REVIEW ARTICLE

EVALUATING GUIDELINES FOR TOBACCO CESSATION IN PREGNANCY: AN APPRAISAL USING THE AGREE II INSTRUMENT

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ABSTRACT

Background: Smoking is the most important preventable cause of adverse outcomes in pregnancy; however, most smokers who become pregnant continue to smoke and/or relapse following delivery. The identification of patients at risk can be challenging, and the treatment options available can be nebulous, including nonpharmacologic and pharmacologic options. The challenges of diagnosing and treating smoking in pregnancy prompt the use of clinical practice guides (CPGs). Several have been published to help identify at-risk patients and guide holistic management of tobacco use in pregnancy, however, to date, there has been no comprehensive review of guideline quality or methodologic rigor.

Methods: We conducted a comprehensive search of EMBASE, MEDLINE/PubMed, SCOPUS, and grey literature sources. The quality of these guidelines was assessed by 4 reviewers using the Appraisal of Guideline for Research and Evaluation, 2nd edition (AGREE II). Domain scores were considered of acceptable quality if they scored >60%, and Interclass correlation coefficients (ICC) were calculated to assess agreement among the appraisers.

Results: Seven guidelines were assessed for evaluation. Among these, only the World Health Organization (WHO) guidelines achieved an overall rating of "high." Three were "average" quality, and the remaining 3 were "low" quality. The "Scope and Purpose" domain achieved the highest mean score (88.7 ± 7.6), and the lowest was "Editorial Independence" (47.0 ± 27.6).

Conclusion: Areas of strength among the CPGs included "Scope and Purpose" and "Clarity and Presentation," as the guidelines were easily understood and described clear goals. The domains requiring improvement were "Editorial Independence," "Applicability," and "Rigor of Development," indicating that not all patients or providers may benefit from these CPGs. This analysis found one strong CPG pertaining to the management of tobacco use during pregnancy; however, several published guidelines lack methodologic rigor and have limited applicability.

INTRODUCTION

Tobacco use during pregnancy is a major public health concern and can have serious adverse effects on maternal and fetal health. In 2021 alone, approximately 4.6% of women who gave birth smoked cigarettes during pregnancy, with the highest rate among non-Hispanic American Indian or Alaska Native women (12.7%).[1] Smoking increases the risk of complications, including preterm birth, low birth weight, placental abruption, and sudden infant death syndrome.[2] Smoking can also affect the development of the fetus, causing impairments in cognitive, behavioral, and physical outcomes. Despite the well-known harms of smoking in pregnancy, many women continue to smoke or are exposed to second-hand smoking during this critical period. Pregnant smokers face several barriers including lack of support and access to effective interventions.[3] Nicotine dependance carries a high comorbidity with anxiety disorders, with heightened symptoms of anxiety reported in pregnant patients.[4,5]

The U.S. Preventative Services Task Force (USPSTF) recommends that physicians inquire about tobacco use during pregnancy,

advise cessation at any stage of pregnancy, and provide behavioral interventions and pharmacotherapy.[6] Pregnant patients and fetuses benefit from smoking cessation at any stage of pregnancy, with the greatest benefits seen when patients quit prior to 15 weeks' gestation. Nevertheless, patients struggling with nicotine addiction face increased difficulties when attempting to quit smoking.[7] While counselling techniques have been found to have positive effects on smoking cessation during pregnancy, pharmacologic methods are also important adjuncts to facilitate this process.[8]

The challenges inherent to diagnosing and treating smoking in pregnancy suggest the use of clinical practice guidelines (CPGs). CPGs are systematically developed recommendations that enable informed physician and patient decisions.[9] It is imperative that CPGs are clear, applicable, and free from bias[10]; the Appraisal of Guidelines for Research and Evaluation (AGREE II) collaboration has developed a system by which to evaluate the quality of CPGs. The AGREE II is currently the most commonly applied and comprehensively validated guideline appraisal tool worldwide.[11] The instrument consists of 23 items that evaluate several quality domains.

The AGREE tools have been utilized for various medical topics and guidelines, and multiple countries and regions worldwide have assessed their local, national, and regional CPGs with this tool.[12] To the authors' knowledge, there has been no comprehensive review of CPGs relating to the care of smoking during pregnancy. This paper aims to assess the current practice guidelines for diagnosis and clinical management of tobacco use in pregnancy.

METHODS

Identification of Guidelines

A literature search was conducted with EMBASE, MEDLINE/ PubMed, SCOPUS, and grey literature sources from inception through October 2022. The following terms were used for the search: "cessation"; "tobacco"; "pregnant"; "smoking"; "guideline"; and "recommendations." The search results were evaluated by 4 reviewers based on the Appraisal of Guidelines for Research and Evaluation, 2nd edition (AGREE II), as described below.

Selection of guidelines

Guidelines were selected based on whether they provided explicit recommendations for diagnosis and treatment of smoking in pregnancy. If multiple guidelines were offered by a single society, the most recent and updated version was evaluated. Supporting documents and appendices that were associated with each guideline were also evaluated by reviewers. Articles that were primary studies, clinical trials, textbook chapters, systematic reviews, letters, editorials, those without available full text, and those that were not published in the English language were excluded. The studied guidelines include those developed by the Australian Family Physicians (AFP), Oregon Health, National Institutes of Health (NIH), American College of Obstetricians and Gynecologists (ACOG), and USPSTF.

Quality appraisal

Four evaluators assessed each identified guideline using the AGREE II tool that is available through the AGREE website (www.agreetrust.org). Evaluators utilized the training material on the evaluation of guidelines that is offered for free on the AGREE website. Evaluation of guidelines using the AGREE II tool consists of assessing 6 domains that contain a total of 23 items. The 6 domains include: (1) scope and purpose, (2) stakeholder involvement, (3) rigor of development, (4) clarity of presentation, (5) applicability, and (6) editorial independence. Each domain was evaluated based on the items within each by assigning a score from 1 (strongly disagree) to 7 (strongly agree). Scores were then calculated and standardized as percentages of the maximum possible score for each domain using the following formula: (obtained score – minimum possible score)/(maximum possible score – minimal possible score). Standardized scores ranged from 0% to 100%. Standardized scores over 60% in a domain were deemed satisfactory. Over 60% on 5 or more domains in a CPG was rated as "high," while 3 or 4 domains over 60% were rated "average," and 2 or less domains over 60% were rated as "low." A mean score for each CPG was also calculated as an overall score.

Statistical Analysis

The interclass coefficients (ICC) analysis with 95% confidence intervals was used to assess agreement between the 4 evaluators. Agreement between evaluators was classified as very good (0.81-1.00), substantial (0.61-0.80), moderate (0.41-0.60), fair (0.21-0.40), or minor (0.01-0.20). Statistical analysis was performed using RStudio (Boston, MA).

RESULTS

Literature search yielded a total of 911 articles, 411 of which were from SCOPUS, 270 from PubMed, and 230 from EMBASE. There were 180 duplicates that were removed, leaving a total of 731 articles for screening. A total of 41 articles qualified for final review, with 5 of those deemed appropriate for appraisal. An additional 2 articles were identified using a Google search for a total of 7 CPGs selected for appraisal using the AGREE II tool (Table 1).

Guideline Characteristics

Analyzed CPGs were published between the years of 2011 and 2021. Information regarding the country of origin, targeted audience, method of development, and funding are noted in Table 1. There were 3 CPGs from the United States, one from Switzerland, one from Australia, and one from the United Kingdom. CPGs were developed through systemic literature review and expert panels. Those involved in the development of CPGs include obstetricians and gynecologists, family physicians, midwives, as well as various subcommittees. Funding was disclosed in 4 of the 7 CPGs.

TABLE 1: CPG CHARACTERISTICS

Developer	Pub. Year	Country	Development Method	Development Committees	Target Audience	No. of References	Funding Source
Society of Obstetricians and Gynaecologists of Canada (SOGC)	2011	Canada	• Systematic literature review • Expert panel	Obstetricians and gynecologists, family physicians	Healthcare providers	51	National Institute on Drug Abuse
World Health Organization (WHO)	2013	Switzerland	• Systematic literature review • Expert panel	• Gender • Reproductive rights • Sexual health and adolescents • Prevention of noncommunicable disease • Mental health and substance abuse • Gender, equity, and human rights • Epidemiology • Monitoring and evaluation • Research, evidence, and norms • Mental health and substance abuse • WP/TFI • Tobacco-free initiative	• Stakeholders • Policy makers	181	Not reported
Australian Family Physician (AFP)	2014	Australia	• Systematic literature review	Not reported	• Public and private health providers	46	None
Oregon Health Committees	2016	USA	• Systemic literature review • Expert panel	Not reported	• Pediatrics	2	None
National Institutes of Health (NIH)	2018	UK	• Systematic literature review	Midwife	• Those who are pregnant, plan to be, or are postpartum • Physicians	Not Reported	Not reported
American College of Obstetricians and Gynecologists (ACOG)	2020	USA	• Systematic literature review • Expert panel	OB/GYN and family physicians	• Clinicians • Those who are pregnant	Not Reported	Not reported
United States Preventive Services Task Force (USPSTF)	2021	USA	• Systemic literature review • Expert panel	Not reported	• Clinicians • Those who are pregnant	65	Agency for Healthcare Research and Quality (AHRQ) and Kaiser Permanente Evidence-based Practice Center (EPC)

TABLE 2: ICC FOR EACH DOMAIN

Society/ Institution	Domain 1 Scope and purpose %	Domain 2 Stakeholder involvement %	Domain 3 Rigor of development %	Domain 4 Clarity and presentation %	Domain 5 Applicability %	Domain 6 Editorial independence %	Domains ≥60/total domains	Overall quality
ACOG	86.1	36.1	37.5	80.5	40.0	27.1	2/6	Low
USPSTF	95.8	88.9	82.8	93.1	54.2	43.8	4/6	Average
AFP	93.1	63.9	22.9	73.6	43.8	50.0	2/6	Low
NHS	75.0	13.9	41.7	75.0	24.0	4.2	2/6	Low
Oregon Health	83.3	58.3	75.0	90.3	72.9	47.9	3/6	Average
SOGC	94.4	83.3	51.0	84.7	58.3	64.6	4/6	Average
WHO	93.1	90.3	93.2	79.2	77.1	91.7	6/6	High
Mean ± SD	88.7 ± 7.6	62.1 ± 28.8	57.7 ± 26.2	82.3 ± 7.4	52.9 ± 18.7	47.0 ± 27.6		

TABLE 3: INTRACLASS CORRELATION COEFFICIENTS (ICCS) FOR EACH DOMAIN

AGREE II DOMAIN	Intraclass Correlation Coefficient	95% Confidence Interval
Scope and purpose	0.988	0.835 to 0.989
Stakeholder involvement	0.821	0.789 to 0.984
Rigor of development	0.855	0.410 to 0.894
Clarity of presentation	0.790	0.110 to 0.915
Applicability	0.811	0.308 to 0.948
Editorial Independence	0.806	0.450 to 0.990

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Quality Assessment of CPGs

The ICC created from the 4 evaluators is presented in Table 2 and demonstrates an overall agreement between evaluators. Mean quality ICC scores for each domain across all CPGs are demonstrated in Table 3.

Scope and Purpose

The "Scope and Purpose" domain evaluates the objectives of the guideline and the patient population that it is targeting. The mean score for the "Scope and Purpose" domain was 88.7 ± 7.6, with all guidelines meeting satisfactory requirements with a score over 60%

Stakeholder Involvement

The "Stakeholder Involvement" domain evaluates whether the relevant stakeholders, including those who work with the target population and the target population itself, were included in the development of the guidelines. The mean score for the "Stakeholder Involvement" domain was 62.1 ± 28.8, with 4 guidelines meeting satisfactory requirements with a score over 60%.

Rigor of Development

The "Rigor of Development" domain assesses how the CPG was created and whether the potential benefits and risks of each recommendation have been considered. The "Rigor of Development" domain had a mean score of 57.7 ± 26.2, with 3 guidelines meeting satisfactory requirements with a score over 60%.

Clarity and Presentation

The "Clarity and Presentation" domain evaluated whether the recommendations presented are clear, concise, specific, and unambiguous so that they may be used effectively. The mean score for "Clarity and Presentation" was 82.3 ± 7.4, with all CPGs meeting the 60% satisfactory requirement.

Applicability

The "Applicability" domain focusses on the ability of the guidelines to be implemented in real-life situations that allow treatment of the target population. This includes barriers to using the guidelines such as resources and the ability to audit the guideline as needed. The "Applicability" domain received a mean score of 52.9 ± 18.7, and only 2 CPGs met satisfactory requirements with a score over 60%.

Editorial Independence

The "Editorial Independence" domain identifies whether the CPG was created with competing interests or funding that may have influenced how recommendations are made. The mean score of the "Editorial Independence" domain was 47.0 ± 27.6, with only one guideline meeting the satisfactory requirement of 60%.

Overall CPG Assessment

Of the 7 CPGs that were evaluated, one guideline created by WHO provided domain scores that achieved an overall rating of "high." The other 6 CPGs received scores of either "average" or "low."

DISCUSSION

Smoking during pregnancy increases the risk of serious adverse maternal and infant outcomes. Despite these known risks, there remains a high proportion of women who continue to smoke before and during pregnancy.[1] For physicians and providers, it can be challenging to diagnose and treat smoking during pregnancy, especially considering that the availability of recommended smoking cessation support remains suboptimal. Clinical practice guidelines provide recommendations aimed at enhancing patient care.[13] Their implementation minimizes variation in practice, in addition to improving the quality and safety of healthcare.[13] Having access to quality CPGs is crucial to improve clinical outcomes. The AGREE II instrument is utilized in this study to assess the quality of CPG in relation to the management of pregnant smokers. Seven CPGs from several countries were evaluated across the 6 AGREE II domains.

Scope and Purpose

Domain 1, "Scope and Purpose", examines whether a guideline expresses its goal clearly, emphasizes the health issues, and outlines its target demographic. All 7 guidelines scored highly in this domain. While all CPGs stated their objective, only USPSTF, Society of Obstetricians and Gynaecologists (SOGC), and the WHO guidelines were detailed and specific in each scenario they sought to answer. The clinical decision-making process and practice suggestions were very well understood with this form of structuring.

Stakeholder Involvement

This domain evaluates the authorship of the CPGs. Most CPGs fared poorly, indicating that there was inadequate professional variety in these developmental groups. The highest scoring guideline in this domain was the WHO guideline and included individuals with content expertise from several relevant fields,

notably obstetrics, family physicians, medicine and tobacco use/control specialists, and epidemiologists.[14] This is essential due to the different aspects of treatment involved for smoking cessation. The WHO also thoroughly gathered public input on its suggestions prior to being published, with patients' expectations and experiences with medical care considered.[15] Moving forward, regional diversity should also be taken into consideration; despite the equal utilization of smoking cessation interventions, indigenous women were observed to experience higher rates of smoking during pregnancy in comparison to nonindigenous women in a study done in Olmsted County, Minnesota.[16]

Rigor of Development

The "Rigor of Development" domain evaluates the process used to develop the CPG and determine if the pros and cons of each guideline have been addressed.[17] Considering that this domain quantifies the empirical basis for published guidelines, it is thought to be the best indicator of overall guideline quality.[11] The WHO guidelines scored the highest quality in this domain, with development including a set of questions and outcomes that were provided to an international multidisciplinary team to review and prioritize.[14] After consulting a guideline development group, these were then employed as a guide for systematic reviews with an effort to include relevant non-English literature that had fulfilled certain inclusion criteria, as well as incorporating important relevant data from these studies.[14] Additionally, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was applied, which is a well-validated method for evaluating the quality of evidence supporting a particular recommendation.[18]

Clarity and Presentation

The CPGs performed best in this domain, with all 7 receiving high-quality ratings. This domain assessed whether the recommendations created were unambiguous, succinct, and explicit enough to be used effectively.[17] Simplicity was discovered to be the strongest independent predictor of guideline use in a survey of pediatricians' attitudes and practices, further supporting the significance of this domain.[19] The USPSTF guidelines, which achieved the highest score, had prominent listings of the main recommendations and highlighted several clear scenarios and the recommended intervention.

Applicability

This domain evaluates how well the guidelines can be applied to the actual cases to treat the intended population, as well as how well the recommendations stand in settings of varying resources and implementation challenges.[17] Only 2 CPGs (WHO, Oregon) achieved a high-quality rating, while the National Health Service (NHS) guideline had the lowest rating since it did not sufficiently examine how the available resources would affect the recommendation or detail advice on how to implement them in resource-limited cases.[20] The highest achiever in this domain is the WHO guideline, which included the most diverse patient presentation and information regarding the preferences of the targeted demographic.[14] The scores in this domain together with the "Stakeholder Development" domain point to a lack of

variety among the developers, as well as the target populations that these recommendations apply to. The only CPG that secured high scores in both domains was the WHO guideline. The WHO developing team involved experts in several fields, who considered feasibility an important factor when assessing the strength of recommendations. Another study highlighted that high expenditure was one of the main causes of pediatricians' lack of adherence to CPGs,[21] further emphasizing the importance of affordability.

Editorial Independence

This domain evaluates whether competing interests or financing could have impacted how the CPGs were developed. Only the WHO and SOGC guidelines achieved satisfactory scores, with the WHO guideline rated the highest since it included conflicts of interests and funding statements, indicating a high degree of transparency. This significant variability aligns with other AGREE II analyses[13,22] potentially due to financial information being less easily accessible in some CPGs. Disclosures are essential for all other academic work and CPGs should adhere to the same requirement.[17]

RECOMMENDATION

Only the WHO CPG was validated by this AGREE II analysis, achieving a score of "high quality" on all 6 domains and is therefore considered a "high quality" guideline. Table 4 summarizes the main recommendations from the WHO CPG for screening and management of smoking during pregnancy. These guidelines highlight screening for tobacco use and various treatment options together with supporting evidence.

LIMITATIONS

This study has several limitations. The accuracy of the medical information contained in CPGs is not evaluated by the AGREE II tool; rather, it assesses the clarity and methodologic rigor of CPGs. It is feasible that well-designed and understandable guidelines could provide false information. The AGREE II analysis cannot assess whether a CPG offers useful and pertinent advice. Thorough analysis is required to establish that the recommended guidelines are in fact indicated. Despite research showing that "Rigor of Development" and "Editorial Independence" are more strongly connected to superior guidelines, the AGREE II tool values all domains equally. Additionally, the AGREE II tool incorporates a subjective review by experts. Finally, suitable guidelines in non-English languages may have been overlooked in the literature search.

CONCLUSION

High-quality clinical practice guidelines can improve patient care and allow for evidence-based decision making. CPGs should be developed by experts along with input from the targeted population. Based on our analysis, the quality of current guidelines

for detection and management of tobacco use during pregnancy requires improvement. Only one clinical practice guideline was identified as high quality using the AGREE II instrument. The study showed that the 2 domains with the most potential for development are "Applicability" and "Editorial Independence."

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