Towards evidence-based clinical practice guidelines in Saudi Arabia

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ABSTRACT

The objective of this review is to provide a brief background on clinical practice guidelines (CPGs) and tools to assess and locally adapt CPGs. Over the last 2 decades, CPGs have become an increasingly popular tool for synthesis of clinical information, so as to change clinical practice and improve quality of health care. Such a quantitative growth in the number of guidelines available in different specialties is a source of concern since there is evidence that recommendations produced by different groups can be conflicting, invalid, unreliable, and even harmful. Various critical appraisal instruments were designed and tested to assess whether developers have minimized the biases inherent in creating guidelines and addressed the requirements for effective implementation. We recommend using the AGREE instrument which was developed by the Appraisal of Guideline Research and Evaluation (AGREE) collaboration. It is the most well-developed guideline appraisal instrument available, and it has been shown to have good reliability and validity. There is a growing recognition that it is not possible for national guidelines to be produced on every clinical problem of concern. The cost is huge and few practices have the resources or skills to develop their own valid evidence-based guidelines. Several developed countries encourage local adaptation of international good quality guidelines to avoid duplication of work and cost involved in guidelines development. Therefore wherever possible, Saudi guidelines should be based on existing good quality guidelines. The methodology for local adaptation of CPGs to meet the local needs and resources are explained in this review.

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The objective of this review is to provide a brief background on clinical practice guidelines (CPGs) and tools to assess and adopt CPGs. Clinical practice guidelines are "systematically developed statements to assist practitioners and patient decisions regarding appropriate health care for specific clinical circumstances."[1] Over the past 20 years CPGs have become an increasingly popular tool for synthesis of clinical information so as to change clinical practice and improve quality of health care. Medical specialty societies have been particularly active in producing such guidelines together with agencies whose remit includes technology assessment and health care evaluation.[2] It has been shown that when health care providers accept and follow CPGs, they have the potential to improve both the process of care and patient health outcomes.[3-6] The revolution in information technology made it possible for almost any health care professional to access some relevant guidelines. There are a number of sites on the internet that catalogue clinical guidelines.[7] Full text versions or abstracts of guidelines are available from some sites (**Table 1**). It is likely that such sites will become the best source to identify potential guidelines to be adapted locally in the future. Such a quantitative growth in the number of guidelines available in different specialties is, however, a source of concern since there is evidence that recommendations produced by different groups can be conflicting and some researchers go so far as to say they are invalid, unreliable, and irrelevant.[2,8] These concerns

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regarding the quality of guidelines might limit their acceptance and application by health care providers.[9] A survey on all CPGs developed by specialty societies in English and identified through Medline between 1988 and 1998 (431 CGPs) has shown that the quality of those guidelines is unsatisfactory despite some improvement over time. Sixty-seven percent did not report any description of the type of stakeholders, 88% gave no information on searches for published studies, and 82% did not give any explicit grading of the strength of recommendations.[2]

Thus, growth in the numbers of guidelines without application of rigorous criteria for their production could undermine their credibility and lead to harm to the patient if the wrong recommendations were put into practice. A recent international survey of 18 clinical guidelines programs in the United States of America, Canada, Australia, New Zealand and 9 European countries has shown that the principles of evidence-based medicine dominate current guideline programs. The authors of this survey called for international collaboration to improve guideline methodology and to globalize the collection and analysis of evidence needed for guideline development.[10] Another recent study has assessed the quality of 86 CPGs from 11 countries using the Appraisal of Guideline Research and Evaluation (AGREE) instrument. Guidelines produced within a guideline program and by governmental agencies had higher scores than their counterparts.[11] It was concluded that CPGs should be produced within a structured and coordinated program to ensure that they are of high quality. Professional organizations or specialist societies that aim to develop guidelines may adopt quality criteria from leading guideline agencies. The development of guidelines is a complex process with multiple tasks and steps **(Figure 1)**. Guideline producers should attempt to minimize all the potential biases inherent in performing each step and how well this is reported. Various critical appraisal instruments were designed and tested to assess whether developers have minimized the biases inherent in creating guidelines and addressed the requirements for effective implementation. In the year 2000, Graham et al[12] identified 13 instruments for evaluation of CPGs. There was insufficient evidence to support the exclusive use of any one instrument, although the Cluzeau instrument[3] has received the greatest evaluation. The work of Cluzeau et al[8] formed the basis for a new instrument for guideline appraisal that was further refined by the (AGREE) collaboration, an international partnership of researchers and policymakers.[13] Detailed description and discussion of the AGREE instrument will follow later.

The conference on guideline standardization (COGS) was convened in April 2002 to define a standard for guideline reporting that would promote guideline quality and facilitate implementation.[14] It is intended to be used prospectively by developers to improve their product by improving documentation. The COGS panel used a systematic and rigorous process to define content of the proposed standard and to achieve consensus. Most of the proposed component items of the COGS checklist are covered in the AGREE instrument. The conference on guideline standardization is a consensus instrument that was recently released and it was not tested for validity and reliability. Therefore, we suggest using the AGREE to assess and critically appraise CPGs. This instrument was selected as it is the most well developed guideline appraisal instrument available, and it has been shown to have good reliability and validity.[15] The cost of developing guidelines is huge and few practices have the resources or skills to develop their own valid evidence-based guidelines.[7] The overall cost can be considerably reduced if guideline developers used high quality guidelines as a basis for producing their own guideline.[11] It can further be reduced by 'owning' or adapting the existing rigorously-developed guidelines rather than attempting to develop de novo guidelines.[16] There is a growing recognition that it is not possible for national guidelines to be produced on every clinical problem of concern. Several developed countries

Table 1 - Electronic guideline resources.

Agency for Health Care Research & Quality (AHRQ)- full text versions of guidelines and other resources http://www.ahrq.gov/clinic/prevenix.htm
Australian National Health and Medical Research Council (NHMRC)- full text versions of guidelines and other resources http://www.health.gov.au/nhmrc/publications/cphome.htm
Canadian Medical association Clinical Practice Guidelines Infobase- Index of clinical practice guidelines, including downloadable full text versions or abstracts of most guidelines http://mdm.ca/cpgsnew/cpgs/index.asp
Canadian Task Force on Preventive Health Care- full text versions of reviews/recommendations and other resources http://www.ctfphc.org/
National Institute for Clinical Excellence- full text versions of guidelines and other resources http://www.nice.org.uk/catcg2.asp?c=20034
New Zealand Guidelines Group- full text versions of guidelines and other resources http://www.nzgg.org.nz/
Scottish Intercollegiate Guidelines Network- full text versions of guidelines and other resources http://www.sign.ac.uk/
US National Guidelines Clearing House-Index of Clinical guidelines including structured synopsis of development methods and key recommendations http://www.guideline.gov/

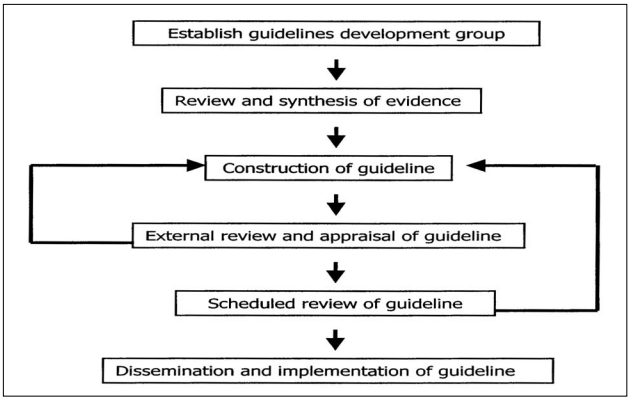

Figure 1 - Steps in guideline development, appraisal, implementation.

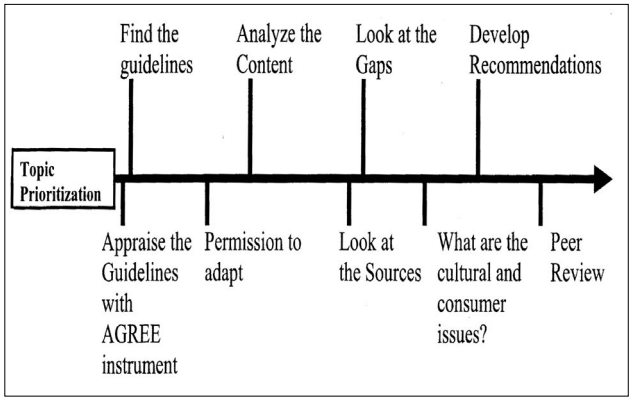

Figure 2 - A suggested methodology for local adaptation of clinical practice guidelines. AGREE - Appraisal of Guideline Research and Evaluation

(such as New Zealand, Germany, and Iceland) encourage local adaptation of international good quality guidelines to avoid duplication of work and cost involved in guidelines development. Therefore wherever possible, Saudi guidelines should be based on existing good quality guidelines. The Guideline International Network (GIN) (http://www.g-i-n.net) suggested a comprehensive methodology for the local adaptation of clinical guidelines (**Figure 2**). Local adaptation of CPGs addresses local clinical issues and circumstances and gives a sense of ownership of the clinical guidelines. Searching primary sources of evidence such as Medline, or searching secondary sources of evidence like the guidelines agencies described in **Table 1** can identify potential CPGs. Once a relevant guideline is identified it should be critically appraised using the AGREE instrument to evaluate its validity. The adaptation group (local group) should include all relevant stakeholders from within (and without) the practice who will be needed for the implementation and evaluation of the guideline.[7] This methodology forms the basis of a common approach to assessing guideline quality in Europe and Canada where there are agencies that critically appraise CPGs to be used by others. In the United Kingdom, a central guideline appraisal service (the Guideline Review Panel of the National Institute for Clinical Excellence: NICE) has been implemented since 1999 to assess all guidelines funded by the National Health Service to help ensure that guidelines are sound before they are deployed.[17] The Scottish Intercollegiate Guidelines Network, in the United Kingdom as well, is following suit.[18] The Guidelines Advisory Committee (GAC) in Canada is empowered by the Ontario Ministry of Health and Long-Term Care and the Ontario Medical Association, for the purpose of conducting standardized assessments of CPGs and helping physicians in deciding which guidelines to follow. The GAC initially used the Cluzeau instrument, then it has adapted the AGREE instrument early in 2001. Their website was launched in October 2001.[19] Up till the present, 388 guidelines have been assessed by at least 3 physician assessors. The AGREE instrument is produced by the AGREE collaboration in 2001. The AGREE collaboration is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment in 9 European countries as well as Canada, New Zealand and the USA.[13] The instrument is designed to assess the process of guideline development and how well this process is reported. It provides an assessment of the predicted validity of a guideline; this is the likelihood that it will achieve its intended outcome. It does not assess the clinical content of the guideline recommendations nor the impact of a guideline on patients' outcomes. The AGREE instrument is designed to assess guidelines developed by local, regional, national or international groups or affiliated governmental organizations. These include: 1. New guidelines. 2. Existing guidelines. 3. Updates of existing guidelines. The AGREE instrument is generic and can be applied to guidelines in any disease area including those for diagnosis, health promotion, treatment or interventions. It is suitable for guidelines presented in paper or electronic format.[7] It is the first appraisal instrument for CGPs that has been developed and tested internationally. Created through a rigorous and iterative process by a collaboration of international experts in CPG, the instrument was applied to 100 guidelines by over 260 appraisers from 11 countries. Previous studies on similar instruments have been limited to appraisers working in the same institution and from the same country. The instrument is sensitive to differences in important aspects of guidelines and can be used consistently and easily by a wide range

of professionals from different backgrounds.[15] The AGREE instrument showed good reliability with Cronbach Alpha ranged between (0.64-0.88) for the 6 domains of AGREE instrument. Inter-rater reliability was also good with k ranged between (0.57-0.91) for the 6 domains of AGREE instrument. As there is no standardized reference test to be used, AGREE instrument was validated using several measures. Face validity of AGREE instrument was high (95%). Construct validity was measured using 3 measures: 1. Guidelines produced as part of an established guideline program had significantly higher scores on editorial independence ($p<0.05$). 2. Guidelines developed as national policies had significantly higher scores on rigor of development ($p<0.005$). 3. Guidelines with technical documentation had higher scores on that domain ($p<0.0001$). Criterion validity was assessed using participants' overall assessment scores as a proxy measure, which was highly significant ($p<0.001$, using Kendall's tau B rank correlation coefficients). The AGREE instrument consists of 23 key items organized in 6 domains. Each domain is intended to capture a separate dimension of guideline quality. The whole instrument can be accessed at http://www.agreecollaboration.org/

In conclusion, CPGs have been shown to have the potential to improve both the process of care and patient health outcomes. Concerns regarding the quality of guidelines are important factors that limit their acceptance and application by health care providers. The cost of developing guidelines is huge and few practices have the resources or skills to develop their own valid evidence-based guidelines. We recommend local CPGs developers to use the AGREE instrument to assess potential CPGs to be adopted locally. Adopted CPGs can be modified to meet the local needs and resources. We encourage local CPGs developers to attend workshops on how to critically appraise CPGs, such as by using the AGREE instrument.

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