#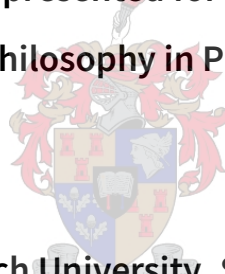 SOUTH AFRICAN PRIMARY CARE CLINICAL PRACTICE GUIDELINES: EXPLORATORY STUDY OF GUIDELINE DEVELOPMENT, IMPLEMENTATION AND USE

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Date: December 2019

Declaration

By submitting this dissertation electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third-party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

This dissertation includes four original papers published or submitted for publication in peer-reviewed journals, and two policy briefs (summaries of the studies). In addition, there are several published papers to which I contributed and that are relevant to the doctoral research that have been included in the thesis as supplementary papers. The development and writing of the thesis papers (published and unpublished) and the thesis overall were the principal responsibility of myself and, where this is not the case, a declaration is included in the dissertation indicating the nature and extent of the contributions of co-authors.

Signature:

Date: December 2019

Abstract

Strong primary health care is indicative of a functioning health system and a necessary precursor to universal health coverage (UHC). The South African government aims to strengthen primary health care and implement UHC. Within the national UHC strategy, clinical practice guidelines are named tools to support evidence-informed, cost-effective practice. However, if poorly developed, guidelines may hinder the quality of patient care; and, if not adequately implemented, they will have no impact. Against this backdrop, this dissertation aimed to explore the role-players, processes, barriers to and enablers of guideline development, implementation and use; and to suggest recommendations for improved guidelines for South African primary care.

Qualitative methods were used to engage role-players contributing to primary care guidelines along the continuum from guideline development through implementation to use. In-depth interviews were conducted with national developers (n = 37) and provincial managers (n = 22); and seven focus group discussions were held with healthcare providers (n = 47) from June 2014 to August 2016. The four provinces selected represented diverse health systems and social conditions (KwaZulu Natal, Western Cape, Eastern Cape and Limpopo). All recorded data were transcribed verbatim. Thematic content analysis was used for data analysis.

The initial phase engaged *guideline developers* who expressed the opinion that, overall, guidelines are an important means to ensure equitable and effective patient care and that the rigour of guideline development was improving. The study identified several factors which may negatively impact guideline credibility and implementability including inadequate human resources and funding for technical and methodological work; poor communication and coordination resulting in fragmentation between national, provincial, private and public sectors; lack of agreed development methods; poor management of potential conflicts of interest; and, insufficient consideration of implementation contexts. Participants felt these challenges could be mitigated by a committed guideline community working to reduce inequity. However, they thought improvements were currently being hampered by resource gaps which enable commercial or personal interests to drive development. Suggested solutions included national coordination of guideline activities which supports collaboration and transparency across sectors and disciplines.

The next phase explored the experiences of *guideline implementation.* Provincial and district managers, clinicians and trainers are supportive of guidelines as a tool for ensuring the delivery of quality healthcare services. They report having roles in guideline adaptation, implementation and evaluation but described feeling unsupported in these tasks. Two significant themes arose in this study - health systems and socio-

cultural-geographic factors. Health systems factors were financial constraints impacting access to guidelines and essential equipment/medicines; inadequate governance and audit capacity, and unclear accountability; insufficient skilled clinical staff; and, a need for interdisciplinary training and post-training mentorship. Socio-cultural-geographic factors considered to be important for improving guideline implementability were authentic consultation with end-users and implementers in the development stages to ensure feasible recommendations are made.

The last phase explored perspectives of *guideline use* finding that healthcare providers, mostly nurses and allied healthcare providers, were knowledgeable about guidelines, generally trusted their credibility and were motivated to use them. Nurses reported that guidelines provide confidence and professional independence where doctors are scarce. Barriers to guideline use were inadequate hardcopy distribution and digital access; insufficient and substandard photocopies; linguistic challenges (e.g. complicated language, no summaries or local language versions); lack of support tools (e.g. posters); limited involvement in development impacting feasibility or acceptability of recommendations; and, patchy training and insufficient post-training supervision.

Overall, the dissertation provides novel insights into the current state of primary care clinical guidelines in South Africa. The findings indicate that guidelines have the potential to strengthen primary health care in South Africa. The predominant view of guideline developers, implementers and users that guidelines add value to the health system creates a strong foundation from which to build. For further advancements the political environment needs to value and foster creativity, transparency and collaboration within and between guideline development and implementation groups to enhance guideline quality and acceptability.

Abstrakt

Florerende primêre gesondheidsorg is een van die aanwysers van 'n funksionele gesondheidsorgstelsel en 'n noodsaaklike voorloper van universele gesondheidsdekking (UGD). Die Suid-Afrikaanse regering het dit as 'n doelwit gestel om primêre gesondheidsorg te versterk en UGD in te voer. Binne die nasionale UGD-strategie word riglyne vir kliniese praktyk beskou as instrumente waarmee bewysgebaseerde, kostedoeltreffende praktyk ondersteun word. Swak uitgewerkte riglyne kan egter juis die gehalte van pasiëntesorg belemmer; en indien dit nie behoorlik deurgevoer word nie, het dit geen uitwerking nie. Dit is die agtergrond waarteen hierdie proefskrif die rolspelers, prosesse, hindernisse en instaatstellers wat met die ontwikkeling, deurvoering en toepassing van riglyne verband hou, wil ondersoek en aanbevelings vir verbeterde riglyne vir Suid-Afrikaanse primêre sorg wil aanbied.

Kwalitatiewe metodes is gevolg om rolspelers wat tot riglyne vir primêre sorg bydra, te betrek, vanoor die hele spektrum heen – vanaf die ontwikkeling tot die deurvoering en toepassing daarvan. Diepgaande onderhoude is met 37 nasionale ontwikkelaars en 22 provinsiale bestuurders gevoer, en sewe fokusgroepbesprekings is tussen Junie 2014 en Augustus 2016 met 47 gesondheidsorgverskaffers gehou. Die vier provinsies waaroor die navorsing gedoen is – KwaZulu-Natal, Wes-Kaap, Oos-Kaap en Limpopo – verteenwoordig uiteenlopende gesondheidsorgstelsels en sosiale omstandighede. Alle data op rekord is woordeliks oorgeskryf, en data-ontleding is aan die hand van tematiese inhoudsontleding gedoen.

Die riglynontwikkelaars wat in die aanvangsfase betrek is, was wat van mening dat riglyne, in die geheel gesien, 'n belangrike manier is om gelyke en doeltreffende pasiëntesorg te verseker en dat die standaarde in riglynontwikkeling besig is om strenger te raak. Die navorsing het verskeie faktore uitgewys wat die geloofwaardigheid en uitvoerbaarheid van riglyne nadelig kan beïnvloed, byvoorbeeld onvoldoende menslike hulpbronne en befondsing vir tegniese en metodologiese werk; swak kommunikasie en koördinering, wat fragmentasie in nasionale, provinsiale, privaat en openbare sektore veroorsaak; 'n gebrek aan ooreengekome ontwikkelingsmetodes; swak bestuur van moontlike belangebotsings; en onvoldoende oorweging van die kontekste waarin deurvoering moet plaasvind. Volgens die deelnemers kan hierdie uitdagings getemper word deur 'n toegewyde riglyngemeenskap wat daaraan werk om ongelykheid uit te skakel. Nietemin reken hulle dat verbeterings tans deur gebrekkige bronne gekortwiek word, wat 'n gaping vir kommersiële of persoonlike belange laat om die gang van ontwikkeling te bepaal. Voorgestelde oplossings is onder meer nasionale koördinering van werksaamhede in verband met riglyne, wat samewerking sal ondersteun, en deursigtigheid en geloofwaardigheid oor alle sektore en vakgebiede heen.

Die volgende navorsingsfase het ondersoek hoe mense die deurvoering van riglyne ervaar. Provinsiale en distriksbestuurders, klinici en opleiers is ten gunste van riglyne as 'n instrument om te verseker dat gesondheidsorgdienste van gehalte gelewer word. Hulle rolbeskrywings sluit die aanpassing, deurvoering en evaluering van riglyne in, maar hulle voel dat hulle nie in hierdie take ondersteun word nie. Hierdie navorsing het twee duidelike temas opgelewer: faktore rakende gesondheidsorgstelsels en sosio-geo-kulturele faktore. Faktore rakende gesondheidsorgstelsels is finansiële beperkings wat toegang tot riglyne en noodsaaklike toerusting of medikasie beïnvloed; ontoereikende bestuursbeheer- en ouditkapasiteit en onduidelikheid oor verantwoordbaarheid; onvoldoende opgeleide kliniese personeel; en 'n behoefte aan interdissiplinêre opleiding en post-opleiding-mentorskap. Onder die sosio-geo-kulturele faktore wat as belangrik vir verbeterde deurvoerbaarheid van riglyne beskou word, is egte beraadslaging met eindpuntgebruikers en deurvoerders, alreeds in die ontwikkelingstadiums, om te verseker dat die uiteindelik aanbevelings uitvoerbaar is.

Die laaste navorsingsfase het perspektiewe op riglyntoepassing ondersoek en bevind dat gesondheidsorgwerkers, meestal verpleegkundiges en verskaffers van verwante gesondheidsorg, goed ingelig is oor riglyne, gewoonlik die geloofwaardigheid daarvan vertrou en gedrewe is om dit toe te pas. Verpleegkundiges was van mening dat riglyne vertroue en professionele onafhanklikheid bring waar dokters skaars is. Hindernisse wat riglyne betref is onvoldoende verspreiding van gedrukte weergawes sowel as onvoldoende digitale toegang; onvoldoende en minderwaardige fotokopieë; taalkundige uitdagings (bv. ingewikkelde taalgebruik en 'n gebrek aan opsommings en weergawes in die plaaslike taal); gebrek aan steunmateriaal (bv. plakkate); beperkte betrokkenheid by die ontwikkelingsfase, wat 'n uitwerking op die uitvoerbaarheid of aanvaarbaarheid van die aanbevelings het; en ongereelde opleiding en gebrekkige post-opleiding-toesig.

In die geheel gesien, verskaf die proefskrif insig in die huidige stand van kliniese riglyne vir primêre sorg in Suid-Afrika. Die bevindings toon dat riglyne die potensiaal het om primêre gesondheidsorg in die land te versterk. Die oorheersende beskouing onder persone wat riglyne ontwikkel, deurvoer en toepas is dat riglyne waarde tot die gesondheidsorgstelsel toevoeg en 'n stewige grondslag vorm waarop voortgebou kan word. Met die oog op verdere vooruitgang moet die politieke omgewing die waarde van kreatiewe denke, deursigtigheid en samewerking binne en onderling tussen groepe wat riglyne ontwikkel en dié wat dit deurvoer, insien en dit bevorder ten einde die gehalte en aanvaarbaarheid van riglyne te bevorder.

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Abbreviations

CPG	Clinical practice guideline
EBHC	Evidence-based Healthcare
EDP	Essential Drugs Programme
EML	Essential Medicines List
HTA	Health-technology assessment
HICs	High-income countries
LMICs	Low- and middle-income countries
NDoH	National Department of Health
NHI	National Health Insurance
PC	Primary care
PHC	Primary health care
QI	Quality improvement
SAGE	South African Guidelines Excellence
SU	Stellenbosch University
UHC	Universal health coverage

Definition of terms

Clinical practice guidelines (CPGs)	CPGs are statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (Institute of Medicine, 2011). There are many synonyms for CPGs – in South Africa, we often use the term 'Standard Treatment Guidelines'.
Primary health care	Primary health care is centred on the individual, the family and the community. The support they receive for treating and preventing disease, and for protecting, maintaining and improving their health is integrated across health and health-related sectors. These include housing, water, sanitation, agriculture, education, social welfare, environment, trade and commerce, etc. Within the health system, the health services provide the principal and most direct support to the community (National Department of Health, South Africa).
Primary care	Primary care is first point of contact with, or the entry point into, the health system. Primary care constitutes the first level of care in a continuing healthcare process and would commonly be delivered at a clinic, health post or a private practitioner's surgery. Primary care focuses on personal health or individual healthcare and is predominantly curative (or therapeutic), preventive and rehabilitative in nature (Health Systems Trust, Health Review 2008).
Universal health coverage (UHC)	UHC is defined as ensuring that all people have access to needed health services (including prevention, promotion, treatment, rehabilitation and palliation) of sufficient quality to be effective while also ensuring that the use of these services does not expose the user to financial hardship (World Health Organization, accessed 21 April 2019, https://www.who.int/healthsystems/universal_health_coverage/en/).
Primary health care re-engineering	Enhancing primary health care through strengthening district managers. In addition to the district-management strengthening, this includes increasing ward-based outreach teams (community workers); integrated school health services and district clinical specialist teams (specialists that provide clinical governance including training).
National Health Insurance (NHI)	NHI is a health-financing system that is designed to pool funds to provide access to quality, affordable personal health services for all South Africans based on their health needs, irrespective of their socioeconomic status (National Department of Health, South Africa).

Essential medicines	Essential medicines are those that satisfy the priority healthcare needs of the population. Essential medicines are selected with due regard to disease prevalence and public-health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness. (World Health Organization, accessed 21 April 2019, https://www.who.int/medicines/services/essmedicines_def/en/).
Professional society	A professional association (also called a professional body, professional organisation, or professional society) seeks to further a particular profession, the interests of individuals engaged in that profession and the public interest (Wikipedia, accessed 21 April 2019).
Health-services research	Health-services research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to healthcare, the quality and cost of healthcare, and ultimately our health and well-being. Its research domains are individuals, families, organisations, institutions, communities, and populations (Lohr, Academy for Health Services Research and Health Policy, 2002).
Health-systems research	Health policy and systems research (HPSR) is a field that seeks to understand and improve how societies organise themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes. The objective is to promote the coverage, quality, efficiency and equity of health systems. (World Health Organization, accessed 21 April 2019, https://www.who.int/alliance-hpsr/about/hpsr/en/).
Policy brief	A policy brief is a concise summary of a particular issue, the policy options to deal with it, and some recommendations on the best option. It is aimed at government policy-makers and others who are interested in formulating or influencing policy (International Development Research Centre, accessed 21 April 2019, https://www.idrc.ca/en/resources/research-tools).

Chapter 1. Introduction and scope of work

Background

World Health Organization (WHO) member countries endorsed the 1978 Primary Health Care Alma Ata Declaration committing to developing primary health care as core national health policy (1). Primary health care, usually the first contact for people with the health system, aims to provide comprehensive, accessible, cost-effective care throughout a person's life (1, 2). A functioning primary health care system is considered indicative of a strong health system and a necessary precursor to achieving Universal Health Coverage (UHC)(2, 3). The UHC definition aligns with that of primary health care as it aims to ensure that 'all people have access to needed health services, including prevention, promotion, treatment, rehabilitation and palliation, of sufficient quality to be effective while also ensuring that the use of these services does not expose the user to financial hardship' (2-4). Ambitions for more countries to achieve UHC was re-iterated in the 2015 United Nations' Sustainable Development Goals (SDGs) agenda for 2030 in which Goal 3, dedicated to 'health and wellbeing', specifies targets for UHC as one of the indicators of success (5). Further, in 2018, the Alma Ata and SDG agenda for UHC were re-affirmed in the WHO and United Nations Children's Fund (UNICEF) led Primary Health Care Declaration of Astana (6).

However, despite clear goals and several multi-national agreements over several decades, a 2017 World Bank and WHO report measuring UHC success stated that at least half of the global population does not yet access basic health services (7). Furthermore, in 2019, the WHO included 'weak primary health care' in their list of top-ten threats to global public health (8). How best to address this gap between the aspirations for healthcare excellence and the current reality is complex. It is likely that the effect of politics, power and the social determinants of health play a part (9-11). In this complex situation, health-systems and services research on and about UHC is essential for taking the health agenda forward and stimulating the uptake of evidence-informed strategies (12).

In South Africa, like other under-resourced settings, there is an urgent need to improve the quality of primary health care to ensure good use of the limited funds, equity of access, and better patient outcomes (13, 14). The National Department of Health (NDoH) has indicated that patient outcomes in South Africa are poor relative to other middle-income countries with a similar health spend of 8.5% of the GDP (15, 16). In addition, South Africa has an entrenched two-tiered health system, including a private health sector catering for less than 20% of the population, alongside a faltering public-health system responsible for the remaining, mostly poor, South Africans (3, 17).

In line with the global agenda, primary health care strengthening in South African is a political imperative. The national government has introduced several programmes to improve health-service delivery over the past two decades including 'primary health care re-engineering' which aligns with global views about district health strengthening by empowering district managers; district outreach teams (community workers); integrated school health services and district clinical specialists (specialists that provide clinical governance including training) (18). More recently, South African government policies have committed to a major re-structuring of the current health system through their UHC policy which will be funded through a National Health Insurance (NHI) mechanism (3, 18-20).

Despite these strategies, primary health care in South Africa is faltering in its progress to achieve the goal of quality, integrated, patient-centred, accessible, affordable care and strategies are needed to aid progress (21, 22). In South Africa the new NHI policy outlines the challenges in the current health system and proposes overarching strategies to achieve UHC, but clarity on the specific steps to reach UHC is still a matter of debate. What is emphasised is the importance of enhanced clinical governance and treatment guidelines, also known as clinical practice guidelines (CPGs), are named tools for supporting evidence-informed, cost-effective patient care (3, 23).

High-quality CPGs bridge the gap between synthesised evidence, policy, context and patient choice . They are recognised as essential quality-improvement tools with a range of purposes including standardisation of care, informing funding decisions and improving access to care (24-28). CPG development and implementation activities have been evolving globally over decades. In order to understand the history, research and innovation in the CPG field, we published a literature review entitled *Guide to clinical practice guidelines: the current state of play* (25) [Appendix 1]. The review 'collates findings from an extensive document search, to provide a guide describing standards, methods and systems reported in the current CPG methodology and implementation literature'. This narrative review informed my understanding of CPG research globally and re-iterated the evidence gap in research and methods development emanating from low- and middle-income country (LMIC) settings.

Furthermore, understanding the landscape of CPGs globally, regionally and in South Africa has been informed by other CPG-related research in which I have participated. This includes the conduct of systematic reviews to inform WHO CPGs which provided insight into the process of CPG development undertaken by WHO (29-31). In 2010 we conducted an evaluation of WHO guideline processes and quality, a follow on from an earlier study in 2007 which criticised the WHO for their expert opinion based CPGs, and found improvements since the introduction of their Guidelines Review Committee and guidance manual (32, 33). We also evaluated CPG development quality using the AGREE II tool and assessed the credibility

of the content for five priority conditions in 14 countries of the Southern African Development Community (34) [Appendix 2]. We found that South Africa is a node of technical expertise in this field, with the number and quality of our CPGs exceeding that of our regional neighbours. Further, we identified the difficulty in the region and that a repository would be helpful for policy-makers, health managers and users (34). These findings were reflected in another cross-sectional analysis we conducted in which we mapped all of the CPGs in South Africa (35) [Appendix 3]. We found 171 CPGs had been disseminated since 2012 developed by many CPG contributors from both the private and public sectors, and at all levels of the health system, including Professional Association CPGs for specialists, hospital-level CPGs addressing specific contextual requirements, and the many NDoH CPGs (35). In addition to contributions to CPG development, South African researchers are global leaders in CPG implementation research, conducting studies evaluating CPG uptake for common primary care conditions such as HIV, asthma and tuberculosis (36-41).

Overall what is known in the field of CPG in South Africa is that South African policy-makers, academics and managers have been contributing to CPG development and implementation activities nationally, regionally and internationally for many decades. From a historical perspective, in South Africa's new democracy in the 1990s, CPGs were perceived to be important vehicles to address inequity entrenched during the apartheid era. Taking a lead from the WHO, the Essential Medicine List and Standard Treatment Guidelines committees were established to enhance equitable access to medicines and other technology throughout the country, particularly in previously disadvantaged provinces (42). Through Essential Medicine List-informed CPGs, government aims to increase their national purchasing power, decrease costs and increase access to essential care (42, 43). This becomes increasingly important in the context of UHC and the need to have CPGs that are credible and integrated across sectors and levels of care.

Therefore, despite innovative South African activities into CPG development and implementation for primary health care, there is room for improvement to reach global CPG standards (44, 45). In addition, information is lacking regarding the context and processes of CPG development, adherence to CPGs, and factors that improve their implementation, accessibility and use. This is particularly concerning when one considers the diverse contexts of care found across the country, and the limited resources available to underwrite South Africa's commitment to the WHO's call for 'health for all' (5, 46). Local research is therefore needed to better understand the continuum of CPGs from development, adaptation or contextualisation through to effective implementation and evaluation. Such knowledge may pave the way for better-focused and more effective and efficient interventions to improve healthcare outcomes.

It was against this backdrop that a broader project was established - the South African Guidelines Excellence (SAGE) project (http://www.mrc.ac.za/cochrane/sage.htm) funded as a Flagship Awards

Project by the South African Medical Research Council (SAMRC-RFA-IFSP-01-2013/ SAGE). The overarching goal of the Flagship funding was to support large-scale, innovative, interdisciplinary research projects to address health problems in South Africa. I was the project principal investigator, and my doctoral research comprised a component of the overall SAGE Project research.

SAGE was a multi-partner initiative to contribute to both understanding and improving standards and capacity for national CPG development, adaptation and implementation for primary health care (PHC). An outline of the project purpose is provided in an editorial we wrote (47) [Appendix 4]. The project consisted of several components. The five goals were:

Goal 1: Mapping primary care CPG development players and processes

Goal 2: Identifying and evaluating local CPG quality

Goal 3: Exploring barriers to and facilitators for CPG implementation and use

Goal 4: Development of an online CPG toolkit

Goal 5: Capacity building for CPG developers and implementers

Each Goal was led by a different research team. I was responsible for Goals 1 and 3 which used qualitative research methods and included my PhD research, alongside other research led by other researchers; Goal 2, 4 and 5 (led by colleagues at the University of South Australia and Stellenbosch University) used a variety of research methods including systematic reviews, cross-sectional designs and qualitative research methods to address their research questions and capacity-building deliverables. The protocol included several research components for the overall SAGE project, including research which formed part of this thesis. Full details of the protocol are provided in Appendix 5. For more information on the project see the website: www.mrc.ac.za/intramural-research-units/Cochrane-SAGE

Outline of doctoral research

Aims

To examine the players, context, processes, barriers to and enablers of South African primary care clinical practice guideline development, implementation and use; and to develop recommendations for enhancing primary care guideline development and implementation.

Research question

What are the current contexts, processes, barriers to and enablers of clinical practice guideline development, implementation and use for South African primary care?

Sub-questions

- Who are the stakeholders involved with South African primary care CPG development and implementation; what is the context in which this is done; what are the processes used; and what are drivers for and barriers to CPG development and implementation?
- What is the role of provincial government officials and district managers in receiving, adapting, disseminating and implementing primary care clinical practice guidelines in four provinces in South Africa?
- What are the perspectives of primary health care providers regarding the barriers to and potential solutions for increasing use of primary care CPGs in South Africa?
- What are the implications for policy and practice based on the findings of the research?

The thesis includes three published manuscripts, one submitted manuscript and two online policy briefs summarising the findings. An overview of the chapters as they relate to the research aim and sub-questions is provided in Table 1.

Table 1. Outline of the PhD thesis chapters

Chapter No.	Outline of research sub-questions and contents
Chapter 1	Introduction and scope of work - this chapter outlines the background to the research including primary health care, universal health coverage and the role of guidelines in this policy context. It also expands on the current status of guidelines in primary health care service delivery and the health system in South Africa.
Chapter 2	Paper 1 addresses the sub-question 'who are the roleplayers in primary care CPG development and what is their perspective about the context, barriers to and drivers of CPG development and implementation?'
Chapter 3	Paper 2 addresses the sub-question 'what are national primary care CPG developer's perceptions of the processes that should inform national CPG development, and their view of what is occurring in practice?'
Chapter 4	Paper 3 addresses the sub-question 'what are the barriers to and enablers of primary care CPG implementation from the perspective of provincial and district implementers in four provinces in South Africa?'
Chapter 5	Paper 4 addresses the sub-question 'what are the perspectives of CPG users working in primary care facilities in four provinces in South Africa about the barriers to and enablers of CPG use?'
Chapter 6	The policy briefs address the sub-question 'what are the implications for policy and practice based on the findings of the research?'

	They are summaries of the evidence from the manuscripts. - *CPG development:* evidence summary about the perspectives of primary care CPG developers and their suggested actions to enhance CPG development. - *CPG implementation and use*: evidence summary about the perspectives of provincial, district health managers and primary care providers and their suggested actions to enhance CPG uptake.
Chapter 7	Discussion and conclusion - this chapter reflects on the findings from all the studies and suggests key learnings, strengths, limitations and research gaps.

Overview of methods

The research was conducted using qualitative research methods. This approach enabled us to learn about the perspectives of the range of role-players involved with primary care CPGs from development to use (48-50). Using in-depth interviews with national developers and provincial managers provided insights into their individual views of the field of CPG development and implementation; whereas the focus group method used when meeting CPG users in primary care ensured that we could gather their joint stories and experiences, reflected in a clinic team where CPGs are part of patient care. Details about the methods and analysis are provided within the four manuscripts reported in Chapters 2 to 5. Reporting of the methods and analysis followed the Consolidated Criteria for Reporting Qualitative research (COREQ) (51).

Study setting

South African primary care and the health system

The research is embedded within South Africa's primary health care system, and specifically explores primary care (first point of contact) CPGs, rather than primary health care CPGs which address broader issues of infrastructure or planning for health-service delivery. Details about South Africa's primary health care system are given above and within each publication.

Sample population

We engaged 107 role-players involved with national primary care CPG development; provincial and district CPG implementation; and primary care health care providers involved with CPG use (Table 2). After initial interviews with national CPG contributors, we learned that there are discrete groups, with differing roles and responsibilities for primary care CPG activities, hence the sample includes three sub-groups: developers of national primary care guidelines; implementers in provinces and districts; and, guideline users/ healthcare providers in primary care facilities.

Development: National CPG development role-players included the public, private sector and pharmaceutical industry representatives, however, we interviewed relatively few of the latter two groups.

Sampling was done purposefully starting with individuals known to be involved with national CPG development. We then used a snowballing approach asking those we interviewed for suggestions of who else we should speak to. Following the initial 25 interviews, the research team suggested that our sample was weighted towards medical doctors and pharmacists and was not representative of all clinical disciplines involved with primary care service delivery who are likely to have CPGs. We therefore proceeded to purposefully identify and interview additional role-players to ensure a representative sample including all primary care disciplines (dentistry, nutrition, nursing, rehabilitation/allied health, pharmacists, medical doctors). It is notable that we interviewed more developers in richer provinces, which likely reflects the position of the largest academic centres that dominate policy formulation and research.

Implementation and use: When exploring CPG implementation and use, four provinces were visited, KwaZulu Natal, Western Cape, Eastern Cape and Limpopo. These provinces were chosen as they differ in population size and density, economic development, healthcare spend and resources, and health outcomes. While the Western Cape, Eastern Cape and Limpopo have similar population sizes, the Western Cape is better funded, and has higher educational levels, lower poverty levels and higher life expectancy. KwaZulu-Natal has the largest population size, a high poverty prevalence and poor life expectancy, despite health expenditure approaching that of the Western Cape. Other factors besides available funds, are likely to play a role in this regard, including a high prevalence of infectious diseases, such as HIV and the urban to rural distribution of health services (52).

Within each province we visited provincial offices and two districts representing rural and peri-urban or urban primary care facilities. We aimed to interview two to five managers in the provincial office, two district managers or trainers in each of the two districts visited and to facilitate two focus groups with primary care healthcare providers in the districts where we had spoken to the district managers. We used both purposeful and convenience sampling based on who was available for interviews and on recommendations of relevant role-players by the Provincial Research Management Offices. As the individual papers only present the specific sample population, to give an overall perspective, we report on the overall sample briefly described in the table below (Table 2).

Table 2. Overview of sample population in the PhD thesis

Stakeholder group	Description of sample
Developers: National	37 interviews

	- Disciplines represented included medicine (19), pharmacy (5), nursing (4), allied health (3), dentistry (1), nutrition (2), non-clinical managers (3) - Provinces included Eastern Cape (1); Gauteng (16); KwaZulu-Natal (3); Western Cape (17) - Roles or sectors included National (10) and Provincial Department of Health (2); Professional Societies (6); private sector (pharmaceutical industry 1; and medical schemes 2) (3); academia (14); non-governmental organisations (2)
Implementers: **Provincial and district**	20 interviews (22 participants) Previous clinical disciplines: nurses = 15, doctors = 7 *KwaZulu-Natal*: 4 interviews (1 in province, 3 in district offices) *Limpopo*: 4 interviews (2 in province and 2 in district offices) *Eastern Cape*: 6 interviews (2 in province, 4 in district offices) *Western Cape*: 6 interviews (5 in province, 1 in district offices)
Users: Healthcare providers	7 focus group discussions (48 participants) *KwaZulu-Natal*: Doctor, nurses, quality assurance officer, dentist, physiotherapist, counsellors (n = 12) *Limpopo*: Dentists, oral hygienist, occupational therapists, physiotherapists, dieticians, counsellors, database administrator (n = 17) *Eastern Cape*: Nurses (n = 12) *Western Cape*: Nurses, dentists, health promotions officer (n = 6)

Data collection and management

Negotiating access

Data collection took place between June 2014 – August 2016, starting with national developers, and proceeding with several trips to the provinces and districts. National developers generally had more autonomy to agree to participate than those in provincial roles. Provincial research is managed and monitored through the National Health Research Database (https://nhrd.hst.org.za/), and each province has their own Research Management Office. The processes and requirements of these offices delayed access in some cases. Provincial and district offices in the provinces had varying responses to requests for interviews. Some individuals were more familiar and comfortable with the process and value of research, while others were reluctant or, at times, suspicious of the purpose of the research, requiring multiple submissions of approval documents to gain access to them or their teams. We anticipated that the

province with greater research experience, the Western Cape, would be the most accessible, however, this was the last province to provide approval. Due to changes in job roles in their Research Management Office, we were only able to complete one focus group, rather than two in this province.

Preparation for interviews and analysis

To build relevant skills to conduct the planned qualitative research, SAGE hosted an in-house workshop on qualitative interviewing skills prior to recruiting participants. Furthermore, I completed a course offered for doctoral students on *Qualitative research methods: Practical approaches to qualitative research* in 2014 through a jointly offered Stellenbosch University and Karolinska University programme. I also attended the University College London's *Centre for Behaviour Change Summer School 2015: Behaviour Change – Principles and Practice*. At the outset of interviews, I received mentoring from experienced qualitative researchers. All interviews were attended by two researchers. I was the observer on initial interviews progressing to lead most of the remaining interviews. There was peer feedback following interviews to improve practice and reflect on skills and learning.

Interviews and focus group discussions

<u>In-depth interviews</u>

In-depth interviews were conducted in English with national developers and provincial health managers all linked with CPGs for primary care (Table 1). Data were collected using the semi-structured questions framework to elicit free-flowing information and ideas. Although guided by the discussion schedule, this was adapted iteratively as I discovered more about the research field and could therefore verify or clarify points made in previous interviews. The main intention was to elicit views regarding processes and context for CPG development, enablers of and barriers to CPG development and implementation, and to identify additional relevant role-players. The discussion schedule is provided in an appendix of the protocol [Appendix 5]. Interviews were usually conducted face-to-face, at the workplace or another convenient venue at the request of participants. Three interviews were conducted via skype or phone due to scheduling challenges or the participant's preference.

<u>Focus group discussions</u>

Focus groups, with primary care healthcare providers, followed a similar approach to interviews in that they were held in English and included two trained researchers, a lead facilitator and observer (Table 1). Focus groups included more diverse participants, and although we held these in English, at times, some of the junior staff chose to answer in their mother tongue. The few sections of non-English language text were translated by members of the research team. A focus-group discussion schedule is shown in the SAGE protocol [Appendix 5]. The guide was used initially, but adapted iteratively to reflect learning from earlier

focus groups and, ultimately, aimed to elicit the following from healthcare providers: What is your understanding of a guideline? What is process of guideline use? What are potential enablers of and barriers to using guidelines?

Ethical considerations

The Ethics Committees at the South African Medical Research Council (SAMRC) and Stellenbosch University provided approval (SAMRC ethics approval EC 002-2/2014; Stellenbosch University ethics approval N14/02/008). As the SAGE Project principal investigator, I was responsible for drafting the protocol with input and final approval from co-investigators. All participants provided signed consent prior to participation.

Chapter 2: Primary care guideline development: role-players, context, barriers and enablers

Summary: This qualitative study explored perspectives of national guideline developers regarding the prominent role-players in national guideline development and the context for development and implementation of primary care guidelines in South Africa. Furthermore, the interviews explored the possible barriers to and enablers of guideline development and implementation. We found that South African guideline development is led by national government but there is an active community of guideline developers spanning the private and public sectors. We found guideline development and implementation were hampered by a lack of financial resources for technical and methodological work; fragmentation between groups, and between national and provincial health sectors; and, a lack of agreed systems for CPG development and implementation. Some CPG contributors steadfastly work to improve processes aiming to enhance communication, use of evidence, and transparency to ensure credible guidance is produced. Many interviewed had shared values, and were driven to address inequity, however, resource gaps were perceived to create an enabling environment for commercial interests or personal agendas to drive the CPG development process.

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Related presentations:

Kredo T, Abrams A, Machingaidze S, Young T, Louw Q, Daniels K. Exploring current players, practices, processes and contexts of clinical guideline development for South African primary care Health Systems Trust Conference 2016, Boksburg, Gauteng. 4-6 May 2016 (poster).

Abrams A, Kredo T, Young T, Louw Q, Daniels K. Reported use and perceptions of value of Cochrane evidence by South African guideline developers. 23rd Cochrane Colloquium. Vienna, Austria. 3-7 October 2015 (oral).

RESEARCH ARTICLE   **Open Access**

Primary care clinical practice guidelines in South Africa: qualitative study exploring perspectives of national stakeholders

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Abstract

Background: Clinical practice guidelines (CPGs) are common tools in policy and clinical practice informing clinical decisions at the bedside, governance of health facilities, health insurer and government spending, and patient choices. South Africa's health sector is transitioning to a national health insurance system, aiming to build on other primary health care initiatives to transform the previously segregated, inequitable services. Within these plans CPGs are an integral tool for delivering standardised and cost effective care. Currently, there is no accepted standard approach to developing, adapting or implementing CPGs efficiently or effectively in South Africa. We explored the current players; drivers; and the context and processes of primary care CPG development from the perspective of stakeholders operating at national level.

Methods: We used a qualitative approach. Sampling was initially purposeful, followed by snowballing and further sampling to reach representivity of primary care service providers. Individual in-depth interviews were recorded and transcribed verbatim. We used thematic content analysis to analyse the data.

Results: We conducted 37 in-depth interviews from June 2014–July 2015. We found CPG development and implementation were hampered by lack of human and funding resources for technical and methodological work; fragmentation between groups, and between national and provincial health sectors; and lack of agreed systems for CPG development and implementation. Some CPG contributors steadfastly work to improve processes aiming to enhance communication, use of evidence, and transparency to ensure credible guidance is produced. Many interviewed had shared values, and were driven to address inequity, however, resource gaps were perceived to create an enabling environment for commercial interests or personal agendas to drive the CPG development process.

Conclusions: Our findings identified strengths and gaps in CPG development processes, and a need for national standards to guide CPG development and implementation. Based on our findings and suggestions from participants, a possible way forward would be for South Africa to have a centrally coordinated CPG unit to address these needs and aspects of fragmentation by devising processes that support collaboration, transparency and credibility across sectors and disciplines. Such an initiative will require adequate resourcing to build capacity and ensure support for the delivery of high quality CPGs for South African primary care.

Keywords: Clinical practice guideline, Primary care, Qualitative interviews, Guideline development, Guideline implementation, Universal health coverage

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Background

Since the first democratic elections in South Africa in 1994, there have been many initiatives aiming to transform the previously segregated and fragmented health sector [1, 2]. These include integrating the public health system at national level, shifting from racialised to integrated health departments; introducing a re-engineered primary health care (PHC) approach delivered through health districts; and, refocusing funding to priority programmes such as immunisation and HIV care [3]. Despite this, and the allocation of 8.5% of gross domestic product (GDP) to health care provision; South Africa's health outcomes are relatively poor when compared to other middle-income countries with similar GDP percentage expenditure on health [1, 3, 4]. In the public sector, inequalities in healthcare delivery and outcomes persist between urban and rural settings and within and between provinces [5]. In response to this inequality and the high burden of disease from communicable and non-communicable causes, and violence and injury; the Minister of Health is driving forward plans for universal health coverage (UHC), as described in the National Health Insurance (NHI) White Paper [6–9].

Quality of health service delivery must be of high standard for UHC to achieve its intended goal [10–12]. Clinical practice guidelines (CPGs) are a common knowledge translation tool in policy and practice, covering clinical decisions at the bedside, governance of health facilities, health insurer and government spending, and patient choices. CPGs summarise rigorously gathered evidence, distilled for use by healthcare providers to standardise and provide best-available care [13, 14]. Within the range of operational tools available for policy implementation, CPGs are recognised as central to clinical service delivery [15, 16].

The South African government has introduced several PHC quality improvement programmes, including appointing District Specialist Clinical Teams (DSCTs) to support services within health districts. The 'Ideal Clinic' programme was initiated in 2013 to systematically consider and ensure adequate infrastructure, human resources, good governance and equipment for primary care [8, 17]. This programme is governed by specific clinical policies, protocols and CPGs, and aims to involve stakeholders across government departments, the private sector and non-governmental organisations (NGOs) to address health and social needs. In part, the intention is to integrate the preventative and curative health services in a patient-centred manner [18]. The 'Ideal Clinic', based on PHC principles, includes the Integrated Clinical Services Management programme, which focuses on efficient, cost-effective chronic disease management [17, 19]. In this context, CPGs are specifically used as clinical training tools for the DCSTs, and as part of clinical audit criteria to assess a facility's attainment of 'Ideal Clinic' status [17].

South Africa has long contributed to CPG development with key players such as the National Department of Health (NDoH), clinical professional societies and NGOs producing guidance for their respective constituents. In particular, the NDoH's Essential Drugs Programme has been producing guidance documents since the mid-1990s to support equitable use of medicines in the public sector. Other research on CPG development has been conducted in South Africa, in particular, exploration of policy development processes for maternal health and there has also been a quantitative evaluation of the quality of CPGs for PHC [20–23]. What is lacking, however, is comprehensive information on the processes, context and challenges for PHC CPG development and implementation in South Africa. The NHI system will require agreement and integration across sectors and jurisdictions, and national CPGs will need to speak to healthcare needs of all to ensure equal service delivery and redress of ongoing 'fault lines' in the system [5]. This transition from the current health system arrangement to NHI provides a window of opportunity to explore the current 'state of play' of CPG development and implementation in order to inform NHI processes.

Currently, there is no available guidance on standard approaches to developing, adapting or implementing CPGs efficiently or effectively in South Africa. To address this gap, the South African Guidelines Excellence (SAGE) project was established as a multi-partner research initiative aimed at setting in motion a stakeholder-driven process to contribute to the understanding of standards of national CPG development, adaptation and implementation [24]. The project consists of several components, including a mapping phase, development of an online CPG resource, and capacity building opportunities for those involved in CPG development, implementation and research. During the mapping phase, a cross-sectional analysis of a sample of 16 PHC CPGs was completed, identifying the strengths and gaps, in relation to global standards for CPG reporting [23, 25]. We found that overall AGREE II scores were poor to moderate, mostly due to poor reporting of rigour of methodological approaches; applicability; and, editorial independence. These findings are of concern as they may impact on the credibility of South African CPGs. In this paper we examine these issues in more depth by identifying the current role players; drivers; and the context and processes of PHC CPG development from the perspective of national stakeholders [26].

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Methods

This research makes use of qualitative methods, drawing on an interpretivist paradigm to explore national role players' experiences in the processes of developing and implementing CPGs [26–28].

Research context

South Africa has a population approaching 55 million, with a health system invested in primary healthcare and district level ownership [8]. Fiscal federalism is in place in which national government designs strategies, policies and clinical CPGs; and provincial governments implement CPGs, sometimes after adaptation, to the levels of healthcare from regional, district to community based health centres [2]. Although government is responsible for CPG development and implementation, many role players contribute to CPG activities to fill clinical guidance gaps, possibly duplicating, and possibly omitting key health areas.

Sampling

Purposeful sampling began with consultations between the research team and CPG developers known to have a role in national CPGs [28]. Stakeholder groups included the NDoH, academics and researchers, specialist professional associations, medical schemes, NGOs, and the pharmaceutical industry. In addition, the five core NDoH-endorsed primary care CPGs were identified: Basic Antenatal Care, Integrated Management of Childhood Illness, the Essential Drug List (EDL) Standard Treatment Guidelines for primary care and Primary Care 101 (PC101), as well as a recently completed CPG for Health Promotion and these were used to guide sampling. We used a 'snowballing' approach in which a core group of individuals actively involved with CPG development or implementation in South Africa for primary care were invited to participate; these individuals were then asked to identify other 'key role players' for inclusion in the sample [28]. During the course of the study we recognised that some groups known to be involved with PHC service delivery or linked with the endorsed PHC CPGs had not been identified through snowballing. At interim analysis, the sample was dominated by doctors and pharmacists, thus, additional groups including allied health, dentistry, nursing, and nutrition were purposefully sought to fill gaps and achieve a satisfactory degree of representivity [28]. Those interviewed occupied senior managerial positions within government, academic or organisations.

Data collection and management

Interviewers received training in semi-structured interviewing techniques from a senior social scientist researcher. All but one of the interviews were conducted in pairs. Interviewers were all female and included various professions including clinicians (medical doctors, allied health professionals), social scientists and basic scientists, all with previous interviewing experience, and in analysis of qualitative data. The lead researcher, present at most interviews, has experience, as a doctor and specialist clinical pharmacologist, in using and teaching CPGs. She is also known to some of those interviewed and is involved with CPG activities at academic institutions and government which may have facilitated access to some interviewees, but could also introduce response bias. For this reason, it was considered important to have two interviewers per interviewee, one of whom who was not engaged in CPG activity, and thus would have more distance so as to ensure objectivity.

Invitations were emailed to potential participants requesting a suitable time and venue for conducting interviews. Participants were provided with information sheets and consent forms prior to their interview. We aimed to interview everyone in person, but four participants requested telephonic interviews. Most participants chose to be interviewed at their place of work, with one exception who opted to do the interview at home. Two of those invited referred us to other colleagues to interview. None of those invited dropped out or requested to withdraw once we started. Interviews lasted 60 min on average (ranging from 40 to 90 min). One interview was spread over two sessions due to time constraints during the first meeting. Before commencing, the focus of the project and purpose of the interview were discussed, and consent was reaffirmed, thereby ensuring that participants understood clearly why they were selected, what the interview was about and what their rights were. The semi-structured interview guide (see Additional file 1) was tailored to the experiences of each interviewee and each interview built on the findings of previous interviews. In other words, as the interviews progressed, assumptions, queries, and gaps in the evolving data set were clarified through further data collection. Data saturation was achieved prior to final interviews. The additional 10 interviews were conducted to ensure a representative sample and that no new themes emerged.

Interviews were recorded using a digital recorder. All interviews were transcribed by a third party, blind to the aims of the study. Transcriptions were reviewed for accuracy by members of the research team, but not by those interviewed, making changes as needed based on the audio files. Data is stored electronically on password-protected computers; a masterlist and the consent forms are stored in a locked cabinet to which the study lead has access.

Analysis

An iterative, thematic content analysis approach was used [29]. A team of four, initially deductively, read the first 24 transcripts to develop a coding list, maintaining a focus on the key research objectives, that is: players, process, context, drivers and barriers to CPG development or implementation [26]. Once this coding list was developed, a single researcher coded the remaining 13 transcripts independently. Coding lists were categorised by identifying common themes within the broad research question. All preliminary findings were presented and discussed with the team to verify further emergent themes at regular intervals until all interviews and analysis were completed (Additional file 2). A summary of the findings and emerging themes were presented to the larger project team – consisting of people who have experience in CPG development, PHC service delivery, and the South African healthcare context - for validation.

Rigour

To ensure rigour [27], we initiated the project ensuring the question was *relevant.* Our study may be of interest to the national policymakers or other researchers, and given the paucity of information on CPG activities in middle or lower income settings generally, this may have global relevance. We ensured *validity* through detailed description of our approach to sampling, data collection, data management, analysis. We considered *reflexivity* as described in the methods and limitations of the manuscript. The results are most *transferable* to the South African context – where history and politics have impacted on policy development. However, some findings may be *transferable* to other developing country settings where transparency and CPG processes are also in transition. There may also be *transferability* within South Africa and learning from primary care CPGs to other CPG development.

Ethics and reporting

The study was approved by the Research Ethics Committees of the South African Medical Research Council (EC002–2/2014) and Stellenbosch University (N14/02/008). All participants provided written informed consent. Names of participants were anonymised, however, it was explained to participants that despite efforts to maintain anonymity, their opinions might be recognisable in the reporting process. An opportunity for them to withdraw before or during the interview was provided (none took this opportunity), and to review how their opinions were conveyed in the final manuscript (some took this opportunity). We referred to the Consolidated criteria for reporting qualitative research (COREQ) reporting guidelines to ensure comprehensive reporting [30].

Results

Overall, CPG development is a complex web of interactions between players and organisations, informed by values, politics and power. Values reported include distributive justice, standardising care and equitable access to medicines. The process for CPG production differs by setting and group and is often poorly articulated. Silos of guideline activity, both nationally and provincially, potentially result in duplicated efforts for the often volunteer teams of technical experts. There is recognition of a transition to more robust processes in some CPG development groups. There is also recognition and acceptance of the need to improve further to align with international standards; however, the financial and human resources are lacking.

We conducted 37 in-depth interviews with high-level policymakers and CPG contributors from national and provincial Departments of Health; professional societies; for-profit groups including pharmaceutical industry and medical schemes; university academics; funders and technical advisors (Table 1).

Role players in CPG development
Public sector players

Those interviewed agreed that NDoH plays the central role driving and developing guidance documents through their various directorates, supported by partners, including academic institutions, funders and technical advisors from multi-lateral organisations such as the WHO and UNICEF.

> Guidelines is a big national Department of Health role … [INT06].

> It's the government who is pushing, the government which defined the date, the approach and so on and

Table 1 Description of stakeholders sampled (37 total)

Background discipline	Medicine (19), pharmacy (5), nursing (4), allied health (3), dentistry (1), nutrition (2), non-clinical managers (3)
Provinces represented	Eastern Cape (1); Gauteng (16); Kwazulu-Natal (3); Western Cape (17)
Sectors and stakeholder groups	National (10) and Provincial Department of Health (2); Professional Societies (6); Private sector (pharmaceutical 1; and medical Schemes 2) (3); academia (14); non-governmental organisations (2)

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as part of development partners, we go there to help. [INT23]

Within government there is a central programme developing CPGs particular oriented to the essential medicines list which is linked with streamlining national medicine and device procurement; and in parallel there are disease or topic specific programmes, such as HIV, tuberculosis, rehabilitation and nutrition, developing CPGs, with potentially overlapping content.

In addition to the NDoH CPG development efforts, medical schemes, professional societies, at times with pharmaceutical industry support, NGOs, provincial hospital or clinic level initiatives all develop CPGs where no or limited guidance exists. Participants, generally academics from outside of government, suggested that their role in CPG development emerged to address gaps in clinical guidance, not covered by NDoH.

But then some of the smaller, neglected diseases don't have a directorate at the Department of Health or whatever ... And so often those are undertaken by professional societies [INT06]

Organisations like the TAC [Treatment Action Campaign] that has driven the engagement and enabled professionals to actually engage with government and get good policies in place and develop good guidelines [INT18]

Furthermore, while PHC providers such as nurses play the central role in service delivery at PHC they are not seen to be driving CPG activities nationally, and were described as noticeably absent in leading roles except perhaps in consultation processes or external review of documents.

Private sector players
Private health insurance is an important player in clinical care in South Africa. Funding of medicines and devices is decided through advanced systems and committees within each scheme. Insurers are governed by the Council for Medical Schemes who develop the prescribed minimum benefit packages - however, updates to these have not been promulgated for more than a decade. Some participants described how the essential medicines programme should form the basis of the prescribed minimum benefit and ideally, aligning private sector with national government.

Ultimately the view is to change the legislation with regard to private health care to make sure that this essential medicines list forms the basis of this minimum benefit package and then you remove a

whole bunch of inequity out of this private health insurance [INT11]

At the end of the day, as we go into an NHI, this divide should not exist [INT14]

The pharmaceutical industry, another private player, may contribute evidence to medical schemes, professional societies and government to encourage investment in their health technology. They provide grants to support some professional society guideline development. Beyond the guideline development they impact pricing of medicines, and influence practice of clinicians.

We have over the years been very conscious of the role and the influence of industry in shaping decision-making, even within the various well-respected national societies [INT18]

Consulting end-users and external groups
Although NDoH aims to involve various sectors and interest groups through workshops and consultation during CPG development, the need for tangible engagement from stakeholders was described as a key area for improvement.

we had people from facilities, we had nurses at different strata, you had unions and you had nurses from facility level giving input to that scale-up plan which is very specific and thus you can say a guideline for getting your clinic to function optimally ... we also involve the civil society organisations, our donor partners and the NGO's that, we call them implementation partners funded by the donor partners, and then other government departments and also private sector organisations [INT27]

We tried, really tried by all means to involve all the stakeholders because with just us alone we won't be able to, to reach you know everybody who really needs to be involved in addressing that particular problem ... I do not think we have really found a better, you know, a better mechanism of really, you know, engaging the people who are, who are at the frontline of implementation on how do you really want us to package some of this document [INT37]

Values and drivers for CPG development
The dominant view expressed by participants was that CPGs are valued for supporting delivery of standardised, equitable healthcare, especially in the post-apartheid South African context to ensure access for all to PHC. CPG development was driven by the same complex influences as other health policies [31], despite different

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disciplinary and ideological backgrounds. According to our participants the values included commitment to the NDoH's tagline "health for all" [INT04]; addressing historical inequalities; and standardisation of quality and cost-effective healthcare.

Driver: equity

The need for greater equity was raised in both public and private sector interviews. As a function of government, the NDoH's Essential Drugs Programme, was viewed as promoting change from the earlier fragmented health systems arrangements and the principles of equity of access to medicines [32].

> the essential drugs programme basically brought together all the formularies from the different homelands throughout South Africa, and tried to level the playing fields to make sure that there is equity in the way medicines are made available and accessible ... So we don't want that disparity between provinces [INT16]

Contrary to this, the medical schemes legislative environment was reported to encourage competition rather than collaboration which raised concerns regarding how this may perpetuate inequity and inappropriate spending.

> And we need to make sure our policy is fair, transparent and equitable within the context of the benefit designs that are ... there are a lot of anomalies in private healthcare because it is hopelessly inequitable. Even the legislation with regard to private health care coverage is inequitable but we are sort of constrained within the sort of legislative environment that we operate in. And so we need to find a mechanism to be able to operate properly within that [INT11]

Drivers: personal, fiscal or political interests

Although equity was a dominant driver, participants discussed the prevalence of personal, fiscal or political values or agendas amongst academics, the pharmaceutical industry or other commercial enterprises and international organisations. In addition, CPG development was described as being driven by priorities of funders including NGOs, international donors or industry for new research or products.

> One of the big issues ... is who is driving its development and why. And if you think about why people develop guidelines, it's actually the fact that a massive amount is driven by industry, and then it's driven by the needs to some extent and personal interest to another extent. [INT20]

> Everybody brings a bias to the table and WHO is a really sore point with a lot of our experts because they're writing policy for .... Africa right, they're writing public health policy ... If anybody should be, we should be telling WHO what to do [INT08]

As CPG development is poorly funded, participants perceived this as an opportunity for the pharmaceutical industry to fund development through unrestricted educational grants, which in turn may undermine the independence and credibility of a CPG. However, this view was not shared by all within academia and professional societies, as in some cases limited funding and the needs of constituents were valued above potential conflicts of interest. It was also suggested bias was perceived as the norm rather than the exception in CPG groups within professional societies.

> we are critically dependent on drug companies. No one else is willing to fund guidelines. I mean, theoretically, if one looked at it in its purest form, the department of health should be funding all of this. They should be intricately involved – we should all be doing it together – but they don't. They don't at all [INT19]

Processes in place for CPG development

As we explored the deductive categories of players, drivers, context and process of CPG development, several sub-themes emerged including the perceived challenge of fragmentation of CPG development and implementation processes; human skills and resource shortages; and, gaps in standardised systematic methods.

Fragmentation: socio-political environment impacts CPG processes

> So all are little silos inside other silos [INT20]

Participants described fragmentation affecting both CPG development and implementation, with most expressing concern regarding inefficient use of limited human and funding resources. Fragmentation occurred between national departments, between the private and public sectors, between national and provincial departments of health, between provinces and within provinces and districts.

Fragmentation impacts development

The fragmentation within government programmes, and between the public and private sectors is described as predominantly affecting CPGs production. Silos within NDoH processes, where individuals work in closed teams, not communicating effectively across departments, teams or working groups, were thought

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to result in duplication, poor resource use and gaps in recommendations. For example participants explained that directorates may produce parallel guidance to that produced by another group or professional society. Some participants described improving coordination of CPG development processes, however, not consistently or universally. The slow progress in addressing known issues of fragmentation was attributed to the limited capacity (administrative, organisational) and inadequate financial resources from central government.

> There is nothing in the department of health that will take on community acquired pneumonia guidelines. Where does it fall? It doesn't fall into any directorate. So the societies have traditionally done this [INT06]

Poorly coordinated national CPG development is perceived to have knock-on effects as healthcare providers receive conflicting guidance, in turn hampering implementation.

Fragmentation impacts implementation
Participants described a disconnection between national and provincial government, suggesting this resulted in CPGs which lacked legislative power to enforce standardised implementation and impact service delivery. These responses reflects South Africa's fiscal federal-oversight system, in which national government develops policies and provinces have independence to implement [33]. This form of governance may perpetuate disparity between provinces, however, there is recognised complexity given that each province has different infrastructure, governance strengths and capacity to adapt and implement policies.

> the whole national - provincial problem is a huge issue that this country has to kind of sort out ... There is incredible frustration in that they [National Department of Health] don't have the power and the provinces can kind of, they may say sort of set this policy but they can't enforce it and no one is reporting, there's no accountability [INT08]

Despite concerns about differences between provinces, global best practice suggests that CPGs should be adapted to local contexts. South African provinces have vastly different contexts, including resources, cultures, and infrastructure that require context-specific adaptations. Thus, as expressed by some, there is an inherent tension in trying to develop CPGs as national standards, when needs might demand different regional or district approaches.

Resource shortages: human capacity and time
Most participants expressed anxiety about lack of technical skills, dedicated time and funding for quality CPG development. This perceived 'insurmountable task' was thought to have a knock-on effects resulting in challenges with transparency and falling short of international standards.

> I sympathize with the department on a lot of levels because they don't have the resources, they're constantly fighting fires but now it's just not appropriate anymore to have this, policy making should be transparent, it should be thought through, it should not be something done hurriedly [INT08]

> As soon as you look at this process it becomes almost insurmountable. Essentially, what is international consensus on how it should be done, and then the reality is that there's just a mass of work to be done to combat that load to be correct, even if you were just to perhaps redevelop from scratch, which is something you should probably do. And there probably isn't the resources either in-house, or even if you were to spread it out, to get everything up and running at the same time [INT20]

Human capacity shortages
Of the limited human resources, medical doctors appeared to dominate the national primary care CPG development groups, followed by pharmacists; with other disciplines working in parallel within different government directorates. Nurses were generally not part of national guideline groups.

> You know, there are very few people who can actually develop the guidelines from nursing. Very few people have that expertise – almost no one [INT18]

Many individuals interviewed mentioned that volunteer clinical experts and members of guideline groups had multiple roles over and above their usual positions. They were often tasked with methodological work of searching for, appraising and synthesising evidence. The same experts may also be involved with CPG design and implementations. Some recognised this as a weakness, while others accepted this as the reality of low-resource environments.

> So they go through a lot of, it's a lot of work, first of all, people who are doing other jobs [INT06]

Lack of skills transfer in guideline groups
CPG development was seen by some as being dominated by the same individuals often included in CPG panels

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over many years. Limited capacity was felt to be, in part, a consequence of poor succession planning within government.

> *I mean, you know, some of these folks have been involved forever [INT08]*

Some participants suggested that this hampered a handover of skills. More inclusive CPG panels were desired as an opportunity for 'on the job' capacity building, but at times, experienced members were lost prior to new members being adequately capacitated. Some participants were encouraged by the addition of new panel members – which they viewed positively as allowing the development of more transparent, inclusive processes.

Conflicts of interest: funding drives agenda

Participants suggested that when skills to conduct the necessary technical work are deficient, groups with financial or other vested interests, often linked with pharmaceutical industry, may use the opportunity to drive their interests for marketing their health technologies. A lack of capacity to synthesise evidence could result in a reliance on the industry for support. Pharmaceutical players have resources to package evidence or fund CPG activities. The implication is due to the resource shortages described the industry may exercise their influence.

> *Now that process is terrible because a lot of the clinical colleagues do not have the skills to put an evidence based discussion together, so that's where a lot of the conflict comes in. They get the industry to write them [INT01]*

Gaps: lack of systems for CPG development
No standardised processes for development

CPG development is not uniformly organised within the different NDoH programmes.

> *It's chaotic, it's uncoordinated, it's opaque [INT08]*

Participants suggested some programmes had structured systems while other programmes' processes were perceived as "ad-hoc" or "chaotic" or in the case of private sector, guided by outdated protocols.

> *Well, I don't know what happens. They seem to be like a complete black box [INT03]*

> *told by the minister, you know, like we need these guidelines out immediately. And then you'll get stuck into it, and then there will be a new HoD [head of department], and then there will be a new this and*

there will be a new that. You know, the process is just very, very chaotic locally [INT14]

> *For instance, like the PMB [prescribed minimum benefit] guidelines, the algorithms are really a mess at the moment. They were published 15 years ago or whatever, and they are just a little one-pager with a few little lines. And they were extensively updated five years ago…. and they are still not promulgated. The private sector is sitting in a vacuum because the medical aids by law only have to fund to that level [INT18]*

Some CPG development groups such as the NDoH Essential Drugs Programme, established with good intentions during the post-apartheid period, were described as improving their processes over time; having put in place rigorous CPG development approaches. They were also criticised for poor communication and lack of transparency in decision-making. This group has explicit documents for ensuring interests are declared and confidentiality respected [34]. What is not apparent in the available documents is how transparency can be improved and processes shared to build public trust. Participants from outside government tended to have less trust in the government processes due to unsatisfactory experiences with trying to contribute to the CPGs which seemed to lead to reluctance to buy-in from some individuals and groups.

> *I mean the EDL seems like a very well-run process. Now I mean I have issues with the EDL not being transparent, I mean I think I would like to see minutes, I think as public sectors, you know, public funds and that sort of thing, we're entitled … [INT08]*

> *And I think we have to really consider what the best means is of documenting evidence and then sharing that evidence in order to get buy-in [INT21]*

Managing conflicts of interest

Our academic participants often held multiple roles, both for government and their institutions. Those involved with professional societies reported their desire to collaborate with or be endorsed by government. Some societies seemed to be successful in working with government or identifying independent funding to develop CPGs, however, most were described to rely on pharmaceutical companies. Some members of professional societies were described as receiving funding from many industry sources, but the processes for reporting or managing these potential conflicts differed.

> *Everyone is going to have a conflict of interest, because everyone is going to have to have received funding*

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from someone for something ... So the answer is probably yes, we should, but I think at the end of the day it's probably not practical [INT19]

Transition to better processes

Participants indicated that improvements are needed for CPG development to meet global standards, however, some reported that over the past 20 years there has been slow but persistent progress and a shift to increasingly transparent systems and methods for CPG development.

I think guidelines have come a long way, I think they're much more evidence based [INT06]

There's a keen awareness that it could be done better and that there should be some sort of debate [INT21]

The commitment of CPG developers to advance CPG processes is an influential enabler of continued progress.

Implementation processes lag behind

Several participants complained that CPG implementation is lagging and requires additional specific skills and adequate funding to ensure recommendations reach end-users and contribute to improved patient outcomes.

in terms of guideline development there's still a lot of work that needs to be done, but in terms of implementation there's more work that needs to be done [INT16]

For the most part, national CPG developers, had fewer responses to questions regarding implementation, and referred us to provincial players to explore this further.

Discussion

Global reporting for CPGs requires adherence to several quality standards including a description of a clear scope for the CPG; inclusion of all relevant stakeholders in development; rigorous methods for finding and assimilating evidence; and ensuring conflicts of interest and funders interests are recognised and managed [14, 35]. Yet there is evidence that South African CPGs fall short of quality reporting standards [23, 36]. We sought to explore the reasons behind this through the perspectives of national stakeholders regarding current processes, drivers, enablers and barriers for primary care CPG development. Our analysis suggests that the context and processes for CPG development represent a complex network of interactions, informed by values and power. There are multiple stakeholders, across government departments, healthcare disciplines, and sectors contributing to CPGs with varying skills and intentions. The NDoH is the key role player in CPG development for

the public sector, with professional societies and other organisations filling in gaps (i.e., topics where guidelines do not exist, or in situations where guideline updates have not been undertaken for a number of years). Despite the common view that CPGs are valued for supporting delivery of standardised, equitable healthcare, there is also a belief that CPGs may in some instances be manipulated by commercial, personal or other interests.

CPGs aim to address health inequity as reflected in the national policies and plans for PHC reform. CPGs are specifically mentioned as useful tools to assist several key programmes including the NHI and the 'Ideal Clinic' [15]. In light of the intended transition to UHC through the proposed NHI funding system, private and public-sector CPGs will need to be aligned to ensure equitable access to quality healthcare services [7, 9]. In this context, concerns were raised regarding the parallel private and public healthcare system wherein private insurers operate independently from national government. The out-dated clinical protocols and Prescribed Minimum Benefits packages mean that private sector funders have freedom to drive healthcare decisions based on criteria other than best evidence or cost-effectiveness. The current proposal for NHI recognises this deficiency, and proposes revision of the medical schemes Prescribed Minimum Benefits and for health technology assessment to underpin clinical recommendations [9].

Processes for CPG development in SA

The slow progress experienced in improvements in the health system and the fact that issues like fragmentation still persist has been highlighted in other health systems research [5]. Despite the introduction of key health policy reforms [5, 37], historical issues like fragmentation, human resource challenges and paucity of standardised systems continue to hamper progress in all areas of healthcare delivery [38]. Interviewees consistently reported concerns about the fragmented health system and its impact on CPG development and implementation. Fragmentation of CPG development may be understood to reflect these longstanding weaknesses in available systems resulting in opaque methods for CPG development; possible duplication due to lack of central oversight and communication between national CPG development groups; under-resourcing of people with specific skills to develop and implement CPGs; and, gaps in feedback and communication systems between stakeholders.

Several well-credentialed international groups have developed standardised methods outlining key steps to ensure trustworthiness of the final CPG [13, 39, 40]. We found that no such guidance exists in South Africa, and most interviewees described ad hoc processes, including inadequate consultation, and poorly managed conflicts

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of interest which may result in biased CPG recommendations, and diminished buy-in for CPGs [41]. These deficits may, in turn, impact on implementation. Implementation particularly was an issue of the national-provincial disconnect, however, only few of those interviewed were closely involved with implementation as this is largely the responsibility of provincial government.

Lack of adequate Human Resources for Health is a commonly reported problem in South Africa, particularly in rural districts [2, 5, 42]. For CPGs, we found that there is a limited pool of skilled contributors to CPG development, who are often working voluntarily or for limited remuneration and are overburdened. The specific technical skills gap identified includes capacity to synthesise and incorporate evidence; regular communication on CPG processes with stakeholders; and design and implementation for CPGs.

Limitations and strengths

Limitations of our study include potential for sampling bias. Our sample is dominated by medical professionals, many from Gauteng and Western Cape Provinces. Our sample probably reflects the reality of skewed power dynamics in CPG development in South Africa, where many who lead national knowledge production, and therefore are able to contribute their voluntary time to the process, may be based in the Western Cape and Gauteng. To minimise and mitigate this potential bias, we allowed for snowballing for any and all national contributors to CPG processes; in addition, we purposively sampled across all primary care disciplines. The skew sample suggests that CPG development needs to become more inclusive of different disciplines in different provinces throughout South Africa. Another possible limitation is response bias as those interviewed are all active members in CPG development and likely to be positively inclined towards the value of the work. Therefore, we explored the players, drivers, processes and context rather than the perceived value of CPGs. Another potential limitation is the impact of where researcher team members are 'situated', their institutional affiliation, and perceived credibility also called 'positionality' [31]. Positionality may facilitate gaining access to policy-makers and discussion of sensitive issues and it may allow for interpretation of nuanced cues, but may also skew responses, similar to the Hawthorn effect [28, 31]. Generally one of the interviewers was from Cochrane South Africa, a recognised specialist unit for evidence synthesis. However, the senior experienced policymakers and CPG contributors interviewed were thought to be peer level to the interviewers and less likely to be influenced by power dynamics commonly ascribed to interviewer/interviewee relationships [28].

Our study also had several strengths such as the teams' prior training in qualitative interviewing; pre-knowledge of the CPG context, augmented by speaking to experts; the inclusion of members from different disciplines who could point to gaps in the process, thus enhancing rigour; and, reaching a range of participants, including senior members of the NDoH.

What does it mean for SA CPG developers and development?

We found overwhelming commitment by those involved and slow but consistent transition to improving systems and processes. Commonly shared values regarding addressing inequitable clinical service through improved access to medicines and care defined by good quality CPGs may serve as an enabler to further processual improvements. Based on our findings, we feel that the key areas requiring attention include the need to reduce fragmentation by considering central coordination of CPG activities with buy-in from public-private stakeholders and ongoing communication between stakeholders already involved. We recommend that this be underpinned by agreed national standards and processes for CPG development and implementation, considering different provincial contexts. Finally, we feel that resourcing of activities is key to develop capacity to conduct methodological work, support clinical recommendation decision-making using transparent processes and improve communication, dissemination and implementation.

Conclusion

As South Africa transitions towards the NHI system and the ideal of "health for all" there is an opportunity to reflect on lessons learned from PHC CPG contributors, and build on global experience and knowledge. WHO's PHC Alma Alta Declaration states that PHC is a fundamental right and that 'primary health care is essential health care based on practical, scientifically sound, socially acceptable methods and technology' – in our context, CPGs provide the bridge and process through which this may happen [19]. However, South Africa is among many countries with faltering progress in advancing principles of WHO's Alma-Ata for universal access to PHC [19, 38]. The data suggests that the current parallel private-public health systems pose a substantial challenge to uniform healthcare access. Participants describe commitment on the part of government, and those who support government in their CPG endeavours, to build collaborative, transparent, adequately funded and staffed systems that foster communication and encourage efficient use of the country's scarce resources. A national CPG coordination unit could assist to develop credible, efficient structures to address the challenges identified.

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Additional files

> **Additional file 1:** Interview schedule for semi-structured interviews (Table of questions asked to participants). (DOCX 13 kb)
>
> **Additional file 2:** Analysis – Sub-themes for theme context (Codes generated from the analysis). (DOCX 16 kb)

Abbreviations
COREQ: Consolidated criteria for reporting qualitative research; CPG: Clinical practice guideline; DSCT: District specialist clinical teams; EDL: Essential drug list; GDP: Gross domestic product; HOD: Head of department; NDoH: National department of health; NGOs: Non-governmental organisations; NHI: National health insurance; PC101: Primary care 101; PHC: primary health care; PMB: Prescribed minimum benefit; SAGE: South African Guidelines Excellence project; TAC: Treatment action campaign; UHC: Universal health coverage

Availability of data and materials
Interview data may be linked to individuals interviewed and as such is not available open use. Should anyone wish to have access or is interested in further exploration of the data, you may contact the author: tamara.kredo@mrc.ac.za.

Authors' contributions
TK drafted the protocol with input from TY, QAL, KD and AA. KD provided interview and analysis training to the team, as well as oversaw the rigour of the data collection and analysis process. TK, AA, KD, TY, QAL contributed to interviews; initial analysis and coding was by TK, AA, KD and another researcher; AA coded remaining interviews; development of coding and analysis with TK, KD; final verification of coding with TY, QAL, JV. TK drafted the manuscript, all authors contributed to versions of the manuscript and approved final draft.

Ethics approval and consent to participate
The study was approved by the Research Ethics Committees of the South African Medical Research Council (EC002–2/2014) and Stellenbosch University (N14/02/008). All participants gave written and verbal informed consent to participate.

Consent for publication
Not applicable.

Competing interests
TK has contributed evidence to the National Department of Health Essential Drugs List Adult level standard treatment guideline (non-funded); and facilitated workshops and capacity development for under and post-graduate students, researchers, policymakers and practitioners on clinical practice guidelines and evidence-informed practices. AA has no competing interests to declare. AA has advised at international level on clinical trial oversight, and teaches on topics related to ethics, social science and medicine, public engagement, anthropology and sustainability. She has no vested interest in CPGs. TY has facilitated workshops and capacity development for under and post-graduate students, researchers, policymakers and practitioners on clinical practice guidelines and evidence-informed practices. QAL has facilitated workshops and capacity development for under and post-graduate students, researchers and practitioners on clinical practice guidelines and evidence-informed practices. JV has been involved in advisory committees for clinical guidelines in the Western province, and has facilitated workshops and capacity development for under and post-graduate students, researchers and practitioners on clinical practice guidelines and evidence-informed practices. KD is on the Editorial Board of this journal. She is not involved in CPG activity.

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Chapter 3: Primary care guideline development: processes for development

Summary: This qualitative study was an in-depth exploration of the processes that underpin primary care guideline development including perceptions from national contributors regarding what they think should be happening and their descriptions of what the processes currently are.

We identified six specific processes that should be strengthened to more effectively develop national primary care guidelines, these include: 1) use of evidence; 2) enhanced stakeholder consultation; 3) processes for transparency; 4) better management of interests; 5) enhanced communication/co-ordination between guideline development groups; and, 6) consideration of the need for 'fit-for-context' guidelines applicable in provinces.

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6069850/pdf/12961_2018_Article_348.pdf

Related publications and presentations:

At the SAGE Project start, we planned an editorial series for the *South African Medical Journal* outlining different aspects of guidelines and an overview of the project purpose: Kredo T, Machingaidze S, Louw Q, Young T, Grimmer K. South African Guideline Excellence (SAGE): What's in a name? *S Afr Med J.* 2016;**106**(1):18-20. [Appendix 4]

The remaining papers are available at: http://www.mrc.ac.za/intramural-research-units/Cochrane-SAGE

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National stakeholders' perceptions of the processes that inform the development of national clinical practice guidelines for primary healthcare in South Africa

Tamara Kredo[1†], Sara Cooper[1*†] , Amber Abrams[1], Karen Daniels[2,3], Jimmy Volmink[1,4,5] and Salla Atkins[6,7]

Abstract

Background: There is increased international focus on improving the rigour of clinical practice guideline (CPG) development practices. However, few empirical studies on CPG development have been conducted in low- and middle-income countries. This paper explores national stakeholders' perceptions of processes informing CPG development for primary healthcare in South Africa, focusing on both their aspirations and views of what is actually occurring.

Methods: A qualitative study design was employed including individual interviews with 37 South African primary care CPG development role-players. Participants represented various disciplines, sectors and provinces. The data were analysed through thematic analysis and an interpretivist conceptual framework.

Results: Strongly reflecting current international standards, participants identified six 'aspirational' processes that they thought should inform South African CPG development, as follows: (1) evidence; (2) stakeholder consultation; (3) transparency; (4) management of interests; (5) communication/co-ordination between CPG development groups; and (6) fit-for-context. While perceptions of a transition towards more robust processes was common, CPG development was seen to face ongoing challenges with regards to all six aspirational processes. Many challenges were attributed to inadequate financial and human resources, which were perceived to hinder capacity to undertake the necessary methodological work, respond to stakeholders' feedback, and document and share decision-making processes. Challenges were also linked to a complex web of politics, power and interests. The CPG development arena was described as saturated with personal and financial interests, groups competing for authority over specific territories and unequal power dynamics which favour those with the time, resources and authority to make contributions. These were all perceived to affect efforts for transparency, collaboration and inclusivity in CPG development.

Conclusion: While there is strong commitment amongst national stakeholders to advance CPG development processes, a mix of values, politics, power and capacity constraints pose significant challenges. Contrasting perspectives regarding managing interests and how best to adapt to within-country contexts requires further exploration. Dedicated resources for CPG development, standardised systems for managing conflicting interests, and the development of a political environment that fosters collaboration and more equitable inclusion within and between CPG development groups are needed. These initiatives may enhance CPG quality and acceptability, with associated positive impact on patient care.

Keywords: Clinical practice guideline, Primary healthcare, Qualitative study, Guideline development

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Background

Clinical practice guidelines (CPGs) have become a familiar tool in policy and clinical practice. CPGs have a range of purposes, intended to improve the efficiency and cost-effectiveness of health system utilisation and to decrease preventable mistakes [1]. They generally include statements of expected practice, benchmarks against which individuals may audit and potentially improve their practices, and guidance regarding undertaking given tasks [1]. CPGs were historically built mostly on expert opinion, which included variable (and often selective) reference to research evidence [2–4]. However, over the last decade there has been increased focus on improving the quality of CPGs and the methodological rigour of their development [5]. Globally, health system pressures are increasingly demanding that resources are effectively allocated and based on research evidence of 'what works' [6]. Within this context, there is growing recognition that high quality, evidence-informed CPGs can serve as practical vehicles for meeting these demands and reducing the gap between evidence, policy and best practice [1, 7].

This maturing CPG development culture is evidenced by the various recent attempts made by well-credentialed international collaborations to standardise and improve the credibility of CPG development practices [8]. Between 2011 and 2013, three sets of standards were independently proposed to assist CPG developers in addressing key issues of quality, as follows: the Institute of Medicine introduced 8 standards for guideline development [9], the Guidelines International Network produced 11 relatively similar standards [10], and McMaster University compiled a checklist of 18 topics and 146 items to guide developers [1]. Concurrently, two checklists (the AGREE II instrument [11] and iCAHE guideline quality checklist [12]) were developed, both providing tools to evaluate the process of CPG development and the quality of its reporting. While there are differences between these standards, they are unified in advocating for CPG development to be guided by transparently constructed and evidence-informed approaches that have a clear and applicable scope and are integrated with stakeholder consultation [8].

Despite a growing knowledge industry centred on CPG development, little is currently known about this topic in low-resource settings generally and in sub-Saharan Africa (SSA) in particular [13–15]. While numerous studies in high-income countries (HICs) have investigated the quality of CPGs and their development methodologies in a variety of settings [16], very few of these studies have been conducted in SSA. For example, a systematic review evaluating 42 guideline appraisal studies, including 626 guidelines published between 1988 and 2007, found only 6 guidelines across the

studies were from Africa [17]. Nevertheless, the situation is beginning to change, with the topic receiving more empirical attention in SSA over the last 5 years. For example, recent quantitative reviews have evaluated the quality of CPGs for priority diseases in SSA generally [13] and in South Africa specifically [18]. Similarly, certain qualitative studies have provided analyses of the development processes of guidelines for eclampsia treatment and malaria control in 3 SSA countries [19, 20], as well as for maternal health [21], lay health workers [22] and primary care [23] in South Africa.

This body of research in SSA has revealed many similar shortcomings in the quality of CPGs and their development as those identified in studies in HICs, including with regards to their methodological rigour, editorial independence and applicability to local practice [13, 18]. However, it has also shed light on certain unique, context-specific challenges facing CPG development in the region. For example, complex political environments and interests, bureaucratic processes and budget struggles, a lack of locally relevant evidence, and limited skills have all been shown to hinder CPG development in SSA [19–23]. Taken together, the findings from this small body of research suggests that more knowledge is needed on the specific circumstances, processes and priorities underpinning CPG development in different SSA settings, and the factors that could improve their construction. This knowledge will help pave the way for better focused, locally tailored and effective interventions to improve CPG quality and development, and associated positive impact on healthcare practices and outcomes in the region.

Against this backdrop, the aim of the current study was to explore national stakeholders' perceptions of current CPG development activity for primary healthcare (PHC) in South Africa. More specifically, it sought to investigate their perceptions of the processes that should inform national CPG development, and their sense of what is actually occurring. This study is a sub-study of a broader qualitative study that provided an overview of the current landscape of PHC CPG activity in the country [23]. This sub-study explores the issue of CPG development in more depth, with a focus on the perspectives of stakeholders operating at the national level. Both the larger study and this sub-study form part of the South African Guidelines Excellence (SAGE) project, which aims to understand and improve the development, adaptation, implementation and use of PHC CPGs in South Africa [24].

Research context

CPGs have been part of South African clinical practice for many decades. Formal national CPG processes were put in place in the mid-90s in a bid to address historical

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inequity in health service delivery in the nine provinces. South Africa's National Department of Health (NDoH) currently spearheads several primary care guideline programmes, including condition-specific guidelines (e.g. malaria, HIV, tuberculosis) and the Essential Medicines Programme, which develops comprehensive Standard Treatment Guidelines for rational prescription at all levels of care in an equitable, cost-effective manner. Additionally, academic departments and professional societies develop CPGs, addressing gaps in what is available from NDoH.

Methods

This study adopted a qualitative approach to understand the phenomena under investigation as experienced and perceived by the actors involved. The methods have been described in detail elsewhere [23], and thus a brief summary is provided here, together with a more detailed description of the analysis methods used in this paper.

Participants and data collection

The sample included 37 participants from a range of disciplines, stakeholder groups and provinces in the country (Table 1). Participants were approached in their capacity as contributing to national South African CPG development. Most were from academic contexts and providing expert input to guideline panels, many had been involved with this for more than 15 years. Besides the government players, the other participants usually held multiple roles, such that, in addition to CPG development, some were responsible for research, clinical teaching and senior management roles in academic or private sector contexts. Only one government member had a specific role in CPG implementation. Data collection comprised in-depth individual interviews, conducted together by two interviewers per interview. The interviews were based on a semi-structured interview guide, including open-ended questions and tailoring to the experiences of each specific interviewee. Key themes explored included players involved in CPG activity, CPG nomenclature and terminology, as well as the processes, contexts and values underpinning CPG development, adaption, contextualisation, implementation and use in South Africa.

Data analysis

The data for this paper were analysed through thematic analysis [25] and the lens of an interpretivist conceptual framework [26].

The larger SAGE project previously developed a list of conceptual components ('open coding'), guided by the research objectives of the SAGE project. After immersion in the transcripts, codes related to 'CPG development' within the SAGE coding framework were used to code the transcripts through multiple line-by-line readings and with the aid of Nvivo10, a software programme that aids in the management of qualitative data. Additional or revised codes were developed iteratively as determined by the data and added to the coding framework. Initial and revised codes were then collated into potential themes and produced into an overall 'thematic map' to guide further analyses. Using the thematic map, the themes related to the processes of developing CPGs were identified, named and extracted. For each theme, the focus was on capturing how the participants were making sense of CPG development, and the values and concerns they attached to this issue. While we focused on identifying common themes, we also paid attention to the presence of potential diversities in participants' perspectives. Further analyses were then undertaken to check if these 'fitted' in relation to the coded extracts, to refine the specifics of each theme and their relationships with each other, and to contextualise these themes within the other emerging topics in the dataset.

Throughout the analysis process, we attempted to adhere to the methodological principle of reflexivity [27]. At regular intervals SC, TK and KD jointly discussed and further unpacked the emergent themes. Along with facilitating verification, validation and refinement of ideas, these discussions also provided opportunities for the researchers' interests and taken-for-granted assumptions to surface and subsequently be examined. Such reflexivity was facilitated further by the different roles the researchers occupied in relation to the research, an awareness of which provided for an illuminating interplay of emic–etic viewpoints. TK, KD and AA had jointly conducted most interviews, both had prior knowledge of many participants and TK is involved with CPG activities within academic and government settings. KD and AA are social scientists, and had been involved from project inception with planning, interviews and initial analysis. KD has been involved with health policy

Table 1 Description of stakeholders sampled (*n* = 37) [23]

Background discipline	Medicine (*n* = 19), pharmacy (*n* = 5), nursing (*n* = 4), allied health (*n* = 3), dentistry (*n* = 1), nutrition (*n* = 2), non-clinical managers (*n* = 3)
Sectors and stakeholder groups	National (*n* = 10) and Provincial Department of Health (*n* = 2), Professional Societies (*n* = 6), Private sector (pharmaceutical *n* = 1 and medical schemes *n* = 2), academia (*n* = 14), non-governmental organisations (*n* = 2)
Provinces represented	Eastern Cape (*n* = 1), Gauteng (*n* = 16), Kwazulu-Natal (*n* = 3), Western Cape (*n* = 17)

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analysis in another project. AA straddles social science and quantitative research in her role at the Cochrane Centre. SC became involved in the research only at the analysis stage and had little prior knowledge of the local CPG landscape. SC's a priori unfamiliarity with the interview content enabled the data to be explored openly and with a 'fresh' perspective. Moreover, the interaction between researchers with both 'distance' and 'closeness' allowed for previous understandings to be opened-up and questioned, and for our own positioning and associated shaping of the research process and outcomes to be critically reflected upon.

Results

The analysis revealed six 'aspirational' processes that participants perceived to be most important when developing CPGs for PHC in South Africa, namely (1) evidence, (2) stakeholder consultation, (3) transparency, (4) management of interests, (5) communication/co-ordination between different CPG development groups, and (6) fit-for-context. We describe each process separately, unpacking both participants' aspirations and their views of the extent to which each process is, in reality, underpinning the development of CPGs. To preserve anonymity, certain phrases have been removed from quotations and replaced with alternative text in square brackets.

Evidence

The concept of an 'evidence-based approach' featured prominently in participants' narratives. An overwhelming majority of participants, across stakeholder groups, strongly emphasised that CPGs should be driven by scientific evidence on the effectiveness, safety and cost-efficiency of a clinical process or treatment. The notion that CPGs "*should be evidence-informed*" (INT33), "*scientifically rigorous*" (INT14) and "*guided by the current evidence-base*" (INT25) was widespread, or as one government participant succinctly stated: "*The department stand is that whatever policies or guidelines we develop are evidence based*" (INT22).

A common sentiment, particularly amongst academic and government participants, was that the development processes of many national CPGs have evolved over time, increasingly being informed by a more robust evidence-informed approach. Many CPGs were described as "*coming a long way*" (INT06) or having "*over time, become more and more evidence based*" (INT4). Whilst perceptions of progress were common, the need for further improvement was also communicated. More specifically, many participants expressed reservations about certain CPGs in the country, and the extent to which they are being guided by an evidence-based approach.

Various reasons were provided for the inadequacies participants saw with regards to the certain CPGs' use of evidence. Here, a lack of dedicated time and funding, as well a scarcity of skills for quality CPG development emerged as overriding themes. The interviews were saturated with accounts of how those involved with CPG development are often doing it voluntarily and afterhours, and there is thus limited capacity to undertake the necessary methodological work:

"*People are stretched... we all have full time jobs and we're doing it, not for money, not for kudos... so you can't expect the kind of rigor that you'd like to see*"

(INT04, Academic)

Along with limited time and funding, many participants also highlighted how there is a dearth of skills in the country for synthesising and incorporating evidence in CPGs. Many spoke about the "*lack of competent people who are able to do this kind of work at a national level*" (INT03) and that "*the distribution of people with skills in evidence-based medicine... is quite a problem in the country*" (INT15).

The shortages of skills in evidence-based medicine within the NDoH, in particular, emerged as a key issue amongst government participants. Many attributed this deficiency to what they perceived as inadequate, or even non-existent, in-house training. As one participant put it succinctly:

"*We have also not been trained on the processes that need to be followed*"

(INT37, NDoH)

Similarly, another government official replied, when asked whether he received training in evidence-based medicine:

"*No training, no training! You learn on the job... when you see courses being offered... in most cases it's out of your own pocket because it's outside of the HR development planning process*"

(INT22, NDoH)

Stakeholder consultation

There was considerable agreement amongst participants and across stakeholder groups that widespread stakeholder consultation also needs to form an essential part of CPG development. Many participants spoke at length about why this is critical. Along with serving as an

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important peer-review mechanism, widespread consultation was seen as essential for facilitating 'buy-in':

> "I think a key for any guideline is inclusivity. Because if you want people to embrace your guideline, it's much easier if they were part of it than if you just thrust it upon them"

(IN19, Professional society member)

Several participants felt that it is particularly important to include the end-users of CPGs in consultation processes to ensure that guidelines are "*practical... at implementation level*" (IN32), are "*acceptable to those implementing them*" (INT22) and "*so nurses understand what you want to say*" (INT05).

Many participants spoke about their own CPG development processes as involving stakeholder consultation, one which they perceived to be fairly wide and extensive. Participants spoke about "*our strategy of wide consultation*" (IN22), that "*we are fairly meticulous about circulating our guidelines to all organisations concerned*" (INT17) and that, ultimately, "*Anybody who is on the ground, who feel they have something to contribute here, they will*" (INT16).

While there was a tendency amongst participants to describe their own consultation processes in relatively positive terms, a more complex picture of stakeholder engagement in CPG development also surfaced. This emerged most prominently when participants talked about their experiences with the development processes of other CPG development groups. This also materialised in certain participants' narratives of their own consultation processes, where certain reservations were revealed.

Many participants spoke about various other CPG development groups as comprising "*a very non-consultative process*" (INT18) or as being "*an authoritative entity, who never... considers clinicians' input*" (INT17). Others described the inherent unresponsiveness of certain CPG groups, and their inadequacies in responding to people's input. As one participant said:

> "The sense that we've had with all the people we've engaged with is that you will send a lot of feedback to the [particular CPG development group] but you'll get no formal response to any of your feedback"

(INT03, Academic)

This failure to provide adequate feedback was recognised by certain participants with regards to their own consultation processes. Many explained how there actually is a very rigorous process for considering and incorporating

stakeholder feedback, and yet due to capacity constraints, they are limited in their ability to adequately respond. As one participant indicated, acknowledging that this is a problem:

> "People will give a comment, but when the book is published they see that their comment hasn't been incorporated... it's not that the committee didn't consider the comment... but because of capacity constraints, we can't respond to each and every comment... but we've got to ask ourselves: how do we make it more publicly available that we have looked at your comment... without responding to each and every person on each and every point?"

(INT16, NDoH)

Certain participants conveyed other reservations with regards to their own consultation processes. Some questioned the level of inclusivity of their engagement processes, highlighting the problems they have engaging with particular groups. For example, many professional society participants alluded to the struggles they encounter consulting with government:

> "I think the process should be more inclusive... that is certainly the weakness of our current situation. But engaging with government is an extremely difficult process... there are very, serious barriers of communication with government"

(INT18, Professional society member)

Many other professional society participants shared this participant's view, providing similar accounts of how "*communication with the DoH has been shocking*" (INT19), and how "*there should be an easier way for us to engage government*" (INT14).

Certain government participants alluded to the difficulties they experience around engaging with various groups. Some felt that particular provinces, other than the Western Cape and Gauteng, are hard to engage with and ultimately remain weak in their participation:

> "I think there are weaknesses within the consultations at provincial level... in a province like Western Cape, it is done widely, but in other provinces, not really that much"

(INT22, NDoH)

Other government officials felt that the end-users of CPGs are another specific group that they have found

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hard to reach and are unsatisfactorily consulted, as reflected by this participant's comment:

> "I don't think we have found a better... mechanism of really engaging the people who are... at the frontline of implementation... I think a lot of programmes struggle with what will be the best way of engaging the end users"

(INT36, NDoH)

Those participants who expressed uncertainties about their own stakeholder consultations suggested various aspects of the engagement process that might limit its inclusivity. For example, some indicated that the process tends to favour those who have the capacity to provide written feedback and the ability to use the internet, as depicted in the following two statements:

> "So [a particular CPG development group] have... collated a whole lot of emails and they send it out and also make it available on the website... but it just depends sometimes though, like nurses in rural areas do not have the capacity to connect online"

(INT33, Academic)

> "The same usual suspects will give their comments because that's their comfortable way of engaging... but there are other people who engage differently... maybe they don't want to write something so they may need a different strategy"

(INT16, NDoH)

Relatedly, other participants suggested that the time given to stakeholders to provide feedback is insufficient, and may be an additional barrier to more widespread and inclusive consultation:

> "The consultation process doesn't always look valid because there wasn't given time to comment"

(INT14, Professional society member)

Transparency

It was widely suggested that CPG development also needs to be guided by a clear, transparent process so people can understand decision-making processes. Many participants spoke about the fact that "*people need to see the validity of the process*" (INT01) and that "*fair transparency is a critical component of guideline development*" (INT23), or as one participant stated:

> "I think the most important thing is that... we have to have a very transparent, clear process... a level of transparency that... someone can understand why decision were made"

(INT08, Professional society member)

The dominant view expressed by participants in all the stakeholder groups was that CPG development in the country tends to lack sufficient transparency. Descriptions were commonplace about how CPG construction processes are "*very untransparent... completely opaque to everybody*" (INT14), "*a complete mystery*" (INT3), or as described by one participant:

> "I have issues with the [particular CPG development group] *not being transparent... what we need is to make that process visible, because it's actually, they have terms of reference, they have criteria, they go through a very evidence-based process*"

(INT30, Academic)

Like this participant, many other participants conveyed a sense of trust in the rigour of various CPG development processes, and yet perceived there to be a significant gap in the documentation and sharing of the logic behind the decisions. Many suggested that there is a need for greater communication about exactly how the process unfolded, so that people can better appreciate the credibility of CPGs:

> "I think the communication... there's a lot of misconceptions... but just talking to people and telling them, okay, this is how we do it, then they get the insights... that there's a rigorous process"

(INT16, NDoH)

Not many participants provided reasons for why the process is not as transparent as it should be, despite probing by interviewers. The few that did reflect on this issue suggested, once again, that limited time and funding was the cause, with stakeholders lacking the capacity to adequately record and elucidate decision-making processes:

> "So there is an awful lot of work going on... but not a lot of capacity to engage in a very clearly documented and open process... but we do need to consider what the best means is of documenting evidence and then sharing that evidence in order to get more buy-in"

(INT21, Academic)

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Given that few participants provided details on why transparency is an issue, it is unclear whether this view is shared by others.

Management of interests

A few participants stated explicitly that the declaration and management of interests need to form a key aspect of CPG development, so that decision-making processes are not influenced by inappropriate forces:

> "*Your governance has to be clear... people have to know... what interest they need to declare, what information they need to keep confidential... and the reason... is because we don't want undue influence on our decision-making processes*"

(INT16, NDoH)

Although not overtly stated in most cases, many participants clearly conveyed the view that vested interests need to be considered and managed when producing CPGs. The interviews were replete with descriptions of people's conflicts of interests and the role these are playing in CPG development. Participants spoke about these interests as being both personal/intellectual and financial. In terms of the former, many described in detail the "*personal agendas*" (INT5), "*little hobby horses*" (INT6) and "*vested interests*" (INT14) people involved with CPG development across the board have:

> "*There's a whole lot of politics... we have all these competing interests... even us sitting at the university... we have these different groups that have their own agenda... to defend their turf*"

(INT25, Academic)

More specifically, many participants described how individuals developing CPGs may be involved with specific programmes or research projects, and often push for guidelines to incorporate these. As articulated by this participant:

> "*There's a lot of individuals or research institutions pushing their own agendas... like those on drug development, clinical trials... the expectation is that you would change your policy based on that... and it creates problems for us in terms of determining what should be in the guidelines... we're put under pressure*"

(INT22, NDoH)

Numerous participants provided analogous accounts, similarly highlighting the problems they have around managing personal interests. Certain participants also expressed uncertainty about how these agendas can and should be managed, as communicated by this participant:

> "*We talked about this... how we probably need to also disclose grant conflicts of interest because if you're sitting on a study that is, you know, if you change* [the policy], *your study is not going to continue, right?... But, then everybody has some sort of bias, so I don't know what the ultimate answer is, like how do you make this so completely transparent*"

(INT08, Professional society member)

In addition to interests of a personal or intellectual nature, many participants were also particularly concerned about financial interests and the fact that a "*massive amount*" of guidelines are "*driven by industry*" (INT20). As aptly revealed by this remark:

> "*My colleagues... they don't see the harm if industry comes and does this. You know, it's so insidious... they're doing subliminal advertising, and people don't get how that can influence how you make a decision*"

(INT16, NDoH)

When talking about the pervasiveness of financial interests, many participants were particularly worried about professional society groups in this regard. Comments about such groups having "*lots of apparent influence of industry*" (INT21) and "*being influenced tremendously by industry*" (INT18) were ubiquitous, along with descriptions of how professional society CPGs are "*essentially drug company driven*" (INT19). Many participants also questioned the sufficiency of the extent to which the financial interests operating amongst professional societies are being managed:

> "*In many instances, if not most instances, there is no process to deal with potential conflicts of interest*"

(INT15, NDoH)

Certain professional society participants themselves expressed analogous concerns, with some conveying similar apprehensions about the presence and inadequate management of financial interests within their own societies. As one member acknowledged:

> "*It depends on the integrity of the individual... you know, I think it's very glib now, the declaration of conflict of interest. It goes up in the first slide and you*

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don't even see it. Here's my title and here's my conflict of interest. It's very glib"

(INT18, Professional society member)

In a similar manner, when asked directly about his experiences of conflict of interests within his own society, another participant explained:

"I'm trying to remember... whether we actually had to declare a conflict of interest. I don't think we did"

(INT19, Professional society member)

This participant went on to articulate why conflicts were not declared within his society, outlining some of the difficulties in this regard. According to him, it would be *"too numerous"* as *"everyone is going to have to have received funding from someone for something"*. He explained that *"all those would all have to be declared ... which would take the first four pages of the guideline"*. He indicated further that *"if you try and put too many rules in place"*, you will ultimately create a hindrance to CPG development, or as he put it: *"It then trumps people's desire to actually do the guidelines"*.

Thus, while most participants felt that management of interests is a key activity for CPG development, certain stakeholders had a different perspective. As with the participant above, some questioned the value as well as the practicality of declaring and managing conflicts of interests.

Communication and co-ordination between CPG development groups

Various participants stressed the importance of communication and co-ordination between different CPG development groups, suggesting that *"those writing guidelines must speak to each other"* (INT37) and that *"there's got to be absolute linkage between programme guidelines"* (INT27). This was identified as essential for ensuring *"harmony between guidelines"* (INT03) and that *"we don't give confusing messages to practitioners"* (INT15). Many participants felt that it is particularly important for CPG developers to communicate with the Essential Drug List (EDL) committee, as exemplified by this comment:

"If I was redesigning the system, I would have a... process for guideline development that has a clearing house effect that goes through the EDL, who then issues it"

(INT14, Professional society member)

There was much consensus amongst the participants that, in reality, communication and coordination between different CPG development groups is noticeably absent. The general picture that emerged was one of fragmentation, whereby a diverse range of groups are developing CPGs relatively independently of each other. Many described this disconnect as occurring between the private and public sectors:

"Private, they do their own thing, only... where they don't have a choice... or where they absolutely don't know, only then do they then refer to the other guidelines"

(INT06, NDoH)

Other participants spoke about divisions within the NDoH and the lack of communication across government departments. CPG development processes within the NDoH were referred to as *"siloed in a way that there's not really good communication"* (INT08), *"disjointed pockets of activities"* (INT15), or as one participant proposed:

"There is a two-parallel process from the department of health, and the one side is the formal process and on the other side you've got stroke management, malaria management, HIV management... so all are little silos inside other silos"

(INT20, NDoH)

At the same time, many participants felt that some, but not all, CPG development groups are communicating with the EDL, or as two participants put it *"communication is stronger with some programmes than with others"* (INT37) and *"often programmes haven't checked the EDL"* (INT20). This view was shared by a member of the EDL committee who, when asked whether CPGs are being circulated through the EDL, responded:

"It doesn't happen with all national departments. So [particular government department], yes, but I'm still struggling to get [particular government department] to send their guidelines to us for peer review"

(INT17, Academic)

This lack of communication between CPG developers was perceived to result in the replication of guidelines and a duplication of work, or in the words of one participant: *"discrete pockets of people reviewing the same data"* (INT11). It was thought to also give rise to contradictions between CPGs, with *"a whole host of conflicting*

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recommendations across the different guidelines" (INT03) and guidelines that "*don't fit together… to make a coherent whole*" (INT02).

Some participants attributed this situation to a matter of timing, suggesting that CPG inconsistencies are related to the fact that different CPGs are developed and updated "*according to different schedules*" (INT37) that are "*not always in sync*" (INT15). However, other participants conceived the problem to be of a more political nature. That is, it was suggested that the difficulties stem from the complex relations of power and control that exist within the CPG development arena in the country, as one participant proposed:

"*There are lots of interest groups competing for control of this, and that's why partly it hasn't been cohesive… The department of health, because they are in the HIV field, I think wants to keep some of that to themselves. The TB people wanted the TB to themselves… there's just lots of competing interests around these things.*"

(INT14, Professional society member)

Fit-for-context

A final issue that featured prominently in the interviews was the need for CPGs to be contextually relevant, and thus the necessity that CPG developers think about "*what is suitable for our context*" (INT01) and "*is this relevant to our situation*" (INT37), or as specifically stated:

"*We feel guidelines need to be relevant to South Africa, I mean, our situations are different and our cost constraints are different, and it has to be relevant*"

(INT18, Professional society member)

When describing CPG development processes, there was considerable agreement amongst participant groups that most CPGs in the country draw heavily on international guidelines and what is being recommended globally, particularly by WHO:

"*In most cases guidelines are guided by the WHO recommendations*"

(INT22, NDoH)

Although there was widespread consensus that CPGs in South Africa are usually based on what is being done and advocated for internationally, there were divergent views amongst the participants about the use of this approach. Some were critical of this tendency, suggesting

that we should not be relying on other sources to do the methodological work of CPG development:

"*I would say there's an over reliance on other guidelines without looking at the primary evidence*"

(INT37, NDoH)

Other participants expressed frustration with the dominance of global discourse, and the pressures they feel to conform to these. This was aptly conveyed by one participant who lamented:

"*WHO is a really sore point with a lot of our experts because they're writing policy for Africa… I mean we do not lack technical expertise… and we have the evidence… I think our experts should be the ones driving the decisions*"

(INT14, Professional society member)

In contrast to these perspectives, other participants supported the widespread use of international guidelines when developing local CPGs. Here, the common view was that it is unwarranted to repeat the work already done by other, well-respected organisations:

"*It's not necessarily developing all the guidelines from scratch… because if it's there, why reinvent the wheel*"

(INT25, Academic)

Many participants shared this view, yet suggested further that international CPGs should be used but a process of contextualisation should ensure the "*critical appraisal of international guideline*" and "*local adaptation*" of these so they suit out local circumstances (INT37). As two professional society participants explained:

"*What I have been pushing for a lot is to say, take the WHO guidelines… and then adapt them to South Africa*"

(INT14, Professional society member)

"*What we want to do,* [which] *we haven't always historically done… is we need to take WHO as the starting point, the baseline and then adapt from there*"

(INT08, Professional society member)

As suggested by these two participants, and sharing the views of other participants, the process of adapting

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international CPGs is currently limited, something which was perceived to be a key area for improvement. However, there were some participants who indicated that they do undertake such a process, stating, for example, that "*we use international ones and then adapt for this context*" (INT25) or that "*a lot of it is based on WHO recommendations and then we decide whether it is suitable for our context*" (INT30). Despite considerable probing, details of exactly how this process of appraisal and adaptation is undertaken was difficult to gage, with participants providing little information in this regard.

While the importance of local relevance was widely emphasised, the majority of participants indicated, simultaneously, that CPGs should not be adapted for contextual difference within South Africa. With one exception, all participants emphasised strongly that "*we don't want disparity between provinces*" (NT16) and that "*you can't have a different standard for Limpopo* [poorly resourced province] *and for the Western Cape* [well-resourced province]" (INT04). In justifying this view, many participants explained how the overriding objective of post-1994 CPGs is to promote justice and ensure everyone has access to the same standard of care, so as to redress the historical inequities instigated by the apartheid regime. Thus, according to them, adapting CPGs for inter-provincial contextual differences would be going against the very socio-political role CPGs are meant to play in the country. However, one participant, a government official from Kwa-Zulu Natal, had a contrasting perspective, explaining how South African provinces have vastly different resources, cultures and infrastructure, and that a failure to accommodate these diversities could have dire consequences:

"*Our needs might not necessarily be the exact same as other provinces... and sometimes you find that a national guideline is... not tailored for the province... and the moment you say you must without considering the situation in the province it will make a situation worse, it won't help us*"

(INT32, NDoH)

Discussion
This paper explored national stakeholder participants' perceptions of the processes informing CPG development for PHC in South Africa, focusing on both their aspirations and sense of what is occurring 'in reality'. While the analysis sought to identify common themes, it also paid careful attention to potential divergences in perspective.

The findings revealed considerable agreement amongst participants about the processes that should inform CPG development in the country. While there were differences in the relative importance given to each of the six aspirational processes identified, all were highlighted as important by the 37 participants. These processes strongly reflect current global standards regarding guideline development, and their emphasis on inter alia use of evidence, stakeholder involvement, transparency, applicability and editorial independence/managing conflict of interest [1, 9, 10]. The importance of 'evidence' was a particularly prominent theme. This widespread culture of evidence-based medicine amongst our respondents, and similarly revealed in other policy development studies in South Africa [21, 28], stands in sharp contrast to the literature describing a lack of access to and awareness of evidence in many low- and middle-income countries [29, 30].

Another theme that featured strongly in the participants' narratives was the importance of CPGs to be 'fit for context'. While there were divergent views about the pervasive use of international guidelines, and evident tensions around whether CPGs should accommodate provincial differences, the imperative to consider 'context' when developing CPGs was a common viewpoint. There is growing interest within the international CPG methodology literature in 'contextualisation', with various frameworks recently developed to guide the adaption of CPGs developed in one country to other settings [31, 32]. However, these approaches tend to be designed for the reconfiguration of CPGs to new, but contextually similar, settings [5, 33]. They thus provide little guidance on how CPGs might be transferred across settings with different healthcare policies and contexts. The Filipino CPG implementation project [33] and Practical Approach to Lung Health in South Africa initiative [34] are examples of the few attempts that have been made to develop practical approaches for contextualising CPGs developed in HICs to low- and middle-income countries. More of these kinds of initiatives are clearly needed, as evidenced by participants' uncertainty in this present study around how to adapt CPGs developed in HICs for effective use in South Africa.

A particularly noteworthy finding from this study was the chasm between participants' aspirations of how things 'should be' and their views of how things are 'in reality'. While many spoke about a transition towards more robust processes, the general view was that CPG development still faces significant challenges with regards to all six aspirational processes highlighted. Across all six thematic areas, there were suggestions for how best to bridge the gap between what is, and what should be happening, in CPG development processes; we explore these suggestions in another paper [23]. Concurring with other guideline development research in in SSA [19–23], many of the problems identified were attributed to a lack of financial and human capacity. More

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specifically, the paucity of dedicated time, funding and skills for CPG development was perceived to hinder the methodological work of synthesising evidence, effectively responding to stakeholders' feedback, and transparently documenting and sharing decision-making processes. A lack of resources is not a unique issue affecting CPG development in South Africa. Despite the introduction of key health policy reforms, human and financial resource challenges continue to hamper progress in all areas of healthcare delivery [35]. The findings in this paper suggest that, like in other areas of healthcare, there is a need for greater dedicated resources for CPG development to build capacity and support for the delivery of high quality CPGs in South Africa.

In addition to resource limitations, our findings suggested that current challenges facing CPG development are also intimately linked with the complex web of politics and power operating within the CPG arena in the country. For example, the fragmentation within government programmes and between public and private sectors was attributed, in part, to issues of control and ownership. Different groups were described as interested in maintaining their authority over specific territories, thus sabotaging efforts for collaborative CPG development work. As proposed elsewhere [23] and supported by this study, a possible way forward would be for South Africa to have a centrally coordinated CPG unit with buy-in from and communication between public and private stakeholders. It would be important for this unit to help foster a political environment that promotes collaboration and integration between different CPG development groups.

Simultaneously, the CPG arena was seen to be saturated with personal, financial and political vested interests, and lacking processes for reporting and managing these. The issue of conflicting interests is not unique to South Africa. Globally, many guideline development groups fail to adequately disclose and manage conflicts of interests [36, 37]. Most certainly, guideline development is never neutral, and is inevitably "*a social as well as technical process*" that "*necessarily reflect*[s] *value judgments*" [38]. However, clear procedures for the documentation and management of interests, including financial relationships and sources, are essential. The varying perspectives participants in this study conveyed around if and how conflicting interests can and should be managed suggests that this is a complex issue in the country. Further research on this topic in South Africa is therefore needed, and substantial stakeholder input and buy-in will be required if we are to move from how interests have been managed to how they should be.

Finally, challenges pertaining to stakeholder engagement were also described as related to power dynamics in the country. The nature of CPG consultation was perceived to favour those individuals and groups who have the time, resources and capacity to provide input. As such, and as reported in other studies in South Africa [22, 39], the views of end-users of CPGs, 'at the coal face' of service delivery remain inadequately incorporated. As suggested by participants in this present study, and similarly highlighted elsewhere [40, 41], a failure to include the perspectives of those who will be implementing CPGs could have a dire impact on their effective uptake and use. A noticeable absence in the stakeholders' narratives in this study pertains to the issue of patient involvement. Internationally, patient engagement is now recognised as an important component of CPG development to ensure the production of more patient-centred and trustworthy guidelines [42, 43]. The silence around this topic in this study suggests that the involvement of patients in CPG development clearly requires more attention in South Africa.

Additionally, it emerged that the process of stakeholder engagement tends to marginalise the opinions of individuals and groups located in the more resource-limited provinces in the country. This is indeed further supported by the fact that, despite our attempts to include national stakeholders from all provinces in the country in this study, our final sample was dominated by participants from Gauteng and Western Cape Provinces, two of the country's most well-resourced provinces. Read in conjunction with the study findings, this sample bias is likely to reflect the reality of skewed power dynamics in CPG development in South Africa, where many who lead national knowledge production, and are therefore able to contribute their time to the process, may be based in the Western Cape and Gauteng. Ultimately, all of this suggests that CPG development in South Africa needs to develop more innovative strategies for better reaching and including the voices of those across professional hierarchies and provinces in the country, as well patients and healthcare consumers.

Study strengths and limitations

The strengths and limitations of the broader study in which this sub-study is embedded, have been described in detail elsewhere [23]. With regards to this sub-study specifically, we have focused on the personal accounts and experiences of respondents. A strength of this approach is that the data represents the perspectives of actors engaged directly with CPG activity in South Africa and therefore provide valuable insights into the thinking behind CPG development processes. However, we recognise that such accounts are inevitably influenced by respondents' position at time of event, their position at the time of being interviewed, their relationship with the researchers and their memory of particular events and processes [44]. Our final sample was dominated by

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participants from Gauteng and Western Cape Provinces, and thus the views and perspectives of stakeholders who may be involved in CPG development from other Provinces in the country might not have been sufficiently reflected. At the same time, we did not speak to patient representative groups or patients, as it emerged during our stakeholder 'mapping exercise' that these individuals and groups are currently limited in their involvement with CPG development in the country. Further research in CPG development in South Africa, which tries to reach more 'marginalised' stakeholders, including patients and patient representative groups, is needed.

Furthermore, and as noted in the previous paper [23], the lead researcher, who was present at most interviews, has experience in evidence synthesis for CPGs and teaching about CPGs. As she may be known to some interviewees as an advocate for evidence-based healthcare, this may introduce response bias. Therefore, we ensured that at least two interviewers were present, including one who was not engaged in CPG activities, with the intention to create more distance and, as much as possible, objectivity. In addition, and as described in the methods section, the researchers discussed the findings at regular intervals during the analysis process. This helped to verify and refine the emerging themes and provided an opportunity for our presuppositions (and how they may be shaping the analysis) to be identified and critically examined.

While the results of this study need to be generalised with caution, as all qualitative research, we have succeeded in providing in-depth insight into CPG development in South Africa. The results corroborate with and extend the findings from other studies on this topic in SSA and South Africa more specifically. The results also shed light on key factors that might help to improve the development of high-quality CPGs in South Africa, and potentially other countries in the region.

Many of the findings in this study are similar to those previously reported. However, two unique issues that emerged, which have not received much discussion elsewhere, were the complexities around managing conflicting interests and adapting CPGs to within-country contextual differences. Participants in this study held contrasting perspectives about these issues, suggesting the need for further research into these factors and greater discussion regarding how they should be addressed.

Conclusion
Growing awareness of the important role CPGs can play in healthcare systems in SSA demands increased knowledge about CPG development activity in the region. Focusing on South Africa, this study has shown that, while there is strong commitment amongst national stakeholders to advance guideline development processes, a

complex mix of values, politics, power and capacity constraints pose significant challenges in this regard. More dedicated resources for CPG development, together with standardised conflict of interest policies and greater guidance for trans-contextual CPG adaption will help enhance the quality and credibility of CPGs for PHC and have an associated positive impact on patient care in the country. Cultivating a political environment that fosters collaboration, reciprocity and more equitable inclusion within and between different CPG development groups and stakeholders could help reduce duplication of efforts, make better use of limited resources and skills, and help redress historical inequities within the South African healthcare context.

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postgraduate students, researchers, policy-makers and practitioners on clinical practice guidelines and evidence-informed practices. JV has been involved in advisory committees for clinical guidelines in the Western province and has facilitated workshops and capacity development for undergraduate and postgraduate students, researchers and practitioners on clinical practice guidelines and evidence-informed practices. SC, SA, AA and KD have no competing interests to declare.

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Chapter 4: Primary care guideline implementation: barriers and enablers

Summary: In this qualitative study, we conducted in-depth interviews with 22 provincial and district health managers, district clinical specialists and trainers involved with guideline implementation in four provinces in South Africa. Two main themes arose that pose barriers to guideline implementation in the provinces: a) health-system factors; and, b) socio-cultural and geographic context factors.

The health-system factors included financial constraints that impact access to guidelines and necessary equipment and medicines to do their jobs as well as the importance of and need for strengthening governance, leadership and accountability. Participants suggested that the health workforce needs support and bolstering including increasing the numbers of skilled nursing and other clinical services; quality assurance of training programmes for primary-care clinicians, particularly nurses; interdisciplinary training to ensure all staff are adhering to current guidelines; and, strengthening of post-training mentorship.

Socio-cultural and geographic contextual considerations resulted in recommendations that guidelines should be fit for the context through consultation with end-users and implementers in the development stages; and, adjusting provincial indicators to match the cultural preferences and values and to ensure recommendations are acceptable and feasible to implement.

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'Building on shaky ground' – challenges to and solutions for primary care guideline implementation in four provinces in South Africa: a qualitative study

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'Building on shaky ground' – challenges to and solutions for primary care guideline implementation in four provinces in South Africa: a qualitative study

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Abstract

Background

Clinical practice guidelines are important tools supporting evidence-informed patient care. In South

Africa, although guidelines are usually developed at national level, responsibility for implementation lies

with provincial government. This study explored perspectives of provincial and district health managers

stakeholders regarding barriers to and enablers for primary care guideline implementation.

Methods

We used qualitative research methods, comprising in-depth interviews with twenty-two participants in

four provinces in South Africa (Eastern Cape, Western Cape, Kwazulu-Natal, Limpopo). We interviewed

provincial and district health managers responsible for implementation and/or training. Analysis

proceeded with inductive thematic content analysis to develop categories and themes; followed by

discussion of results and finalization of themes with a multidisciplinary team.

Results

Participants recommended urgent consideration of health system challenges, particularly financial

constraints impacting on access to both guidelines themselves and to the basic medical equipment and

supplies to adhere to the guidelines. They suggested that to overcome health service gaps, leadership

should be strengthened, roles clarified and accountability measures, such as audit and feedback, be

improved. Participants suggested that the inadequate numbers of skilled nursing and other clinical staff

hampered guideline use and ultimately patient care. Quality assurance of training programmes for

clinicians, particularly nurses; interdisciplinary training to ensure all staff are included; and

strengthening post-training mentorship was recommended. Furthermore, fit for purpose guideline

implementation needs to consider the unique settings in each province and district, including local

culture and geography. This should start from guideline development stages by including guideline end-users.

Conclusions

Universal health coverage is planned for the coming decade and guidelines are one of the named tools to achieve evidence-informed, effective healthcare. Increasing access to guidelines and enhancing training and clinical supervision may enable short to medium term benefits. However, investing in health system strengthening is a pre-requisite to evidence-informed practice.

Key words: qualitative research, clinical practice guidelines, implementation, primary care, quality of care, health systems research, health services research, policy implementation, quality improvement

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Article summary

Strengths and limitations of this study

- Clinical practice guidelines are named tools for bridging the gap between policy and practice to support implementation of equitable and cost-effective health services. Yet, there is a paucity of research on clinical guidelines from low- and middle-income countries.

- Strengths of the study are that we report interviews with provincial and district health managers in four culturally and geographically diverse South African provinces.

- The qualitative research methods enable us to explore perspectives of those involved with guideline implementation who shared their views regarding what is working and

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what can be improved. The research identified two themes impacting guideline

implementation: Health system factors and socio-cultural and geographic context.

- o According to participants, several insights emerged for how these factors might be

    addressed: Strengthening the health system through adequate financial

    investment and ensuring availability of medical equipment and supplies are

    necessary for guideline adherence.

- o Strengthening leadership and putting in place constructive accountability

    measures, including appropriate use of audit and feedback.

- o Quality assurance of training programmes for primary health care providers,

    particularly nurses, and facilitating interdisciplinary training to ensure all staff are

    adhering to guidelines.

- o Mentorship and clinical support are provided through District Clinical Specialists

    but requires further strengthening.

- o Consideration of the unique settings in each province, including culture,

    geography and social needs is required to ensure effective implementation.

- Limitations of the study include that there are many primary care guidelines available in

    South Africa with different target users. Further interviews may elucidate additional

    specific barriers to and enablers of guideline implementation. Furthermore, the health

    system is an evolving environment, and continuous research of this kind is likely

    necessary to keep abreast of developments to inform guideline implementation.

Background

Primary health care (PHC) remains an important focus globally and part of the foundation for Universal

Health Coverage (UHC)(1). The South African government, like other lower- and middle-income

countries, have indicated a commitment to enhancing in primary care for UHC (2-4). However, PHC has

had faltering progress at best, and despite political will, investment has not been sufficient to overcome

challenges posed by colliding communicable and non-communicable epidemics alongside recognized

health system deficiencies (5, 6). Health outcomes remain poor relative to other middle-income

countries with similar health spend; and healthcare remains inequitably distributed within a two tiered

public and private system where 40% of the health budget is consumed by the private sector, despite

serving 17% of the population (7-9).

In South Africa, several strategic initiatives aim to address health system fragmentation, including PHC

re-engineering, with emphasis on district health system strengthening; and advancing policy planning

for National Health Insurance (6, 10, 11). These initiatives place importance on clinical governance, with

clinical practice guidelines (CPGs) one named strategy for healthcare strengthening.

CPGs are recognized tools for health policy implementation and quality improvement (12-14). Evidence-

informed CPGs aim to recommend effective diagnostic, prevention and management interventions,

while minimising harm, within the limits of what a health system can afford. In South Africa, at least 175

CPGs have been developed since 2012, largely for management of non-communicable diseases and

mostly by the Department of Health (15). While the number of CPGs available may be substantial, they

provide no benefit if inadequately implemented. Studies in South Africa and elsewhere have found

potential implementation gaps where, despite the availability of CPGs, clinical care does not meet

required standards (16-21).

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Evidence-to-practice gaps pose a substantial challenge and the how best to overcome them has been a longstanding debate (22-25). There are checklists available that outline potential approaches for best - practice CPG implementation (26-28). However, which strategies work, under which conditions, remains a complex and evolving research field. Generally, tailored, multifaceted interventions addressing specific barriers may be better, but the benefit to health or process outcomes is often modest at best and difficult to extrapolate to different contexts (25, 29, 30). Increasingly, theory-informed approaches are used to design the complex interventions required to change behavior, yet the cost of doing this relative to the benefit remains unclear (31-34). In South Africa, several trials evaluating evidence-informed approaches for CPG implementation find a small, but consistent benefit from targeted strategies, yet, roll-out of these context-specific strategies remains a gap (35).

Given the limited resources allocated to health, particularly in low- and middle-income settings, knowing how best to intervene in efficient and effective ways is paramount. (36, 37). In this context, exploring the views of those involved with CPGs is a reasonable way to learn about local needs. The South African Guidelines Excellence (SAGE) project aimed to understand primary care CPG development, implementation and capacity needs (38). For the qualitative component of SAGE we interviewed diverse role players involved in primary care CPG development, implementation and/or use. Elsewhere we report the findings fromt national CPG developers (39, 40) and frontline healthcare workers who use CPGs (33). Related SAGE studies have engaged allied healthcare providers (41-44). In this paper, we explore findings that emerged amongst health managers occupying senior management roles in the provincial or district government offices. The district managers include those with strictly management roles and those with clinical governance and support roles (e.g. members of the District Specialist Clinical Teams) or those responsible for training. All participants we spoke to have roles in primary care

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CPG implementation. We aimed to explore their perspectives regarding barriers to and enablers for

primary care CPG implementation in four provinces in South Africa

Methods

Design

We used qualitative methods to understand the phenomena under investigation as experienced by

those involved. The methods and study context have been described in detail elsewhere (33), and thus

only a brief summary is provided here, together with more detailed description of participants and

analysis methods used in this paper.

Study settings

Over several decades, the South African national government has increased emphasis on PHC services

managed through district offices (6, 45-48). Districts are administrative sub-sections of the province,

usually run as part of the local government. More recently, legislation has been introduced which

supports the implementation of UHC, through a National Health Insurance system (11). However, its

implementation is planned for the decade ahead. In general, national government develops strategies

and CPGs; and provincial governments implement them through regional, district, or community

healthcare facilities (7). Several programmes to strengthen district clinical governance have been

introduced and are linked to CPG implementation: 1) The Ideal Clinic is defined as a 'clinic with good

infrastructure, adequate staff, adequate medicine and supplies, good administrative processes, and

sufficient adequate bulk supplies' includes ensuring access to and use of CPGs (49); and 2) 'primary

health care re-engineering' aims to strengthen district healthcare through ward-based outreach teams;

school health programmes; and District Clinical Specialist Teams (DCSTs)(10). DCSTs include clinical

specialists: family physician, primary health care nurse, obstetrician, advanced midwife, paediatrician,

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paediatric nurse and anaesthetist. The family physician and primary health care nurse are central to

primary care CPG implementation through their clinical governance role, including provision of training

and mentorship with nationally endorsed CPGs.

Sampling and recruitment

Sampling, both purposive and convenience, took place in four of nine provinces in South Africa chosen

for their diversity in socioeconomic status, geography and cultures: Western Cape, Kwazulu-Natal,

Eastern Cape and Limpopo provinces (33, 46). Within each province, we aimed to interview provincial

and district managers, or district clinical specialists face-to-face at their place of work or preferred

venue, lasting between 30 to 60 minutes. Prior to conducting interviews, we obtained approval from

Provincial Research Units. In the Eastern Cape we were invited to present at a provincial research day,

receiving buy-in for our planned research (33). In the Western Cape we contacted known provincial

policymakers involved with PHC CPGs. In other provinces, we invited individuals recommended by the

Provincial Research units. Once access was negotiated, all those invited agreed to participate.

Patient and Public Involvement

CPGs are tools that aim to directly impact patient care and guide clinician-patient engagement. In South

Africa, there is little known from research evidence regarding patients views about CPGs. The research

question was developed with patients in mind, but did not engage patients views in the design, conduct

or analysis. In this SAGE sub-study we were seeking perspectives of health managers in primary care,

and neither patients or the public were included in the sample. The results of the research will be shared

with the participants.

Data collection and management

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We explored experiences of CPG implementation and use for health service delivery. We used a semi-structured interview guide, asking about experiences of CPG adaptation and implementation processes and about potential barriers to and enablers of successful implementation. The guide was adapted iteratively drawing on insights from previous interviews and included open-ended questions to allow participants to direct the emphasis of the interview (50). Interviewers received training in interviewing and two interviewers were present at all interviews. Interviews were conducted in English. There were no requests for translation despite the various first languages spoken in the provinces. All interviews were individual, with two exceptions 1) a provincial manager interview in Eastern Cape, where our invited participant invited two additional colleagues to participate; 2) the district manager interview in Kwazulu-Natal, where both the district PHC manager and training coordinator were present. One interview, with a Kwazulu-Natal manager, took place telephonically at their request due to challenges with scheduling.

All interviews were recorded. After each interview, reflections and summaries were written to capture initial insights and to identify points for further exploration in subsequent interviews. Interviews were transcribed verbatim, and reviewed for accuracy (TK, TM). Data were stored electronically on password-protected computers; and consent forms stored in a locked cabinet.

Analysis

We used an iterative, thematic content analysis approach (50, 51). Two researchers read initial transcripts (TK, SA) and agreed on the general meaning and main issues presented. One researcher (TK) then re-read transcripts, performing open coding to explore barriers to and enablers of CPG implementation, extracting the relevant quotes/coding units. TK then used the quotes to develop the condensed manifest descriptions, and from these data were placed in categories (52). Categories and their related quotes were further examined (TK, SC, BS, SA) for manifest and latent meanings and to

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identify meaningful themes (53). Following this, results were discussed with SA to develop the analysis further and then presented to all authors for input and verification prior to finalization.

Rigour

Credibility was ensured through detailed capturing and description of our approach to sampling, data collection, data management, and analysis. Quotations were included to provide readers the opportunity to interpret data, establish confirmability and to show data richness. Complementary research competencies and experience of the multidisciplinary team of researchers (social science, medical practice, CPG development and implementation) influenced data interpretation and strengthened study rigour.

Results

Twenty-two interviews were held from September 2015 to August 2016. Participants had previously worked in clinical positions as nurses (n = 15), or doctors (n = 7), but were currently occupying management posts. Provincial and district managers were responsible for health service delivery and worked in PHC generally or specific clinical programmes (e.g. HIV, non-communicable diseases), or in operational roles. District Clinical Specialists worked at primary and district healthcare facilities providing clinical governance support. Our final sample included provincial managers representing four provinces; district managers from two districts in each of the four provinces; and district family physicians in Limpopo, KZN and Eastern Cape. The Western Cape has not implemented the DCST programme.

Most participants considered CPGs credible sources guiding clinical practice and importantly, believed that CPGs impact positively on patients' health. Some participants described that CPGs can '*save a life*'.

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District medical doctors particularly shared views regarding the value of CPGs, stating that they are *'evidence-based and it works… mortality goes down when we do things properly'.* Further arguments supporting CPGs included '*harmonisation of practice'*, '*quality improvement',* and '*rational*' medicine use.

We present the findings within two emergent themes, namely: health system factors and socio-cultural contextual issues.

Health system factors

Senior provincial managers experienced CPG implementation as challenging, under-resourced, and sometimes insufficiently planned. They suggested that CPGs were not the issue, but rather the health systems capacity to support implementation. An experienced senior manager who had worked in several provinces explained:

training and the guidelines are fine, but the bed rock on which we are building is – we are building on shaky ground (Provincial manager, doctor, WC*)*

Financial constraints

Financial constraints were recurring issues across provinces. One aspect was reflected in the frustration expressed by some that funding across different conditions was inequitable, with more funding for HIV and tuberculosis, '*but the other big killers'* such as non-communicable diseases received little or *'no support'.* This situation was driven by international donor funding, which influenced which CPGs were prioritized for implementation.

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Access to the right tools and equipment was perceived as a pre-requisite for successful CPG implementation. However, all participants spoke about budgetary constraints, and resulting lack of, or poorly serviced, clinic equipment and stocks and the associated impact on implementation. A PHC district manager expressed concerns, stating:

Budgetary constraints are still a challenge, the systems are still a challenge they are hindering the implementation of these guidelines. For you to get a blood pressure machine, you have to wait for more than 2 months. If this scale is broken, you should follow a tender process for that scale to be repaired, so the systems are killing the implementation of guidelines also, the procurement and supply chain systems. (District manager, nurse, EC)

Furthermore, the simple issue of limited access to CPG copies on site, due to budgetary constraints, was highlighted as an additional barrier for using CPGs. As captured in this quote from a district doctor in rural Eastern Cape '*I mean you just lucky if you get them*'.

Several district managers also mentioned that '*the challenge is about printing the guidelines'* due to budget allocations from national government. Solutions were offered to overcome both the poor quality of, and poor access to, CPG copies. A dominant view was that digital access would mitigate these issues and increase '*click and check*' CPG access. Several managers suggested, however, that both the book and digital versions are needed, as a rural district doctor said:

'*They [older healthcare providers] like the booklet, but the young ones like the app'* (Provincial manager, nurse, LPP)

Despite many participants highlighting the potential value of increasing digital CPG access, financial barriers were expressed in all provinces, as some managers suggested:

'*no computers, no internet, there's no connection'* (District manager, nurse, KZN)

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'I don't think you will find a single computer that's got any connection to anything' (District manager, doctor, KZN)

In addition, a district manager in an urban context explained the dilemma of investing in digital solutions in the face of limited funding. She asked: '*do you want to buy more computers, or do you want more medication'* (District manager, nurse, WC)

Governance and leadership

Senior managers explained that effective CPG implementation required strong governance including clarity regarding responsibility, and how implementation should be delivered and monitored.

…it's an issue of governance, how is implementation of guidelines governed and whose responsibility is it and do we have enough capacity to manage governance (Provincial manager2, doctor, WC)

District management were perceived as demotivated because of the volume of policies requiring implementing, leaving them feeling *'completely bombarded and confused'.* In addition, lack of support for implementation, or in some circumstances the punitive approach taken towards managers struggling with implementation within very challenging health systems, was demoralizing. A senior manager, having worked in several provinces with differing infrastructure, described his experience:

There are good people at ground level, but without a level of protection and support they kind of just get nailed. So every new policy is looked upon with dread because you are worried that at some point somebody is going to come and say you are not implementing it (Provincial manager, doctor, WC)

Managers offered solutions explaining that it was not only the remit of public servants to lead CPG implementation. Community champions and leaders were suggested as additional enablers of CPG implementation. Within the health workforce, this included senior academics who inspired junior staff;

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in the community it was community leaders including traditional chiefs or religious leaders who endorsed local facilities and encouraged patients to follow guidance.

Further recommendations to support governance included developing relationships with non-governmental organizations (NGO), known as 'partners'. Given the limited provincial budgets, partners were often perceived as the only means for providing training or developing materials for CPG dissemination. Partners were mentioned, particularly in the Eastern Cape, both at the provincial and district level, as one district manager explained *'when the guideline is out, we need to call them [NGO partners] to be part of us'*. The issue of sustainability arose as there was a risk that when NGO funding ended, services were withdrawn, and local government lacked capacity to maintain the activities, potentially undermining care.

Accountability approaches

Several managers suggested accountability mechanisms to enhance implementation. For example, use of audit and feedback to measure CPG use was an accountability and quality improvement approach cited by various participants. This approach was reportedly better functioning in certain provinces. A provincial programme manager in the Western Cape described a constructive experience:

*(Based on the) situational analysis and audits ……. we pick up the gaps in quality and we start looking at what is our opportunity to, either tweak a guideline, develop a guideline or a tool or piece of stationary or an algorithm or flow chart that will close that gap (*Provincial manager, nurse, WC*)*

While accountability mechanisms were perceived by some as essential, most managers, on the contrary, described audits as punitive and obstructive with potential negative consequences. As stated by a provincial manager:

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then comes the monitoring and evaluation people to monitor that thing, not in a nurturing way, but in a

*'why didn't you hit your targets kind of way' (*Provincial manager, doctor, WC*)*

This concept of punitive audits emerged from several provinces. One senior manager spoke about a

'*compliance culture*' in which focus was directed primarily to what is measurable, such as structural

inputs like infrastructure, and the blame that ensues if these targets are unmet. As described:

… when it comes to focusing on clinical guidelines if no one is auditing that in the same way. So, the

Auditor General is this big bogey man out there. If anything goes wrong, then of course the province gets

into big trouble. So, there is a lot more gravitas or seriousness attached when the Auditor General says

something… (Provincial manager2, doctor, WC).

Another participant from the Eastern Cape provided an analogous account:

We will comply and complain later, if there is a time to complain. But what is emphasized, is compliance.

There is that strict compliance. Compliance. If you don't comply, it means you are failing your district, or

your sub-district, or your clinic or your people. *There is no time for complaining or reflecting, it is*

compliance. (District manager, nurse, EC)

The compliance culture and aversion to punitive action was thought to have negative effects on CPG

implementation and patient care. Participants indicated how the compliance and audit systems '*just*

adds to the frustration', 'distracts' from the focus on clinical care and ultimately results in rushing ahead

to meet targets, or as one manager put it: 'r*unning around like a headless chicken' (*District manager,

nurse, EC).

Human resource constraints

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Health workforce constraints were emphasised as pertinent to CPG implementation. Managers

described the mismatch between the growing workload and unchanging staff numbers:

we have this burden of disease that is growing. We have resources that are shrinking. So more of our

*health workers are being asked to do more with less resources (*Provincial manager, nurse, WC*)*

Health workforce barriers to CPG use were described to be three-fold: staff shortages, insufficient time,

and inappropriately qualified staff unable to fulfill required tasks. These issues resulted in staff being

'*overstretched'* and '*not coping'*. It was suggested that staff experience considerable time pressures due

to their heavy workloads, '*continuously dealing with patients'* as well as pressure from patients wanting

them to work '*fast, fast, fast'.* As one provincial manager lamented:

…they [nurses] have no time to look at guidelines, they have no time to do quality work to check the

*quality issues because they are continuously dealing with patients (*Provincial manager, nurse, LPP).

Capacity gaps and opportunities

Linked with human resources is capacity building. Training was emphasised as the primary means by

which CPGs are implemented. Participants generally agreed that to support implementation '*you can't*

just automatically know how to do things, you need to be trained'. Therefore, building skills and

knowledge was understood as a pre-requisite to changing practice.

Primary care nurse training gaps

An issue raised mostly by nurse managers was the poor state of professional training of PHC nurses.

Nurses were described as '*not skilled'* and the nurse training syllabuses '*outdated'*, raising concerns that

nurses entering practice were inadequately prepared. In the most extreme example, a provincial

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manager suggested that '*student nurses come out blank….they are the ones that are causing all these deaths.*'

Several suggestions were made for optimizing training and support through 1) training delivery approaches and 2) post-training clinical support.

Considerations during training

Regarding training itself, access to workshops and ensuring adequate coverage of staff was identified as a significant challenge. Various participants indicated that '*onsite training is the best one'*, as when training was delivered off-site, fewer staff could attend, and disseminating learning when back at facilities was ineffective: '*they [the nurses] don't cascade the information'*. However, '*lack of time*' and '*budgetary constraints'* to provide training in every facility was their reality. Therefore, finding contextually appropriate training approaches were suggested, such as '*training local people to be trainers*' and working with NGO's who have more training resources. Furthermore, ensuring DCSTs are maximally used to provide training were considered key. As a district manager in Limpopo suggested:

DCST staff are now doing the training per facility, no more calling people to a centralized place….and also [doing] the support visit in the facility (District manager, nurse, LPP)

Several participants recommended that training should be interactive, not didactic. Many commended the practical skills training, so-called '*fire drills'*, used for maternal health training. This training require staff to demonstrate a response to an emergency during the training, but also subsequently on-site at unexpected intervals.

It was reported that doctors are excluded from training. Ideally, training should be interdisciplinary, bringing all clinical disciplines onto the same level. As a senior doctor suggested, '*the nurse now knows more than the doctor. So you have to train everybody at the same time.'* (District clinician, doctor, KZN)

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Post-training recommendations

Following training, a critical gap raised repeatedly was the absence of '*clinical support'* and '*mentoring*'.

As a district clinician suggested, '*we desperately, desperately need mentors*'. It was emphasized that

regardless of access to up-to-date, high quality CPGs, when post-training support is poor,

implementation gaps were likely, as captured by the following quote:

on-site facility mentoring, it's a problem….without that, we can have much, much guidelines, good

guidelines, but if there's no on-site mentoring, we are just wasting the government's money (District

clinician, nurse, KZN)

Socio-cultural and geographic challenges to CPG implementation

In addition to health system factors, socio-cultural and geographic factors were raised by most

participants, particularly those in district settings presumably closer to the day-to-day requirements of

health service delivery. The explanation given was that there is a mismatch between what is

recommended in CPGs and what was acceptable due to culture or feasible due to challenges of living in

rural settings.

Acceptability and cultural considerations

Several specific CPGs that posed challenges to implementation were mentioned. The CPG

recommending voluntary male medical circumcision was emphasized as being at odds with cultural

beliefs and norms in settings where traditional circumcision required specific rituals. As one female

nurse manager described:

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…. male circumcision, it is a taboo for me to talk about circumcision. Now you tell people go and do the medical male circumcision. It is as now you are insulting their culture. (District manager, nurse, EC)

Another example related to when mothers with newborns require follow-up clinic visits after delivery, whereas, in some traditional cultures, leaving home for a specified period post-delivery is frowned upon:

*after birth, she must stay at home until 10 days (*District manager, nurse, EC*)*

Geographic barriers

Geography posed barriers to CPG implementation. The distance and difficult environmental circumstances under which many patients must travel to attend clinic appointments make the implementation of certain CPG recommendations unfeasible:

A woman in the Eastern Cape will have to travel 5 kilometers or even more to reach the clinic, so how would you ensure that you reach the clinic 6 days after birth? Those are things that, at times, are impossible when you look at the guidelines. (District manager, nurse, EC)

in rural areas, people are scattered, and there are rivers when it is raining, they can't go to that facility, …….there was rain for the whole month and then there were floods, and maybe the bridges are then just swept away with the floods. And then people who can't go to that clinic to go and fetch their treatment for diabetes and hypertension. (Provincial managers, nurses, EC)

One size fits all approach to CPG development

Critically, the disparity between CPG recommendations and their feasibility were perceived to result in unsuccessful CPG implementation and subsequent failure on standardized national indicator '*report cards'*:

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*Most of the time we will be Number 0 [on audit reports] …., because it [the guideline] is not implemented in the Eastern Cape. It's not working. But they [national government] will always say Eastern Cape is Number 0. It's Number 0 because the tool does not fit here, it's [the guideline] is just not right, they are using something which is round in a square hole… (*Provincial managers, nurses, EC*)*

Many provincial managers reported that consultation between national and provincial government was happening, even prior to finalization of a CPG, to address contextual barriers:

So I think in terms of implementation what I've seen works really well is when people have been part of the process from the policy development side from the word go (Provincial manager, nurse, WC)

However, many participants, particularly district managers did not feel consultations were done consistently and in meaningful ways to ensure that the final CPGs and linked indicators were aligned with geographical and cultural contexts. Many felt that CPG content was '*one size fits all'* and that examples of contextually-appropriate implementation were limited.

Despite participants emphasizing the importance of context, processes for the contextual adaption of CPGs was not routinely described. One exception was an example provided about the structured approach to adopt, adapt, or develop new CPGs in the Western Cape. A provincial manager noted:

*either use the policy from national as is or we either translate it for the local context or we develop policy, because national just hasn't done it (*Provincial manager, nurse, WC)

Discussion

This study explored perspectives of South African provincial and district health managers on potential barriers to and enablers of primary care CPG implementation. Two major themes emerged, the first

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related to broader health system factors such as financial constraints, governance and health workforce

capacity gaps. The second emphasized the importance of socio-cultural and geographic factors, and the

need for CPGs to be adapted to fit local contexts.

Regarding health system issues, we found that despite managers' willingness to support PHC CPGs use,

the relative dysfunction of the health system posed barriers to doing so. Aspects of this theme mirrored

several of the often cited WHO health system building blocks, including leadership and governance;

financial arrangements; health service arrangements and implementation strategies, such as training

(54, 55).

Strong leadership is required to drive CPG implementation (55, 56). Participants, all of whom occupy

responsible management positions, described governance gaps affecting CPG implementation, a factor

also identified in other studies of countries in sub-Saharan Africa (57). Participants described volumes of

incoming policies without time for consultation, adaptation or planning; and rushed implementation

responding to political drivers rather than healthcare quality considerations. To address this challenge,

managers often partnered with community leaders and NGOs. This was deemed necessary, particularly

in the Eastern Cape, a province where many health system and financial issues were emphasised by our

participants and highlighted in national reports (4, 6). CPG implementation strategies take many forms,

including professional development, dissemination of summary products to patients and healthcare

providers, use of key opinion leaders, to name a few (29). In the South African setting, delegating

responsibility to partners with relevant skills and resources is necessary, however, participants were

concerned about sustainability of donor funded activities.

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Relatedly, accountability was a reported gap, specifically clarity regarding who is responsible for CPG

implementation and how best to monitor success. For monitoring, audit and feedback was proposed, a

quality improvement strategy premised on the notion that clinicians may change their performance

when they receive feedback regarding sub-standard practice (58). Those we spoke to provided examples

of constructive audit and feedback allowing managers to adapt implementation to address gaps.

However, mostly, audits were experienced as punitive, driving managers to '*comply*' rather than

innovate. A systematic review of 49 trials of audit and feedback found this approach should offer benefit

in CPG implementation (58). Importantly, this review identified success factors that need be considered

including whether the baseline performance of health professionals is low to start with; feedback is

recurrent and given both verbally and in writing; and the process includes clear targets and action plans

(58). Findings from our study suggest that further factors may need to be considered, such as feasibility

and context, to ensure that implementers feel empowered, rather than discouraged or demotivated, by

audit and feedback systems.

Most participants described CPG implementation as reactive, rather than proactive, driven by demands

to implement without adequate time or funds to do so effectively. Participants spoke of a '*compliance*

culture' and explained that requirements were heavily weighted towards administrative reporting rather

than consideration of clinical quality improvement. Within the field of 'quality of care' measurement, a

long-standing model posited by Donabedian proposed three measurable facets of quality of care, 1)

structure (e.g. inputs to care such as facilities, staffing); 2) process (e.g. clinical care) and 3) outcomes

(e.g. health outcomes, patient satisfaction) (59, 60). In South Africa, the apparent emphasis on structural

measurement, is unlikely sufficient, as shown by a multi-country cross-sectional study in similarly poor

settings which reported that infrastructure reports correlated poorly with clinical care or CPG

adherence (61). Drawbacks of this narrower structural and process focus have also been described in

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the UK's National Health Service, where attempts to create efficiency, resulted in '*compliance-oriented bureaucratised management*' and was felt to hinder quality service delivery rather than enable it (62).

Financial constraints were identified as critical factors limiting effective CPG implementation. Lack of basic equipment, and CPG books was described as the norm. Additionally, lack of infrastructure, including internet or devices, was a perceived barrier to using CPGs. These views mirrored those of PHC providers in the same districts that we spoke to who described that they would be more likely to use CPGs if digital access was possible (33). However, like the managers, lack of internet in facilities, and exorbitant costs of data required for downloading CPGs was a barrier (33).

Human resource constraints such as clinical workload and understaffing were another health system issue hindering CPG implementation, a finding that echoes a sub-study of PHC clinical staff in these districts (33).

Training is the mainstay of capacity building for human resources for health. Training is vital for building skills and knowledge to implement CPGs, but also as a form of enablement for teams more generally. In South Africa, like many low- or middle-income settings, nurses are the backbone of PHC services. Yet, poor quality nurse training, found in our study and others, was a concerning issue associated with outdated curricula and inaccessible training sites (63).

To overcome these challenges, many participants pointed to the importance of post-training clinical mentorship. When in place, this clinical mentorship was perceived to provide the necessary, case-based, in-facility support for CPG implementation and role-modelling CPG use. This view has been reported by other South African studies, in particular a study exploring the Ideal Clinic programme

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implementation suggested that family doctors in the DCSTs have similar perspectives regarding the

importance of mentorship (64, 65).

In addition to health systems issues, the importance of context emerged as a significant theme. Within

the public sector, CPG production in South Africa is generally the responsibility of the National

Department of Health and implementation a provincial mandate, with further devolvement of decision-

making to districts (6). This decentralised approach is advocated globally, particularly for health systems

progressing to UHC to enable more responsive ground-up health services (66). However, from our

participants we learned that the problem with this is two-fold. Firstly, health indicators are aligned with

national strategies, which do not consider differences between provinces. Secondly, local teams lack

time and specific training in the adaptation of the CPGs for their setting. These concerns were also

expressed by national primary care CPG developers, who described that fragmentation between and

within provinces likely hampers implementation (39). According to our participants, implementation of a

'one size fits all' national CPG may result in several negative consequences including poor scores on

national indicators due to unfeasible recommendations that are not adequately implemented ('round

peg in a square hole' analogy); and rushed implementation to align with a national programme or

political drive.

Despite, and perhaps because of, the contextual challenges these managers encountered, many of them

described innovative approaches to overcome geographic barriers or cultural issues. For example, a

female nurse manager in the Eastern Cape led the development of a male nurse-led programme for

medical male circumcision because in her setting for women to discuss circumcision is a cultural taboo.

In addition, where geographical barriers arose, such as flooding rivers, district managers tried to provide

vehicles and airtime to community healthcare workers to reach patients. This was not always successful,

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due to financial barriers and inadequate procurement processes. A number of managers described plans

that required impressive ingenuity and commitment to overcome health system and contextual barriers,

despite all odds, and seemingly with little recognition. Additionally, despite the managers' evident

wealth of knowledge, experience and creative solutions, when pressed, there was a notable absence of

examples provided by participants of opportunities to share lessons learned, innovative approaches, and

successes or challenges between and within districts or provinces.

Taken together these health system and contextual barriers to CPG implementation are recognized in

various CPG frameworks as potential challenges to implementation (27, 67) . However, arguably, those

frameworks, largely developed in higher-income settings, contain more detail regarding the CPG and

healthcare provider characteristics and less regarding the social, political and contextual factors. In

South Africa, availability of CPGs and motivation of healthcare providers and managers to support CPG

use are less of an issue than those of context and health systems (33).

Implications for policy and practice

Although substantial research about district health services and systems exists in South Africa and

elsewhere, there is a paucity of evidence published through the lens of CPG implementation. CPGs are

amongst the tools used for policy implementation. In this study, participants made recommendations

regarding structural barriers that hinder CPG implementation and ultimately impact patient care.

Participants emphasised the importance of strengthening leadership, clarifying roles and putting in place

constructive accountability measures. Skilled nursing and other clinical services are required to address

the health burden, along with the equipment and supplies to deliver their services as recommended by

evidence-informed CPGs. Quality assurance of PHC training programmes, particularly nurses, and

facilitating interdisciplinary training to ensure all staff are adhering to CPGs was suggested. Innovations,

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such as the DCSTs, are filling a reported gap in providing clinical mentorship, but needs further strengthening. Finally, effective CPG implementation in health services need to consider the unique settings in each province, including culture, geography and social needs. Systematic use of available CPG implementation checklists to explore, understand and plan for implementation will assist to tailor strategies to address local needs, making best use of limited resources (27, 30, 67).

Limitations

Elsewhere we have discussed limitations within the broader SAGE qualitative study (33, 40). In brief, exploring CPG implementation for all PHC CPGs encompasses a very broad research area. Many PHC CPGs are available, each likely has different barriers. However, in our exploratory research, we found many cross-cutting issues likely to affect most of PHC CPGs, such as access, training and supply chain factors. Future research can build on our findings and identify CPG-specific barriers and enablers.

Regarding this sub-study, a potential limitation is the sample, including provincial and district managers in four provinces, which may not sufficiently capture all views for this sub-group of the health services. Additionally, we used a mix of purposive and convenience sampling, resulting in inclusion of participants who were more likely to be available or responsive. Despite this, common themes emerged and triangulated between provinces and with previous research. As this is not a static situation, research in the evolving process to UHC is likely necessary. Finally, we cannot rule out the possibility of response bias, in which participants respond according to what they believe we want to hear (50). However, from most participants, many rich issues arose. Using the individual interview approach may have provided a safe space and achieved the depth that we have been able to capture and share in this paper.

Conclusion

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UHC is planned for the coming decade with CPGs one of the named tools to achieve evidence-informed, effective and cost-effective healthcare (11). We found that health system challenges; and socio-cultural and geographic context are central issues requiring attention for successful CPG implementation. Our study adds to a body of CPG implementation knowledge providing practical and local insights, from the perspective of provincial and district health managers, regarding what needs attention to effectively implement primary care CPGs in lower-resourced settings.

List of abbreviations

CPG   Clinical practice guideline

DCST   District Clinical Specialist Team

EC   Eastern Cape

HIV   Human immunodeficiency virus

KZN   Kwa-Zulu Natal

LPP   Limpopo

PHC   Primary health care

UHC   Universal health coverage

WC   Western Cape

Declarations

Ethics approval and consent to participate

The study was approved by the Research Ethics Committees of the South African Medical Research Council (EC002-2/2014) and Stellenbosch University (N14/02/008). The informed-consent form was sent to the individuals prior to the interviews and was also explained and confirmed at the start of interviews. All participants provided individual written informed consent. The names of participants

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have been captured and have restricted access. We referred to the Consolidated criteria for reporting

qualitative research (COREQ) to ensure comprehensive reporting (36).

Consent for publication

Not applicable

Availability of data and material

The datasets generated and/or analysed during the current study are not publicly available as this may

be linked to specific clinic staff that were interviewed and as such is not available open use data.

Should anyone wish to have access or is interested in further exploration of the data, you may contact

the author: tamara.kredo@mrc.ac.za.

Competing interests

TK has contributed evidence to the National Department of Health Essential Drugs List Adult level

standard treatment guideline (non-funded); and facilitated workshops and capacity development for

under and post-graduate students, researchers, policymakers and practitioners on clinical practice

guidelines and evidence-informed practices. JV has been involved in guideline development globally and

regionally, he has been on advisory committees for clinical guidelines in the Western Province and has

facilitated workshops and capacity development for under and postgraduate students, researchers and

practitioners on clinical practice guidelines and evidence-informed practices. SC, SA, AA, BS and JM have

no competing interests to declare.

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Authors' contributions

TK drafted the protocol, with input from JV, and AA, amongst others involved with the initial SAGE

project. TK, AA and JM were involved with data collection. TK, SA, JV, AA, JM, SC and BM contributed to

discussions regarding analysis of findings. TK drafted the manuscript, with input from all authors. All

authors approved the final version of the manuscript.

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Chapter 5: Primary care guideline use: barriers and enablers

Summary: This qualitative study describes the views of primary care healthcare providers and end-users of guidelines. Healthcare providers, generally nurses and allied health workers, are knowledgeable about guidelines, generally trust their credibility and are receptive and motivated to use them. Guidelines are seen by nurses to provide confidence and reassurance, as well as professional authority and independence where doctors are scarce. Barriers to guideline use include: 1) inadequate systems for printed book distribution; 2) insufficient and substandard photocopies; 3) linguistic inappropriateness (e.g. complicated language, lack of summaries, unavailable in local languages); 4) unsupportive auditing procedures; 5) limited involvement of end-users in guideline development; and, 6) patchy training that may not filter back to all providers. Recommendations from participants include: 1) improving the design features of guidelines; 2) accessible places to find guidelines; 3) making digitally-formatted versions available; 4) more supplementary materials (e.g. posters) to support patient engagement; 5) accessible clinical support following training; and, 6) in-facility training for all professional cadres to ensure fair access, similar levels of capability and interdisciplinary consistency.

Related presentations:

Kredo T, Muller J, Mokganyetji T, Abrams A, Daniels K, Atkins S. Exploring barriers and facilitators to South African primary care clinical guideline implementation: perspective of clinicians. Global Evidence Summit, Cape Town, South Africa. Cochrane Database of Systematic Reviews 2017, Issue 9 (Suppl 2). dx.doi.org/10.1002/14651858.CD201702 (oral).

Kredo T, Cooper S, Muller J, Mokganyetji T, Abrams A, Daniels K, Volmink J, Atkins S. Using the Theoretical Domains Framework to explore barriers to and facilitators of South African primary care clinical guideline implementation: perspectives of primary care clinicians. Abstract of the Behaviour Change for Health: Digital and beyond, 21-22 February 2018, University College London, United Kingdom (poster).

Kredo T, Cooper S, Muller J, Mokganyetji T, Abrams A, Daniels K, Volmink J, Atkins S. Using the Theoretical Domains Framework to explore barriers to and facilitators of South African primary care clinical guideline

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RESEARCH ARTICLE   **Open Access**

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Using the behavior change wheel to identify barriers to and potential solutions for primary care clinical guideline use in four provinces in South Africa

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Abstract

Background: Clinical practice guidelines risk having little impact on healthcare if not effectively implemented. Theory informed, targeted implementation may maximise their impact. Our study explored barriers to and facilitators of guideline implementation and use by South African primary care nurses and allied healthcare workers in four provinces in South Africa. We also proposed interventions to address the issues identified.

Methods: We used qualitative research methods, comprising focus group discussions using semi-structured topic guides. Seven focus group discussions were conducted (48 providers) in four South African provinces (Eastern Cape, Western Cape, Kwazulu-Natal, Limpopo). Participants included mostly nurses, dieticians, dentists, and allied health practitioners, from primary care facilities in rural and peri-urban settings. The analysis proceeded in three phases. Firstly, two analysts conducted inductive thematic content analysis to develop themes of data. This was followed by fitting emergent themes to the Theoretical Domains Framework and finally to the associated Behaviour Change Wheel to identify relevant interventions.

Results: Participants are knowledgeable about guidelines, generally trust their credibility and are receptive and motivated to use them. Guidelines are seen by nurses to provide confidence and reassurance, as well as professional authority and independence where doctors are scarce. Barriers to guideline use include: inadequate systems for printed book distribution, insufficient and substandard photocopies, linguistic inappropriateness (e.g. complicated language, lack of summaries, unavailable in local languages), unsupportive auditing procedures, limited involvement of end-users in guideline development, and patchy training that may not filter back to all providers. Future aspirations identified include: improving the design features of guidelines, accessible places to find guidelines, making digitally-formatted versions available, more supplementary materials (e.g. posters) to support patient engagement, accessible clinical support following training, and in-facility training for all professional cadres to ensure fair access, similar levels of capability and interdisciplinary consistency.

Conclusions: South African primary care nurses and allied health practitioners have high levels of motivation to use guidelines, but face many systemic barriers. We used the Behaviour Change Wheel to suggest relevant, implementable interventions addressing identified barriers. This theory-informed approach may improve clinical guideline implementation and impact healthcare for South Africa.

Keywords: Qualitative research, Clinical practice guidelines, Implementation, Primary care, Focus groups, Theoretical domains framework, Behaviour change, Quality improvement

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Background

Internationally, high-quality, evidence-informed clinical practice guidelines (CPGs) are recognised as essential quality improvement tools [1–3]. CPGs have a range of purposes, intended to standardise care, improve its quality and safety, decrease costs, and improve patient outcomes [3, 4]. They offer a 'one-stop shop' for end-users, by providing synthesised information from systematic reviews regarding best practices [5]. However, despite growing availability of CPGs, if not used, they cannot impact on the quality of the care that is delivered.

South Africa has long been developing CPGs, most pronounced during the post-apartheid period when CPGs were considered important tools to redress inequity, standardise care and promote cost-effective care for all. Many CPG development players have been identified: national government, professional societies, hospitals and clinics all contribute according to their needs and agendas [6, 7]. However, despite development and distribution of CPGs, health outcomes remain poor, and generally worse than expected given the per capita health spend relative to other similar middle-income countries [8, 9]. As CPGs aim to optimise care, and yet care appears not to be optimally delivered, it may be helpful to understand the barriers to CPG implementation and use [10, 11].

We know there are no 'magic bullets' for improving CPG implementation [12, 13]. Systematic reviews suggest many potential implementation strategies, such as audit and feedback, outreach education and key opinion leaders [14]. Available evidence suggests that tailored, multi-faceted approaches may do better than generic and single-focused interventions [13, 14].

Several pragmatic trials of CPG implementation for lung health, Human Immunodeficiency Virus (HIV) and broader primary care have been conducted in South Africa, finding some improvements when educational outreach is used [15–17]. It is therefore possible that, when used, CPGs may improve health outcomes. If we better understood when and how CPGs are used by South African primary care providers, then CPG developers may design evidence-informed strategies to enhance enablers and overcome barriers.

The Theoretical Domains Framework (TDF) is a useful approach for identifying facilitators of and barriers to behaviour change, and for developing tailored interventions when implementing CPGs [18]. Understanding how best to enhance healthcare providers' use of CPGs requires consideration of the complex interplay of clinician and patient behaviours, environmental context and social influences. The TDF intends to integrate theories of behaviour change, and bridge health psychology, organisational theory and health services, providing a theoretical basis for implementation research [19]. Several studies have used the TDF to evaluate healthcare implementation challenges or to design theory-informed implementation strategies. Examples include hand hygiene, children's health checks, human papilloma virus vaccination, dental infections, and lower back pain [10, 11, 20–22]. Some of these explorations further informed the design of complex interventions for research or public health programmes [20].

Utilising the TDF, this study aimed to explore primary care healthcare providers' perspectives regarding the context, potential barriers to and enablers of CPG use in four provinces in South Africa. Based on the findings, and drawing on concepts from the Behaviour Change Wheel (BCW), this study also sought to provide recommendations for potential interventions to improve CPG usage and implementation.

Methods

Theoretical framework

We used a qualitative study design, including semi-structured focus group discussions (FGDs). The overarching conceptual framework used for this article was the Theoretical Domains Framework (TDF) that also formed part of our analysis process described below. The TDF provides a basis to understand behaviours theoretically and therefore target processes most likely to implement desired change [19, 23]. The 14 domains of TDF have been further mapped onto the Capability, Opportunity, Motivation – Behavioural model (COM-B model), a 'behaviour system' model which seeks to encapsulate the conditions internal to individuals and those within their social and physical environment necessary for achieving specified behavioural targets [18]. Three essential conditions: Capability, Opportunity, and Motivation (COM-B) are at the core of this system, which posits that these components interact to generate behaviour, which in turn influences them in a back-and-forth cycle. These components form the hub of what is termed a 'Behaviour Change Wheel' (BCW), around which are a number of interventions which may be implemented at the individual (e.g. education and training), or policy level (e.g. legislation or fiscal measures) to enable the COM-B elements [18]. The BCW is a practical tool that can be applied in implementation research to move from identifying barriers and enablers to aligning these with tailored interventions [24]. Definitions for the COM-B domains, how they map to the TDF and to the BCW intervention functions are shown (Table 1).

Study settings

South Africa has a population approaching 57 million and a health system invested in primary healthcare [25–29]. The country is currently striving for universal health coverage, publishing a White paper (2015) describing aspects of the National Health Insurance system [30]. Financial federalism is in place in which national government develops strategies, policies and clinical CPGs; and

Table 1 Links between COM-B, Theoretical Domains Framework and Behaviour Change Wheel intervention functions

COM-B model		Theoretical Domains Framework	Behaviour Change Wheel Intervention functions
Motivation Definition: *all those cognitive processes that direct behaviour, including habitual processes, emotional responding, as well as analytical decision-making.*	Reflective motivation	Professional/ social role and identify	Education, persuasion, modelling
		Beliefs about capabilities	Education, persuasion, enablement
		Optimism	Education, persuasion, modelling, enablement
		Beliefs about consequences	Education, persuasion, modelling
		Intentions	Education, persuasion, incentivisation, coercion, modelling, enablement
	Automatic motivation	Reinforcement	Training, Incentivisation, coercion, Environmental restructuring
		Emotion	Persuasion, incentivisation, coercion, modelling, enablement
Capability Definition: *the individual's psychological and physical capacity to engage in the activity concerned, and includes having the necessary knowledge and skills.*	Physical capability	Physical skills	Training
	Psychological capability	Knowledge	Education
		Cognitive and interpersonal skills	Training
		Memory, attention and decision processes	Training, environmental restructuring, Enablement
		Behavioral regulation	Education, training, modelling, enablement
Opportunity Definition: *all the factors that lie outside the individual that make the behaviour possible or prompt it.*	Physical opportunity	Environmental context and resources	Training, restriction, environmental, restructuring, enablement
	Social opportunity	Social influences	Restriction, environmental, restructuring, modelling, enablement

provincial governments implement CPGs, sometimes after adaptation, to healthcare facilities (from regional, to district, to community healthcare facilities) [8].

Sampling and recruitment
South Africa is a large and diverse country. We therefore selected four of the nine provinces to represent a spectrum of primary healthcare settings: Western Cape, Kwazulu-Natal, Eastern Cape and Limpopo provinces. Each province is different in terms of population size and density, economic development, healthcare spending and resources, and health outcomes (Table 2). While the Western Cape, Eastern Cape and Limpopo have similar population sizes, the Western Cape is better funded, and

Table 2 Key health and demographic indicators by South African province[a]

Indicator	Year	Province			
		WC	KZN	EC	LPP
Area as a % of total area of South Africa	2011	10.6	7.7	13.8	10.3
Population	2016	6,279,730	11,065,240	6,996,976	5,799,090
Population % by province	2016	11.3	19.8	12.6	10.4
GDP per capita (USA)	2010	8.69	4.77	3.65	4259
Education level (% population with no schooling)	2015	1.5	6.7	6.1	9.8
Poverty prevalence (food poverty line)	2011	23.2	37.4	40.5	41.5
Population % dependent on public sector	2016	75.96	88.22	90.13	91.58
Health as % of total expenditure	2000	30.0	26.7	20.9	17.8
Per capita public sector health expenditure	2015	4242.5	3623.1	3304.4	2957.7
Life expectancy at birth	2010	68.0	52.9	53.8	63.6
Adult mortality rate (probability of dying between 15 and 60 years)	2010	26.6	52.8	52.2	37.7
Under 5 mortality rate	2015	23.1	57.8	59.6	36.6

[a]*Adapted from South African Health Review 2017* [27]

has higher educational levels, lower levels of poverty and a higher life expectancy than the others. Kwazulu-Natal has the largest population size, a high poverty prevalence and poor life expectancy, despite health expenditure approaching that of the Western Cape. Other factors besides available funds, are likely to play a role in this regard, including high prevalence of infectious diseases, such as HIV [25]. Within each province, we targeted two public sector primary care clinics, one rural and one urban or peri-urban. While we intended to conduct eight FGDs, we completed seven due to delayed access in the Western Cape. To identify clinics, we contacted the provincial research directorates and colleagues working in the provinces for guidance. All healthcare providers working at clinics, regardless of cadre, were invited to participate (Table 3).

Data collection and management
The FGDs enabled us to explore collective experiences of CPG use at the frontline of healthcare delivery. This method is suited for exploring complexity surrounding CPG use within the context of lived experiences, in ways that encourage participants to engage actively with the research topic [31, 32].

Seven FGDs were held from November 2015 to August 2016. Group sizes ranged from three to eleven participants and lasted from 60 to 90 min. A total of forty-eight providers participated. Primary care providers who took part included nurses, occupational therapists, physiotherapists, dieticians, dentists, oral hygienists and medical doctors.

The FGDs were guided by a semi-structured topic guide which explored the following topics: the context of CPG awareness and use; specific CPGs used (and frequency of usage); access to CPGs; general views and experiences of using specific CPGs; perceptions of barriers to and enablers of CPG use; and recommendations of strategies that might address current barriers to use. The guide was flexible to ensure that participants could express what was important to them, and so learnings from previous FGDs could be clarified and probed further in subsequent FGDs. The FGD guide was not

Table 3 Schedule of Focus Groups

Location	Discipline	Number of focus groups (participants)
Western Cape	Nurses, dentists, health promotions officer	1 (n = 6)
Eastern Cape	Nurses	2 (n = 12)
Limpopo	Dentists, oral hygienist, occupational therapy, physiotherapy, dietician, counsellors, database administrator	2 (n = 17)
Kwa-Zulu Natal	Doctors, nurses, quality assurance officer, dentist, physiotherapist, counsellors	2 (n = 12)

based on the TDF, but rather sought to understand nurses' perceptions about and experiences with using CPGs on their own terms and their own meaning frames. The TDF was used during the analysis stage to help analyse and organise the data as described below. FGD facilitators received training in facilitation techniques. All FGDs were conducted in pairs; members of the research team (all females) took turns to facilitate.

FGDs were recorded digitally. Reflections and summaries were written after FGDs to capture insights. Initial coding and thematic analysis were conducted after each FGD to guide the sampling process and to ensure data saturation.

FGDs were transcribed verbatim, and transcriptions were reviewed for accuracy by the research team (TK, TM). A few participants including a lay counsellor and entry level nurse chose to share their views using their mother tongue which was not English. A research team member assisted to translate these short sections for us to include in the analysis. Data were stored electronically on password-protected computers; a master list and consent forms were stored in a locked cabinet for which only the project lead had access.

Analysis
We used an iterative, thematic content analysis approach [31, 33]. Specifically, two researchers read the transcripts (TK, SA) and agreed on the general meaning and central issues presented. One researcher (TK) then re-read transcripts, performing open coding related to general questions posed, including context, use, barriers to and enablers of CPG use, extracting the related quotes [34]. Quotes were then further examined (TK, SA) for manifest and latent meanings [35]. At this point, we searched for conceptual frameworks that might help us better understand and organize the data. The TDF was considered to provide a useful model in this regard, enabling us to encapsulate the individual and context factors that facilitate and /or hinder CPG use that we saw emerging from the data. The model was also deemed valuable to facilitate the subsequent translation of our findings into actionable recommendations for interventions which target specific barriers. This model has been used successfully by others to evaluate healthcare implementation challenges and to design theory-informed implementation strategies [20, 21].

Having examined individual quotes for manifest and latent meanings, two researchers (TK, SC) then used the TDF to further categorise the data. In particular, specific quotations and their meanings were matched to the 14 domains within the TDF. The two researchers performed the matching independently, and

subsequently discussed these with each other and the third researcher (SA) to reach agreement and resolve uncertainties. Each quotation was coded to at least one TDF domain, but some we felt could be coded into two or three domains. In the case of the latter, judgments were made about which specific domain the quotes should be categorized, in a manner that captured the meaning of individual quotes and fitted with the broader themes that were emerging. Once our findings were aligned with the TDF domains and associated COM-B system, then proceeded to map the findings onto the respective intervention functions to generate recommendations based on the BCW [24]. The process of developing recommendations was informed by the methods used by Michie and colleagues to link their analysis of the targeted behaviours to appropriate interventions for controlling tobacco and reducing obesity [18].

Rigour
Credibility was ensured through detailed capturing and description of our approach to sampling, data collection, data management, analysis and interpretation [35]. Consideration of issues regarding reflexivity and transferability were considered throughout the process. Quotations were chosen to provide readers the opportunity to interpret data, establish confirmability and to show the richness of the data. Complementary research competencies and experiences among all researchers influenced data interpretation and strengthened study rigour.

Results
Most participants were nurses; two were doctors at one FGD in Kwa-Zulu Natal (Table 3). Although we collected limited demographic data, we observed that those in rural facilities had worked for a longer time and lived in the area, whereas at the more urban facilities, participants were generally younger, more recently appointed and potentially more mobile.

In this section we report the potential enablers of and barriers to CPG use in terms of the COM-B domains of 'Motivation' (reflective, automatic), 'Capability' (psychological, social) and 'Opportunity' (social, physical) (Table 1) [23], and reflect on and unpack the TDF categories within them.

Motivation – Reflective and automatic
Motivation includes behaviors corresponding to reflective motivation and those that are more automatic or habitual. We report on both reflective and automatic motivation as they include issues of emotion, professional identify, beliefs about capability and consequences. Strikingly, across all FGDs, the overwhelming majority of participants expressed motivation to use CPGs. CPG use appeared to evoke a range of positive emotional responses, particularly amongst nurses. Sentiments included *'reassuring,'* inspiring *'confidence'* and providing a sense of autonomy or *'independence'*. The latter was particularly pronounced in more rural settings, with few doctors:

*It makes [allows] us to be in line with the doctors, it makes us doctors ourself [*sic*], so it means you will be independent* (Nurse_LPP_rural).

Additionally, CPGs were perceived as useful tools to engage the community, share information and protect healthcare providers' professional integrity, which further motivated use:

Even if there is a complaint among the community members that we have mismanaged this client, so we say, I have managed this client ... through the guidelines and we show him the guidelines (Nurse_EC_rural).

Overall, CPGs were perceived as credible sources. Nurses and allied healthcare providers in several clinics described having first-hand experience of CPGs improving patient care. One particularly significant example cited was that of HIV, where CPGs had changed rapidly as the field of HIV care changed in South Africa. Providers described having seen patients transition from dying prior to the availability of HIV CPGs, to patients living with HIV after CPGs were implemented. This underscored for them the perceived value that using CPGs bring:

It's working, because when we want to find out our statistics, people they are now...[HIV] negative...they have got ARV's [antiretrovirals] and they are fine... (Nurse_KZN_rural).

Compared to nursing staff, the link between CPGs, professional identity and enablement seemed lesser for doctors, as one doctor suggested:

I must confess, we doctors are not very good at seeing this is what the guidelines says. This is the way I do things and then you go on. It's not just here but if you go to another place you'll find the same thing. (Doctor_KZN_peri-urban).

Capability – Knowledge and skills
Capability includes knowledge, understanding, decision-making and skills as fundamental drivers of behaviour. A consistent narrative amongst participants was that knowledge of CPGs was not a barrier to usage. Participants conveyed considerable awareness of CPGs, with many naming several that were in regular, perhaps even daily use. In addition to knowledge, remembering and deciding to use CPGs was not perceived as a barrier. Some participants even voiced curiosity about why we

would conduct research on something that was so obviously part of routine clinical care.

While some participants described using CPGs for *'each and every patient'*, others suggested that they were most likely to use CPGs in particular instances. That is, they tended to use CPGs when faced with an unfamiliar clinical case or a change in the recommendations that sparked curiosity, and required learning:

> *…what makes me want to read some of them is because I came across such a patient, and I didn't know what to do then I go back to read. That is what makes me wanna read, otherwise I don't think I'll just sit down and read the guideline*
> (Oralhealth_LPP_peri-urban).

Despite their own knowledge, participants expressed an important gap in CPG awareness amongst patients and the public. Many felt that increasing public awareness of CPGs was important for successful CPG implementation. That is, a more health-literate and empowered public was perceived to encourage accountability of healthcare providers. Several approaches for raising public awareness were proposed, including engaging journalists, use of radio, television and social media:

Maybe when you're listening to [the] radio and reading news, they should introduce this change everywhere, because even [the] patients should know (Oralhealth_LPP_peri-urban).

Another significant gap identified by participants was training in CPG usage. Training was perceived as an essential tool to *'keep abreast'* or *'get up to speed'* with CPG content. It was also considered important for enhancing clinical practice and ensuring that all disciplines *'will be on the same level'* and thus preventing a *'clash of information'*. While training was unanimously perceived as necessary for proficient CPG usage, participants were undecided about the setting in which training should take place. Specific feedback about the pros and cons of on-site training and off-site workshops were provided, which are detailed in Additional file 1. Though training was considered key to CPG use, many participants felt that skills building through training was inadequate. Training, regardless of whether providers were from urban or rural settings, was considered insufficient or patchy, not covering all topics and not inclusive of all clinical disciplines. This inadequacy was perceived to result in CPGs which are *'hard to interpret'* and thus staff having to *'struggle'* on their own to use CPGs properly. The management process for deciding who would attend workshops was also described as non-transparent and unfair, with *'no consistency'* surrounding attendance. Thus, while participants were categorical about

the need for more training, the issue of how best to do this remains complex.

Opportunity – Social and physical

Opportunity includes both physical opportunity and social opportunity. Social opportunity considers the social influences that may impact CPG use. While this domain did not generate substantial discussion amongst participants, what emerged consistently, particularly in rural facilities, was the value of supportive social and professional systems as enabling quality clinical care and CPG use. These systems, including involvement of non-governmental organisations, and associated cohesive teams and strong leadership, were perceived to enable the culture of CPG use.

So it's team work that matters, if you are working as a team you do (Nurse_EC_peri-urban).

Whereas we found generally supportive social and professional environments, the physical environment emerged as a considerable obstacle to CPG use. This domain generated extensive discussion, with several sub-themes emerging, namely: the need to adapt to local context; health system challenges; access to CPGs; CPG design needs; and digital CPGs. In addition to describing these barriers in great depth, participants from all disciplines also provided practical recommendations for how these contextual barriers might be addressed.

CPGs being insufficiently adapted to local contexts emerged as a key issue. Given the diversity in a large country like South Africa, the context in which CPGs are used may differ by province. Some CPG recommendations were experienced as *'not practical'* and not appropriate to local healthcare contexts. Many agreed that for CPGs to become *'something that can really apply to us'* and that *'actually works to suit the PHC* [primary health care]*,'* healthcare providers should be part of CPG development processes.

Health system challenges emerged as another major barrier to CPG implementation. The ability to operationalise CPG recommendations was described as significantly hindered by *'no budget'*, *'slow procurement'*, or the lack of equipment where staff simply *'don't have the machine'*. Stock outs of medicines was highlighted as an issue:

> *when there is a recommendation and the medication is not there… we are stuck* (Nurse_LPP_rural).

Relatedly, primary care clinic pressures were perceived to limit providers' ability to properly read CPGs. All cadres described that the *'long queues outside'* and the time needed to *'page and page'* through a CPG was not feasible during a consultation.

Participants also identified barriers related to the design, layout and language of CPGs, and made

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suggestions for how these might be improved to enhance CPG use (Additional file 2). Many spoke about the lengthy nature of CPGs and the *'big jargon English,'* which limited understanding and use. They expressed a wish for *'much more user friendly'* CPGs, including using *'short directive'* and more simple language, and incorporating *'summarised'* versions, more definitions, local vernacular and supplementary tools (e.g. posters) to aid understanding and support patient engagement. A doctor suggested that, as people maybe *'visual learners,'* use of more attractive and appealing formats, such as graphics, charts, and colour, would enhance CPG use. Colour-coding in one of the primary care CPGs (PC101) was described as effective, as one nurse said, it *'keeps you on the toes'* (EC_peri-urban).

Poor access to good quality and up-to-date CPGs materialised as an especially pertinent physical barrier to CPG usage. Many participants, particularly those in rural settings, provided detailed narratives about how *'hard to reach'* CPGs were. Many described how they frequently *'get them late'* or have access to *'only one copy'* in their clinics. Others spoke about the way in which CPGs are often stored inaccessibly outside of consulting rooms, while others highlighted the poor systems that exist for CPG version control, ultimately resulting in *'confusion'* and outdated information. Furthermore, it emerged that even when CPGs are available, they are frequently of sub-standard quality:

> They make copies and pages are missing, the
> arrangement of the pages, [it] becomes bulkier
> and all these things. So that's a problem, I mean
> people don't really get the real thing, a reprint or
> make a copy and make your own.
> (Doctor_KZN_peri-urban).

Numerous participants, both rural and urban, highlighted that many of these barriers around access would be addressed if CPGs were available digitally. They explained that access to digital CPGs would enable them to read them in their own time, not only during consultations, which would in turn make keeping up-to-date easier. They also suggested that it would improve knowledge transfer after workshops, reducing issues related to information sharing. Additionally, many believed that digital CPGs would result in all healthcare providers receiving CPGs in a timely manner and further support in-facility capacity building when new CPGs were disseminated.

Despite general agreement that digital CPGs may facilitate usage, a number of complexities associated with this medium emerged. Some participant wondered whether use of digital CPGs in front of patients would generate negative patient perceptions, who might believe that healthcare providers are *'busy on Whatsapp,'* accessing other nonwork-related content, or that they lack knowledge. At the same time, while some participants had CPGs on their phones, including the CPG app or electronic books, this was a minority, and mostly seen in peri-urban facilities. Most clinics did not have internet access either via computer stations or wireless internet, and healthcare providers did not consistently have smart phones, data and internet access through other means. This was particularly evident in the more rural clinics where in a FGD of 11 staff, one nurse reported having opened a personal email account, and even that was a recent development. Although participants in the Western Cape FGD described having personal internet access, they suggested that limited phone memory, high data costs and the need to download CPGs at their own expense was a barrier. Thus, use of digital CPGs was described to come with its own set of access issues, and while evidently desirable, remains aspirational from providers perspectives.

Implications for policy and practice: Theory informed interventions

The barriers most often expressed by participants were related to the environmental context, resources and training needs. We thus used the BCW approach to map the most relevant intervention functions to address these specific barriers, as shown in Fig. 1 [18]. In this matrix we provide specific suggestions for possible interventions to increase use of South African primary care CPGs.

Therefore, from our findings, 'physical and psychological capacity', in particular poorly supported training was a barrier to CPG use; and most strikingly, the 'physical opportunity', in that the environmental context and available resources were substantial challenges to CPG use. Based on our results, the following intervention functions are suggested that align the COM-B domain, behavioural barriers and possible interventions:

- Training - imparting skills (for example workshops, on site mentoring and supervision, post-training support)
- Education – increasing knowledge or understanding about specific CPG recommendations (e.g. workshops, post workshop support and clinical support)
- Environmental restructuring – changing the physical environment (e.g. making the CPGs more accessible through different formats, greater design consideration, summarized simple language, more appealing tools that support implementation that help engage patients such as posters and algorithms;

Fig. 1 Matrix of COM-B Model barriers and suggested intervention functions. This figure represents a Matrix of barriers that were identified from participants and the potential interventions to overcome them, as guided by the BCW. The matrix is colour coded and all blue coloured areas represent where the COM-B domain aligns with the intervention functions. The darker the shade of blue, the more pertinent the need for an intervention, in light of our findings

ensuring supply chain functioning and access to medicines and equipment; building ICT infrastructure and creating digital access)

– Enablement – increasing means and reducing barriers to increase capability or opportunity (for example, this may include audit and feedback, clinical support and team building).

Discussion

This study explored the perspectives of primary care healthcare providers, working in public sector clinics, regarding the context, potential barriers to and enablers of CPG use in four diverse provinces in South Africa. We investigated these issues through the lens of the TDF, in order to categorise the barriers and enablers in terms of COM-B: Capability, Opportunity, and Motivation.

Enablers – motivation, knowledge and social opportunity.

Our findings revealed that primary healthcare nurses and allied health practitioners generally trust the credibility of CPGs and are highly motivated to use them. CPG usage was perceived to be associated with a range of positive emotional and professional consequences, experiences that have been described elsewhere as potential benefits of CPGs [3]. In addition, knowledge of CPGs, along with regular use, were reported by most healthcare providers, a finding of importance, given that both knowledge about and positive attitude towards a CPG are factors that have been identified as potentially enhancing CPG implementation [36].

Participants in our study, particularly nursing staff, emphasised the importance of cohesive teams, clinical supervision and strong leadership to enable CPG use.

This corroborates reports from higher income settings, which describe the importance of socio-behavioural factors, such as peer support, to enhance CPG use [36–38]. Studies in South Africa have revealed that support and supervision for healthcare providers are currently inadequate. For example, a qualitative study in which allied health practitioners and health managers were interviewed, found a lack of support for allied health practitioners in their practice [39, 40]. Similarly, a recent survey among primary healthcare nurses suggests that many felt unsupported by supervisors to provide best quality clinical care [37, 41]. Against this backdrop, and in light of the findings from our study, enhancing CPG use in South Africa necessitates developing cohesive professional teams and building clinical support for practitioners.

Barriers – Physical capability (skills and training)

Despite apparent knowledge of CPGs and motivation to use them, patchy and non-inclusive training in CPGs emerged as an important barrier to their usage. Lack of requisite skills and self-efficacy are reported barriers to CPG implementation [36]. The participants in our study considered skills building in CPGs essential for enhancing proficiency to use CPGs properly, ensuring similar levels of capability and knowledge amongst healthcare providers, and for facilitating standardised use across disciplines.

However, exactly how this training should be delivered emerged as a complex issue, with participants suggesting advantages and disadvantages of both on- or off-site training. Our participants talked about off-site educational meetings, on-site educational outreach and supportive

clinical audits as desirable. In an overview of systematic reviews, several skills building strategies for implementing health systems in low- and middle-income settings were reported with varying levels of effectiveness, including practice facilitation, educational outreach, audit and feedback, educational meetings, and local opinion leaders [14]. In South Africa, there have been several trials of educational outreach for nurse-driven primary care evaluating CPG implementation [15, 17]. As such, we have supporting evidence regarding feasibility of this approach for managing co-morbidity, and in some studies, evidence of effectiveness for tuberculosis and HIV CPG implementation [15, 17, 42, 43]. Thus, while this study revealed a clear stated need for increased skills building, the best means of providing this in South African primary care might consider using a combination of methods to enable CPG uptake and use.

Barriers - physical opportunity (environmental context and resources)

While other COM-B constructs emerged as enablers of CPG usage, 'physical opportunity' materialised as the most substantial barrier, with participants highlighting numerous contextual issues that hinder effective CPG use. These may be further understood as pertaining to two aspects, the CPG itself or the environmental context in which CPGs are implemented.

Regarding the CPG itself, participants perceived that usage of CPGs is hindered significantly when their content is impractical to implement and linguistically inappropriate; when CPG design features are not user-friendly; and if there are inadequate CPG supplementary tools (e.g. pictures) or no summarised versions. This resonates with a review of different features for ensuring CPG 'implementability', together with a supporting checklist for CPG developers to consider [44]. These resources suggest that specific features of CPGs are likely to enhance their usage, including structured recommendations; providing contextual information regarding clinical cases; explicit resource implications; and supporting algorithms and clinical tools [44, 45].

In terms of the physical environment, several factors were identified as critical obstacles to CPG implementation. In particular, a lack of necessary equipment and reported budgetary and supply constraints, including stock outs of medicines, were a concern and perceived to be related to poor district or provincial management systems. These health system challenges are well described in the country, including a recent qualitative study in which access to equipment or medicines posed serious challenges to delivery of health services for both users and providers of care [6, 9, 26, 46, 47]. In our study, inadequate systems for distribution of printed CPGs and

CPG-related circulars, as well as poor CPG version and quality control, appeared to impact upon CPG use. Taken together, this collection of environmental issues was seen by participants to result in CPGs that are frequently unavailable, inaccessible, of a suboptimal quality and/or difficult to implement. While these barriers emerged across the different study settings, they appeared to be particularly pertinent and heightened in rural areas.

Aspirational enabler - digital access to CPGs

Participants consistently suggested that making digitally-formatted CPGs and associated technologies (e.g. internet, computers, laptops) available was a key strategy to increase CPG access and use. Digital CPGs were suggested to redress many of the contextual challenges they currently face, such as lack of sufficient CPG hard copies or poor version control. There is growing evidence regarding the role of handheld devices to support CPG use. A systematic review reported that doctors and nurses using a CPG on a handheld device may increase access to information, adherence to a CPG and support for diagnosing conditions, in comparison to peers using paper-based resources [48]. However, despite this promising evidence, results emanate predominantly from high-income settings where access and availability of technologies are different to those in low- and middle-income settings. Therefore, despite interest in this area and fast-growing opportunities in technology, current data costs, lack of infrastructure, internet or devices, particularly in rural settings, present major challenges to this becoming a reality, as revealed in our study.

Implications for policy and practice: Strategic theory informed interventions to overcome barriers

Given the limited resources to invest in CPG implementation in many settings, ensuring that the interventions best match the issues and barriers that emerge is a rational approach. We identified that investment for implementing primary care CPGs should consider environmental restructuring, enablement, and training and education (Fig. 1).

Training and education is already a major means for delivering information to primary care via regional training centres and responsible district training personnel. However, the results of this and other studies, suggest specific adaptations and enhancements need to be considered and implemented [39, 40] such as enhanced in-facility training and post-training clinical support. Another intervention function is enablement. Given the motivation of healthcare providers to use CPG, further enablement using evidence-based strategies, such as constructive clinical audit and feedback, clinical support

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and mentoring or team building, may be effective methods to build on the current foundation [17]. Finally, the most substantial barrier, environmental resources, requires considerable resources and planning regarding how best and most cost effectively to restructure the environment to enhance CPG use. Some approaches, such as making more CPG books available or changing the physical appearance of the paper resources enhanced with design features, may be more feasible to achieve short to medium term; however addressing health system reforms including equipment supplies and infrastructure upgrades are important to have on a government agenda for urgent consideration.

Choosing and implementing these interventions will require government buy-in, priority setting and feasibility assessment. Where possible, interventions already in place could be enhanced while others may need to be initiated. The COM-B model is further complemented by a set of specific criteria that can aid decisions when considering interventions. These criteria include: affordability, practicality, effectiveness and cost effectiveness, acceptability, side effects, safety and equity [24]. The relative effectiveness of the priority options should be informed by available systematic reviews [14].

Limitations
Our study has several limitations. Given the volume of CPGs and CPG users at play in South Africa, we set out with a very broad topic - exploring perceptions of all primary care CPG users for all available primary care CPGs. It is likely we would have identified more specific responses had we evaluated a specific CPG and a specific CPG user. However, given the paucity of published work in our setting, we considered this research exploratory, and the best approach to understanding the state of CPG use in primary care, guiding us to further define the research and policy needs for CPG implementation. A SAGE linked sub-study explored perspectives of allied health workers, adding to our more specific knowledge [39, 40].

Our sample is a fair reflection of the South African public sector primary care, which is predominantly managed by nurses [37]. We have sufficient data on nurse and allied health providers perspectives, however, further work with other cadres is required [40]. The two doctors we spoke to stated that doctors generally do not use CPGs, suggesting that this cadre of professionals may hold differing views to nurses and allied health providers. However, given the small number of doctors participating in our study, it is unclear whether this perspective is widely held by primary care doctors and further exploration is therefore required.

A possible limitation may be the positionality of the researchers in eliciting certain responses [31]. It may be that the presence of researchers asking about CPGs

resulted in more positive responses about CPG use, and thus positive reporting bias. However, to pre-empt this possibility, each interview was facilitated by a social scientist, along with a healthcare provider (who understood the clinic context), which we hope brought balance to our interviewing, rather than prompting for specific responses. Given the consistent narratives, regardless of setting, we hope that most participants felt free to provide their true experience and perspective.

We reflected on our choice to use the COM-B and TDF approach, where, following inductive coding, we mapped the codes and themes to the domains of the TDF [18, 23]. We found it assisted us to make sense of the data that emerged, a manner relevant for understanding this aspect of health services research. However, following open coding, the deductive mapping process was challenging. Several of the constructs were related to each other, and could be categorised under more than one domain, for example, professional identity forms a part of social opportunity, and therefore affects motivation. In addition, judgments were required regarding how and where to categorise our findings to best report our understanding of the views of participants. During the process, where items were unclear, we discussed this to resolve discrepancies. In this way, we were able to ensure consistent application of the TDF to our data.

Conclusions
We found that South African primary care nurses and allied health practitioners are aware of CPGs and have high levels of motivation to use them, however, they face many systemic barriers to doing so. Strategies addressing the most pertinent identified barriers, including physical access to CPGs, training to use them and the equipment and resources to implement CPGs, should build on and enhance processes already in place in South Africa. Prioritising potential interventions, including effective training, clinical audit and feedback, and equipment supply, may strengthen primary care and improve CPG implementation ultimately impacting on the health of South Africans.

Additional files

Additional file 1: Training: Advantages and disadvantages of training delivered in-facility or off-site. This file reports on perceptions and suggestions of primary care healthcare providers to meet guideline training needs. (DOCX 14 kb)

Additional file 2: Design features for improving use of CPGs. This file reports features that were suggested by participants to improve implementability and use of the available clinical practice guidelines. (DOCX 12 kb)

Abbreviations
BCW: Behaviour Change Wheel; COM-B: Capability, Opportunity, Motivation - Behaviour; CPG: Clinical practice guideline; EC: Eastern Cape; FGD : Focus

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group discussion; HIV: Human immunodeficiency virus; KZN: Kwa-Zulu Natal; LPP: Limpopo; PHC: Primary Healthcare; TDF: Theoretical Domains Framework; WC: Western Cape

Availability of data and materials
The datasets generated and/or analysed during the current study are not publicly available as this may be linked to specific clinic staff that were interviewed and as such is not available open use data.
Should anyone wish to have access or is interested in further exploration of the data, you may contact the author: tamara.kredo@mrc.ac.za.

Authors' contributions
TK drafted the protocol, with input from AA and JV. TK, JV, SA, SC, JM were involved with data collection and/ or early workshopping of findings. TK drafted the manuscript, with input from all authors. All authors approved the final version of the manuscript.

Ethics approval and consent to participate
The study was approved by the Research Ethics Committees of the South African Medical Research Council (EC002–2/2014) and Stellenbosch University (N14/02/008). The informed-consent form was sent to the facilities prior to the FGDs and was also explained and confirmed at the start of the FGDs. All participants provided individual written informed consent. Participants were advised that information shared in FGDs has the potential to be more widely shared, and therefore we encouraged participants to respect privacy and confidentiality. The names of FGDs have been captured and has restricted access, and any identifying information were redacted from all transcripts.

Consent for publication
Not applicable.

Competing interests
TK has contributed evidence to the National Department of Health Essential Drugs List Adult level standard treatment guideline (non-funded); and facilitated workshops and capacity development for under and post-graduate students, researchers, policymakers and practitioners on clinical practice guidelines and evidence-informed practices. JV has been involved in guideline development globally and regionally, he has been on advisory committees for clinical guidelines in the Western province, and has facilitated workshops and capacity development for under and postgraduate students, researchers and practitioners on clinical practice guidelines and evidence-informed practices. SC, SA, AA, and JM have no competing interests to declare.
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Chapter 6: Policy briefs - summarising the research findings for policy and practice

Summary: Taken together, the research findings from national, provincial role-players and primary care healthcare providers has provided an overview of processes and context of primary care CPG development, implementation and use. Participants shared views regarding what they perceived to be working, what could be improved and suggested ways to enhance or address primary care CPG challenges. The results are summarised in two policy briefs, one which shares the views from national primary care CPG development perspective, and the second to inform CPG implementation and use from the perspective of implementers and users.

A policy brief is defined in a multitude of ways. I have opted to follow a definition and recommendations from the International Development Research Centre (IDRC). They state that a policy brief is '*a concise summary of a particular issue, the policy options to deal with it, and some recommendations on the best option. It is aimed at government policymakers and others who are interested in formulating or influencing policy*'. (IDRC https://www.idrc.ca/en/resources/research-tools).

Dissemination plan: SAGE has a dissemination strategy for all products. The policy briefs will be shared with the network of national and provincial policy-makers and implementers involved with primary care CPG involvement, who may share it more widely amongst their networks.

Available online at:

- South African Primary Care Clinical Practice Guideline Implementation and Use: Gaps & Opportunities (Policy Brief)
- South African Primary Care Clinical Practice Guideline Development: Gaps & Opportunities (Policy Brief)

Related report:

The SAGE project ended in March 2019. It included many components, including those outlined in this thesis. For an overall report of SAGE, see final report.

SOUTH AFRICAN PRIMARY CARE CLINICAL PRACTICE GUIDELINE DEVELOPMENT:
GAPS & OPPORTUNITIES

This policy brief addresses the following questions from the perspectives of national primary care guideline developers:

- What are the processes for national primary care guideline development?
- What are strengths and gaps in guideline-development processes and how can we enhance transparency and public trust in guideline development?

WHY ARE PRIMARY CARE GUIDELINES IMPORTANT IN THE SOUTH AFRICAN CONTEXT?

Clinical practice guidelines (CPGs) are common tools used for policy and clinical practice. Guidelines inform clinical decisions at the bedside, governance of health facilities, health insurer and government spending, and patient choices.

South Africa's health sector is transitioning to Universal Health Coverage (UHC) funded through a National Health Insurance (NHI) system. The planned NHI aims to build on available primary healthcare initiatives to transform the previously segregated, inequitable services. Within these plans, guidelines are a named tool for supporting the delivery of equitable, standardised, evidence-informed, cost-effective care.

Our study undertook research on the current context and processes for South African primary care guideline development. We hope that what we have learned may inform improvements in guideline activities nationally.

KEY ACTIONS FOR PRIMARY CARE GUIDELINE DEVELOPMENT

The key actions identified from the studies are listed below, with further details about the study methods and findings provided at the end of the brief.

National guideline developers had the following recommendations:

1. Strengthen coordination of guideline activities nationally.
2. Set minimum standards for all national guideline development and adaptation activities.
3. Allocate funds and resources for technical and administrative tasks required to develop high–quality, credible guidelines.
4. Build capacity for guideline development group members, technical support teams and methodologists, to keep up to date with global standards for development.
5. Put in place processes to manage actual and potential conflicts of interests.
6. Establish consultation processes that bridge: national guideline groups; national, provincial and district groups and implementers; private and public-sector role players including professional societies; developers, end-users and patients.

The World Health Organization (WHO) definition of a guideline suggests that it offers "*recommendations for clinical practice or public health policy*" with the aim of telling guideline end-users *"what he or she can or should do in specific situations to achieve the best health outcomes possible"*. In this way a guideline can offer choices *'among different interventions or measures'* that are known to positively impact health or the use of resources.

WHO Guideline for Guidelines Manual, 2nd edition, 2014

This policy brief targets national and provincial policy makers, health managers, and healthcare providers with an interest in primary care clinical practice guideline development processes. The brief summarises qualitative research findings from interviews with national guideline development role players throughout South Africa.

These research findings are part of the South African Guidelines Excellence Project (SAGE). SAGE was a multi-partner collaborative project that aimed to explore South African primary care guideline development, implementation and capacity needs. Further information on SAGE can be found at ***http://www.mrc.ac.za/intramural-research-units/Cochrane-SAGE***

The SAGE Guideline Toolkit is a repository of global guideline resources. This may be useful for those who want to find, appraise, develop, adapt, implement or evaluate guidelines. To access this free resource, go to: ***https://guidelinetoolkit.org.za/***

GUIDELINE DEVELOPMENT:
PERSPECTIVES OF NATIONAL PRIMARY CARE GUIDELINE DEVELOPERS

METHODS

Qualitative research methods were used. Interviews were conducted with 37 role players involved in primary care CPG development and implementation and/or use in four provinces in South Africa (Eastern Cape, Gauteng, Western Cape, KwaZulu-Natal). The in-depth interviews were analysed using thematic content analysis.

FINDINGS

CHALLENGES IDENTIFIED BY ROLE PLAYERS

Despite a committed guideline community wishing to address inequities, guideline development and implementation are affected by:

1. insufficient funding for technical and methodological work;

2. fragmentation between groups, and between national and provincial health sectors;

3. lack of standardised systems for CPG development and implementation;

4. resource gaps create an enabling environment for commercial interests or personal agendas; and,

5. no centrally coordinated CPG unit to address these needs.

Recommendations from participants suggested **six processes** should be strengthened to more effectively inform national primary care guideline development:

1. Systematic use of evidence following agreed **standards** to ensure trustworthy guidelines.

2. Enhanced **stakeholder consultation**, to create a better understanding of end-users and patients' needs in development processes, ultimately to enhance guideline uptake.

3. Ensure **transparency** in processes and communication to avoid the view of guideline development as a 'big black box' and create credible guidance.

4. Build systems for better management of **interests** for conflict free, trustworthy guidelines;

5. Create systems for national **co-ordination** between guideline development groups to avoid duplication and support or endorse various national guideline players.

6. Consider the need for **'fit-for-context' guidelines** that consider unique health system, geographic and cultural factors in the different provinces.

Citations:

1. Kredo T, Abrams A, Young T, Louw Q, Volmink J, Daniels K. Primary care clinical practice guidelines in South Africa: qualitative study exploring perspectives of national stakeholders. *BMC Health Serv Res* 2017;**17**(1):608. *www.ncbi.nlm.nih.gov/pmc/articles/PMC5575947/pdf/12913_2017_Article_2546.pdf*

2. Kredo T, Cooper S, Abrams A, Daniels K, Volmink J, Atkins S. National stakeholders' perceptions of the processes that inform the development of national clinical practice guidelines for primary healthcare in South Africa. *Health Res Policy Syst* 2018;(1):68. *www.ncbi.nlm.nih.gov/pmc/articles/PMC6069850/pdf/12961_2018_Article_348.pdf*

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SOUTH AFRICAN PRIMARY CARE CLINICAL PRACTICE GUIDELINE IMPLEMENTATION AND USE:

GAPS & OPPORTUNITIES

This policy brief aims to answer the following questions from the perspectives of provincial and district guideline implementers, healthcare providers and end users:

- What are the experiences of provincial and district health managers of primary care guideline implementation? What is working and what can be improved?
- What do healthcare providers recommend for better primary care guideline implementation and use?

WHAT DO WE KNOW ABOUT THE CURRENT STATE OF PRIMARY CARE GUIDELINE IMPLEMENTATION AND USE IN SOUTH AFRICA?

National Health Insurance (NHI) is planned for the coming decade with guidelines being one of the named tools to achieve evidence-informed, cost-effective healthcare that spans the sectors, supports equitable access and ensures better patient outcomes. Globally, one of the greatest challenges with healthcare is the 'evidence-practice gap' between what is recommended based on best-available evidence and what is done in clinical practice.

Evidence-informed guidelines have little impact if they are not implemented. In South Africa, guidelines are usually developed at a national level while the responsibility for implementation lies with provincial and district managers. Understanding the barriers to and enablers of effective guideline implementation from the perspective of those provincial and district managers, and healthcare providers may provide insights for prioritising resource allocation in primary care guideline implementation.

KEY ACTIONS FOR PRIMARY CARE GUIDELINE IMPLEMENTATION

We conducted two studies to identify the gaps and opportunities in guideline implementation. The overall key actions identified from both studies are listed below, with further detail about each study at the end of the brief.

HEALTH SYSTEM LEVEL ACTIONS:

- Financial investment in guideline implementation activities including printing and distribution of sufficient numbers of guideline books; responsive procurement able to provide necessary basic equipment, medicines and supplies to adhere to guideline recommendations; and, development of infrastructure to enable digital access to guidelines in all parts of South Africa.
- Strengthening and supporting governance by setting clear roles and responsibilities for guideline implementation in provinces.

HEALTH WORKFORCE LEVEL:

- Health managers request support and training to be able to adapt national guidelines for provincial contexts.
- Quality-improvement initiatives should include constructive, rather than punitive, audit and feedback processes.

This policy brief is targeted at national and provincial policy makers, health managers and healthcare providers with an interest in primary care clinical practice guideline development, implementation and use. The brief summarises qualitative research findings from interviews and/or focus group discussions with two groups of role players – provincial and district health managers, district clinical specialists and primary care trainers; and, primary care healthcare providers.

These research findings are part of the South African Guidelines Excellence Project (SAGE). SAGE was a multi-partner collaborative project that aimed to explore South African primary care guideline development, implementation and capacity needs. Further information on SAGE can be found at ***http://www.mrc.ac.za/intramural-research-units/Cochrane-SAGE***

The SAGE Guideline Toolkit is a repository of global guideline resources. This may be useful for those who want to find, appraise, develop, adapt, implement or evaluate guidelines. To access this free resource, go to: ***https://guidelinetoolkit.org.za/***

Cochrane South Africa

PROJECT SAGE
SOUTH AFRICAN GUIDELINES EXCELLENCE
An innovative partnership for clinical guideline excellence

saMRC
advancing life

- Healthcare provider training should be part of the requirements of clinical service, with time and support allocated to attend training events.
- Training should be accessible and interactive, including both off-site training and on-site case-based clinical mentorship.
- Training should be interdisciplinary, including nurses, allied health practitioners, pharmacists and doctors to ensure cooperation and standardisation of patient care.

GUIDELINE LEVEL:

- Guidelines need improved design features to attract attention and interest through better use of formatting, colours, simplified language and use of local languages.
- Digitally-formatted versions will increase ease of access and potentially use; this can also ensure access to the most up-to-date guidelines, avoiding confusion with changing versions.

- Supplementary materials (e.g. posters) can support patient engagement.
- Clinical support should be available for questions that arise following training.

RESEARCH METHODS

Qualitative research methods were used in the two studies including interviews and focus groups with 70 role players involved in primary care guideline implementation and/or use in four provinces in South Africa (Eastern Cape, Western Cape, Kwazulu-Natal, Limpopo). The data were analysed using thematic content analysis. Some data were considered through the lens of behaviour-change theory (Theoretical Domains Framework and Behaviour Change Wheel). The findings of the two studies are described below.

STUDY 1: GUIDELINE IMPLEMENTATION FROM THE PERSPECTIVE OF PROVINCIAL AND DISTRICT GUIDELINE IMPLEMENTERS

We interviewed 22 role players in four provinces who are involved with primary care guideline implementation. These included provincial and district health managers, members of the District Clinical Specialist teams and district primary care trainers. Two main factors impact implementation: **health-system barriers** and **socio-cultural and geographic context.**

HEALTH-SYSTEMS FACTORS:

- Financial constraints impact access to guidelines as well as access to the necessary equipment and medicines to adhere to guideline recommendations.
- Governance needs to be strengthened including clarifying roles and accountability for guideline implementation. Audit and feedback should be constructive rather than punitive.
- A 'compliance culture' results in a focus on reporting on administrative issues for the Auditor General, rather than on a clinical audit of health outcomes.
- Health workforce challenges result in insufficient numbers, and inadequately trained primary care providers with limited clinical support and mentorship post training.
- There is inadequate interdisciplinary training to ensure all clinical disciplines are up-to-date.
- Managers working with non-governmental organisations 'partner', to deliver training and disseminate guidelines, but this may not be sustainable and is funding dependant. This also drives the kinds of guidelines that are distributed (e.g. HIV has greater investment than diabetes).

GEOGRAPHIC AND CULTURAL CONTEXTUAL FACTORS:

- National guidelines are not sufficiently considerate of provincial differences including geographic and cultural factors, and this results in national indicators that may not be applicable or feasible in all provinces.
- Insufficient consultation with end-users and patients limits the usability of guidelines which may be result in guidance that is not fit for the cultural or geographic context.
- Provinces may need to adapt the guidelines to better fit their context, however, there is limited technical knowledge on how to go about this and limited support in how to adapt guidelines.

Citation: Kredo T, Cooper S, Abrams A, Muller J, Schmidt B, Volmink J, Atkins S. Building on shaky ground – challenges to and solutions for primary care guideline implementation in four provinces in South Africa: a qualitative study. *BMJ Open* (submitted May 2019).

STUDY 2: GUIDELINE USE FROM THE PERSPECTIVE OF PRIMARY CARE HEALTHCARE PROVIDERS AND END-USERS

We interviewed 48 primary care healthcare providers, generally nurses and allied health workers, in four provinces in South Africa. We found that they are knowledgeable about guidelines, generally trust their credibility and are receptive and motivated to use them. Guidelines are seen by nurses as providing confidence and reassurance, professional authority and independence where doctors are scarce. Despite this, many barriers to guideline use were reported:

BARRIERS TO GUIDELINE USE INCLUDE:

- inadequate systems for hardcopy distribution;
- insufficient and substandard photocopies;
- linguistic inappropriateness (e.g. complicated language, lack of summaries, no availability in local languages);
- unsupportive audit and feedback procedures;
- limited involvement of end-users in guideline development; and,
- patchy training that does not filter back to providers.

SUGGESTIONS FROM PARTICIPANTS

- improving the design features;
- increasing accessibility including making digitally-formatted versions available;
- more supplementary materials (e.g. posters) to support patient engagement;
- accessible clinical support following training; and,
- in-facility training for all professional cadres to ensure fair access, similar levels of capability and interdisciplinary consistency.

Citation: Kredo T, Cooper S, Abrams A, Muller J, Volmink J, Atkins S. Using the Behavior Change Wheel to identify barriers to and potential solutions for primary care clinical guideline use in four provinces in South Africa. *BMC Health Services Research* 2018;**18**(1):965. *www.ncbi.nlm.nih.gov/pmc/articles/PMC6295099/pdf/12913_2018_Article_3778.pdf*

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Chapter 7: Discussion and conclusions

Countries worldwide are striving to achieve strong primary health care systems and UHC that ensure access to quality health services without negative financial repercussions for patients or health systems (6). However, the best approach to strengthen primary health care and progress to UHC remains a prominent debate (53).

Taking steps towards strong primary health care, the South African national government has introduced programmes to improve district-driven health-service delivery (e.g. primary health care re-engineering and the Ideal Clinic) and is outlining policies for UHC funded through a NHI mechanism (3, 18-20). Within these policies, CPGs are named as potential tools to support evidence-informed, cost-effective and standardised decision making.

CPGs are evidence-based guiding statements developed by policy-makers; and implemented and used by health managers, healthcare providers and patients to inform their decisions about options for care (54). By their design, CPGs include consideration of evidence of effectiveness alongside aspects of 'quality care' outlined by the WHO, including cost effectiveness, feasibility and acceptability (4, 55). Therefore, CPGs have the potential to bridge not only evidence and patient care but may also to be tools to guide funding decisions and health-system structuring required to ensure access to the recommended care.

Overall, in South Africa, the planned NHI system will require agreement and integration across sectors and jurisdictions. National CPGs will need to speak to the healthcare needs of all to ensure equal service delivery and redress of persistent 'fault lines' in the current health system (21). This transition from the current health system to NHI-funded UHC provides a window of opportunity to explore the 'state of play' of CPG development and implementation to help inform NHI goals and processes. Thus, in this global and national health policy context, the research conducted as part of this dissertation explored the role-players, context, processes, barriers to and enablers of South African primary care CPG along the continuum of guideline activities from development, to implementation and use.

Primary care guideline developers

Overall, from the many role-players involved with CPG development, we found that there is a committed CPG community aiming to address inequities through CPG development and implementation. As our participants stated their views about the current context of private and public health sectors and its impact on access to healthcare as '*hopelessly inequitable*' suggesting that CPGs are a means to '*level the playing fields*'. Corresponding with other studies, we also found that the NDoH leads several CPG

programmes (35). For primary care these include condition-specific guidelines (e.g. malaria, HIV, tuberculosis) and the Essential Drugs Programme (EDP) which develops comprehensive Standard Treatment Guidelines for rational prescription at all levels of care (primary, secondary and tertiary). Additionally, academic departments and professional societies develop CPGs, addressing gaps in what is available from the NDoH. However, CPG work is affected by inadequate funding for the increasingly demanding technical and methodological work required to underpin trustworthy CPG development. CPG processes were described as *'chaotic', 'uncoordinated'* and *'opaque',* which may be indicative of the lack of national standards to underpin CPG development and implementation, without which, regardless of commitment and best intentions, CPGs continue to be developed that do not meet global quality standards.

Guidance and standards for CPG development are available from the Institute of Medicine and Guidelines International Network including checklists for assessment, conduct and implementation of trustworthy guidelines (56-59). However, despite the evolution of methods for CPG development, the capacity to do what is required has lagged (60, 61). For example, more recent AGREE II quality assessments of CPGs, including in the United States of America, continue to report that editorial independence and methodological rigour are poor, reflecting our findings from South Africa (34, 60, 62). Improvements to the WHO CPG programme since implementing their Guideline Review process highlights the importance of setting standards and effective oversight of CPGs and the potentially positive impact on CPG credibility (32, 33).

Findings suggest that the gap in agreed standards and insufficient resourcing of CPG development processes in South Africa creates an enabling environment for commercial interests or personal agendas to influence recommendations. The main intention of CPG development - wellbeing of patients and efficient use of limited resources - should be the primary interest of developers. However, poorly managed secondary interests, either of a personal or financial nature, may dominate decision making. As stated by one of our participants '*we have been very conscious of the role and the influence of industry in shaping decision-making, even within the various well-respected national societies…*'. The potential influence of secondary interests has been documented, one example is the case study of two iterations of the American College of Chest Physicians Antithrombotic Guidelines where the most-recent version ensured that guideline panel conflicts were more actively managed, and that there was more methodological support and rigour in the process. This impacted on not only what was recommended, but also on the strength of the recommendations (conditional and strong) with fewer strong recommendations made when the evidence base was less robust (63). Two systematic reviews evaluating conflicts of interest reported a paucity of studies and evidence about this topic (64, 65). The more recent 2011 review found that the effect

of interests on CPG recommendations was limited to case studies, usually about financial conflicts, where the secondary interests are likely to impact decisions. However, there was very little about non-financial interests (64). The Guidelines International Network have published guidance on managing interests for CPGs that several organisations have adopted (66, 67). Additionally, prominent CPG groups, such as the US Preventive Services Task Force, have ongoing research and 'continuous improvement processes' to manage potential conflicts and enhance public trust in CPG panels (68). From our participants, it was evident that conflicts of interest were not well understood or consistently managed, suggesting that further research would assist to understand this issue further and recommend changes.

Additional concerns raised by participants were inadequate investment in coordinated communication and linkages within and between CPG groups and other role-players, including national government programmes (e.g. maternal and child health, HIV, etc.) and the EDP CPGs; and between national, provincial and district managers; healthcare providers and patients; and between the private health insurance and public-sector systems. The resulting silos increase the potential for duplication, competition for technical skills and resources and, at times, recommendations that are not feasible to implement – as one of the national developers described it *'I do not think we have really found a mechanism of really engaging the people who are at the frontline of implementation on how do you really want us to package some of this document'.*

National CPG developers suggested that to improve CPG development there needs to be better coordination of CPG activities. To explore the role of CPG coordination, the SAGE Project team undertook a cross-sectional analysis of national CPG units to find out about their structure and function (69) [report available here: Scoping project: Evaluating clinical guideline coordination units globally]. We identified 21 units, including nine in a more detailed evaluation (Table 1). We found that units had vastly differing tasks ranging from CPG development (7 units); providing a clearinghouse for accessing CPGs (4 units); approval/endorsement of CPGs or implementation (3 units); methodological support (2 units); conduct of HTA (2 units). Other tasks mentioned included multi-stakeholder engagement; commission CPGs; critical appraisal; develop standards for guideline development; capacity building; implementation; and, monitoring and evaluation. Only the National Institute for Health and Care Excellence (NICE) in the United Kingdom and the Guideline Review Committee and Secretariat (WHO) had coordination or governance functions. This scoping review provides some guidance on the kinds of tasks that could be considered for South Africa.

Table 3. Guideline Units included in SAGE cross-sectional analysis, 2017

1. Agency for Healthcare Research and Quality (AHRQ) / National Guideline Clearinghouse
2. (United States)
3. CONITEC – National Committee for Health Technology Incorporation (Brazil)
4. Guideline Review Committee and GRC Secretariat (WHO)
5. Haute Autorité de Santé (HAS) (France)
6. National Clinical Effectiveness Committee (Ireland)
7. National Guideline and Pathway Committee (Qatar)
8. National Institute for Health and Care Excellence (NICE) (UK)
9. Saudi Center for Evidence Based Healthcare (EBHC) (Kingdom of Saudi Arabia)
10. Scottish Intercollegiate Guidelines Network (SIGN) (Scotland)

Overall, the dissertation research found that primary care developers are invested in CPGs and want support to improve their credibility. Suggestions comprise development and endorsement of agreed standards that increase systematic evidence use and transparent processes; enhanced stakeholder consultation, including end-users and patients; better management of interests; enhanced communication and coordination between and within CPG development groups and end-users; and, systematic consideration of 'fit-for-context' CPGs that consider local context, feasibility, culture and preferences in the recommendations.

Provincial and district managers and guideline implementers

We visited four provinces and spoke to health managers, trainers, district clinical specialists and healthcare providers, mostly nurses and allied health practitioners, about their experiences with primary care CPGs. This provided further insights into CPG uptake and expanded on the findings from the national role-players. Like CPG developers, those we spoke to were inherently driven to improve patient care and support uptake and use of CPGs. Yet, they reported several challenges to doing this. These included perceived structural barriers to CPG use, such as access to CPGs, or supply chain issues blocking adequate equipment supply, along with inadequate clinical training and supervision.

From the literature, individual motivation to use a CPG may be more difficult to shift than the structural or physical/environmental issues (e.g. providing more guideline copies, conducting training or ensuring essential equipment) (70). Stated differently, the baseline motivation of participants to implement or use CPGs is an encouraging springboard for enhancing CPG use. Activities that make CPGs more 'implementable' may further motivate and support their uptake and use.

CPG implementation falls within the ambit of implementation research in which exploring and understanding context and behavioural theories about capacity, opportunity and motivation to use a CPG provides insight into how to effectively enhance CPG use or change practice (71-74). Effective implementation strategies to change practice have been researched and recommended for decades, yet how best to do this and the relative cost-effectiveness in different settings remains areas for further research (75-77). Outreach education is a known strategy that has been evaluated in systematic reviews and reported to offer benefits (78). Importantly, this strategy has been tested in pragmatic trials in primary care in South Africa also finding modest but consistent benefits (79-82). Considering both local and global implementation evidence, strategies such as this can and should be considered for scale up.

During interviews, a few managers were wary of our questions, seemingly fearful of punitive action from senior management related to implementation. Further interviews revealed that this was a common challenge experienced by provincial and district managers where the emphasis on 'compliance culture' and punitive audits were perceived to have negative professional consequences when CPG implementation was delayed, inefficient or unsuccessful. Audit and feedback are amongst the most well-researched implementation strategies, generally showing modest but consistent benefits (78, 83, 84). However, there were stories of mixed success from our participants, some using the process to identify gaps and amend practice, while others felt audits were regimentally applied and not constructive. Further research on how this can be enhanced, learning from the extensive literature, is warranted.

Despite reported negative experiences, managers continued to strive to address the everyday challenges they faced with commitment and innovation, including linking with better-funded non-governmental partners to overcome barriers to CPG implementation. Managers expressed that poor funding of CPG activities such as training, printing of CPG books and development of additional supportive implementation resources (e.g. posters) impacted on CPG distribution and access and were perceived to impact use. Primary care healthcare providers corroborated this, explaining that poor CPG distribution and version control, as well as lack of supporting materials in accessible local languages, limited their use. It stands to reason that insufficient investment in CPG implementation may result in poor CPG uptake. Identifying the most cost-effective strategies for CPG activities and how to sustain these remains uncertain. Funding could be considered the role of government, however, in the absence of a budget for CPG activities, other funders may step in, with their own agendas and priorities. Our participants described the role of 'partner' non-governmental organisations (NGOs) as important and helpful, however, NGO interests drove the support that was offered, resulting in greater investment in HIV and tuberculosis relative to non-communicable diseases.

Contextual factors were consistently described as a hindrance to CPG adherence. In rural districts, culture, social norms (e.g. traditional practices) and geography (access to facilities) hindered the uptake of CPGs. Implementers indicated that what was recommended was at odds with what was either acceptable or feasible within their setting. As with our research, the role of context emerged as a dominant theme from an overview of systematic reviews exploring causes of the evidence to practice gaps for complex interventions in primary care (85). The themes identified in the review included: external context; organisation; professionals and intervention. One of the main findings was the importance of the 'fit' between the context and the intervention and its critical role in determining successful implementation (85). Although the review included only studies from high-income primary care settings, the results reflect ours, and particularly the critical importance of considering the context in which the service is delivered. Considering the range of cultural and geographic barriers raised by our participants, how best to contextualise South African primary care CPGs will likely be a challenging but necessary area for further investigation. However, it is evident that, if not addressed, implementation remains strained and potentially ineffective.

Guideline implementation guidance consistently puts forward the importance of considering context and views of end-users including healthcare providers and patients when developing recommendations and implementation strategies (59, 73, 86). Our participants also suggested consultation and involvement of provincial role-players in national CPG development to ensure feasible CPGs. One approach that could help is the inclusion of 'evidence-to-decision' frameworks that guide CPG panels to systematically consider evidence of effectiveness and safety, alongside evidence about feasibility, acceptability, costs and equity, such as the approach used by the GRADE Working Group (87). Although, this does not remove the need for expert judgment, it does capture different views more transparently, and ensures that issues of cost, cultural and social norms, equity and acceptability, amongst others, are all considered as part of final recommendations. The evidence-to-decision frameworks can also be used for CPG adaptation at the provincial or district levels. That is, evidence of efficacy and safety may remain unchanged, but provincial health managers can consider contextual issues of culture and preferences which can play a prominent role in guiding recommendations and implementation planning (88).

It was striking that although there were many examples of innovations and successes from healthcare managers in provinces and districts, they described few occasions to share these between managers and within and between districts and provinces. These success stories offer a potential opportunity for mutual learning and scale up of projects in other districts. Further research exploring case studies of 'champions' of primary care may offer examples of approaches for enhancing primary care service delivery.

Building skills and knowledge for CPG activities was a cross-cutting need for health managers and healthcare providers. Capacity building requirements for *healthcare managers* and those involved with implementation including learning about CPG contextualisation or adaptation, constructive audit, quality improvement approaches and implementation planning and evaluation. Training for *healthcare providers* in the content of the CPG is central to successful CPG adherence and use (78, 80, 82). In South Africa, regional training centres, which have a coordination function, are already in place in most provinces. However, those we interviewed consistently reported that training is patchy and there is a need for inter-disciplinary training bringing all practitioners in a facility onto the same level. We found that healthcare providers valued both in-facility, case-based training and opportunities for training off-site. However, they strongly expressed the wish for post-training clinical mentorship and supervision.

Implications for policy and practice

CPGs are intended to provide evidence-informed statements to improve patient care but can only do so if effectively developed and implemented. The research conducted for this dissertation has explored views of those directly involved with CPGs and identified gaps and opportunities for enhanced CPG development and implementation for South African primary care. For example, CPG development is already institutionalised in national government, with academics, clinicians and health managers committed to the process of evidence-informed CPG development. If nationally accepted standards can be adopted to support the process, along with capacity building for CPG technical and methodological work, the rigour of development and likelihood of credible, trustworthy CPGs may improve. Additionally, if development is more consistent with consultation of end-users, and considerate of the health service and system issues that limit CPG implementation, it is possible that more contextually relevant, acceptable CPG implementation may occur, resulting in enhanced CPG use and, importantly, better patient care.

Decisions about how best to allocate resources to address the CPG implementation and development gaps should be led by healthcare managers and policy-makers. One suggested approach for prioritising the necessary activities includes the use of the APEASE criteria which include: affordability, practicability, effectiveness/cost-effectiveness, acceptability (to public, professional groups and the political role-players), safety/harms, equality (89).

Strengths and limitations of the research

The planned NHI fund heralds a major shift in health system arrangements for South African primary health care. Health-technology assessment (HTA) and CPG development are both named in the national NHI strategy (3). Yet, to date, our understanding of the players and processes for HTA and CPGs has been

limited and anecdotal. Therefore, the strength of the research is that it addresses a gap in knowledge at a time when changes in CPG governance are taking place. Additionally, the findings suggested specific actions that could be considered by national and provincial decision-makers to improve processes for CPG development and implementation as outlined in the policy briefs. A further possible strength is that this formative research has thrown light on many research gaps to further enhance our understanding of CPG activities but, more importantly, to improve how CPGs are developed and implemented.

The involvement of a multi-disciplinary team along with external support and guidance from the project's inception can be considered a strength of the research. The team has changed over the years, but has included clinical epidemiologists, social scientists, doctors, allied health practitioners and public health specialists, all with research training and experience. The ability of the team to share their views and differing perspectives regarding the data has enriched and deepened the analysis and interpretation of the participants' views.

A limitation of the research is the breadth of the topic we have chosen to investigate. Primary health care is a wide-ranging field of study and, as mentioned throughout the papers, by having this broad focus, we may have missed CPG- or condition-specific contextual issues for development or specific barriers to and enablers of implementation. However, given the paucity of published literature on CPG development and implementation, this may be a reasonable approach for formative research to inform a future research agenda.

An additional consideration of the broad topic of primary care CPGs was that, unlike most countries globally, South Africa has consolidated/amalgamated CPGs that address all conditions for a level of care, rather than many condition-specific CPGs. For example, there are two CPGs for public sector healthcare providers that address all primary care conditions. One is the national Essential Medicines List Standard Treatment Guideline which is a medicine-driven CPG developed by the EDP at the NDoH. The related CPG, Primary Care 101, is a symptom-based CPG which covers all conditions and is tailored for nurse practitioners. These two CPGs form the basis of CPGs used for South African public-sector primary care, complemented by a core set of infectious diseases guidelines (HIV, tuberculosis and malaria), Basic Antenatal Care guidelines for maternal and childcare and a health promotion CPG.

Furthermore, despite the broad research question, identifying gaps in capacity and health system arrangements mirror other health services and systems research from South Africa and is likely generalisable regardless of the CPG (14, 21). However, accepting that important specific contextual issues

have likely been missed and that healthcare service delivery evolves, these findings provide the groundwork for further research.

A further limitation may be that we used only qualitative research methods to explore perspectives of developers, implementers and users. Further mixed-method or quantitative studies would be complementary. For example, a review evaluating implementation strategies for LMICs is important to take stock of what has been tested in similar settings to South Africa. Such a review has recently been published by Cochrane's Effective Practice and Organisation of Care Review Group (78). Further, surveys or delphi studies may be helpful to prioritise barriers and enablers for implementation, however, this approach may be most appropriate when a specific CPG is being explored in depth. Overall, use of a qualitative method was appropriate for the research question and enabled the gathering of rich data about the experiences of those involved with CPG development and/or implementation, which would not have been possible with other study designs (50).

Finally, a limitation may be that the important voices of patients have not yet been captured along the continuum from CPG development to use. Unquestionably, exploring patients' views of CPGs is a critical gap in understanding what will work for CPG uptake. However, this research may be appropriate to hinge on a specific condition and its linked CPG recommendations. This is therefore another prospect for future research.

Research gaps

Several knowledge gaps have emerged during the conduct of the studies within this thesis and suggest some future research aspects outlined below.

Clinical audit and understanding baseline standards for key conditions and treatments: One of the greatest challenges for those developing policy is there is not a good source of data regarding the indicator clinical outcomes that are linked with the CPGs produced and disseminated. This is particularly so in the public sector, where there are very few electronic medical records in place outside of HIV care; performance measures and indicators are not set; and, clinical audits are not always in the public domain. One way to explore the gaps between what is recommended and what is happening in practice may be to systematically evaluate available audit reports and baseline data of primary studies. We have drafted a protocol to take this forward [Appendix 6].

Managing conflicts of interest for guideline groups: management of interests is poorly understood and probably equally poorly implemented across CPG development groups in South Africa, and likely in other

countries in the region. Further exploration of current practice, decisions and potential impacts of financial and personal interests is indicated. Additionally, interventions to increase transparency in funding of CPGs can be tested. This research could be explored for different sub-populations, including private health insurance, patient representative and consumer groups, and professional associations. Guidance could be developed to inform interest management.

Development and implementation barriers for specific guidelines: Exploration of specific CPGs and their development and use can inform needs and opportunities for tailored implementation and enhanced use. There are some important examples of this research in South Africa, particularly from the University of Cape Town's Knowledge Translation Unit which has led pragmatic cluster trials and informed our understanding of some of the local successes and challenges with specific CPGs for tuberculosis and primary care (40). Additionally, a thesis by Pather has provided in-depth understanding of the asthma guidelines in South Africa and suggested a framework for implementation that may be applied and should be further tested (37). Views of different role-players from those we spoke to are required, particularly, views of medical doctors who may have different perspectives from the nurses and allied health practitioners we interviewed. Research exploring innovations and lessons from district health managers regarding how they have overcome implementation gaps, would be helpful to explore further.

Community and patient's involvement in development and implementation: Substantial research and experience exists elsewhere for patient involvement in CPGs – such as the Guidelines International Network Public Toolkit, the NICE patient involvement guidance and the James Lind Alliance priority setting to name a few examples. However, patients and the public's views on CPGs remain a knowledge gap in South Africa and regionally. Patient's representatives have little or no formal involvement in CPG development and their views about the CPGs in use in the health services is limited. Clinic committees (linked with specific primary health care facilities) may play an important role in the delivery of health services and CPG advocacy and uptake – it would be valuable to explore how their role could be maximised to support CPG implementation for South Africa.

UHC and guidelines: The planned NHI provides an important research opportunity. Understanding how the health system can and should transition in constructive, progressive ways requires substantial health systems and services research. Examples include understanding how training of health staff around CPGs should be done optimally; how the private and public sector will intersect to make decisions about service packages; healthcare access and provision for all and how this would be reflected in CPGs; and, importantly, how the public and the community can participate in the process of UHC decision-making that reduces inequity and increases health for all.

Conclusion

Overall, the dissertation findings consider South African health services and systems through the lens of CPGs. As the South African government aligns with the global community to strive to attain strengthened primary health care systems and UHC, there needs to be investment in development and implementation of high-quality CPGs informed by evidence and implemented according to global experience and local context. Overall, this work requires the political commitment of national and provincial governments to provide the leadership and funding for training, technical work and revitalisation of the, at times, defunct systems that hamper development, implementation and adherence to national primary care CPGs. If addressed, this has the possibility to enhance the provision of trustworthy and effective care for all in South Africa.

Appendices

Appendix 1: Literature review: clinical practice guidelines

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OXFORD

Perspectives on Quality

Guide to Clinical Practice Guidelines: The Current State of Play

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Abstract

Introduction: Extensive research has been undertaken over the last 30 years on the methods underpinning clinical practice guidelines (CPGs), including their development, updating, reporting, tailoring for specific purposes, implementation and evaluation. This has resulted in an increasing number of terms, tools and acronyms. Over time, CPGs have shifted from opinion-based to evidence-informed, including increasingly sophisticated methodologies and implementation strategies, and thus keeping abreast of evolution in this field of research can be challenging.
Methods: This article collates findings from an extensive document search, to provide a guide describing standards, methods and systems reported in the current CPG methodology and implementation literature. This guide is targeted at those working in health care quality and safety and responsible for either commissioning, researching or delivering health care. It is presented in a way that can be updated as the field expands.
Conclusion: CPG development and implementation have attracted the most international interest and activity, whilst CPG updating, adopting (with or without contextualization), adapting and impact evaluation are less well addressed.

Key words: clinical practice guidelines, guideline development, implementation, adaptation

Introduction

High-quality, evidence-informed clinical practice guidelines (CPGs) offer a way of bridging the gap between policy, best practice, local contexts and patient choice. Clinical guidelines have been upheld as an essential part of quality medical practice for several decades. An early definition of CPGs by the Institute of Medicine (IOM) [1] described it as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.' This definition was updated in 2011 to more strongly emphasize rigorous methodology in the guideline development processes: 'Clinical guidelines are 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]. In this rapidly evolving field

of research, a more recent definition suggested a modern twist to the guideline description: 'Guidelines are a convenient way of packaging evidence and presenting recommendations to healthcare decision makers' [3].

Guidelines have a range of purposes, intended to improve effectiveness and quality of care, to decrease variations in clinical practice and to decrease costly and preventable mistakes and adverse events. They generally include statements of expected practice; provide benchmarks or standards against which individuals can audit; compare and potentially improve their practices; or guidance regarding undertaking particular tasks [4, 5]. Quality improvement initiatives are linked with CPGs, as evidence-informed recommendations form the basis for identifying core outcomes and measurable standards of care [6]. Internationally, over the past decade in particular, an industry seems to have developed around CPG development, reporting, adoption, contextualization or adaptation, evaluation and implementation. The growing volume of evidence and the acronyms used in this field can be overwhelming, even for those involved. This article is targeted at individuals and organizations working in health care quality and safety; and responsible for either commissioning, researching or delivering health care. We aim to provide a guide describing common standards, methods and systems used in current international CPG activities and the various activities to produce and communicate them.

Terminology

Guidelines, CPGs, protocols and care pathways are commonly used terms, but without common agreement about their definitions [7]. Definitions that we have found useful are that *guidelines* relate to broader systems, such as those found in primary care (e.g. water or air quality, food security, incident reporting and investigation, etc.) and are generally developed and used by policy-makers, service organizations, funders or regulatory authorities. *CPGs* relate to clinical matters, generally dealing with clinical conditions or symptoms, and are typically intended for use by health care providers and clinic managers [4]. They can include best-practice statements for any one or combination of concerns regarding screening, diagnosis, management or monitoring. The term 'protocol' is commonly used to prescribe behaviours at diplomatic and societal events. In health, it has the meaning of rules or instructions about how to do a particular process explicitly, and without error. *Care pathways* generally relate to a series of evidence-informed steps, which can involve a multidisciplinary team at various care levels (i.e. primary, secondary), which should underpin the journey of care of patients with a particular diagnosis [8, 9]. Whilst broadly similar to CPGs, clinical pathways differ by being more explicit about the sequence, timing and provision of interventions. They are usually based on CPGs and contextualized for use within specific environments or circumstances [9].

Development

There are detailed processes available for developing a CPG. Notably, there are well-credentialed international and national guideline development groups, including the World Health Organization (WHO) [10], the Scottish Intercollegiate Guidelines Network (SIGN) [11], the National Institute for Health and Care Excellence (NICE) [12] and the Australian National Health and Medical Research Council (NHMRC) [13], each with their own approach to guideline construction and writing, usually described in a guideline development manual.

Globally, potentially many hundreds more health departments, insurers and other health care organizations, professional associations, hospitals, specialty colleges and individuals have attempted to produce recommendations to improve and/or standardize local clinical practices, all using their own interpretations of the best way to construct and write CPGs. The most common approach to CPG development seems to come from the efforts of small teams of dedicated volunteers, often working with minimal funding and variable understanding of CPG development methods, to produce recommendations for practice in local settings, based on a range of evidence sources. These include peer-reviewed literature, grey literature, other CPGs and expert opinion. Historically, CPGs were built mostly on expert opinion, which included variable (and often selective) reference to research evidence [14, 15]. Such CPGs are still found today, albeit in decreasing numbers, as transparently constructed evidence-informed approaches integrated with expert opinion and patient values have rapidly gained acceptance over the past two decades as the best approach to CPG development [14, 15]. To add to the complexity of the evolution of CPG development, developers around the world have used a range of different and purpose-built approaches to identify, appraise, synthesize and describe the evidence base underpinning best-practice statements. Thus, there is no standard approach to any aspect of CPG activity.

However, evidence of a maturing CPG development culture internationally is seen in recent attempts to standardize practices. In 2011, the Institute of Medicine (IOM) introduced eight standards for CPG development [16], which are similar to those promoted by the Guidelines International Network (G-I-N) [17] (Table 1).

In addition, a recent enterprise, conducted by McMaster University, systematically and comprehensively reviewed the methodological

Table 1 Comparing the elements of clinical practice guideline development between the Institute of Medicine (IOM) and the Guidelines International Network (G-I-N)

IOM [2]	Guidelines International Network (G-I-N) [17]
Standard 1: Establishing transparency	1: Composition of Guideline Development Group
Standard 2: Management of conflict of interest	2: Decision-making Process
Standard 3: Guideline development group composition	3: Conflicts of Interest
Standard 4: Clinical practice guideline – systematic review intersection	4: Scope of a Guideline
Standard 5: Establishing evidence foundations for and rating strength of recommendations	5: Methods
Standard 6: Articulation of recommendations	6: Evidence Reviews
Standard 7: External review	7: Guideline Recommendations
Standard 8: Updating	8: Rating of Evidence and Recommendations
	9: Peer Review and Stakeholder Consultations
	10: Guideline Expiration and Updating
	11: Financial Support and Sponsoring Organisation

content of 35 international CPG development manuals, to identify key CPG development components. This work included the G-I-N and IOM criteria. The McMaster Group developed a checklist of 18 topics and 146 items [18]. This project, Guidelines 2.0, itemized all potentially relevant CPG steps, linked to primary resources and is able to be contextualized or adapted to local contexts. This provides a comprehensive resource; however, given the extensive list of items included, it may not be user-friendly. In another example of efforts to standardize methods, a step-by-step manual was developed to assist CPG developers in the area of head and neck cancer surgery [19].

Given these widely available best-practice approaches to CPG development that are now available to all, it seems sensible to reconsider the need for future *ad hoc* CPG development that does not comply with recommendations from at least one of these approaches [16]. Moreover, there is a wealth of freely accessible, good-quality CPGs from internationally respected development agencies [9–12] that can be adopted and then configured to meet local needs, using emerging CPG contextualization or adaptation methods (refer to 'adopting, contextualising, adapting' section) [10–13]. Thus there seems little merit in producing new CPGs, unless a true gap exists in available guidance. This gap should be verified by a comprehensive search of CPG repositories before any *de novo* activities take place. Where *de novo* CPGs are required, there are many comprehensive evidence-synthesis resources available (such as the Cochrane database of systematic reviews), which should make the CPG development processes less demanding. Given these efficiencies in sourcing the research evidence, the key issues for discussion by the development teams could then be oriented to the use and inclusion of local contextualized evidence regarding resource requirements, feasibility, cultural issues, patient preferences, values and approaches for shared decision-making.

Determining the strength of the body of evidence

A critical methodological quality issue in CPG development is how best to describe the strength of the evidence underpinning recommendations. Numerous approaches to grading evidence have been developed. However, in the last few years, two main approaches have emerged to support systematic and comprehensive evidence synthesis: Grading of Recommendations Assessment, Development and Evaluation (GRADE) [20–23] and the Australian NHMRC approach, Formulating Recommendations Matrix (FORM) [24]. The GRADE approach has gained momentum internationally, with acceptance by, among other organizations, the WHO's Guideline Review Committee [10]. The GRADE and FORM approaches not only assist CPG developers to summarize the evidence body for a recommendation and consider its local relevance but

also provide advice on how to proceed from evidence to recommendations in a standardized and transparent manner.

Quality appraisal

Similar to evidence grading, a number of tools have been developed to support critical appraisal of CPG quality. Many of them have focused on structural issues such as the composition of the CPG team, the review dates, the layout and the CPG purpose and end use, whilst others focus on rigour of methodological development and applicability [25–27]. The AGREE II instrument (Appraisal of Guideline ResEarch and Evaluation) [28, 29] emerged internationally five years ago. It comprises six domains with a total of 23 items, each scored 1–7 (Strongly Disagree through to Strongly Agree). More than one scorer is required to determine a valid score, and a scoring rubric is required to combine scores into one composite score for each domain. A new, simplified tool, the iCAHE CPG quality checklist, was recently developed as an alternative to the AGREE approach [30]. The iCAHE instrument items were based on perspectives of CPG quality of busy clinicians, educators and policy-makers. It has similar domains to AGREE II, but only 14 questions, each with a binary response (Yes/No), requiring one scorer, and the overall score is the sum of the 'Yes' responses. Both instruments include questions regarding the CPG process, that is, the identification and reporting of the body of evidence underpinning the CPG. The two instruments show moderate to strong correlation in pilot testing ($r = 0.89$) with the iCAHE tool requiring significantly less time to administer.

Updating

Considering the substantial international effort invested in CPG development, there has been much less research into the process of CPG updating. Whilst the importance of updating is noted in most CPG development manuals, specific processes for doing so are poorly described [31]. Examples of guidance on updating from the G-I-N and IOM development standards are provided in Table 2.

A recently published systematic review aimed to identify best practices for updating CPGs [31]. The review authors systematically identified and appraised 35 CPG development handbooks which included information on CPG updating. They concluded that the available guidance on updating processes was lacking in detail, used variable terminology, and that more rigorous and explicit guidance would increase the trustworthiness of updated CPGs. This review did not include the systematic approach published in 2003 by Johnston *et al.*

Table 2 Examples of guidance for updating from the Institute of Medicine (IOM) and the Guidelines International Network (G-I-N)

IOM STANDARD 8: Updating [2]	Guidelines International Network (G-I-N) [17]
The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.	Guidelines become outdated at different rates depending on the availability of new evidence. Therefore, it is important to identify the expiration date of a guideline, as well as an update process, if planned. Developers should prospectively determine whether and when they will update a guideline or when it should be considered inactive if an update is not performed.
CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm, that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective, or that a recommendation can be applied to new populations.	

Table 3 Clinical Practice Guideline Update elements [32]

1	The new evidence is consistent with the data used to inform the original practice guideline report. The recommendations in the original report remain unchanged.
2	The new evidence is consistent with the data used to inform the original practice guideline report. The strength of the recommendations in the original report has been modified to reflect this additional evidence.
3	The new evidence is inconsistent with the data used to inform the original practice guideline report. However, the strength of the new evidence does not alter the conclusions of the original document. Recommendations in the original report remain unchanged.
4	The new evidence is inconsistent with the data used to inform the original practice guideline report. The strength of the new evidence will alter the conclusions of the original document. Recommendations in the original report will change. This change is a priority for the working party members. Modifications to the guideline are in progress.

from the Cancer Care Ontario Practice Guidelines Initiative, which reports four criteria for use after an updated literature review has been performed. These criteria provide clear guidance regarding how recent literature might alter the earlier strength of the body of evidence (p. 648) (Table 3) [32]. These criteria have been used for the last three updates of the Acute pain management CPG by the Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine [33].

Technologies for 'dynamic updating' of CPGs are also emerging [34]. The GRADE group is currently piloting an international collaborative initiative in CPG writing with corresponding implementation plans, aimed at ready implementation of recommendations – DECIDE: Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence [3]. This Consortium has supported the development of two interactive CPG development tools, the GDT (http://gdt.guidelinedevelopment.org/) [35] and 'Making GRADE the Irresistible Choice' MAGICapp (http://www.magicapp.org/) [36]. These multi-layer development and dissemination software tools could put up-to-date CPGs literally 'in the pockets' of clinicians via smartphones and tablets. These tools also allow for dynamic updating of evidence sources, and integration of evidence with electronic medical record tools [34].

Presentation and communication

Concurrent with the evolution of standardized CPG development principles, there has been increasing interest in the manner in which recommendations are *written* and *presented* to best support uptake. This interest has stemmed from concerns with the need to address structural barriers to CPG uptake, in the way recommendations are worded and presented, as well as external barriers to implementation such as access and relevance [37]. To address this, a specific tool was developed for CPG developers and implementers (GuideLine Implementability Appraisal (GLIA)) that provided 10 dimensions of 31 items, including decidability and executability, global, presentation and formatting, measurable outcomes, apparent validity, flexibility and effect on process of care [38]. The DECIDE consortium is exploring methods to ensure effective communication of evidence-based recommendations targeted at key stakeholders: health care professionals, policy-makers and managers, as well as patients and the general public. Their multi-layer development and dissemination

software tools allow one-click adaptation of display of content depending on the audience [3].

Implementation

Another recently launched tool, GUIDE-M, is intended to enhance quality, implementability and acceptability of CPGs, the 'Guideline Implementability for Decision Excellence Model' (www.guide-m.ca) [39]. This tool was developed to reflect an evidence-informed, international and multidisciplinary perspective to putting CPGs into practice.

There is surprisingly little decisive guidance on how CPGs can be successfully *implemented*, and the knowledge gap regarding the effectiveness of CPGs on patient health outcomes is substantial. More is known about the effectiveness of various implementation strategies on process outcomes (how the system works) rather than clinical outcomes, although this impact is often modest [37, 40]. An overview by Grimshaw (2012) showed effects of evidence implementation strategies (not specific to CPGs) such as educational measures, audit and feedback, opinion leaders and tailored interventions, which resulted in 4.3–12% in median absolute improvements in care [41]. CPG implementation often requires behaviour change by health care professionals, patients and other stakeholders within the health care system, because they may need to change or discard 'usual' practices in light of current best-evidence recommendations.

CPG recommendations often include the introduction of new technologies or interventions or discontinuation of ineffective, costly or harmful interventions. To do this requires significant and often swift changes in clinician behaviour. For behaviour change to be successful, consideration of the context in which the CPG is to be used is paramount [42–44]. Several implementation theories account for context explicitly, e.g. the Promoting Action on Research Implementation in Health Services framework [45], the Consolidated Framework for Implementation Research [46] and the Theoretical Domains Framework (TDF) [47, 48]. The TDF is a validated framework that includes 14 domains of theoretical constructs and has been tested for developing complex interventions to implement changes in health care settings [49].

Theoretical frameworks of implementation can facilitate planning and executing implementation of CPG recommendations, as well as support evaluation of CPG impact [50–53]. However, few published CPG implementation interventions use specific theories. A recent systematic review reported that only one-fifth of the 235 CPG implementation studies reviewed used a specific theory [54]. Moreover, critics of implementation theories have highlighted the poor evidence supporting them and suggested that a common-sense approach may do just as well [55, 56]. However, there seems to be emerging evidence that behaviour-change processes applied in CPG implementation, that are informed by theory are more effective than those that are not and that theory should be used to establish causal relationships between theoretical constructs and effects of aspects of implementation [56, 57]. Further research is required to understand the practical aspects of how CPG recommendations can be effectively and efficiently implemented in ways that produce improvements in processes and clinical outcomes.

Configuring CPGS to different settings: adopting, contextualizing or adapting

Since the early 2000s, there has been increasing international recognition of the potential for efficiency and value of taking CPGs developed in one country and applying them to other countries. This is intended to avoid duplication of effort in *de novo* guideline development, when

useful CPGs may exist elsewhere [26, 58]. There is no consensus on the appropriate terminology to use for transferring CPGs from one health system or health setting to another, or for subsequent configuration of CPGs for local contexts and needs. The ADAPTE Collaboration, a strategic collaboration between two international CPG research groups (ADAPTE and Practice Guideline Evaluation and Adaptation Cycle) proposes an 'adaptation' approach in their resource manual (distributed via G-I-N (ADAPTE Collaboration 2009)) [59]. Their work describes the direct transfer of CPGs across similar income and health systems settings.

Another approach, that of adopting and then contextualizing, underpinned an innovative Filipino CPG implementation project [60]. The ADAPTE process lacked detail on the specifics of 'how to' transfer recommendations from CPGs developed in high-income to low-income country settings, where health care policy and contexts, funding, workforce, resources and training are significantly different. The CPG working group from the Philippines Academy of Rehabilitation Medicine differentiated between the notions of 'adaptation' and 'contextualization' and proposed an innovative adoption and contextualization approach, by mapping recommendations from multiple CPGs into a typical Filipino patient pathway, and then developing local 'context points' to support local uptake [61]. This work has since been recognized as best practice for lower- and middle-income countries by the *International Society of Physical and Rehabilitation Medicine (ISPRM)* and provides a practical, cost-effective and efficient alternative approach to developing local context *de novo* CPGs.

Shared decision-making

Shared decision-making occurs when patients and their health care providers make joint decisions about health care interventions based on best research evidence, and layered by patient preferences, values, clinical judgement and local contexts [62, 63]. When done well, shared decision-making and mutual agreement on the way forward for the management of a patient's condition could be considered the desired end-point of CPG implementation [62, 64]. Where high-quality evidence is lacking, shared decisions will rely more heavily on clinician perspectives and patient preferences [65]. Barriers to effective shared decision-making include lack of time, skills, knowledge, mutual respect and effective communication processes [63, 66]. A Cochrane review evaluating shared decision-making interventions reported low-quality evidence for the effectiveness of any intervention targeting health care professionals, patients or both. However, the authors conclude that despite the low-quality evidence, any intervention targeting both parties is consistently better than targeting either one or no intervention [63].

Decision aids are tools designed specifically to help with decision-making, with particular application in the context of low-quality or uncertain evidence [66]. These tools have been reported to increase absolute knowledge of patients amongst other benefits; however, effects on clinical outcomes are to date uncertain [67]. Rapid developments in evidence mean that decision aids may be out-of-date, and the process for updating may be onerous and, in many cases, not done [66]. There is a move to use new technology to support this process. Point-of-care decision aids include short one-page summaries as in 'Option Grids' (www.optiongrid.co.uk) [68]. Technology in development includes the previously mentioned MAGICapp group, where the layered approach extends to patient end-user tools for use in consultation, linked with the SHARE-IT project evaluating the value of the decision aid in clinical care (http://magicproject.org/share-it/) [69].

Conclusion

This paper explores the standards, methods and systems in use by those involved with CPGs and provides a synthesis of the current state of play of international guideline activity. It also highlights the immense efforts being made by researchers, clinicians and policy-makers who are committed to optimizing ways in which evidence is packaged to improve care.

The tools described in this paper are not all uniformly accessible or user-friendly. They have variable evidence of psychometric properties and utility, and many require additional research to ensure that they can be applied appropriately in different CPG contexts.

CPG activities are evolving processes. We anticipate that the next decade will see significant further research into tools to underpin best practices in CPG activities. Given the increasing number of high-quality CPGs that are freely available internationally for a range of health conditions, we propose that the growth areas in CPG methods in the next decade will be in updating, adopting, contextualizing and/or adapting, and implementing. Moreover, the next generation of CPG activities should build on knowledge of current activities in development, advance processes of end-user engagement, and evaluate CPG impact on health outcomes.

Authors' contribution

K.G. lead the design and execution of the paper. Q.A.L., T.Y., T.K., S.M., S.B. and E.O. contributed to the conception or execution of the paper. All authors approved the final version

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Appendix 2: Guidelines quality appraisal: Southern African Development Community

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HEALTH RESEARCH POLICY AND SYSTEMS

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Clinical practice guidelines within the Southern African development community: a descriptive study of the quality of guideline development and concordance with best evidence for five priority diseases

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Abstract

Background: Reducing the burden of disease relies on availability of evidence-based clinical practice guidelines (CPGs). There is limited data on availability, quality and content of guidelines within the Southern African Development Community (SADC). This evaluation aims to address this gap in knowledge and provide recommendations for regional guideline development.

Methods: We prioritised five diseases: HIV in adults, malaria in children and adults, pre-eclampsia, diarrhoea in children and hypertension in primary care. A comprehensive electronic search to locate guidelines was conducted between June and October 2010 and augmented with email contact with SADC Ministries of Health. Independent reviewers used the AGREE II tool to score six quality domains reporting the guideline development process. Alignment of the evidence-base of the guidelines was evaluated by comparing their content with key recommendations from accepted reference guidelines, identified with a content expert, and percentage scores were calculated.

Findings: We identified 30 guidelines from 13 countries, publication dates ranging from 2003-2010. Overall the '*scope and purpose*' and '*clarity and presentation*' domains of the AGREE II instrument scored highest, median 58% (range 19-92) and 83%(range 17-100) respectively. '*Stakeholder involvement*' followed with median 39%(range 6-75). '*Applicability*', '*rigour of development*' and '*editorial independence*' scored poorly, all below 25%. Alignment with evidence was variable across member states, the lowest scores occurring in older guidelines or where the guideline being evaluated was part of broader primary healthcare CPG rather than a disease-specific guideline.

Conclusion: This review identified quality gaps and variable alignment with best evidence in available guidelines within SADC for five priority diseases. Future guideline development processes within SADC should better adhere to global reporting norms requiring broader consultation of stakeholders and transparency of process. A regional guideline support committee could harness local capacity to support context appropriate guideline development.

Keywords: clinical practice guidelines, quality, evidence-based, alignment

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Introduction

Clinical practice guidelines bridge the gap between policy and practice and should be based on up-to-date, high quality research findings [1,2]. Reducing the burden of disease in resource-poor settings relies on the availability of such evidence-based clinical practice guidelines [3]. Gaps in these guidelines may impact on the health of the public they are meant to serve. These omissions may be a result of opinion-based rather than evidence-based guidance; recommendations from guideline development groups with undisclosed conflicts of interest; or poor planning for implementation of a guideline [4-8]. There is little data regarding the quality and content of guidelines in Southern Africa, a region facing serious health issues including poorly contained communicable diseases, increasing non-communicable diseases and under-resourced, often poorly managed health systems. This demands increasing attention from both development agencies and researchers to support research aimed at strengthening guidelines and policy [9].

Several guideline appraisal tools have been developed to assess the quality of guidelines [10]. Of these, the Appraisal of Guidelines for Research and Evaluation (AGREE) tool has been validated and is most widely accepted [11-13]. None of the available instruments assesses the clinical content of the guideline or the quality of the supporting evidence [10]. It is important to develop methodology for assessing alignment of published guidelines with current best evidence.

Our project aimed to evaluate clinical practice guidelines (CPGs) from the Southern African Development Community (SADC) member states, for priority diseases, with respect to availability, quality and alignment with current reference guidelines. This study formed part of a larger programme, the Southern African Regional Programme on Access to Medicines (SARPAM) for harmonising CPGs and essential medicine lists for reforming regional procurement.

Methods

Prioritising guidelines

We considered two issues: firstly, priority diseases should be representative of the following key components: adult & paediatric conditions; communicable & non-communicable diseases; chronic and acute onset diseases; maternal health; hospital-based & primary health care conditions. Secondly, time and feasibility limited our selection to five diseases. The following conditions were prioritised by the SARPAM study team: HIV in adults; malaria in children and adults; essential hypertension in primary care; pre-eclampsia; and diarrhoea in children.

Search strategy for guidelines

A public health clinician used an electronic search and e-mail enquiry strategy to obtain the CPGs for each

SADC country: Angola, Botswana, the Democratic Republic of Congo (DRC), Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe. The search strategy incorporated possible document and disease terms which were added to the country names (Table 1). Medline and Google were searched using an iterative approach. We contacted Ministries of Health via the SADC secretariat. Only English language guidelines were accepted for this evaluation.

AGREE II instrument

Two reviewers (TK, AG) independently evaluated the global quality of the five CPGs for each of the SADC states and the reference guidelines using AGREE II. This tool is a recently revised and validated version of the AGREE instrument [14-18]. AGREE II contains 23 key quality items categorised in six domains scored with a 7-point Likert scale. Standardised guideline domain scores were calculated by summing scores of individual items and standardising the total as a percentage of the maximum possible score for that domain. The six domain scores are independent and were not aggregated into a single quality score. Uncertainties in the application of AGREE II were resolved in consultation with a third investigator (NS). We used Microsoft™ Excel to record the scores. As the data was nonparametric, we calculated a median (range) for each domain across countries to provide overall results.

Alignment with reference standard guidelines and expert opinion

We invited one South Africa-based content expert for each of the five priority areas to give input on this project. The current gold standard reference guideline for each topic was identified in consultation with the content expert [19-26]. The key items of evidence that should appear in a current guideline on that topic were then extracted (TK) and the list judged and summarised by the relevant content expert. These lists represent the recommendations against which alignment with current best evidence could be checked with the in-country guideline. The list of recommendations from each of the reference guidelines was assigned a point score according to the number of recommendations that should be present to indicate alignment with the reference guideline. For example, 25 key items were identified for HIV guidelines from the WHO 2010 guidelines for the management of HIV/AIDS in adults and adolescents(19); all current HIV management guidelines should include these and would score 100% if all 25 points were identified (Table 2; tables for list of recommendations for all reference guidelines are available on request). All

Table 1 Search terms used for finding clinical practice guidelines within SADC

Search concepts	Search terms
Medical terms	HIV; AIDS; ART; ARV; HAART; Anti-retroviral treatment/therapy; Communicable disease/s Malaria Diarrhoea; acute; paediatric; child/ren Hypertension: cardiovascular disease; CVD Pre-eclampsia: hypertension; pregnancy
Countries	Angola, Botswana, The Democratic Republic of Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe
Clinical practice guidelines	Standard treatment guideline/s; STG/s; Standard Treatment; Treatment; Treatment guideline/s
Essential medicine lists	Essential medicine list; EML; Essential drug list; EDL; Central medical store; procurement list; CMS; Medicine procurement list
Ministries of health	Department of Health; DOH; Ministry of Health; MOH; National Aids Commission; Aids Commission; NAC

in-country CPGs were assessed for concordance with the recommendations list. There were no specific weightings for the individual recommendations, as each item is considered a key item for inclusion in current guidelines on those topics. For each of the five diseases, we summarised the concordance of the CPGs using a percentage score and noted any differences.

Results
Search results
The search was conducted between June and October 2010, including feedback from a SADC secretariat meeting in September 2010. The MEDLINE search yielded no results. Using Google™ and personal contacts the search yielded 30 guidelines from 13 SADC states (Table 3). The publication dates of the available guidelines ranged from 2003 to 2010. HIV guidelines were available from 13 of the 14 states; three were in languages other than English. Malaria treatment guidelines were available from 13 of the states, two were not in English, leaving 11 evaluable for this review, three of which were sections within other CPGs. Hypertension guidelines were available from nine countries, only two of which were disease-specific guidelines (South Africa and Mauritius)[27]. We did not locate guidelines dedicated to management of diarrhoea in children or pre-

Table 2 Key recommendations from the reference guideline for the management of HIV in adults

	WHO 2010	Details	Points
Recommendation 1	When to start	- CD4 count < 350 - WHO Clinical stage 3 and 4 irrespective of CD4 count	2
Recommendation 2	What to start	- AZT+3TC +EFV - AZT+3TC+NVP - TDF+3TC/FTC+EFV - TDF+3TC/FTC+NVP	4
Recommendation 3	ART for HIV/TB	- Start ART in all patients with TB - Start TB treatment first - Prefer EFV - Start ART within 2-8 weeks of starting TB treatment - If CD4 count < 200, start ART within 2 weeks	5
Recommendation 4	ART for HIV/Hep B	- Start ART in all patients who require treatment for their Hepatitis B - Start TDF and 3TC/FTC	2
Recommendation 5	ART for pregnancy	- Start ART in all pregnant women if CD4 count < 350 - Start ART in all women with clinical stage 3 or 4 disease irrespective of CD4 count - AZT preferred in pregnancy - EFV or NVP can be used - Do not start EFV in first trimester	6
Recommendation 6	When to switch - (note: if VL 5000 or less, will be accepted e.g. 1000)	- VL > 5000copies/mL on at least two occasions - Use CD4 count if VL not available	2
Recommendation 7	Second line ART (note: if any one of the protease inhibitors included, will accept)	- Boosted PI + 2 NRTIs recommended - Atazanavir/ritonavir or Lopinavir/ritonavir or darunavir/ritonavir recommended - If TDF used in first line, use AZT/D4T next - AND if AZT/D4T used in first line, use TDF in second line	4

ART = antiretroviral therapy; TB = tuberculosis; Hep B = hepatitis B; VL = viral load; PI = protease inhibitor; NRTIs = nucleoside reverse transcriptase inhibitors; TDF = tenofovir; AZT = zidovudine; D4T = stavudine; EFV = efavirenz; NVP = nevirapine

Table 3 SADC member state guidelines and the reference standard guidelines

SADC countries	HIV therapy in adults	Malaria therapy in adults and children	Diarrhoea therapy in children	Hypertension therapy in primary care	Pre-eclampsia therapy	Primary care clinical practice guideline[iv]
Angola	N/A[i]	N/A	N/A	N/A	N/A	N/A
Botswana	2008[ii]	2007	N/A	N/A	N/A	N/A
Democratic Republic of Congo	2005 (French)[iii]	2005 (French)	N/A	N/A	N/A	N/A
Lesotho	2010 draft	N/A	N/A	N/A	N/A	2005
Malawi	2008	N/A	N/A	N/A	N/A	2009
Mauritius	2009 (French)	?date	N/A	?date	N/A	N/A
Mozambique	2009 (Portuguese)	2006 (Portuguese)	N/A	N/A	N/A	N/A
Namibia	2009	2005	N/A	N/A	N/A	2010
Seychelles	N/A	N/A	N/A	N/A	N/A	2003
South Africa	2010	2009	N/A	2006	N/A	2008
Swaziland	2006	2009	N/A	N/A	N/A	N/A
Tanzania	2005	2006	N/A	N/A	N/A	2007
Zambia	2007	N/A	N/A	N/A	N/A	2008
Zimbabwe	2010 draft	N/A	N/A	N/A	N/A	2006
Standard reference guideline	World Health Organization, 2010[19]	World Health Organization, 2010[20]	World Health Organization, 2005[22,23]	National Institute for Clinical Excellence 2004[24-26]	Royal College of Obstetricians Gynaecologists, 2006[21]	

[i] N/A indicates that the guideline was not available during the search period
[ii] Dates of publication indicated where was available. Where date was not clear we have indicated this with '?date'
[iii] The language of the guideline-if other than English-is indicated in brackets
[iv] Primary care guidelines were used to assess alignment when no disease-specific guideline existed

eclampsia. We did evaluate the broader primary care CPGs for these diseases in seven member states for the former condition and eight member states for the latter.

Summary of AGREE II findings

We present the results according to diseases (Table 4). Matrices are shown which report the intersection of AGREE II by domain and alignment with best evidence (Figures 1, 2, 3, 4 and 5). AGREE II evaluation of the reference guidelines is shown in Figure 6.

HIV/AIDS

Of the available HIV guidelines, most were disease-specific guidelines, except that from Seychelles, which had an abbreviated guideline on HIV management, forming part of the larger primary care CPG. Two of the guidelines were in the process of being revised after the release of the recent WHO 2010 guideline (Table 3) [19]. The 'clarity and presentation' and 'scope and purpose' domains scored highest with median scores of 88% (range 33-94) and 57% (range 19-78) respectively across all countries. 'Rigour of development' and 'editorial independence' were most poorly reported scoring a median score of 16% (range 6-30) and 4% (range 0-29) respectively.

Malaria

The 'scope and purpose' and 'clarity and presentation' domains scored highest, median scores of 71% (range

Table 4 Aggregated AGREE II Scores across diseases [median(range)]

Priority diseases	Domains of AGREE II					
	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence
HIV (n = 10)	57(19-78)	43(22-58)	16(6-30)	88(33-94)	22(0-58)	4(0-29)
Malaria (n = 11)	71(19-89)	38(6-53)	20(6-32)	88(17-97)	15(0-52)	0(0-25)
Pre-eclampsia (n = 8)	58(31-83)	36(22-61)	14(5-20)	75(36-89)	10(0-27)	0(0-25)
Diarrhoea in children (n = 7)	58(25-83)	36(22-58)	14(6-20)	83(42-100)	10(0-27)	4(0-25)
Hypertension (n = 9)	75(39-92)	42(22-64)	11(6-44)	81(53-97)	10(0-42)	4(0-50)
Overall	58(19-92)	39(6-75)	14(5-44)	83(17-100)	10(0-58)	0(0-50)
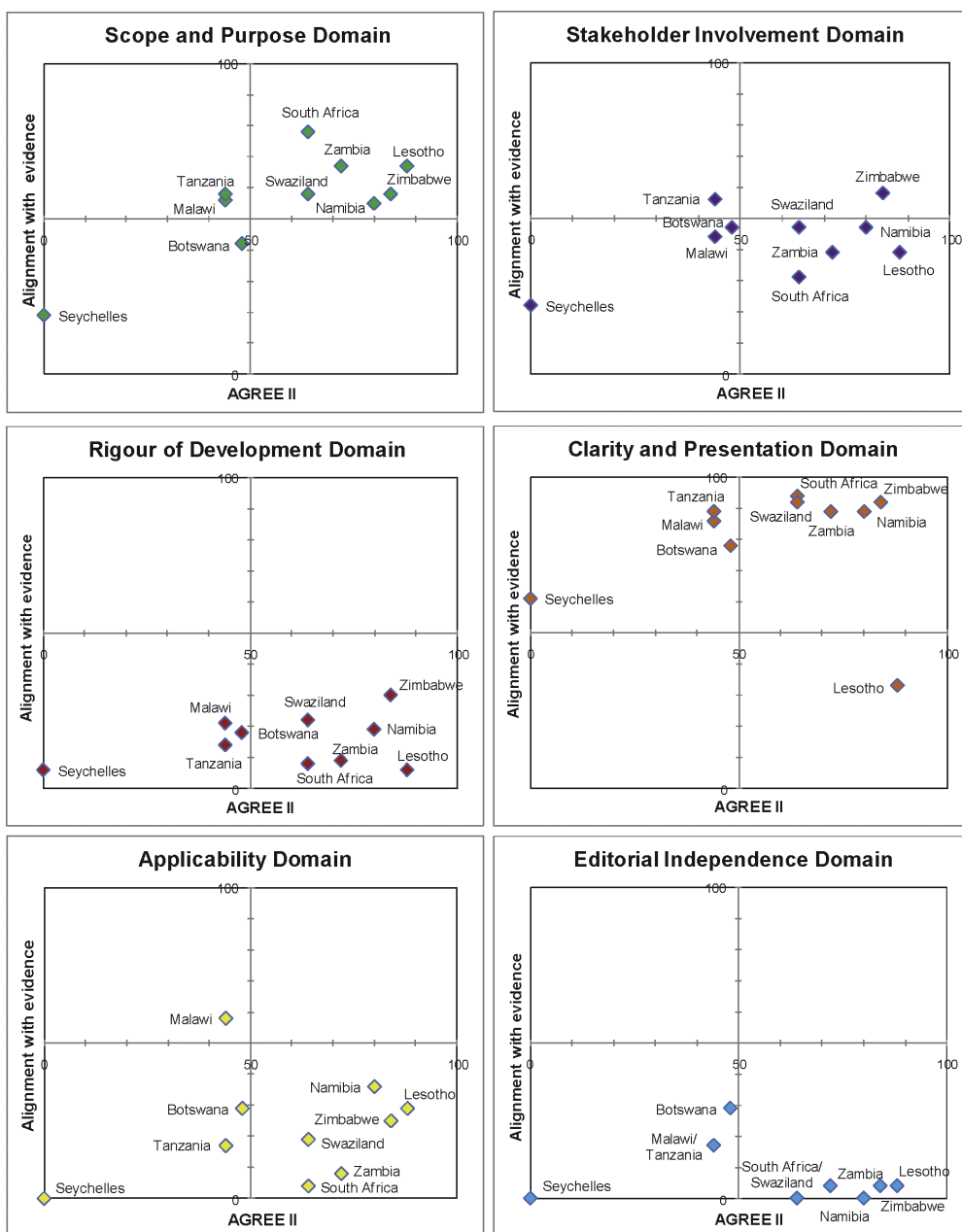
Figure 1 Matrix of AGREE II and alignment with evidence-HIV guidelines within SADC.

19-89) and 88% (range 17-97), whereas the 'applicability' and 'editorial independence' scored poorly, median 15% (range 0-52) and 0% (range 0-25) respectively.

Pre-eclampsia
Eight guidelines were evaluated, including the 2010 draft version of the Namibian CPG. The lowest score was seen for the 'editorial independence' domain, median 0% (range 0-25) and the highest score was seen in the 'clarity and presentation' domain median 75% (range 36-89).

Diarrhoea in children
Domains 'scope and purpose', 'stakeholder involvement' and 'clarity and presentation' received highest scores; the lowest score was seen for editorial independence median 4% (range 0-25).

Hypertension in adults
The median score for the domain on 'clarity and presentation' was 81% (range 53-97), and the 'scope and purpose' median score was 75% (range 39-92), however the
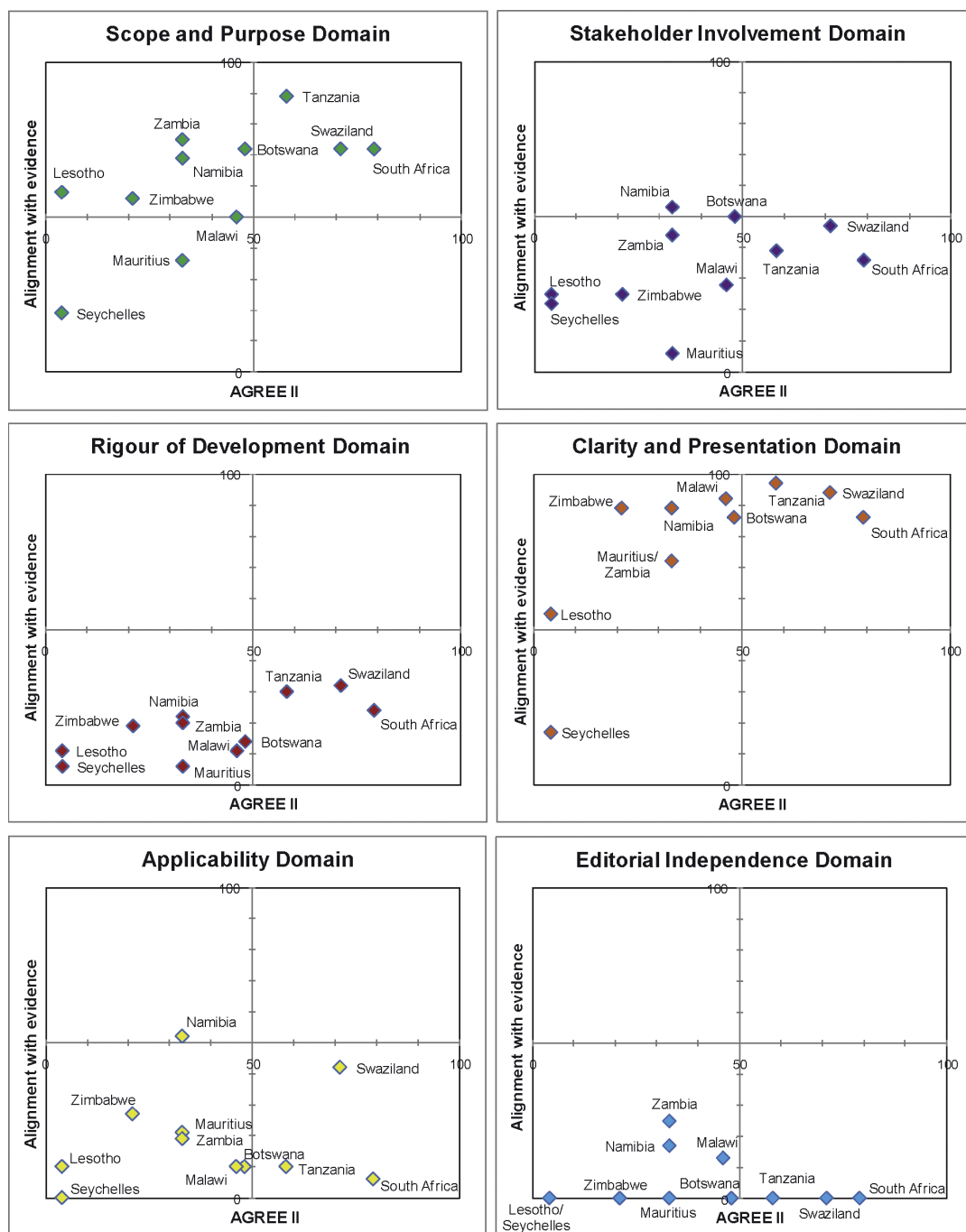
Figure 2 Matrix of AGREE II and alignment with evidence-Malaria guidelines within SADC.

other domains scored largely below 50% with 'editorial independence' scoring lowest, median 4% (range 0-50).

Alignment of CPGs with reference standards

Key recommendations from the reference guidelines were identified with input from experts in the respective fields.

HIV/AIDS

The Zimbabwe (2010) and Lesotho (2010) guidelines, both in draft form, were best aligned with current evidence-based guidelines and expert opinion, achieving > 80% alignment (Figure 1). Older guidelines, such as that from Tanzania (2005), were not well aligned and presented out-dated recommendations such as the use of
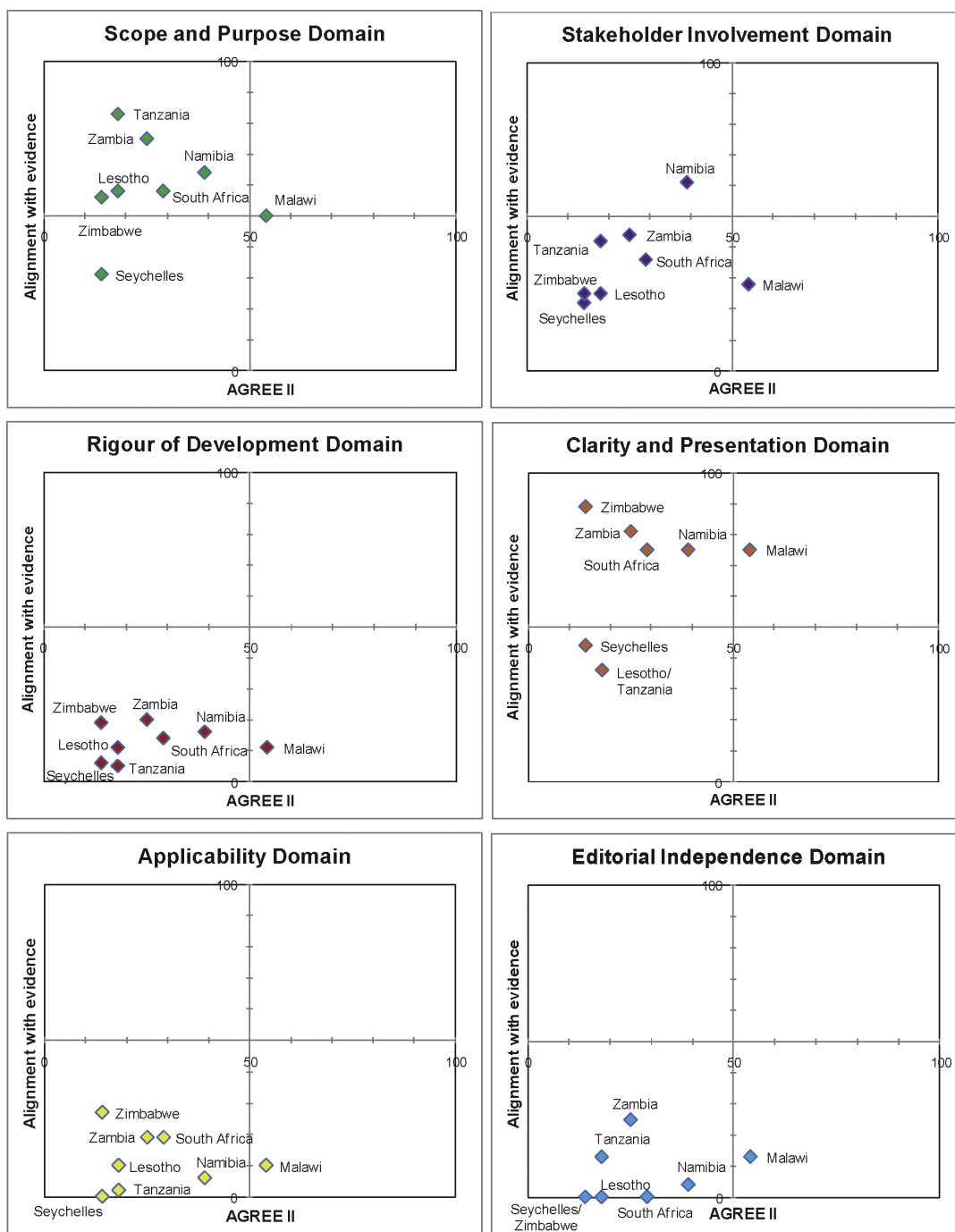
Figure 3 Matrix of AGREE II and alignment with evidence-Pre-eclampsia guidelines within SADC.

stavudine as first-line antiretroviral therapy. The guideline from Zambia (2007), achieved good alignment despite having been published prior to the current WHO recommendations. This guideline made provisions for recommending the antiretroviral Tenofovir prior to, but in anticipation of, its availability for first-line therapy in the country.

Malaria

The five malaria guidelines that were part of a larger primary care CPG were limited in their scope and generally did not provide comprehensive management advice (Figure 2). Older primary care CPGs were less likely to be in-line with current evidence and tending to score lower in their alignment (Lesotho 2005, Seychelles

Figure 4 Matrix of AGREE II and alignment with evidence-Childhood diarrhoea guidelines within SADC.
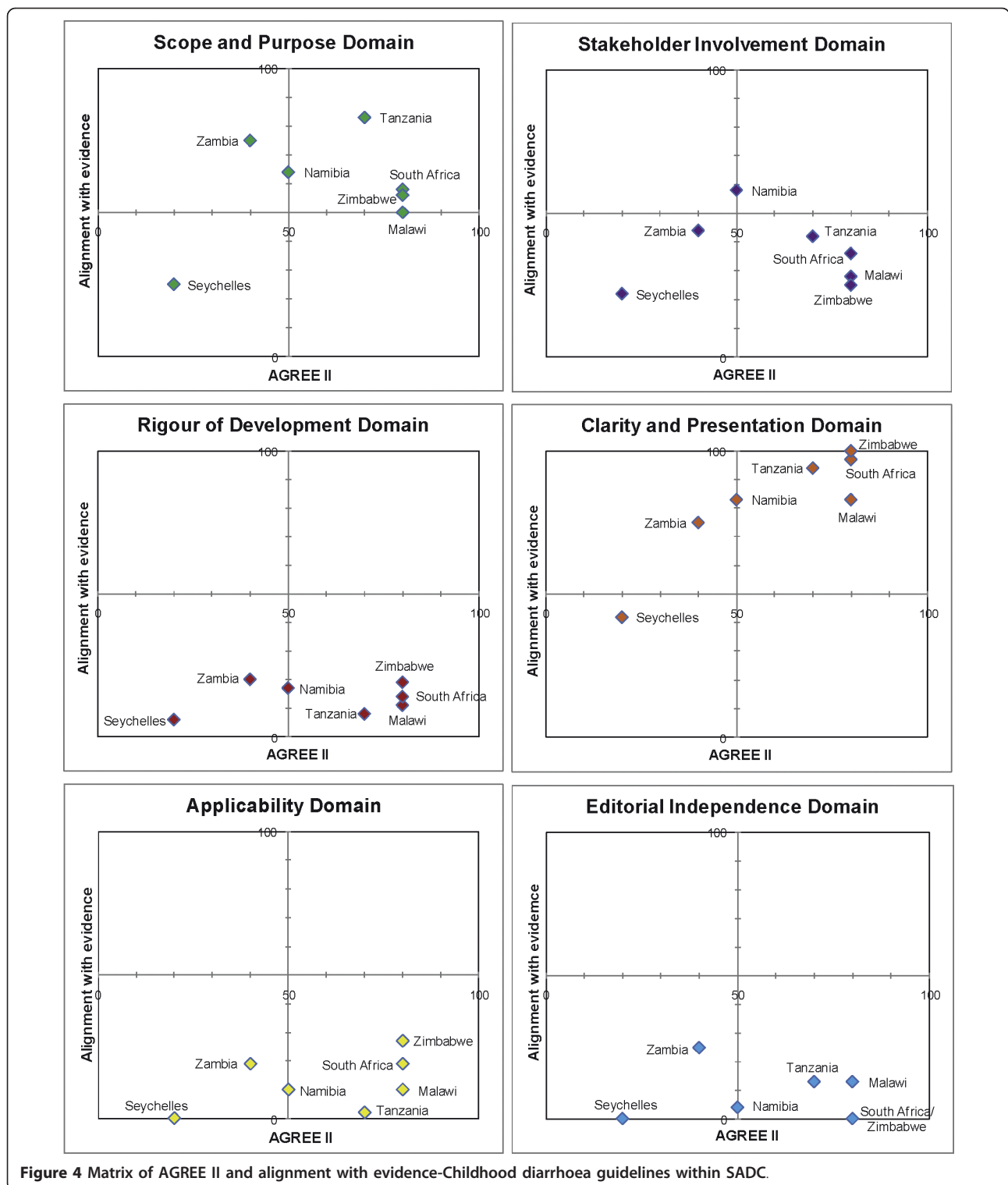
2003). Guidelines from South Africa (2009) and Swaziland (2009) were best aligned with current evidence-certain recommendations that differed from reference standard advice were justified due to local cost or regulatory constraints, rather than lack of adherence to best standards (e.g. use of parenteral quinine rather than artesunate in South Africa where the drug is not yet registered by the National Regulatory Authority).
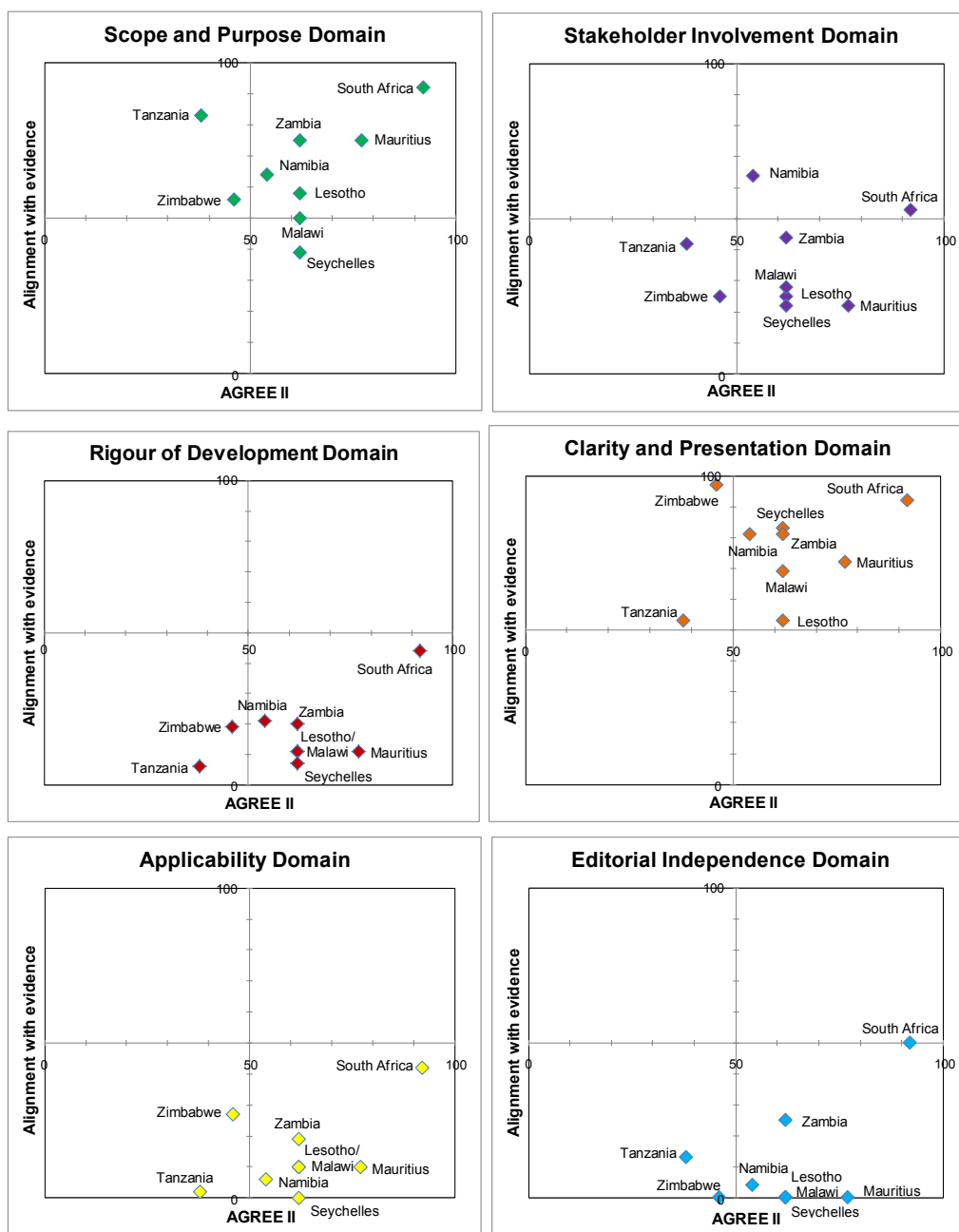
Figure 5 Matrix of AGREE II and alignment with evidence-Primary care hypertension guidelines within SADC.

Pre-eclampsia

Most guidance regarding the management of pre-eclampsia was brief, scoring poorly overall. Malawi (2009) was most recently published and was current in its recommendations and scored above 50% (Figure 3).

Diarrhoea

Diarrhoea management has not changed significantly in the recent years and as such, most CPGs produced after

the WHO publication in 2005 (22,23) had fair concordance with recommendations, including the use of zinc in all guidelines. Zimbabwe (2006), South Africa (2008) and Malawi (2009) scored 80% alignment (Figure 4).

Hypertension

Two countries with dedicated hypertension guidelines, South Africa (2006) and Mauritius (unknown date), scored best in their alignment with current best evidence [27] (Figure 5). The remaining primary care
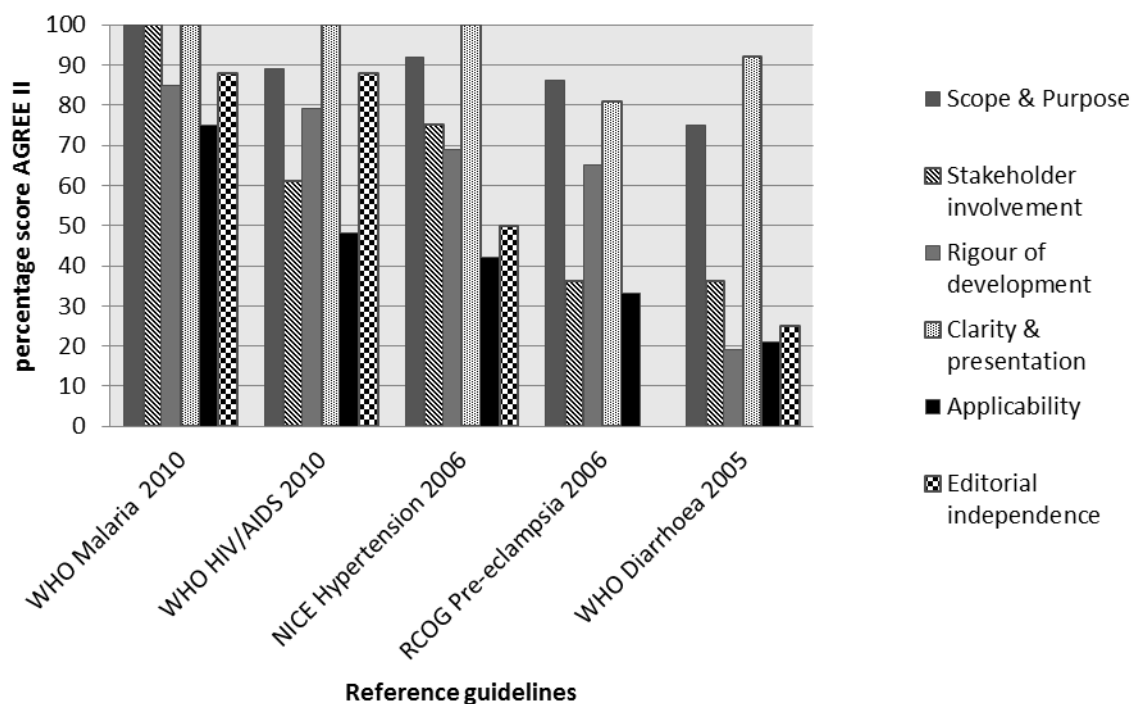
Figure 6 AGREE II scoring for reference guidelines.

guidelines did not provide adequate diagnosis and care recommendations hence scoring poorly.

Discussion

To our knowledge this is the first study to report on the availability and appraisal of quality and content of clinical guidelines for five priority diseases within the SADC region. Of the available guidelines overall scores were poor using the AGREE II assessment-particularly with respect to rigour of development, applicability and editorial independence. Alignment with best evidence was highly variable, with better scores for guidelines that were more recently published and those that were disease-specific rather than sections within larger primary health care CPGs.

Summary of main findings

HIV and malaria were most likely to have disease-specific guidelines which may reflect the global funding streams and political impetus targeting these conditions. The other priority diseases occupied sections within larger primary care CPGs. Our review found that the sections within other manuals that we evaluated were not comprehensive and provided incomplete guidance and were less likely to be up-to-date. Overall, the 'scope and purpose' and 'clarity and presentation' domains of the AGREE II tool were reported most comprehensively. However, the purpose, health question and target users

were not explicitly described. Rather, the information was incorporated within the introduction and foreword sections and required extraction in order to identify the scope and objectives.

Most documents employed clear and consistent methods for identifying key recommendations, such as flow diagrams, tables and highlighted text, making the documents accessible for end-users and resulting in good scores in 'clarity and presentation'. The value of the clarity and presentation has been questioned as it does not strictly reflect the internal and external validity of a guideline document [28]. However, the usability of a guideline may impact on the applicability of the document. Target-users are not necessarily trained to discriminate on the quality of the guideline, but may be encouraged to use it if simple to navigate and apply [29].

The remaining four domains scored poorly across all diseases. The guidelines described the 'stakeholder involvement' of multidisciplinary professional groups; however, little was reported about the contribution of primary-care doctors and target patients. This is increasingly recognised as important for assuring that guidelines represent the needs of both the target users and patients. Involving these groups in the guideline development process, for example by pre-testing the guideline, or evaluating and incorporating preferences and values, may aid in securing the successful implementation of the guideline [30,31].

In our study, as in previous studies, 'rigour of development' scored poorly [12]. A minority of guidelines provided references to the primary data and despite this many guidelines were highly aligned with current evidence (Figures 1, 2,3, 4 and 5). A plausible explanation is that the data required to evaluate this domain may exist in supporting documentation, such as appendices, which our search failed to locate. In addition, many of the SADC guidelines base their recommendations on other reference guidelines, such as WHO publications. Within SADC there may be members that have the capacity to appraise, synthesise and apply current evidence but generally it is accepted that few SADC countries are currently equipped with the necessary technical and financial resources. Despite this, had the guidelines we assessed clearly referenced their source guideline, they should have scored higher in this domain. In future similar evaluations, it may be prudent to augment the 'rigour of development' domain to clearly interrogate the source of the guidelines document, including whether it is based on another reference guideline. Many of the guideline documents we evaluated indicated that there would be a process for updating but none were explicit in their methods or the timing of updates. An important finding from this report is the lag between revisions of some of the guidelines with the result that the recommendations are no longer informed by current evidence potentially posing a risk to public health.

The methods necessary to successfully implement the guidelines, were not clearly delineated, hence the low scoring 'applicability domain'. Facilitators and barriers to applying the guidelines should be described to support implementation. The process of defining facilitators and barriers to application should be integrated early in the guideline development process and include professionals proficient in implementation strategies [29].

The low score in the 'editorial independence' domain reflects the poor reporting of potential conflicts of interest of stakeholders and the potential influence of funders in the guideline development process. Although the absence of these declarations does not necessarily imply that inappropriate influences guided the final recommendations, the presence of such declarations ensures that a guideline can be considered trustworthy [8,13,32].

Higher alignment scores were attained when guidelines were dedicated to a specific illness as seen with the malaria, HIV and hypertension guidelines. Gaps in the key recommendations occurred when the guidelines were out-of-date, occurring more frequently in the primary care CPGs. Pre-eclampsia scored poorly for alignment-indicating that the primary care CPGs we evaluated did not reflect current evidence. This condition requires hospital-based care and we did not identify any secondary or tertiary hospital guidelines during this review. Good alignment was achieved in guidelines despite poor scores in the 'rigour of development' domain-indicating a possible mismatch of the tool with the local practice of basing guidelines on WHO or equivalent high quality guidelines.

Agreement with previous research

A systematic review evaluating 42 guideline appraisal studies, including 626 guidelines, between 1988 and 2007 using the AGREE tool found similar distributions of low and high scores, supporting the notion that the domains within the guidelines that require improvement are similar despite disease or region [12]. Our scores for rigour of development, editorial independence and applicability were substantially lower than those described-indicating areas that require particular attention for future guideline development within SADC. Our study further highlights the need for support to improve the quality of guidelines by implementation of current normative standards of reporting within guidelines such as those developed by established guideline developers [33-35].

Strengths and limitations

We were mandated by the SADC Secretariat Pharmaceuticals Programme and therefore received cooperation from the ministries within the member states to assist with locating the relevant guidelines. We have attempted to address the research-knowledge gap by communicating a technical summary of the results to the SADC secretariat with specific recommendations for improving the availability, content and quality of CPGs within SADC. Although the AGREE II tool has been adopted widely as the reference tool to be used to evaluate guideline quality, this is the first time, to our knowledge, that it has been systematically applied across several diseases in a number of resource-constrained countries in Africa. This study can therefore contribute to a validation of the AGREE II tool and support uptake in our setting. The assessment of the alignment of the contents of the CPGs in this review was conducted with both published normative standard guidelines, such as WHO guidelines, and the input from experts in the respective fields.

We did not locate all relevant documents given the absence of a central or country-level repository. The outstanding documents would be required to provide a representative baseline analysis for SADC. The guidelines we evaluated included a combination of disease-specific guidelines and sections within larger primary care manuals. These guidelines may not lend themselves to be pooled in analysis, but do provide a true reflection of current guidance of the management of the included

diseases. AGREE collaborators recommend that increasing the number of reviewers increases validity [11,19]. Cost and time constraints dictated the feasible number of content experts and reviewers for this evaluation. There is currently no validated method for assessing alignment with evidence; therefore we used a method that will need future review to assess validity. Lack of timely translation prevented us from reviewing the guidelines from French- and Portuguese-speaking countries. This should be addressed in a future evaluation. The overall appraisal of quality of the guidelines would be enhanced by supplementary consultation and interview-based data collection with ministries, giving particular attention to guideline development processes and strategies and the roles of various members of the ministries of health, scientists and technical experts in formulating the guidelines [10]. Although the AGREE II tool may be applied across regions and settings, our experience suggests that 'rigour of development' domain may have scored more poorly than warranted, as the majority of SADC guidelines rely on guidance from the WHO, and therefore do not reference primary research as the domain requires. For this reason we recommended that this domain be amended for future evaluations for use in our setting.

What have we learned?

It is important that gaps in the availability of CPGs be identified and addressed. A repository of all guidelines in an accessible database will facilitate access for all SADC member states. It will facilitate cataloguing of guidelines and enable identification of those that may be relevant but missing or out-of-date. This could be done in collaboration with organisations such as the Guideline International Network [36].

There may be value in creating a SADC guideline support committee, through the SADC Pharmaceutical Programme, to assist all member states to adapt, maintain and update in-country guidelines of high standard [37]. This will facilitate that expertise in guideline development be shared. This committee may enlist expertise in reviewing current evidence with regards its applicability and generalisability to local healthcare needs. Such a committee should include, amongst others, the following relevant stakeholders-content experts; funders; policy makers; public health professionals; physicians, nurses and pharmacy staff; patient representative groups and an external review committee. Collaboration with experts in the field of guideline development could support capacity development and aid the process of bridging research and practice.

The value of this review has been to identify specific gaps in the quality and content of the guidelines within SADC. There is increasing awareness that the transfer of research evidence into policy and practice is a complex issue, sensitive to the context of each country. In order to inspire confidence in the quality and evidence-base of guideline recommendations and in the transparency of the development process, each newly developed or updated guideline should adhere to the recommended reporting norms currently in use globally.

Non-standard abbreviations

CPG: clinical practice guideline; AGREE: Appraisal of Guidelines for Research and Evaluation.

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Authors' contributions

TK, NS, SC and JvH designed the protocol. AG, TK scored the guidelines using AGREE, NS provided input during process. TK evaluated alignment with key evidence-based recommendations from reference guidelines and content experts. TK drafted the manuscript, NS, JvH, AG and SC contributed to the final report. All authors have read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Appendix 3: South African clinical practice guidelines: A landscape analysis

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South African clinical practice guidelines: A landscape analysis

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Background. South Africa (SA) is in the process of implementing National Health Insurance (NHI), which will require co-ordination of health provision across sectors and levels of care. Clinical practice guidelines (CPGs) are tools for standardising and implementing care, and are intended to influence clinical decision-making with consequences for patient outcomes, health system costs and resource use. Under NHI, CPGs will be used to guide the provision of healthcare for South Africans. It is therefore important to explore the current landscape of CPG developers and development.
Objective. To identify and describe all CPGs available in the public domain produced by SA developers for the SA context.
Methods. We conducted a cross-sectional evaluation using a two-part search process: an iterative, electronic search of grey literature and relevant websites (161 websites searched), and a systematic search for peer-reviewed literature (PubMed) after publication year 2000. CPGs were identified, and data were extracted and categorised by two independent reviewers. Any discrepancies were referred to a third reviewer. Data extracted included a description of the developer, condition, and reporting of items associated with CPG quality.
Results. A search conducted in May 2017 identified 285 CPGs published after January 2000. Of those, 171 had been developed in the past 5 years. Developers included the national and provincial departments of health (DoH), professional societies and associations, ad hoc collaborations of clinicians, and the Council for Medical Schemes. Topics varied by developer; DoH CPGs focused on high-burden conditions (HIV/AIDS, tuberculosis and malaria), and other developers focused on non-communicable diseases. A conflict of interest statement was included in 23% of CPGs developed by societies or clinicians, compared with 4% of DoH CPGs.
Conclusion. Accessing CPGs was challenging and required extensive searching. SA has many contributors to CPG development from the public and private sectors and across disciplines, but there is no formal co-ordination or prioritisation of topics for CPG development. Different versions of the CPGs were identified and key quality items were poorly reported, potentially affecting the usability and credibility of those available. There was substantial variation in CPG comprehensiveness and methodological approach. Establishing a national CPG co-ordinating unit responsible for developing standards for CPG development along with clinical quality standards, and supporting high-quality CPG development, is one essential step for moving forward with NHI.

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Decisions made by healthcare professionals on the prevention and management of ill health are at the core of an effective, efficient and trusted health system. Clinical practice guidelines (CPGs) can have a substantial influence on clinical decision-making, with consequences for health outcomes, patients' access to care, health system costs and resource use.

The white paper on National Health Insurance (NHI) policy for South Africa (SA)[1] released in June 2017 suggests that detailed treatment guidelines, based on the best available clinical and cost-effectiveness evidence, will be used to guide the delivery of health services under NHI. Under NHI, standard treatment guidelines (STGs) developed by the National Department of Health (NDoH) for primary, secondary, tertiary and quaternary levels of care will play an integral role in determining access to and quality of care, and additional treatment guidelines will be used or developed where gaps in the therapeutic areas covered by the STGs are identified. In addition, the NHI Policy states that 'efforts will be put into place to ensure that the general public is provided with the relevant information to support access and ensure empowerment regarding these guidelines'.[1]

However, no central, accessible database of CPGs developed in SA currently exists.[2] The CPG mapping project described in this article aimed to address this gap in knowledge of up-to-date guidelines, and to assist the NDoH by: (*i*) improving the current understanding of the CPG landscape in SA; and (*ii*) providing a starting point for a co-ordinated CPG review and development programme under NHI. The primary objective of this project was to identify and collate all publicly available CPGs and, where available, to provide the details of the developers/commissioners of such guidance.

For the purpose of this research, and the intended NHI-focused requirements of guideline production in SA, we defined CPGs in their broadest sense as documentation that advises on the clinical management (including screening, prevention, diagnosis, treatment, rehabilitation and palliation) of individuals in a particular setting for a particular disease area/condition. The use of a more restrictive definition of CPGs, for example the Institute of Medicine's 2011 definition that includes a requirement that CPG statements/recommendations 'are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options',[3] was not considered practical or appropriate, as the

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CPG landscape in SA is fragmented and not currently standardised, with limited technical skills available.[4] As a result, the CPGs included in the database vary considerably in terms of their development methods, quality and comprehensiveness.

Objective

To identify and describe all CPGs available in the public domain, produced by SA developers for the SA context.

Methods

We conducted a cross-sectional evaluation of publicly available CPGs through an iterative, electronic search of grey literature and relevant websites, as well as a systematic search for peer-reviewed literature.

Documentation relevant to the clinical management of individuals in SA (see full definition above) produced and published after 1 January 2000 in English was included in the CPG database. Only one version or presentation of any CPG was included, and non-clinical guidelines describing ethical, legal, organisational or infrastructure factors for healthcare were excluded. Continuing medical or professional education articles and academic textbooks were also excluded.

The electronic search of grey literature and relevant websites (national and provincial departments of health, professional societies, associations, universities) was conducted between 1 September 2016 and 15 November 2016, and repeated between 22 and 25 May 2017. The list of society and association websites searched was informed by a separate Society, Association and Council Mapping Project,[5] as well as the list provided on the Health Professions Council of South Africa's website (http://www.hpcsa.co.za/Links). In the initial search, terms including 'clinical guideline', 'treatment protocol' and 'recommendations' were used to identify websites and grey-literature sources. This was followed by a pragmatic, within-site strategy to ensure that the search was comprehensive and that sources were fully examined.

The systematic search for peer-reviewed literature was conducted in PubMed and the *South African Medical Journal* (*SAMJ*) on 18 October 2016, and updated by the first reviewer and repeated by the second reviewer on 12 May 2017. Articles published between 1 January 2000 and 12 May 2017 were identified using search terms that included 'South Africa' and variations of the following keywords: guideline; clinical management; treatment; protocol; recommend; algorithm; clinical practice guideline; decision support;

managed care; diagnoses; preventive; public health; and health service. Two reviewers independently reviewed the abstracts against the prespecified inclusion and exclusion criteria, with any disagreement discussed and referred to a third reviewer if not resolved. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart for the literature search is presented in Fig. 1.

Two independent reviewers extracted and categorised relevant information from the CPGs, with any disagreement discussed and referred to a third reviewer if not resolved. Information extracted included a description of the developer, condition and reporting of items associated with quality CPGs (e.g. declarations of conflicts of interest, funding sources, references or evidence base, and stakeholder involvement).

Results

In total, 285 CPGs published online after the year 2000 were retrieved. Fig. 2 provides an overview of the CPGs developed and published between January 2000 and May 2017 in SA and the broad therapeutic areas they relate to. Most CPGs provide guidance on non-communicable diseases (NCDs) (46%, 130/285), maternal, neonatal and child health (MNCH) (21%, 59/285) and HIV/AIDS, tuberculosis (TB) or malaria (12%, 35/285). We found that 171/285 CPGs

(60%) were developed after 1 January 2012. The apparent increase in CPG development since 2000 (Fig. 2) could in part be explained by the fact that only the latest version of any CPG was included in the database.

CPGs were categorised based on their scope as:
- **Covering multiple conditions and populations.** Short guidelines/algorithms covering multiple unrelated conditions or interventions.
- **Detailed.** Guidelines that include the following information regarding the condition or intervention: general information, symptoms and presentation of disease, diagnosis, and management/treatment recommendations.
- **Position statement.** *S*hort (usually 1 - 3 pages) recommendations or statements where the content is mainly based on the collective views of the organisation and not necessarily supported by analysis or synthesis of local evidence.
- **Poster/algorithm.** Algorithm or poster on the management of a particular condition or use of an intervention.

We identified five groups of CPG developers: (*i*) the NDoH; (*ii*) provincial departments of health; (*iii*) societies or associations; (*iv*) collaborations of clinicians and academics; and (*v*) the Council for Medical Schemes (CMS).
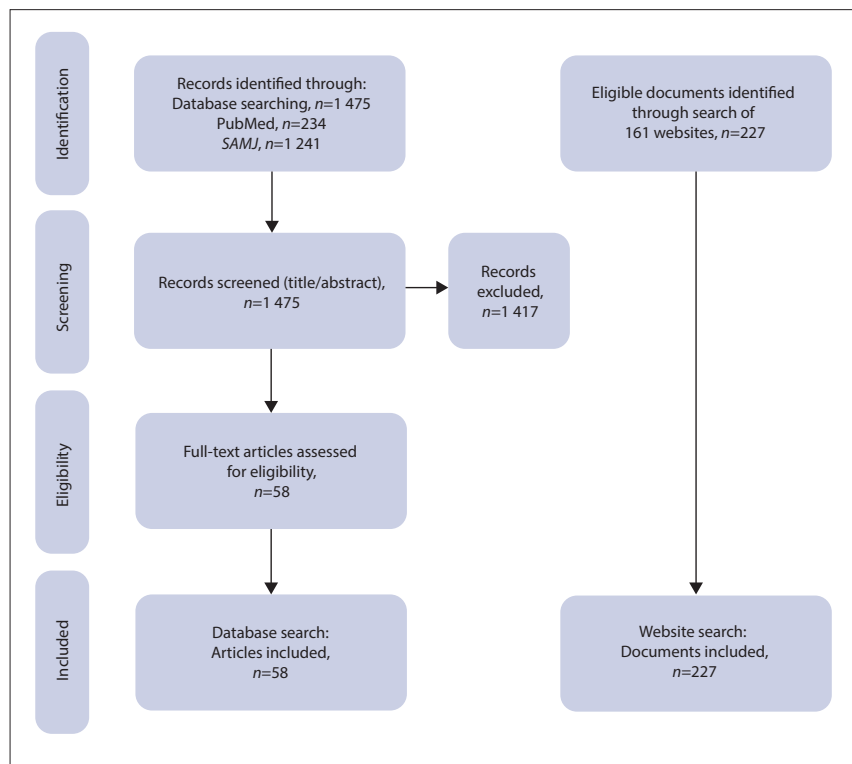

Fig. 1. PRISMA flow diagram of clinical practice guidelines (May 2017).

CPG developer types and categorisation are shown in Table 1. CPGs in each category vary in development methodology, length, target audience and scope (guidance on an individual intervention v. management of a condition).

Department of Health CPGs

Nine NDoH CPGs 'covering multiple conditions and populations' were identified: (*i*) three STGs for SA (primary care level, and hospital level for adults and children); (*ii*) Tertiary and Quaternary Level Essential Medicines Recommendations, 2016; (*iii*) Integrated Management of Childhood Illness (IMCI), 2014; (*iv*) Adult Primary Care guide, 2016/2017; (*v*) Newborn Care Charts, 2014 (these were developed by the Limpopo Initiative for Newborn Care, a joint initiative of the Department of Paediatrics and Child Health at the University of Limpopo and the Limpopo Department of Health, but have been categorised as an NDoH guideline owing to their national implementation and use); (*vi*) Guidelines for Neonatal Care, 2008; and (*vii*) the STG for common mental

health conditions. Outdated versions (when newer versions of the CPGs are available) of the STGs, the IMCI and the Adult Primary Care guide (previously named Primary Care 101) were found on multiple websites, including those of the NDoH, universities, provincial DoHs and professional societies and associations.

Most of the 'detailed' NDoH guidelines (*n*=45) were for HIV/AIDS, TB or malaria (28%, 15/45), followed by CPGs for MNCH (20%, 9/45), NCDs (20%, 9/45) and communicable diseases and infections (19%, 8/45). Some of the NDoH CPGs were adaptations of World Health Organization (WHO) guidelines, and many were developed in collaboration with, or with financial or technical support from, international development aid agencies such as the United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID), United Nations Population Fund (UNFPA) and Joint United Nations Programme on HIV/AIDS (UNAIDS).

Only three of the 'detailed' CPGs by provincial DoHs were produced in the past

5 years. Two of these were developed by the KwaZulu-Natal DoH for preventing and managing malnutrition, and one by the Western Cape DoH on antimicrobial management. The KwaZulu-Natal DoH also produced protocols for management of mental health conditions, and two paediatric CPGs 'covering multiple conditions and populations' in 2007.

Society or association CPGs

A total of 156 CPGs developed by 63 societies or associations were identified, with the majority of organisations (54%, 34/63) producing or contributing to more than one CPG. Some of the CPGs were adaptations of guidelines developed by professional societies outside SA.

The majority of the CPGs were 'detailed' (67%, 104/156) and were mostly produced after 1 January 2012 (62%, 96/156). Sixty percent (94/156) of the CPGs advised on the management of NCDs, with many referring to musculoskeletal (14/94), cardiovascular (13/94) and gastrointestinal (12/94) conditions.

None of the position statements identified (*n*=41) were published in a peer-reviewed journal, and they were mainly developed by five societies: the South African Spine Society (*n*=12), the South African Vitreoretinal Society (*n*=6), the South African Gastroenterology Society (*n*=4), the South African Society of Cardiovascular Intervention (*n*=4) and the South African Society of Obstetricians and Gynaecologists (*n*=4).

Ten poster/algorithm guidelines were included in the CPG database, of which nine were produced by the Resuscitation Council of South Africa.

CPGs produced by clinicians and academics

Thirty-seven CPGs containing no formal statement linking their development to the DoH or a specific society or association were included as clinician/academic-produced CPGs. The majority of the CPGs were for MNCH (40%, 15/37), followed by NCDs
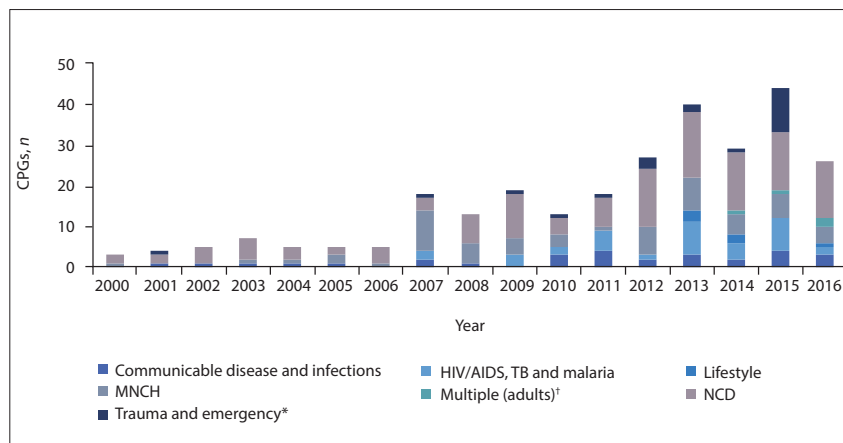
*Fig. 2. CPGs produced in SA between January 2000 and May 2017 by broad therapeutic area (N=285). (CPGs = clinical practice guidelines; SA = South Africa; TB = tuberculosis; MNCH = maternal, neonatal, and child health; NCD = non-communicable disease (NCD). *One CPG on the use of blood products in SA has been included under the 'Trauma and emergency' field; however, this document includes guidance covering more than one broad therapeutic area for both adults and children. †The 'Multiple (adults)' field includes four documents that consist of a package of adult-focused CPGs covering more than one broad therapeutic area. Paediatric CPGs covering more than one broad therapeutic area are included under the MNCH field.)*

Table 1. Overview of clinical practice guidelines in South Africa by developer type

	National Department of Health, *n*	Provincial department of health, *n*	Society/ association, *n*	Clinicians/ academics, *n*	Council for Medical Schemes, *n*	Total, *N*
Multiple conditions and populations	9	3	1	0	1	14
Detailed	45	10	104	37	14	210
Position statement	2	1	41	0	0	44
Poster/algorithm	3	4	10	0	0	17
Total	59	18	156	37	15	285

Table 2. Summary of findings: Items associated with good-quality CPGs

	National Department of Health (*n*=59)	Provincial department of health (*n*=18)	Societies / associations (*n*=156)	Clinicians and academics (*n*=37)	Council for Medical Schemes (*n*=15)
Funding statement	Funding source not stated* (81%) or unclear† (3%) *n*=1 stated pharmaceutical industry involvement	None stated pharmaceutical industry involvement	Funding source not stated* (73%) or unclear† (2%) 22% declared pharmaceutical industry involvement	Funding not stated* (59%) or unclear† (5%) 32% declared pharmaceutical industry involvement	Not stated (100%)
Conflict of interest statements, %	0	17	21	30	0
References available, %	54	28	74	100	93
Description of stakeholder consultation process, %	32	28	26	30	0

CPG = clinical practice guideline.
*A CPG funding source was categorised as 'not stated' if there was no explicit statement in that regard. There were cases where the involvement of international partners or the pharmaceutical industry in CPG development was stated, but the nature of their involvement (human resources or financial) was not declared.
†A CPG funding source was categorised as 'unclear' if the funding source was not stated, but a commercial advertisement or logo of a pharmaceutical company appeared in the CPG.

(32%, 12/37), other communicable diseases and infections (14%, 5/37) and HIV/AIDS, TB and malaria (8%, 3/37).

Most (33/37) of the CPGs were published in the *SAMJ*, with the rest available on journal and university websites: African Journals Online (AJOL) (*n*=1), the *Journal of Endocrinology, Metabolism and Diabetes of South Africa* (*JEMDSA*) (*n*=1), the University of KwaZulu-Natal (*n*=1) and the University of Cape Town (*n*=1).

Council for Medical Schemes CPGs
Fifteen CPGs developed by the CMS were identified. These consist of one CPG 'covering multiple conditions and populations', which contains the algorithms specifying the minimum standards required (under Prescribed Minimum Benefits (PMB)) in the management of the 25 chronic conditions on the Chronic Diseases List, and 14 'detailed' Diagnosis Treatment Pair CPGs published on the CMS website as a result of the PMB Definition Project.[6] The Diagnosis Treatment Pair CPGs all relate to cancer, cardiovascular disease and organ transplants.

Key quality criteria of included CPGs
Sixteen percent (47/285) of CPGs contained a statement regarding the authors' conflicts of interest, and 23% (65/285) explicitly declared the funding source. The methods for stakeholder consultation as part of the CPG development process was described in 26% (75/285) of CPGs, and 71% (203/285) included references. A brief summary of the findings by developer type is presented in Table 2.

Seventeen of the 59 NDoH CPGs (29%) stated the involvement of international development partners (e.g. WHO, UNICEF, USAID) in the CPG development process. These CPGs had a strong focus on MNCH (*n*=8) and the management of HIV/AIDS, TB and malaria (*n*=6). Pharmaceutical industry involvement was declared or assumed (based on pharmaceutical industry advertisements directly within the CPG) in the development of 54 CPGs, of which two-thirds (36/54) were focused on NCDs.

Discussion
CPGs developed in SA vary considerably in terms of their topics, scope, development methods, funding streams and accessibility. This variability is not surprising considering the number and diversity of CPG developers, and the lack of formal co-ordination or standardisation between them with regard to CPG topic selection and prioritisation, development methodology and reporting principles.

The individual topic selection/prioritisation process followed by the developers was generally not reported, and therapeutic topics vary considerably. The majority of DoH CPGs were focused on high-burden conditions such as HIV/AIDS, TB and malaria, while CPGs from other developers were more likely to provide guidance on NCDs. One possible explanation for this variation in CPG topics is the difference in the type of conditions treated by public and private healthcare providers, and as a result the types of CPGs they need or are likely to access. The effect of the aims and objectives of funding organisations (e.g. pharmaceutical industry, international development partners) on CPG topic selection was not considered as part of this mapping project, but may warrant future research to ensure that CPG topics are prioritised and selected based on the needs of the population and the healthcare community.

CPGs identified in the public domain were often out of date (with more up-to-date versions available elsewhere) and key quality items we extracted were poorly reported, potentially impacting on the usability and credibility of those available.

Accessing CPGs was challenging, as no central database of CPGs currently exists. CPGs can be submitted to the *SAMJ* for publication, but no formal 'clinical guidelines' were published in the period between the introduction of the AGREE II assessment to the *SAMJ* critical appraisal process for clinical guidelines in 2014[7] and May 2017. The systematic search for CPGs in the *SAMJ* retrieved 87 Continuing Medical Education (CME) articles published between 2014 and May 2017 that contained the features of a CPG. However, these articles were not subject to a peer review process prior to publication[8] and were not included in the CPG database. Some societies, associations, departmental organisations and universities publish CPGs on their websites, but in many cases the CPGs were out of date. The Ideal Clinic programme website consistently contained up-to-date versions of most of the core DoH guidelines (https://www.idealclinic.org.za). The Ideal Clinic programme is an NDoH initiative, initiated in 2013, with a strong focus on the use of guidelines to support its aim of 'systematically improving the quality of care provided in Primary Health Care facilities'.[9]

Strengths and limitations of the literature search

A systematic approach to identifying CPGs produced in SA and extracting the relevant data was followed. Detailed inclusion and exclusion criteria were established, based on a clear scope for the literature search. Dual review and data extraction of CPGs, as well as a search of grey literature, were conducted to minimise potential selection bias.

Despite the comprehensive search, given the difficulty with identifying CPGs it is probable that CPGs are missing. Non-English-language CPGs were excluded, so guidance produced in any of the other official languages in SA will not have been retrieved, and guidelines that were not dated may potentially have been missed.

Key criteria regarding funding and conflicts of interest were extracted, but a robust quality assessment of CPGs was not conducted. Two prior studies have evaluated the quality of a sample of CPGs in SA using the AGREE II checklist, and consistently found the reporting on several aspects of the methods for CPG development to be of low to moderate quality.[2,10] Further quality appraisal on the full set of CPGs may not provide additional insight.

Conclusions

SA has a diverse CPG-developing community, but the challenges faced by clinicians in accessing up-to-date CPGs and the lack of co-ordination between developers may limit the impact of CPG developers' efforts to guide and improve the delivery of high-quality patient care.

Developing and maintaining an accessible, up-to-date CPG repository is a practical and useful first step towards improving the availability of CPGs in SA. The 285 CPGs identified through this mapping project provide a starting point for such a repository. In addition to a point of access for clinicians, this CPG database can also be used to inform the planning and determination of service benefits under NHI, and provide information for a clinical guidance gap analysis to identify topic areas where future CPG development will be most beneficial. Useful lessons can be learnt from information technology organisations such as the Open Medicines Project and Essential Medical Guidance (EMGuidance), which are already working collaboratively, developing and maintaining smartphone applications that provide access to the most up-to-date versions of NDoH CPGs (STGs, Tertiary and Quaternary Level Essential Medicines Recommendations, TB and HIV)[11] and some CPGs produced by other SA developers.[12]

Stakeholder involvement is a crucial component that needs to be incorporated in all stages of the CPG development process. The South African Medical Association (SAMA) is currently 'engaging its medical practitioner members to contribute substantively to the development of guidelines, sharing their experience and expertise in the process'.[13] This could potentially improve the credibility and acceptability of CPGs by healthcare professionals across both the private and public sectors, and ultimately result in meaningful changes in clinical practice. Clinical quality standards are useful tools that can be used to further aid and enhance CPG implementation, and evaluate their clinical impact under NHI. Patient involvement in the CPG development process should also be considered, to ensure that patients are involved and empowered in decisions affecting their health.

In addition, the findings from this CPG mapping project and the South African Guidelines Excellence (SAGE) project[4] demonstrate the need for a national, co-ordinating CPG unit that will enable a standardised, co-ordinated and evidence-based approach to CPG development. A national co-ordinating body will be essential if CPGs are to inform patient care under NHI, with a likely impact on quality of care. Ideally it will be responsible for developing and upholding key components of CPG production, which includes robust processes for topic selection and prioritisation, development, publication/implementation and review.

Full lists of CPGs and CPG developers are available on the PRICELESS SA website (www.pricelesssa.ac.za).

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Appendix 4: South African Guidelines Excellence - editorial

Citation: Kredo T, Machingaidze S, Louw Q, Young T, Grimmer K. South African Guideline Excellence (SAGE): What's in a name? *S Afr Med J.* 2016;**106**(1):18-20.

South African Guidelines Excellence (SAGE): What's in a name?

South Africa (SA) remains one of the most unequal societies in the world.[1] Addressing the various challenges we face requires multidisciplinary, multipronged approaches, including consideration of strategies for improving the delivery of healthcare. Quality of healthcare can be understood to encompass a number of dimensions, including effectiveness, efficiency, accessibility, patient-centredness, equity and safety.[2] SA's call for primary healthcare re-engineering suggests an acute awareness of local challenges. The planned restructuring, including the National Health Insurance initiative, is a means for reducing inequality in the provision of healthcare, which will require new approaches to healthcare delivery, with greater emphasis on health promotion and preventive activities.[3,4] These changes necessitate a collaborative approach for achieving improvements in key health processes and outcomes, as well as changes in clinician and patient behaviours, all underpinned by innovative interventions.[5] In the changing healthcare system, healthcare providers need clear, trustworthy guidance on how best to care for their patients so that all can reasonably reach the ideals of quality in healthcare. High-quality, evidence-informed clinical practice guidelines (CPGs) are potentially reassuring tools for healthcare providers, as they are a means of bridging the gap between policy, best practice, local contexts and patient choice.

CPGs have long been upheld as an essential part of quality medical practice. 'Clinical guidelines are statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.'[6]

CPGs have a range of purposes, intended to improve the efficiency and cost-effectiveness of health system utilisation and to decrease costly and preventable mistakes. They generally include statements of expected practice, and provide benchmarks or standards against which individuals may audit and potentially improve their practices, or guidance with regard to undertaking particular tasks.[7] Internationally, over the past decade there has been a growing volume of research evidence around CPGs, including the processes of guideline development, adaptation, contextualisation, implementation and evaluation. There are detailed processes available for the development of CPGs, but there is no standard approach. Notably, there are well-credentialled international and national guideline development groups, including the World Health Organization,[8] the Scottish Intercollegiate Guidelines Network,[9] the National Institute for Health and Care Excellence[10] and the National Health and Medical Research Council,[11] each with its own approach to guideline construction and writing, usually described in a guideline development manual.

Globally and locally, potentially many hundreds more groups (such as health departments, insurers and other healthcare organisations, professional associations, hospitals, specialty colleges and even small unaffiliated groups of individuals) have attempted the task of producing guidelines with the purpose of improving or standardising local clinical practice. They often use their own interpretations of the best way to construct and write clinical guidelines. Historically, CPGs were built mostly on expert opinion, which included variable (and often selective) reference to research evidence.[12,13] Such guidelines are still found today, albeit in decreasing numbers. Better and more transparently constructed evidence-informed approaches integrated with expert opinion and patient values have gained acceptance as the best approach to clinical guideline development. To support this

progress, in 2011 the Institute of Medicine (IOM) introduced eight standards for guideline development (IOM 2011), the Guidelines International Network produced 11 relatively similar standards,[14] and McMaster University compiled a checklist of 18 topics and 146 items to guide developers.[15]

SA has been a contributor to CPG development and implementation for several decades. Guideline development occurs at national, provincial and hospital levels. In addition, professional societies have played an important role, developing guidance based on their areas of expertise. For example, the National Department of Health spearheads an Essential Medicines Programme that drives the development of standard treatment guidelines to inform rational prescription at all levels of care (primary, secondary and tertiary, quaternary) in an equitable, cost-effective manner throughout the country. Regionally, there is evidence that SA is a node of technical expertise in this field, with the quality of our guideline development exceeding that of our regional neighbours in the Southern African Development Community.[16] However, against a global backdrop SA's guidelines do not yet demonstrate all the aspects of expected guideline quality indicators according to recognised global standards. To address concerns with the quality of CPGs, the *SAMJ* has introduced a Guideline Review Committee to provide peer review before publication in the *Journal*.[17]

In addition to contributions to guideline development, SA researchers are global leaders in research into implementation, conducting high-quality cluster trials of complex interventions evaluating guideline uptake. For instance, the Knowledge Translation Unit at the University of Cape Town has conducted pragmatic trials evaluating outreach education and task shifting of care from doctors to other health professionals, compared with standard care for implementing guidelines for respiratory conditions, including tuberculosis and more recently HIV.[18-20] The guidelines, developed and implemented by this team for SA, are now being rolled out to other settings in Botswana and Malawi, where a similar trial to contextualise the effectiveness of the educational intervention has been tested.[21] This research team is currently expanding its work to include guideline implementation for a package of primary care conditions, the results of which are impacting on clinical care at primary care level throughout SA,[22] and has recently gone into partnership with the *British Medical Journal*.[23]

Despite these innovative SA research activities into CPG development and implementation, there is still limited knowledge of the overall context and processes of guideline development, adherence by clinicians to clinical guidelines, and factors that could improve accessibility and use of guidelines in the local healthcare context. Our work is based on the premise that high-quality, evidence-informed CPGs offer a cogent and persuasive way of bridging the gap between evidence and best practice, local contexts and health provider behaviour. Understanding the current state of play in SA primary care CPG development and implementation can therefore pave the way for better-focused and more effective and efficient interventions to improve healthcare. Project SAGE (South African Guidelines Excellence) is a 3-year research project, funded by the South African Medical Research Council through the Flagship Project scheme (http://www.mrc.ac.za/cochrane/sage.htm).[24] The overarching goal of the Flagship Projects is to support large-scale, innovative, interdisciplinary research projects to address health problems in SA.

Project SAGE is an innovative research partnership between Cochrane South Africa, the Centre for Evidence-based Health Care
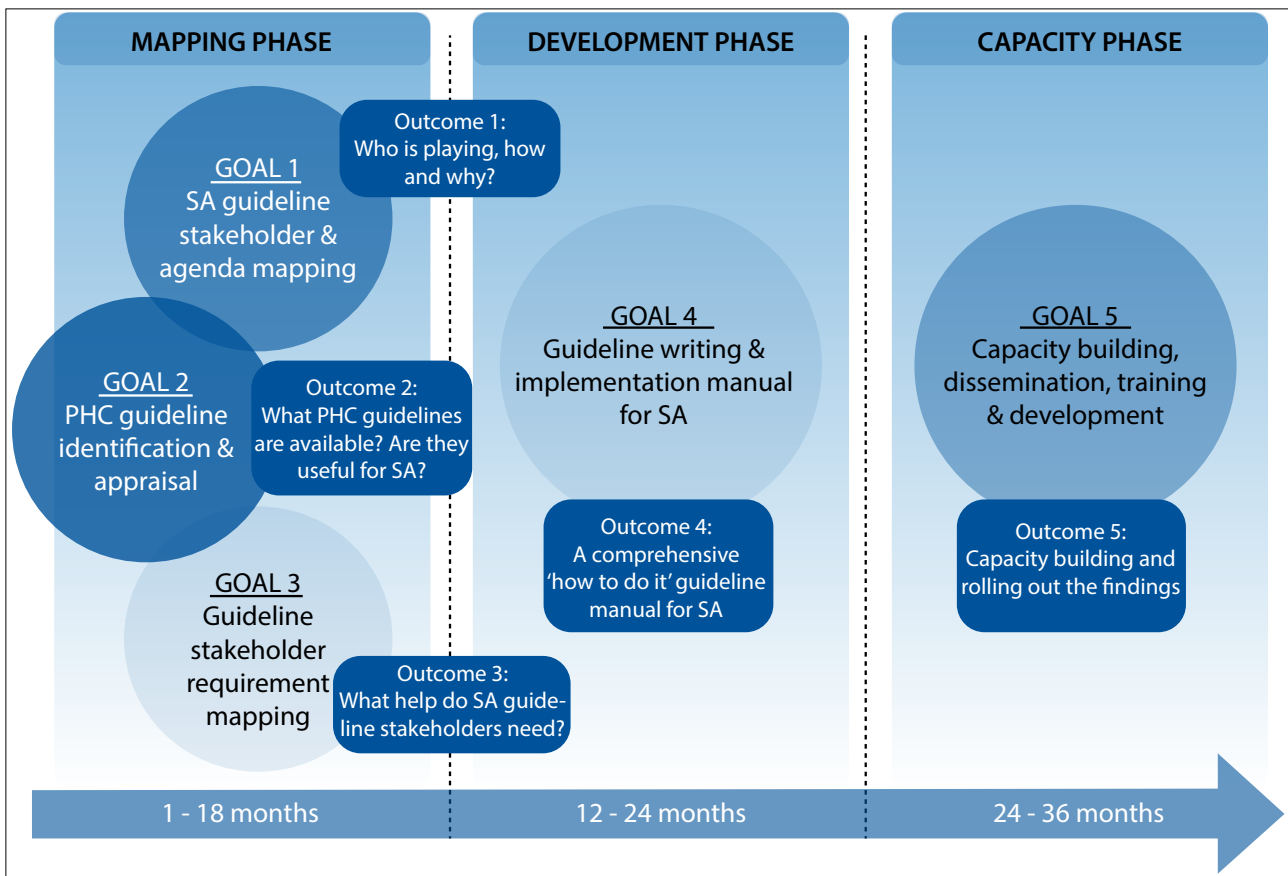
Fig. 1. South African Guideline Excellence (SAGE) – project outline. (PHC = primary healthcare.)

and the Department of Physiotherapy in the Faculty of Medicine and Health Sciences, Stellenbosch University, and the International Centre for Allied Health Evidence, University of South Australia. Project SAGE has five goals that aim to improve the quality and reach of SA primary care CPGs (Fig. 1). Using stakeholder-driven processes, SAGE will provide tools to assist effective SA CPG activities in developing, adapting, adopting, contextualising and implementing primary care CPGs.[24]

In a resource-limited setting such as SA, where access to resources for health is limited, ensuring the best use of effective and cost-effective primary care diagnostics and treatments is key to reducing waste, improving access and hence improving quality of care.[25] CPGs should be seen to transparently and systematically consider best research evidence to produce believable recommendations, which can then be credible vehicles for knowledge translation. Once there is agreement on what constitutes SA best practices in CPG development, implementation and evaluation, primary care clinicians can be assured that the CPGs developed and implemented in SA will support best practice, are achievable by all end users, and will lead to improved patient care.

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Appendix 5: SAGE Project protocol for ethics

PROPOSAL

Project SAGE: South African Guideline Excellence

Mapping the role players, processes and context for clinical practice guideline development and use for primary health care conditions in South Africa

Ethics application to:

Stellenbosch University Ethics Committee,

South African Medical Research Council Ethics Committee and University of South

Australia Human Research Ethics Committee

List of investigators

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Version 3 Date: May 2015

Key words: *guideline, clinical practice guideline, primary healthcare, health system, descriptive, mapping*

Declaration of Principal Investigator

I*, Tamara Kredo* have read the MRC and Stellenbosch University Guidelines on Ethics for Medical Research and have prepared this proposal with due cognisance of its content. Furthermore, I will adhere to the principles expressed when conducting this proposed research project.

22 May 2015

……………………………   ……………………………

Tamara Kredo   **Date**

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PROTOCOL SYNOPSIS

Title

Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)

Introduction

Little is known about the quality or amount of clinical practice guideline (CPG) activity in SA. This is particularly concerning considering the diverse contexts of care across the country, and limited resources available to underwrite quality healthcare for all. There is an urgent need to improve the quality of PHC practices across SA, to ensure good use of available resources, equity of access, and best value for spend. The proposed research will bring together key individuals and organisations to problem solve, establish current practice and activities, and support the development of a standardised approach to underpin the production of high quality, evidence-based, timely, appropriately-implemented guideline recommendations contextualised to SA PHC need.

Aims

- To conduct SA guideline stakeholder and agenda mapping to understand 'players', drivers and context for PHC CPG development and implementation

- To conduct CPG stakeholder requirement mapping to inform the barriers and facilitators to guideline implementation in the SA PHC context.

Objectives

1. Describe/map the role players, processes and context for CPG development and use for PHC conditions in South Africa

2. Evaluate the needs of CPG users based in South African PHC facilities to understand context-specific facilitators and barriers to guideline use.

Methodology

Study 1:

Qualitative research methods will be used. Stakeholders involved with PHC guideline development, implementation or use will be purposively sampled and data collection will be undertaken using interviews. In order to capture the voice of stakeholders such as doctors, nurses, pharmacists and community health care workers, focus groups will be conducted. The interviews and focus groups will be conducted by trained interviewers, and captured using a digital voice recorder. Additional field notes will be taken to ensure full and accurate data capturing. Data will be transcribed for analysis purposes. Names of participants will not appear in the transcriptions and data analysis and interpretation will be done by the investigators by identifying key themes which emerged.

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Study 2:

Qualitative and quantitative research methods will be used. Stakeholders similar to those described above will be purposively sampled, using a snowballing approach, starting with well-networked change champions from Study 1 (clinicians, policy-makers, academics, managers, insurers, patients). The sample will then be classified into end-user clusters (e.g. clinical disciplines, healthcare sectors etc.). Lists of factors (barriers and facilitators) will be compiled, without order or preference, and will be grouped into preliminary factors. Following this, a Delphi study will be conducted by email of the sample. Using the priority PHC conditions, participants will rank the barriers, match barriers with facilitators and offer their suggestions on useful solutions to barriers. Barriers and facilitators not previously identified will also be sought. The findings will go to broad public consultation in South Africa (including media releases, academic publications, clinical meetings, policy briefings). Feedback will be sought from interested individuals, on barriers, or facilitators on effective evidence application, particularly CPG use. Data management and analysis will be conducted using de-identified data to ensure confidentiality

Anticipated risks

The risks of participating in this form of research are anticipated to be low. We will invite a range of stakeholders affected by clinical care guidelines. Most participants will be working in the healthcare sector, at various levels including public and private care. We will also engage patient advocacy or consumer groups, and they will receive the same support to ensure full informed consent procedures are followed before enrolment in the study. All those invited will be free to withdraw at any stage without any negative impacts.

Anticipated benefits

The findings of these two studies will allow us to map the networks of players involved with CPG development and use in PHC in SA. This will inform the development of a stakeholder driven manual as part of the larger Project on South African Guideline Excellence (SAGE) proposal which aims to provide an innovative leadership plan for applying SA relevant CPGs efficiently and effectively, to improve practices and outcomes, within the context of PHC. The links and relationships built through this process may be harnessed for longer term collaborative work to ensure high quality guideline processes are inculcated in the SA CPG development and use community. Of importance is the broad buy-in which will be sought by engaging the public in the wider consultation. We anticipate this will encourage a broader audience to engage with the value of CPGs.

Ethical considerations

Ethical approval will be sought from the South African Medical Research Council, Stellenbosch University and University of South Australia Ethics Committees. Where indicated, the relevant Department of Health will be asked for permission to conduct the research. Participants will be asked to sign informed consent for participation in the study, for digital recording of the interviews, and for using and disseminating the anonymous information provided by them. Participation in these studies will be voluntary and participants will be informed of their right to withdraw at any moment. There will be no monetary compensation provided for participation. For face-to-face meetings, the researchers will aim to visit interviewees at their places of work. Any travel costs that arise for participants (e.g. taxi), will be paid for by the project, with travel arrangements made by the MRC operations. Refreshments will be served where appropriate for. The confidentiality of the participants will be protected and data will be analysed using participant numbers.

BACKGROUND

Clinical practice guidelines in the South African primary healthcare context

Little is known about the quality or amount of clinical practice guideline (CPG) activity in South Africa (SA). Currently, there is little known about the leadership in SA to support efficient, effective and timely activities by groups developing, adapting, contextualising and/ or implementing CPGs for SA health conditions. This is particularly concerning considering the diverse contexts of care found across the country, and the limited resources available to underwrite quality healthcare for all.

Internationally, over the past two decades, CPGs have increasingly become a familiar tool in policy and clinical practice [Turner 2008]. Clinical decisions at the bedside, governance of health facilities including hospitals and clinics, health insurer and government spending, and patient choice are all being influenced by CPG recommendations. CPGs were defined by the Institute of Medicine (IOM) in 2011 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' [IOM 2011].High quality, evidence-informed CPGs offer a way of bridging the gap between policy, best-practice, local contexts and patient choice. Good quality CPGs offer a 'one stop shop' for end-users, by providing composite information from comprehensive literature reviews regarding best practices in assessment, diagnosis, management and/ or monitoring of specific conditions. The development of CPGs has traditionally been motivated by the need to improve efficiency and cost-effectiveness of health system utilization, and to decrease costly and preventable mistakes and adverse events. CPGs are intended to provide transparent synthesis of the evidence on which sound 'on balance' judgments can be made by clinicians, administrators, policy-makers and patients. Evidence-informed decisions should minimise over-, under- or mis-use of services.

There is an urgent need to improve the quality of primary healthcare practices across South Africa, to ensure good use of available resources, equity of access, and best value for spend [Kleinert.2009; Mayosi 2012]. There is international acceptance of the value of CPGs in improving healthcare practices, in all countries. However there is no standard international approach to developing, contextualizing or implementing CPGs efficiently or effectively. There is also no current way for SA end-users (stakeholders) to access advice on the best way forward to use CPGs in their local context. The proposed SAGE project, lays out a three year plan which will develop the platform and background knowledge to support context driven implementation of guidelines for SA.

SA Healthcare system changes: The current transformation in the healthcare system in SA provides a window of opportunity for reviewing the current practices in guideline development, to make recommendations for supporting and improving the current guideline groups to ensure high quality products with strong, context specific implementation plans. CPGs [DoH 10 Point Plan 2009]. These should be relevant to healthcare delivery at all levels and sectors of healthcare, including primary, secondary and tertiary care, public and private sectors. To ensure consistency in the quality of healthcare delivery, clinicians and managers need to access and use high quality evidence and context informed CPGs. These guidelines should be rigorously and transparently developed, up-to-date and based on the best available evidence of what works, what doesn't work and what may be harmful in the South African context. These guidelines should be aligned with the national essential drug list and increasingly to address health inequity with the introduction of National Health Insurance (NHI).

SA's evidence-implementation needs: There are complex drivers for developing CPGs, fragmented guidance as to how to develop good quality and implementable guidelines, and variable knowledge about, and experience in the methodology of CPG development, adaptation/ contextualisation and implementation. High quality CPGs, produced by several organisations in high income settings exist, but cannot readily be contextualised and implemented in developing countries. This is due to differences in

clinical care pathways, limited resources, barriers and facilitators and readiness of all stakeholders, including patients, to embrace the uptake of evidence. As outlined previously, the key international institutions which develop guidelines use different processes to identify guideline topics and review questions, as well as different literature review mechanisms, critical appraisal approaches and ways of evidence synthesis and reporting. Each CPG development group has produced manuals to assist its users to understand and replicate its processes. However, after a decade or more of high quality CPG development globally, there are issues which have not been addressed comprehensively, even in the well-resourced high-income countries.

The issues that have not yet been addressed globally include:

❖ For countries which do not have the resources to develop de novo guidelines, why do so? Why not use already available guidelines and contextualise to local settings and need?

❖ How can evidence for high priority primary care conditions be embedded in current practice, to ensure that decisions are evidence-informed, context-appropriate and patient-centred?

❖ What implementation plans should support guidelines to ensure that evidence is translated sustainably into practice?

❖ Could a standard approach be developed for SA that builds on high-income country processes for guideline development?

❖ What local environmental, philosophical, educational, policy and funding barriers would attenuate the success of such an approach?

❖ What education is required in methodology to ensure that decisions regarding the best evidence to use in guideline recommendations are standardised?

The research proposed in this application will bring together key individuals and organisations to problem solve, establish current practice and activities, and support the development of a standardised approach to underpin the production of high quality, evidence-based, timely, appropriately-implemented guideline recommendations contextualised to SA need. The context for doing this is PHC, although the learning from this research would be applicable more broadly. The outcomes of this research will make a direct impact on SA PHC health processes, outcomes and costs, as well as key deliverables of the re-engineering of PHC plan. This project will support clinicians to practice according to the national essential drug list and locally available resources. The process of the research requires an integrated, multi-step, multi-disciplinary approach, with each step informing the next. The main product of the overall project will be a stakeholder-driven guideline development manual specifically for SA guideline activities. Secondary products include a better understanding of current guideline users (including their processes, CPG applications, and end-users needs), networking and capacity development across stakeholders, including National Department of Health, professional societies and private health insurers, and training for stakeholders in CPG activities and quality improvement practices. Such a collaborative approach is essential to improve SA PHC practices and impact.

Project SAGE (South African Guideline Excellence)

Project SAGE is a collaborative project of the South African Cochrane Centre and Health Systems Research Unit at the South African Medical Research Council and the Centre for Evidence-based Health Care and Physiotherapy Division of the Faculty of Medicine and Health Sciences, Stellenbosch University, and the International Centre for Allied Health

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Evidence (iCAHE), University of South Australia. It aims to provide an innovative leadership plan for applying SA relevant CPGs efficiently and effectively, to improve practices and outcomes, within the context of PHC. This project includes 5 phases (Table 1, Figure 1). Phase 1 and 3 are included in this proposal to ethics, as they form the basis for the qualitative methodology needed to underpin the other phases of the project.

Table 1: Overview of full Project SAGE plan

Goals and methods
1. ***SA Guideline stakeholder and agenda mapping:*** Describe/map the role players, processes and context for CPG use for PHC conditions in SA. Qualitative research methods and social network analysis will be used.
2. ***PHC Guideline identification and appraisal:*** Evaluate the quality of international PHC-related CPGs, and those currently in use in SA
3. ***CPG stakeholder requirement mapping:*** Evaluate the needs of CPG users based in SA PHC facilities to understand context-specific facilitators and barriers to guideline use.
4. ***CPG Writing and implementation manual for SA***: Develop a stakeholder-driven guideline manual specific for SA including templates for *de novo* guideline development, and guideline adaptation/ contextualisation, with a focus on implementation of context-specific recommendations using comprehensive dissemination strategies.
5. ***Capacity building, dissemination, training and development:*** Develop, implement and evaluate best-practice training modules regarding CPG use.

Figure 1: Project SAGE overview

MAPPING PHASE   DEVELOPMENT PHASE   CAPACITY PHASE

GOAL 1
SA Guideline Stakeholder & Agenda Mapping

Outcome 1: Who is playing, how and why?

Outcome 2: What PHC guidelines are available? Are they useful for SA?

GOAL 2
PHC Guideline Identification & Appraisal

GOAL 4
Guideline Writing & Implementation Manual for South Africa

GOAL 3
Guideline Stakeholder Requirement Mapping

Outcome 3: What help do SA guideline stakeholders need?

Outcome 4: A comprehensive 'how to do it' guideline manual for South Africa

GOAL 5
Capacity Building, Dissemination, Training and Development

Outcome 5: Capacity building & rolling out the findings

1-18 months   12-24 months   24-36 months

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1. STUDY ONE METHODS

1.1 AIM

Map the role players and processes of primary healthcare guideline development and implementation in South Africa

1.2 OBJECTIVES

1.1.1. Establish new knowledge regarding 'current players and practices' in PHC CPGs

1.1.2. Describe what processes of PHC CPG development, contextualisation and implementation are in place

1.1.3. Determine key role players in PHC CPG development, contextualisation and use

1.1.4. Determine what the needs for implementation of CPGs are by users

1.1.5. Determine how CPGs are received by end-users

1.3 STUDY DESIGN

Qualitative research methods and social network analysis will be used. The qualitative methodology is proposed as narrative discourse analysis, using a validated theoretical analysis framework designed for behaviour change implementation research [Cane 2012]. This approach is proposed because rich data is required to explain South African implications of CPG use, now and in the future. This is an appropriate strategy as its aim is to examine the structures within which decisions are made by asking the questions 'what is happening' and 'why is it happening'? [Liamputtong 2005]. The qualitative findings will be interpreted using social network analysis models, to assess important 'player' clusters.

Qualitative research is by tradition emergent in design (Newton Suter, 2012). This means that the process is not predetermined and that researchers anticipate that they may have to adjust their data collection techniques once the research starts so as to better answer their central research question. As the initial phase of our data collection has unfolded it has become clear to us that we need a stronger focus on understanding the collective experience of guideline implementation at the frontline of health care delivery. While we are developing a very good understanding of guideline development from speaking with researchers and policy makers, we need to also understand how practitioners, who use the guidelines, receive and interpret these documents. We therefore wish to expand our techniques so as to include focus groups within an expanded constituency of doctors, nurses, pharmacists, community health workers in addition to the currently listed participants in the protocol. Since information gathered through group discussions (Kitzinger, 1994) can be different from that collected in individual interviews (O'Kane 2008) focus groups can provide useful data on the context and the intra-spacial/political/social dynamics of guideline writing. Focus groups can provide a useful means of triangulation. Such triangulation will make an important contribution to this study because it will allow us to compare the guideline and policy intention (as espoused by guideline developers) with the actual practice of using them at the frontline (as collectively expressed by health workers participating in the focus groups). This comparison will lead to a deeper and richer understanding of the guideline terrain within South Africa.

1.4 STUDY POPULATION AND SETTING

For the purposes on this study we have attempted to engage with as many stakeholders as possible within South African health sector who are relevant to understanding CPG development and use. We will identify the individuals for the first round of interviews in each of these sectors through our own networks who will then in turn suggest others to ensure a comprehensive sample. Our sample will therefore include guideline developers, implementers and users for example:

- National Department of Health

- National Health Insurance field

- University settings

- Pharmaceutical Industry

- Medical Aids

- Allied Health Associations

- Professional Societies (e.g. HIV, renal, hypertension)

- Non-Governmental organisations (e.g. MSF)

- Doctors

- Nurses

- Pharmacists

- Community health workers

- Consumer groups

- Patients

The data collection will be conducted in conference rooms and offices within the participants' working environment.

1.5 SAMPLING TECHNIQUE AND ENROLMENT

In-Depth Interview Sampling and Enrolment:

A core group of individuals with lead roles in guideline development, implementation and/or application will be identified through the investigators' networks, and invited to join the study. These individuals are 'key players' in primary care guideline activities in South Africa. The core group of individuals will then be asked to nominate others who meet the eligibility criteria of a 'key player', who may not be known to the investigators. Thus the participant sample for In-

Depth Interviews for Study 1 will be recruited purposively initially, then enlarged using a snowballing approach until no new names of 'key players' are identified (i.e. until participant saturation has been reached). This approach is appropriate when a reference population is difficult to identify [Noyes 2008, Atkinson & Flint 2001].We will invite between 10-20 stakeholders

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for the first round of interviews. Through the suggestions, further stakeholders will be invited to be interviewed. The list of the names of decision-makers will be captured in a Microsoft Excel spread sheet. Each participant will be given a study number for identification purposes. All the available participants will be invited to participate and appointments with participants will be arranged telephonically or via email.

Focus Group Sampling and Enrolment:

Focus group attendees will be recruited through purposeful sampling of the stakeholders listed in this protocol, including health carers such as doctors, nurses and pharmacists, by researchers with experience in conducting focus groups. We aim to conduct two focus groups in each of the following four provinces: Kwazulu-Natal, Western Cape, Limpopo and Eastern Cape, with consideration to expand to additional provinces should it be relevant (e.g. Gauteng or Mpumalanga etc). We will invite participants from one peri-urban clinic and one rural clinic from each province. Focus groups will include anywhere from 6 – 10 participants. The list of the names of focus group participants will be captured in a Microsoft Excel spreadsheet, which will have restricted access. Each participant will be given a study number for identification purposes.

We recognize that hierarchy exists in clinic settings and would constitute the focus groups accordingly as follows. We intend to conduct focus groups with all tertiary-trained health professionals per clinic in one group in order to understand how guidelines are received, implemented and used as a team at the clinic/facility level. We want to understand the interactions around guidelines within the clinic between the different professionals. We agree that there is a power difference, especially if community health workers were involved. We know that there are differences in understanding between levels of training and job descriptions, but we believe that tertiary trained people would have some common language to discuss how one guideline is used and interpreted. These focus groups are about norms across the group, but we will augment our understanding by interviewing individuals involved in the focus groups (as already approved) in order to tease out additional information. Community health workers and other non-tertiary trained clinic staff would be interviewed separately.

1.6 DATA COLLECTION AND OUTCOMES

In-Depth Interviews:

Data will be collected using key informant interviews using the semi-structured questions framework that elicit free-flowing information and ideas. The questions are outlined in the guide (Appendix B). The interviews will be conducted by trained interviewers, whose role is to facilitate the conversation, and ensure that the interviewee is encouraged to provide as many insights into clinical practice guideline use for primary health care in South Africa. The interview data will be captured using a digital voice recorder. Additional field notes will be taken by an independent observer in each interview.

One-on-one interviews may be conducted face-to-face, by telephone, Skype or videolink as required, by trained interviewers.

Focus Groups:

Focus groups will be recorded using a digital voice recorder, with additional field notes taken by the group faciliitator and/or independent observer when available and present. Focus group recordings will be transcribed by an independent transcriber. The investigators will retain written notes and participatory materials created during focus group sessions. Photographs will be taken

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of any materials made during participatory activities and stored digitally on the investigators' computers under password protection. Additional field notes will be taken to ensure full and accurate data capturing. Data will be transcribed for analysis purposes. Names of participants will not appear in the transcriptions and data analysis and interpretation will be done by the investigators by identifying key themes which emerged.

1.7 DATA MANAGEMENT AND ANALYSIS

Digitally recorded interviews and focus groups will be transcribed in full using a professional service (which ensures independence of transcription). Audiotapes shall be transcribed verbatim, including any nonverbal or background sounds. All transcripts shall be audited for accuracy by the interviewer who conducted the interview. Where appropriate, member checking will occur to ensure accuracy of capture of information. Names of participants will not appear on the transcriptions. Data analysis will be undertaken both by hand coding, and by use of qualitative analysis software (ATLAS Ti) to identify key themes, associated sub-themes and exemplar quotations relating to these. Differences between the findings from hand coding and software analysis will be discussed within the research team. Interpretation of the meaning of the themes will be undertaken by the entire investigator team by discussing what the themes mean in terms of the study objectives.

Network analysis: The links between 'players' and how and why 'players' interact will be mapped using social network theoretical modelling [Wasserman 1994]. This will illustrate clusters of 'players' and how these can be used to drive best practices in CPG use in the research conducted in later components of the overall project.

1.8 ETHICS AND CONSENT

Individual consent forms (Appendix A) will be signed and they will fully explain the purpose and conduct of the study. Participation in this study will be voluntary and participants will be informed of their right to withdraw at any moment. The confidentiality of the participants will be protected and data will be analysed using participant numbers. Names of participants will not appear in the transcriptions (these will be coded, with the principal investigator holding the only master list of codes and names). No monetary compensation will be provided for participants. The researchers will travel to the interviewees. However, if travel costs do arise (e.g. taxi) these costs will be covered by the project. Refreshments will be served, if appropriate. Ethical approval will be sought from the South African Medical Research Council, University of Stellenbosch and the University of South Australia Research Ethics Boards.

Focus groups have limitations that must be acknowledged. Participants will be warned that information they share in focus groups has the potential to be more widely shared, while at the same time we will remind all participants that information shared in the group setting may be private and should be considered confidential. The potential for information shared in focus groups to cause conflict, political strife or other forms of discomfort will be avoided as best as possible by constantly reminding participants of their right to leave the focus group at any point, and their ethical responsibility to one another to respect each other's opinions and private information. Appropriate permission to conduct the focus groups will be sought from the relevant provincial office and the local clinical setting, as required.

1.9 ANTICIPATED BENEFITS

The findings of study 1 will provide new knowledge regarding politics, drivers and contexts of CPG use in SA, and assist to identify ways in which the quality and impact of SA-relevant CPG activities

can be improved. This study will identify 'Change Champions' who could assist the overall SAGE project and ensure that the research is informed and driven by the stakeholders. This will be part of the sampling approach to identify the participants in the Study 2 described below.

1.10 DATA DISSEMINATION PLAN

This study is the first step in understanding the field of CPG development and use in SA in the PHC field. Results of this study will inform later steps in the overall project. We would share this report with the 'change champions' identified through this study, to allow their comment and feedback and ensure our 'map' is comprehensive and inclusive. We anticipate sharing the results of this study in a published report in a relevant peer-reviewed journal. We will also disseminate the results at relevant conferences in which methodological issues regarding guidelines and knowledge translation are presented. Finally, if requested, we would share results in other public forums, particularly with those working in the field of PHC CPGs at national and provincial government levels.

1.11 TIMELINES STUDY 1

Activity	Dates
Ethics application	January 2014
Recruitment (invitations for interviews)	April 2014
Recruitment (focus groups)	February 2015 (depending on ethics approval)
Data collection	May 2014 – September 2015
Data management and analysis	June 2014 - April 2015 (Interviews); February – August 2015 (Focus Groups)
Writing-up and communication	December 2015 – January 2016

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2. STUDY TWO METHODS

2.1 AIM

To understand context-specific facilitators and barriers to guideline use we aim to conduct CPG stakeholder mapping to evaluate the needs of CPG users based in SA PHC facilities.

2.2 OBJECTIVES

2.2.2. A list of factors of PHC CPG users' preferences, barriers and facilitators regarding CPG use for PHC conditions

1.1.1. Common and innovative local strategies for addressing barriers

1.1.2. Broad public engagement in the project, to ensure buy-in across sectors, disciplines and agendas

2.3 STUDY DESIGN

Mixed methods (descriptive qualitative and quantitative research approaches) will be used. This study is conducted in three stages.

2.3.1 Stage 1: Collating data items

Preliminary lists of barriers and facilitators to guideline implementation will be compiled, without order or preference from the study 1 interviews. This list will be based on the priority PHC conditions also identified in study 1 interviews. These will be grouped into preliminary factors for the Delphi study.

2.3.2 Stage 2: Delphi study

A Delphi study will be conducted by email, using the entire sample from Study 1, Participants will be invited to rank the barriers, match barriers with facilitators and offer solutions to barriers. Barriers and facilitators not previously identified will also be sought. It is proposed that it may take 3-4 iterations of the Delphi approach to obtain consensus on priority barriers, and mechanisms to address them [Barras 2009].

2.3.3 Stage 3: Obtaining broad buy-in

The findings of the Delphi study will be sent for broad public consultation in South Africa via a range of strategies (media releases, academic publications, clinical meetings, policy briefings etc). Feedback will also be sought directly from interested individuals, on barriers, or facilitators on effective evidence application, particularly CPG use in primary health care.

2.4 STUDY POPULATION AND SETTING

The study population will include well-networked stakeholders involved with guideline implementation, contextualisation and on the ground use of guidelines for PHC conditions in South Africa. Guidelines implementers may include policy makers, guideline developers, researchers or other academics, and health facility managers.

Guideline users may include multi-disciplinary public and private clinical health care workers including doctors, nurses, pharmacists, allied health practitioners. In addition, where possible, feedback will be sought from patient's representative groups, consumer groups and patients. All participants should be linked with PHC facilities and be using or expected to be accessing and using CPGs.

The Delphi study will occur via email, with reminders sent at 1 month intervals to those who have not completed for the duration of the survey (up to 4 months).

The broad buy-in phase will use multiple vehicles of communication to engage the public (media releases, academic publications, clinical meetings, policy briefings etc).

2.5   SAMPLING TECHNIQUE AND ENROLMENT

A snowballing sampling approach will be applied by asking the purposively sampled group of individuals for the Delphi approach to identify others who currently play similar roles, or who could provide insights into how to change the system from within. Snowball sampling will continue until no new names are identified. No limits will be placed on sample size, as it is important that this Study captures as broad a voice for change as possible. The sample will then be classified by the investigator team into end-user clusters (e.g. clinical disciplines, healthcare sectors, patient groups).

2.6   DATA COLLECTION AND OUTCOMES

Delphi component: Data will be collected electronically, via email contact. Using the priority PHC conditions identified in Study 1, participants will be invited to rank the barriers, match barriers with facilitators and offer solutions to barriers. Barriers and facilitators not previously identified will also be sought. It is proposed that it may take 3-4 iterations of the Delphi approach to obtain consensus on priority barriers, and mechanisms to address them.

The framework for identifying potential barriers will follow the suggestions outlined in Table 2, however, these may be adapted based on the emerging themes from the data (Michie 2005, Michie 2011).

Table 2: Framework for grouping preliminary factors

Factor	Potential barrier(s)
Patient	Expectations and knowledge
Evidence-based process	Identifying and implementing evidence based healthcare can be difficult & time-consuming
Team Issues	Different configurations of multidisciplinary teams, lack of uniformity of team approaches
Care process	Lack of uniformity of decision-making, range of service delivery models

Management Support	Changes in leadership and direction
Time/facilities/cost	Time pressures, cost effectiveness, structural limitations
Health System	Aligning stakeholder expectations

Broad-buy-in component: Feedback will be sought from the wide audience on barriers, or facilitators on effective evidence application, particularly CPG use in primary health care. This may be sought via a range of strategies (media releases, academic publications, clinical meetings, policy briefings etc). Feedback may be written or verbal and will be recorded anonymously.

2.7 DATA MANAGEMENT AND ANALYSIS

The list of the names of stakeholders included in the Delphi process and the broader engagement will be captured and de-linked in a Microsoft Excel spread sheet. Each enrolled participant will be given a study number for identification purposes.

A dedicated survey feedback mechanism will be developed using available, accessible software such as Survey Monkey. All the de-identified responses to the Delphi consultation and the broader engagement that follows will be collected in a purpose built MS Excel based framework. Round 1 responses to questions will be collected, collated and subsequently reported back to the stakeholder clusters. These will then continue to further rounds for agreement, consensus or rejection. The iterative process will continue until there is a greater than 70% agreement in the factors and therefore stability of data.

Data analysis will be conducted on the Delphi and public consultation data, using quantitative methods such as mean values, measures of variability, percentages. The electronic survey file will also collect free text responses which will be analysed qualitatively, into themes.

2.8 ETHICS AND CONSENT

Individual electronic informed consent forms (Appendix C) will be provided in the invitation email. These will fully explain the purpose and conduct of the study. Participation in this study will be voluntary and participants will be informed of their right to withdraw at any moment. The confidentiality of the participants will be protected and data will be analysed using participant numbers. No monetary compensation will be provided for participants. The researchers will travel to the interviewees. However, if travel costs do arise (e.g. taxi) these costs will be covered by the project. Refreshments will be served, if appropriate. Ethical approval will be sought from the South African Medical Research Council, University of Stellenbosch and the University of South Australia Research Ethics Boards.

2.9 ANTICIPATED BENEFITS

Global standards in CPG development and use require that the intended end-users of guidelines are identified, and engaged. Barriers to guideline uptake are multi-pronged, and mean different things to different end-users. Barriers to improving healthcare practices are the subject of considerable research, without current resolution. Common factors and barriers are listed in Table 2. A successfully-implemented CPG means it is consistently used without barriers. This Delphi survey and broad public consultation of CPG users in PHC settings will identify local barriers and facilitators to CPG use. This provides important formative information for the Goal 4 of the overall SAGE project to ensure the SA CPG Manual's capacity to influence future SA CPG

use is locally acceptable and feasible.

2.10 DATA DISSEMINATION PLAN

Study 2 will inform later steps in the overall SAGE project. We anticipate disseminating the results of this study in a published report in a relevant peer-reviewed journal. We will also disseminate the results at relevant conferences in which methodological issues regarding guidelines and knowledge translation are presented. Finally, if requested, we would share results in other public forums, particularly with those working in the field of PHC CPGs at national and provincial government levels.

2.11 TIMELINES STUDY 2

Application to ethics	January/February 2014
Recruitment (invitations for interviews and Delphi)	February –March 2015
Data collection	April – October 2015
Data management and analysis	May – November 2015
Writing-up and communication	December 2015 – January 2016

3. COLLABORATORS

Dr Tamara Kredo, South African Cochrane Centre, South African Medical Research Council

Prof Karen Grimmer, iCAHE, University of South Australia

Prof Taryn Young, Centre for Evidence-based Health Care, Stellenbosch University

Prof Quinette Louw, Department of Physiotherapy, Stellenbosch University

Dr Karen Daniels, Health Systems Research Unit, South African Medical Research Council

Prof J Volmink, Stellenbosch University and South African Medical Research Council

Dr Simon Lewin, South African Medical Research Council & Norwegian Knowledge Centre

Amber Abrams, South African Medical Research Council

Shingai Machingaidze, South African Medical Research Council

4. BUDGET

Refer to full Flagship proposal to MRC, included with this application

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APPENDIX A:

1. INFORMATION LEAFLET AND INFORMED CONSENT FORM FOR INTERVIEWS FOR STUDY 1

TITLE OF THE RESEARCH PROJECT:

Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)

SAMRC ETHICS REFERENCE NUMBER: EC002-2/2014

PRINCIPAL INVESTIGATOR: Dr Tamara Kredo

ADDRESS:

> South African Cochrane Centre
> South African Medical Research Council
> Francie van Zijl Drive, Parow Valley, 7505
> Cape Town, South Africa

CONTACT NUMBER:

> +27-21-938 0508
> Email address: Tamara.kredo@mrc.ac.za

Dear participant

My name is Tamara Kredo. I would like to invite you to participate in a research project. The purpose of this study is to explore the needs of stakeholders involved with clinical practice guidelines in the context of the South African primary health care system.

Background

High quality, evidence-informed guidelines offer a way of bridging the gap between policy, best-practice, local contexts and patient choice. Good quality guidelines offer a 'one stop shop' for end-users, by providing comprehensive information from literature reviews regarding best practices in assessment, diagnosis, management and/ or monitoring of specific clinical conditions. Very little is known about the accessibility, quality and acceptability of guidelines used in primary health care facilities in South Africa. This study aims to explore the 'landscape' of guideline development, implementation and use by engaging with participants who are actively involved with guidelines in various levels of government, public health and private health care.

Your Rights

Should you agree to participate in this study, you will be asked to participate in an interview, lasting no more than an hour. The interviewer will ask you questions about who is involved in the development and

Ethics application - Version 3 22 May 2015

use of guidelines, when, where and under what circumstances guidelines are used and developed, how this happens and what gets included and excluded in this process. Your answers will be audio taped. This ensures that valuable information from this interview is not missed. The information on the tape will be transcribed for analysis purposes. Your name will NOT appear on the transcription. The research team of this project will do the analysis of the interviews. Your audio recording will not be released to any persons or entities other than the research team of this study. The audio recording and typed transcription of the interview will be stored in a password protected computer file to which only the PI of this study will have access and will be destroyed within 12 months of your interview. The anonymous scientific data – in which no individuals will be named or identified – resulting from the study may be presented at meetings, used for Masters and/or PhD theses and published in national or international journals, for dissemination purposes.

Your participation in this study is completely voluntary, choosing to or not to participate in this study will not have any negative repercussions. You are free to withdraw from the interview at any moment, or decline to answer any of the questions without penalty. The information obtained from this interview will be treated with strict confidentiality, the data collection forms will not contain any names and data analysis will be performed anonymously. You will not be paid to participate in the study, but reasonable travel or other related costs will be re-imbursed, and refreshments may be provided where appropriate.

Important contact information for you

This study has been approved by the South African Medical Research Council Research Ethics Committee and will be conducted according to accepted and applicable National and International ethical guidelines and principles, including those of the international Declaration of Helsinki October 2008 (updated October 2013).

If you have any queries related to the ethos of the project, you are invited to contact the Chair of the MRC Ethics Committee, Prof Danie du Toit, tel (021) 938 0687; email: adri.labuschagne@mrc.ac.za.

If you are willing to participate in this study please sign the attached Declaration of Consent and hand it to the investigator /interviewer at the beginning of the interview.

Yours sincerely

Tamara Kredo

Principal Investigator

Declaration by participant

By signing below, I agree to take part in a research study entitled *Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)*

I declare that:

- I have read the attached information leaflet and it is written in a language with which I am fluent and comfortable.

- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ....…..……………………. On (*date*) ………….…………. 2015

Participant name: ………………………………… ……………………

Signature of participant: ………………………………………..

Audio taping:

I understand and agree that the interview will be audio recorded

Signature of participant: ………………………………………..

Investigator name: ………………………………… ……………………

Signature of investigator: ………………………………………..

Ethics application - Version 3 22 May 2015

2. INFORMATION LEAFLET AND INFORMED CONSENT FORM FOR FOCUS GROUPS FOR STUDY 1

TITLE OF THE RESEARCH PROJECT:

Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)

SAMRC ETHICS REFERENCE NUMBER: EC002-2/2014

PRINCIPAL INVESTIGATOR: Dr Tamara Kredo

ADDRESS:

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CONTACT NUMBER:

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Dear participant

My name is Tamara Kredo. I would like to invite you to participate in a research project. The purpose of this study is to explore the needs of stakeholders involved with clinical practice guidelines in the context of the South African primary health care system.

Background

High quality, evidence-informed guidelines offer a way of bridging the gap between policy, best-practice, local contexts and patient choice. Good quality guidelines offer a 'one stop shop' for end-users, by providing comprehensive information from literature reviews regarding best practices in assessment, diagnosis, management and/ or monitoring of specific clinical conditions. Very little is known about the accessibility, quality and acceptability of guidelines used in primary health care facilities in South Africa. This study aims to explore the 'landscape' of guideline development, implementation and use by engaging with participants who are actively involved with guidelines in various levels of government, public health and private health care.

Your Rights

Your participation in this study is completely voluntary, choosing to or not to participate in this study will not have any negative repercussions. You are free to withdraw from the focus group at any moment, or decline to answer any of the questions without penalty. The information obtained from this interview will be treated with strict confidentiality, the data collection forms will not contain any names and data analysis will be performed anonymously.

Focus groups have the potential for information shared in focus groups to be shared more widely by focus group cohort members. We will ask all members to respect confidentiality and anonyminity, but take this

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opportunity to remind all focus group participants that we cannot ensure that what is shared in the focus group will remain private or confidential. While all of our investigators have undertaken to respect confidentiality, and all participants have been asked to respect this, we cannot be held responsible for the actions of other focus group participants.

Should you agree to participate in this study, you will be asked to participate in an focus group, lasting no more than an hour. The facilitator will ask you questions about who is involved in the development and use of guidelines, when, where and under what circumstances you make use of guidelines, how you choose the guidelines you use and what the barriers and facilitators are in your implementation of these guidelines. Your answers will be audio taped. This ensures that valuable information from this focus group is not missed. The information on the tape will be transcribed for analysis purposes. Your name will NOT appear on the transcription. The research team of this project will do the analysis of the focus group. Your audio recording will not be released to any persons or entities other than the research team of this study. The audio recording and typed transcription of the focus group will be stored in a password protected computer file to which only the PI of this study will have access and will be destroyed within 12 months. The anonymous scientific data – in which no individuals will be named or identified – resulting from the study may be presented at meetings, used for Masters and/or PhD theses and published in national or international journals, for dissemination purposes.

Anticipated risks

The risks of participating in this form of research are anticipated to be low. As described above, where group discussions take place the greatest challenge is to ensure that confidential information is not shared in a wider audience beyond the focus group setting. We remind you that we cannot maintain control over information shared by other focus group members after the focus groups has ended, and encourage all participants to maintain confidentiality, but cannot assume responsibility for breaches of confidentiality beyond our research staff. The potential for information shared in focus groups to cause conflict, political strife or other forms of discomfort will be avoided as best as possible by constantly reminding participants of their right to leave the focus group at any point, and an ethical responsibility to one another to respect each other's opinions and private information.

Anticipated benefits

Although there may be no specific benefit for individuals participating in this study, we anticipate that the findings of this research will allow us to understand who and what is involved with clinical guideline development and use in primary health care in South Africa. This will inform the larger Project on South African Guideline Excellence (SAGE). This project aims to improve guideline development and implementation of primary care guidelines to improve practices and outcomes, within South African primary care context.

Important contact information for you

This study has been approved by the South African Medical Research Council Research Ethics Committee and will be conducted according to accepted and applicable National and International ethical guidelines and principles, including those of the international Declaration of Helsinki October 2008 (updated October 2013).

If you have any queries related to the ethos of the project, you are invited to contact the Chair of the MRC Ethics Committee, Prof Danie du Toit, tel (021) 938 0687; email: adri.labuschagne@mrc.ac.za.

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If you are willing to participate in this study please sign the attached Declaration of Consent and hand it to the investigator /facilitator at the beginning of the focus group.

Yours sincerely

Tamara Kredo

Principal Investigator

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Declaration by participant

By signing below, I agree to take part in a research study entitled *Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)*

 I declare that:

- I have read the attached information leaflet and it is written in a language with which I am fluent and comfortable.

- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is voluntary and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ....….........……………. On (*date*) ………….…………. 2015

Participant name: .... ………………………

Signature of participant: ………………………………………..

Audio taping:

I understand and agree that the interview will be audio recorded

Signature of participant: ………………………………………..

Investigator name: .... ………………………

Signature of investigator: ………………………………………..

Ethics application - Version 3 22 May 2015

APPENDIX B:

1. IN DEPTH INTERVIEW GUIDE FOR STUDY 1

Introduce researchers

This study is being organised by Tamara Kredo and colleagues who work with the South African Medical Research Council and Stellenbosch University.

The study is being funded through the MRC Flagship grant for our proposal entitled: Project SAGE (South African Guideline Excellence)

Explanation of consent form

Before we begin, it is important for you to understand why the research is being done and what it will involve. We hope you have read the information sheet carefully. Is anything that is not clear?

You do not have to take part in this study. It is up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time.

Explanation of process

The discussion will be tape-recorded and will then be typed out in an anonymous format, so that they can be analysed. This typed record of the conversation will be available for you to see if you wish and will be stored in a secure environment. You, or any comments you make, will not be personally identified in our report.

NOTE: Key probes for each question will be added to ensure the stated objectives are achieved

Record participant name, qualifications, how long they have worked in this department, their position and brief description on their job:
....
....
....
....
....
....
....
....

1. ***Who are you?***

Ask about the demographic and institutional profiles of CPG 'players'.

2. ***What do you think?***

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Ask them what they understand by the concept of PHC in South African context. What are the key PHC conditions that this project should focus on?

Explore their views on the current processes of identifying appropriate guidelines, developing and/or contextualising guidelines, putting them into practice, educating others about them, using them to assess changes in clinical behaviours etc.

3. *What do you require?*

Assess their role, skills and resources and what their needs are with respect to CPGs for improving practices.

4. *What processes do you have in place?*

Identify existing frameworks, supports, activities that are being used.

5. *What is your experience of using research?*

Assess their experience in using research to inform CPG development. Ask about their understanding and knowledge about end-user experiences regarding putting appropriate CPG recommendations into practice.

6. *What barriers and facilitators have you considered/ experienced in implementing guidelines?*

Discuss the barriers and potential solutions, including any 'good news' stories for use of guidelines in PHC facilities in SA.

7. *What context are you working in?*

Explore internal and external contexts in which guidelines are formulated and implemented, including the drivers/ motivation for these activities.

8. *What networks exist already?*

Explore the contexts and networks within which South African CPGs are developed, implemented, used and evaluated, and who the stakeholders are in these activities.

2. FOCUS GROUP GUIDE FOR STUDY 1

Introduce researchers

This study is being organised by Tamara Kredo and colleagues who work with the South African Medical Research Council and Stellenbosch University.

The study is being funded through the MRC Flagship grant for our proposal entitled: Project SAGE (South African Guideline Excellence)

Explanation of consent form

Before we begin, it is important for you to understand why the research is being done and what it will involve. We hope you have read the information sheet carefully. Is anything that is not clear?

You do not have to take part in this study. It is up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time.

Explanation of process

The discussion will be tape-recorded and will then be typed out in an anonymous format, so that they can be analysed. This typed record of the conversation will be available for you to see if you wish and will be stored in a secure environment. You, or any comments you make, will not be personally identified in our report. Focus groups participants should be aware that information you share has the potential to be more widely shared by other participants in the focus group. Although we do remind all participants that information shared in the group setting may be private and should be considered confidential, we do not have control over who and what the other participants will share. The potential for information shared in focus groups to cause conflict, political strife or other forms of discomfort will be avoided as best as possible by constantly reminding participants of their right to leave the focus group at any point, and their ethical responsibility to one another to respect each other's opinions and private information.

NOTE: Key probes for each question will be added to ensure the stated objectives are achieved

Record participant name, qualifications, how long they have worked in this department, their position and brief description on their job.

1. What guidelines do you use in your work?

2. Can you name the ones you use . . .

3. How often you use them?

4. Where do you find these guidelines?

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5. Where do you get access to them?

6. Why do you choose these ones? What is good about them?

7. Which type or source of guideline is your prefered?

8. What are some challenges you have faced in following the guidelines provided for you?

9. What types of guidelines do not work in your job context?

10. Experience with specific guidelines – specific guideline to be identified.

Participatory Exercises:

"Visual tools provide . . .a rich, multilayered and mediated form of communication which is facilitated both by the image and by its very process of production" (Christensen and James, 2007: 160). Christensen and James (2007) highlight the importance of the drawing process, as a "routine activity", so that the exercise of drawing is both a familiar (and ice-breaking) activity which would not necessarily be understood as a "research activity" thus avoiding responses that participants believe are expected of them, and adding richness to the data collected. Focus group participants will be asked to illustrate the usefulness of guidelines, and to describe these illustrations. This will work as both a ice-breaking activity and an opportunity to learn about people's diverse perceptions of the usefulness of guidelines.

Ranking Activity:

Groups of participants will be asked to rank their preference for certain aspects within a guideline. These ranked lists will then be hung in the room and rankings will be tallied. This method allows for the focus group participants to take part in deciding what topics or questions will be broached in their focus group session. This method will allow the researchers to better understand the topics most pertinent to those involved in the focus group and allow these topics to guide the avenues of inquiry as the research moves forward, ensuring that the topics focused on are those most pertinent to the study cohort.

APPENDIX C: **INFORMATION LEAFLET AND INFORMED CONSENT FORM FOR INTERVIEWS FOR STUDY 2**

TITLE OF THE RESEARCH PROJECT:

Understanding the context-specific facilitators and barriers to guideline use we aim to conduct CPG stakeholder mapping to evaluate the needs of CPG users based in SA PHC facilities.

SAMRC ETHICS REFERENCE NUMBER: EC002-2/2014

PRINCIPAL INVESTIGATOR: Dr Tamara Kredo

ADDRESS:
> South African Cochrane Centre
> South African Medical Research Council
> Francie van Zijl Drive, Parow Valley, 7505
> Cape Town, South Africa
> +27-21-938 0508
> Email address: Tamara.kredo@mrc.ac.za

Dear participant

My name is Tamara Kredo. I would like to invite you to participate in a research project. The purpose of this study is to explore the barriers and facilitators to implementing guidelines in the South African primary health care context.

Background

High quality, evidence-informed guidelines offer a way of bridging the gap between policy, best-practice, local contexts and patient choice. Good quality guidelines offer a 'one stop shop' for end-users, by providing comprehensive information from literature reviews regarding best practices in assessment, diagnosis, management and/ or monitoring of specific clinical conditions. This study aims to identify barriers and facilitators to getting guidelines into use in primary healthcare settings in South Africa. We will engage many stakeholders at various levels of government, public health and private health care.

Your rights

Should you agree to participate in this study, you will be asked to participate in Delphi process. This is an email based survey that aims to gain consensus through asking many individuals the same question and getting consensus about the answer. However, with the Delphi technique, we will engage you in several rounds of the survey to get to the best consensus. The process of the survey should not take longer than up to 30 minutes each time.

Your answers will be recorded electronically and strictly confidentially. The anonymous data that we

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collect– in which no individuals will be named or identified –may be presented at meetings, used for Masters and/or PhD theses and published in national or international journals, for dissemination purposes.

Your participation in this study is completely voluntary, choosing to or not to participate in this study will not have any negative repercussions. You are free to withdraw from the interview at any moment, or decline to answer any of the questions without penalty.

Important contact information for you

This study has been approved by the South African Medical Research Council Research Ethics Committee and will be conducted according to accepted and applicable National and International ethical guidelines and principles, including those of the international Declaration of Helsinki October 2008 (updated October 2013).

If you have any queries related to the ethocs of the project, you are invited to contact the Chair of the MRC Ethics Committee, Prof Danie du Toit, tel (021) 938 0687; email: adri.labuschagne@mrc.ac.za.

If you are willing to participate in this study please tick the box allocated on the electronic survey and add the date.

Yours sincerely,

Tamara Kredo

*Principal Investigat*or

Declaration by participant

By signing below, I agree to take part in a research study entitled *Mapping the role players, processes and context for clinical practice guideline (CPG) development and use for primary health care (PHC) conditions in South Africa (SA)*

 I declare that:

- I have read the attached information leaflet and it is written in a language with which I am fluent and comfortable.

- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ....…...........……………….. On (*date*) ………….....………. 2015

Participant name: ……………………………………. ……………………

Signature of participant: ………………………………………..

Investigator name: .... ……………………

Signature of investigator: ………………………………………..

Appendix D: Photographic Consent Document

SAGE Photographic / Media Consent Form

TITLE OF THE RESEARCH PROJECT:

Understanding the context-specific facilitators and barriers to guideline use we aim to conduct CPG stakeholder mapping to evaluate the needs of CPG users based in SA PHC facilities.

SAMRC ETHICS REFERENCE NUMBER: EC002-2/2014

PRINCIPAL INVESTIGATOR: Dr Tamara Kredo

ADDRESS:
> South African Cochrane Centre
> South African Medical Research Council
> Francie van Zijl Drive, Parow Valley, 7505
> Cape Town, South Africa
> +27-21-938 0508
> Email address: Tamara.kredo@mrc.ac.za

INFORMATION

I hereby consent to the collection and use of my personal images by photography or video recording.

I acknowledge these may be used on the SAGE website, in newsletters and in publications. I further acknowledge that my image may be used by the SAGE Project based at the South African Medical Research Council to promote the project, and disseminate its findings in the future. I understand that no personal information, such as names, will be used in any publications unless express consent is given.

I also understand that my consent can be withdrawn at anytime in writing to the SAGE Principle investigator at the South African Cochrane Centre, South African Medical Research Council. Email: Tamara.kredo@mrc.ac.za ; telephone: 021 9380508

………………………………………………………………………………………….

CONSENT FORM

I …………………………………………………………………………………………… consent to the use of my personal images in photographs or video footage for use on the SAGE website, in newsletters and publications as well as for distribution of research findings. I consent to the use of my personal image, photographs or video footage being used to promote future SAGE events and programmes.

I further understand that this consent may be withdrawn by me at anytime, upon written notice.

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I give this consent voluntarily.

Signed at (*place*) ....….......……………….. On (*date*) ……………..……….. 2015

Participant name: ………………………

Signature of participant: ………………………………………….

Investigator name: ………………………

Signature of investigator: ………………………………………..

Appendix 6: Protocol – review of primary care evidence to practice gaps in South Africa

Protocol

Evidence-practice gaps: Systematic evaluation of the quality of primary care disease management in South Africa over the last five years

Register title Prospero, submit protocol to BMJ Open

Keywords: clinical guidelines, primary care, guideline adherence, evidence-practice gaps

Background

South Africa's health system has undergone a major process of primary healthcare re-engineering over the past few decades (1-3). However, challenges remain, and despite the continuing commitment to delivering quality primary healthcare services the health outcomes relative to health spend are not reassuring of cost-effective health investments (2, 4). In 2015, the South African government issued a White paper outlining steps to achieving a National health Insurance (NHI) system with the aim of redressing persistent inequity in the country and achieving universal health coverage (UHC) (5). Within universal health coverage (UHC), quality of care is one of the core features. UHC aims at "ensuring that all people can use the promotive, preventive, curative, rehabilitative and palliative health services they need, [and that these are] of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship"(6). The World Health Organisation defines 'quality health care' as having six dimensions, these include providing health services that are 1) Effective (providing evidence-based healthcare services that result in improved health outcomes to individuals and the community based on needs); 2) Safe (minimising risks and harm); 3) People-centred (providing care that responds to individual preferences, cultures, needs and values); 4) Accessible (delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need; 5) Efficient (delivering health care in a manner which avoids waste and maximises resource use); 6) Equitable (health care services do not vary in quality due to gender, race, ethnicity, geographical location, or socioeconomic status) (7).

To ensure delivery of the effective quality health services, we need tools to bridge the evidence base and clinical practice (8). Clinical practice guidelines are amongst the knowledge translation tools in the policy implementation armamentarium to address this evidence-practice divide. According to definitions of clinical guidelines, they should include evidence-informed statements that are intended to enhance patient care (9, 10). In the setting of UHC, clinical guidelines are intended to support standardised, equitable, accessible, cost effective care and are part of the planning for several developed or emerging national health insurance systems, such as those found in the United Kingdom, Japan, and Brazil (11).

In South Africa, there is a large, committed community of guideline developers, and more than 250 guidelines have been developed in the past 10 years (12, 13). However, there is very little coordination between these guideline groups and limited evidence of accompanying quality improvement initiatives to evaluate whether the guidelines are meeting their purpose of improved health outcomes. In trying to prioritise how and where to direct resources for quality improvement and guideline implementation initiates we need to consider the South African burden of disease (14). However, with the extent of the burden and its effect on both communicable and non-

communicable conditions, more specific evidence is needed to guide action. Within primary care health services, it would be helpful to explore where there may be gaps in evidence-based health service delivery, so called 'evidence-practice' gaps.

We have little systematic evidence regarding whether effective care, a key element of quality, is provided in health care services in South African primary care. Published evaluations conducted in the United Kingdom, Australia and New Zealand were able to identify stark deficiencies in what was desired for healthcare compared to what should be delivered (15, 16). These studies highlighted the gaps and informed quality improvement strategies in their countries (17, 18).

To date there has been no systematic evaluation of published research on the quality of primary care practice against evidence-informed standards of care in South Africa. An understanding of the current areas of good or poor clinical effectiveness relative to local clinical guidance may inform future quality improvement endeavours.

In the proposed research we aim to describe and summarise published evaluations of the quality of South African primary care disease management in order to report on the any gaps between standards of care that should be delivered and what in fact is delivered.

Methods

Study eligibility:

Study designs:

We will include both analytical and cross-sectional, descriptive studies which have evaluated the quality of disease management in primary care settings. Surveys of self-reported behaviour will be excluded. we anticipate three kinds of studies:

1) descriptive studies that asses quality of healthcare delivery
2) evaluations of audit programmes where we can use pre-feedback baseline data
3) intervention studies where the baseline or control data will be used.

Population:

Reports should provide data on patients attending primary healthcare services in South Africa. This may include public or private sector health services.

Outcomes of interest:

We are interested in clinical outcomes, relative to evidence-based standards. That is, reports on delivery of clinical primary healthcare services for which primary care guidelines are available in South Africa within the Essential Medicine List or PC101 guidelines specifically developed for and disseminated within primary care. Standards of care will be based on the available clinical practice guidelines for South African primary care, matched for the timing of the publication we find. We will not include process outcomes. (e.g. for a report on asthma care, we want to extract whether those with mild persistent asthma were prescribed a bronchodilator and a steroid inhaler (Asthma guidelines/ Essential Drug List standard treatment guidelines - EDL); or patients who have had a heart attack are prescribed aspirin and a beta-blocker (EDL)).

Search methods

We will include all published data providing baseline information about quality performance standards. The standards should be explicitly provided by authors of documents else, standards will be derived from evidence-based sources, including available primary care clinical guidelines. Where standards are not provided, we will consider national guidelines available at the time of the publication.

We will search three online databases: PubMed, Embase and Cochrane's trial registry. Search terms will include: family practice or general practice, primary care, primary health care, quality of health care, audit, clinical competence, guideline adherence, quality improvement, health care quality indicators, and health care quality assurance, amongst others.

A detailed search strategy will be developed in collaboration with an information specialist.

In addition, we will review local Southern African medical journals (e.g. African Journal of Primary Care and Family Medicine; South African Family Practice, South African Medical Journal). We will search reference lists of reviews or related studies. We will contact authors in the field. We will review relevant conference lists (e.g. Family Practice, Perinatal Care Conference proceedings). Where necessary, authors will be contacted to clarify or complete missing information. Titles and abstracts of all documents will be independently evaluated for possible inclusion using an agreed eligibility form. Where necessary, full texts will be required to finalise eligibility and disagreements will be resolved by consensus. Reasons for exclusion of full texts will be captured and reported in a table of excluded studies.

Data collection and management:
A standardised, pre-piloted data extraction form will be used to extract data from the included studies for assessment of study quality and evidence synthesis.

We will extract the following:
study design, sampling strategy and size, setting (private, public, urban, peri-urban, rural), clinical condition, quality of care attained for each condition compared with explicit standards from evidence sources, date of data collection.

Two review authors will extract data independently, discrepancies will be identified and resolved through discussion (with a third author where necessary). Missing data will be requested from study authors if needed. Descriptions of included studies will be captured in a table of 'characteristics of included studies' table.

Analysis approach
We will provide a narrative synthesis of the findings from the included studies, structured around the diseases condition, population characteristics, type of clinical outcome and intervention content. Where feasible, we will report summaries of outcomes using percentage relative to standard. That is, for each outcome, we will have an agreed standard (e.g. 100% of people with moderate asthma should be prescribed an inhaler); and we will capture the actual percentage of the outcome (e.g. 40% of people with asthma received an inhaler) [see table 1]. We anticipate that there will be

limited scope for meta-analysis because of the range of diseases conditions and outcomes measured across the varying study designs.

Quality assessment of included studies:

We will assess study quality to consider issues of bias that may arise from inclusion of different study designs. A modified Newcastle-Ottawa tool for assessing risk of bias will be used considering the different non-randomised studies that will be included. Some elements will include sample selection and consideration of confounders in the design, conduct or analysis of the included study.

The following criteria will be systematically collected: study design, sample size (number of practices/ clinics and patients), whether random methods for sampling were used or not, whether potential confounders were specified and addressed in the design or analysis of the data.

As we are only reporting on single arms of any intervention studies, full risk of bias assessment for intervention studies will not be undertaken.

Presentation the results

We anticipate identifying data from cross-sectional descriptive studies, national and provincial audits, and various types of analytical studies. The summary of results will include the condition; number of studies, setting, criteria (e.g. management of blood pressure or use of aspirin post myocardial infarction), and target of the standard, based on evidence base, source of evidence base, including national guideline or a clinical trial.

Table 1. Example of presentation of results:

Condition	# of studies	Setting	Criteria	Target standard	Percentage meeting the standard	Source of standards
e.g. asthma	10	urban and peri-urban	use of steroid inhaler	100% in moderate asthma	55% met target	SA Asthma guideline, 2005, SAMJ

Dissemination plan

We plan to publish the results in relevant journal, share results in relevant conferences and events. Depending on findings, there may be specific stakeholders who would benefit from direct communication of results, this will be determined after the analysis.

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