# South African Guidelines Excellence (SAGE): Clinical practice guidelines – quality and credibility

Over the past 15 years, the processes for developing clinical practice guidelines (CPGs) have shifted from their being written by experts (or based on expert opinion) to being largely written by methodologists. CPGs are quality improvement tools, and although they are presented in different ways, their aims are commonly to standardise care, improve its quality and safety, reduce wastage, decrease unnecessary costs, and improve access to care and patient outcomes.[1-3]

With the emergence of international collaborations such as the Guidelines International Network (G-I-N),[4] there have been concerted attempts to standardise CPG writing practices across countries, to increase the credibility of the final products.[5-7] Without adherence to rigorous guideline development and reporting standards, the considerable time and effort put into developing guidelines may be wasted, as intended users may not have confidence in the recommendations made.

South Africa (SA) is an emerging African leader in CPGs. However, there is room for improvement if SA CPG activities are to match global standards.[7] In April 2014, the *SAMJ* signalled on its website the appointment of an editorial subcommittee whose specific mandate would be to review guidelines submitted for publication. The *SAMJ* has regularly published guidelines and recommendations for the management of a variety of conditions. These will in future be adjudicated using the AGREE II instrument (www.agreetrust.org). An editorial in the May issue entitled 'AGREE to disagree' recognised the important role that CPGs play in setting standards of clinical practice in SA, and introduced a formalised mechanism to assess CPG quality prior to publication.[8]

This editorial outlines and discusses key aspects of CPG quality, and sets the scene for the South African Guidelines Excellence (SAGE) project, funded for 3 years by the South African Medical Research Council. This innovative research partnership aims to improve the quality and reach of SA primary care CPGs. Using stakeholder-driven processes, SAGE will provide tools to assist effective SA CPG activities in developing, adapting, adopting, contextualising and implementing primary care CPGs.

## International standards for guideline developers

Between 2011 and 2013, three standards were independently proposed, to assist CPG developers in addressing key issues of quality (Institute of Medicine (IOM) 8 standards,[2] G-I-N 11 standards,[4] and McMaster University group 18 standards[9]). Concurrently, two checklists were independently developed to appraise CPG quality. The AGREE II checklist (**A**ppraisal of **G**uideline **Res**(**E**)arch and **E**valuation) uses six domains incorporating 23 items (each scored 1 - 7),[10] while the iCAHE checklist (International Centre for Allied Health Evidence) provides a simpler alternative for policy makers and clinicians, with seven domains incorporating 14 binary items.[11] Table 1 compares the items in each checklist, using the AGREE II domains to standardise comparison. Domains common to all instruments are 'stakeholder involvement', 'underlying evidence', 'currency' and 'clarity'.

**Stakeholder involvement.** Stakeholder (end-user) involvement directly links CPGs to ownership, and downstream implementation. It is therefore an essential initial step to identify all relevant stakeholders within a CPG's scope and purpose, and then determine the role each stakeholder might play in the CPG development process. This assists determination of clear terms of reference. Stakeholder engagement can either occur individually ('experts' working with the methodology team) or as a collective (providing feedback on CPG drafts, or at public consultations).

**Table 1. Common domains and strategies for clinical guideline quality from various quality assessment tools***

| Domains† | IOM standards | G-I-N elements | McMaster topics | AGREE II questions | iCAHE questions |
|---|---|---|---|---|---|
| Scope and purpose | | 4. Scope of a guideline | 2. Priority setting<br>5. Identifying target audience and topic selection | Q1. The overall objectives of the guideline are specifically described<br>Q2. The health questions covered by the guideline are specifically described<br>Q3. The population to whom the guideline is meant to apply is specifically described | Q13. Are the purpose and target users of the guideline stated? |
| Stakeholder involvement | 3. Guideline development group composition<br>7. External review | 1. Composition of guideline development group<br>3. Conflicts of interest<br>9. Peer review and stakeholder consultations | 3. Guideline group membership<br>6. Consumer and stakeholder involvement<br>15. Reporting and peer review | Q6. The target users are clearly defined<br>Q4. The guideline development group includes individuals from all relevant professional groups<br>Q5. The views and preferences of the target population have been sought | Q11. Are the developers clearly stated?<br>Q12. Do the qualifications and expertise of the guideline developers link with the purpose of the guideline and its end users? |
| Underlying evidence/ rigour | 1. Establishing transparency<br>4. Clinical practice guideline – systematic review intersection<br>5. Establishing evidence foundations for and rating strength of recommendations | 2. Decision-making process<br>5. Methods<br>6. Evidence reviews<br>8. Rating of evidence and recommendations | 8. PICO question generation<br>9. Considering importance of outcomes and interventions, values, preferences and utilities<br>10. Deciding what evidence to include and searching for evidence<br>11. Summarising evidence and considering additional information<br>12. Judging quality, strength or certainty of a body of evidence | Q7. Systematic methods were used to search for the evidence<br>Q8. The criteria for selecting the evidence are clearly described<br>Q9. The strengths and limitations of the body of evidence are clearly described<br>Q10. The methods for formulating the recommendations are clearly described<br>Q11. The health benefits, side-effects and risks have been considered in formulating the recommendations<br>Q12. There is an explicit link between the recommendations and the supporting evidence | Q7. Does the guideline provide an outline of the strategy used to find underlying evidence?<br>Q8. Does the guideline use a hierarchy to rank the quality of the underlying evidence?<br>Q9. Does the guideline appraise the quality of the evidence which underpins its recommendations?<br>Q10. Does the guideline link the hierarchy and quality of underlying evidence to each recommendation?<br>Q6. Does the guideline provide dates for when literature was included? |
| Currency | 8. Updating | 10. Guideline expiration and updating | 18. Updating | Q14. A procedure for updating the guideline is provided | Q4. Is there a date of completion available?<br>Q5. Does the guideline provide an anticipated review date? |
| Clarity | 6. Articulation of recommendations | 7. Guideline recommendations | 13. Developing recommendations and determining their strength<br>14. Wording of recommendations and of considerations of implementation, feasibility and equity | Q15. The recommendations are specific and unambiguous<br>Q16. The different options for management of the condition or health issues are clearly presented<br>Q17. Key recommendations are easily identifiable | Q14. Is the guideline readable and easy to navigate?<br>Q1. Is the guideline readily available in full text?<br>Q2. Does the guideline provide a complete reference list?<br>Q3. Does the guideline provide a summary of its recommendations? |
| Independence | 2. Management of conflict of interest | 11. Financial support and sponsoring organisation | 7. Conflict of interest considerations | Q13. The guideline has been eternally reviewed by experts prior to its publication<br>Q22. The views of the funding body have not influenced the content of the guideline<br>Q23. Competing interests of guideline development group members have been recorded and addressed | |

PICO: P = patient, population, problem; I = intervention (or exposure); C = comparator (or control); O = outcome.
*The table only lists common domains with agreement from at least four/five instruments.
†The relevant item in each instrument, and its item number, are mapped against each AGREE II domain, hence item numbers of instruments other than the AGREE II may be out of numerical order.

**Scope and purpose.** The CPG *purpose* intrinsically links with end-users and the target audience (people to whom the guidance is being directed). The CPG *scope* also underpins the framing of the research questions. For instance, for a CPG aimed at primary care clinicians, research questions would not be raised about care provided in other sectors. Defining scope and purpose early, and clearly, assists in determining which stakeholders need to be engaged, how, and in what ways.

**Independence.** It is critical that everyone involved in CPG development is identified, their qualifications listed and their role on the guideline team described, and potential conflicts of interest declared in writing throughout the CPG activity. Funding for the CPG and endorsements should be stated clearly.[12] Independence is essential when sourcing and critiquing the evidence, so that one person's or group's view of the literature does not dominate.[13]

**Underlying evidence.** A good-quality CPG should include a comprehensive 'Methods' section, which outlines the research questions, how the literature was accessed (databases, search terms/key words, inclusion/exclusion criteria), how the research was critiqued (hierarchy of evidence, critical appraisal tools), how data were extracted, and how the strength of the body of evidence was determined and reported for each recommendation. A comprehensive reference list of included papers should be provided, so that end-users can identify literature underpinning each recommendation.

**Currency.** With an estimated 1.8 million peer-reviewed articles published in academic journals by the end of 2012,[14] ensuring that CPGs are based on current evidence is a constant challenge. This requires regular updating, using the protocols established during initial CPG development. Before updating, CPG developers should first identify new issues that have arisen since the previous CPG was published. They should also consider the relevance of the questions 'carried forward' from the last CPG. Literature searches should be undertaken from the date of completion of the previous search to the present, to update the evidence base. The relevance of any new findings should be factored into previous recommendations, using a standard approach.[1]

**Clarity.** Clearly written CPGs and comprehensive supporting documentation are essential to ensure that end-users can be confident that they can trust the recommendations. This reduces barriers to uptake and implementation.[2] Moreover, the use of standard clear wording when writing recommendations is encouraged, to clearly link the strength of the evidence body with the wording of the recommendation.[6,15]

## Conclusion

In this editorial, the first in a series of six, we present issues critical to CPG development and uptake, relevant to SA and beyond. While recent local efforts to improve CPG quality and credibility in SA are commendable,[8,7] opportunities to progress SA CPG quality and uptake are limited by the lack of a central, nationally recognised and accepted CPG development unit. Such a unit has the potential to significantly increase SA efforts to improve and standardise high-quality, credible CPG development, reporting and uptake. To this end, the Project SAGE team is engaging in a 3-year stakeholder-driven process that aims to better understand the guideline development arena in SA, and improve the standard of local guideline development, adaptation, contextualisation, and ultimately implementation of primary healthcare guidelines.

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