

CLINICAL GUIDANCE TERMINOLOGY IN SOUTH AFRICA: *Producing believable, appropriate, and implementable evidence statements*

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Background

South African primary care practitioners provide health care for patients over their lifespan, and they generally coordinate their healthcare needs, requiring them to be conversant with, and able to apply, best practice across all the conditions presenting at their facilities. To assist them to do this requires access to, and application of, current evidence-based clinical guidance.

The most common term for evidence-informed guidance is clinical practice guidelines (CPGs).¹ While there is growing international consensus on the key quality components of CPGs, there is no international consensus on how CPGs should 'look', as the term can refer to multiple presentations of evidence, all intended to guide clinical practice.

Within South Africa, clinical guidance documents are developed by various groups including the National and Provincial Departments of Health, at district and facility levels, as well as professional societies, with no central, nationally recognised and accepted CPG development unit in place.

Objectives

To propose appropriate terminology and a classification system for describing different forms of evidence-based clinical guidance appropriate to the South African primary care context.

Research design

We applied a mixed methods approach to combine findings from three data sets. The analysis approach was based on a realist synthesis framework in which the data was combined to produce a new concept (Figure 1).

The three data sets included are listed below:

- DATA SET 1:** a rapid review of literature outlining quality practices in the development of CPGs;
- DATA SET 2:** quality appraisal of 16 purposively-sampled South African primary care CPGs by Machingaidze and colleagues as part of the South African Guidelines Excellence (SAGE) project²
- DATA SET 3:** details extracted of the development and presentation of the evidence in the CPGs from Data Set 2.

Mixed methods analysis: We synthesised the findings of the three data sets above into a theoretical model (Figure 2) which we believe outlines the elements of how credible clinical guidance could be developed, described and presented in South Africa.

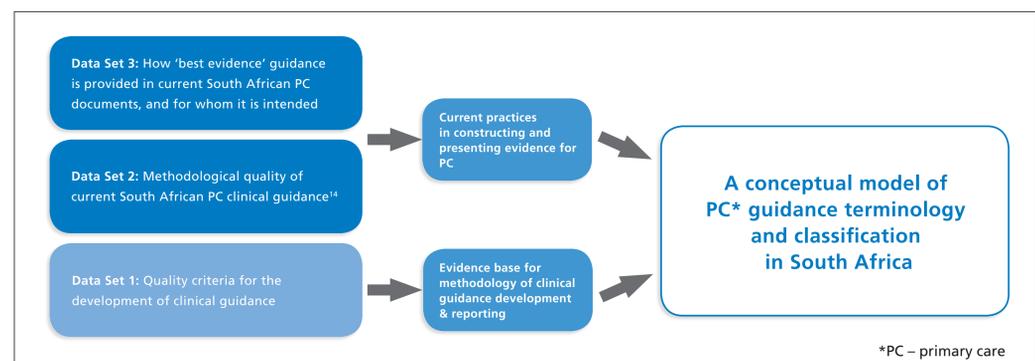


Figure 1. Realist synthesis framework for evaluation of findings

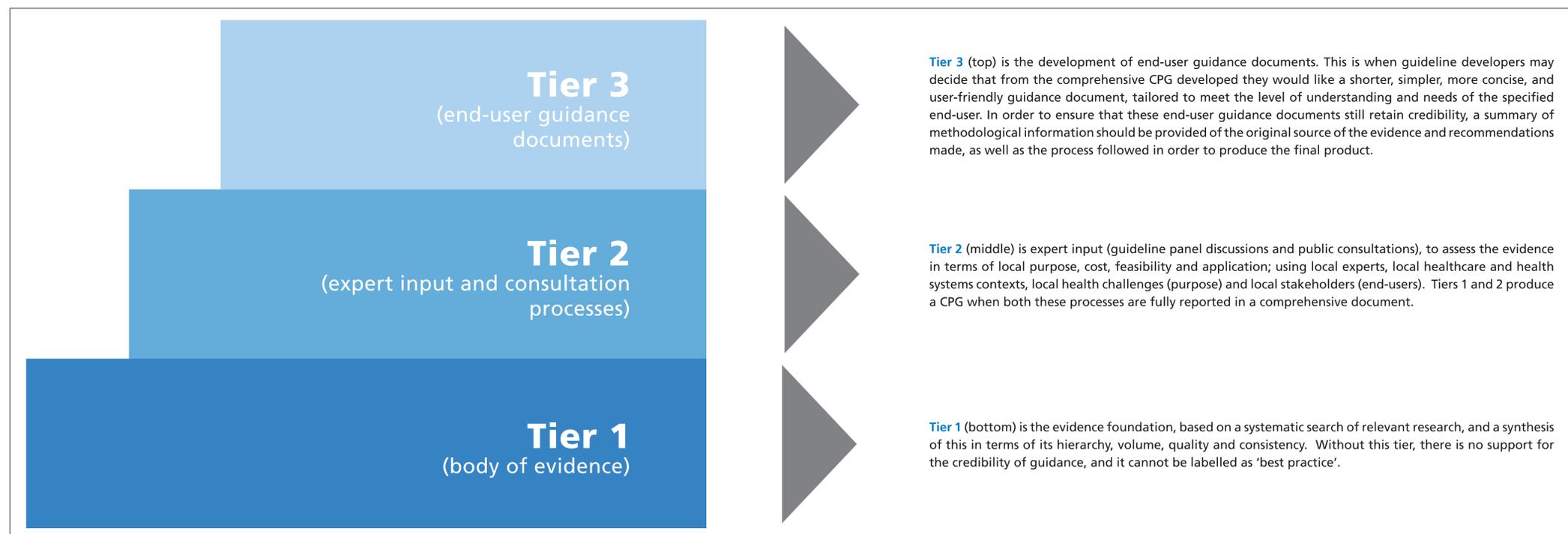


Figure 2. The SAGE Clinical Practice Guideline (CPG) Development Framework

Results

DATA SET 1: From 82 potentially eligible documents (both peer-reviewed and grey literature), we found a recent comprehensive systematic review of literature describing critical development criteria for healthcare guidelines, undertaken at McMaster University (Schunemann et al. 2014). This became our quality framework.³

DATA SET 2: Machingaidze et al (2015) reported variable domain scores in 16 purposively selected South African primary care CPGs - with two domains obtaining fair scores [clarity of presentation (69% (range 44-94%), and scope and purpose (55% (range 19-92%)); and the remaining four domains largely concerned with the guideline development process as well as use of evidence generally obtaining poor scores [stakeholder involvement (22% (range 0-64%)); applicability (13% (range 0-83%)); rigour of development (4% (range 0-30)); and editorial independence (0% (range 0-29%))].²

DATA SET 3: There was no standard format for construction or presentation of evidence in the included primary care CPGs in Machingaidze et al (2015), even though all 16 publications were labelled as 'guidelines'.²

Mixed methods analysis: We synthesised the findings of the three data sets into a theoretical model which we have called the 'SAGE CPG Development Framework' (Figure 2) which we believe outlines the elements of how credible clinical guidance could be developed, described and presented in South Africa. We propose standards for reporting, and terminology that is more descriptive of the guidance.

Discussion

The SAGE CPG development framework proposes a base of transparent evidence synthesis processes (Tier 1), layered with clinical contexts (Tier 2), which in turn supports end-products tailored specifically for different contexts, users and purposes (Tier 3). We propose the guidance documents designed specifically to cater to the needs of the end-users (Tier 3), be classified as one of (but not limited to) the following:

- Evidence-based Summary Recommendations - where recommendations and explanatory text have been transparently extracted from good quality CPGs with relevant contextual information often provided, and presented in short form as resource material for specific conditions and specific health care requirements.
- Patient Management Tools (PMTs) - which describe decision-support tools to address situations where front healthcare professionals have to make explicit health care decisions on presenting conditions. These tools could include algorithms, referral pathways, checklists, or recommendations for practice, with little explanatory or contextual information regarding the various options the healthcare professional could decide to take for that particular patient. e.g. The SA National Department of Health Guidelines
- Protocols - which provide step-by-step guidance on how to do specific tasks, and these may be embedded within the two options mentioned above. In these instances there is only one correct way to do the task, and no decision-making required.

Implications for Guideline Developers/Users

Reporting practices for primary care clinical guidance in South Africa could be improved, where all guidance documents are appropriately classified, with an agreed standard set for minimum reporting criteria when clinical guidance is adopted and contextualised from existing CPGs to suit South African primary care requirements.

References
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3. Schunemann HJ, Wiercioch W, Etzeandria I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. Canadian Medical Association Journal. 2014;186(3):E123-E42