Clinical Quality Standards in South Africa:

Proposed development framework

DRAFT

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Contents

Abbreviations

BCA	Best Care Always
BIA	Budget Impact Analysis
COHSASA	Council for Health Service Accreditation of Southern Africa
CPG	Clinical Practice Guideline
DoH	Department of Health
HCP	Health Care Professional
HHS	Health and Human Services
HTA	Health Technology Assessment
ISQua	International Society for Quality in Health Care
JCAHO	Joint Commission on Accreditation of Healthcare Organisations
NGO	Non-Governmental Organisation
NHI	National Health Insurance
NICE	National Institute for Health and Care Excellence
NQMC	National Quality Measures Clearing House
NSDA	Negotiated Service Delivery Agreement
OHSC	Office for Health Standards Compliance
PDSA	Plan, Do, Study, Act
QS	Quality Standard
SA	South Africa
US	United States

1. Introduction

According to a policy brief produced in 2012 (Health Economics Unit, Cape Town), patients consider the acceptability and quality of health services in South Africa (SA) varied and suboptimal (1). Poor quality care has a profound effect on individual health outcomes, leading to morbidity and deaths, and huge potential cost implications for the health system as a whole. Challenges with health care quality are, at least partly, a contributing factor to the exponential increase in the number of medico-legal claims seen in the past five years in both the public and private sectors (2). The Department of Health (DoH) is planning to address the current health care quality challenges within a unified health system, and is in the process of implementing National Health Insurance (NHI) for South Africans.

The *National Health Insurance (NHI) Policy for South Africa* (released in June 2017) defines quality of care as "the safe, effective, patient-centred, timely, efficient and equitable provision of health care services to achieve desired health outcomes. It takes into account patient safety, meaning the prevention of harm to patients and it employs clinical governance processes to assure quality" (3). In addition, the DoH uses the following working definition of quality improvement: "Quality improvement is achieving the best possible results within available resources. To this end, quality improvement includes any activities or processes that are designed to improve the acceptability, efficiency and effectiveness of service delivery and contribute to better health outcomes as an ongoing and continuous process" (4). Both of these definitions demonstrate the DoH's position that in order to provide high quality and equitable care to the population, the delivery of health care interventions should be prioritised based on their clinical and cost-effectiveness.

The availability and use of standardised, evidence-based clinical practice guidelines (CPGs) is an approach utilised by many countries to reduce variation in health care practice and improve the quality of care provided. CPGs empower health care professionals (HCPs) to deliver the best possible care with available resources, and reduce the risk of outdated, uncertain and/or potentially harmful health care practices. The *NHI Policy for South Africa* states the DoH's commitment to use detailed clinical guidelines, based on the best available clinical and cost-effectiveness evidence, to guide the delivery of health services, and declares 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" (3). A recent landscape analysis of CPGs in SA (5) identified 285 CPGs published by the DoH, professional societies, the Council for Medical Schemes and other South African organisations since the year 2000. These CPGs provides a starting point to help inform the planning and determination of services benefits under NHI, but further work is required to (a) identify the most relevant and high-quality CPGs for use in SA, and (b) successfully implement and monitor the cost and impact of the CPGs.

Clinical quality standards (QS) can be useful tools to aid and enhance CPG implementation and uptake, and evaluate their clinical impact. QS describe high-priority areas for quality improvement in clear, concise statements derived from evidence-based CPGs, and include quality measures that can be used to drive and monitor quality improvement. Attempts to assess and measure quality in health care against predetermined standards have been increasing in recent years (6,7), and led to an evolving discipline of using QS to improve the quality of health services provided (6). The availability of QS promote responsibility and accountability for the quality and safety of care provided by empowering patients and the public with a better understanding of the care they can expect in a particular clinical situation, and thereby allowing them to make more informed health care choices (8).

No national, coordinated programme to develop and implement clinical standards currently exists in SA. The Office of Health Standards Compliance (OHSC) is responsible for "monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister of Health in relation to the national health system"(9), but these norms and standards are minimum requirements for quality and safety in health care and not clinical and/or aspirational in nature.

PRICELESS SA is dedicated to improving the way in which health priorities are set, resources are allocated and the impact on health outcomes are evaluated through the use of evidence. Consequently, PRICELESS SA has a keen interest in the fields of health technology assessment, CPG production and use, and QS development. PRICELESS SA convened a workshop in April 2016 to discuss and explore the applicability of the QS approach to the South African context. At this workshop, it was agreed that although international approaches to QS development and use can be considered, SA should lead on the development and implementation of local QS to ensure they are relevant, practical and applicable.

The development of clinical standards in SA would provide policy makers, funders, HCPs, and patients with clear and transparent definitions of what high-quality, safe and reliable health care looks like, and the quality measures to drive, track and prove quality improvement and consistency in care across health care providers (8,10). When developed and used efficiently, it is envisaged that QS would improve health outcomes, save lives and potentially save costs to the health system, particularly in the form of unfunded mandates arising from malpractice litigation (2). In addition, careful consideration of the budget impact and potential economic implications of QS implementation enables decision-makers to determine the best course of action from the various available health care practices.

This document outlines a proposed approach to developing QS in SA, based on a review of existing QS development practices in SA and abroad; and aims to provide a consistent and uniform approach to QS development.

The South African health system is undergoing major change with the implementation of NHI, and the standardisation and improvement of the quality of care provided will be a vital success factor moving forward. QS, in coordination with health technology assessment and CPG production, represents a viable mechanism for encouraging the implementation of high-quality, evidence-based, cost-effective and coordinated care in the South African health care setting, and could also provide a practical basis for future initiatives relating to strategic purchasing and payment for performance (3).

2. Background

A review of QS development, publication, implementation, use and evaluation practices in SA and abroad was conducted to inform the development of this QS framework for SA. A summary of relevant health care policies and organisations identified is presented in this section.

SOUTH AFRICA

South African Policy Environment

The South African Government's strategic plan for the 2014-2019 electoral term (Medium Term Strategic Framework (11)), identified ten priority areas in which the Government will take decisive action. This led to the development of twelve Key Outcomes with accompanying outputs and metrics. The delivery of these high-level outcomes has been negotiated with key partners, and converted into the Negotiated Service Delivery

Agreements (NSDA) which stipulates the timelines, roles and responsibilities, and budgets available to achieve the outputs.

The second Key Outcome is focussed on health care: *Outcome 2: A long and healthy life for all South Africans*. Outcome 2 is organised into four domains/outputs (see below) (12), with the relevant performance measures provided in *The Measurable Performance and Accountable Delivery* document (13). Any QS developed for SA should be clearly linked to one of these four domains.

Output 1: Increasing life expectancy
Output 2: Decreasing maternal and child mortality rates
Output 3: Combating HIV and AIDS and decreasing the burden of disease from TB
Output 4: Strengthening health system effectiveness

The approach to monitoring and evaluation suggested in *Delivery Agreement for Outcome 2: A long and healthy life for all South Africans* has been considered in the development of this QS development framework, and includes the following steps (12):

a) Conducting a readiness assessment
b) Agreeing on outcomes to monitor and evaluate
c) Selecting key indicators to monitor outcomes
d) Reviewing baseline data on indicators
e) Planning for improvement – selecting results and targets
f) Monitoring for results
g) Defining the role of evaluations
h) Reporting findings
i) Using findings
j) Sustaining the M&E within the organisation

Quality Improvement Activities in South Africa

The development and use of standards to improve the quality of health services has been increasing in recent years. In SA, quality and safety norms and standards are used to licence, certify and accredit health care establishments and personnel. See Table 1 for overview of these evaluation methods.

Professional councils are responsible for the licencing of HCPs, and Provincial DoH have delegated authority to licence health care establishments. In terms of certification, the OHSC has been established to "inspect and certify health establishments as compliant or non-compliant with prescribed norms and standards or, where appropriate, withdraw such certification"(16). The standards used to licence health care establishments, and the norms and standards used by the OHSC to inspect and certify them, are focussed on improving the general quality and safety of health care, and mainly contain measures for waiting times, cleanliness, drug stock outs, infection control, staff attitudes etc. They do not include specific clinical statements and measures.

A quality improvement accreditation programme run by the Council for Health Service Accreditation of Southern Africa (COHSASA) is in operation in SA. In addition, many other structured quality improvement support initiatives, coordinated by organisations like Best Care Always! (BCA), the Aurum Institute, and the Institute for Healthcare Improvement (IHI), are contributing to this field of work, but their scope, clinical topic areas, development processes, and implementation are not coordinated at present.

Table 1: Evaluation methods and standards used to evaluate health care professionals and establishments in South Africa (6,14,15)

Process	Issuing organisation	Object of evaluation	Components / Requirements	Standards	Examples
Licencing • Aim: Quality Assurance • Mandatory	Government authority	Individual or an organisation	• Regulations to ensure minimum standard of care. • On-site inspection, proof of education or competence.	• Set a minimum level to ensure a minimum risk to health and safety • Designed to identify unacceptably low levels of standards compliance	*South Africa* • Professional Councils (licencing HCPs) • Provincial Departments of Health (licencing of health care sites)
Certification • Aim: Quality Assurance or Quality Improvement • Mandatory or voluntary	Government authority or NGO	Individual or an organisation	• Demonstrate compliance with pre-determined standards (beyond what is required for licencing). • On-site inspection, proof of education.	• Set at a minimum level • Identify unacceptably low levels of care. • Object of evaluation scored as being compliant, partially compliant or non-compliant with the standards. • Non-compliance can result in a notice of corrective steps needed to achieve mandatory requirements.	*South Africa* • Office of Health Standards Compliance (OHSC) • Continuing professional development
Accreditation • Aim: Quality Improvement • Voluntary	Recognised tools Usually an NGO	Facilities and organisation	• Compliance with published standards • Compliance not required by law and / or regulations • On-site evaluation	• Set at an aspirational, but achievable level to stimulate improvement over time, leading to increasing overall excellence. • Scored as being compliant, partially compliant or non-compliant with the standards.	*South Africa* • COHSASA

Adapted from Whittaker et al 2011 (6) [original source: Rooney and Van Ostenberg 1999 (15)].

A summary of some of the South African quality improvement initiatives reviewed in the development of this report is provided in Appendix 1, with specific aspects considered relevant to the QS development framework included under sections 3 and 4.

INTERNATIONAL

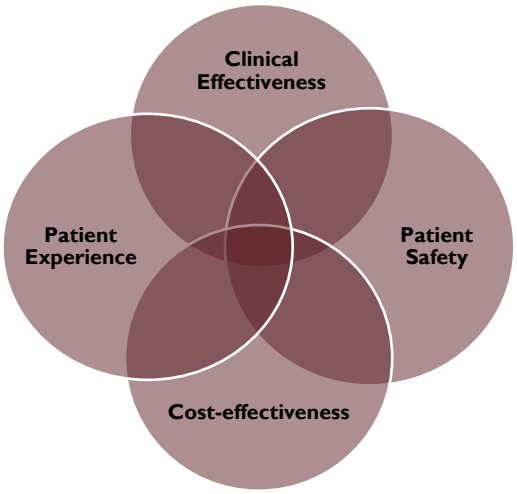
Valuable information on QS development processes and content from international organisations/collaborations are available online, e.g. the National Institute of Health and Care Excellence (NICE), the Joint Commission on Accreditation of Healthcare Organisations (JCAHO), the International Society for Quality in Health Care (ISQua), Health Quality Ontario, the Canadian Patient Safety Institute (CPSI), the Health Information and Quality Authority (HIQA) the Australian Commission on Safety and Quality in Health Care, SafeCare Initiative, the National Quality Forum (NQF), the National Quality Measures Clearing House (NQMC) and the Health and Human Services (HHS) Measures Inventory.

A summary of these organisations and their scope of work is provided in Appendix 1, with specific aspects considered relevant to the QS development framework included under sections 3 and 4.

3. Definition and Structure of Quality Standards

The SA Government uses the 'Logic Model' to interrogate and manage the links between the inputs, processes/activities, outputs, outcomes and the impact of interventions or programmes (16). The development of QS are broadly based on the same principle, but with due consideration of the following dimensions of quality (3,17,18):

(1) **clinical effectiveness** (evidence-based health care),
(2) **cost-effectiveness** (optimal use of resources)
(3) **patient safety** (avoid avoidable harm and risks to safety), and
(4) **patient experience** (patient is treated according to individual wants or needs, and with compassion, dignity and respect).



In this framework, QS are defined as:

Clear, measurable, practical, aspirational yet achievable, and evidence-based statements regarding optimal clinical care, which can be used in combination with the associated quality measures to stimulate and evaluate clinical quality improvement over time

Adapted from: National Institute of Health and Care Excellence [NICE] (10)
Institute of Healthcare Improvement [IHI] (19)

Structure of Clinical Quality Standards

A review of QS available in SA and internationally was conducted to identify the most crucial structural components of a QS (summary of the findings is presented in Appendix 2). These components were considered with respect to the South African context, and the proposed structure for QS in SA is presented in Figure 1.

Figure 1: Proposed structure of SA clinical QS

Quality Statement	• Describe high-priority, cost-effective areas for quality improvement, in a clear and concise manner • Should include: what trying to achieve, for whom, how much, by when, compared to what.
Quality Measure	• Quantitative measures of care quality or service provision specified in the statement • Can consist of structure, process and/or outcome measures
Rational for inclusion	• Description of why certain aspects of quality are selected. E.g. significant clinical variations or access to services.
Meaning for different stakeholders	• Describe how QS can be used by different stakeholder groups, including (1) patients and the public (2) HCPs (3) service providers (e.g. hospitals) (4) funders (5) policy makers
Supporting evidence / guidance	• Present all sources of evidence and data used in development of QS
Data sources for quality measures	• Guidance on type of data sources to use for quality measurements
Definitions	• Define key terms used in the quality statement

Each clinical QS topic will consist of 5-10 quality statements (with its associated components) that describe the key aspects of care a patient should be offered (18,20,21).

A budget impact analysis (BIA) for a set of QS will also be developed in addition to the QS themselves, which will provide decision-makers with the estimated costs of implementing the changes required to achieve the QS, and the potential savings due to its use.

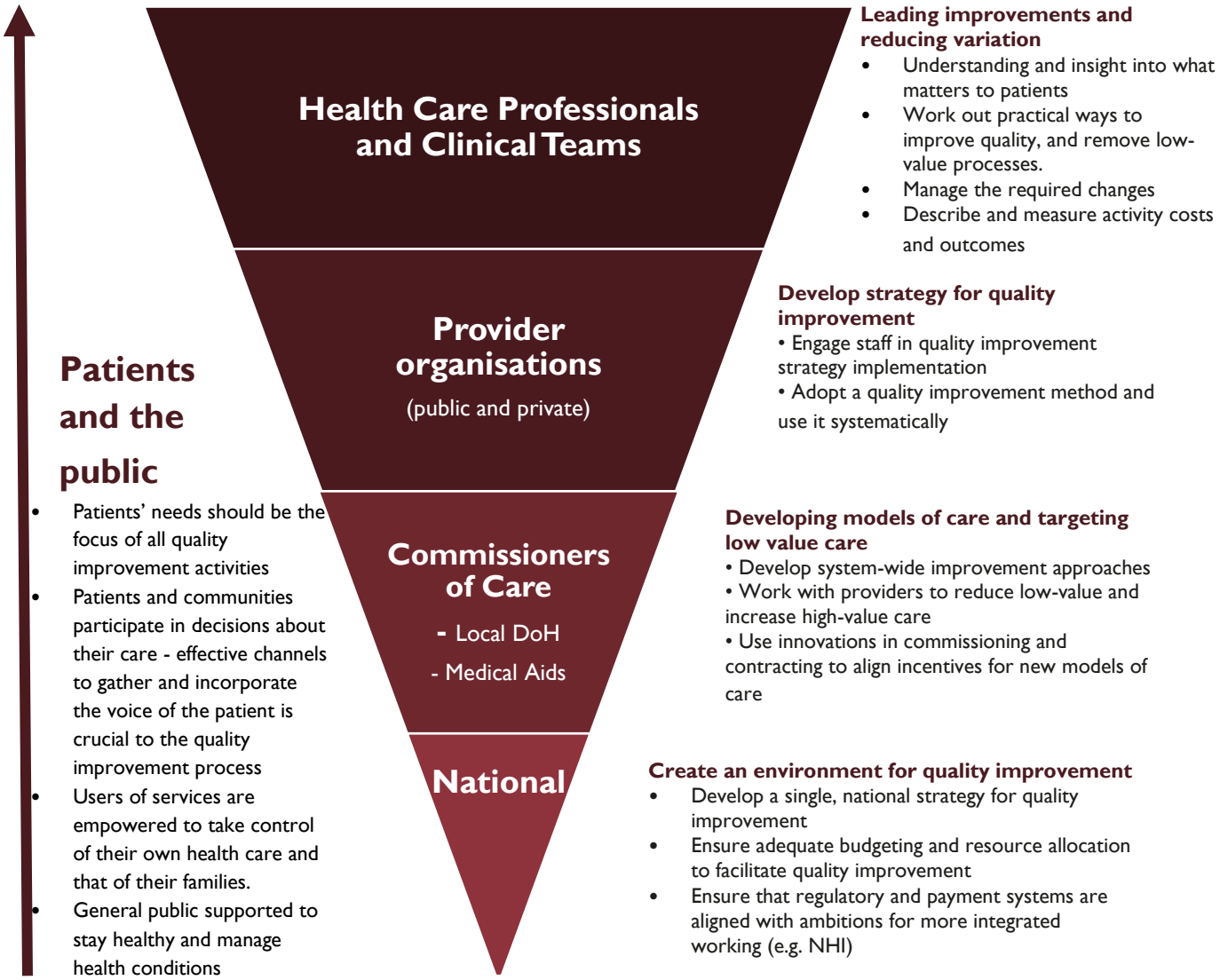
4. QS Development Process

Learnings from South African and international organisations and initiatives involved in the development of QS have been utilised in the development of this framework. The work of the organisations/initiatives were not all specifically focused on developing clinical standards, so some of the information was adapted to make it more appropriate to clinical decision-making and/or practice.

WHO SHOULD BE INVOLVED IN DEVELOPING QUALITY STANDARDS?

The successful implementation and use of quality standards relies heavily on the multi-disciplinary, multi-stakeholder approach to its development. Figure 2 (adapted from the *Agenda for Action* framework developed by the Kings Fund (22) with information included from *The Policy for Quality in Health Care in South Africa* (23) and the *Quality Improvement Guide* (4)) illustrates the vital role the different stakeholders in health care play in ensuring that high-quality health care is delivered.

Figure 2: Role of different stakeholders in the quality improvement process (4,20,22,23)



The different types of stakeholders presented in Figure 2 will each view the opportunities and complexities of quality improvement in health care through a unique lens and contribute to the success of quality improvement initiatives in different ways. Engaging the right stakeholders at the right times to receive the right type of input will offer a quality improvement initiative its best chance of success (24), and in the case of QS ensure they are relevant and fit for purpose.

Stakeholder input in the development of QS can be achieved by engaging stakeholders through different means (18,25):

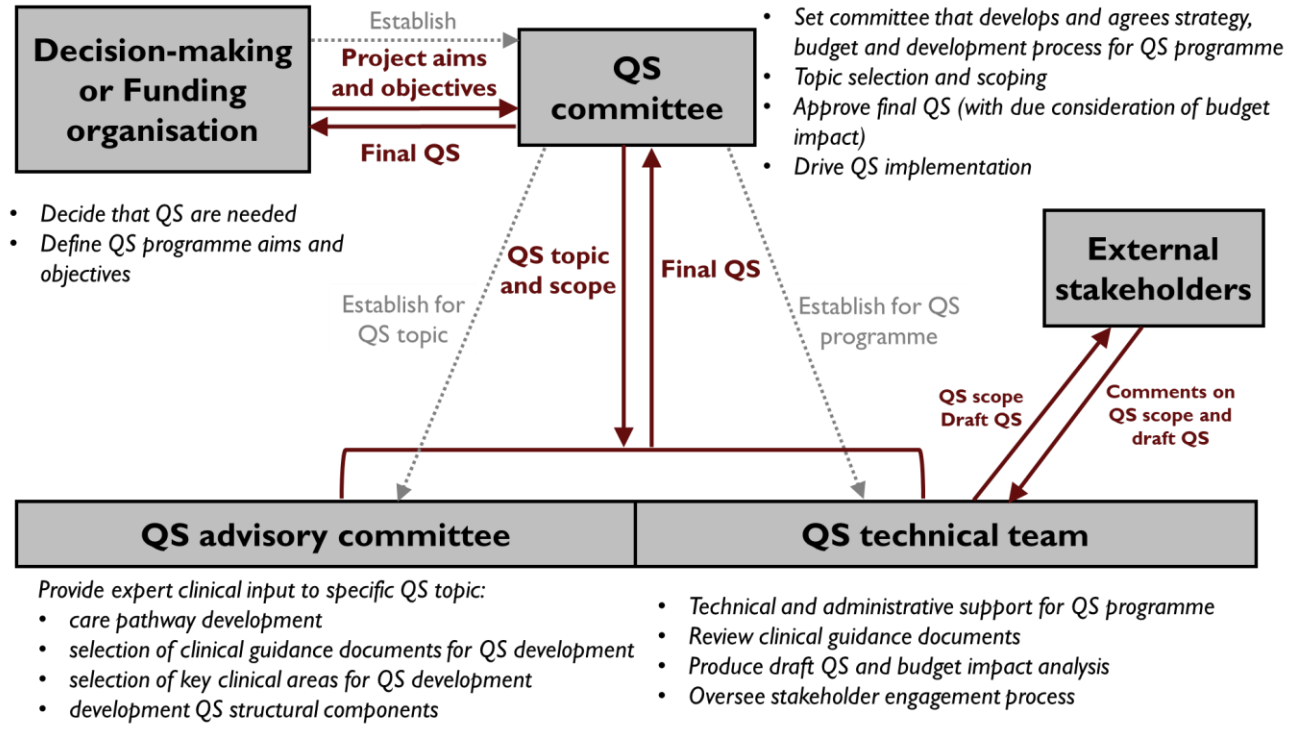
1. Representation on QS development teams or committees, including:
    - QS committee;
    - QS advisory committee; and/or
    - QS technical team
2. Targeted consultation with specific stakeholders (with technical and clinical expertise)
3. Public consultation (include patients, carers, public).

The respective roles of these groups in the QS development process are outlined in Table 2 and the links between the groups are presented in Figure 3.

Table 2: Groups involved in QS development and their respective roles (18,20,25,26)

	Composition	Roles and responsibilities in QS development process
Decision-making organisation	• Organisation funding or requesting the development of QS e.g. policymaker (DoH), regulator (OHSC), commissioner or funder (medical aids), Non-Governmental Organisation (NGO).	• Conduct a situational analysis to determine need for QS • Convene QS committee • Define QS programme aims and objectives
QS committee	• Decision-making committee convened by the decision-making organisation • A set group overseeing QS programme • Ideally, membership will include policymakers, health insurers, professional societies, health care providers, health economists, and service users	• Develop and agree the overall strategy and budget arrangements for the QS development programme, and processes that will be followed. • Select and scope topics for QS development • Approve final QS (with due consideration of budget impact and resource allocation) • Oversee and drive implementation of QS • Review/initiate update of QS
QS advisory committee	• 15-20 people convened for a specific QS topic • Independent group of topic matter experts – include practicing HCPs (primary care and hospitals) from a range of disciplines (medical doctors, nurses, pharmacists, and other relevant allied health professionals), and service users (patients and carers). • Will include some members of the QS technical team	• Support strategic direction of the work in specific topic area • Identify relevant evidence sources for QS development • Discuss and select clinical recommendations to be developed into QS • Review and finalise the draft QS and budget impact analysis
QS technical team	• A set group that supports the whole QS programme (not only individual clinical topics) • Will ideally include a range of technical skillsets such as: e.g. evidence-based medicine, health economics, clinical audit, quality improvement and implementation, impact evaluation and administrative (e.g. project management)	• Provide technical and administrative support to the QS committee and QS advisory committee • Draft QS and present to the QS advisory committee • Conduct budget impact analysis and present to QS committee
Technical and clinical experts	• Experts not included in QS committee or QS advisory committee, that are approached to provide input for a specific QS topic. • Includes recognised experts and stakeholders in relevant fields, including HCPs, industry, patient groups, hospitals, funders, universities, professional societies	• Review the QS agreed by the QS advisory committee • Endorse and support dissemination the QS
Public	• Public, including patients and carers • Engaged online, through workshops etc.	• Contribute to QS topic scoping process • Review the QS agreed by the QS advisory committee • Use QS to better understand the care they can expect

Figure 3. Links between groups or stakeholders involved in QS development (18,20,27)



Adapted from QS Process Guide by NICE International (23)

FIVE STEPS TO QUALITY STANDARD DEVELOPMENT AND USE

A five-step framework to QS development has been developed to describe the components and considerations that form part of the QS development process (see Figure 4). The structure and content of the framework was informed by the five-step improvement approach proposed by NHS Improving Quality (24), the approach to monitoring and evaluation suggested in *Delivery Agreement for Outcome 2: A long and healthy life for all South Africans* (12), and *Principles for Developing Clinical Quality Standards in Low and Middle Income Countries* (18).

Figure 4: Five-step framework to QS development (12,18,24)

The activities related to each step are presented in Table 3, with an indication of the group or committee that will be responsible for overseeing those actions. A schematic presentation of these activities is provided in Appendix 3.

Table 3: Five-step framework to QS development (12,18,20,24)

Step in process		Description of stage	Activities	Responsibility
1	Preparation	Planning stage that includes the activities required prior to start of QS development	1. Conduct situational analysis 2. Define QS programme aims and objectives 3. Convene QS committee	Decision-making or funding organisation
			4. Develop and agree the overall strategy and budget arrangements for the QS development programme, and processes that will be followed. 5. Establish the QS technical team 6. Agree the structure and terms of reference for the QS advisory committee	QS committee
2	Initiation	Official start of the project Scoping and defining the project.	1. Select condition or health care practice for QS development (topic selection) 2. Establish QS advisory committee(s) for selected topic(s) 3. Identify and select clinical evidence base 4. Topic scoping 5. Understanding the clinical pathway and processes	QS committee and QS advisory committee, supported by QS technical team
3	Development	Review of evidence and QS development	1. Review source documents / evidence base	QS technical team
			2. Agree clinical areas for QS development and corresponding draft quality statements	QS advisory committee, supported by QS technical team
			3. Produce quality measures and other QS components	QS technical team
			4. Undertake budget impact analysis and review relevant cost considerations	QS technical team
			5. Agree draft QS (quality statements, measures and other components)	QS advisory committee
			6. Stakeholder consultation (selected experts or public)	External consultation
			7. Agree final QS	QS advisory committee
			8. Approve final QS (with due consideration of budget impact and resource implications)	QS committee
			9. Review/update	QS committee supported by QS technical team
4	Implementation	Implementation of QS	1. PDSA cycle 2. Training and education	QS committee supported by QS technical team
5	Evaluation	Evaluation of QS	1. Monitoring framework 2. Economic evaluation	Local health care team

STEP 1 : Preparation

Situational analysis

Prior to initiating a QS development programme, the need for new or revised QS must be established by the decision-making organisation that will be driving the work (DoH, regulatory, medical aid, or international aid organisation). Key factors that could be considered in this analysis include (25,27):

- Developing trends relevant to the specific health care area
- Recommendations from national committees, subject matter experts, and service users (patients, carers and family)
- Needs identified from service delivery and patient outcome evaluations, or health care providers themselves
- Cost/benefit of developing QS to all relevant stakeholders (developers, implementers, users, patients).

If the situational analysis indicate that the use of QS will be an appropriate approach to addressing the needs identified, a QS committee should be convened to oversee and drive the QS programme. The decision-making body must provide the QS committee with clear aims and objectives for the QS development (25).

Convene QS committee

A QS committee, located in a relevant department of the decision-making organisation or in an independent agency commissioned to run the QS programme on behalf of the decision-maker (18), should be established as soon as the need for a QS programme is determined. Ideally, QS committee membership will include a broad range of representatives, including policymakers, health insurers, professional societies, health care providers, health economists, as well as service users and patients.

In this preparation stage, the QS committee should perform the following vital functions:

1. Develop and agree the strategy and budget for QS development, with consideration of:
    - the aims and objectives provided by the decision-making body;
    - available resources; and
    - the 5-step framework to QS development (as presented in this QS framework).
2. Develop and agree the processes that will be followed for QS topic selection, scoping, development, approval, implementation and evaluation.
3. Establish the QS technical team
4. Agree the structure and terms of reference for the QS advisory committee(s) (18).

STEP 2 : Initiation

In the initiation stage, background work that will inform the QS content and evidence base is started.

Topic selection

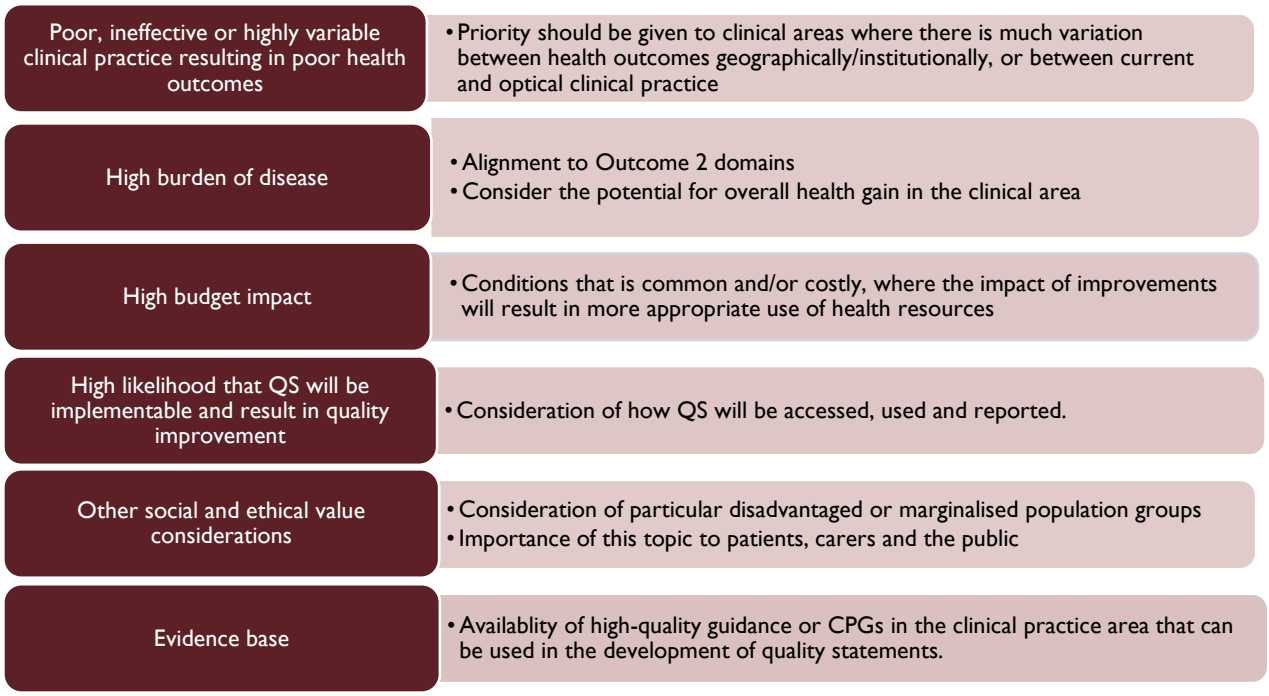
The selection of the condition, clinical area or health care practice for QS development will be led by the QS committee (if this has not been determined already by the decision-making or funding organisation). The main aim of this stage in the process is to ensure that topics with the greatest potential to impact health outcomes are selected for QS development.

The *Policy for Quality in Health Care in South Africa* (2007) suggests that the following criteria should be used to prioritise and select quality improvement topics (23):

- Conditions where most improvement can occur, with the greatest impact on:
    - reducing the burden of disease and mortality, and
    - improving patients' quality of life and their ability to function.
- Conditions where there is wide variation in service quality and outcomes
- Conditions that is common and/or costly, where the impact of improvements will result in better health of the population and more appropriate use of health resources.

These criteria have been combined with the topic selection criteria used by other QS developing organisations (NICE, Health Quality Ontario, Australian Commission on Safety and Quality in Health Care) to produce the QS topic selection criteria presented in Figure 5. These criteria should ideally be used by the QS committee as part of the topic selection process.

Figure 5: QS topic selection criteria (18,20,27)



Some of the topic selection criteria presented in Figure 5 can also be used later in the QS development process to identify the specific clinical recommendations that will be developed into QS.

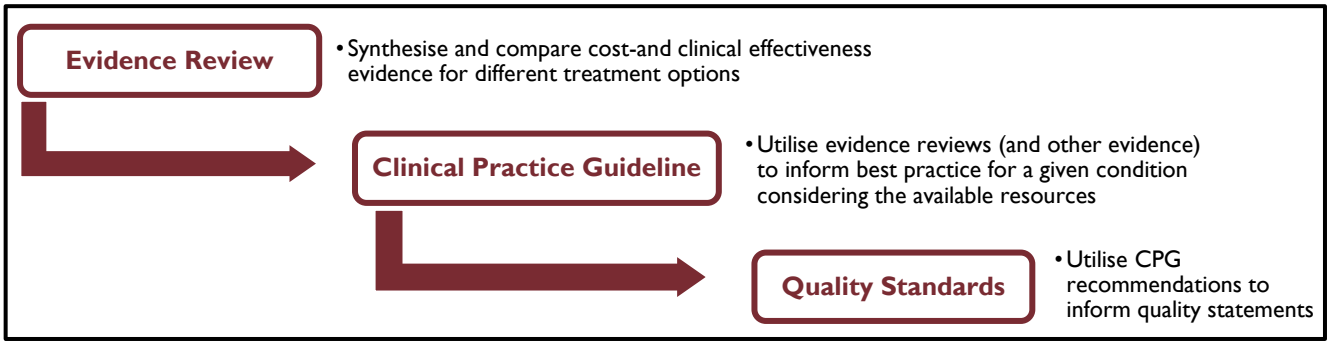
Once the QS topic has been selected, recruitment of the QS advisory committee should commence. Depending on the plan and strategy for QS development, the QS advisory committee could be convened for the development of a specific QS topic only. Alternatively, standing and specialist members for the QS advisory committee may be recruited, with standing members continuing to serve on the committee in future QS developments, and specialist members only appointed for the duration of the development of the specific set of QS. All members of the QS advisory committee should however be viewed as full members of the committee for the duration of the QS development (10).

Identification of clinical evidence base

A key principle of QS is that they are based on evidence-informed clinical recommendations (20,27,28). Specialist members of the QS advisory committee will be best placed to identify and select the source documents/evidence that should be used by the QS technical team when developing the QS (if this has not been determined already). Limiting the evidence sources to only those most relevant to local clinical practice will reduce the burden of work, but also make the QS more applicable to the local context, and thereby easing implementation (18). A literature search to identify additional guidance sources should however be conducted to ensure all relevant information is considered (27). It is important that the evidence sources selected are considered of acceptable quality by the decision-making organisation, as the recommendations made in those guidance documents will form the basis for the QS.

High-quality CPGs (developed through a systematic review of the best available evidence) are good evidence sources for QS development (18,25). The relationship between evidence reviews, CPGs and QS is illustrated in Figure 6 (adapted from *Principles for Developing Clinical Quality Standards in Low and Middle Income Countries* (18))

Figure 6: Relationship between Evidence Review, CPG and QS



Other evidence sources could include recommendations from WHO and other national/international professional organisations (25).

Topic scoping

The QS committee (with support from the QS technical team) develops the draft scope for the QS topic selected (18). The scope should be clearly defined in terms of (18,25,27)

- the type of health or social care organisation and populations they will be applicable to
- whether they are designed for use by the whole organisation or a specific service
- the range of services/interventions that will be covered
- evidence that will be used for QS development

The draft QS scope should then be consulted on with the QS advisory committee (if already in place) and relevant stakeholders (which could include the general public) to ensure the QS content will be relevant and fit for purpose.

The final scope of the QS could be summarised in a 'topic brief', which will provide background information and guidance to the QS advisory committee and technical team that will develop the QS (27,28).

Understanding the clinical pathway and processes

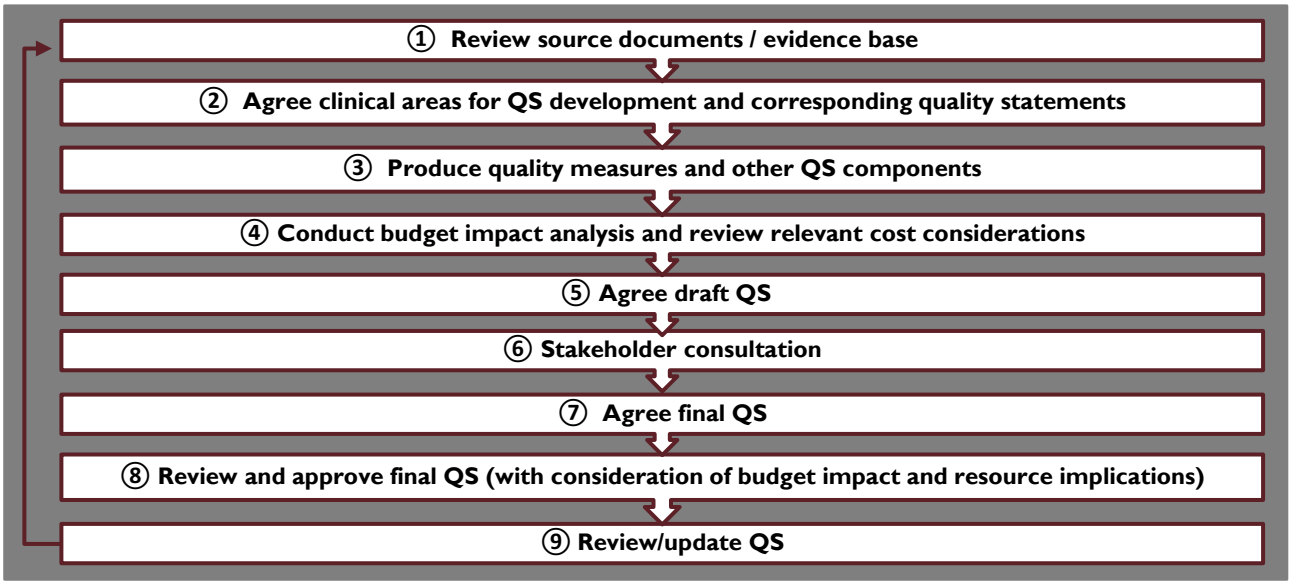
Once the QS topic area has been selected and the scope defined, it is important that all parties contributing to the QS development process have a good understanding of the relevant care pathway from beginning to end. Clearly identifying the point(s) in the care pathway where QS will be applicable will improve understanding of the health outcomes that can be expected when the QS are implemented.

Developing or using a 'map' of a care pathway can be useful when looking strategically at the care processes and stakeholders involved. Care pathway mapping can be conducted by the QS technical team, but should be reviewed by the QS advisory committee if it is to be used formally in the QS development process.

STEP 3 : Development

The development of the QS will take place in several stages. An overview of this process is provided in Figure 7.

Figure 7: Schematic overview of QS development stage



3.1 Review source documents / evidence base

The QS technical team critically appraise (using internationally recognised tools like the Appraisal of Guidelines for Research and Evaluation [AGREE] II tool (29)) and review the evidence sources recommended by the QS advisory group.

A search for QS developed locally and internationally in the selected topic areas can also be conducted. It is unlikely that QS developed outside of SA will be directly suitable for the local context, so careful consideration to its use will be required.

The relationship of the QS in development to any other national/local quality standards identified, as well as any relevant policies or legislation, should also be considered at this stage in the process (25,27).

Additional information to collect include (27):

- existing performance indicators and datasets available to monitor/evaluate the selected clinical area,
- evidence on the particular types of interventions that is considered, and
- any specific information relevant to the population whose needs will be addressed by the QS.

The QS technical team use this information (with consideration of the agreed scope for the QS [see section 2.2] and the prioritisation criteria [see section 2.1]) to identify and prioritise CPG recommendations that can be used for QS development. Alternatively, QS advisory committee members may be asked to identify 5-10 clinical recommendations they consider of high potential for quality improvement in the topic area selected (27), and their responses are then used by the QS technical team to prioritise recommendations for QS development.

The quality statements derived from the prioritised recommendations can also be formulated at this stage. Each quality statement should specify only one requirement for high-quality care or service provision (for

example, a single intervention, action or event) except if two actions are closely linked (e.g. treatment type depend on outcome of assessment) (18,27). The wording of the quality statements should be clear and unambiguous, describing what is required, by whom, and in what situation. Words that require subjective interpretation (e.g. adequate, good, well or sufficient) are best avoided, and QS should be written in declarative form (not using words like should or will) (25,27).

3.2 Agree clinical areas for QS development and draft quality statements

The QS technical team present the prioritised recommendations to the QS advisory committee at their first meeting, along with the rationale for selecting the recommendations, and the evidence sources used in the process (10,27). The QS advisory committee discuss and select the 5-10 most relevant recommendations for QS development based on the topic prioritisation criteria listed in section 2.1. If the corresponding quality statements for the recommendations are available they should also be discussed and agreed, but only once the recommendations for QS development has been determined.

3.3 Produce quality measures and other components

Once the quality statements have been agreed, the quality measures and the other components of the QS can be developed (18).

Quality measures are quantitative measures of the care quality or service provision specified in the quality statement, and can be used to assess and drive improvement by setting the expected degree of achievement and evaluating clinical quality improvement over time (18,19). Structural, process and/or outcome measures can be developed (18,27).

Structural measures are visible and measurable, and assess the necessary practical arrangements or resources that influence and enable the implementation of the quality standard e.g. display of flowcharts on the walls of the delivery ward, existence of teams or protocols (18,27). These measures are binary or categorical, so don't require the definition of a numerator and denominator. Structural indicators should only be developed for quality statements if it is supported by strong evidence or clear expert consensus (27).

Process measures assess the activities involved in providing high-quality care. They measure the proportion of a (specific) population that received a particular intervention or for which an activity is performed, and is specified in the form of a numerator and a denominator (numerator/denominator) (18,27). The numerator should specify the timeframe in which the activity is to be performed (27).

Outcome measures assess the end results, and are also specified as a proportion (same format as process measures). However, outcome measures should only be developed if they are easily measurable and attributable to the intervention suggested in the quality statement (18). Factors to consider when developing outcome measures include its relevance to patients, clinicians, funders, the strength of the outcome's association with the quality statements, and the balance of the outcome measures in relation to the different domains of quality (clinical effectiveness, cost-effectiveness, patient safety, and patient experience). Outcome measures include mortality rates and patients' experience of care (27). An example of a quality standard developed for use in Kerala, India is provided in Appendix 4.

It is important that the data used when calculating process and outcome measures is of good quality, and it should ideally be collected and documented using standardised processes across health care organisations. This will enable comparisons between organisations, and integration of the data when required. Therefore, an

important consideration at this stage is the feasibility of collecting the required data, the limitations of the measures, and the approach that will be followed in the implementation and evaluation stages (27).

Other QS components developed by the QS technical team are the rationale for including a specific quality statement, the meaning of the QS to different stakeholders, the supporting evidence utilised in the development of the QS, and definitions of terms used in the quality statement (as presented in Figure 1).

3.4 Conduct budget impact analysis and review relevant cost considerations

The technical team initiate work on the budget impact analysis (BIA), focussed on a national level. The BIA will identify cost drivers, estimate the costs of implementing the changes required to achieve the QS (i.e. the upfront investment required), and highlight potential savings due to the use of QS. This will provide context to the QS committee when they are approving the QS, as well as health care organisations involved in the local implementation of the standards.

To conduct the analysis, a range of costs related to current clinical practice, together with data on epidemiology, patient numbers, current infrastructure and capacity, and clinical outcomes where relevant to costing (such as length of stay) will be required.

Provinces and local health care organisations will need to apply the BIA using locally relevant estimates to generate local estimates of the budget impact at provincial and the individual health facility level (18).

3.4 Agree draft QS (quality statements, measures and other components)

The draft QS, which includes the quality statement, measure(s) and other QS components, and BIA are presented to the QS advisory committee for review (at a meeting or online). The wording of the statements or other components might be adjusted based on the discussion, but as the quality statements have been agreed already, these changes should be minimal. The BIA should also be updated based on the comments, if required.

Once the QS advisory committee reached consensus on the content of the QS, the QS can be sent out for consultation.

3.5 Stakeholder consultation

Interested parties that have not been involved in the QS development up to this point should be invited to comment on the draft QS agreed by the QS advisory committee (18). The QS committee should decide if the consultation will be limited to technical and clinical experts or organisations, or if the public will also be invited to comment. This external consultation will validate if the QS are clear and unambiguous, and provide feedback on the feasibility of the implementation of the QS in clinical practice. This engagement activity will also stimulate interest (and potentially buy-in) from health care organisations, which will be essential for successful implementation of the QS later on (24).

The QS technical team will collate feedback from the consultation and make the required changes, before presenting it to the QS advisory committee (18,20).

3.6 Agree final QS

The QS advisory committee review the stakeholder comments and updated QS, and agree the required changes or refinements to the QS. The final QS are now ready for QS committee review and approval.

3.7 Approve final QS (with consideration of budget impact and resource implications)

The final QS, as agreed by the QS advisory committee, with the updated BIA, are presented to the QS committee who review the documents and make the decision to approve it or not (18,25).

The QS committee's trust in the QS development process and the evidence sources used in the production of the QS will influence the ease with which decisions are made. Factors like patient experience, safety, equality and economic implications of implementing the QS (as presented in the budget impact analysis) should be considered as part of the decision-making process (9). If QS committee members have conflicting opinions regarding the QS content, additional meetings/workshops may be required to reach consensus (18).

Once the QS committee approved the QS, the implementation of the QS should be adequately budgeted for with a view to optimise resources for maximum benefits. With limited health budgets, careful planning is vital to ensure that the right resources are available to ensure the successful implementation of the QS.

The QS can then be disseminated through appropriate channels as agreed by the decision-making body who initiated the QS development and the QS committee (18).

3.8 Review / update of QS

QS are based on the best and most up-to date evidence available. Therefore, they need to be updated regularly to ensure they stay current and relevant to clinical practice (27). The QS committee should review the QS content every two years and determine if an update is necessary.

STEP 4 : Implementation

The Plan, Do, Study, Act (PDSA) approach is used by many quality improvement organisations to assess the impact of QS on a small scale prior to wholesale implementation (4,19,30,31). Using this approach is highly recommended for QS in South Africa, as it will verify if the standards are fit for purpose and meet the needs in the targeted clinical settings, while ensuring that patient care and safety are not compromised (25,32,33). Local health facilities who can act as pilot sites could be identified by (specialist) members of the QS advisory committee, who would be expected to champion the use of the QS in clinical practice.

The PDSA cycle for Learning and Improvement produced by the Institute for Healthcare Improvement (IHI) (19) is presented in Figure 8, along with the three questions to ask before implementing a change programme (like QS).

Figure 8: PDSA Cycle for Learning and Improvement (19)

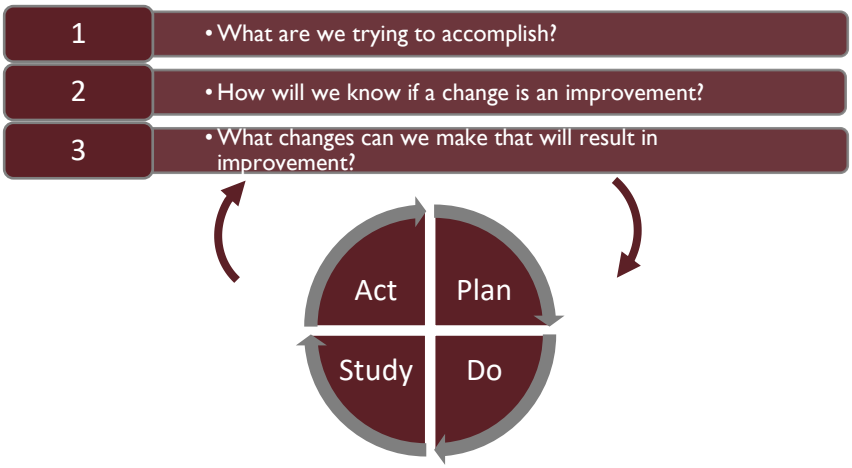


Table 6 outlines a proposed approach to using the PDSA cycle in the QS implementation process.

Table 6: PDSA cycle in QS implementation

	Stage overview	Main activities	Responsibility
Plan (18,24)	QS developed/updated. Plan the QS testing	1. Ensure QS ready for implementation / testing, and that adequate budget and resources for implementation are available 2. Define objectives for the testing phase 3. Plan testing stage: - Setting (identify and agree appropriate QS implementation pilot sites) - Stakeholders involved - Data collection - Timeline - Communication plan	QS committee oversee local implementation teams (supported by QS technical team)
Do (24,25)	Testing the change for a specific time on a small scale	1. Train health care staff to use QS and comply with data collection requirements	QS technical team
		2. Use QS in clinical practice 3. Collect relevant data	Health care team at pilot site
Study (17,24,25)	Study/evaluate the results	1. Analyse data collected 2. Discuss with peers: - Experience of using QS (positive and negative) - Outcomes - How QS could be improved 3. Findings documented and reported to QS technical team	Health care staff at pilot site (supported by QS technical team)
Act (25)	Act on the results and make required changes	1. The outcomes and recommendations from the 'study' stage are used to adjust QS (if required)	QS technical team
		2. If substantial changes are required, the QS development process might need to start again, as would be the case if a QS is reviewed or updated (see Figure 6) 3. If slight changes are required, an online review of the updated QS can be conducted, and the final QS agreed	QS technical team QS advisory committee QS committee
		4. Final QS is approved	QS committee

The PDSA cycle should be repeated until the QS is considered fit for purpose and ready for wholesale implementation by the decision-makers.

Ideally, a national QS programme will be in place to coordinate and guide the implementation of QS, as well as the evaluation of their impact on health care quality. However, in the absence of such a national programme, QS implementation and evaluation activities will need to be locally driven by health care teams. This process will require local leadership and a shared sense of purpose between management and the staff that will be using the QS (4,25). Presenting QS to users in a clear and simple manner will make it easier for organisations to use (25), and some QS developing organisations develop toolkits to support implementation (27,28).

Data management

A data management plan should be developed in the planning stage of the PDSA cycle. A data plan provides clarity to the data collection and measurement process in the 'do' stage, and should include information on:

- What you are trying to measure (quality statement)
- What data you require to answer the question (quality measure)
- Where will you get this data from (data sources – could be routine data collected or might require manual data collection)
- Who will collect the data?
- How often will the data be collected?
- Data analysis plan (including who will be responsible for analysing the data and when)

Some organisations involved in the development of quality standards or quality improvement initiatives include a data management plan/tool with their offering. E.g. *Best Care… Always!* propose the use of the IHI Extranet for data collection purposes. The IHI extranet is a web-based application that allows teams to collaborate on projects from different geographical locations, by creating a team home page with team members, roles and responsibilities, data, graphs and other information for reports (34). Another example is the COHSASA Quality Information System (CoQIS), which supports the COHSASA accreditation process by helping clients to 'prioritize identified deficiencies and manage and monitor health quality improvement projects until substantial compliance with standards is reached' (35).

STEP 5: Evaluation

As suggested above, ideally there would be a national QS programme team responsible for evaluating the impact of the QS (economic evaluation). National thresholds or targets for compliance with the QS could be determined or suggested, but ultimately local teams will be responsible for monitoring how well they implement the care described in the quality statement (20) by assessing and comparing their own performance over time.

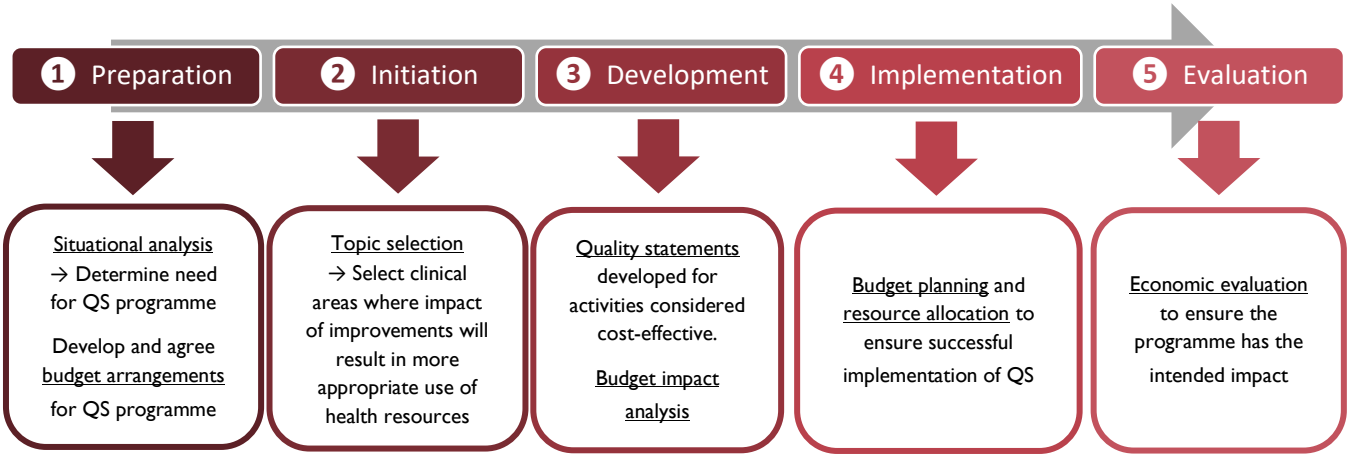
The QS implementation toolkit could include a monitoring framework to support local teams to plan their improvement by selecting results and targets.

5. Financial and Economic Considerations in Quality Standard Programme

Financial and economic considerations should be taken into account in the development and implementation of QS to ensure their use are appropriate, the content relevant, implementation is possible, and the programme has the intended impact on health outcomes.

Figure 9 provides a summary of how financial and economic considerations are taken into account in QS development and implementation in the 5-step process described in more detail in previous sections.

Figure 9: Financial and economic considerations in QS development and implementation



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Appendix 1: Organisations involved in formal quality improvement or implementation initiatives in South Africa and internationally

Name	Quality improvement / implementation activities	Website
SOUTH AFRICA		
Office of Health Standards Compliance (OHSC) (6,36)	• National inspectorate of health establishments was set up within the DoH in 2011 • Responsible for carrying out inspections of health establishments (in public and private sector) to determine if they meet National Core Standards of health care (as per regulations). • National Core Standards are basic requirements for quality and safe care that reflect the level of performance that is expected and required from health establishments. • 7 domains: (1) Patient rights (2) Patient safety, clinical governance and clinical care (3) Clinical Support Services (4) Public Health (5) Leadership and Governance, (6) Operational Management and (7) Facilities and Infrastructure	http://www.ohsc.org.za/
The Council for Health Service Accreditation of Southern Africa (COHSASA) (6,32,37)	• Established in 1995 and based in Pineland, SA • Assists health care facilities to meet and maintain pre-defined standards for safety and quality. • Builds capacity in local organisations so that they can take ownership of the quality improvement programme. • COHSASA's Standards for Hospitals (Version 6.7) have been accredited by the International Society for Quality in Health Care (ISQua). Standards are devised according to a set of principles developed by ISQua. • Clinical standards are one of the five types of standards developed by COHSASA. • During the accreditation survey process, each standard is reviewed and assigned a criterion based on the degree to which the standard has been met (compliant, partially compliant, non-compliant) • Performance against standards are rated as (1) Good, (2) Acceptable, (3) Poor – requires quality improvement, or (4) Weak – requires upgrading. • COHSASA has also worked in Botswana, Lesotho, Swaziland, Namibia, Rwanda, Tanzania and Nigeria • Is one of the founding partners of SafeCare Initiative	http://www.cohsasa.co.za/
Best Care Always! (BCA) (38)	• Campaign launched in 2009 • Focused on infection prevention and antibiotic stewardship • Multi-agency, cross-sectoral collaboration – partners include medical aids, private hospitals, provincial departments of health, and professional societies. • Under the BCA model, participating hospitals set their own specific, measurable improvement goals.	http://www.bestcare.org.za
The Aurum Institute (31)	• Formed in 2005 in SA • African public-benefit organisation focussed on TB and HIV. • Projects active in 9 provinces • Provides support for "continuous quality improvement through the development of a culture and organisational processes that enable and support its application" (31) • Developed a "How To" guide/tool for quality improvement – support organisations to develop their own health care standards.	http://www.auruminstitute.org/index.php

Appendix 1: Organisations involved in formal quality improvement or implementation initiatives in South Africa and internationally (continued)

Name	Quality improvement / implementation activities	Website
SOUTH AFRICA		
Institute for Healthcare Improvement (IHI) (39)	• Independent, not-for-profit organisation founded in 1991 in the United States (US) • Provides support for design and execution of specific health systems improvement projects, strategic advising for program leadership, capacity building for quality improvement, and expertise in analysis and dissemination of results. • IHI publish successful quality improvement change protocols and guidelines (produced by supported organisations) on IHI.org for others to use or adapt in their own organisations. • Involved in MNCH quality improvement initiatives in Ethiopia, Malawi and Ghana. • Partners include 20 000 + Partnership, The Aurum Institute, Best Care Always!	http://www.ihi.org/Pages/default.aspx
INTERNATIONAL		
National Institute for Health and Care Excellence (NICE) (10,18,28,40,41)	• NICE established in 1999 in England • First quality standard (QS) published in June 2010. • QS are developed through a systematic, consultative process that includes topic selection, standard development, consultation, publication, and implementation stages. • QS developed for high-priority areas for quality improvement, but do not provide a comprehensive service specification • Use and implementation of QS are not compulsory, but are used as an CPG implementation and quality improvement tool. • NICE QS provide a mechanism for the Department of Health and other National Health Service (NHS) institutions such as the Care Quality Commission (CQC) to drive quality improvement initiatives like the Quality and Outcomes Framework (annual, voluntary payment for performance incentive scheme that rewards general practitioners for improving care) and clinical inspection/audit. • QS empower patients by giving them the tools to demand appropriate level of quality care from the NHS. • NICE International adapted the NICE QS Process Guide for use in low and middle-income countries. NICE International worked with policy-makers and clinicians in Kerala (India) and Vietnam to develop quality standards for improving maternal care and stroke management, respectively. NICE International changed its name to Global Health Development (GHD) and now based at Imperial College, London.	https://www.nice.org.uk/standards-and-indicators
SafeCare Initiative (6,42)	• Founded in 2010 by PharmAccess Foundation (The Netherlands), the Joint Commission International (US), and COHSASA (SA). • "Support basic health care providers in resource-restricted settings to go through stepwise structured safety and quality improvement programs, according to internationally recognised standards"(42). • SafeCare standards version 3.1 has been accredited by ISQua • Operational in Kenya, Tanzania, Ghana and Nigeria and plans to extend operations to the rest of Africa.	http://www.safe-care.org/index.php?page=standards

Appendix 1: Organisations involved in formal quality improvement or implementation initiatives in South Africa and internationally (continued)

Name	Quality improvement / implementation activities	Website
INTERNATIONAL		
International Society for Quality in Health Care (ISQua) (43)	• Initially established in 1995 in Australia, but now based in Ireland • Not-for-profit, independent, health care quality organisation with members and contacts in over 100 countries • Responsible for assessing and accrediting the standards of organisations who set the benchmarks in health care safety and quality.	http://www.isqua.org/accreditation-iap/our-programmes#Standards
The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) (44)	• Established in 1951 and based in US • An independent, not-for-profit organisation that accredits and certifies health care organisations and programs in the US to meeting certain performance standards.	https://www.jointcommission.org/standards_information/standards.aspx
National Quality Measures Clearinghouse (NQMC) (45)	• The Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse is a public resource for summaries of evidence-based quality measures and measure sets.	https://www.qualitymeasures.ahrq.gov/
Health and Human Services (HHS) Measures Inventory (46)	• Repository of measures in use or in development by the agencies of the U.S. Department of Health and Human Services (HHS) for quality measurement, improvement, and reporting. • Hosted by National Quality Measures Clearinghouse (NQMC)	https://www.qualitymeasures.ahrq.gov/hhs/index.aspx
Health Quality Ontario (21,27)	• A provincial advisor on the quality of health care in Ontario (Canada) • Develops quality standards, based on (or in line with) CPGs and protocols.	http://www.hqontario.ca/portals/0/documents/evidence/quality-standards/qs-process-guide-1610-en.pdf
National Quality Forum (NQF) (47,48)	• Not-for-profit, nonpartisan, membership-based, voluntary consensus-standards setting organisation. • Established in 1999 in US after the *President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry* concluded that an organization like NQF was needed to promote and ensure patient protections and health care quality through measurement and public reporting. • Health care measures are submitted to NQF for evaluation and endorsement. • NQF approved measures are used by US federal government and many private sector organisations • Contains a repository of endorsed measures that are in use	https://www.qualityforum.org/Measures_Reports_Tools.aspx

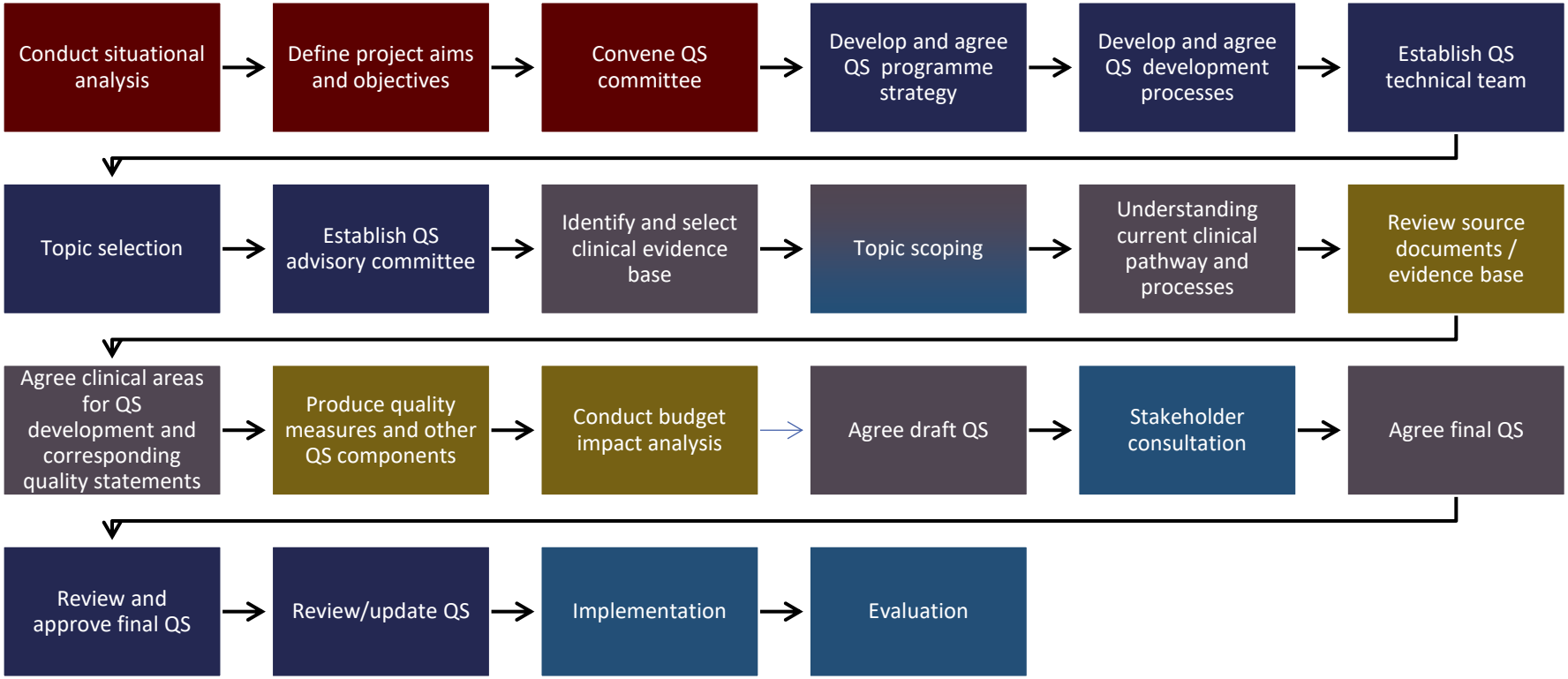
Appendix 1: Organisations involved in formal quality improvement or implementation initiatives in South Africa and internationally (continued)

Name	Quality improvement / implementation activities	Website
INTERNATIONAL		
Australian Commission on Safety and Quality in Health Care (20)	• Established in 2006 by Australian state and territory governments to coordinate national improvements in safety and quality of health care. • Scope of work includes development of Accreditation and National Safety and Quality Health Service (NSQHS) Standards, Clinical Care Standards, and National Standards in Mental Health Services.	https://www.safetyandquality.gov.au/our-work/clinical-care-standards/
Centers for Medicare & Medicaid Services (26,49,50)	• The Centers for Medicare and Medicaid Services created 'Hospital Compare', which contains information about the quality of care provided at over 4,000 Medicare-certified hospitals (including over 130 Veterans Administration [VA] medical centers). • In 2005, the first set of core process measures were displayed. • The main aim of Hospital Compare is to help consumers of health care to make informed decisions. • Data on other areas also available, including nursing homes, physicians, home health, dialysis facilities, hospices, inpatient rehabilitation facilities, long-term care hospitals and medical equipment suppliers. • Standards are developed in line with NQF guidance	https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html# https://data.medicare.gov/
Health Information and Quality Authority (HIQA) (8,51)	• Board was established in 2007 • Is an independent authority, established to drive high-quality and safe health and social care for people in Ireland. • Key function is to develop standards, and inspect and review the standards for health and social care. • Do not include clinical quality standards	https://www.hiqa.ie/areas -we-work/standards-and-quality
Canadian Patient Safety Institute (CPSI) (52)	• Established by Health Canada in 2003 after the National Steering Committee on Patient Safety published a report outlining a national, integrated strategy for improving patient safety in the Canadian health care system, which named establishing the *Canadian Patient Safety Institute* as its number one recommendation. • Works with governments, health organisations, leaders, and health care providers to 'inspire extraordinary improvement in patient safety and quality'(52). • Tools and resources include checklists, frameworks, 'getting started kits', metrics, patient and family resources, presentations, toolkits, reports, research and references to other relevant resources.	http://www.patientsafetyinstitute.ca/en/Pages/default.aspx

Appendix 2: Structural components of QS (findings overview)

QS component	Description	Reference
Quality Statement	Quality statements describe what high-quality care looks like in clinical practice, addressing the critical infra-structural and clinical requirements as well as the desirable/expected outcomes.	(10,20,26,27,32,38,43,51)
Quality Measure	Structural, process and/or outcome measures that accompany each quality statement and can be used to the assess the quality of care or service provision specified in the statement and evaluate clinical quality improvement over time.	(10,20,27,32,38,43,51)
Meaning of QS for different stakeholders	Statements / clarification of what the QS means to different stakeholders, including patients, clinicians and health services.	(10,18,20,27,51)
Rational for inclusion	Explain why the quality statement is important and provides context	(10,18,20,38,43)
Definitions	Definitions of key terms used in the quality statement	(18,20)
Supporting evidence / guidance	Statement regarding the evidence on which the QS is based	(10,18,20,38,43)
Economic evaluations of the health interventions	Statement on economic evidence that was considered as part of the QS development process	(10)
Data collection detail	Information on the suggested frequency and methods for data collection. Might also include a statement on which team(s) or personnel are responsible for data collection and/or analysis.	(21,26,38,43)

Appendix 3: QS development process



Key

	Decision-maker / Funder
	QS committee
	QS advisory committee
	QS technical team
	External stakeholders

Appendix 4: QS for active management of third stage of labour

Quality Statement:
Women who have given birth either vaginally or by caesarean are offered a bolus dose of Oxytocin, Ergometrine or Protaglandin F2 Alfa at the time of delivery of the shoulder or within 1 minute of the delivery of foetus to prevent post-partum haemorrhage and to assist delivery of the placenta.

Quality Measures:
Structure:
a) Evidence of agreed guidelines or protocols in the hospital for the active management of the third stage of labour.
b) Display of flow charts based on agreed guidelines, protocols or clinical pathways in the labour room.
c) Evidence of availability of Oxytocin, Ergometrine and PG F2 Alfa at the place of delivery.
d) Evidence of suitable storage facilities (refrigerator) for the drugs.
e) Evidence of equipment for measuring blood loss.

Example of process measure for vaginal deliveries:
Proportion of women giving birth vaginally who receive the Oxytocin,
Ergometrine or PGF2 Alfa during third stage management of labour during the month (including numerator/denominator indicators).

Example of outcome measure for vaginal deliveries:
Proportion of women who experience an estimated blood loss equal to or more than 500 ml during and or following a vaginal delivery (including numerator/denominator indicators).

Definitions:
Definitions of, e.g., "third stage of labour", "active management of third stage of labour", "Oxytocin".

Explanations of what the QS means for each audience
Service providers, healthcare professionals, payers.

Data Sources
Data collection needs and procedures for the monitoring of the QS implementation (e.g., labour room register, monthly reporting forms to the NHM).

Reference: WHO recommendation
- The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births.
- Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug for the prevention of PPH.
- If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 μg) is recommended.