enanthate	Testoviron	Injection
Testosterone	AndroGel	Transdermal (gel)
	Testim	
	Fortesta	
	Testogel	
	Tostran	
	Vogelxo	
	Androderm	Transdermal (patch)
	Testoderm	
	Testopatch	
	Axiron	Transdermal (solution)
	Natesto	Intranasal
	Striant	Buccal
	Nebido	Implant
	Testopel	
Dihydrotestosterone	Andractim	Injection
Testosterone cypionate + estradiol cypionate	Depo-Testadiol	Injection

Hormone Therapy Drugs	Brand Name	Route
Testosterone enanthate + estradiol valerate	Ditate-DS	Injection
Selective estrogen receptor modulators (Estrogen blocker)	Tamoxifen	Oral
Aromatase inhibitors (Estrogen blocker)	Anastrazole	Oral
Transfeminine Adolescents and Adults		
Conjugated estrogens	Premarin	Oral, injection, vaginal
	Cenestin	
	Enjuvia	
Esterified estrogens	Amnestrogen	Oral
	Estratab	
	Evex	
	Femogen	
	Menest	
Estradiol acetate	Femring	Vaginal
	Femtrace	Oral
Estriol	Synapause	Oral
	Ovestin	
Estropipate	Estropipate	Oral
	Ogen	
	Ortho-Est	
Ethinyl estradiol	Estinyl	Oral
Ethinyl estradiol + norethisterone acetate	FemHRT	Oral
Estradiol cypionate	Depo-Estradiol	Injection
Estradiol valerate	Progynova	Oral
	Delestrogen	Injection
Estradiol (17-β estradiol)	Alora	Transdermal (patch)
	Climara	
	Esclim	
	Estraderm	
	Fempatch	
	Menostar	
	Minivelle	
	Vivelle	
	Divigel	Transdermal (gel)
	Elestrin	
	Estrogel	
	Sandrena	
	Evamist	Intranasal

Hormone Therapy Drugs	Brand Name	Route
	Estrace	Oral
	Gynodiol	
	Innofem	
	Vagifem	Vaginal
	Imvexxy	
	Estring	
Estradiol benzoate	Progynon-B	Injection
Polyestradiol phosphate	Estradurin	Injection
Estradiol hemihydrate	Estrasorb	Transdermal (solution)
Spironolactone	Aldactone	Oral
Progesterone	Prometrium	Oral
Hydroxyprogesterone caproate	Makena	Injection
	Proluton	
Dydrogesterone	Duphaston	Oral
Norethisterone acetate	Primolut-Nor	Oral
Medroxyprogesterone acetate	Provera	Oral
	Depo-Provera	
Cyproterone acetate	Androcur	Oral
Enzalutamide	Xtandi	Oral
Epalutamide	Erleada	Oral
Bicalutamide	Casodex	Oral
Nilutamide	Anandron	Oral
	Nilandron	
Leuprorelin	Lupron	Injection
Goserelin	Zoladex	Injection
Buserelin	Suprefact	Injection
Triptorelin	Trelstar	Injection
Histrelin	Supprelin LA	Implant
Nafarelin	Synarel	Intranasal
Degarelix	Firmagon	Injection
Elagolix	Orilissa	Oral
Abarelix	Plenaxis	Injection
Cetrorelix	Cetrotide	Injection
Ganirelix	Orgalutran and Antagon	Injection

Table 3: List of Outcomes of Interest

Domain	Specific Measurement
Physical Health Outcomes	
Adiposity	• BMI • Weight • Height
Metabolic	• Glucose metabolism • Lipid levels • Potassium (serum electrolytes)- If MTF on spironolactone • Hemoglobin A1c or glucose levels • Prolactin levels – (Only if symptoms of Prolactinoma develop) • Total testosterone level [only transgender women]
Bone health/bone outcomes	All measures of bone mineral density; fractures
Mental Health Outcomes	
Cognitive ability	• Perception [Recognition and interpretation of sensory stimuli] • Memory • Visual and Spatial Processing
Mental health	• Suicide • Mood disorders/disturbance (depression/anxiety)
Quality of life and Satisfaction regarding outcome	Validated scales
Transition-related Outcomes	
Delay of puberty (children)	
Uterine, Ovarian, Cervical, Vaginal, and Breast pathology (transgender men)	Changes during testosterone administration
Breast, Testicular, Prostate and Penile tissue (transgender women)	Changes during estrogen administration
Impact on fertility	• Pregnancy rates • Sperm counts • Egg counts • Ability to conceive
Voice change	• Acoustic (pitch, quality, pitch range, resonance, intonation) • Perceptual (self-perception, listener perception)
Masculinization	Caused by testosterone: • Facial and body hair growth • Redistribution of subcutaneous fat (away from the face, hips, and extremities; towards the abdomen) • Increased muscle mass • Deeper voice pitch • Baldness • Clitoral growth • Cessation of menses

Domain	Specific Measurement
Feminization	Caused by estrogen (usually in conjunction with an anti-androgen): • Breast development • Redistribution of subcutaneous fat (towards the face, hips, and extremities) • Reduction of muscle mass • Reduction of body hair • Arrest of scalp hair loss • Reduction in erectile function • Reduced testicular size
Adverse events	• VTE (DVT and PE) • Myocardial infarction • Stroke • Hyperprolactinemia/prolactinoma (Pituitary adenoma)/ Prolactinomas, confirmed by imaging • Meningiomas • Hematocrit/hemoglobin • Acne and hair loss in transgender men • Any side effect of hormone

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions: We will search PubMed®, Embase®, and Pyscinfo, We will also review the reference lists of relevant systematic reviews and hand search the International Journal of Transgenderism (IJT) journal to identify articles that may have been missed by the database searches.

We will use DistillerSR (Evidence Partners, 2010) to manage the screening process. DistillerSR is a web-based database management program that manages all levels of the review process. All applicable citations identified by the search strategies are uploaded to the system and reviewed in the following manner:

i. Abstract screening: Two reviewers will independently review abstracts, which will be excluded if both reviewers agree that the article meets one or more of the exclusion criteria listed in Table 2. Differences between reviewers regarding abstract eligibility will be tracked and resolved through consensus adjudication.

ii. Full-text screening: Citations promoted on the basis of abstract review will undergo another independent parallel review using full-text of the articles to determine if they should be included in the final systematic review. The differences regarding article inclusion will again be tracked and resolved through consensus adjudication.

C. Data Abstraction and Data Management: We will create and pilot test forms for data extraction. Each article will undergo double review for data abstraction. The second reviewer will confirm the first reviewer‘s data abstraction for completeness and accuracy. A third reviewer will audit a random sample of articles by the first two reviewers to ensure consistency in the data abstraction of the articles.

Articles referring to the same study will be abstracted on a single review form if reporting the same data or on separate forms if necessary with clear information that the results should be interpreted as from the same study.

For all articles, reviewers will extract information on eligibility criteria, study characteristics (e.g., study design, study period, and follow-up), population characteristics (MF or FM, comorbid psychiatric conditions, mean age and number of participants), intervention characteristics (type, dose, route and duration of hormonal treatment), outcome measures, and the results of each outcome.

We will complete the data abstraction process using the Systematic Review Data Repository™(SRDR). Data will be exported from SRDR into a project-specific Access database (Microsoft, Redmond, WA) to serve as archived or back-up copies and to create detailed evidence tables and summary tables.

D. Data Synthesis: We will create a set of detailed evidence tables. We will include and synthesize the data only for transgender population if study targets transgender populations in addition to other populations and report data for transgender participants separately.

We plan to conduct meta-analyses of summary data when there are sufficient data (at least 2 studies of the same design) and studies are sufficiently homogenous with respect to key variables (population characteristics, intervention, and outcome) using a random effects model. Randomized controlled trials and nonrandomized studies will be analyzed separately. Statistical significance (will be set at a two-sided alpha of 0.05). All studies, including those that are not amenable to pooling, will be summarized qualitatively.

E. Assessment of Methodological Risk of Bias of Individual Studies: The assessment of risk of bias of included trials of treatment interventions will be conducted independently and in duplicate using the Cochrane Collaboration's Risk of Bias Tool.[6] For non-randomized studies of treatment interventions, we will use the Cochrane Risk Of Bias Assessment Tool for Non-Randomized Studies of Interventions (ROBINS-I tool).[7] For before-after (pre-post) studies with no control group, we will answer the question about intervention independent of other changes[8] in addition to the questions from ROBINS-I tool
Differences between reviewers will be resolved through consensus adjudication.

F. Grading the Strength of Evidence: At the completion of our review, two reviewers will independently grade the strength of evidence by adapting the GRADE methodology.[9] Conflicts will be resolved through consensus or third-party adjudication

References

1. Unger CA. Hormone therapy for transgender patients. Transl Androl Urol. 2016 Dec;5(6):877-884.
2. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism. 2017 102(11), 3869–3903.
3. Olson J, Garofalo R. The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7.
4. Deutsch, M. B. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People. Center of Excellence for Transgender Health at the University of California at San Francisco, 2016. http://transhealth.ucsf.edu/protocols
5. Drug information online: https://www.drugs.com
6. Higgins JPT, Green S (eds). Cochrane handbook for systemic reviews of interventions Version 5.1.0. The Cochrane Collaboration. 2011;Oxford, England. Available from: http://handbook.cochrane.org.
7. Sterne JAC, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. BMJ 2016; 355; i4919.
8. Cochrane Effective Practice and Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for review authors, 2017. Available at: http://epoc.cochrane.org/resources/epoc-resources-review-authors
9. Guyatt GH, Oxman AD, Vist GE, et.al. GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008 Apr 26;336(7650):924-6.

From: Karen Robinson
To: "Eli Coleman"; Jon Arcelus; Asa Radix
Subject: SOC Methods: draft document for review
Date: Wednesday, May 2, 2018 1:12:31 PM
Attachments: WPATH Guideline Development Methodology_Draft_2May2018.docx

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All –
Thank you for the helpful call earlier today. Please find attached a revised methods document.
I look forward to your feedback. I will make further revisions based on your input then send to a) WPATH Board and b) chapter leads. The plan, as I understand it, is to distribute the document by early next week (i.e., not wait for Board approval and with sufficient time for review prior to call on May 9th).
Thanks,
Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
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WPATH Standards of Care: Guideline Development Methodology

2 May 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 transsexual, transgender, and gender nonconforming[1] 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
The recommendations in the Standards of Care are developed to apply to transsexual, transgender, and gender nonconforming people[1]. Transsexual people are individuals who seek to change or who have changed their primary and/or secondary sex characteristics through feminizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role. Transgender people are a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth. Gender nonconformity refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex.

Footnote: 1 Terminology for Standards of Care to be determined by members of "Chapter 2- Terminology"

While the Standards of Care are intended for broad use across countries, WPATH acknowledges that much of the recorded clinical experience and knowledge in this area of health care is derived from North America and Western Europe.

History of the Standards of Care
The Standards of Care were originally published in 1979. Updated Standards of Care were published in 1980, 1981, 1990, 1998, 2001, and 2011.

About Standards of Care 8th Version
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. This document provides an overview of the methodological approach for updating the Standards of Care.

Overview of Process

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

- Establish Guideline Steering Committee
- Determine topics for chapters (scope of guidelines)
- Select Chapter Members and Evidence Review Team
- Refine the topics and review questions
- Conduct the systematic reviews
- Draft the recommendation statements
- Distribute Standards of Care for review
- Disseminate the Standards of Care
- Plan to update

Establish Guideline Steering Committee

The WPATH Guideline Steering Committee oversees the guideline development process for all chapters of the Standards of Care. Members of the Guideline Steering Committee are nominated to the WPATH Board which then vets and approves membership. The Guideline Steering Committee:

- Appoints the Chapter Leads and Members for each chapter
- Selects topics for the chapters
- Provides general oversight of the guideline development process

The Guideline Steering Committee reviews all chapters of the Standards of Care to confirm adherence to the WPATH guideline methodology and to ensure consistency of statements across the Standards of Care.

Members for Standards of Care 8th Version include:

- Eli Coleman, PhD (Chair)
  Professor, Department of Family Medicine and Community Health
  Director and Chair in Sexual Health, Program in Human Sexuality
  University of Minnesota
- Asa Radix, MD, MPH (Co-chair)
  Director, Research and Education
  Callen-Lorde Community Health Center
  Assistant Clinical Professor of Medicine
  New York University
- Jon Arcelus, MD, PhD (Co-chair)
  Professor, Youth Mental Health, Transgender Health
  University of Nottingham
- Karen A. Robinson, PhD (Lead, Evidence Review Team)
  Associate Professor of Medicine, Epidemiology and Health Policy & Management
  Johns Hopkins University

Determine Topics for Chapters

The Guideline Steering Committee determines the chapters for inclusion in the Standards of Care. The chapters in the Standards of Care 8th Version are:

1. Global Applicability of the Standards of Care
2. Terminology – Diagnostic Criteria
3. Epidemiologic Considerations
4. Overview of Therapeutic Approaches for Gender Health
5. Assessment, Support and Therapeutic Approaches for Children
6. NEW: Assessment, Support and Therapeutic Approaches for Adolescents with Gender Variance/Dysphoria
7. Assessment of Adults
8. Assessment, Support and Therapeutic Approaches for Non-Binary Individuals
9. Managing Mental and Behavioral Health Conditions in Adults
10. Primary Care for Adults
11. Hormone Therapy for Adolescents and Adults
12. NEW: Sexual Health Across The Lifespan
13. Reproductive Health for Adolescents and Adults
14. Voice and Communication Therapy
15. Surgery For Adolescents and Adults
16. Postoperative Care and Follow-Up
17. Applicability of the Standards of Care to People Living in Institutional Environments
18. Applicability of the Standards of Care to People with Intersex Conditions
19. NEW: Applicability of the Standards of Care to Eunuchs
20. NEW: Competency, Training, Education, Ethics

Select Chapter Members

Members of the transgender community apply to serve as a Chapter Members (Chapter Lead or Member) (http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1352&pk_association_webpage=11139). The Guideline Steering Committee appoints the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members are expected to be WPATH Full Members in good standing, and have expertise in transgender health, including in the specific chapter topic. Chapter Leads are expected to be well known advocates for WPATH and the Standards of Care. Chapter Leads report to the Guideline Steering Committee and are responsible for coordinating the participation of Chapter Members. Chapter members report directly to the Chapter Lead.

Each chapter also includes stakeholders as members. The stakeholders are expected to be Associate Members of WPATH and bring perspective of trans health advocacy or work in the community, or as a member of a family that includes a transgender child, sibling, partner, parent, etc.

The Chapter Members are expected to:

- participate in 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
- with other members, review and assess evidence and draft recommendations
- participate in consensus process to draft and confirm recommendations
- as appropriate and as requested, draft section(s) of the guidelines document
- review comments from peer review process and assist in revision of guidelines, as necessary
- provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members will be provided, as needed. Training content includes formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation statements, grading the evidence and the recommendations, and information about the guideline development program and process.

Select Evidence Review Team

The WPATH Board issues a request for applications. For Standards of Care 8th Version the WPATH Board has engaged an Evidence Review Team at Johns Hopkins University.

Conflict of Interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team are asked to disclose any conflicts of interest. Also reported, in

addition to potential financial and competing interests 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.

Commented [K1]: These need to be collected.
-Are disclosures available?
-How are potential COI managed?

Refine the Topics and Review Questions

The Evidence Review Team abstracts 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 determine which recommendation statements need to be updated, which should be evidence-based (based on a systematic review), and which will be consensus-based statements. Additional chapters and/or decisions/topic areas requiring recommendations statements are also identified during this stage.

For the statements requiring a systematic review, the Evidence Review Team drafts review questions, specifying the population, interventions, comparisons, and outcomes (PICO elements). Chapter Leads and Members review the research questions and provide feedback.

Conduct the Systematic Reviews

The Evidence Review Team conducts systematic reviews. Details of the systematic review methodology can be found in the Systematic Review Methodology document. The Evidence Review Team presents evidence tables and evidence matrices to the members of the relevant chapter.

Draft the Recommendation Statements

Chapter Leads and Members draft recommendation statements. The statements are crafted to be explicit and actionable.

For evidence-based recommendation statements, with assistance from the Evidence Review Team, the Chapter Leads and Members also assign a grade of the recommendation (using GRADE system); describe the health benefits, side effects, and risks; and provide an explicit link between the recommendations and the supporting evidence.

For consensus-based statements a formal consensus method, such as Delphi, will be used. Consensus is sought within the chapter for each consensus-based recommendation statement.

The Guidelines Steering Committee, Chapter Leads and Evidence Review Team review all recommendation statements for clarity and consistency in wording, and where relevant, grading. During this review any overlap between chapters is also addressed.

Distribute Standards of Care for Review

The draft Standards of Care document is circulated among the broader SOC Revision Committee and International Advisory Group. Feedback from these groups is considered, and any necessary revisions are made, by the Chapter Leads and the Guideline Steering Committee, with assistance from the Evidence Review Team.

The revised draft version of the Standards of Care document is posted for comment from the public, including WPATH members, on the WPATH website.

The Chapter Leads and Guideline Steering Committee, with assistance from Evidence Review Team, considers feedback and makes any necessary revisions. The final document is presented to the WPATH Board of Directors for approval.

Disseminate the Standards of Care

The Standards of Care are disseminated in a number of venues and in a number of formats.

Commented [K2]: Specify:
-URL?
-Examples of other formats?

Plan to Update

The Standards of Care are reviewed at 3 years after the release date to determine if an update is needed. In addition, updates may be triggered by events such as new evidence or new therapies. The WPATH Board of Directors determines the timing of any revision of the Standards of Care.

WPATH Systematic Review Methodology

2 May 2018

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

Literature Search
The Evidence Review Team will develop a search strategy appropriate for each research question. At a minimum, the Evidence Review Team will search MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team may search additional databases as deemed appropriate for the research question. The search strategy will include MeSH and text terms and will not be limited by language of publication or date.

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

We will update the searches during the peer review process.

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

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

Studies that do not meet the eligibility criteria will not be considered as evidence, but may be used in background sections of the Standards of Care.

Data Extraction
The Evidence Review Team will use standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer will abstract the data, and a second reviewer will confirm the abstracted data.

Assessment of Risk of Bias
Two reviewers from the Evidence Review Team will independently assess the risk of bias for each included study. For randomized controlled trials, we will use the Cochrane Risk of Bias Tool. For observational studies, we will use Risk of Bias in Non-Randomized Studies – of

Interventions (ROBINS-I) tool. Where deemed appropriate, existing recent systematic reviews may be considered and will be evaluated using ROBIS.

Data Synthesis and Analysis
The Evidence Review Team will create evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups will review and provide comment on the evidence tables.

Grading of the Evidence
The Evidence Review Team will assign evidence grades using the GRADE methodology. The Evidence Review Team will assign evidence grade to pre-defined critical outcomes for each question. We will assess the strength of the evidence by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

We will classify evidence pertaining to the review questions into four basic categories: 1) "high" grade (indicating high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of the effect); 2) "moderate" grade (indicating moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of the effect and may change the estimate); 3) "low" grade (indicating low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate); and 4) "insufficient" grade (evidence is unavailable or does not permit a conclusion).

From: Karen Robinson
To: Stan Monstrey; Loren Schechter; Jon Arcelus
Subject: SOC8: Systematic Review Protocol
Date: Tuesday, November 20, 2018 3:14:00 PM
Attachments: WPATH_Draft Protocol_Surgery_20Nov18.docx

All –
Please find attached a revised protocol for the systematic reviews to be completed for the surgical chapter. Revisions were made based on discussion in Buenos Aires. There are now 5 general questions with sub-questions related to subgroups, comorbidities, etc.
Please review and let me know of any questions or concerns. Please let me know as soon as possible as we are starting the review process.
Thanks,
Karen

Karen A. Robinson, PhD
Director JHU Evidence-based Practice Center
Associate Professor of Medicine, Epidemiology, and Health Policy and Management
Johns Hopkins University
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REDACTED

SYSTEMATIC REVIEW PROTOCOL

Effects of Gender-Affirming Surgeries for Treatment of Gender Dysphoria in Transgender People

(Surgery Chapter)

November 15, 2018

OBJECTIVE: Update the Standards of Care recommendations/statements about the effects of gender-affirming surgeries for treatment of gender dysphoria in transgender people. This protocol does not include voice-related surgeries as these topics will be addressed in reviews for the voice chapter. We will address the following key questions in this review.

Breast/Chest Surgery:

KQ1: What are the benefits and risks of chest reconstruction surgery ("top surgery") for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

> KQ1a: What are the benefits and risks of top surgery in terms of factors aside from gender dysphoria (e.g., BRCA-1 mutation, family history of breast cancer, identification of pre-cancerous breast pathology) for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1b: How does hormone therapy status affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1c: How does chest binding status affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1d: How does the presence of potential contraindications for surgery (e.g., smoking, BMI, active psychotic conditions or other serious mental illness) affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1e: How does age affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth, particularly for those under age 18?

KQ2: What are the benefits and risks of breast augmentation surgery ("top surgery") for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

> KQ2a: What are the benefits and risks of top surgery for transfeminine individuals and gender-nonconforming individuals assigned male at birth in terms of factors aside from gender dysphoria (e.g., BRCA-1 mutation, family history of breast cancer)?

KQ2b: How does hormone therapy status affect the benefits and risks of top surgery for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ2c: How does the presence of potential contraindications for surgery (e.g., smoking, BMI, active psychotic conditions or other serious mental illness) affect the benefits and risks of top surgery for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ2d: How does age affect the benefits and risks of top surgery, particularly for those under age 18 for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

Genital Surgery:

KQ3: What are the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ3a: How does hormone therapy status affect the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ3b: How does a prerequisite of 12 months of living in a gender role that is congruent with the gender identity of the patient (the "real life test") affect the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ3c: How does the presence of potential contraindications for surgery (e.g., smoking, BMI, active psychotic conditions or other serious mental illness) affect the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ4: What are the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4a: How does hormone therapy status affect the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4b: How does a prerequisite of 12 months of living in a gender role that is congruent with the gender identity of the patient (the "real life test") affect the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4c: How does the presence of potential contraindications for surgery (e.g., smoking, BMI, active psychotic conditions or other serious mental illness) affect the benefits and

risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

Other Surgeries/Procedures:

KQ5: What are the benefits and risks of facial gender confirmation surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ5a: How does hormone therapy status affect the benefits and risks of facial gender confirmation surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ5b: How does the presence of potential contraindications for surgery (e.g., smoking, BMI, active psychotic conditions or other serious mental illness) affect the benefits and risks of facial gender confirmation surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

METHODS

A. Inclusion and Exclusion Criteria: Inclusion and exclusion criteria in PICOTS format are provided in Table 1.

Table 1: Inclusion/Exclusion Criteria

	Inclusion	Exclusion
Population	• Transfeminine individuals (male-to-female [MTF], transsexual or transgender woman/female, assigned male at birth [AMAB]) • Transmasculine individuals (female-to-male [FTM], transsexual or transgender man/male, assigned female at birth [AFAB]) • Gender-nonconforming individuals	Animal studies Cisgender-only
Interventions	**1. Gender-affirming surgeries for transmasculine individuals:** • Top surgery: o Subcutaneous mastectomy o Nipple grafts o Chest reconstruction/contouring • Top surgery techniques: o Keyhole o Peri-areolar o Double incision • Bottom surgery: o Hysterectomy	No surgical intervention of interest

	○ Salpingo-oophorectomy ○ Urethroplasty ○ Vaginectomy/colpectomy ○ Vulvectomy ○ Scrotoplasty ○ Implantation of erectile and/or testicular prostheses ○ Phalloplasty ○ Metoidioplasty • Phalloplasty techniques: ○ Free flap ○ Pedicle • Metoidioplasty techniques: ○ Simple release ○ Ring ○ Centurion • Body contouring/liposuction/lipectomy **2. Gender-affirming surgeries for transfeminine individuals:** • Facial gender-confirmation surgeries: ○ Rhytidectomy (“facelift”) ○ Blepharoplasty ○ Rhinoplasty ○ Osteoplasty ○ Genioplasty ○ Platysmaplasty ○ Chondrolaryngoplasty • Top surgery: ○ Breast augmentation (mammaplasty/mammoplasty) • Bottom surgeries: ○ Orchiectomy ○ Prostatectomy ○ Penectomy ○ Clitoroplasty ○ Vulvoplasty ○ Labiaplasty ○ Urethroplasty ○ Vaginoplasty • Vaginoplasty techniques: ○ Penile inversion ○ Intestinal/sigmoid ○ Peritoneal • Body contouring/liposuction/lipectomy • Hair transplant • Electrolysis	

	• Laser hair removal	
Comparison	No comparison, before/after, or any other procedure	
Outcomes of interest	**1. Health-related quality of life** **2. Patient satisfaction** **3. Mental health:** • Depression/anxiety • Gender dysphoria o Patient self-report o Utrecht Gender Dysphoria Scale score o Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults (GIDYQ-AA) score o Body Uneasiness Test (BUT) score **4. Sexual functioning** • Physical functioning and appearance • Sexual/erotic functioning **5. Harms**	Studies that do not report the outcomes of interest
Study designs	Any study design except single case reports	• Single case reports • Publications with no original data (e.g., editorials, letters, comments, reviews) • Full text not presented or unavailable, abstracts
Setting	Any setting	

B. Searching for the Evidence: We will search PubMed®, CINAHL, and Embase® for relevant studies to answer the key questions. We will also review the reference lists of relevant systematic reviews and hand search the *International Journal of Transgenderism* (IJT) to identify articles that may have been missed by the database searches.

We will use DistillerSR (Evidence Partners, 2010) to manage the screening process. DistillerSR is a web-based database management program that manages all levels of the

review process. All applicable citations identified by the search strategies will be uploaded to the system and reviewed in the following manner:

I. **Abstract screening:** Two reviewers will independently review abstracts, which will be excluded if both reviewers agree that the article meets one or more of the exclusion criteria listed in Table 2. Differences between reviewers regarding abstract eligibility will be tracked and resolved through consensus adjudication.
II. **Full-text screening:** Citations promoted on the basis of abstract review will undergo another independent parallel review using full-text of the articles to determine if they should be included in the final systematic review. The differences regarding article inclusion will again be tracked and resolved through consensus adjudication.

C. **Data Abstraction and Data Management**: We will create and pilot test forms for data extraction. Each article will undergo double review for data abstraction. The second reviewer will confirm the first reviewer's data abstraction for completeness and accuracy. A third reviewer will audit a random sample of articles by the first two reviewers to ensure consistency in the data abstraction of the articles.

Articles referring to the same study will be abstracted on a single review form if reporting the same data or on separate forms if necessary with clear information that the results should be interpreted as from the same study. Reviewers will extract the following information from each included study:

- **Description of the population**
  - Transmasculine, transfeminine, or gender-nonconforming individuals
  - Comorbid psychiatric conditions
  - Mean age
  - Number of participants
  - Surgery status
  - Hormone therapy status
  - Puberty delay medication status
  - Demographic and health factors such as race/ethnicity and smoking status
- **Description of the exposure**
  - Type of surgery (i.e., top surgery, genital surgery, other procedure)
  - Specific surgical technique
- **Study design**
- **Outcomes**

We will complete the data abstraction process using the Systematic Review Data Repository™ (SRDR). Data will be exported from SRDR into a project-specific Access database (Microsoft, Redmond, WA) to serve as archived or back-up copies and to create detailed evidence tables and summary tables.

D. **Data Synthesis:** We will create a set of detailed evidence tables. From studies that include cisgender participants as well as transgender participants, we will only include data from transgender participants. Different surgical techniques will not be compared. For studies that

compare different techniques, we will pool and present the results across techniques wherever possible.

We plan to conduct meta-analyses of summary data when there are sufficient data (at least 2 studies of the same design) and studies are sufficiently homogenous with respect to key variables (population characteristics, intervention, and outcome) using a random effects model. Randomized controlled trials and nonrandomized studies will be analyzed separately. Statistical significance will be set at a two-sided alpha of 0.05. All studies, including those that are not amenable to pooling, will be summarized qualitatively.

E. Assessment of Methodological Risk of Bias of Individual Studies: The assessment of risk of bias of included trials of treatment interventions will be conducted independently and in duplicate using the Cochrane Collaboration's Risk of Bias Tool.[1] For non-randomized studies of treatment interventions, we will use the Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies of Interventions (ROBINS-I tool).[2] For before/after (pre/post) studies with no control group, we will answer the question about intervention independent of other changes[3] in addition to the questions from ROBINS-I tool. Differences between reviewers will be resolved through consensus adjudication.

F. Grading the Strength of Evidence: At the completion of our review, two reviewers will independently grade the strength of evidence by adapting the GRADE methodology.[4] Conflicts will be resolved through consensus or third-party adjudication.

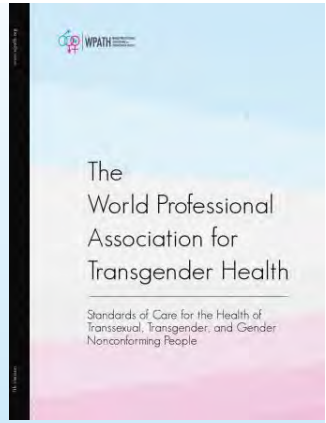
REFERENCES

1. Higgins JPT, Green S (eds). Cochrane handbook for systemic reviews of interventions Version 5.1.0. The Cochrane Collaboration. 2011;Oxford, England. Available from: http://handbook.cochrane.org.
2. Sterne JAC, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. BMJ 2016; 355; i4919.
3. Cochrane Effective Practice and Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for review authors, 2017. Available at: http://epoc.cochrane.org/resources/epoc-resources-review-authors
4. Guyatt GH, Oxman AD, Vist GE, et.al. GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008 Apr 26;336(7650):924-6.

WPATH Review Status Report
5 November 2019

Chapter	Number of included studies	Abstractions	Second review/Data Check	Evidence tables	Synthesis	Submission Status
Hormone therapy	138 studies (reported in 136 articles)*	Done	Done	Done	Done: KQ 4 KQ6 KQ7 KQ8 Ongoing: KQ11 KQ5-9 Not started: KQ3 KQ12 KQ1 KQ2 -10	4 Sep: all draft evidence tables, flow diagram, list of included and list of excluded studies 5 Nov: reports/synthesis/tables for KQ 4, 5, 6, 7, 8, 9 submitted
Surgery	111 studies*	Done	Done	Ongoing Data being updated in SRDR**	Not started yet	
Voice	35 studies (reported in 41 articles)*	Done	Done	Completed	Not started yet	
Adolescent	17 studies	Done	NA	Done	Done	24 Sep: report and tables sent to chapter leads.

*Numbers may change after second review/synthesis
** Systematic Review Data Repository – will be publically available repository of extracted data



STANDARDS OF CARE- 8 (SOC-8)

WPATH Meeting
Buenos Aires, November 2018

Update

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

JHU_000003256

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

INTRODUCTION

- **Chair:** Eli Coleman, USA
- **Co-Chairs:**
  - Asa Radix, USA
  - Jon Arcelus, UK

JHU_000003257

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

JHU_000003258

Hierarchy of Evidence

http://sciencedrivennutrition.com/science-in-fitness/

How do we move from questions to guidelines creation?

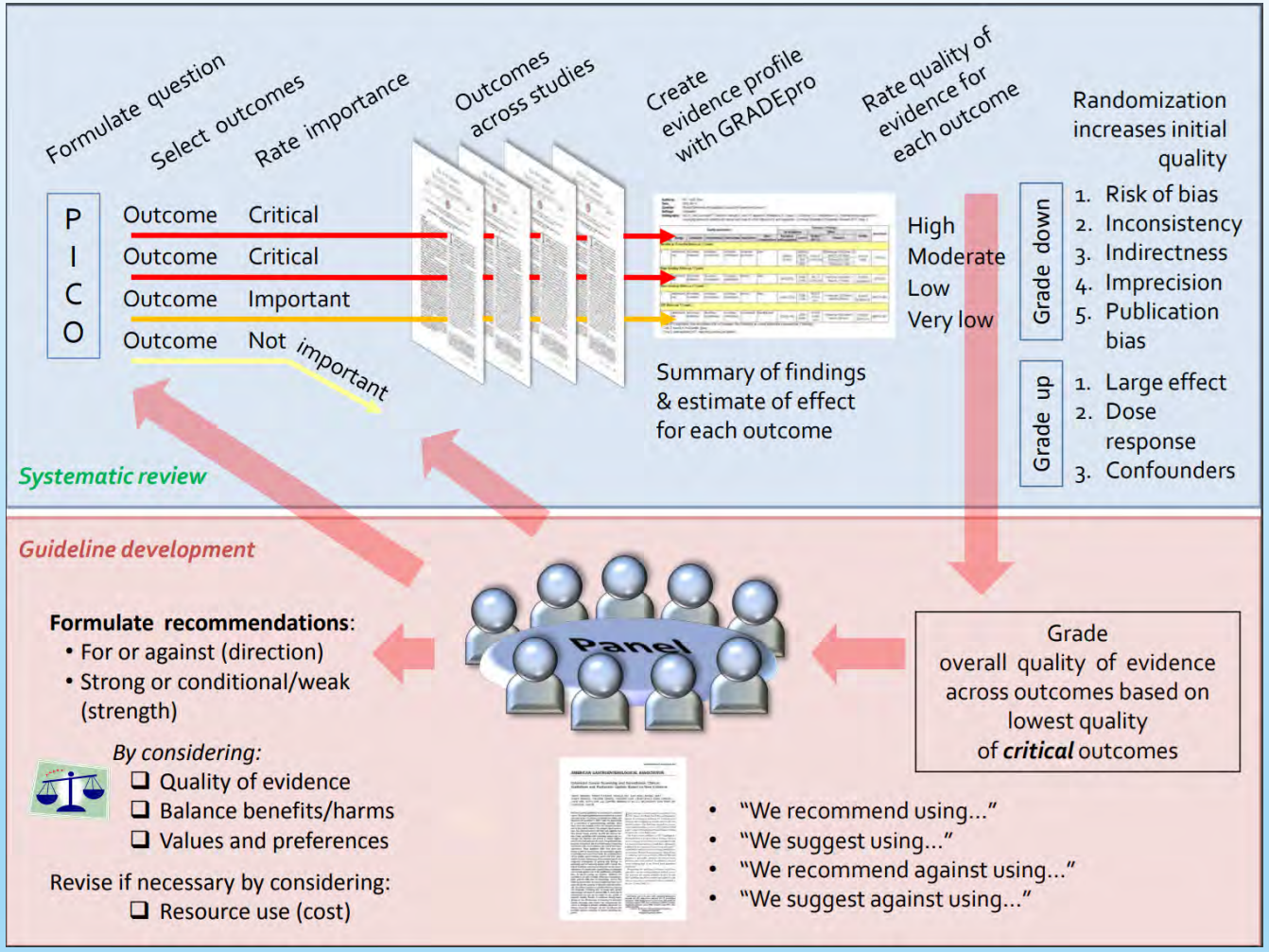


Image from: https://www.cdc.gov/vaccines/acip/recs/grade/downloads/guide-dev-grade.pdf

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Formulate a Question

Does breast augmentation improve health outcomes?

- Population: *Transgender women, non-binary AMAB*
- Intervention: *Gender affirming surgery (Breast augmentation)*
- Comparison: *No surgery*
- Outcomes: *Psychological outcomes (depression, anxiety)*

JHU_000003261

GRADE

- Quality of evidence:
  - ⨁⨁⨁⨁ (High) *RCTs*
  - ⨁⨁⨁ (Moderate)
  - ⨁⨁ (Low) *Observational studies*
  - ⨁(Very low)
- Recommendation:
  - Weak
  - strong

JHU_000003262

Criteria for SOC8 Involvement

- WPATH member
- Advocate for WPATH and the SOC
- Recognized expert in trans health
- Scholar/researcher (publication record)
- Can assess the evidence-based literature
- Able to volunteer 2-5 hours/week
- Works collaboratively
- No conflicts of interest

JHU_000003263

Guidelines Committee

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

Nomination of co-chairs

- Eli Coleman (chair)
- Jon Arcelus & Asa Radix (co-chairs)

Chapter leads

- 50 Applications received
- 18 countries
- 24 Leads chosen

Working groups/stakeholders

- 164 Applications received
- 18 countries
- Team formation

JHU_000003264

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)

JHU_000003265

Community Feedback

- 43 TGNB members of the guidelines committee
- Transgender advisory group (international organizations) to provide feedback
- Beta version to be posted online for comments for revision

JHU_000003266

Chapter Members

JHU_000003267

What's New for SOC8?

- Assessment, Support and Therapeutic Approaches for Children
- Assessment, Support and Therapeutic Approaches for Adolescents
- Primary Care for Adults
- Assessment, Support and Therapeutic Approaches for Non-binary individuals
- Sexual Health Across The Lifespan
- Reproductive Health for Adolescents and Adults
- Applicability of the Standards of Care to Eunuchs
- Competency, Training, Education, Ethics

JHU_000003268

Feedback from some chapters….

JHU_000003269

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WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

I. Global applicability of the standards of care

Chapter members:

Sam Winter (Australia) **LEAD**
Jack Byrne (New Zealand)
Mauro Cabral (Argentina)
Alexus D'Marco (Bahamas)
Katherine Johnson (UK)
Alicia Kruger (Brazil)
Shane Morrison (USA)
Georgios Paglakos (Greece)
Nittaya Phanuphak (Thailand)
Joshua Sehoole (South Africa)

JHU_000003270

15 core principles (provisional list)

1. Involve trans people in development of services.
2. Respect diversity.
3. Respect fundamental human rights.
4. Be enabling and inclusive.
5. Become knowledgeable.
6. Match care to patient.
7. Provide (or refer on to) affirmative healthcare.
8. Promote overall health and wellbeing.
9. Do harm reduction.
10. Reject reparative approaches.
11. Ensure informed decision-making.
12. Ensure continuity of care.
13. Provide contact with communities.
14. Be aware of social, cultural, legal and economic factors.
15. Engage in advocacy.

JHU_000003271

II. Terminology- Diagnostic Criteria

Chapter members:

Sari Reisner (USA) - LEAD

Koray Başar (Turkey)

Sand Chang (USA)

Aaron Devor (Canada)

G. Nic Rider (USA)

Cianán Russell (Germany)

Kirill Sabir (Russia)

JHU_000003272

Status

- Terminology and what is considered current/affirming varies greatly depending on culture/context/history
- Important not to have a US/Euro-centric way of introducing terms in the SOC document
  - What words should we use for transgender people and receivers of gender related care in the SOC?
  - What words should we use for professionals and others providing care to trans people?
  - What are the best ways to describe medical treatment, services or interventions?
  - How do we describe other aspects of lived experience?
  - What should the document be called?
- Status so far
  - Reviewed SOC7 to identify language used in the document
  - Reviewed other documents to identify best practices for language use
  - Reviewed the literature for historical context
  - Chapter outline in progress

JHU_000003273

III. Epidemiologic considerations

Chapter members:

- Michael Goodman (Atlanta, USA)
- Noah Adams (Toronto Canada)
- Trevor Cornell (Vancouver, Canada)
- Baudewijntje Kreukels (Amsterdam, Netherlands)
- Joz Motmans (Ghent, Belgium)

JHU_000003274

Progress to date

- 43 articles retrieved and summarized to-date
- Years of publication ranged from 1968 to 2018
- 23 from Europe, 13 from the US, 2 from Japan, 2 from New Zealand and one (each) from Iran, Australia and Singapore
- Estimates of proportion of transgender people in the population vary widely

- Main determinant of disagreement across estimates is definition of what constitutes 'transgender' or 'gender non-conformity'
- Other factors include:
  - Study design
  - Time of study
  - Place of study
  - Age of population under study
- Chapter draft is in preparation

JHU_000003275

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IV. Overview of Therapeutic Approaches for Gender Health

Chapter members:

Mick van Trotsenburg - LEAD (Vienna/Austria) Obs&Gyn
Tamara Adrian (Caracas/Venezuela) Lawyer
Steven Arver (Stockholm/Sweden) Internal Medicine
Elizabeth Kvach (Denver/USA) Family Medicine
Blaine Paxton Hall (Durham/USA) Internal Medicine
Katie Spencer (Minneapolis/USA) Family Medicine/Community Health

JHU_000003276

Chapter
Overview of therapeutic approaches

- Start in a later phase when first outlines and recommendations of the various chapters are available
- Give a vision of what the SOC accomplish in a very succinct fashion
- Pointing out that therapeutic approaches are options rather than a obligation, and decision-making is dependent on various factors
- Summarize all therapeutic approaches of the various chapters
- Pointing out to sensible sequencing of possible therapeutic interventions

JHU_000003277

V. The role of primary care in gender health

Chapter members:

Madeline B. Deutsch, MD, MPH (US) – **Lead**
John Dean, MD (UK)
Justus Eisfeld (US,)
Jamie Feldman, MD, MPH (US)
Joshua Safer, MD (US)
Linda Wesp, FNP (US)

JHU_000003278

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Primary Care

Controversies in our chapter are rooted in a lack of health outcome data to inform screening and prevention recommendations

- Cancer
- Osteoporosis
- Coronary artery disease

Draft example recommendations from the chapter:

- Hormone therapy is within the scope of practice of primary care providers
- Witholding hormone therapy to prevent cardiovascular disease is not supported by evidence and may worsen mental health outcomes, including suicidality

JHU_000003279

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VI. Assessment, Support and Therapeutic Approaches for Children

Chapter Members:

Amy Tishelman (USA) – LEAD
Dianne Berg (USA)
Diane Ehrensaft (USA)
Laura Edwards-Leeper (USA)
Susie Green (UK)
Aron Janssen (USA)
Jiska Ristori (Italy)
Thomas Steensma (Netherlands)
John Strang (USA)

JHU_000003280

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VII. Assessment, Support and Therapeutic Approaches for Adolescents with Gender Diversity/Dysphoria

Chapter Members:
Annelou de Vries (Netherlands) – CO LEAD
Scott Leibowitz (USA) – CO LEAD
Gayathri Chelvakumar (USA)
Laura Edwards-Leeper (USA)
Jean Malpas (USA)
Ren Massey (USA
Stephanie Roberts (USA)
John Strang (USA)

JHU_000003281

Outline of the statements adolescent chapter

- General care principles
- Role of MHP
- Assessment for affirmative medical care
- General health
- Pubertal suppression
- Affirming hormones
- Surgery

JHU_000003282

Discussion Points

- Which statements can be evidence based reviewed?
- How to come to consensus?
- Which values and rationales prevail?

JHU_000003283

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VIII. Assessment, support and therapeutic approaches for non binary people

Chapter members:

Walter Pierre Bouman MD PhD (UK) – Co Lead
Joz Motmans PhD (Belgium) – Co Lead
Stefan Arver MD PhD (Sweden)
Jeremi Carswell MD (USA)
Randall Ehrbar PhD (USA)
Laura Jacobs, LCSW-R (USA)
Laura Kuper PhD (USA)
Loren Schechter MD FACS (USA)
Leighton Seal MD PhD (UK)
Thomas Steensma PhD (Netherlands)
Ben Vincent PhD (UK)

JHU_000003284

Draft Statements (before lit review or consultation):

- We recommend/advise that health professionals should accept that gender is on a continuum and may not conform to a traditional binary model
- We recommend/advise that GNB people are entitled to receive person-centered assessment and treatment that affirms their non-binary experiences of gender
- We recommend/advise that access to social transition and/or gender affirming medical interventions are not dependent on any particular gender identity or gender expression
- We recommend/advise that GNB people wishing gender affirming medical interventions (hormonal treatment or surgery) may require additional support in view of a higher prevalence of mental health problems (compared to binary trans and cisgender people)
- We recommend/advise that gender affirming medical interventions (hormonal treatment or surgery) may be appropriate in the absence of social gender transition
- We recommend/advise that gender affirming surgical interventions may be appropriate in the absence of hormonal treatment
- We recommend/advise that GNB people have access to fertility preservation prior to starting hormonal treatment

JHU_000003285

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IX. Assessment of Adults with Gender Diversity or Dysphoria

Lead: Dr. Christina Richards (UK)

Chapter members:

Ms. Harjit Bagga (Australia)

Dr. Koray Basar (Turkey)

Dr. Griet De Cuypere (Belgium)

Dr. Cecilia Dhejne (Sweden)

Dr. Kelly Ducheny (USA)

Dr. E. Kale Edmiston (USA)

JHU_000003286

Draft Statements (before lit review or consultation):

- We recommend that people with gender dysphoria or diversity should have the highest degree of professional care which is realistically available to them.
- We recommend that assessors have the ability to recognize and diagnose co-existing mental health or other concerns and to be able to distinguish these from gender dysphoria or diversity
- We recommend that assessors work within their local professional standards while continuing to improve the care provided.
- We suggest that assessors give priority to the informed consent of the person with an assumption to treat where the onus is on the assessing professional to facilitate treatment as well as identifying any reasons why treatment should not go ahead at that time; rather than the person with gender dysphoria or diversity needing to prove why they should receive treatment.
- We recommend that, a biopsychosocial approach is adopted to mitigate risk.

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X. Managing mental and behavioural health conditions in adults

Chapter members:

Dan Karasic (USA) - Lead
Koray Basar (Turkey)
Griet DeCuypere (Belgium)
Cecilia Dhejne (Sweden)
Randall Ehrbar (USA)
Laura Erickson-Schroth (USA)
Aron Jannsen (USA)
Lida Vala (USA)

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Statements: Replacing "well controlled"

- Mental health conditions should be addressed so that the patient is able to give informed consent and participate in essential medical and perioperative care.
- The presence of mental illness should not be a barrier to starting hormones, as long as there is capacity to give informed consent and the potential benefits of treatment outweigh the risks.
- Often treating gender dysphoria with hormones and social transition is best done simultaneously with treating mental illness and substance abuse.
- Genital reconstructive surgery, with complications common and the need for active patient engagement for best outcomes, has a higher bar for mental health stability than other transition care.
- Mental illness and substance abuse before genital reconstructive surgery should be stabilized to the extent that the patient can give informed consent, and that the patient can participate in needed perioperative care.
- In treating patients with treatment resistant mental illness seeking gender-confirming surgery, the risks and benefits of providing surgery versus delaying surgery should be weighed.

JHU_000003289

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XI. Hormone therapy for adolescents and adults

Chapter members:

- Vin Tangpricha (USA) - Lead
- Martin den Haijer (Netherlands)
- Michael Irwig (USA)
- Colt Keo-Maier (USA)
- Daniel Klink (Netherlands)
- Stephen Rosenthal (USA)
- Joshua Safer (USA)
- Guy T'Sjoen (Belgium)

JHU_000003290

Planned Systematic Reviews to inform additional recommendations

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- For transgender women, what are the safety and efficacy of androgen lowering medications compared to Spironolactone vs cyproterone vs GnRH agonists in terms of surrogate outcomes, clinical outcomes, and harms?
- For transgender adolescents, what are the long term effect of GnRH agonists compared to no treatment, in terms of surrogate outcomes, clinical outcomes, and harms?
- For transfeminine people on gender-affirming hormone therapy with estrogen, what are the comparative risks of prolactinomas and hyperprolactinemia between spironolactone, cyproterone, and GnRH agonists, in terms of prolactin levels and presence of prolactinomas confirmed by imaging?
- For transgender people, what are the effect of progesterones (cyproterone) compared to Medroxyprogesterone and other progesterones in terms of breast growth (adults), delay of puberty (children), and side effects?
- For transgender women, what are the comparative risks of different regimens of gender-affirming hormone therapy with estrogens (conjugated estrogen, estradiol, ethinyl estradiol) in terms of pulmonary embolism, deep-vein thrombosis, stroke, and myocardial infarction?
- For transgender men, what is the risk of polycythemia among transgender men on gender-affirming therapy with testosterone, as measured by hematocrit and hemoglobin levels?
- For transgender men, what is the effect of testosterone therapy on uterine and ovarian (and cervical?) pathology in transgender men who have not had a hysterectomy or oophorectomy?
- For transgender women, what is the safety of different routes of administration for estrogen (oral, cutaneous, intramuscular) in terms of myocardial infarction, stroke, deep-vein thrombosis, and pulmonary embolism?

JHU_00000291

- For transgender adolescents, what are the effects of suppressing puberty with GnRH agonists on quality of life?
- For transgender people, what are the psychological effects (including quality of life) associated with hormone therapy
- For transgender people, what are the effects of hormone therapy on metabolic syndrome?
- For transgender people, what are the effects of hormone therapy on fertility?

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XII. Sexual Health Across the Lifespan

Chapter Members:

Timo Nieder (Germany) – Lead
Cecilia Dhejne (Sweden)
Els Elaut (Belgium)
Maurice Garcia (USA)
Luk Gijs (Netherlands & Belgium)
Sally Robbins-Cherry (UK)
Liberty Matthyse (South Africa)
Ayden Scheim (Canada)
Katherine Spencer (USA)
Jennifer Vencill (USA)

JHU_000003293

JHU_000003294

Chapter Structure

- Introduction
- Sexual Development
- Family and Loved Ones
- Social Context
- Sexual Functions and Sexual Dysfunctions
- Sexual Pleasure and Sexual Satisfaction
- Sexually Transmitted Infections
- Sexual Orientation
- Transition and Gender-Related Medical Interventions

JHU_000003295

Example recommendation: Introduction

- We advise that counselling on sexuality (and its potential meanings and implications before, during and after one's transition) is itself a best practice for long-term healthcare for trans people and not merely a topic to be addressed during assessment when referring a client for medical interventions.

JHU_000003296

Example recommendation: Family and loved ones

- We advise that clients who present with sexual difficulties within a relationship should be offered trans-friendly sex therapy. According to the preference of the client, and of the indication of the sex therapist, this should be possible both with the individual and at the relationship(s) level.

JHU_000003297

Example recommendation: Sexual Functions and Sexual Dysfunctions

- We recommend that healthcare professionals respectfully inform all trans clients about how sexual functioning and sexuality may be affected by gender-related medical interventions depending on sexual preference, orientation, and behavior.

JHU_000003298

Example recommendation: Sexual Pleasure and Sexual Satisfaction

- We recommend that healthcare professionals, at a minimum, introduce a discussion about sexual satisfaction and pleasure, and consent.

JHU_000003299

Example recommendation: Sexually Transmitted Infections

- We recommend that healthcare professionals offer ongoing HIV/STI testing in correspondence with national guidelines, with more frequent testing for trans individuals at higher risk (e. g., patients sexually active with cis men and trans women). As national guidelines infrequently offer specific guidance for trans persons, risk assessment should be based on current anatomy and sexual behaviors, as well as consideration of the risk profile of a client's sexual partners.

JHU_000003300

Example recommendation: Transition and Gender-Related Medical Interventions

- We recommend that healthcare professionals who provide gender-related medical interventions are sufficiently informed about sexual function, and common challenges to achieving satisfactory sexual function, for the clients they provide care to. If the provider cannot provide information about the effects of their treatment upon sexual function, they should at a minimum be able to refer the individual to someone qualified to do so. It is not acceptable to provide treatments with such far-reaching effects without being able to counsel clients about the potential effects on sexual function.

JHU_000003301

XVIII. Reproductive Health Chapter

Chapter Members:

- **Lead:** Leena Nahata - USA
- Juno Obedin-Maliver - USA
- Kenny Rodriguez Wallberg - Sweden
- Bernard Taylor - USA
- Kelly Tilleman - Belgium
- Norah van Mello - Netherlands
- Aedan Wolton – UK

JHU_000003302

Status (as of September 2018)

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- Outline completed in July 2018
- First drafts complete of 3 (of 9) sections – example of preliminary recs:
- We advise that patients and families receive information and counseling from their health care team regarding the potential risks of hormone treatment on future fertility *prior to* initiation of these therapies, in order to optimize long-term reproductive and psychosocial outcomes.
- Providers who are prescribing hormonal therapies to TG youth should receive specific training on 1) potential risks to future fertility; 2) FP options; and 3) psychosocial implications of infertility.
- TG care teams should partner with local reproductive specialists and facilities so that the discussion on methods for fertility preservation can be timely planned and sperm and oocyte cryopreservation may be offered.

JHU_000003303

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XIV. Voice and Communication

Chapter lead: Adrienne Hancock, PhD, *USA*

Chapter members:

David Azul, PhD, *Australia*

Teresa Hardy, PhD, *Canada*

Ulrika Nygren, PhD, *Sweden*

Jenni Oates, PhD, *Australia*

Vica Papp, PhD, *New Zealand*

Caroline Temmermand, *USA*

JHU_000003304

Voice and Communication

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- Informed by a person-centered approach
  - Acknowledging agency limitations of person & provider in production of gender
- Provider and Assessment standards
- Interventions (IF necessary or desired by an individual!)
  - Behavioral approaches
  - Voice surgeries
  - Hormones
- For individuals
  - AMAB (feminize positioning)
  - AFAB (masculinize positioning)

JHU_000003305

XV. Surgery chapter for adolescents and adults; post operative care and follow up

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Chapter members:

- Stan Monstrey, MD (co-lead), Belgium
- Loren Schechter, MD (co-lead), USA
- Javier Belinky, MD Argentina
- Jens Berli, MD USA
- Rachel Bluebond-Langner, MD USA
- Marci Bowers, MD USA
- Pierre Brassard, MD Canada
- Mark Bram Bouman, MD Netherlands
- Luis Capitan, MD Spain
- Griet De Cuypere, MD Belgium
- Maurice Garcia, MD USA
- Scott Mosser, MD USA
- Michaela West, MD, PhD, USA

JHU_000003306

Systematic Reviews

- 1. We believe that Gender Affirming Surgery (GAS or GCS), when indicated and requested, improves quality of life, helps to alleviate gender dysphoria, and is medically necessary
- 2. We believe that Facial Gender Confirming Surgery (FGCS) improves quality of life, helps to alleviate gender dysphoria, and may be medically necessary
- 3. We believe that breast augmentation improves quality of life, helps to alleviate gender dysphoria, and may be medically necessary
- 4. Should feminizing hormone therapy be a prerequisite for top surgery for transgender women?
- 5. We believe that chest surgery (subcutaneous mastectomy) improves quality of life, helps to alleviate gender dysphoria, and is medically necessary
- 6. We believe that vaginoplasty improves quality of life, helps to alleviate gender dysphoria, and may be medically necessary
- 7: What are the benefits and risks of different techniques (e.g., penile inversion, intestinal/sigmoid, peritoneal) for genital surgery for transgender women?
- 8. We believe that phalloplasty and metoidioplasty improve quality of life, help to alleviate gender dysphoria, and may be medically necessary
- 9. Does a prerequisite of 12 months of continuous hormone therapy improve readiness for and outcomes of genital surgery ("bottom surgery") in transgender patients?
- 10. Does a prerequisite of 12 months of living in a gender role that is congruent with the gender identity of the patient (the "real life test") improve readiness for and outcomes of genital surgery in transgender patients?

JHU_000003307

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XVI. Applicability of the standards of care for people living in institutional environments

- Randi Ettner (USA) – Co Lead
- George R. Brown (USA) – Co Lead
- Ren Massey (USA)
- Tom Mazur (USA)
- Sarah Murjan (UK)
- Jude Patton (USA)

JHU_000003308

Draft Concepts for Inclusion

- The Standards of Care, in their entirety, apply irrespective of where people are housed.
- Neglect of medical care IS mistreatment.
- Delay of assessment and/or treatment may place individuals at risk for negative health and mental health outcomes.
- Violence and sexual assault by staff or residents, even if anecdotal, requires investigation and appropriate disciplinary action.
- Institutions should provide training for staff and enlist consultants if local competently trained employed staff do not exist.
- Sexual orientation should not be used as a criterion for sex segregated housing (sex vs. gender concepts).
- Suicidal ideation, attempts, or surgical self-treatment are indications that treatment for gender dysphoria or a co-occurring condition is required. These should not be the basis for segregating individuals in solitary confinement or other isolated areas.
- Age should not be used a barrier to evaluation or treatment.
- Chronic mental health conditions, e.g. PTSD, personality disorders, bipolar disorder, should not be used as a pretense for denying access to transgender health care.

JHU_000003309

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XVII. Applicability of the standards of care to people with intersex conditions

Chapter Lead: Heino F. L. Meyer-Bahlburg, Dr. rer. nat. (USA)

Chapter Members:

- David Bathory, PsyD (USA)
- Katherine Dalke, MD (USA)
- Alessandra Fisher, MD, PhD (Italy)
- Baudewijntje Kreukels, PhD (Netherlands)
- Matthew Malouf, PhD (USA)
- Thomas Mazur, PhD (USA)
- Josh Safer, MD (USA)

JHU_000003310

SOC-8 Ch. 17: Status 10/1/2018

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- Suggested topics for "systematic review of the evidence"
  - None, because of the large number of diverse intersex conditions and the scarce psych. literature.
- Decision re overall chapter focus
  - Individuals with gender dysphoria and somatic intersexuality rather than individuals with intersexuality in general.
- Selection of intersex-specific ethical issues
  - Unresolved.
- List of "recommendations for clinical care"
  - Tentatively 13 listed and partially drafted; additional ones are likely.
- General difficulty
  - Chapter title is "Applicability of the SOCs to people with somatic intersex conditions", but we don't know yet what the SOCs-8 are going to be.

JHU_000003311

XVIII. Applicability of standards of care to Eunuchs

Chapter members:

Thomas Johnson (USA) – Lead

Chris Cargill (USA)

Michael Irwig (USA)

Kit Rachlin (USA)

JHU_000003312

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12 Best Practice Statements

1. We recognize that misunderstanding of the historical roles of eunuchs will likely cause stress for many eunuchs whose status is known to outsiders. Providers will need to be prepared with adequate knowledge of stereotypes and misperceptions, as well as with accurate information.

2. We recognize that eunuchs may not voluntarily disclose their identity and/or desires, even to their medical or mental health providers, due to stigma and fear of rejection by the medical community

3. We recognize that individuals with male-to-eunuch gender dysphoria may seek medical or surgical care (hormone suppression or orchiectomy) without having had an appropriate psychological assessment by a qualified mental health professional.... (plus 9 more....)

JHU_000003313

XIX. Competency, training, education and ethics

Jaimie Veale - New Zealand

Jamie Feldman- USA

Paula Neira- USA

Lin Fraser - USA

Gail Knudson - Canada

Terry Reed - UK

Jamison Green- USA

Carol Bayley- USA

Joz Motmans- Belgium

JHU_000003314

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Process

Education

- Reviewed available literature including practice and educational guidelines across disciplines
- Literature is scant and no systemic reviews were performed
- Made recommendations across disciplines and institutional levels
- All statements are prefaced with:
  - We advise
  - We recommend

Ethics

- Reviewed available literature
- Literature is scant and no systematic reviews were performed
- Surveyed chapters within SOC 8 to identify ethical challenges
- Held GEI pre-course in Ethics in BA to gather ideas
- Held Ethics mini-symposium in BA to gather ideas

JHU_000003315

Examples of Recommendations

- LAW: We advise that legal education programs, legal program accreditation boards, and licensing boards should specifically include transgender cultural-competency as a required topic and identify expectations of practice competencies for legal professionals.

- NURSING: We advise that entry-level nursing education programs (associate, diploma, bachelorette, or masters), nursing program accreditation boards, and testing boards must specifically name transgender health as a required topic and identify expectations of clinical competencies.

- MEDICINE: We advise separating transgender health content from the larger LGBTQ umbrella.

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Questions Comments

JHU_000003317

Voice

KQ1: For transfeminine individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ2: For transmasculine individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ3: For non-binary individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ4: For any (but particularly transmasculine and non-binary) individuals, what are the effects of (sustained) chest binding compared to no binding in terms of valving efficiency and projection?

KQ5: For transfeminine individuals, what are the effects of surgical interventions for voice feminization compared to no surgical intervention, surgery in conjunction with voice therapy or with hormone therapy, or other surgical interventions for voice feminization in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ6: For transmasculine individuals, what are the effects of surgical interventions for voice masculinization (see list in Table A) compared to no surgical intervention, surgery in conjunction with voice therapy or with hormone therapy, or other surgical interventions for voice masculinization in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ7: For transfeminine individuals, what are the effects of feminizing hormone therapies compared to no hormone therapy or hormone therapy in conjunction with voice therapy or with surgery in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ7A: Do these effects differ for pre-pubertal children being treated with hormone blockers?

KQ7B: Do these effects differ for people who were treated with hormone blockers before being treated with estrogen?

KQ7C: Do these effects differ for adults being treated with estrogen?

KQ8: For transmasculine individuals, what are the effects of masculinizing hormone therapies (e.g., testosterone) compared to no hormone therapy or hormone therapy in conjunction with voice therapy or with surgery in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ8A: Do these effects differ for pre-pubertal children being treated with hormone blockers?

KQ8B: Do these effects differ for people who were treated with hormone blockers before being treated with testosterone?

KQ8C: Do these effects differ for adults being treated with testosterone?

Surgery

KQ1: What are the benefits and risks of chest reconstruction surgery for transgender men and gender-nonconforming individuals assigned female at birth?

KQ2: What are the benefits and risks of breast augmentation surgery ("top surgery") for transgender women and gender non-conforming individuals assigned male at birth?

KQ2a: What are the benefits and risks of top surgery for transfeminine individuals and gender non-conforming individuals assigned male at birth in terms of factors aside from gender dysphoria (e.g., BRCA-1 mutation, family history of breast cancer)?

KQ2b: How does hormone therapy status affect the benefits and risks of top surgery for transgender women and gender non-conforming in transfeminine individuals and gender non-conforming individuals assigned male at birth?

KQ2c: How does age affect the benefits and risks of top surgery, particularly for those under 18 for transfeminine individuals and gender non-conforming individuals assigned male at birth?

Reproductive health

KQ1: What are the effects of gender-affirming hormone therapy in terms of psychosocial and clinical outcomes on the future off-spring of transgender or gender non-conforming individuals?

KQ2: What is the impact of hormone (GnRH analogues, testosterone, estrogen) treatments on fertility?

KQ3: What is the impact of hormone (GnRH analogues, testosterone, estrogen) treatments on ability to breast/chest feed?

Primary Care

KQ1: In transfeminine populations on estrogen therapy, does the specific route (intramuscular, transdermal, oral, sublingual) of exogenous estrogen increase or decrease risk for breast cancer?

KQ4: In transfeminine populations on estrogen therapy, does serum estrogen level impact risk for development of breast cancer? Do transfeminine populations with higher serum estrogen levels (>200) have greater risk for breast cancer compared with transfeminine populations with lower serum estrogen levels (<200)?

KQ5: Do transmasculine persons on testosterone therapy, when compared to cisgender women of average risk, have an increased risk of ovarian cancer?

Hormones

KQ1. For transgender women, what are the safety and efficacy of androgen-lowering medications compared to spironolactone vs cyproterone vs GnRH agonists in terms of surrogate outcomes, clinical outcomes, and harms?

KQ2. For transgender adolescent, what are the long term effect of GnRH agonists compared to no treatment, in terms of surrogate outcomes, clinical outcomes, and harms?

KQ10. For transgender adolescent, what are the effects of suppressing puberty with GnRH agonists on quality of life?

KQ3: For transgender women on gender-affirming hormone therapy with estrogen, what are the comparative risks of prolactinomas and hyperprolactinemia between spironolactone, cyproterone, and GnRH agonists, in terms of prolactin levels and presence of prolactinomas confirmed by imaging?

KQ4. For transgender people, what are the effect of progesterones (cyproterone) compared to medroxyprogesterone and other progesterones in terms of breast growth (adults), delay of puberty (children), and side effects?

KQ5. For transgender women, what are the comparative risks of different regimens of gender-affirming hormone therapy with estrogens (conjugated estrogen, estradiol, ethinyl estradiol) in terms of pulmonary embolism, deep-vein thrombosis, stroke, and myocardial infarction?

KQ9. For transgender women, what is the safety of different routes of administration for estrogen (oral, cutaneous, intramuscular) in terms of myocardial infarction, stroke, deep-vein thrombosis, and pulmonary embolism?

KQ6: For transgender men, what is the risk of polycythemia among transgender men on gender-affirming therapy with testosterone, as measured by hematocrit and hemoglobin levels?

Question 7. For transgender men, what is the effect of testosterone therapy on uterine, ovarian, cervical, vaginal, and breast pathology in transgender men who have not had a hysterectomy or oophorectomy?

Question 8. For transgender women, what is the effect of estrogen therapy on breast, testicular, prostate, and penile tissue in transgender women who have not had a gonadectomy?

KQ11. For transgender people, what are the psychological effects (including quality of life) associated with hormone therapy?

KQ12. For transgender people, what are the effects of hormone therapy on metabolic syndrome?

Assessment

Key Question 1. What is the effect of assessment by a health professional prior to initiation of cross-sex hormones?

Key Question 2. What is the effect of assessment by a health professional prior to gender-affirming surgery?

Key Question 3. What is the effect of transition prior to initiation of gender-affirming hormone therapy?

Key Question 4. What is effect of transition prior to initiation of gender-affirming surgery?

Adolescents

Question 1: What is the effect of rejection or acceptance on the mental health and psychosocial wellbeing of transgender and other gender-diverse children and adolescents?

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 transsexual, transgender, and gender nonconforming[1] 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
The recommendations in the Standards of Care are developed to apply to transsexual, transgender, and gender nonconforming people[1].

Footnote: 1 Terminology for Standards of Care to be determined by members of "Chapter 2- Terminology"

While the Standards of Care are intended for broad use across countries, WPATH acknowledges that much of the recorded clinical experience and knowledge in this area of health care is derived from North America and Western Europe.

History of the Standards of Care
The Standards of Care were originally published in 1979. Updated Standards of Care were published in 1980, 1981, 1990, 1998, 2001, and 2011.

About Standards of Care 8th Version
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. This document provides an overview of the methodological approach for updating the Standards of Care.

Overview of Process

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

- Establish Guideline Steering Committee
- Determine topics for chapters (scope of guidelines)
- Select Chapter Members and Evidence Review Team
- Refine the topics and review questions
- Conduct the systematic reviews
- Draft the recommendation statements
- Distribute Standards of Care for review
- Disseminate the Standards of Care
- Plan to update

Establish Guideline Steering Committee

The WPATH Guideline Steering Committee oversees the guideline development process for all chapters of the Standards of Care. Members of the Guideline Steering Committee are selected by the WPATH Board from WPATH members applying for these positions. The Chairs of the Guideline Steering Committee:

- Appoint the Chapter Leads and Members for each chapter
- Selects topics for the chapters

The Guideline Steering Committee provides general oversight of the guideline development process. The Committee reviews all chapters of the Standards of Care to confirm adherence to the WPATH guideline methodology and to ensure consistency of statements across the Standards of Care.

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

- Eli Coleman, PhD (Chair)
  Professor, Director and Academic Chair, Program in Human Sexuality, Department of Family Medicine and Community Health, University of Minnesota Medical School (USA)

- Asa Radix, MD, PhD, MPH (Co-chair)
  Director, Research and Education
  Callen-Lorde Community Health Center
  Assistant Clinical Professor of Medicine
  New York University, USA
- Jon Arcelus, MD, PhD (Co-chair)
  Professor of Mental Health and Transgender Health
  University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team)
  Associate Professor of Medicine, Epidemiology and Health Policy & Management
  Johns Hopkins University, USA

Determine Topics for Chapters

The Guideline Steering Committee determines the chapters for inclusion in the Standards of Care. The chapters in the Standards of Care 8th Version are:

1. Global Applicability of the Standards of Care
2. Terminology – Diagnostic Criteria
3. Epidemiologic Considerations
4. Overview of Therapeutic Approaches for Gender Health
5. Assessment, Support and Therapeutic Approaches for Children
6. NEW: Assessment, Support and Therapeutic Approaches for Adolescents with Gender Variance/Dysphoria
7. Assessment of Adults
8. Assessment, Support and Therapeutic Approaches for Non-Binary Individuals
9. Managing Mental and Behavioral Health Conditions in Adults
10. Primary Care for Adults
11. Hormone Therapy for Adolescents and Adults
12. NEW: Sexual Health Across The Lifespan
13. Reproductive Health for Adolescents and Adults
14. Voice and Communication Therapy
15. Surgery For Adolescents and Adults: Postoperative Care and Follow-Up
16. Applicability of the Standards of Care to People Living in Institutional Environments
17. Applicability of the Standards of Care to People with Intersex Conditions
18. NEW: Applicability of the Standards of Care to Eunuchs
19. NEW: Competency, Training, Education
20. Ethics

Select Chapter Members

Those interested in working on the Standards of Care can apply to serve as Chapter Members (Chapter Lead or Member). The Chairs of the Guideline Steering Committee appoint the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members are required to be WPATH Full Members in good standing, and have expertise in transgender health, including in the specific chapter topic. Chapter Leads are expected to be well known advocates for WPATH and the Standards of Care. Chapter Leads report to the Guideline Steering Committee and are responsible for coordinating the participation of Chapter Members. Chapter members report directly to the Chapter Lead.

Each chapter also includes stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that includes a transgender child, sibling, partner, parent, etc. The stakeholders are not required to be WPATH Full Members.

The Chapter Members are 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
- with other members, review and assess evidence and draft recommendations
- participate in consensus process to draft and confirm recommendations
- as appropriate and as requested, draft section(s) of the guidelines document
- review comments from peer review process and assist in revision of guidelines, as necessary
- provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members will be provided, as needed. Training content includes formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation statements, grading the evidence and the recommendations, and information about the guideline development program and process.

Select Evidence Review Team

The WPATH Board issues a request for applications. For Standards of Care 8th Version the WPATH Board has engaged an Evidence Review Team at Johns Hopkins University.

Conflict of Interest

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Statements that will be evidence-based cover topics that are likely to have a body of evidence and reflect areas of uncertainty (e.g. in people X, therapy Y should be provided). Consensus-based statements, sometimes called good practice statements, reflect areas which may not have an evidence based or may be considered common-sense (e.g., people X, with Y, should be referred to specialist Z).

Chapter Members develop statements, they also review and confirm the statements and the classification as to type of statement.

For the statements requiring a systematic review, the Evidence Review Team drafts review questions, specifying the population, interventions, comparisons, and outcomes (PICO elements). Chapter Leads and Members review the review questions and provide feedback.

Conduct the Systematic Reviews

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Drafting of the Recommendation Statements

Chapter Leads and Members draft recommendation statements. The statements are crafted to be explicit and actionable.

Evidence-based recommendation statements are based on the results of the systematic reviews. For evidence-based recommendation statements, with assistance from the Evidence Review Team, the Chapter Leads and Members assign a grade of the recommendation (using GRADE system); describe the health benefits, side effects, and risks; and provide an explicit link between the recommendations and the supporting evidence.

Consensus-based recommendations, also called good practice statements, provide guidance for decision makers which may not have an evidence base. A formal consensus method, such as Delphi (a structured solicitation of expert judgements in two or more rounds), will be used for consensus-based statements. Consensus is sought within the whole SOC Committee for each consensus-based recommendation statement.

The Guidelines Steering Committee and Chapter Leads review and approve all recommendation statements for clarity and consistency in wording, and where relevant, grading. During this review any overlap between chapters is also addressed.

All recommendation statements are as specific as possible and actionable. Consensus-based recommendation statements will be clearly identified as such within the Standards of Care. Recommendation statements will be explicit and easily identified.

In addition to the recommendation statements, each chapter includes background, rationale for the each statement including details about the evidence base, the level of agreement and other considerations; information about implementing the recommendations; and, recommendations for future research.

Grading

Once the statements of a chapter have passed the Delphi process, chapter members will grade each statement using GRADING. Recommendation statements are either for or against an intervention/therapy/strategy and strength will be indicated as either:

- We recommend
- We suggest

The strength of recommendation considers four domains:

1. The balance of potential benefits and harms
2. Confidence in that balance or quality of evidence
3. Values and preferences of providers and patients
4. Resource use and feasibility

Evidence-based recommendation statements may be strong or weak:

- 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 that effects will be achieved in practice)
    - there are few downsides of therapy/intervention/strategy
    - there is a high degree of acceptance among 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 patients or those for whom the recommendation applies.

Text should precede each statement providing the rationale or reasoning for the recommendation. This should include outlining the available evidence, providing details about potential benefits and harms, a description of uncertainty, role of values and experience in developing the recommendation, and information about implementation of the recommendation, including expected barriers or challenges. References should be used, using APA style, to support the information in the text. Links to resources should also be provided, as appropriate. Reasons as to why the statement is strong or weak should be clearly described. The text, including whether a recommendation has been described as strong or weak, will be reviewed and approved by the Chairs. In addition, references used to support the statements will be validated.

To maintain difference and help readers distinguish between recommendations informed by systematic reviews and those not, the statements should be followed by certainty of evidence for those informed by systematic literature reviews.

Only statements supported by the systematic literature review should be followed by:

++++ strong certainty of evidence

+++ moderate certainty of evidence

++ low certainty of evidence

+ very low certainty of evidence

The level of agreement from the final round of Delphi should be presented for each as an appendix at the end of the document (such as in a table).

Example:

We recommend that people with X receive Y (++)

Structure for chapters

This is the general structure for each chapter.

- Background – brief introduction outlining scope of chapter (1-2 pages maximum).
  - As part of the introduction the principal of care can be added whether as bullet points or as part of the text.
- Summary of Recommendations – a list of each recommendation statement in a box.

- Within main text, with subheadings/sections of chapter as warranted, the recommendations with accompanying text as described above. (Maximum of approximately 3 paragraphs per recommendation statement.)

Distribute Standards of Care for Review

The draft Standards of Care document is circulated among the broader Standards of Care Revision Committee and the WPATH International Advisory Group. Feedback from these groups is considered, and any necessary revisions are made, by the Chapter Leads and the Guideline Steering Committee, with assistance from the Evidence Review Team.

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Disseminate the Standards of Care

The Standards of Care are disseminated in a number of venues and in a number of formats.

Plan to Update

The Standards of Care are reviewed at 3 years after the release date to determine if an update is needed. In addition, updates may be triggered by events such as important new evidence or therapies. The WPATH Board of Directors determines the timing of any revision of the Standards of Care.

WPATH Systematic Review Methodology

2 May 2018

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

Literature Search
The Evidence Review Team will develop a search strategy appropriate for each research question. At a minimum, the Evidence Review Team will search MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team may search additional databases as deemed appropriate for the research question. The search strategy will include MeSH and text terms and will not be limited by language of publication or date.

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

We will update the searches during the peer review process.

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

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

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Data Extraction
The Evidence Review Team will use standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer will abstract the data, and a second reviewer will confirm the abstracted data.

Assessment of Risk of Bias
Two reviewers from the Evidence Review Team will independently assess the risk of bias for each included study. For randomized controlled trials, we will use the Cochrane Risk of Bias Tool. For observational studies, we will use Risk of Bias in Non-Randomized Studies – of

Interventions (ROBINS-I) tool. Where deemed appropriate, existing recent systematic reviews may be considered and will be evaluated using ROBIS.

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The Evidence Review Team will create evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups will review and provide comment on the evidence tables.

Grading of the Evidence

The Evidence Review Team will assign evidence grades using the GRADE methodology. The Evidence Review Team will assign evidence grade to pre-defined critical outcomes for each question. We will assess the strength of the evidence by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

We will classify evidence pertaining to the review questions into four basic categories: 1) “high” grade (indicating high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of the effect); 2) “moderate” grade (indicating moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of the effect and may change the estimate); 3) “low” grade (indicating low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate); and 4) “insufficient” grade (evidence is unavailable or does not permit a conclusion).

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 transsexual, transgender, and gender nonconforming[1] 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
The recommendations in the Standards of Care are developed to apply to transsexual, transgender, and gender nonconforming people[1]. Transsexual people are individuals who seek to change or who have changed their primary and/or secondary sex characteristics through feminizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role. Transgender people are a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth. Gender nonconformity refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex.

Footnote: 1 Terminology for Standards of Care to be determined by members of "Chapter 2- Terminology"

While the Standards of Care are intended for broad use across countries, WPATH acknowledges that much of the recorded clinical experience and knowledge in this area of health care is derived from North America and Western Europe.

History of the Standards of Care
The Standards of Care were originally published in 1979. Updated Standards of Care were published in 1980, 1981, 1990, 1998, 2001, and 2011.

About Standards of Care 8th Version
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. This document provides an overview of the methodological approach for updating the Standards of Care.

Overview of Process

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

- Establish Guideline Steering Committee
- Determine topics for chapters (scope of guidelines)
- Select Chapter Members and Evidence Review Team
- Refine the topics and review questions
- Conduct the systematic reviews
- Draft the recommendation statements
- Distribute Standards of Care for review
- Disseminate the Standards of Care
- Plan to update

Establish Guideline Steering Committee

The WPATH Guideline Steering Committee oversees the guideline development process for all chapters of the Standards of Care. Members of the Guideline Steering Committee are selected by the WPATH Board from WPATH members applying for these positions. The Chairs of the Guideline Steering Committee:

- Appoint the Chapter Leads and Members for each chapter
- Selects topics for the chapters

The Guideline Steering Committee provides general oversight of the guideline development process. The Committee reviews all chapters of the Standards of Care to confirm adherence to the WPATH guideline methodology and to ensure consistency of statements across the Standards of Care.

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

- Eli Coleman, PhD (Chair)
  Professor, Department of Family Medicine and Community Health
  Director and Chair in Sexual Health, Program in Human Sexuality
  University of Minnesota, US
- Asa Radix, MD, MPH (Co-chair)
  Director, Research and Education
  Callen-Lorde Community Health Center
  Assistant Clinical Professor of Medicine
  New York University, US
- Jon Arcelus, MD, PhD (Co-chair)
  Professor of Mental Health and Transgender Health
  University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team)
  Associate Professor of Medicine, Epidemiology and Health Policy & Management
  Johns Hopkins University, US

Determine Topics for Chapters

The Guideline Steering Committee determines the chapters for inclusion in the Standards of Care. The chapters in the Standards of Care 8th Version are:

1. Global Applicability of the Standards of Care
2. Terminology – Diagnostic Criteria
3. Epidemiologic Considerations
4. Overview of Therapeutic Approaches for Gender Health
5. Assessment, Support and Therapeutic Approaches for Children
6. NEW: Assessment, Support and Therapeutic Approaches for Adolescents with Gender Variance/Dysphoria
7. Assessment of Adults
8. Assessment, Support and Therapeutic Approaches for Non-Binary Individuals
9. Managing Mental and Behavioral Health Conditions in Adults
10. Primary Care for Adults
11. Hormone Therapy for Adolescents and Adults
12. NEW: Sexual Health Across The Lifespan
13. Reproductive Health for Adolescents and Adults
14. Voice and Communication Therapy
15. Surgery For Adolescents and Adults: Postoperative Care and Follow-Up
16. Applicability of the Standards of Care to People Living in Institutional Environments
17. Applicability of the Standards of Care to People with Intersex Conditions
18. NEW: Applicability of the Standards of Care to Eunuchs
19. NEW: Competency, Training, Education, Ethics

Select Chapter Members

Those interested in working on the Standards of Care can apply to serve as Chapter Members (Chapter Lead or Member). The Chairs of the Guideline Steering Committee appoint the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members are required to be WPATH Full Members in good standing, and have expertise in transgender health, including in the specific chapter topic. Chapter Leads are expected to be well known advocates for WPATH and the Standards of Care. Chapter Leads report to the Guideline Steering Committee and are responsible for coordinating the participation of Chapter Members. Chapter members report directly to the Chapter Lead.

Each chapter also includes stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that includes a transgender child, sibling, partner, parent, etc. The stakeholders are not required to be WPATH Full Members.

The Chapter Members are 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
- with other members, review and assess evidence and draft recommendations
- participate in consensus process to draft and confirm recommendations
- as appropriate and as requested, draft section(s) of the guidelines document
- review comments from peer review process and assist in revision of guidelines, as necessary
- provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members will be provided, as needed. Training content includes formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation statements, grading the evidence and the recommendations, and information about the guideline development program and process.

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relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

Commented [A1]: These need to be collected.
-Are disclosures available?
-How are potential COI managed?

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Commented [A2]: A recommendation is drafted and agreed in Chapter and then sent to all SOC8 members for Delphi vote?

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Overview of Methods and Status

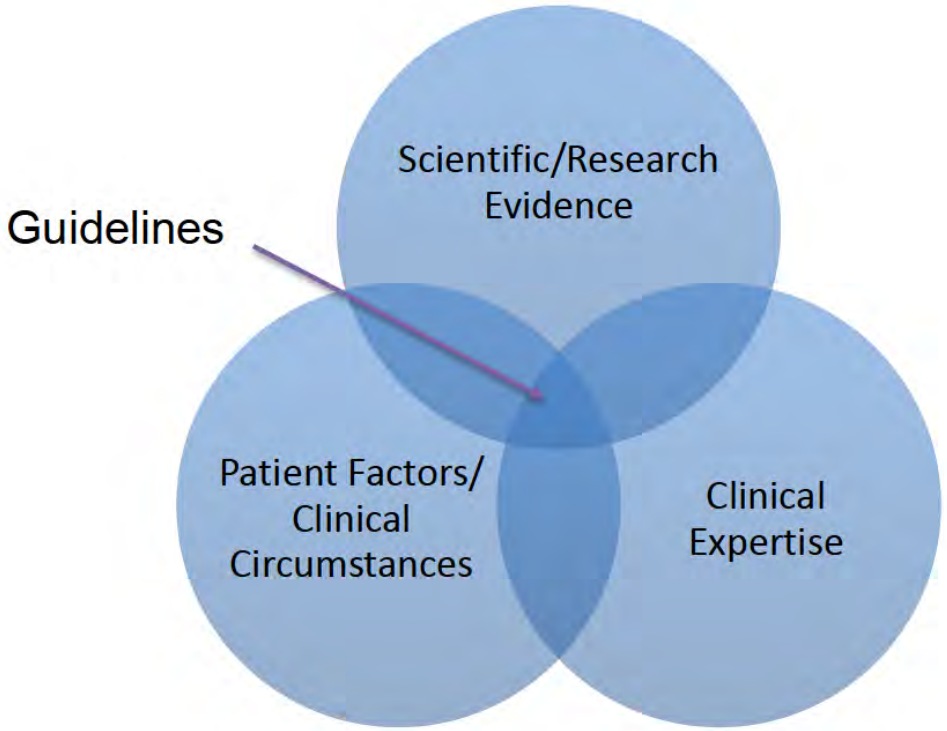
November 2018

WPATH SOC8 Chairs, Chapter Leads
and ERT (JHU)

JOHNS HOPKINS
SCHOOL OF MEDICINE

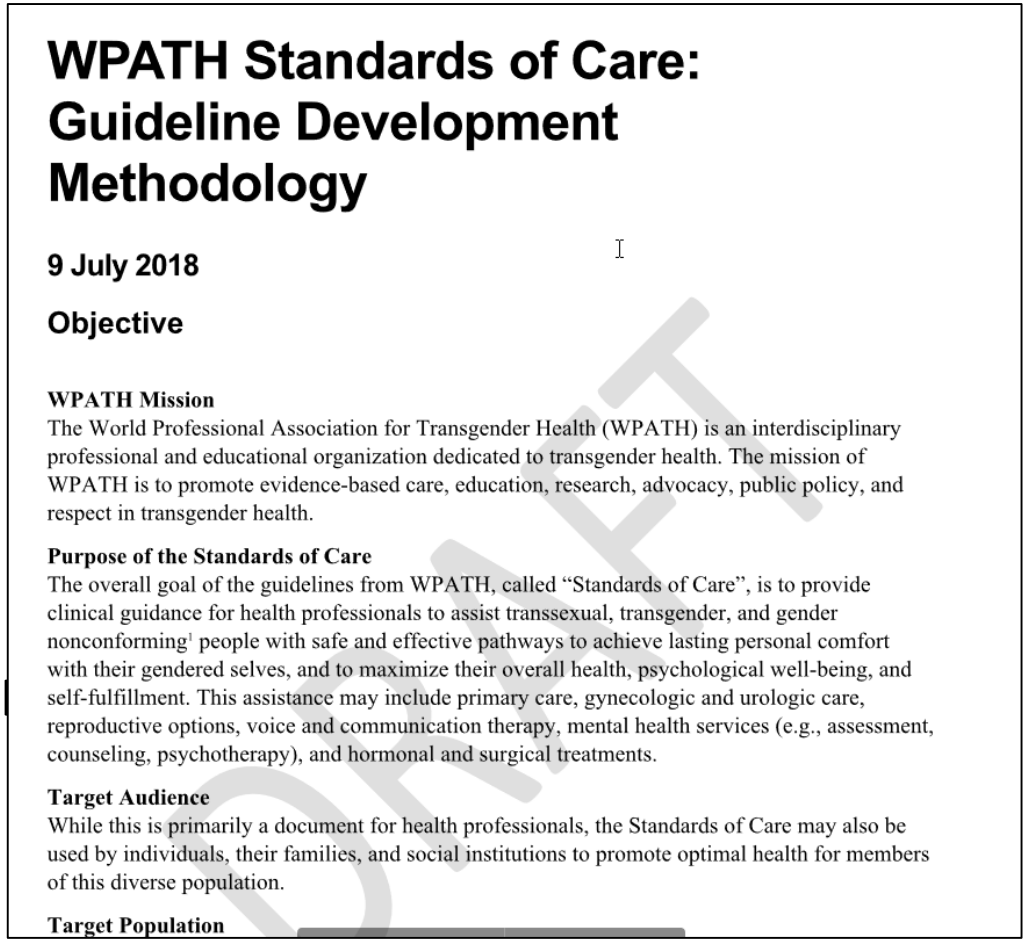
Clinical Practice Guidelines

Systematically developed statements that include recommendations, strategies, or information that assist physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.


Guidelines
Scientific/Research Evidence
Patient Factors/ Clinical Circumstances
Clinical Expertise

Guideline Process

1. Identify scope
2. Convene group
3. Refine questions
4. Assess evidence
5. Draft guideline
6. External review
7. Disseminate guideli



WPATH Standards of Care: Guideline Development Methodology

9 July 2018

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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

JHU_000003797

What makes a good guideline?

Domains:

1. Scope & Purpose
2. Stakeholder Involvement
3. Rigour of Development
4. Clarity of Presentation
5. Applicability
6. Editorial Independence

1. Identify Scope

- Develop SOC8
  - Chapters, including new chapters identified

AGREE

- Scope and Purpose

2. Convene group

- Chairs
- Chapter Leads and Members
- Methodologist

AGREE

- Stakeholder involvement
- Editorial independence

AGREE Domain 6. Editorial Independence

Items:

- View of funding bod
  have not influenced
  content
- Competing interests
  development group
  members recorded a
  addressed

WPATH

WPATH Policy for Disclosures of Interests and Management of Conflicts
Standards of Care 8

The World Professional Association for Transgender Health (WPATH) develops the Standards of Care (SOC) for the health of Transsexual, Transgender and Gender Nonconforming People. Appointment to the SOC8 Committee as a Chair, Methodologist, Chapter Lead or Chapter Member is subject to approval of the WPATH Board.

Interests must be disclosed using the WPATH Disclosure Form. The Disclosure Form collects information about financial relationships with entities with direct interest in the SOC8 as well as any non-financial interests such as previously published opinions, institutional relationships, advocacy or policy positions, or specialty practice that may relate to the topics in SOC8.

Management of Conflicts of Interest
The WPATH Board reviews and assesses disclosure forms. Management of conflicts may include prohibiting membership in SOC8, open discussion with other chapter or SOC8 members, and/or recusal from decisions specific to disclosed interests.

Completed and signed forms should be submitted for review of the WPATH Board to blaine@wpath.org

Disclosure Form of Interests
Part 1. Identifying Information

Name:

Complete Mailing Address:

Email Address:

Telephone Number (Daytime):

Current Employer/Affiliation:

Chapter(s):

Part 2. Complete All Parts of the Disclosure Form.

- *Check "No" if no disclosure exists.*
- *Check "Yes" – please providing the requested information next to each item where "Yes"*

JHU_00003801

3. Refine questions

Task discussed during initial calls:

To identify and refine questions for systematic reviews

- Review statements from SOC7
- Draft recommendations

AGREE

- Scope
- Rigour of development

SOC7 Statements
(May)

		adolescent's specific clinical situation and goals for gender identity expression.		
21	Risks of Withholding Treatment for Adolescents	Refusing timely medical interventions for adolescents might prolong gender dysphoria and contribute to an appearance that could provoke abuse and stigmatization. As the level of gender-related abuse is strongly associated with the degree of psychiatric distress during adolescence (Nuttbrock et al., 2010), withholding puberty suppression and subsequent feminizing or masculinizing hormone therapy is not a neutral option for adolescents.		Good Clinical Practice Statement
NEW: Assessment, Support, and Therapeutic Approaches for Adolescents with Gender Diversity/Dysphoria				
Chapter VII - Mental Health				
22	Competency of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria	The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria: 1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country. 2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.		Good Clinical Practice Statement

Page	Subheading	SOC7 Statement	Research Questions to Address Recommendations	Systematic Review
		3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria. 4. Documented supervised training and competence in psychotherapy or counseling. 5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria. 6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with		

From: Karen Robinson
Sent: Thursday, July 26, 2018 8:26 AM
To: soc8chapterleads@wpath.org
Cc: Eli Coleman <colem001@umn.edu>; Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>; Asa Radix <asa.radix@gmail.com>; Blaine Vella <blaine@wpath.org>
Subject: Register

All –

Thanks for joining the calls last Friday and yesterday.

As a brief reminder, what we need now are questions that you think need to be addressed by systematic reviews. These should be very specific (such as in PICO format) and should clearly lead to one or more recommendations. To ensure both of those characteristics, I suggested that people think about the end product and draft recommendation statements – what is it that they need to say in the chapter? What are the decision points for which people need or could benefit from guidance from WPATH We do not expect the statements to be in final format and the statements may be stems without details (i.e., pending review to determine most appropriate intervention, assessment tool, timing, criteria, etc.).

In preparing protocols for the systematic reviews we have conducted some preliminary searching. The chapter members will need to describe the available evidence to provide the reasoning underlying best practice statements and for the background section of the chapter. We hope the attached might be helpful.

The file lists studies (broadly defined and not limited by design), systematic reviews, and guidelines. We have tagged each citation with the relevant chapter(s).

	A	S	T	U	V	
1						
2	**Bibliography**	**Chapter XVII. Applicability of the Standards of Care to People with Intersex**	**Chapter XVIII. NEW: Applicability of the Standards of Care to**	**Chapter XIX.NEW: Competency, Training, Education, Ethics**	**Other - Please enter the topic (e.g. HIV, sport etc.)**	**Oth spor**
1269	Clinics in plastic Surgery -Series				Journal Series	
1270	Practice parameter on gay, lesbian or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. American Academy of Child and Adolescent Psychiatry. NGC:009316				Guideline	
1271	Care of the HIV-infected transgender patient. New York State Department of Health. NGC:009206				Guideline	
1272	Kreukels BPC, Köhler B, Nordenström A, Roehle R, Thyen U, Bouvattier C, de Vries ALC, Cohen-Kettenis PT; dsd-LIFE group. Gender Dysphoria and Gender Change in Disorders of Sex Development/Intersex Conditions: Results From the dsd-LIFE Study. J Sex Med. 2018 May;15(5):777-785.	Study				
1273						

4. Assess Evidence

- ERT:
  - Conduct systematic reviews
  - Strength of evidence
- Chapter Members:
  - Provide guidance
  - Confirm summary and strength of evidence

AGREE

- Rigour of development

JHU_000003805

AGREE Domain 3. Rigour of Development

Items:

- Systematic search
- Clear selection criteria
- Strengths and limitations of body of evidence
- Methods for formulating recommendations
- Health benefits, side effects and risks considered
- Explicit link between recommendations and evidence
- Externally reviewed
- Procedure for updating

5. Draft guideline

- Chapter Members:
  - Write/Revise recommendation statements (informed by systematic review, as applicable)
  - Rate strength of each statement (as applicable)
  - Write accompanying text

AGREE

- Clarity of presentation

Structure for chapters

20 July 2018

The following is the general structure. See following pages for a template and a mockup using the template.

- 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)
    - Text should precede each statement providing the rationale or reasoning for the recommendation. This should include outlining the available evidence, providing details about benefits and harms, a description of uncertainty, role of values and experience in developing the recommendation, and information about implementation of the recommendation, including expected barriers or challenges. Links to resources should also be provided, as appropriate.
    - Following the text the recommendation statement is provided in a standard, consistent format (see below)

<u>Recommendation statements</u>

- Evidence-based statements (wording followed by grading information in parentheses):
    - Strong recommendation: We recommend
    - Weak recommendation: We suggest

Example: We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

- Best practice statements (wording followed by 'ungraded best practice statement')
    - We advise

Example: We advise that people with X be referred to Y (ungraded best practice statement)

Background

This is where the scope of the chapter is described in 1-2 pages. Provide background information from a general review, including any definitions, as needed.

Summary of Recommendations

List all recommendations from this chapter here.

We recommend that people with X receive Y (certainty of evidence, grade of recommendation)

We advise that people with X be referred to Y (ungraded best practice statement)

Subheading for Chapter Topic A

Brief paragraph about what is included in this topic.

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

Here is where text providing rationale for the recommendation statement would go (about 3 paragraphs maximum). See notes about what should be included here.

Here is the text for recommendation statement. Here is an evidence-based statement (grade). Here is a good practice statement (ungraded best practice statement).

6. External review

- External to SOC8 members:
  - Presentation to WPATH Board
  - Public review
- SOC8 members respond to comments and revise guideline

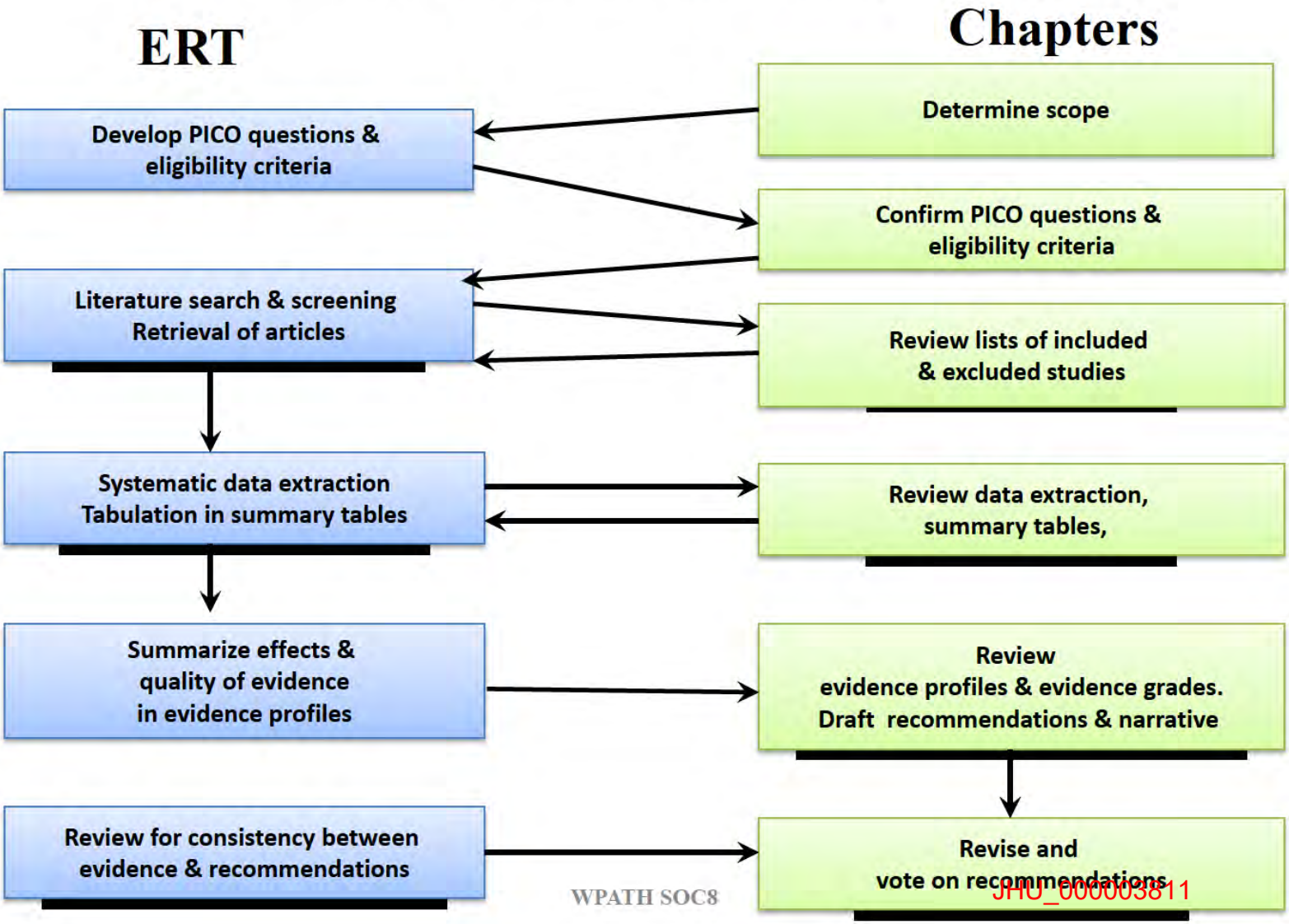
AGREE

- Rigour of development

7. Implementation

- Publication
- Other formats or method?

Chapter Members & ERT: Collaboration and Responsibilities



Systematic Reviews 101

Systematic Reviews

A review of existing evidence that uses explicit methods of identification, selection and validation of included information

- *Meta-analysis* uses statistical methods to quantitatively summarize results of similar but separate studies

Systematic Review Process

Definition of question(s)

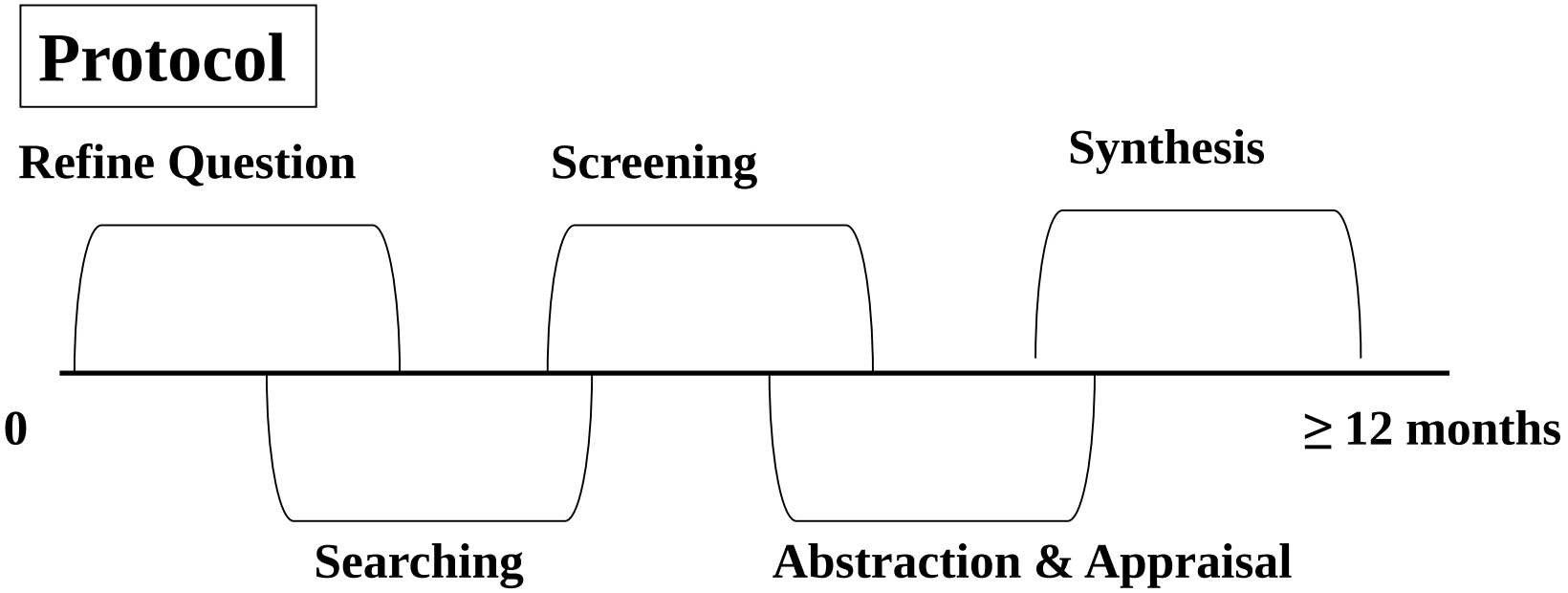
Identification of evidence

Selection of evidence

Evaluation of evidence

Synthesis of evidence

Timeline for Systematic Review



Definition of Questions

- Can it be answered?
  - uncertainty
  - availability of evidence
- Clear and specific
  - specify inclusion/exclusion criteria

 Drive ALL steps in process

Example of vague question:

What is the best strategy to prevent smoking in young people?

Well-Formulated Question

Patient (Population)	Intervention	Comparison	Outcome
• young people • under 25 • smoking frequency, consumption	Media: TV, radio, newspaper, booklets, posters, billboards…	No intervention	• objective (thiocyanate, alveolar CO) • self-reported behavior • intermediate • process

Well-Formulated Question

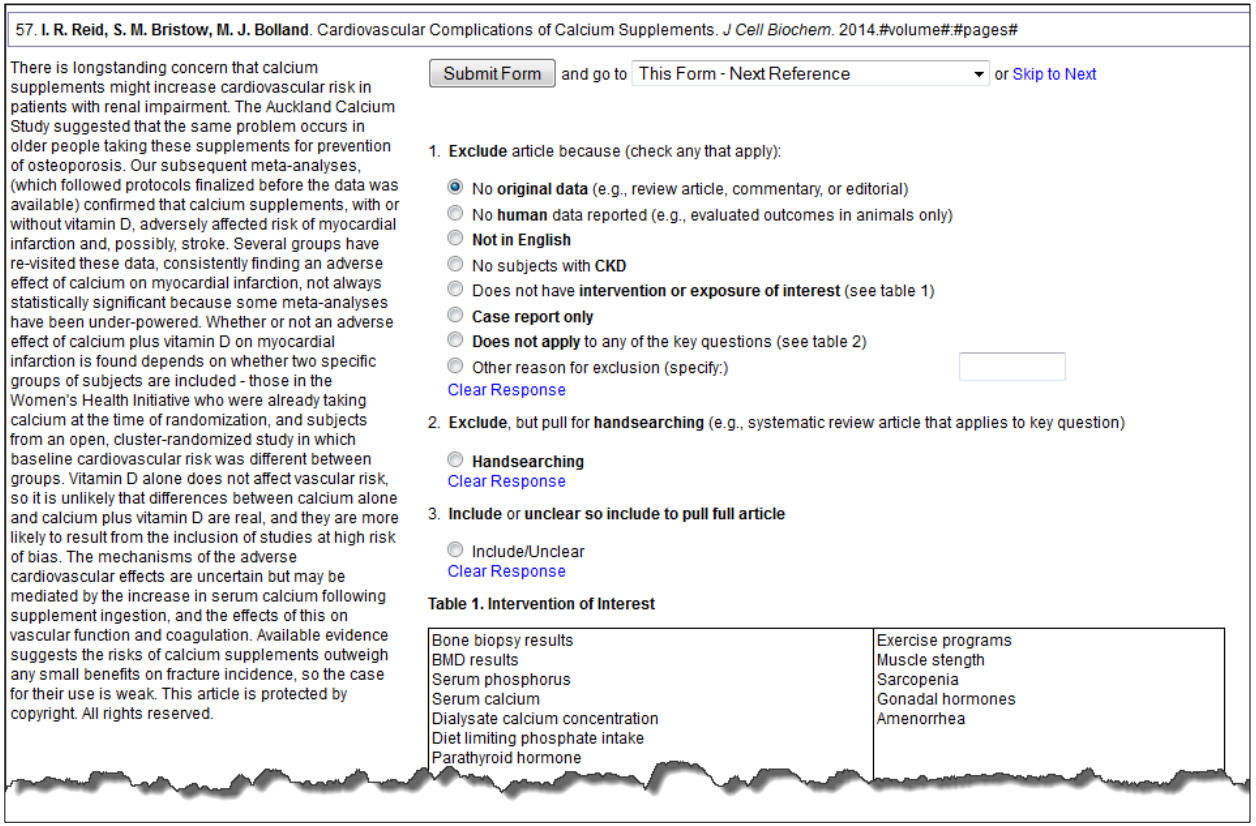
P	Patient, population
I	Intervention (Exposure)
C	Comparison
O	Outcome
T	Timing
S	Setting
D	Study design

Identification of Evidence

- Identify all possibly relevant studies
- Develop search protocol:
  - Sources: databases and hand searching
  - How searched
  - Dates
  - Strategies
  - Tracking
  - Documentation

Selection of Evidence

- Apply specific pre-defined inclusion/exclusion criteria
- Screen at two levels:
  - abstracts and titles
  - full-text
- Tracking



57. **I. R. Reid, S. M. Bristow, M. J. Bolland**. Cardiovascular Complications of Calcium Supplements. *J Cell Biochem*. 2014.#volume#.#pages#

There is longstanding concern that calcium supplements might increase cardiovascular risk in patients with renal impairment. The Auckland Calcium Study suggested that the same problem occurs in older people taking these supplements for prevention of osteoporosis. Our subsequent meta-analyses, (which followed protocols finalized before the data was available) confirmed that calcium supplements, with or without vitamin D, adversely affected risk of myocardial infarction and, possibly, stroke. Several groups have re-visited these data, consistently finding an adverse effect of calcium on myocardial infarction, not always statistically significant because some meta-analyses have been under-powered. Whether or not an adverse effect of calcium plus vitamin D on myocardial infarction is found depends on whether two specific groups of subjects are included - those in the Women's Health Initiative who were already taking calcium at the time of randomization, and subjects from an open, cluster-randomized study in which baseline cardiovascular risk was different between groups. Vitamin D alone does not affect vascular risk, so it is unlikely that differences between calcium alone and calcium plus vitamin D are real, and they are more likely to result from the inclusion of studies at high risk of bias. The mechanisms of the adverse cardiovascular effects are uncertain but may be mediated by the increase in serum calcium following supplement ingestion, and the effects of this on vascular function and coagulation. Available evidence suggests the risks of calcium supplements outweigh any small benefits on fracture incidence, so the case for their use is weak. This article is protected by copyright. All rights reserved.

Submit Form and go to This Form - Next Reference or Skip to Next

1. **Exclude** article because (check any that apply):
   - (●) No **original data** (e.g., review article, commentary, or editorial)
   - ( ) No **human** data reported (e.g., evaluated outcomes in animals only)
   - ( ) **Not in English**
   - ( ) No subjects with **CKD**
   - ( ) Does not have **intervention or exposure of interest** (see table 1)
   - ( ) **Case report only**
   - ( ) **Does not apply** to any of the key questions (see table 2)
   - ( ) Other reason for exclusion (specify:)

   Clear Response

2. **Exclude**, but pull for **handsearching** (e.g., systematic review article that applies to key question)
   - ( ) **Handsearching**

   Clear Response

3. **Include** or **unclear so include to pull full article**
   - ( ) Include/Unclear

   Clear Response

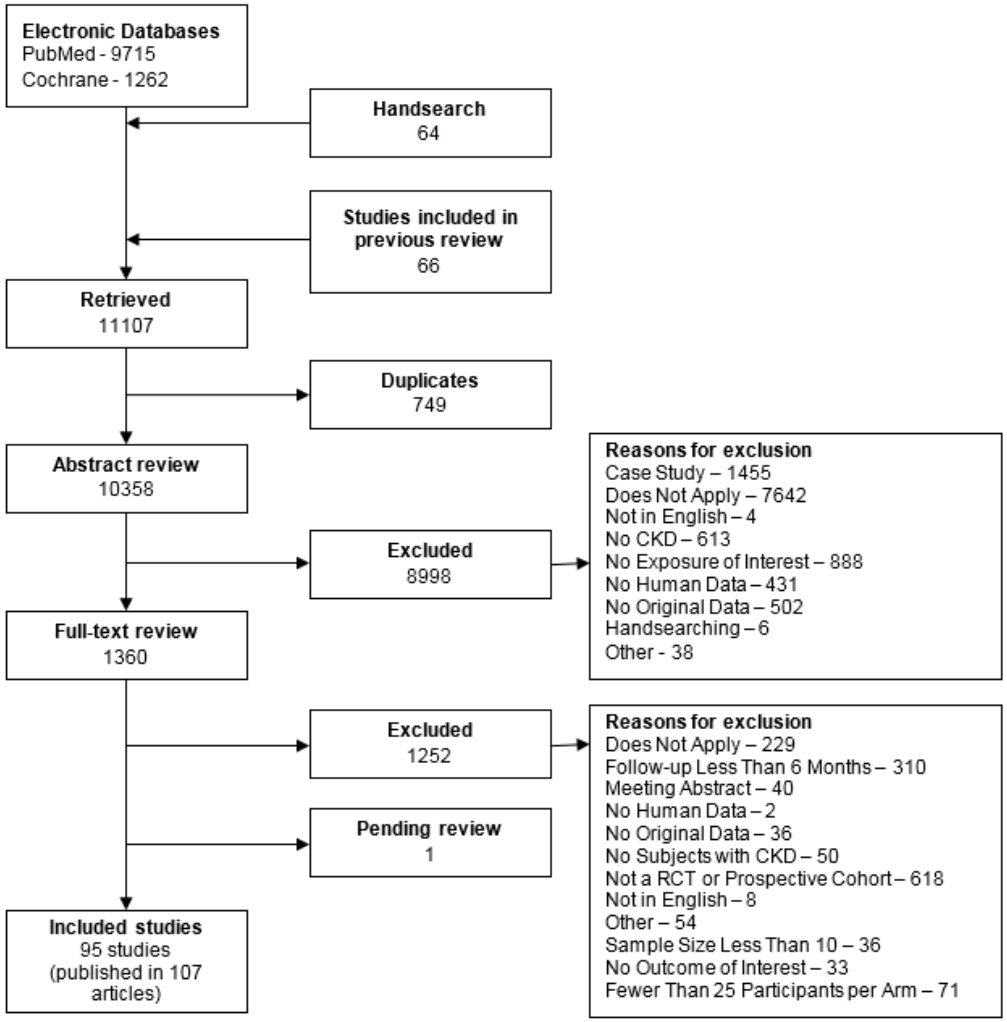
Table 1. Intervention of Interest

Bone biopsy results	Exercise programs
BMD results	Muscle stength
Serum phosphorus	Sarcopenia
Serum calcium	Gonadal hormones
Dialysate calcium concentration	Amenorrhea
Diet limiting phosphate intake	
Parathyroid hormone	

- **Two independent screeners**
- **All data entered into database**
- **Disagreements resolved by consensus or by third reviewer**

JHU_000003822

Summary of Search and Review Process



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Listing of Excluded Articles

ID:1772
Cystic fibrosis and diabetes link. Podiatry Now 2008; 11 (10):20.
Unable to Retrieve

ID:1086
RCN Paediatric and Adolescent Diabetes Group 2002 Conference. Pract. Diabetes Int. 2003; 20 (2):77.
No original data (review, commentary, etc.)

ID:1893
Abbott, J., Conway, S. P., Etherington, C., Titzjohn, J., Gee, L., Morton, A., and et. al. Cystic Fibrosis related diabetes, eating behaviors and body satisfaction. Pediatric Pulmonology 98; Suppl 17:395.
Meeting abstract only

ID:80
Adler, A. I., Gunn, E., Haworth, C. S., and Bilton, D. Characteristics of adults with and without cystic fibrosis-related diabetes. Diabetic Medicine 2007; 24 (10):1143-8.
Pathophysiology and epidemiology

ID:611
Alagappan, V., Thiruvengadam, K. V., Deivanayagam, C. N., Mohan, V., Ramachandran, A., Viswanathan, M., Sreeram, D., and Doraiswamy, K. R. Secondary diabetes due to cystic fibrosis with multisystem involvement. Journal of the Association of Physicians of India 85; 33 (7):492-4.
Does not address any review questions

ID:600
Allen, J. L. Progressive nephropathy in a patient with cystic fibrosis and diabetes. New England Journal of Medicine 86; 315 (12):764.
No original data (review, commentary, etc.)

ID:16
Amadori, A., Antonelli, A., Balteri, I., Schreiber, A., Bugiani, M., and De Rose, V. Recurrent exacerbations affect FEV(1) decline in adult patients with cystic fibrosis. Respiratory Medicine 2009 ; 103 (3):407-13.
Unable to abstract data specifically for patients with CFRD / CF with IFG / CF with IGT

ID:673
Amendt, P. [Diabetes mellitus and mucoviscidosis]. Kinderarztliche Praxis 73; 41 (12):517-22.
Not in English

ID:236
Arrigo, T., De Luca, F., Lucanto, C., Lombardo, M., Rulli, I., Salzano, G., and Lombardo, F. Nutritional, glycometabolic and genetic factors affecting menarcheal age in cystic fibrosis. Diabetes Nutr Metab 2004; 17 (2):114-9.
Effect of CFRD on menarcheal age

ID:330
Augarten, A., Akons, H., Aviram, M., Bentur, L., Blau, H., Picard, E., Rivlin, J., Miller, M. S., Katznelson, D., Szeinberg, A., Shmilovich, H., Paret, G., Laufer, J., and Yahav, Y. Prediction of mortality and timing of referral for lung transplantation in cystic fibrosis patients. Pediatric Transplantation 2001; 5 (5):339-42.
Addresses CF but not AGM AND article does not address diagnosis / screening of CFRD

ID:375
Augarten, A., Dubenbaum, L., Yahav, Y., Katznelson, D., Szeinberg, A., Blank, A., and Sack, J. Lundh meal: a single non-invasive challenge test for evaluation of exocrine and endocrine pancreatic function in cystic fibrosis patients. International Journal of Clinical and Laboratory Research 99; 29 (3):114-6.
Does not address any review questions

ID:668
Banicevic, M., Joksimovic, I., Vulovic, D., Filipovic, D., and Sicevic, S. [Diabetes mellitus and cystic fibrosis]. Srpski Arhiv Za Celokupno Lekarstvo 75; 103 (7-8):681-6.
Not in English

ID:286
Banjar, H. The first case report in Saudi Arabia of diabetes mellitus and cystic fibrosis in two siblings. Annals of Tropical Paediatrics 2002; 22 (4):383-4.
No original data (review, commentary, etc.)

ID:228
Banjar, H. H. Cystic fibrosis: presentation with other diseases, the experience in Saudi Arabia. Journal of Cystic Fibrosis 2003; 2 (3):155-9.
Does not address any review questions

WPATH SOC8

- **Articles excluded at full-text level listed with reason(s) excluded**
- **Included in report**

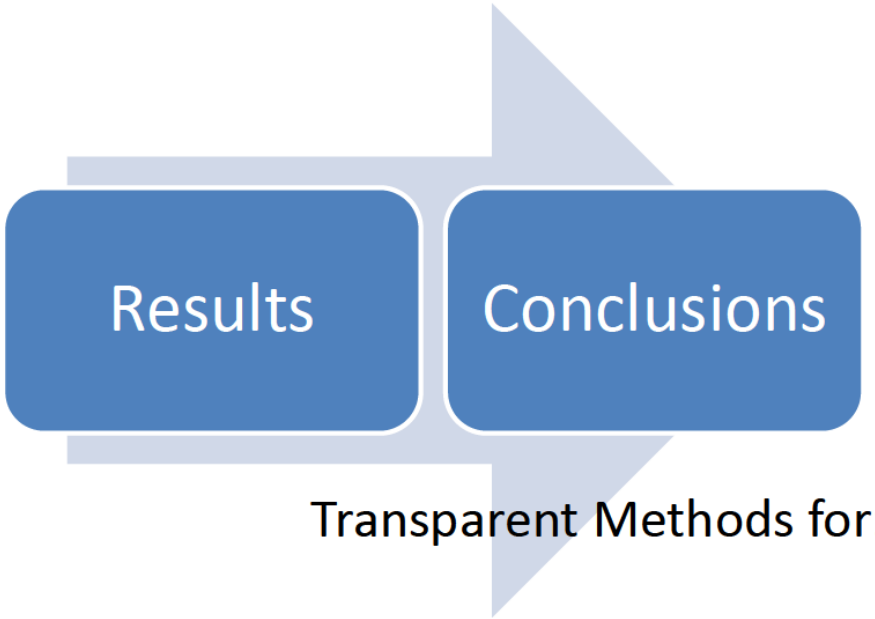
JHU_000003824

Evaluation of Evidence

- Assess risk of bias of individual studies:
  - Select tool based on study design
- Abstraction of relevant data
  - Including elements of PICO

Synthesis of Evidence

- Qualitative
- Quantitative



Transparent Methods for:

- Interpretation of results: Evaluate body of evidence addressing each question and outcome. We have stated in protocols we will use GRADE approach.

- Presentation of interpretation: Present results and interpretation to users. Suggest use Summary Tables.

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Evaluating Body of Evidence

Key element is to consider separately:

- Magnitude of Effect
- Certainty in the Evidence

Figure 1. Belief and confidence: a two-dimensional weather report. (Reprinted by permission from the Wall Street

Certainty in Evidence

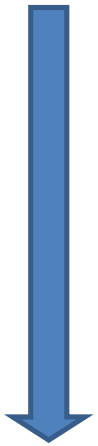
GRADE *Quality of the Evidence*

Four levels

A	High	We are very confident that the true effect lies close to that of the estimate of the effect
B	Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
C	Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
D	Very low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

GRADE System

HIGH	⨁⨁⨁⨁	A
MODERATE	⨁⨁⨁◯	B
LOW	⨁⨁◯◯	C
VERY LOW	⨁◯◯◯	D



Confidence

- Randomised controlled trials start as High
- Observational studies start as Low

FACTORS THAT CAN REDUCE THE QUALITY OF THE EVIDENCE

FACTOR	CONSEQUENCE
Limitations in study design or execution (risk of bias)	↓ 1 or 2 levels
Inconsistency of results	↓ 1 or 2 levels
Indirectness of evidence	↓ 1 or 2 levels
Imprecision	↓ 1 or 2 levels
Publication bias	↓ 1 or 2 levels

FACTORS THAT CAN INCREASE THE QUALITY OF THE EVIDENCE

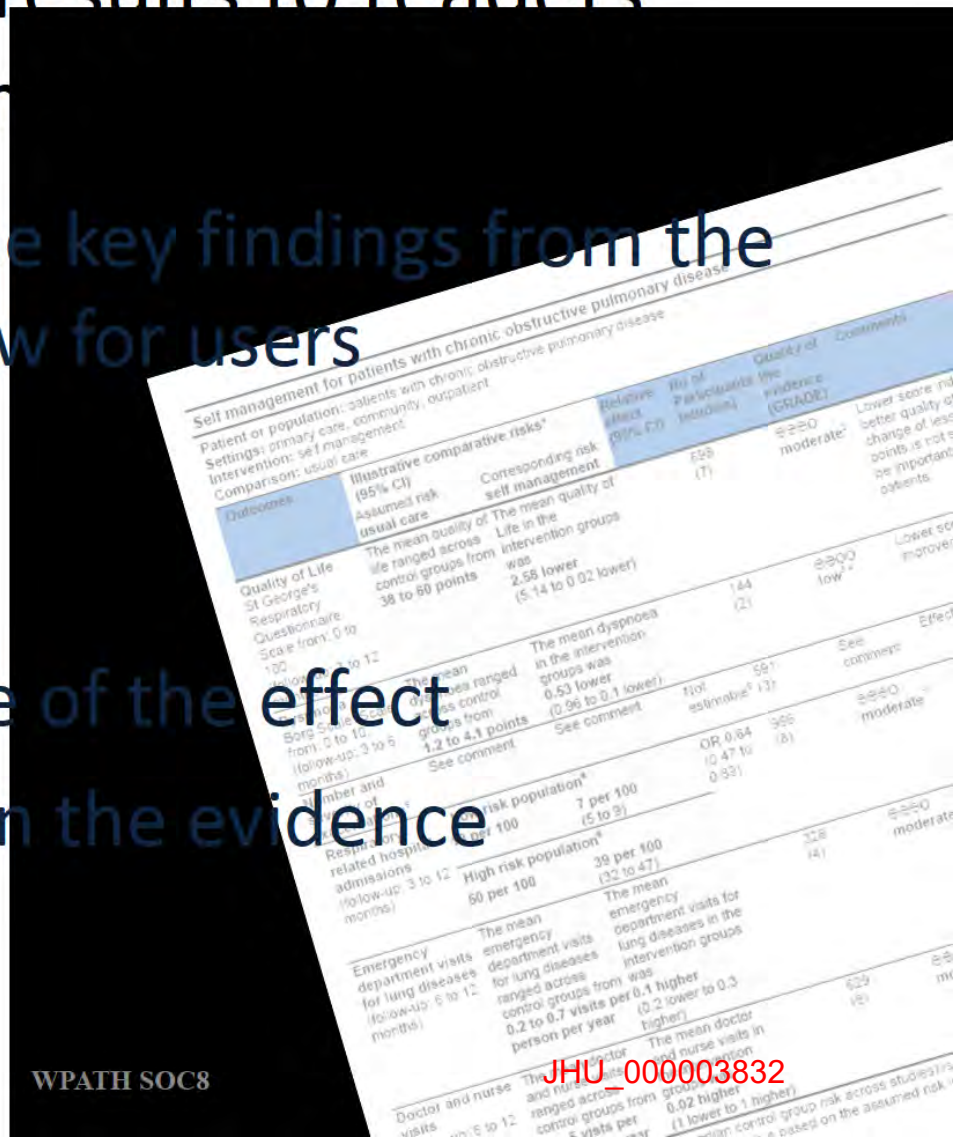
FACTOR	CONSEQUENCE
Large magnitude of effect	↑ 1 or 2 levels
All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed	
Dose-response gradient	

Only use for observational studies not already downgraded

Presenting results to readers: Summ

- a summary of the key findings from the systematic review for users

- Presents
  - –the magnitude of the effect
  - –the certainty in the evidence



Current Status of SRs

Chapter	Number of SR questions	Protocol	Searching electronic databases	Citations screen at the title-abstract screening	Citations screen at the article screening	Data abstraction
Hormone Therapy	13	Completed	Completed (PubMed®, Embase®, and Pyscinfo)	N =1508 Completed	N =390 Ongoing	Not started yet
Voice	8	Completed	Completed (PubMed®, CINAHL, Embase®, and Pyscinfo)	N =631 Ongoing	Not started yet	Not started yet
Surgery	11	Drafted				

REDACTED

REDACTED

Recommendations

WPATH SOC8: Notes regarding initial identification of recommendation statements

Clinical Practice Guidelines: Systematically developed statements that include recommendations, strategies, or information that assist physicians and/or other health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.

"Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options." IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.

Evidence-based Recommendation Statements:

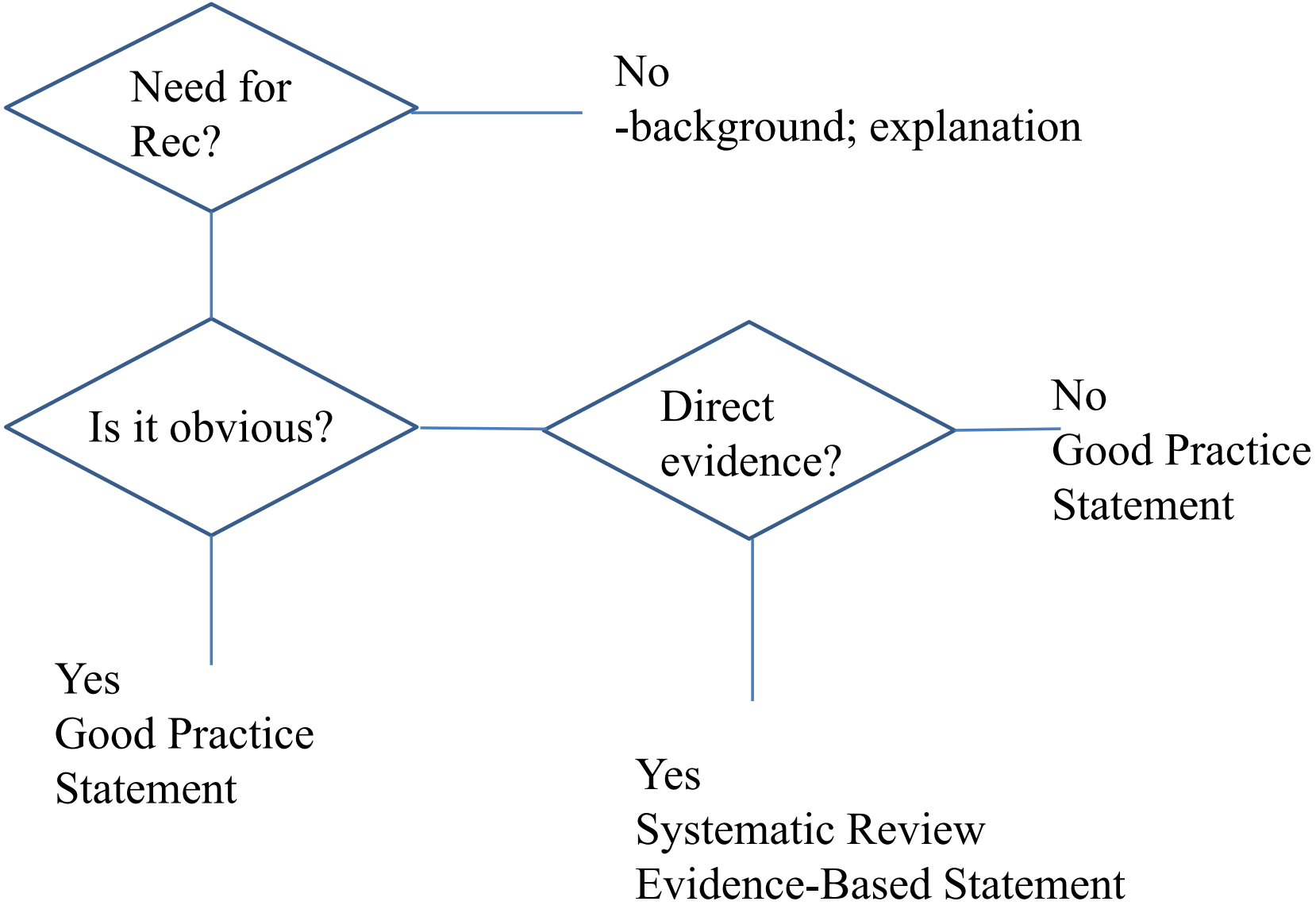
- Based on systematic review with clear link to evidence
- Will be graded

Good Practice or Consensus-based Statements:

- Common sense or reminders of obvious
- Not appropriate for a systematic review or formal assessment of evidence

Recommendation Statements

- Clear, explicit and actionable
- Define all elements needed to implement
- Clear link with evidence

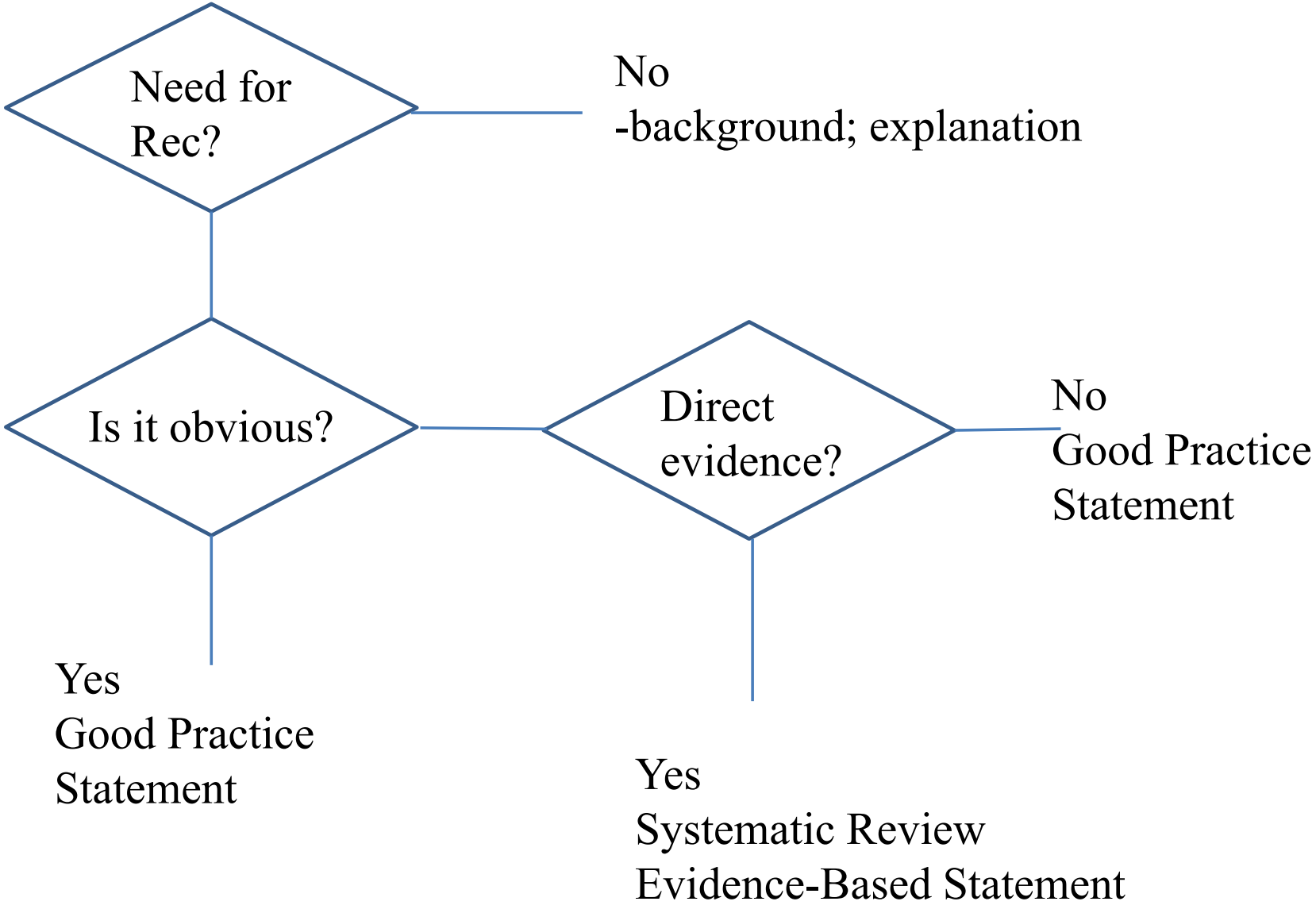


Examples of Good Practice Statements

- In patients presenting with heart failure, clinicians should make an initial assessment of the patient's ability to perform routine/desired activities of daily living.
- Health services should be made available, accessible, and acceptable to sex workers based on the principles of avoidance of stigma, nondiscrimination, and the right to health.
- For patients with congenital adrenal hyperplasia, we advise monitoring of patients for signs of glucocorticoid excess.

For patients with congenital adrenal hyperplasia, we advise monitoring of patients for signs of glucocorticoid excess.

- No *direct evidence* of effect of monitoring
- Confident that monitoring a good idea based on linked bodies of *indirect evidence*:
  - Symptoms appear not infrequently
  - Risk of suffering if fail to catch
  - Therapy can correct problem


Need for Rec?
No
-background; explanation
Is it obvious?
Direct evidence?
No
Good Practice Statement
Yes
Good Practice Statement
Yes
Systematic Review
Evidence-Based Statement

Chapter	Number of SR questions
Hormone Therapy	13
Voice	8
Surgery	11

Need SR Questions

[redacted]

≥ 12 months

JHU_000003842

Consensus Process

20 July 2018

We need the draft recommendation statements from each Chapter. Recall that recommendation statements should be explicit and actionable (please see notes on identifying recommendations).

<To be added to the WPATH Guideline Development Methods document>

The following is the consensus process for recommendation statements. This will be used for the best practice statements and for the evidence-based recommendation statements:

1. Chapter members draft and reach consensus within chapter on recommendations statements.
2. All recommendation statements are sent to the Guideline Steering Committee for review and revision.
3. An online Delphi will be set up to be used by all SOC8 members to vote on recommendation statements. Members will be able to opt out of voting on statements they feel are outside of their expertise or experience, and will also have opportunity to provide feedback on each statement. Consensus will be considered reached if recommendation statement is agreed to by 80% or more of votes. Those statements not reaching consensus will be sent back to all for another round of voting. These statements may be, as appropriate, revised based on feedback received. Three rounds will be held. Recommendation statements reaching consensus will be included in SOC8.

WPATH: Systematic Review Questions

31 March 2019

Adolescent Chapter (n=1)

Protocol completed January 2019; reviewed by chapter leads 29 Jan 19

KQ1. What is the effect of acceptance/rejection of family, school or community on the mental health and pyschosocial wellbeing of transgender and gender-diverse adolescents?

NOTE: During meetings at Buenos Aires, JHU offered to help identify relevant articles for medical decision making, an area that may be informed by indirect evidence. This is NOT a systematic review or a review. As of 31 Mar 19, awaiting further clarification about which types of studies are considered relevant (i.e., entry into clinical trials, brain development, cognitive development, etc.).

Assessment Chapter (n=4)

Plan to address questions in reviews being conducted for other chapters:

1. What is effect of assessment by a health professional prior to initiation of cross-sex hormones?
2. What is effect of assessment by a health professional prior to gender-affirming surgery?
3. What is effect of transition prior to initiation of gender-affirming hormone therapy or surgery?
4. What is effect of absences of transition or intent to transition prior to gender-affirming hormone therapy or surgery?

Hormone Chapter (n=13)

Protocol completed October 2018. Screened 1508 citations, 254 eligible studies. Data abstraction ongoing.

KQ1. For transgender women, what are the safety and efficacy of androgen lowering medications compared to Spironolactone vs cyproterone vs GnRH agonists in terms of surrogate outcomes, clinical outcomes, and harms?

KQ2. For transgender adolescent, what are the long term effect of GnRH agonists compared to no treatment, in terms of surrogate outcomes, clinical outcomes, and harms?

KQ3. For transfeminine people on gender-affirming hormone therapy with estrogen, what are the comparative risks of prolactinomas and hyperprolactinemia between spironolactone, cyproterone, and GnRH agonists, in terms of prolactin levels and presence of prolactinomas confirmed by imaging?

KQ4. For transgender people, what are the effect of progesterones (cyproterone) compared to Medroxyprogesterone and other progesterones in terms of breast growth (adults), delay of puberty (children), and side effects?

KQ5. For transgender women, what are the comparative risks of different regimens of gender-affirming hormone therapy with estrogens (conjugated estrogen, estradiol, ethinyl estradiol) in terms of pulmonary embolism, deep-vein thrombosis, stroke, and myocardial infarction?

KQ6. For transgender men, what is the risk of polycythemia among transgender men on gender-affirming therapy with testosterone, as measured by hematocrit and hemoglobin levels?

KQ7. For transgender men, what is the effect of testosterone therapy on uterine, ovarian, cervical, vaginal, and breast pathology in transgender men who have not had a hysterectomy or oophorectomy?

KQ8. For transgender women what is the effect of estrogen therapy on breast, testicular, prostate and penile tissue in transgender women who have not had a gonedectomy?

KQ9. For transgender women, what is the safety of different routes of administration for estrogen (oral, cutaneous, intramuscular) in terms of myocardial infarction, stroke, deep-vein thrombosis, and pulmonary embolism?

KQ10. For transgender adolescent, what are the effects of suppressing puberty with GnRH agonists on quality of life?

KQ11. For transgender people, what are the psychological effects (including quality of life) associated with hormone therapy

KQ12. For transgender people, what are the effects of hormone therapy on metabolic syndrome?

KQ13. For transgender people, what are the effects of hormone therapy on fertility?

Primary Care

Questions received from chapter lead mid-December 2018; Received priority ordered list of 14 questions from SOC8 Chairs 29 January. Decision has not been made as to which questions to address in systematic reviews.

1. In trans feminine populations on estrogen therapy, does the specific route (intramuscular, transdermal, oral, sublingual) of exogenous estrogen increase or decrease risk for breast cancer?
2. In trans feminine people on estrogen who otherwise meet age requirements for breast cancer screening per local guidelines, does screening mammogram after 3 years on estrogen, as opposed to screening mammogram after 5 years on estrogen, improve overall detection of malignancy and long term mortality?
3. Among transgender populations with pre-existing modifiable cardiac risk factors (obesity, hypertension, type 2 diabetes, hyperlipidemia, smoking), does gender affirming hormone therapy significantly affect these conditions, independent of other interventions?
4. In trans feminine populations on estrogen therapy, does serum estrogen level impact risk for development of breast cancer? (or, reworded as specifically PICO: Do trans feminine populations with higher serum estrogen levels (>200) have greater risk for breast cancer compared with trans feminine populations with lower serum estrogen levels (<200)?

5. Do trans masculine persons on testosterone therapy, when compared to cisgender women of average risk, have an increased risk of ovarian cancer?
6. In trans masculine persons, does testosterone therapy increase risk for endometrial cancer, when compared with cisgender women of average risk?
7. In transgender populations presenting for primary care, does providing a supportive clinic physical environment (waiting room signs, bathroom policy, ability to use chosen name and pronoun) improve patient satisfaction and retention in care?
8. Among transgender populations with modifiable cardiovascular risk factors (obesity, hypertension, type 2 diabetes, hyperlipidemia, smoking) receiving hormone therapy, does receiving hormone therapy from a primary care provider, as opposed to a specialty provider, result in improved control of cardiovascular risk factors?
9. Among transgender populations receiving gender affirming care (hormone therapy, breast procedures or mental health interventions), do outcomes differ between comprehensive gender centers and decentralized clinics/providers?
10. In transgender populations presenting to general primary care settings, does a trauma-informed approach to sexual health improve access to preventive and screening services?
11. In transgender populations seeking hormone therapy, does integrating prescribing of hormones into primary care, as opposed to receiving the hormones from a specialty provider, improve patient satisfaction and retention in care?
12. For transgender populations seeking general primary care services, does routine screening for sex work (versus not routinely asking about history of sex work) increase access to HIV prevention services and HIV testing?
13. In trans masculine persons, does self-collected HPV swab testing detect cervical cancer at similar rate in comparison with trans masculine people who have had cervical cytology testing?
14. In transgender populations seeking gender affirming surgery, does requiring a second supporting mental health referral improve rates of surgical regret, satisfaction with outcome, or postoperative complications?

Reproductive Chapter (n=3)

Plan to address in reviews for hormone chapter:

1. What are the effects of gender-affirming hormone therapy in terms of psychosocial and clinical outcomes on the future offspring of transgender or gender non-conforming individuals?
2. What is the impact of hormone (GnRH analogues, testosterone, estrogen) treatments on fertility?
3. What is the impact of hormone (GnRH analogues, testosterone, estrogen) treatments on breast/chest?

Surgery Chapter (n=6 questions + 13 subquestions)

Protocol completed; protocol and questions revised 30 Jan 2019. Screening 1185 citations.

Breast/Chest Surgery:

KQ1: What are the benefits and risks of chest reconstruction surgery ("top surgery") for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

> KQ1a: What are the benefits and risks of top surgery in terms of factors aside from gender dysphoria (e.g., BRCA-1 mutation, family history of breast cancer, identification of pre-cancerous breast pathology) for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1b: How does hormone therapy status affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth?
>
> KQ1c: How does age affect the benefits and risks of top surgery for transmasculine individuals and gender-nonconforming individuals assigned female at birth, particularly for those under age 18?

KQ2: What are the benefits and risks of breast augmentation surgery ("top surgery") for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

> KQ2a: What are the benefits and risks of top surgery for transfeminine individuals and gender-nonconforming individuals assigned male at birth in terms of factors aside from gender dysphoria (e.g., BRCA-1 mutation, family history of breast cancer)?
>
> KQ2b: How does hormone therapy status affect the benefits and risks of top surgery for transfeminine individuals and gender-nonconforming individuals assigned male at birth?
>
> KQ2c: How does age affect the benefits and risks of top surgery, particularly for those under age 18 for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

Genital Surgery:

KQ3: What are the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

> KQ3a: How does hormone therapy status affect the benefits and risks of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?
>
> KQ3b: How does a prerequisite of 12 months of living in a gender role that is congruent with the gender identity of the patient (the "real life test"; social transition) affect the benefits and risks

of genital surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ3c: How does age affect the benefits and risks of top surgery, particularly for those under age 18 for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ4: What are the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4a: How does hormone therapy status affect the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4b: How does a prerequisite of 12 months of living in a gender role that is congruent with the gender identity of the patient (the "real life test"; social transition) affect the benefits and risks of genital surgeries for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

KQ4c: How does age affect the benefits and risks of top surgery, particularly for those under age 18 for transmasculine individuals and gender-nonconforming individuals assigned female at birth?

Other Surgeries/Procedures:

KQ5: What are the benefits and risks of facial gender confirmation surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

KQ5a: How does hormone therapy status affect the benefits and risks of facial gender confirmation surgeries for transfeminine individuals and gender-nonconforming individuals assigned male at birth?

General Questions

KQ6: What is the effect of mental health assessment prior to surgery?

Voice Chapter (n=8 + 6 subquestions)

Protocol completed October 2018. Screened 604 citations; 54 eligible studies.
JHU was informed by SOC8 Chairs on 29 Jan 19 to limit review to first two questions. Protocol and work process revised based on this decision. On February 14th SOC8 chair reopened prioritization with the Chapter Lead who would like to keep questions 5, 6, and 8.

Behavioral Interventions

KQ1: For transfeminine individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ2**:** For transmasculine individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ3: For non-binary individuals, what are the effects of speech therapy, voice therapy, or communication therapy compared to no intervention, the intervention in conjunction with hormone therapy or with surgery, or another intervention in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ4: For any (but particularly transmasculine and non-binary) individuals, what are the effects of (sustained) chest binding compared to no binding in terms of valving efficiency and projection?

Surgical Interventions

KQ5: For transfeminine individuals, what are the effects of surgical interventions for voice feminization (see list in Table A) compared to no surgical intervention, surgery in conjunction with voice therapy or with hormone therapy, or other surgical interventions for voice feminization in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?
KQ6: For transmasculine individuals, what are the effects of surgical interventions for voice masculinization (see list in Table A) compared to no surgical intervention, surgery in conjunction with voice therapy or with hormone therapy, or other surgical interventions for voice masculinization in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

Endocrine Interventions (Hormone Therapy)

KQ7: For transfeminine individuals, what are the effects of feminizing hormone therapies (e.g., estrogen, progesterone) compared to no hormone therapy or hormone therapy in conjunction with

voice therapy or with surgery in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ7A: Do these effects differ for pre-pubertal children being treated with hormone blockers?
KQ7B: Do these effects differ for people who were treated with hormone blockers before being treated with estrogen?
KQ7C**:** Do these effects differ for adults being treated with estrogen?

KQ8: For transmasculine individuals, what are the effects of masculinizing hormone therapies (e.g., testosterone) compared to no hormone therapy or hormone therapy in conjunction with voice therapy or with surgery in terms of acoustic outcomes, perceptual outcomes, satisfaction, and harms?

KQ8A: Do these effects differ for pre-pubertal children being treated with hormone blockers?
KQ8B: Do these effects differ for people who were treated with hormone blockers before being treated with testosterone?
KQ8C: Do these effects differ for adults being treated with testosterone?