

SAGE MATTERS

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SHARING ORGANISATIONAL PERSPECTIVES

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South Africa has a rich history of clinical guidelines development with both the public and private sectors supporting clinical care for their respective settings. In this issue of the *SAGE Matters* newsletter we share perspectives of the roles, value and future plans of several organisations working on clinical guidance development, implementation and research.

The South African Medical Association (SAMA, www.samedical.org) is a professional association founded to support the interests of medical doctors in both the private and public sectors. In addition to clinical governance manuals, SAMA shares the National Department of Health Essential Drug List standard treatment guidelines on their website. In their article (p. 4) SAMA describes how they are enlivening their guideline efforts, under the management of the Knowledge Management team, by encouraging participation and feedback for current clinical care recommendations.

Another organisation tackling the challenges of developing guidance is the Council for Medical Schemes (CMS, www.medicalschemes.com). Their driving purpose is to provide regulatory supervision of private health financing through the medical schemes. The CMS are currently regularly featured in the media as the country unpacks the place of private care within the proposed National Health Insurance (NHI). In this issue (p. 5) they share how they proceed to guide practice by updating the Prescribed Minimum Benefits to ensure evidence-informed and cost-effective decisions.

The Pharmaceutical and Technology Clinical Management Association (PCMA, pcma.org.za) hosted the SAGE Project to present at an event in 2016. The PCMA is a non-profit organisation providing learning opportunities for private-sector members. On page 6 they share their appreciation of the immense pressures and often conflicting primary interests of clinicians, medical schemes and the pharmaceutical industry, and they reflect on the call from the CMS for

transparent evidence and cost-informed decision making.

Given the active role many groups play, an informative piece of research is being led by researchers from the University of the Witwatersrand (Wits) School of Public Health, PRICELESS (www.priceless.ac.za). They describe the landscape of clinical guideline players and products by mapping all available South African guidelines since 2000 (see p. 2). This gives some clues to the current state of play of clinical guidance and identifies signals for potential duplication or areas perceived as priorities. They suggest the need for co-ordination of activities to avoid waste and promote collaboration across the various groups.

In South Africa we continue to address challenges in the health system and forge the way forward to the NHI. Understanding and sharing news and views about the drivers, needs and strengths of current guideline contributors, along with consideration of clinical priorities and the country's burden of disease allows me to believe that co-ordination across sectors, disciplines and organisations is increasingly possible and likely.



ENCYCLOPAEDIA OF CLINICAL GUIDELINES IN SOUTH AFRICA: A MAPPING PROJECT

Maryke Wilkinson, Independent Consultant, Cape Town; Tommy Wilkinson, Kim MacQuilkan and Karen Hofman, PRICELESS SA, Wits Rural Public Health and Health Transitions Unit, School of Public Health, University of Witwatersrand; and Tamara Kredo, Cochrane SA

Clinical practice guidelines (CPGs) can have a substantial influence on clinical decision making, with consequences for patient outcomes, access to care, and health-system costs. *The White Paper on National Health Insurance (NHI) for South Africa*¹ suggests that detailed CPGs, based on the best-available clinical and cost-effectiveness evidence, will be used to guide the delivery of health services under the NHI. The White Paper provides a clear policy signal that the current Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) for primary, hospital, and tertiary and quaternary-level care (developed by the National Department of Health) will guide most clinical practice under NHI, but that additional CPGs will be developed where there are gaps in therapeutic areas not covered by the STGs. Therefore, it is important to explore the current landscape of CPGs in South Africa, including what is available and who is leading their development.

We conducted a cross-sectional evaluation of all CPGs available online in South Africa. The search involved a two-part process: an iterative, electronic search of the grey literature and relevant websites (143 websites searched); and a systematic search for peer-reviewed literature (PubMed). CPGs were extracted by one reviewer, and the data collected on each guideline include a description of the developer, condition and reporting of items associated with quality CPGs.

WHAT WE FOUND

We identified 243 CPGs published online after 2000, of which 140 were developed in the past five years (in/post 2012). The main developers of CPGs identified are the Department of Health (DOH), professional societies and associations, *ad hoc* collaborations of clinicians and academics, and the Council for Medical Schemes (CMS). The DOH CPGs consist of guidelines covering multiple conditions and populations (e.g. STGs) (n=6), supported by detailed programme guidelines (n=33). CPGs were considered 'detailed' if they provided in-depth guidance that included information on the condition, indications for particular intervention(s) and treatment or management recommendations. The majority of the society and association (n=100), clinician and academic (n=36) and CMS (n=9) guidelines were also considered 'detailed'.

Seventy four per cent of the CPGs developed in the last five years were classified as 'detailed' (104 of the 140). Fifty two per cent (54/104) of these were focused on non-communicable diseases (NCDs), of which 70% were produced by professional societies or associations. Figure 3 gives an overview of the detailed guidelines developed



Figure 1: South African CPGs by developer

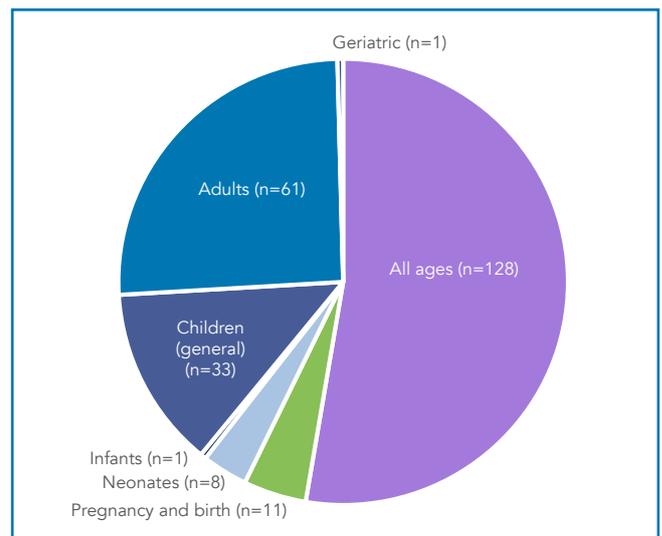


Figure 2: South African CPGs by target population

since 2012 by broad therapeutic area and developer type.

CPGs available online differ noticeably in terms of their development processes, funding streams, level of detail and availability. The topic selection/prioritisation process followed by the developers was generally not reported, and therapeutic topics vary considerably between developer types, with DOH CPGs focused on high-burden conditions (HIV/AIDS, TB and Malaria) and CPGs from other developers more focused on NCDs.

Accessing CPGs was challenging and required extensive searching. South Africa has many contributors to CPG development from all sectors and across disciplines, but there is no evidence of co-ordination or prioritisation of CPG development. CPGs identified were often out of date

and quality was poorly reported, impacting on the usability and credibility of those available.

RECOMMENDED NEXT STEPS FOR CPG DEVELOPMENT IN SOUTH AFRICA

Exploring the CPG landscape suggests that the next steps needed to support the soon to be introduced NHI

may include maintaining an accessible CPG repository, and establishing a national co-ordinating unit responsible for developing standards and supporting high-quality development. The need for a national co-ordinating unit was also recommended by participants at the 2016 SAGE summit.²

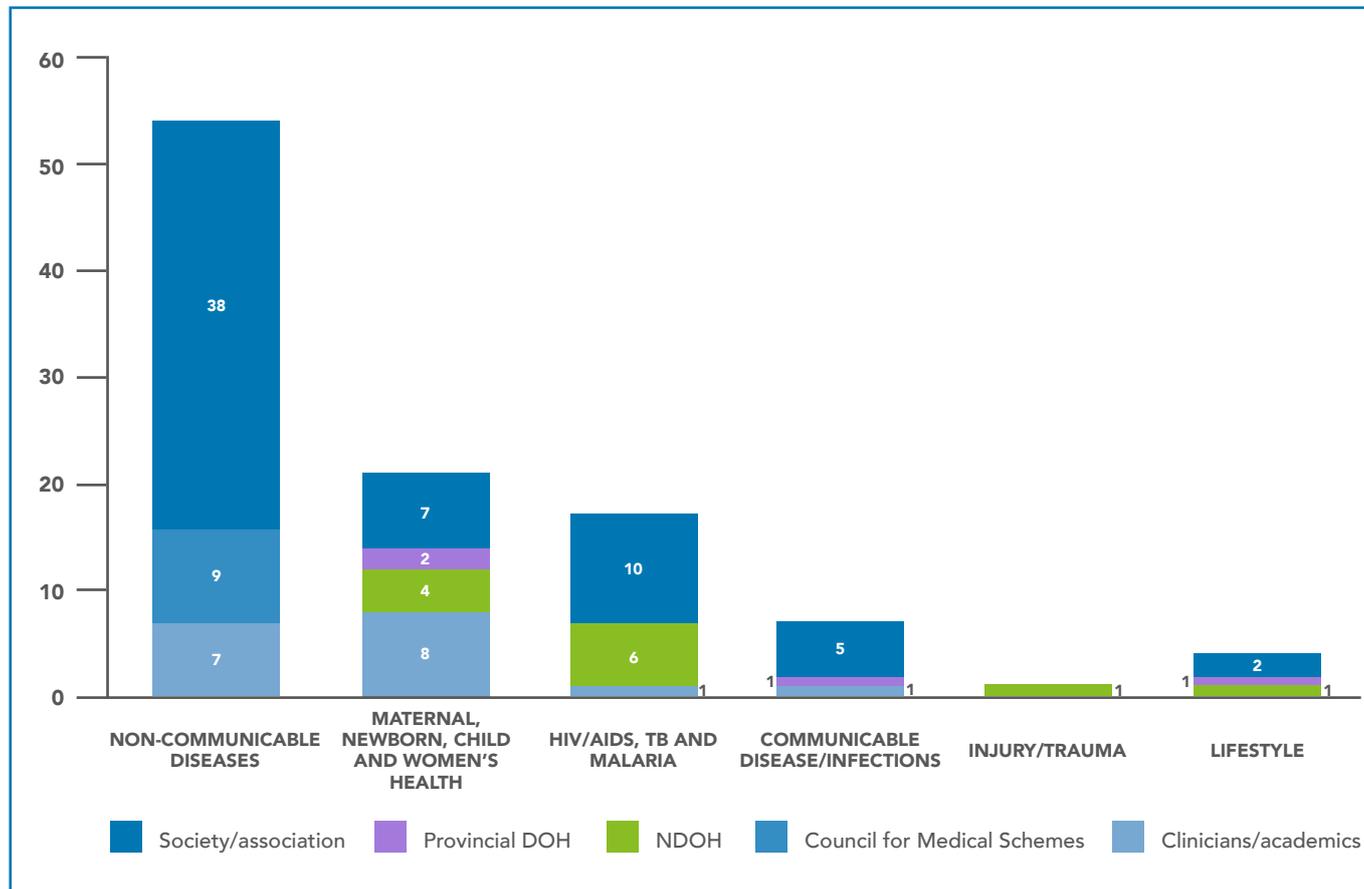


Figure 3: Content areas covered by CPGs developed in South Africa since 2012 (n=104)

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INVOLVING MEDICAL DOCTORS IN CLINICAL PRACTICE GUIDELINE DEVELOPMENT

Shelley McGee, Knowledge Management and Research Department, South African Medical Association

Clinical Practice Guidelines (CPGs) are playing an increasingly important role in the lives of practising physicians. CPGs are increasingly being used in efforts to improve the quality of health care¹ and in efforts to constrain costs.²

For physicians, CPGs can be a valuable source of information and unbiased reviews for addressing illnesses, but can also be a source of defence or prosecution in medical malpractice cases,³ barriers to reimbursement from health insurance agencies and even a source of frustration where a patient's clinical status does not allow for following guideline-recommended treatments.

Clinical guidelines *per se* are not intrinsically valuable. Value is derived from a combination of the quality of the evidence consideration and the implementation of the guidelines to achieve the intended outcomes. Thus CPG development has become increasingly analytical and methodological to ensure that the best-available evidence is incorporated. In several countries, the national medical associations have set the standards for the development and publishing of guidelines, and participate proactively in their development and implementation.⁴

Busy medical doctors in clinical practice are frequently not able to fully participate in these processes individually because of time constraints, lack of technical skills and, in some instances, because they are unaware of the methodological processes to be followed.

Yet, the inputs of those deciding on the treatment of patients at the bedside remain paramount and necessary for both context and acceptability of any produced clinical guidelines. Research in the early years of CPG development and implementation found multiple barriers to physicians' implementation of guidelines, including lack of familiarity, previous practice inertia and disagreement with the content.^{5,6}

South Africa's fragmented health system has also translated into fragmented guideline development processes.

The National Department of Health has published the Standard Treatment Guidelines (STGs) and Essential Medicines Lists (EMLs) since 1998.⁷ Multiple specialist societies have also produced their own guidelines, with varying levels of and criteria for consideration of evidence-based medicine. In addition, medical schemes are entitled, in terms of the Medical Schemes Act (Act 131 of 1998) to draw up their own protocols for treatment of covered diseases, and may make use of international guidance to do so (for example, medical schemes may adopt guidance from the National Institute for Health and Care Excellence [NICE], which also includes economic considerations).

The Council for Medical Schemes in South Africa is also busy with a project defining clinical entitlements of medical scheme members for Prescribed Minimum Benefits – a process which is also highly clinical evidence and consensus driven.⁸

At the centre of all this reside the treating physicians and their patients, who must navigate through the complexities of clinical management, divergent clinical practice guidelines and the pressures of reimbursement issues.

In the last year, the South African Medical Association (SAMA) has initiated a process of engaging its medical practitioner members to contribute substantively to the development of guidelines, sharing their experience and expertise in the process. As an association, our emphasis is largely on the importance of evidence-based medicine and its important role in guideline development and implementation. This has been in the form of awareness of development procedures and opportunities to contribute, as well as substantive submissions to published CPGs and Council of Medical Schemes benefit definitions (a process that has recently been accelerated).

Through co-ordinating and encouraging participating and evidence-based inputs from its members, SAMA has been able to provide a platform for ensuring the inclusion of inputs of treating physicians to clinical practice guidelines, which directly affect their practice.

We intend for this to become a substantially more formal and structured process as the country works towards a unified health-care system, for which we believe well-constructed and implemented CPGs are imperative.

With SAMA offices forming a secretariat function and directing the necessary research and submissions to clinical guidance development, we believe that the standards of input into clinical guidelines development in South Africa can be improved, standardised and achieve better acceptability and implementation from and by medical practitioners.

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DEVELOPMENT OF THE PRESCRIBED MINIMUM BENEFITS USING EVIDENCE-BASED MEDICINE

Evelyn Thsehla, Clinical Researcher, Clinical Unit, Council for Medical Schemes



The Medical Schemes Act, (Act 131 of 1998) introduced Prescribed Minimum Benefits (PMBs) as a policy instrument for defining minimum allowable levels of benefits to be covered by medical schemes. The regulations made in terms of the Act were promulgated on 20 October 1999 and came into effect on 1 January 2000. According to the regulations, the prescribed minimum benefits are defined as a list of 270 diagnosis and treatment pairs (DTPs), a list of chronic conditions as well as emergency medical conditions that must be provided for by each medical scheme, without financial limits in at least one provider setting. The objectives of specifying a set of PMBs are given in the regulations as:

- i. to avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals; and,
- ii. to encourage improved efficiency in the allocation of private and public health-care resources.

In 2010 the Council for Medical Schemes (CMS) in consultation with different stakeholders initiated a process to define the prescribed minimum benefits to clarify members' entitlements, and the liabilities that schemes face, in respect of the PMB provisions in the Act and Regulations. The process was initiated because stakeholders felt that the manner in which PMBs are currently defined makes it difficult for members and service providers to prospectively know whether specific benefits are covered or not. The CMS therefore established a benefit-definition process using a participatory approach to better define the PMB package.

The benefit-definition process is co-ordinated by the CMS in collaboration with the National Department of Health in consultation with funders, providers, the academic sector, colleges and other relevant regulatory

bodies. The current PMB definitions are developed by a clinical advisory committee that meets quarterly to discuss and deliberate around proposals by stakeholders as an input to making recommendations for inclusion or exclusion of benefits. Once proposals are finalised by the clinical advisory committee, a team of technical experts comprising individuals including, but not limited to, clinical researchers, epidemiologists, health economists, pharmaco-economists, public health experts and those involved in the management of the condition under review, systematically collate existing and new evidence to inform the inclusion and exclusion of health technologies. The PMBs are then developed based on integration of best research evidence with clinical expertise and local patient's unique values and circumstances using local guidelines. A hierarchy of evidence is used to guide decision making and funding for the benefits. Evidence from the highest position in the hierarchy (such as systematic reviews and clinical trials) is used wherever possible. Where necessary, the cost effectiveness and affordability of interventions are taken into account using internationally comparable studies to ensure sustainability of the defined benefits. Deliberation on the definition by the clinical advisory committees and the technical committee ends with recommendations to the CMS which then publishes documents for industry comments and implementation.

Over the past few years the CMS has published over 10 benefit definitions using this process. The challenge, however, has been the lack of local clinical guidelines that could be used to inform the benefit definitions. The benefit definitions themselves are not clinical guidelines but funding guidelines that are used to inform the benefits to which members of medical schemes are entitled. In the coming months, CMS would like to accelerate the process to ensure uniformity in the interpretation of the benefits by members, funders and health-service providers.

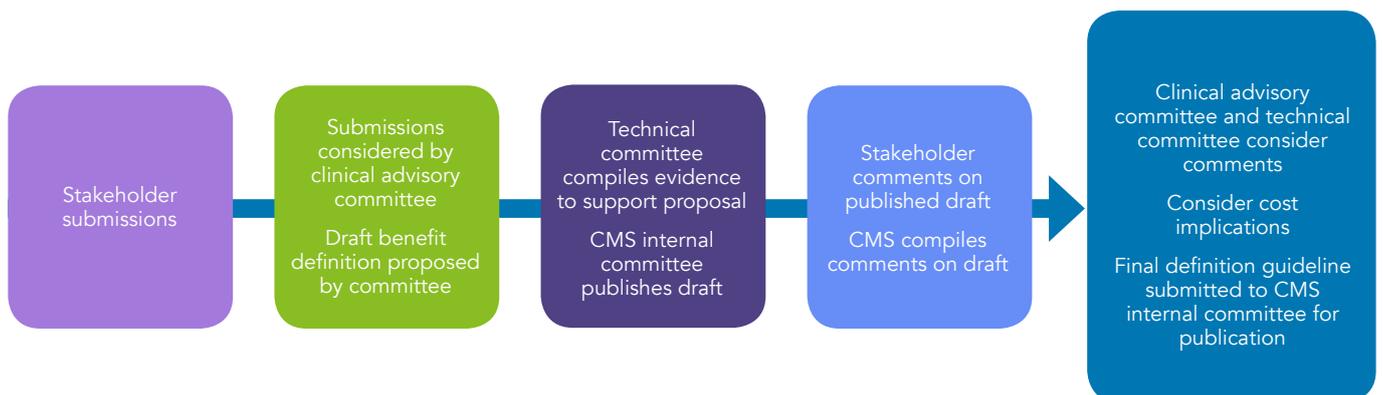


Figure 1: PMB definition process

PCMA GUIDELINE WORKSHOP REVIEW

Adie Bryson, PCMA

The PCMA (Pharmaceutical and Technology Clinical Management Association) has for the past 17 years brought together health-care stakeholders for monthly Continuing Professional Development (CPD) meetings in Johannesburg, Pretoria and Cape Town. PCMA also hosts workshops on topical issues and, recently, focused on guidelines.

The need for greater collaboration between role-players with an interest in strengthening evidence-based practice is broadly recognised. Synergies were prompted by the publication of the editorial *AGREE to disagree – critical appraisal and the publication of practice guidelines* in the *South African Medical Journal*.

PCMA welcomed this opportunity and held two guideline workshops. Various groups have different reasons for wishing to foster evidence-based practice, however, a common denominator is found in clinical guidelines where barriers and facilitators to implementation should be clear.

BACK TO BASICS

The first workshop went back to basics covering what is meant by a guideline and where guidelines are applicable in the funding environment. Roger Wiseman, one of the members of the *SAMJ* guideline editorial sub-committee, was the chairperson and highlighted the fact that stakeholders from the clinical practice and funding environments are constantly faced with tension due to perceived competing interests. The clinician being the fierce advocate for their patient while funders, on the other hand, focus on the fairness and transparency in the allocation of health-care resources, trying to achieve optimal clinical outcomes for both the patient and insured population.

We live in a resource-poor environment. There is greater access to health care in the private than the state sector, but resources remain finite and there are competing needs. As a result, there is a greater obligation to make good choices and huge value in evidence-informed priority setting.

TOO MUCH INFORMATION

The health-care fraternity is faced with an explosion of clinical literature. Therefore we need to bring this information together in a manner which is clear, reliable, unbiased and locally applicable.

Great care needs to be exercised in ensuring the validity of guidelines which calls for due process throughout their development and publication. Sadly, this is where the disconnect comes in. In the absence of the necessary rigour, guideline documents tend to be grouped somewhere alongside Expert Opinion, a consensus statement – or even ‘Someone once said...’. Consensus vs. Guidelines can range

from simple endorsement by societies to fully comprehensive, properly researched and reviewed guidelines. An opinion piece by a specialist should not be accepted in place of a guideline, nor an endorsement document/letter or formal statement from a society. A clinical guideline by a society (not peer reviewed or published) does not pass the rigour test. A formal, published, peer-reviewed clinical guideline as agreed to by all stakeholders is the way to go.

In order to establish common understanding and implementation in view of the soon to be introduced National Health Insurance, it is imperative we have a common reference point, and this should be clear in using authentic guidelines. The **Appraisal of Guidelines for REsearch & Evaluation (AGREE)** Instrument was developed to address the issue of variability in guideline quality. AGREE is a tool that assesses the methodological rigour and transparency with which a guideline is developed. This involves scope and purpose, stakeholder involvement; rigour of development; clarity and presentation; applicability; and, editorial independence. Dr Jacqui Miot, also one of the *SAMJ* editorial sub-committee members, introduced the **AGREE II** tool to workshop attendees, getting back to basics and establishing a broader understanding of a guideline.

The workshops reflected on the barriers to guideline development – including capacity development and the need for co-ordinated efforts across sectors and disciplines. Concepts that resonate strongly with the provisions of the AGREE tool. There was first-hand, practical insight into the application of the tool into the process of developing guidelines within the South African context.

As we move forward, we need to recognise a quality guideline. Debate on guidelines must be expected as they address complex clinical decisions and are fraught with alternatives, exceptions and uncertainties. Competing perspectives will always exist and reaching a common place will take time. We need to be constantly reminded of the responsibility in applying due process throughout guideline development and publication, because they influence public health policy and the allocation of financial resources.

By ensuring sufficient rigour during development, a clinician’s ability to make informed clinical decisions will be enhanced, leading to improved patient care by discouraging ineffective and wasteful interventions. If the goal of clinical practice guideline development is high-value health care for all, we should do everything possible to make sure that we hear the evidence speak.

IMPLEMENTATION OF GUIDELINES BY MEDICAL AIDS

Dr Noluthando Nematswerani and Niri Bhimsan, Discovery Health

Clinical guidelines are used by funders as an important aid in clinical-benefit design. This is to ensure that benefits offered are clinically appropriate, transparent and consistent. Provision of clinical care is therefore standardised, making it more predictable for the majority of patients and thus easier to budget for.

While guidelines apply to the most patients, there are sometimes cases of clinical complexity that fall outside of the guideline recommendations. Funders need to take this into account and ensure that there are clear processes in place to accommodate such cases in clinical-benefit provision.

The Medical Schemes Act (Act 131 of 1998) makes provision for cover of “clinically appropriate” medical services by medical schemes.

- Managed health care incorporates the management of health care, clinical and financial risk assessment, with a view to facilitating the appropriateness and cost-effectiveness of health-care services within the constraints of affordability, through the use of rules-based and clinical management-based programmes
- Rules-based and clinical management-based programmes refer to a set of formal techniques designed to monitor the use of, and evaluate the clinical necessity, appropriateness, efficacy and efficiency of health-care services, procedures or settings, on the basis of which appropriate managed health-care interventions are made.

As much as there is reliance on guidelines, funders are cognisant of the current limitations of these tools hence the need for careful evaluation of the quality of each guideline prior to adoption in clinical policy development.

A GOOD QUALITY GUIDELINE SHOULD:

- be based on systematic reviews of robust evidence;
- include grading of the levels of evidence, using a reputable model;
- show insights into trial design, randomisation, consistency of results and parameters including long-term safety and efficacy;
- resort to expert opinion when data are limited, e.g. rare or advanced diseases. However, a formal process of consensus for objectivity and transparency is required;
- highlight benefits and harms of treatment. Harms can lead to expensive consequences or impact on positive benefits;
- be authored by a task group representing relevant professional associations and all stakeholders for whom the guideline has been written;

- take into account issues of cost-effectiveness, affordability and budget impact; and,
- be adapted to the setting in which they apply. From a funder’s perspective, such guidelines need to be appropriately contextualised to be clinically relevant for the South African population.

CURRENT CHALLENGES WITH GUIDELINES:

- Paucity of local guidelines and outdated guidelines resulting in the reliance on international guidelines which may not always be relevant.
- Unstandardised guideline quality ranging from position statements to full evidence-based guidelines.
 - * Bias with unintentional or intentional influence on recommendations arising from sources including author skills, vested interests and sponsorship.
- In South Africa we often have different guidelines for the different health sectors, i.e. private versus public sectors. This indicates that we have varying standards for care provision.
- Many guidelines do not take costing into consideration which means funders have to determine the cost impact posing further concerns around affordability and budget impact. This also creates tensions between clinicians and funders as the clinical aspects of the guidelines are viewed in isolation to the treatment costs.
- Adherence to guidelines is often an issue with health-care providers resulting in conflict with funders where these are enforced through clinical benefits. This non-adherence has quality implications for health-care provision and may drive health-care costs.

As we move towards an era focused on demonstrating the value of therapies and policies implemented by funders, using real-world administrative and clinical data is becoming more relevant. The use of good guidelines based on best-available evidence and the findings from real-world data will lead to responsible implementation of disease-management processes, improved compliance and process measures. Good evidence-based guidelines may assist in ensuring access to appropriate interventions by opening up care pathways and treatment baskets, leading to a more patient-centred approach and higher-quality, affordable health care.

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SAGE UPDATE MAY 2017

Project SAGE is entering its fourth year with support from the SAMRC Flagships funding. The project continues to focus on research on the current landscape of clinical guideline development and implementation, and on building capacity to develop and implement guidelines in South Africa and the region. This year we will focus on completing the analysis of the interview and focus-group data collected from primary care policymakers, health managers and clinical staff in four of South Africa's provinces.

In addition, we are rolling out the Clinical Guideline Learning Opportunities Masters level module through Stellenbosch University (mclinepi@sun.ac.za) and hosting workshops on the content. As part of a recent student engagement, we hosted a SAGE Panel Discussion in April entitled 'Shifting the way we do it: Clinical practice guideline adaptation' to share methods that South African developers are using to adapt guidelines for our context. This was attended by 35 delegates representing different organisations, sectors and disciplines. We look forward to sharing

the report and video clips of this event on our website (www.mrc.ac.za/cochrane/sage) soon.



The SAGE team is delighted to congratulate colleague Dr Dawn Ernstzen on the awarding of her PhD - seen here at the ceremony with Prof. Quinette Louw. Her dissertation topic is: The development of a contextualised evidence-based clinical practice guideline for the primary health care of chronic musculoskeletal pain in the Western Cape, South Africa.

UPCOMING EVENTS

GLOBAL EVIDENCE SUMMIT 2017: USING EVIDENCE. IMPROVING LIVES.

Join Cochrane, the Campbell Collaboration, the Guidelines International Network, the International Society for Evidence-based Health Care and the Joanna Briggs Institute who are joining forces to create a premier global event focusing on evidence-based policy in September 2017 in Cape Town, South Africa.

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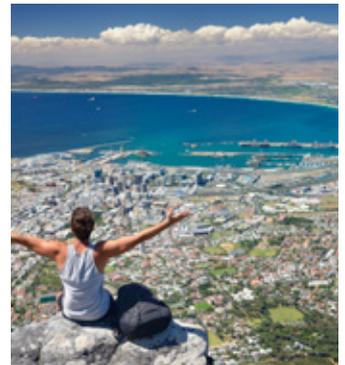


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