Journal of Clinical Epidemiology 83 (2017) 31–36

Journal of Clinical Epidemiology

Series: Clinical Epidemiology in South Africa. Paper 2: Quality and reporting standards of South African primary care clinical practice guidelines

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Accepted 9 September 2016; Published online 5 November 2016

Abstract

Objectives: Clinical practice guidelines (CPGs) development has evolved over the past decade, with greater emphasis now being placed on transparency, rigor of development, and reporting standards. Our evaluation assesses the quality of the guideline development processes and reporting of selected South African primary care (PC) CPGs.

Study Design and Setting: CPGs were iteratively identified by two authors, seeking CPGs reflecting common conditions with which patients present in South African PC settings. CPGs could address diagnosis, treatment, or clinical management. Each CPG was independently appraised by two reviewers using the AGREE II (Appraisal of Guideline REsearch and Evaluation) quality checklist, and the weighted scoring algorithm to calculate scores for the six domains.

Results: We included 16 CPGs from the National Department of Health and clinical professional associations. Overall, the domains of rigor of development, editorial independence, and applicability had the lowest median scores (0, 4%, and 13%, respectively). Clarity of presentation reported the highest median score (69%), with seven CPGs scoring above 70%.

Conclusions: The methodological quality of the selected South African PC CPGs was generally poor to moderate. Concerted efforts should be made to ensure that transparent, rigorous, and up-to-date evidence assessments are conducted and well reported by CPG developers.

Keywords: Clinical practice guidelines; South Africa; Primary care; AGREE II; Quality; Reporting standards

1. Introduction

Clinical practice guidelines (CPGs) have been recognized as an essential part of good medical practice for several decades [1]. CPGs have been described as ''statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options'' [2]. When they are rigorously developed and effectively implemented, they offer a convincing way to bridge the gap between scientific evidence, policy, best-practice, local contexts, and patient choice. However, there is no standard approach to constructing CPGs [1]. Despite resources being made available for developing CPGs by credible international organizations such as the Institute of Medicine (IOM) [2], the World Health Organization [3], the Guidelines International Network (G-I-N) [1], the National Institute for Health and

Conflicts of interest: None.

Funding: The authors are funded, partially or in full, by the South African Guidelines Excellence (SAGE) project, a 3-year (2014–2016) flagship grant from the South African Medical Research Council (SAMRC) Project SAMRC-RFA-IFSP-01-2-13/SAGE. The Flagship Grant programme was not involved in the conceptualization or conduct of this study.

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http://dx.doi.org/10.1016/j.jclinepi.2016.09.015
0895-4356/

Challenges and Opportunities in Low and middle income countries (LMICs)

Challenges in Low and middle income countries

- Lack of a central repository or established and recognized guideline network made guideline retrieval difficult.
- A clear communication strategy is required to ensure all Clinical practice guideline (CPG) stakeholders are working together, limiting duplication of efforts and maximizing on limited resources.
- Potential differences in the definition of a CPG between developers in the South African primary care (PC) setting may explain the variation in the type of guideline documents produced.
- We found that many of the South African PC guideline documents were specifically targeted at implementation with limited reporting on evidence and methodology.

Opportunities in Low and middle income countries

- CPGs used in PC in South Africa require improvement particularly regarding the rigor of development, reporting of methodologies, editorial independence, and applicability to the local context.
- CPG development groups should aim to constitute all necessary stakeholders including content and methods experts.
- Procedural standards (in both guideline development and reporting) as well as establishing a central repository for CPGs in South Africa can help improve standardization and dissemination of CPGs.
- Providing declarations of potential conflicts of interest within the guideline team and clearly stating the involvement of the funding body will help to ensure that a CPG can be viewed as trustworthy and unbiased.

Clinical Excellence [4], and the Scottish Intercollegiate Guideline Network [5], countless CPGs of varying quality are being produced by a range of different organizations in different countries around the world [6]. CPG development processes have improved significantly over the past decade, with greater emphasis now being placed on transparency, rigor of development, and reporting standards. Other factors such as accessibility, evaluation, adaptation, contextualization, and implementation are also being addressed [1]. However, contingent with an ever-increasing volume of CPGs now becoming available is the challenging issue of identifying a well-developed and credible guideline that best suits one's needs. This situation poses two dangers: first, poor-quality guidelines may be adopted by policy makers, funders, and/or clinicians who do not have the knowledge and skills to assess guideline quality and make informed choices; and second, that a lack of easily accessible, well-developed, credible clinical guidelines may undermine the commitment and efforts made by clinicians, health care workers, policy makers, and managers to ensure current best evidence is put into practice, especially within the developing-country context where both time and skills are scarce [6].

To assist guideline developers globally to address key issues related to the quality of guidelines, three sets of standards were independently proposed between 2011 and 2013. The IOM group proposed 8 standards [2], the G-I-N group proposed 11 standards [1], and the McMaster group proposed 18 standards [7]. In addition, two checklists have been developed independently, both providing relatively quick and easy tools to appraise the quality of a guideline. The AGREE II instrument (Appraisal of Guideline REsearch and Evaluation) uses six domains with a total of 23 items (each scored 1−7) and is currently internationally recognized as the tool of choice for evaluating the process of CPG development and the quality of its reporting [8]. The iCAHE guideline quality checklist, developed by the International Centre for Allied Health Evidence (iCAHE), at the University of South Australia, provides a simpler and faster alternative for clinicians and policy makers with seven domains and 14 binary (yes or no) items [6].

South Africa is currently implementing a primary health care re-engineering strategy, which aims to strengthen the district health system through the establishment and efficient functioning of District and Sub-District Management Teams. These will facilitate better district and subdistrict planning, supervision, and clinical governance at the primary health care level [9,10]. The National Department of Health is responsible for ensuring that all patients accessing public health care services receive standardized treatment. However, although overall CPG development is led at national level, it also occurs at provincial and hospital or clinic levels, with professional societies also contributing to the development of CPGs relevant to their area of expertise. Through the Essential Medicines Programme, the National Department of Health leads the development of standard treatment guidelines used to inform rational prescribing at the primary, secondary, and tertiary/quaternary levels in an equitable and cost-effective manner. Individual disease clusters such as the tuberculosis (TB) cluster and the HIV syndrome cluster are responsible for producing their national disease-specific guidelines which are then distributed to provinces.

South Africa has been acknowledged as an emerging leader in the African region for guideline development [11], with multiple ongoing efforts by researchers and