


Sri Lankan clinical practice guidelines: A methodological quality assessment utilizing the AGREE II instrument

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Abstract

Rationale, aims, and objectives: Clinical practice guidelines (CPG) play a major role in patient care in Sri Lanka. This study evaluates the methodological quality of the Sri Lankan CPGs developed in 2007.

Methods: A total of 94 CPGs developed by several professional colleges in Sri Lanka in the year 2007 were evaluated by 2 independent reviewers using AGREE II instrument for their methodological quality. Item score being ≤ 3 points was defined as “poor quality”. Each domain score was calculated according to AGREE II. A guideline was labelled as “strongly recommended” if 4 or more domains scored above 60%, “recommended for use with certain modification” if only 3 domain scores were above 60% or if 4 or more domain scores were between 30% and 60%, and “not recommended” if 4 or more domains scored less than 30%.

Results: Most (22.3%) guidelines were developed by the College of Pathologists. Most of the guidelines (>55%) poorly reported on all the items, except for items 1, 2, and 22 of AGREE II. Median domain scores [range] and the proportion of the guidelines with domain score of <30% were as follows: domain on scope and purpose (33.3% [2.8%-83.3%]; 42.6%), stakeholder involvement (14.9% [0.0%-61.1%]; 81.9%), rigour of development (6.1% [0.0%-49%]; 98.9%), clarity and presentation (30.5% [8.3%-61.1%]; 46.8%), and applicability (8.3% [4.2%-14.6%]; 100%). All CPGs scored 50% for “editorial independence”. Reviewers reported the overall quality was poor in 86 (91.5%). Based on the definitions used in the study, of 94 CPGs, 8 (8.5%) could be recommended to be used with modifications, while 86 (91.5%) could not be recommended for clinical practice.

Conclusions: The methodological quality of the CPGs was poor irrespective of the source of development. Major efforts are essential to update the CPGs according to the principles of evidence based medicine.

KEYWORDS

AGREE II instrument, clinical practice guidelines, methodology, patient care, quality, Sri Lanka

1 | INTRODUCTION

In the ever-evolving world of Medicine, evidence-based medicine integrating the clinical expertise, best research evidence, the patient's unique sociocultural factors, and the circumstances plays a major role in the patient care, in doing the "right thing" for the patient.¹ In this process of evidence-based clinical practice, the usage of clinical practice guidelines has thus become increasingly familiar during the last decade. As defined by the Institute of Medicine, USA, clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".² Irrespective of the source of origin, these clinical guidelines may generally provide a concise background of the particular disease or condition and its complications, clinical symptoms and signs, what diagnostic tests to be ordered, potential medical or surgical services and procedure options, complications related to the possible medical or surgical treatment, when, how, and to which level of care the patient has to be referred to, and other relevant details.

As in other countries of the world, the clinical guidelines developed in Sri Lanka—a middle-income country in the South Asia—also mainly aim at limiting the variations in service delivery among the providers, provide more consistent and efficient care to the patients, and to bridge the gap between the current research evidence and what actually being practiced by the clinicians. In addition, the clinical guidelines are also driven by the aging population, increased cost of care, increased demand, new and expensive technologies, and overutilization or underutilization of the services.³

Considering the several potential advantages of the clinical guidelines such as improving health outcomes by reducing morbidity, mortality, and improving the quality of life of the patients; improved quality of decision making; improved consistency and quality of care by the practitioners; alert policy makers and planners by highlighting the unidentified health issues, gaps in services and risk population groups and benefit the researches by identifying the research gaps,³ the Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka had undertaken the initiative to support the development of clinical guidelines in collaboration with the World Bank. Thus, several professional bodies of Sri Lanka had formulated and published several clinical guidelines for various diseases and conditions in the year 2007 with the financial support from the Sri Lanka Health Sector Development Project of the World Bank. These guidelines have since been the base for the medical practice by the clinicians in the country. However, the methodological quality of these developed guidelines has not been assessed so far.

It is evident in the literature that despite the many advantages of the clinical guidelines, the quality of guidelines and guideline development remains questionable.^{4,5} Although it is recommended and expected that a scientific methodology should be undertaken for the development of clinical guidelines, a study which evaluated the quality of the guidelines that were published in the peer-reviewed medical literature between years 1985 and 1997 had found that the guidelines do not quite adhere to the methodological standards. Authors further state that all areas of guideline development required development, which emphasize on identification, evaluation, and synthesis of scientific evidence.⁶ This denotes the importance of evaluating the quality

of the formulated guidelines to assess whether they can be recommended for clinical practice or not.

The Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument is a validated⁷ tool that is developed and used to assess the methodological quality of the clinical practice guidelines.^{7,8} A systematic review conducted among 24 different clinical practice guideline appraisal tools found that AGREE has the most potential to serve as the basis for the development of clinical guidelines.⁹ The AGREE II is widely used in many scientific publications¹⁰⁻¹³ and has been adopted by many health care organizations including the World Health Organization for the evaluation of clinical practice guidelines.¹⁴

Therefore, the current study was aimed at evaluating the methodological quality of the clinical practice guidelines in Sri Lanka that were developed in the year 2007, utilizing the AGREE II instrument. Having an insight about the methodological quality of the guidelines would allow the policy makers and health planners of the country to undertake necessary actions in order to uplift the health care services in the country. Also, findings of this study would provide evidence on the methodological quality of the clinical guidelines for other countries in the region and in the world.

2 | METHOD

There were 94 clinical practice guidelines formulated and published in the year 2007, by the various professional colleges of Sri Lanka. The AGREE II tool was utilized to evaluate the methodological quality of all these clinical practice guidelines.

2.1 | AGREE II instrument

The AGREE II instrument assesses the methodological quality of a clinical practice guideline through 23 key items under 6 domains (scope and purpose [3 items]; stakeholder involvement [3 items]; rigour of development [8 items]; clarity of presentation [3 items]; applicability [4 items] and editorial independence [2 items]), followed by 2 global rating items by the reviewer. According to the instructions provided in the AGREE II manual, each of these items are to be rated using a 7-point scale, with 1 for "strongly disagree" to 7 for "strongly agree". Then, considering the criteria that were used in the process of quality assessment, the reviewer is expected to make an independent individual judgement of the overall quality of the guideline and then would report whether he/she would recommend the particular guideline to be used in the clinical practice.⁷

2.2 | Quality assessment

Independent assessment of all 94 guidelines was done by 2 reviewers in the current study, according to the instructions given in the AGREE II manual.⁷ Any item (in each domain) with a discrepancy of more than 3 points between the 2 reviewers was discussed further to come in to consensus, and any further disagreement was resolved by assessment by a third independent reviewer. The scores of both the reviewers were then used to calculate an average item score to be used for the calculation of the scores for each domain (domain score). The

domain scores were calculated by summing the average scores for the individual items in each domain and scaling the total as a percentage of the maximum possible score for that domain. The scaled domain score was calculated as (obtained score – minimum possible score) / (maximum possible score – minimum possible score).⁷

2.3 | Definitions used in the study

Poor quality of any item (within each domain) was defined as the item score being equal or less than 3 points. In this study, a guideline was labelled as “strongly recommended” if the domain scores of 4 or more

domains scored above 60%, “recommended for use with certain modification” if only 3 domain scores were above 60% and if 4 or more domain scores were between 30% and 60%, and “not recommended” if 4 or more domains scored less than 30%.

2.4 | Data analysis

Data were analysed using the IBM SPSS 22.0 version. Descriptive statistics with mean (SD), median (inter quartile range) for continuous data, and proportions for categorical data were used.

TABLE 1 Proportion of guidelines which scored low for the key items of AGREE II

AGREE II Key Items	Guidelines with Poor-Quality Items (Item Score ≤ 3 Points)	
	Number (N = 94)	Percentage
Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic	44	46.8
Report the health question(s) covered by the guideline, particularly for the key recommendations	38	40.4
Describe the population (ie, patients, public, etc.) to whom the guideline is meant to apply	63	67.0
Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence, and individuals involved in formulating the final recommendations	62	66.0
Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were	93	98.9
Report the target (or intended) users of the guideline	54	57.4
Report details of the strategy used to search for evidence	91	96.8
Report the criteria used to select (ie, include and exclude) the evidence. Provide rationale, where appropriate	92	97.9
Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept	93	98.9
Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them	92	97.9
Report the health benefits, side effects, and risks that were considered when formulating the recommendations	94	100
Describe the explicit link between the recommendations and the evidence on which they are based	92	97.9
Report the methodology used to conduct the external review	94	100
Describe the procedure for updating the guideline	94	100
Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence	53	56.4
Describe the different options for managing the condition or health issue	73	79.8
Present the key recommendations so that they are easy to identify	58	61.7
Describe the facilitators and barriers to the guideline's application	94	100
Provide advice and/or tools on how the recommendations can be applied in practice	91	96.8
Describe any potential resource implications of applying the recommendations	94	100
Provide monitoring and/or auditing criteria to measure the application of guideline recommendations	94	100
Report the funding body's influence on the content of the guideline	0	0
Provide an explicit statement that all group members have declared whether they have any competing interests	94	100
Overall quality of the guidelines	86	91.5

3 | RESULTS

Among the total 94 clinical practice guidelines, most (22.3% [n = 21]) were developed by the College of Pathologists of Sri Lanka. Sri Lanka College of Obstetricians and Gynaecologists, Sri Lanka College of Paediatricians and Sri Lanka College of Radiologists each had produced 11.7% (n = 11) guidelines, while 10.6% (n = 10) each were formulated by the College of Anaesthesiologists and Intensivists of Sri Lanka, Sri Lanka College of Microbiologists, Ceylon College of Physicians, and the College of Surgeons of Sri Lanka.

Table 1 shows the proportion of guidelines that scored low (≤ 3 points, which was defined as poor quality) for each item in the AGREE II instrument. All (100%) the guidelines had well reported the funding body's influence on the content of the guideline. Majority of the guidelines had well reported the health question(s) covered by the guideline (59.6%) and had reported the overall objective(s) of the guideline (53.2%).

On the other hand, all (100%) the guidelines failed to report on the health benefits, side effects, and risks that were considered when formulating the recommendations; report the methodology used to conduct the external review; describe the procedure for updating the guideline; describe the facilitators and barriers to the guideline's application; describe any potential resource implications of applying the recommendations; provide monitoring and/or auditing criteria to measure the application of guideline recommendations; and provide an explicit statement that all group members have declared whether they have any competing interests.

Of the guidelines assessed, almost 99% did not report how the views and preferences of the target population were considered for the development of the guideline and what the resulting outcomes were. Also, 97% poorly reported on the details of the strategies used to search for evidence, 98% poorly reported on the criteria used to select the evidence, 99% poorly described the strengths and limitations of the evidence, and 98% poorly described the methods used to formulate the recommendations. Considering these assessment criteria of AGREE II instrument, the reviewers reported that for 91.5% (n = 86) of the guidelines, the overall quality of the guideline to be poor (item score ≤ 3 points).

Summary of the domain scores of all the clinical practice guidelines using the AGREE II instrument is given in Table 2.

Of the guidelines, nearly 15% (n = 14) had scored more than 60% for reporting the scope and the purpose of the guideline (domain 1 of AGREE instrument), while almost all (99%-100%) reported poor on the

rigour of development (domain 3 of AGREE) and the applicability (domain 4 of AGREE) of the guideline. However, all the guidelines scored 50% for the domain on the editorial independence.

Going into further details, Table 3 presents the median score and the range of scores obtained for each domain of the AGREE II instrument by the guidelines formulated by the different professional colleges of Sri Lanka. The scope and the purpose of the guidelines are well reported in the guidelines formulated by the College of Microbiologists of Sri Lanka (range = 69.4-83.3) and the College of Obstetricians and Gynaecologists (range = 47.2-66.7); stakeholder involvement is reported in many of the guidelines formulated by the College of Radiologists (range = 47.2-50), while the rigour of development and the applicability of the guideline were reported poorly by all the professional colleges.

In addition to these findings, it was also evident that the scores obtained for a particular domain of AGREE II by the guidelines formulated by the same professional college also widely varied (eg, the scores for the domain of scope and purpose among the 10 guidelines developed by the College of Anaesthesiologists and Intensivists ranged between 5.6 to 61.1; the scores for the domain of stakeholder involvement among the 11 guidelines developed by the College of Pathologists ranged between 2.8-44.4).

Based on the definitions used in this study, none of the clinical practice guidelines assessed in the current study, which were formulated in the year 2007 by the professional colleges of Sri Lanka, were strongly recommended (4 or more domains of AGREE II scoring above 60%) for the use in clinical practice according to the assessment based on the AGREE II instrument. On the other hand, 8.5% (n = 8) of the assessed guidelines could be recommended for use with certain modification (having only 3 domain scores above 60% and 4 or more domain scores between 30% and 60%), while 91.5% (n = 86) of the assessed guidelines could not be recommended for use in the clinical practice (having 4 or more domains scoring less than 30%) according to the criteria of AGREE II instrument.

4 | DISCUSSION

The current study found that majority of the clinical practice guidelines formulated by various professional colleges of Sri Lanka in the year 2007 could not be used in the clinical practice based on the AGREE II methodological standards. This finding of the current study

TABLE 2 Summary of the domain scores of all the guidelines using the AGREE-II instrument (N = 94)

Domains	Mean	Median	Standard Deviation	Range	Interquartile Range	Domain Score < 30% No. (%)	Domain Score 30%-60% No. (%)	Domain Score > 60% No. (%)
Scope and purpose	34.7	33.3	22.1	2.8-83.3	34.0	40 (42.6)	40 (42.6)	14 (14.9)
Stakeholder involvement	18.9	13.9	14.9	0.0-61.1	16.7	77 (81.9)	16 (17.0)	1 (1.1)
Rigour of development	1.97	0.0	6.1	0.0-49.0	1.0	93 (98.9)	1 (1.1)	0.0 (0.0)
Clarity and presentation	30.6	30.5	14.7	8.3-61.1	22.2	44 (46.8)	48 (51.1)	2 (2.1)
Applicability	8.02	8.3	3.1	4.2-14.6	2.1	94 (100)	0.0 (0.0)	0.0 (0.0)
Editorial independence	50.0	50.0	0.0	-	-	0.0 (0.0)	94 (100.0)	0.0 (0.0)

TABLE 3 Median and the range of scores obtained for each domain of the AGREE-II by the guidelines formulated by the professional colleges

Professional College of Sri Lanka	Scope and Purpose Median % (Range)	Stakeholder Involvement Median % (Range)	Rigour of Development Median % (Range)	Clarity and Presentation Median % (Range)	Applicability Median % (Range)	Editorial Independence Median % (Range)	Overall Quality Score Median (Range 1-7)
College of Microbiologists (n = 10)	69.4 (69.4-83.3)	13.9 (5.6-61.1)	0 (0-3.1)	43.0 (33.3-61.1)	6.2 (6.3-12.5)	50 (50-50)	3.0 (2.5-4.0)
College of Pathologists (n = 21)	11.1 (2.8-44.4)	16.7 (2.8-44.4)	0.0 (3.1)	22.2 (8.3-50.0)	6.2 (4.2-8.3)	50 (50-50)	2.0 (1.5-3.0)
College of Radiologists (n = 11)	47.2 (22.2-50.0)	50 (47.2-50)	0.0 (3.1)	13.9 (8.3-47.2)	8.3 (4.2-14.6)	50 (50-50)	2.0 (1.5-3.0)
College of Anaesthesiologists and Intensivists (n = 10)	31.9 (5.6-61.1)	2.8 (0-19.4)	2.1 (0-5.2)	43.1 (22.2-61.1)	11.5 (4.2-16.7)	50 (50-50)	2.5 (1.5-3.0)
College of Obstetricians and Gynaecologists (n = 11)	55.5 (47.2-66.7)	13.9 (13.9-30.6)	1.0 (0-4.2)	41.7 (27.8-58.3)	8.3 (8.3-14.6)	50 (50-50)	2.5 (2.5-3.0)
College of Paediatricians (n = 11)	25 (2.8-47.2)	11.1 (0-19.4)	0.0 (0-12.5)	27.8 (13.9-44.4)	8.3 (6.3-10.4)	50 (50-50)	2.5 (2.0-4.0)
College of Physicians (n = 10)	25 (5.6-38.9)	9.7 (2.8-25)	0.0 (0-16.7)	38.9 (11.1-58.3)	6.2 (6.3-10.4)	50 (50-50)	2.0 (2.5-3.5)
College of Surgeons (n = 10)	18.0 (2.8-44.4)	15.3 (5.6-25)	0.0 (0-49)	20.8 (11.1-55.6)	6.2 (4.2-18.8)	50 (50-50)	2.0 (1.5-5.0)

is similar to the findings of other studies conducted elsewhere as well, where guidelines do not quite adhere to the methodological standards established, and there is a great need of improving the process of guideline development.^{6,10,11} It is also shown that despite several recommendations available in the literature, there is no improvement in the overall methodological quality of the guidelines or improvement within the domains of the AGREE II over the years¹¹ as well.

Considering the key items of methodological assessment, one positive finding of the current assessment was that the role of the funding body on the process of the guideline formulation and on its content was sufficiently reported in all the guidelines.

Considering the scope and the purpose domain (domain 1) of the AGREE II, it was aimed at assessing the overall objective of the guideline, the specific health issue that is being addressed by the particular guideline, and the population that the recommendations of the guideline were meant for. Of the guidelines under study, the highest score achieved for this domain was 83%. However, there were guidelines which scored as low as 3% as well. In the future development of the guidelines in Sri Lanka, this is an important aspect to be focused on as the scope and the purpose of the guideline has to be clearly, specifically reported, and documented for the ease of its users, and it definitely would have an impact on the effective and successful implementation of the guideline.

Domain 2 of the AGREE II was to assess the stakeholder involvement in the process of developing the guideline. Majority of the guidelines in the current study had scored poorly for reporting on the individuals who were involved in the formulation process of the guideline. This raises an issue of transparency in the methodology of the guideline development. Involvement of individuals from relevant different fields in the process will have an added advantage of preventing the recommendations being biased towards one particular speciality as well. The current study also identified that almost all (99%) guidelines had not reported whether the views and the preferences of the target population were considered for the development of the guidelines. It is shown that inclusion of the view and preferences of the target population in to consideration during the guideline formulation is essential for the effective and successful implementation of the guideline,¹⁵ and this also may support in preventing the recommendations biased towards a particular treatment option.

The current study also noted that there was a significant lack in the reporting related to the rigour of development of the guidelines, which is the largest domain (domain 3) in the AGREE II instrument. Thereby, the guidelines poorly reported information related to the systematic methods used for the search of evidence, the criteria used for the selection of the evidence, the strengths and limitations of the available evidence, the methods for formulating the recommendations, health benefits, side effects and risks that have been considered for the formulation of recommendation, and link between the formulated recommendations and the available evidence. In the era of practicing evidence-based medicine approach in clinical medicine, it is essential that the guidelines are developed and the recommendations are formulated based on the available latest research findings. A national survey conducted among the Australian general practitioners has found that the guideline being evidence based was the most

important factor to decide whether to follow the guideline or not,¹⁶ thus affecting the successful implementation and utilization. One possible explanation for the lack of literature utilization in the process of development of guidelines could be the limited availability of evidence related to a particular disease or condition, especially the evidence specific for Sri Lanka or for the Asian region. Also, the limited access to the available literature unless published in an open source could be another reason, especially in low-resource settings like Sri Lanka.

Also, the guidelines under study have failed to report on the details related to external review process and a procedure for updating the guideline. It is recommended in the literature that the guidelines have to be updated regularly at least at 3-year intervals, as owing to the fast evolving nature of medicine, the new evidence might result in significant changes to the recommendations that the guideline has previously formulated.¹⁷ Thus, it is essential that the guidelines are kept up to date on the new findings of research, if we are to practice Medicine based on the latest evidence.

Low clarity of presentation (domain 4) and the applicability (domain 5) of all the guidelines of the current study suggest that the guidelines have failed in providing clear key recommendations and in advising the user as to how the key recommendations of the guideline to be applied in the clinical practice. This is of utmost importance especially in low-resource settings like Sri Lanka, in order to maximize the utilization of the limited resources of the country in practicing latest evidence-based Medicine. Future guideline development should therefore consider the gravity of this domain so that the key recommendations are clearly mentioned, different treatment options are provided, with special emphasis to the local setting and clear advice on the applicability are provided, which may allow the practitioners to easily adopt the recommendations, thus improve the outcome.

According to Detsky, the most common bias in the process of guideline development is the conflicts of interests.¹⁸ While the guidelines under assessment of the current study made clear statements about the influence of the funding body on the content of the guideline, all the guidelines failed to explicitly mention that all the group members do not have any competing interests. This could be either because there were existing conflicting interests or that they failed to report the absence of any conflicting interests in the guideline. Thus, it is of importance that the editorial independence (domain 4) is well assured in the future development of guidelines.

In addition to these findings, it was also evident that there was no consistency in the methodology of the formulation of guidelines within the same professional college as well. It was evident by the wide range of scores for each domains of AGREE II among the various guidelines developed by the same professional college. Possible explanations for these differences could be the different composition in the different guideline development working groups, citation selection bias, and evidence interpretation bias. However, it is essential that consistency is maintained in the methodology of development of clinical practice guidelines. This could be well achieved by all guideline-formulating working groups following one method, and as the literature suggests, AGREE II is potentially a good guide.^{9,10}

5 | CONCLUSION

There were several methodological flaws of the clinical practice guidelines that were under the current study, irrespective of their sources of development. We recommend major efforts to be undertaken by the policy makers to uplift the quality of the process of guideline development based on the principals of evidence-based Medicine in Sri Lanka.

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