Original Article

Appraisal of Maternity Management and Family Planning Guidelines Using the AGREE II Instrument in India

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Abstract

Introduction: Guideline development gathered pace in India after the inception of National Rural Health Mission (NRHM) in 2005. However, there is a lack of adequate information about guideline development process, review, and update. This paper reports on the systematic appraisal of Indian guidelines related to maternity management (MM) and family planning (FP) using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument, which was one of the components of a pilot research in 2012-13. **Materials and Methods:** Forty-four selected guidelines about MM and FP, identified through a consensus building workshop, were independently appraised by two appraisers with AGREE instrument having six different domains. Mean item scores, domain scores, and standardized scores were calculated by averaging the scores across the two appraisers. **Results:** Most guidelines scored high in scope and purpose and clarity of presentation. However, they had little documentation about the development group member details, incorporation of patient views, evidence search method, method chosen for formulating recommendations, tools for application, potential barriers, cost implications, and information about the funding body. Nonclinical guidelines scored higher than clinical guidelines ($P = 0.01$) for MM in the domain applicability. Clinical FP guidelines scored higher than nonclinical guidelines in the domain of rigor of development (0.01). **Conclusion:** Despite being clinically sound, Indian guidelines score poorly due to weak documentation about their development process. It is recommended that the guideline development process be improved with systematic documentation for achieving standardization.

Keywords: Guideline appraisal, guidelines, maternity management (MM) guidelines

Introduction

Progress in medical science is evolving. In response to the rapid advances in biomedical science, technology, and diagnostic criteria, clinical practice guidelines (CPGs) that will hereafter be referred to as guidelines help health care providers to make informed decisions about optimum treatment for patients.[1,2] They provide recommendations about best practice based on evidence.[1,3,4] Numerous national and international professional bodies, educational institutes, and government agencies have developed guidelines covering specialty-specific topics including issues of public health importance in respective geographical areas.[5]

The pursuit of equity and quality in health and health care has gained momentum recently in India and formed the guiding basis of national health policy.[6,7] However,

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fewer efforts were made in achieving generalization of quality health services until 2005.[8] With the inception of the National Rural Health Mission (NRHM)[9,10] health care in India started to change rapidly. The move toward Universal Health Care (UHC)[11,12] and expansion of health insurance coverage[13] and health financing[14,15] have prompted the need to improve quality care including the use of standardized guidelines.

Maternal health is an important focus of NRHM as a part of its commitment to meet the millennium development goals (MDGs).[16] Several guidelines, manuals, and reference materials focusing on maternal health have been developed to enhance the quality of antenatal care, safe delivery, perinatal care and to avert maternal deaths.[17] Guidelines have also been developed in family planning[18] (FP) in an effort to cover the high unmet need of the community and to improve the quality of services.[19] However, to date there is no information available on the research, evidences, or experiences underpinning the development of guidelines in India. Given the potential impact of such documents and their direct synergy with the quality in health care and medical education, it is crucial to appraise the available guidelines, especially in the domain of maternity management (MM) and FP. This paper reports on an attempt to conduct a systematic assessment of Indian guidelines related to MM and FP, using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument. The AGREE II instrument has been validated widely and is considered as the gold standard for assessing the quality of guidelines.[20-23]

Materials and Methods

Searching Indian guidelines
The NRHM and Ministry of Health and Family Welfare (MOHFW) website[24] were searched for guidelines related to pregnancy, skilled birth attendance, and FP. Additionally, guidelines developed by several nongovernment professional bodies[25,26] were accessed through their web portals. Nondigital copies of some guidelines were obtained from the authors.

Selecting priority clinical areas for guidelines
At a workshop organized by the Foundation for Research in Community Health at Mumbai, Maharashtra, India in 2012, senior obstetricians and public health researchers from different parts of India agreed on priority clinical areas of maternal care for selecting guidelines for appraisal. These included anemia, malaria in pregnancy, eclampsia, sepsis, postpartum hemorrhage (PPH), and referrals. Guidelines covering these key clinical conditions and FP were prioritized. Documents/guidelines pertaining to selected clinical areas developed by Indian agencies after 2000 that were available in the public domain were selected for appraisal. Documents in the form of circular, memos, checklists, government orders but labeled as "guidelines" were excluded.

Appraisal process
During the workshop, the National Institute of Health and Care Excellence (NICE), International, UK provided technical assistance for assessing guidelines through the AGREE II Instrument. Participants learnt how to use the instrument using real guidelines and including qualitative comments based on their observations.

Following the workshop, a guideline appraisal advisory group was formed involving eight obstetricians including three from India, four from the UK, and one from the USA. The UK obstetricians were affiliated to the Royal College of Obstetrics and Gynaecology. Four public health researchers from India and one member of NICE International also participated in the appraisal.

As per the AGREE II recommendation, repeated attempts were made to contact the guideline authors to seek additional information about guideline development process; however, only one author responded with details. The selected guidelines were randomly distributed among the appraisers and each guideline was examined by two independent appraisers which was a prerequisite of AGREE II to ensure the reliability of guideline assessment. The appraisers had declared conflicts of interest regarding their nonparticipation in the development of the selected guidelines before undertaking their assessment. The AGREE II user manual served as a reference document for the appraisers.

The AGREE II instrument
The original AGREE instrument published in 2003 and designed by the AGREE collaboration aimed at assessing the process of guideline development and reporting.[23] It was revised in 2010 by the AGREE Next Consortium (AGREE II) through extensive research and psychometric testing, extending the response scale to a 7-point Likert scale instead of a 4-point scale.[20] The AGREE II comprises 23 items organized into six domains:

1. Scope and purpose
2. Stakeholder involvement
3. Rigor of development
4. Clarity of presentation
5. Applicability, and
6. Editorial independence.

The scores ranged from 1 (strongly disagree) to 7 (strongly agree), based on the completeness and quality of reporting. A score of 7 is given for exceptional quality and fulfillment of all criteria of AGREE II manual. A score of 1 is given for missing or poorly reported information. A score between 2 and 6 is assigned based on availability of information in the ascending order. In addition to the six domains, a 3-point scale (1 = not recommended, 2 = recommended with provision or modifications, and 3 = strongly recommended) provides an overall judgement on the potential use of the guideline.[27]

In this study the appraisers' scores for each item were collated and analyzed. Standardized domain scores (expressed on 0-100 scale) were calculated as using the AGREE II method [(obtained score- minimum possible score)/(maximum possible score-minimum possible score) * 100]. AGREE II neither recommends the usage of a threshold for acceptance of a guideline and nor does it advocate aggregating the domain scores. Instead, it recommends reporting the standardized score for each of the six domains. The standardized domain scores were compared regarding the different characteristics by applying Mann-Whitney *U* test.[28] Statistical Package for the Social Sciences (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.) was used for statistical analysis and *P* value < 0.05 was considered as significant. Intraclass correlation coefficient (ICC) was used as a measure of agreement between two appraisers with values above 0.7 as strong agreement, 0.4-0.6 as moderate agreement, and less than 0.4 as poor agreement among appraisers.

Results

Profile of the guidelines

A total of 91 documents related to MM and FP were identified through a wide search of all possible national sources from June 7, 2012 to September 3, 2013. Forty-four guidelines met the inclusion criteria, out of which 30 were related to MM and 14 related to FP [Table 1]. Most of the excluded guidelines did not have background information about their development, which made their assessment with AGREE II unfeasible.

Table 1: Characteristic and profile of selected guidelines

Characteristics	Number of guidelines	
	Maternity management-related guidelines	Family planning-related guidelines
Nature of guidelines (*n*=44)		
Clinical	14	6
Clinicomanagerial	16	8
Development agencies (*n*=44)		
Government	22	13
Nongovernment professional bodies	8	1
Development year (*n*=39)[†]		
2003-04	1	1
2005-2010	15	11
2011 onward	10	1

[†]Five guidelines were without date of publication or development and were hence, not included

All except two guidelines were developed after 2005 (post-NRHM). The agencies that developed them were MOHFW (30 guidelines), nongovernment professional bodies (seven guidelines), health departments of selected states (five guidelines), and private hospitals (two guidelines). There were 20 clinical and 24 clinico-managerial guidelines, respectively. The clinical guidelines covered MM (14) and FP (six) targeting end-line users such as doctors including obstetric consultants, medical officers at Primary Health Centre (PHC) level, staff nurses, and auxiliary nurse midwives (ANMs) etc. The clinicomanagerial guidelines covered MM (16) and FP (eight) targeting primarily policy makers, program managers, and training institutes. Notably, 10 guidelines did not have any reference about their target users.

Evaluation of the AGREE II domains of appraised guidelines

The overall quality of the selected guidelines varied considerably, both within and across the six domains of AGREE II [Figure 1]. The result depicted in each bar of the Figure 1 represents the 75th (Q3) and 25th (Q1) percentile (interquartile range). The band near the middle of the bar represents the median. A small dot (o) represents outliers and (*) represents extreme outliers.[27] There were also score variations between the groups of guidelines, i.e., MM and FP, which is detailed here.

The mean score for the first domain of scope and purpose was 70 [standard deviation (SD) 19.5] for MM guidelines and 70 (SD 22.7) for FP guidelines, indicating that there was a clear mention about the objective of the document and target population in both groups of guidelines [Figure 1].
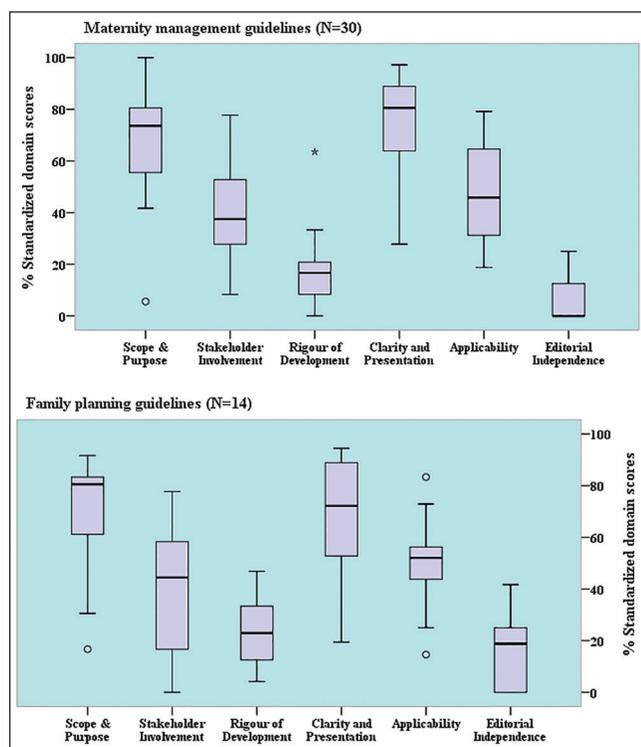
Figure 1: Comparison of the standardized AGREE domain scores for maternity management and family planning guidelines

The mean score for the second domain of stakeholder involvement was 40.3 (SD 17.2) for MM guidelines and 43 (SD 25) for FP guidelines. This indicates an overall moderate level of documentation about the experience, involvement, roles, and responsibilities of members of guideline development groups as well as inclusion of patients' views as one of the key stakeholders.

The mean score for the third domain of rigor of development was 17 (SD 12.2) for MM guidelines and 23 (SD 14) for FP guidelines. There was an extreme outlier in the MM guidelines' rigor of development domain score [refer to Figure 1], which might be the reason behind the closeness of mean and SD for MM guidelines. There was no such outlier in FP guidelines, indicating the possibility of most of the scores being clustered around the mean. This was one of the two domains that scored the lowest in the guidelines of both the groups. In other words, most of the selected guidelines lacked information about a systematic method for the search of evidence, criteria for selecting evidence, method for consensus-building, discussion about health benefits and side effects, external review of guideline, and procedure for updating guideline.

The mean score for the fourth domain of clarity and presentation was 77.2 (SD 16.8) for MM guidelines

and 69.6 (SD 22.1) for FP guidelines. Similar to the first domain of scope and purpose, most of the selected guidelines were rated high for this domain. These guidelines presented clarity in recommendations, different options for the management of health conditions, and tools for the application of recommendations.

The mean score for the fifth domain of applicability was 46.1 (SD 18.2) for MM guidelines and 50.7 (SD 17.5) for FP guidelines. There was inadequate information about potential organizational barriers and cost implications of the recommendations. Additionally, there was insufficient mention regarding the review criteria for the monitoring and auditing of suggested recommendations to ensure quality.

The mean score for the sixth domain of editorial independence was 6.8 (SD 9.3) for MM guidelines and 17.5 (SD 15.4) for FP guidelines. This was the second domain that scored the lowest in the guidelines of both the groups. Information about the funding bodies and conflict of interest of guideline development group members was missing in almost all the selected guidelines.

Overall, most of the Indian guidelines for MM and FP demonstrated relatively better documented information about the scope and objectives of the guidelines and clarity in presentation of all recommendations.

AGREE II domain scores
Domain scores were further analyzed across various characteristics of guidelines.

In case of MM guidelines, clinicomanagerial guidelines scored significantly higher as compared to clinical guidelines (*P* value = 0.01) for the domain of applicability because they presented more details about facilitators and barriers for implementation of recommendations as well as discussed the cost implications of suggested recommendations. The MM guidelines developed by other professional bodies have significantly scored high as compared to the government guidelines (*P* value = 0.03) in the domain of rigor of development, as they included relatively more information about evidence search and review process. However, the year of development of the guidelines did not have any significant relation with any of the six domains of guideline appraisal [Table 2].

In FP guidelines, clinical guidelines scored significantly high as compared to clinicomanagerial

guidelines for the domain of rigor of development (*P* value = 0.02) since they included relatively more details about the information on evidence search, review process, and criteria for selecting evidence. However, the development agency as well as year of development of guideline did not have any significant relation with any of the six domains of guideline appraisal [Table 3].

Table 2: Standardized AGREE domain scores (mean and median) of maternity management guidelines with different characters expressed as percentage (values represents the median compared as per the characteristics of Mann-Whitney *U* test)

Characteristics of guidelines	Standardized AGREE domain score					
	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence
Nature of guidelines						
Clinical guidelines (*n*=14)						
Mean	66.1	41.1	20.7	79.0	36.6	7.4
Median	66.7	37.5	19.3	84.7	32.3	2.1
Std. deviation	17.2	19.3	14.7	16.2	13.0	9.7
Clinicomanagerial guidelines (*n*=16)						
Mean	73.8	39.8	13.9	75.7	54.4	6.3
Median	76.4	40.3	14.6	77.8	59.4	0.0
Standard deviation	21.3	15.8	8.8	17.8	18.5	9.3
P value	0.10	0.87	0.12	0.50	0.01*	0.60
Development organizations						
Government-developed guidelines (*n*=22)						
Mean	72.5	40.9	13.0	75.0	48.2	6.3
Median	76.4	43.1	14.6	79.2	49.0	0.0
Standard deviation	19.3	17.9	7.4	16.8	18.6	9.3
Nongovernment (*n*=8)						
Mean	63.9	38.9	28.4	83.3	40.4	8.3
Median	54.2	31.9	25.0	87.5	33.3	4.2
Standard deviation	20.2	16.3	15.9	16.6	17.1	9.7
P value	0.18	0.58	0.03*	0.17	0.39	0.36
Development year						
2005-2010 (*n*=15)						
Mean	73.5	45.6	20.4	80.2	49.7	7.8
Median	77.8	50.0	17.7	80.6	47.9	4.2
Standard deviation	15.2	16.9	15.1	14.1	19.5	9.4
2011 onward (*n*=10)						
Mean	69.2	36.4	15.7	72.5	41.0	6.7
Median	69.4	34.7	16.7	72.2	37.5	0.0
Standard deviation	15.2	12.2	6.3	14.3	14.4	11.0
P value	0.33	0.19	0.57	0.24	0.24	0.53

Table 3: Standardized AGREE domain scores (mean and median) of family planning guidelines with different characters expressed as percentage (values represents the median compared as per the characteristics of Mann-Whitney *U* test)

Characteristics of guidelines	Standardized AGREE* domain score					
	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence
Nature of guidelines						
Clinical guidelines (*n*=14)						
Mean	83.3	54.6	33.2	78.7	58.7	25.0
Median	83.3	54.2	34.9	77.8	54.2	25.0
Standard deviation	3.0	10.3	12.0	11.5	12.2	14.9
Clinicomanagerial guidelines (*n*=16)						
Mean	60.1	34.4	15.6	62.8	44.8	12.0
Median	62.5	30.6	15.1	61.1	47.9	8.3
Standard deviation	26.2	29.8	10.7	26.3	19.3	14.2
P value	0.09	0.18	0.02*	0.36	0.13	0.06

*AGREE: Appraisal of Guidelines for Research and Evaluation

Of the total 44 selected guidelines, two guidelines were strongly recommended by the reviewers without any provision or modification; Six guidelines received a comment of not being recommended due to gaps in the background information and clarify of recommendations while the remaining 36 guidelines were recommended with modifications. This indicates that despite the relatively moderate low scores on application of AGREE II across various domains, some guidelines had the potential to be recommended with modifications.

Agreement among appraisers regarding the recommendation of MM-related guidelines was low (ICC-0.269); however, appraisers had a moderate level of agreement while recommending FP guidelines (ICC-0.606). At the domain level, stakeholder involvement had the highest level of agreement ICCs 0.750 and 0.881 for MM and FP guidelines, respectively. Additionally, there was strong agreement among appraisers with regard to the domain scope and purpose (0.717) for FP guidelines. The disagreement between the appraisers in some domains might be due to the challenge in interpretation of the review point, for example, in "Guidelines for home delivery of emergency contraceptive pills by ASHA* workers" there may be differential assumptions on what should be the pivotal health question — home delivery of contraceptives or emergency contraceptive pill. Accordingly, the scores could differ for the same item under appraisal. Such a disagreement would probably be minimal in case of exclusively clinical guidelines where the health question would be more explicit as compared to any operational or mixed type of guideline.

Discussion

To our knowledge this is the first time Indian guidelines have been appraised using an internationally validated approach. The important finding of the study is that although the number of guidelines in maternal care and FP has increased since the inception of NRHM, these are still few (clinical 30) as recorded by the study. This suggests that there is a need for developing new guidelines on various prevalent clinical conditions related to MM and FP and increasing their accessibility in the public domain.

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*Accredited Social Health Activist (ASHA) - A woman developed as a community health worker in the NRHM since 2005, selected from the village itself and accommodation to it, the ASHA has been trained as a link worker between her community and Public Health System.

The results indicate that selected guidelines scored very low in the domains of rigor of development and editorial independence. This compares with Korean guidelines,[27] which similarly failed to provide information on rigor of guideline development. A guideline becomes obsolete within a period of 3-4 years,[29] thus the validity of all guidelines should be reevaluated every 3 years, one of the key components under the domain of rigor of development. The second domain with the lowest scores, editorial independence, includes recording conflict of interest of guideline development group members and influence of a funding body. Conflict of interest (COI) is an important potential source of bias in the development of guidelines.[30,31] Practices for declaring COI, association with the industry, and the funding body need be promoted in guideline development.

An appraisal study conducted in Argentina questioned the relevance or application of the AGREE II tool in the national guidelines in low- and middle-income countries,[32] arguing that the AGREE II standard may be too high for these countries.[33] However, this assumption does not entirely hold true in the Indian context as Indian guidelines present differential strengths across the six domains and have definite scope for further improvement in the domains of stakeholders' involvement, editorial independence, and applicability. It is important to note that the appraisers in this study, despite giving a particular guideline the score of "low" for various domains, recommend the same guidelines for further use with some modifications. As per AGREE II ,this process of appraisal should not be considered as a comprehensive evaluation of a particular guideline but an attempt to appraise guidelines regarding various characteristics; it is not about labeling any guideline "good" or "bad."

This study has some limitations. First, the lack of a dedicated guideline database or electronic repository may have limited the access to Indian guidelines, raising a possibility that some important guidelines have been missed. At the international level, the United States National Guideline Clearinghouse website hosts 2,216 guidelines related to various diseases, 549 specifically about female urogenital diseases and pregnancy complications.[34] NICE UK has 41 guidelines related to pregnancy care that are available on a single web portal. Second, the assessment is based on documented information about the guideline development process, indicating the fact that systematic development of guidelines is not sufficient but has to be supported with

a systematic documentation of the development process. Given the lack of documentation in the guidelines appraised, it is difficult to be certain of their intrinsic quality.

Recommendations

There should be a robust process for developing guidelines with a thrust on documentation in line with international standards,[35-37] for example, NICE UK guidelines are explicitly based on openness and inclusiveness. The NICE process involves setting up advisory groups that bring together technical expertise and relevant "lay" or service user experience. Such activity brings strengths in terms of plurality of experiences, perspectives, and backgrounds to inform evidence-based recommendations.[38] Similar experiences from international organizations could provide a useful basis for developing a guideline development process in India.

Roadmap for guideline development in India

Establishing or nominating an independent national agency for guideline development, implementation, and monitoring housed within the Directorate of Health Services could be an option in strengthening guidelines in India. Involving stakeholders from the group of care givers, nurses, and users in the development process will improve the quality and inclusiveness of guidelines. The scope of guidelines should be broadened to cover varied clinical conditions and operational or health system issues. Development of clinical guidelines should be a central mandate to safeguard standardized and evidence based clinical care; the development of operational guidelines should be prioritized by state level[†] policy makers according to local needs and priorities. These may not need to be developed *de novo* and can be adapted from existing nationally or internationally recognized guidelines.[33]

Adherence and down streaming

Guideline development is a step toward quality instillation with adherence and downstreaming being the crucial aspects of ensuring quality. Hence, adherence to guidelines should be prioritized through national health policy and strengthened by relevant regulations. Additionally, guidelines should be embedded as teaching tools in medical and paramedical education to inculcate the value of evidence-based practice. This attempt at appraising guidelines has thrown light on various aspects of guideline development and the prerequisites for their implementation in the Indian context.

Conflicts of interest

Francoise Cluzeau was a member of the research team that designed the AGREE II instrument. The other authors declare that they do not have any competing interests.

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