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ORIGINAL ARTICLE

Review and Analysis of International Transgender Adult Primary Care Guidelines

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Abstract

Purpose: To examine and critique current international clinical practice guidelines (CPGs) related to providing primary care to transgender adults and to assess their applicability to practice.

Methods: A review was conducted to obtain English language clinical guidelines. Guidelines included in this review were obtained from published journals and gray literature. Guidelines were critiqued using the AGREE II instrument.

Results: Seventeen documents were included in the final review. Eleven were specifically designed for primary care practitioners, whereas the remaining six were deemed applicable to primary care. Overall, across the CPGs, the scope, purpose, and clarity of presentation were done well. However, the overall methodological rigor in guideline development was poor. Many CPGs included useful tools that could be helpful for the primary care practitioner.

Conclusions: CPGs can be an important support for primary care providers' clinical practice with transgender people, particularly after having received limited formal education in transgender care. Improvements in transgender health CPG rigor and transparency are needed. Future CPGs would benefit from recommendations on the nuanced discussion of gender concepts and interpersonal communication that can create conflict in health care interactions.

Keywords: transgender persons; primary health care; standard of care; delivery of primary health care

Introduction

Identified transgender persons, those experiencing some degree of gender incongruence between their identified gender and their sex assigned at birth, represent at least 0.5% of the global adult population, translating to ~25 million people.[1] Despite this significant volume, high-quality research in transgender care is lacking[2,3] and gender identity data are not included in relevant randomized control trials[4] or population surveys.[5] There has been increasing recognition that the needs of transgender persons are markedly underserved, with wide variability in access to informed and clinically competent practitioners.[6]

Movement of transgender care provision from speciality endocrinology to the primary care setting has also increasingly occured.[7] This change to primary care allows for improved care access and more comprehensive and holistic care across the lifespan.[8]

Competent transgender care is particularly important given the high rates of depression, anxiety, and suicidality in the transgender population.[9] Transgender people in large studies consistently report experiences of microaggressions related to providers' implicit and unconscious biases and lack of knowledge in transgender care. These negatively affect patients' trust and likelihood of return to care.[10–14]

Unfortunately, little content in health care education is devoted to care for marginalized groups including transgender people.[15–18]There is evidence that primary care providers feel underprepared to competently provide for the medical, surgical, and psychosocial needs of the transgender person.[19,20] This can be due to factors such as little to no exposure and training through formal medical and nursing education,[16,17,21,22] lack of awareness of resources and services,[19,23,24] and a lack of understanding of the relevance of identity to patient

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health.[25–27] Given their limited educational exposure, primary care practitioners must rely extensively on available clinical practice guidelines (CPGs) to inform and direct gender-affirming care.

What are CPGs?

Most primary care practices are generalized, in that persons from across the lifespan present with an extensive variety of acute and chronic health care needs requiring a diverse knowledge base on the part of primary care practitioners. CPGs form the foundation of evidence-based primary care practice as, when done well, they provide a comprehensive review of all relevant content in a subject matter area.[28] For effective use in primary care, CPGs must provide clear and accurate recommendations, based on high-quality evidence, presented in an easily accessible format.[29]

The application of CPGs is part of a larger care approach known as evidence-based or evidence-informed care. The term evidence-based care is the inclusion of research in the decision-making process for care.[30] Ideally, the evidence-informed practitioner, collaboratively with the patient, applies guidelines recommendation and primary research to the individual patient context.[31]

Gender-affirming CPGs

Qualitative research about practitioner practice and evidence-informed care describes changes in practitioners' perspectives on gender with experience in transgender health, influencing CPGs use in practice. Buckner[32] interviewed 15 practitioners with varying levels of experience. Those with less experience expressed more rigid views of gender as an inborn trait and bodily function. Those with more experience with trans people understood gender as either a freedom of expression or choice, or as fluid and something all people negotiate.[32]

Poteat et al.[25] interviewed 55 transgender people and 12 health practitioners about stigma, discrimination, and health care experiences to construct a theory of stigma model. Stigma results in poorer health outcomes[33,34] and is complicated by intersectional factors such as race, age, gender presentation, and income.[11,12] In the model, the practitioner uses stigmatizing behavior to re-exert the traditional practitioner/client power dynamic lost through the practitioner's uncertainty and lack of knowledge about transgender care compared with the transgender client.[25] Perpetual asserting of interpersonal and structural power in the clinical space, such as refusing to accept pronouns or names, using only binary language, asking unnecessary or invasive questions, or by promoting an idea of a "complete transition," is stigmatizing and shifts the onus of maintaining a positive relationship to the patients to get the care they need.[35] Interviewing 23 clinicians, Shuster[36] found that citing a higher authority like a CPG alleviates both uncertainty and lack of knowledge.

Although there remains a significant incongruence between care need and access for transgender patients, there is an increasing body of CPGs available internationally to support transgender care practice. Previous studies have critiqued primary care guidelines for lesbian, gay, and bisexual individuals,[37] and lesbian, gay, bisexual, and transgender individuals.[38] To date, there are no known critiques specific to transgender adult primary care CPGs. Therefore, the purpose of our study was to critically appraise the methodological rigor and clinical utility of adult transgender CPGs.

Methods

For our review, we employed the Institute of Medicine definition of CPGs as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"(p. 4).[29] CPGs are like, and commonly confused with, clinical protocols. Clinical protocols are typically developed from CPGs as specific adaptations to a local clinical practice setting.[39] For this review, clinical protocols were included as well to reflect a wide variety of practice policy documents available to practitioners in transgender primary care.

Search strategy

The databases and search strategy, including search terms, are given in Table 1. After the database search was completed, it was noted that key guidelines used in our own primary care practice were missing[40–43] from the published literature. Therefore, a search of reference lists of included documents and gray literature was conducted. The gray literature was searched using Google and included searching for web-based guidelines from primary care organizations, community agencies, medical societies, government agencies, and guideline databases from an international perspective. Google search terms included "guideline," "CPG," "standard of care," "protocol," and "tool kit." This search method located additional CPGs.

Table 1. Search Results

	Initial results	Satisfied inclusion criteria	Selected for full appraisal
Search source—electronic databases (Medline, CINAHL, PsychInfo, Cochrane, Science Direct, ProQuest, and Research Library)		122	6
Transgender Persons AND Practice Guidelines as Topic	155		
Transgender Persons AND Primary Health (Care)	255		
Practice Guidelines as Topic AND Health Services for Transgender Persons	72		
Transgender Persons AND Standards of Care	153		
Transgender AND Treatment Guideline	101		
Transgender Persons AND Endocrinology	14		
Transgender Person AND Family Practice	2		
Transgender Person AND Clinical Pathways	1		
Primary Care Organizations and Academic Institutions	8	6	6
Government Departments of Health and Community Agencies	5	4	2
Medical Societies and Associations	4	2	1
Guideline Databases	2	2	2
Total included in final appraisal			17

Inclusion and exclusion criteria

Primary inclusion criteria were guidelines published after 2010, written in English and addressed primary health care for transgender adults. Exclusion criteria included non-English documents, textbooks, and children and youth guidelines. Initial database search yielded 753 documents. Duplicates were removed and abstracts were reviewed for relevance. Abstracts that addressed providing primary care services, including counselling, hormone therapy, or assessment for surgery, were selected for full assessment. Six documents were found from this database search.

The gray literature search found an additional 19 documents; after reviewing for relevance, 11 documents met the inclusion criteria. In total, 17 documents were selected for full review (see Table 2 for the full review documents). Transgender clinical guidelines included in the full review originate from a variety of sources, from stand-alone community agencies[40,44–47] to larger regional,[41,42,48,49] national,[50–55] and international[56] professional associations as well as an electronic CPG database.[43]

Appraisal process

The selected CPGs were appraised using the AGREE II instrument.[57] The AGREE II instrument provides reviewers with a formal tool to assess the quality of CPGs. AGREE II defines quality "as the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice"(p. 2).[58] For this project, a group appraisal program was set up using the *My AGREE Plus* online application. A group appraisal program allowed each reviewer to individually score the guidelines and coordinate the results and overall scores.[59]

All authors independently appraised the 17 documents using the AGREE II instrument following the AGREE II overview tutorial and practice exercise. The AGREE II has six domains including scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. There is an additional score for overall assessment of the document related to its applicability and recommendation for use in practice. Twenty-three items within the six domains were rated using a 7-point scale: 1 = strongly disagree to 7 = strongly agree.[57] Scores were calculated by domain. Individual scores for the domain were added together and reported as a percentage of the maximum possible score for that domain.[59]

Overall agreement within two points on the individual AGREE II scores was achieved. Mean scores for each domain were calculated using the online group appraisal process on *My AGREE Plus* and recorded out of 100. Scores correspond to the strengths and limitations and identify the quality of the CPG. Scores can be used to compare the methodological quality between guidelines. The AGREE II tool does not provide a specific score that identifies a high-quality guideline, instead suggesting that the appraisal team determine the value.[57] Our team decided that high-quality CPGs are those with scores >80% (see Table 3 for the AGREE II scores for all documents).

Results

The first domain, *Scope and Purpose*, scored highest overall. This domain focuses on the objective and target population of the CPG. All documents clearly articulated that the purpose was related to medical, primary care, or hormonal therapy for adult transgender individuals. Although all the documents are applicable to primary care, only 11[40–47,53–55] were specifically aimed at primary care practice.

The *Stakeholder Involvement* domain addresses who is involved in the development of the CPG, including directly consulting the target population and users

Table 2. Full Appraisal Documents

	Title	Author/organization and year	Country	Source
1	*Endocrine Therapy for Transgender Adults in British Columbia: Suggested Guidelines*	Dahl et al. (2015)[48]	Canada	Online document
2	*Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*	Hembree et al. (2017)[50]	United States	Published article
3	*Gender-Affirming Care for Trans, Two-Spirit, and Gender Diverse Patients in BC: A Primary Care Toolkit*	TransCare (2019)[42]	Canada	Online document
4	*Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria*	Wylie et al. (2014)[51]	United Kingdom	Published article
5	*Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*	Oliphant et al. (2018)[52]	New Zealand	Published article
6	*Guidelines for Gender-Affirming Primary Care with Trans and Non-Binary Patients*	Bourns (2019)[40]	Canada	Online document
7	*Guidelines for the Care of Trans* Patients in Primary Care*	Royal College of General Practitioner (2015)[53]	Ireland	Online document
8	*Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*	Center of Excellence for Transgender Health (2016)[41]	United States	Online document
9	*Position Statement on the Hormonal Management of Adult Transgender and Gender Diverse Individuals*	Cheung et al. (2019)[54]	Australia	Published article
10	*Primary Care of Transgender Individuals*	Feldman and Deutsch (2019)[43]	United States	Guideline database
11	*Protocols for Hormonal Reassignment of Gender*	Tom Waddel Health Center (2013)[44]	United States	Online document
12	*Protocols for the Provision of Hormone Therapy*	Callen-Lorde Community Health Center (2014)[45]	United States	Online document
13	*Standards of Care for the Health of Transsexuals, Transgender and Gender Nonconforming People, Version 7*	Coleman et al. (2011)[56]	International	Published article
14	*Taking Charge: A Handbook for Health Care and Social Service Providers Working with Trans People*	Santé Trans Health (2011)[49]	Canada	Online document
15	*The Medical Care of Transgender Persons*	Fenway Health (2015)[46]	United States	Online document
16	*Transgender Health in Primary Care*	Towards Optimized Practice (2019)[47]	Canada	Guideline database
17	*Transgender Patients Providing Sensitive Care*	Hyderi et al. (2016)[55]	United States	Published article

during development. Scores for this domain varied with only 3 documents scoring >80.[42,44,51] Target users were clearly identified in most documents.[40,41,43,44,46,47,49,52,53,55,56,60] Input from transgender individuals was sought in the development of eight documents.[40,42,44,45,49,51,52,54] Statements such as "we developed our protocols by compiling the collective knowledge of…patients, and members of the transgender community" (p. 3)[45] and "members came from diverse practice settings, rural and urban communities,

Table 3. AGREE II Scores

	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence	Overall
1	87	48	41	100	76	22	78
2	100	46	77	100	74	89	94
3	89	80	10	83	71	0	44
4	81	80	17	52	42	11	38
5	74	59	23	87	78	28	72
6	94	56	40	87	92	0	83
7	52	63	9	37	6	39	17
8	91	70	71	98	88	0	94
9	67	63	54	63	47	100	67
10	98	41	56	85	61	50	78
11	85	80	19	89	72	11	56
12	93	69	24	83	57	8	56
13	98	74	64	85	61	36	83
14	56	46	13	37	40	52	63
15	83	9	13	89	51	0	56
16	67	46	1	44	35	50	39
17	67	31	9	56	19	50	28

and were cis and trans identified people" (p. 4)[42] were made, but the specific role of the transgender community contributions to the CPG was not consistently clear.

The *Rigor of Development* domain focused on the systematic search and selection of evidence, recommendations made, and the procedure for external review and updates. Overall, this domain scored poorly, with no document scoring >80. Three documents[41,43,50] used a systematic approach to search for evidence and clearly described the strengths and limitations of the evidence.

Health benefits, risks, and side effects were considered in the recommendations from 10 documents,[40,41,43–46,48,50,54,56] however, only 5 documents[41,43,48,50,56] clearly linked the recommendations to evidence. Six documents were published in peer review journals,[50–52,54–56] demonstrating external review. However, only two of those documents[50,56] identified the peer review process as part of the formal external review for the document. Only one document[43] clearly articulated a procedure and timeline for updating. Feedback for further updates was encouraged in two documents.[40,44]

The Clarity of Presentation domain explores if the recommendations made are clear and easy to identify. Scores varied for this domain, with 11 documents[40–46,48,50,52,56] scoring >80. Documents that have clear and specific recommendations[40,41,43–45,48,50,52] allow primary care practitioners to easily integrate them into practice. Documents were presented in a variety of formats, including articles from electronic databases,[50–52,54–56] online documents,[40–42,44–49,53] and a subscription-based document.[43]

The *Applicability* domain scores ranged from 6 to 92. This domain explored the facilitators and barriers, recommendations for implementation, and monitoring criteria. Tools, resources, and information to apply recommendations to clinical practice were presented in five documents.[40–42,45,47] To further aid in implementing recommendations into practice, eight documents[40,41,43,44,46,48,50,52] provided specific monitoring criteria for hormone therapy that was considered very relevant to primary care practice. Only one document[40] discussed facilitators and barriers to implementation of recommendations.

Editorial Independence concerns competing interest and influence on CPG development. Scores for this domain varied, however, most scored very poorly (0–50) except for two.[50,54] Although funding for guideline development was acknowledged by some,[42,44,45,48,49,51,56] its influence on development was not clearly indicated.

Total overall scores for the documents ranged from 17 to 94. None of the included documents scored >80 in all domains. Four documents[40,41,50,56] scored as high quality overall, and these are recommended for use in primary care practice. Six documents[43–46,48,52] would be recommended for use if modifications are made to strengthen the quality. Seven documents[42,47,49,51,53–55] are not recommended based on the overall quality of the guidelines for use in primary care.

Discussion

Quality CPGs provide practitioners with a tool to deliver evidence-based gender-affirming care and increase their capacity to care for the transgender population. This is key to addressing the barriers transgender individuals experience accessing knowledgeable practitioners. The AGREE II tool provides an approach for objectively determining the rigor and quality of CPGs. To provide evidence-based gender-affirming care, it is important to ensure that the recommendations that are being put into practice are high quality. Although 17 documents were included in this review, only 4 documents[40,41,50,56] scored high enough on the AGREE II tool to be recommended for regular use in primary care.

In this review, two guidelines scored highest overall: *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*[50] from the Endocrine Society in the United States and *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* from the Center of Excellence for Transgender Health in the United States.[41]

These guidelines were methodologically strong, and recommendations were clear, practical, and easy to use. Both scored high in the *Scope and Purpose* and the *Clarity of Presentation* domain by clearly identifying the target population and treatment recommendations. The Endocrine Society CPG[50] scored high in *Editorial Independence,* clearly articulating conflicts of interest and identifying sources of funding. Overall, both CPGs scored low in the *Stakeholder Involvement* and *Rigor of Development* domain, which can be improved in future revisions.

The third highest score was the *Standards of Care for the Health of Transsexuals, Transgender, and Gender Nonconforming people, Version 7*[56] developed by the World Professional Association for Transgender Health (WPATH). The WPATH guideline[56] is the most cited transgender CPG. Twelve of the articles

reviewed in this project directly referenced the WPATH guideline as supporting and/or foundational to their recommendations. However, although it scored highly overall, the WPATH advocates for the paternalistic model (i.e., gatekeeping, readiness assessments, and a binary view of gender)[36] of transgender health provision that creates ethical problems regarding consent.[61]

Meeting the criteria for the pathological psychiatric label gender dysphoria in the *Diagnostic and Statistical Manual V*[62] is not congruent with fluid conceptualizations of gender[61,63] that are affirming of a range of gender nonconformity.[64] The criteria of dysphoria persistence is often not met by patients in clinical practice,[63,65] yet it remains a standard in many CPGs, most notably the WPATH guideline. We hope that the forthcoming WPATH 8th edition will integrate the informed consent model of transgender care to better support both patients and providers.[66,67]

Challenges with quantitative assessment of transgender health guidelines

The AGREE II tool favors quantitative data. For example, in evaluating applicability, the AGREE II tool user manual[58] suggests that monitoring or auditing criteria are clearly defined and "may include process measures, behavioural measures, clinical or health outcome measures" (p. 36) citing examples of only measurable biochemical markers, assessment data, or symptom duration. Such discrete outcome criteria are not necessarily always present or desirable in intersectional inclusive and holistic transgender care.[36]

Although accurate prescribing and surgical referral guidelines are important, transgender health care also includes social and relational interactions that are important factors in creating a supportive environment.[12] All guidelines assessed included some discussion of the social and relational aspects of transgender care; however, there was no ability in the tool to allow scoring for guidelines in this regard.

Similarly, the scoring of the AGREE II tool does not accommodate inclusion of broad conceptualizations of gender as essential to care provision. For example, the Santé-Health[49] and TransCareBC[42] guidelines were exceptional in this regard but scored poorly overall. The objective conceptualization of gender as a binary measure on surveys and in clinical data by the biomarker of sex limits the applicability of primary care, general medical, population level, and longitudinal research to transgender populations. Furthermore, this reduction of gender to a binary in research reinforces this conceptualization in every setting into which that research is translated: clinical education, policy, and practice.

Guideline development and structure

We identified several recommendations for guideline development and structure. Many documents reviewed did not describe a systematic evidence-based approach to the development of individual recommendations. We acknowledge that several reviewed documents are clinical protocols, meant for use in specific practice settings, this may explain the lack of inclusion of detailed methodological information[68]; however, methods remain essential information if subsequent practitioners are to consider cross-setting applicability. Second, it is imperative that authors of future guidelines explicitly outline all aspects of their process of development, including but not limited to all authors and their backgrounds, approach to literature review, methodology, recommendation formulation, suggested revision iterations, and conflicts of interest.

Previous research has identified transgender individuals as being experts in their care needs, often having to educate their care providers.[69] Therefore, we were particularly concerned that more than half of the guidelines appeared to be developed without direct formal input from the transgender community. We recommend that all future CPGs directly involve input from the transgender community at all phases of development. Last, guidelines that included clear tools, tables, or algorithms for quick reference were highlighted as useful for practice. If the goal of these guidelines is applicability to practice, prioritizing ease of use and rapid review is essential.

Limitations

This study only explored documents pertaining to transgender adults, as a critique of pediatric CPGs was beyond the scope of this project. Therefore, there remains a specific need to explore and critique pediatric and youth guidelines. An additional potential limitation is that there may be some rating differences using the AGREE II tool during this review. Although all members of the team used the AGREE II tool to critique the documents, weighting differences may have occurred based on individual perspectives due to varied clinical, academic, and personal backgrounds.

A systematic approach was used to search the literature; however, a traditional academic literature search was not sufficient to capture all the available documents. As discussed previously, we were personally

aware of multiple web-based documents[40–43] that were not found in the electronic database literature search but did meet the inclusion criteria. To resolve this limitation, a further search of reference lists and gray literature was conducted. Although using Google has some benefits such as finding literature not indexed in databases and the ability to find documents published by organizations or government agencies, there are some limitations to this search method. Google personalizes searches based on previous searches. This "echo chamber" can result in search results being based on your personal previous searches, therefore, individuals using the same search terms can potentially get varying results.[70]

Although this gray literature search added to the completeness of the document list, it would, therefore, be difficult to replicate. Furthermore, authors used varying terms to identify documents, such as guidelines, CPG, standard of care, protocol, and toolkit. The different terms acted as a limitation to this search as there is a possibility that there are existing documents that would have met our project criteria but did not turn up in our search as they named or classified the document outside of our search terms. Therefore, we acknowledge that there are likely documents available that we did not find.

Conclusions

Primary health care practitioners have limited formal or postgraduate exposure to educational resources on transgender health care. CPGs are an important resource for practitioners in providing nuanced, holistic psychosocial, medical, and/or surgical care in collaboration with their transgender patients. This study sought to evaluate 17 international CPGs on primary health care for transgender people using the AGREE II tool. We found a wide range of objective quality with all guidelines scoring strongly on scope, purpose, and clarity. However, improvements in transparency and rigor are needed for all documents.

There are limitations in both the quality of recommendations for the aspects of transgender health that fall outside of the biomedical model and their evaluation using the AGREE II tool. Improvements to future transgender primary health CPG development are needed to fully support provision of well-communicated, safe, nonjudgmental psychosocial, medical care, and surgical referral. Development committees that include transgender stakeholders would support these improvements. Supporting quality health care interactions are imperative for improving care for an underserved patient population who are at risk for both health care avoidance and poorer health outcomes.

Authors Disclosure Statement

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Abbreviations Used

CPG = clinical practice guideline
WPATH = World Professional Association for Transgender Health