Regulating the Quality of Health Services: Benchmarking of Approaches, Institutions and Systems

Towards the establishment of an Office of Health Standards Compliance (OHSC)

National Department of Health
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Abbreviations

CMS Council for Medical Schemes
CQC Care Quality Commission
dti Department of Trade and Industry
EWS Early Warning System
FAIS Financial Advisory and Intermediary Services Act
GDP Gross Domestic Product
FSB Financial Services Board
HAS Haute Autorité de Santé
HPCSA Health Professions Council of South Africa
IEC International Electrotechnical Commission
IOM Institute of Medicine
ISO International Standards Organisation
MCC Medicines Control Council
MEC Member of the Executive Council
NCR National Credit Regulator
NCS National Core Standards
NDoH National Department of Health
NDSA Negotiated Service Delivery Agreement
NHC National Health Council
NHI National Health Insurance
NHS National Health Service
NSQHS National Safety and Quality Health Service Standards
OHSC Office of Health Standards Compliance
OSC Office of Standards Compliance
QRP Quality Risk Profiles
SANAS South African National Accreditation System
SANC South African Nursing Council
SAPC South African Pharmacy Council
UK United Kingdom
WHO World Health Organization
Executive Summary

All over the world, the drive towards better health outcomes is a fundamental concern for governments and its citizens alike. Following the Second World War, significant health reforms in the developed countries were driven by the need to ensure universal coverage and better quality of healthcare for citizens. The most significant reforms revolved primarily around the introduction of national health insurance schemes in countries such as the United Kingdom, United States, France, Canada and Australia. While the approach to financing healthcare remains a hotly debated topic around the world, the need for better quality health services is largely uncontested.

South Africa’s healthcare system is characterised by a legacy of racial segregation, reflected in unequal access to health services for the majority of the population; an underfunded and under capacitated public sector responsible for servicing around 85 per cent of the population and a large private healthcare sector funded mainly through medical aid contributions.

In general, the quality of health services in the public sector remains poor and is further exacerbated by understaffed health establishments, poorly maintained infrastructure and equipment, stifling bureaucracy and unethical and unprofessional conduct among healthcare professionals. In contrast, the private sector faces different challenges. Over provisioning of health services has led to rapidly rising costs, real declines in the purchasing power of users of health services and impacts negatively on the quality of care received.

Following the 1994 democratic elections, expanding access to healthcare was among the most important priorities for the newly elected government. This commitment was subsequently embedded in the Constitution, which guarantees everyone the right of access to healthcare services, including reproductive health services. In terms of the Constitution, the state is required to take progressive measures to realise this right of access to healthcare. However, as the South African health system evolved, it became apparent that the progressive realisation of the right of access to health services was inextricably linked to the quality of services offered. Put differently, poor quality health services could undermine access by discouraging communities from using public facilities plagued by long waiting times, unhygienic conditions and rude staff.

Changes to the legislative landscape

Subsequent legislative changes have sought to fulfil this important constitutional obligation. The National Health Act (2003) develops the overarching legislative framework for a structured and uniform national healthcare system. In relation to quality, Section 47 of the Act allows the Minister to prescribe quality standards relating to among others: human resources, health technology, equipment, premises, the delivery of health services, business practices, safety and any matter that influences the way users are accommodated and treated. This section of the Act, therefore, provides the legal basis for a set of national core standards. In addition, Chapter 10 of the Act introduced a quality assurance mechanism through the establishment of the Office of Standards Compliance (OSC). This signalled an explicit move towards regulating the quality of health services in South Africa against prescribed norms and standards.

At the time of the promulgation of the Act in 2003, no clear and common framework existed to measure the quality of health services. Indeed, norms and standards for organisational performance and clinical governance were (and to a certain extent still are) set by a myriad of different government
departments and regulatory agencies. What was required is a set of national norms and standards to measure and benchmark compliance of health facilities, and could subsequently be used as basis for regulation.

The development of a formal set of norms and standards culminated in the adoption and publication of a set of National Core Standards for Health Establishments in 2011. The main purpose of the National Core Standards is to “develop a common definition of quality care which should be found in all health establishments in South Africa, as a guide to the public and to managers and staff at all levels” and “provide a benchmark against which compliance can be measured”.

Early on in the norms and standards development process, the National Health Council (NHC) had indicated clear preferences for the establishment of a process and a mechanism to systematically respond to the poor quality of health services. The form and structure of any such process and mechanism had to engender the trust of both patients and healthcare staff, ensure public accountability and credibility, and – importantly – establish consequences for non-compliance.

Hence, a stronger quality assurance mechanism was proposed to foster clear and sustained improvements in the quality of health services. Although Chapter 10 of the National Health Act (2003) was never promulgated, the intention to regulate the quality of care was revisited by the National Department of Health (NDoH) following the publication of the National Core Standards in 2011. It was thought that the regulation of norms and standards would promote the widespread adoption of these norms and standards and link non-compliance to clear sanctions.

Ultimately, these deliberations led to the tabling of the National Health Amendment Bill (2011), which establishes the Office of Health Standards Compliance (OHSC) as an independent regulator with powers to enforce compliance against norms and standards. The National Health Amendment Bill (2011) is now in the final stages of the parliamentary process and aims to protect and promote the health and safety of users of health services by monitoring and enforcing compliance by health establishments with prescribed norms and standards and ensuring that complaints relating to non-compliance are considered, investigated and disposed of.

The rationale for regulation

The National Health Amendment Bill (2011) sets the tone for a new system of explicit regulation in the health sector. In its most basic form, regulation can be defined as “a government measure that seeks to change the behaviour of individuals or groups” (Frieberg, 2010). Government may choose to regulate a sector for a number of reasons. The most important among these is the “public interest” argument, where regulation is used to protect people against serious harm. This argument makes it clear why the health sector is one of the most highly regulated. It falls to government to protect the users of the health system from serious physical harm, by regulating the competencies of health practitioners, safety of medicines and medical devices and even the quality of health services.

However, implementing a system of regulation is a significant step that should only be taken where circumstances and reasons warrant it. The South African experience supports the argument for regulation. When the National Core Standards for Health Establishments (2011) was first developed, a number of functional areas were selected for fast-track improvements, and these included cleaner facilities, shorter waiting times and better patient safety and care. Although the implementation of these fast-track improvements led to some success and improvement in the quality of care, it was clear that simply reminding healthcare staff of their basic duty was not enough and that quality
assurance mechanisms linked to enforcement action would be needed. Therefore, the South African experience demonstrates that a voluntary compliance model did not lead to the desired health outcomes or meet the expectations by the public for accountability in the delivery of quality health services.

Having opted for a system of regulation, the National Department of Health embarked on a process to learn from other regulatory bodies and benchmark, review and analyse current regulatory practice in this area of work. This was done to provide the research and evidence necessary to establish a regulator for health establishments as an independent entity, in line with the intentions of the draft legislation.

This report is the result of that process of learning and benchmarking and it draws on extensive work done by a range of technical teams during the course of 2011 and 2012. It provides the detail of the international and national benchmark studies and reviews of current regulatory practice.

**The structure of regulation**

The structure of regulation is invariably the first consideration when developing any new regulatory system. How will regulation be structured and who will administer it are often questions posed by policy makers.

Regulation comes in various forms and structures, ranging from voluntary regulatory approaches (such as accreditation) to more explicit forms of regulation (such as licensing). The decision to adopt a specific type of approach depends on the regulatory problem government seeks to address.

Two different types of quality assurance systems have evolved worldwide. The first involves ensuring the quality of health services through explicit regulation, as practised in the United Kingdom. Here, a traditional regulator with inspection and enforcement powers is established to regulate health establishments. The second involves a system of quasi-regulation where health establishments submit to accreditation and certification processes voluntarily or as required by legislation. Under this system, the quality assurance body does not have explicit enforcement powers, but may coordinate its actions with other agencies to deliver on regulatory outcomes.

Issues around independence are more critical for traditional regulators with clear enforcement powers. In particular, decision-making autonomy ensures that the regulator can make decisions on its work approach and compliance without fear or prejudice. As a result, most traditional regulators are creatures of statute established by way of a governing act. These acts set out the scope of regulation and confer upon the regulator specific powers and functions. The review also found that while most regulators carry out an authorisation function, in the form of registration, licensing, accreditation and certification, many of them do not have direct enforcement powers but have relied on coordinated approach of working with other regulators or government to achieve regulatory outcomes.

**The functions of a regulator**

The scope of regulation largely depends on the powers and functions conferred on the regulator. In general, most regulators are involved in the following six regulatory functions to a greater or lesser extent:

- norms and standards setting;
- external quality assessment;
- compliance and risk monitoring;
• complaints management, resolution and redress;
• communication, stakeholder management and reporting; and
• enforcement and sanctions.

Setting norms and standards is a difficult exercise, and raises questions around definitional issues, their purpose as well as the process of development of norms and standards. Although the terms norms and standards are sometimes used interchangeably, they refer to different concepts. In general, norms refer to the expected rate of delivery of a service or utilisation of a resource. In contrast, standards are a set of rules that ensures the quality and safety of a product or service.

The international review points to the importance and experience of clarifying policy choices between:
• using optimal or minimum standards;
• accreditation, certification and licensing; and
• the costs versus benefits of utilising national or international standards.

While in some countries, the regulator is involved in setting standards, other jurisdictions separate the standard setting and the external quality assessment functions. Few countries have set norms for the rate of utilisation or delivery of health services and where such norms are used, they are linked to financing arrangements.

External quality assessment involves the regular evaluation of health facilities by external assessors against defined standards. External assessment is but one element of a country’s broader health system, and is intended to complement internal quality improvement initiatives such as clinical audits, clinical governance, and the surveillance of adverse patient events and avoidable deaths as well as routine monitoring and evaluation systems used by health establishments.

Findings from the benchmarking exercise suggest that there is an increase in the number of programmes managed by governments with an associated increase in state contributions to the financing of national external quality assessment programmes. In general, there is a shift from the traditional collegial peer-review model to quasi-regulatory systems, and an increase in the number of systems with mandatory accreditation rather than voluntary accreditation.

Therefore, when designing an external quality assessment programme, policy makers should determine whether the major purpose of the programme is for internal improvement or external regulation. In the case of the latter, appropriate mix of different regulatory instruments (such as onsite inspection and off site compliance monitoring) is needed to maximise the effectiveness of regulation. The choice between regulatory instruments (for example between regular or routine inspections as opposed to ad hoc or unannounced inspections) influences the responsiveness and overall effectiveness of the regulatory system. Finally, the international review confirms the importance of hiring competent staff to carry out external quality assessments as the credibility of regulators rests on the rigour of their external findings.

Compliance and risk monitoring covers the collection, analysis and synthesis of the information needed by regulators to discharge their other regulatory functions. This form of informational regulation is increasingly popular among regulators as a way of managing risk within the sector. With a wealth of data at their fingertips, regulators are increasingly using statistical methods to predict risky behaviour, making regulation more pro-active. Moreover, by collecting the right types
of information, analysing and publishing it, regulators are able to reduce the information asymmetry between users and health establishments, thus allowing users to make more informed choices about health services. In whatever form the compliance and risk monitoring system are finally developed, specialised analytical capability is needed to ensure that they operate effectively and support regulatory action. This requires not only significant investments in information and communication technology but also a highly skilled complement of staff to operate the compliance and risk monitoring system. International experience also cautions against over-reliance on compliance and risk monitoring as a possible substitute for external quality assessment. “Light-touch” regulation as practised in the United Kingdom had led to a series of scandals that raise questions about the veracity of self-reported information and subsequent statistical analysis.

In the health sector, complaints from users are particularly important as they can relate to poor service standards or system failures but may also denote more serious and life-threatening issues such as medical errors or dangerous practices/conditions within health establishments. Research shows that complaints management, resolution and redress systems are important for three reasons. First, a good complaints management system can often resolve a problem before it worsens and impacts negatively on the quality of health services. Specifically, complaints can provide managers with information about service delivery failures or breaches of standards. Second, government departments and agencies that handle, respond, and resolve complaints are able to foster a more open relationship with users and members of the public. Finally, these systems can provide a remedy to a client who has suffered disadvantage by way of a simple gesture such as an acknowledgement or apology or in the extreme through financial compensation.

Ombud offices have been established worldwide and serve as a channel for consumers or users to complain about the quality of services received and/or to report unfair treatment at the hands of organisations in either the public or private sector. Hence, the presence of an Ombud in a sector offers a complainant an opportunity for remedy, which can be pecuniary or non-pecuniary depending on the jurisdiction’s legal frameworks. Ombuds are normally established as independent and impartial offices with the task of resolving complaints and disputes between consumers and the service providers in a fair, economical and expeditious manner. The benchmarking exercise showed that considerable care should be exercised in setting up an Ombud office, with clear frameworks for both the scope of the complaints that can be considered, as well as for the determination or adjudicative powers vested in such an office.

As the practice of regulation has evolved, it has become apparent that the non-traditional regulatory functions such as communication, stakeholder engagement and reporting play an important role in promoting voluntary compliance, strengthening the credibility of regulators and educating the public about their rights and recourses. The review shows that most regulators now have strong communications arms, which work in tandem with their core regulatory functions to achieve better compliance within sectors. Moreover, regulators routinely summarise and report their findings on compliance to promote public awareness around the standards users can expect and the quality of health services.

The ability to enforce compliance and institute sanctions is often seen as central to the credibility of a regulatory scheme. Without the ability to enforce compliance and impose sanctions, regulators are largely ineffectual. In South Africa, regulators have traditionally relied on civil sanctions (such as compliance notices, administrative warnings, suspension or deregistration) to enforce compliance. Less use is generally made of criminal sanction such as imprisonment, with cases...
involving pervasive non-compliance infrequently reaching the courts. Whatever the type of sanction used, the benchmarking exercise has demonstrated the importance of ensuring that enforcement action is proportionate to the degree of non-compliance. Moreover, enforcement action should be transparent, predictable and progressive, allowing health establishments the opportunity and time to explain and remedy non-compliance.

The results of the benchmarking exercises presented here enrich the debate about the necessity to institutionalise mechanisms to regulate the quality of healthcare establishments. In addition, the conclusions support the establishment of an independent and national health quality regulator to enhance public accountability and credibility, with a single benchmark and with consequences for non-compliance.
PART A: CONTEXT
1. Introduction

The quality of health services is a major concern for the thousands of South Africans who use the healthcare system on a regular basis. While it is true that government has made significant inroads in extending access to health services, the quality of health services delivered by both the public and private sectors remains problematic, albeit for different reasons. Problems with the quality and acceptability of health services in South Africa are widely publicised. Long waiting times, unhygienic conditions, discourteous staff, unavailability of essential medicines and derelict facilities are among the most common challenges faced by the public sector. In contrast, resource utilisation in the private sector is sub-optimal and leads to wastage and inefficiencies in the delivery of health services.

The root causes for the problems underlying the poor quality of health services are varied and complex, and resolving these challenges requires a system-wide approach and the collective efforts of role-players in the health sector. From a health system-wide perspective, enhancing quality outcomes needs policy and legislation emphasising all dimensions of quality; standards and regulation that measure quality of health services; and institutions and processes that are geared towards quality improvement. It is important to recognise that the responsibility for improving the quality of services lies with various role-players within the healthcare system. In other words, improvements in quality are unlikely to be achieved through any single approach, for example regulation alone. It is only through the collective efforts of national and provincial departments, health establishments, health practitioners, public agencies and regulators that improvements to the quality of health services can be made and sustained.

1.1 What is quality?

The preoccupation with improving the quality of health services is not new and has been an important component of health reforms in both developed and developing countries over the last three decades. The earliest attempts at measuring quality within the healthcare system were hamstrung by the subjective nature of the concept of quality. Quality can be simply defined as “getting the best possible results with the available resources”. A better definition of quality in the context of the health sector is provided by the Institute of Medicine (IOM, 1990) which states: “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge, and meet the expectations of healthcare users”.

The World Health Organization (WHO) breaks down the concept of quality into six dimensions that are intrinsically measurable. These dimensions, as identified by the WHO (2006), are:

- **Safety**: delivering health services that minimises risks to users.
- **Efficiency**: delivering health services that optimise the use of scarce resources while minimising waste.
- **Patient-centeredness**: delivering health services that take into account the patient’s rights, preferences and cultural differences.
- **Accessibility**: delivery of health services in a timely manner while optimising coverage.
- **Equity**: delivering health services in a manner that does not discriminate on the basis of race, gender or socio-economic status.
- **Effectiveness**: delivering health services in a manner that achieves policy priorities and desired health outcomes.
As governments started to understand the concept of quality better, the need for quality assurance processes, that identify and detect areas where the quality of care and safety of patients may be compromised, was evident.

Quality assurance has been defined as “all the arrangements and activities that are meant to safeguard, maintain, and promote the quality of care” (Donabedian, 1980 cited in Brown et al, 1993). Quality assurance is a wide-ranging concept that covers “all matters that individually or collectively influence the quality of a product or service” (WHO, 2012). Given the breadth of activities falling under quality assurance, governments can choose to regulate certain aspects to achieve their policy outcomes.

While quality assurance focuses on the quality control measures and identifies any deficiencies within these controls, quality improvement is a systematic approach to addressing the deficiencies identified during quality assurance processes within health establishments.

1.2 The changing policy context

Enacted in 2003, the National Health Act provides the overarching legislative framework for a structured and uniform healthcare system. It highlights the rights and responsibilities of healthcare providers and healthcare users, and ensures broader community participation in healthcare delivery from a health facility up to national level.

Although, chapter 10 of the Act never came into effect, it sought to regulate the quality of healthcare services by developing structures to monitor the compliance of healthcare services and establishments with healthcare standards. Recognising that health is an area of concurrent national and provincial competence, the Act provided for the creation of an Office of Standards Compliance with the National Department of Health and an Inspectorate of Health Establishments within each province. Each provincial Inspectorate of Health Establishments would be responsible for monitoring and evaluating the compliance of health establishments with standards and on a quarterly basis would submit a report to their respective MEC on the findings. The Act established an Ombudsperson within the Office of Standards Compliance but failed to define his/her powers and functions.

The National Health Act (2003) envisaged a broader role for the Office of Standards Compliance in advising on health standards, setting new standards, monitoring compliance, reporting on non-compliance, and reviewing existing standards. In centralising the standard-setting function, the Act attempted to overhaul the current situation where each province set their own quality standards, which has led to the inconsistent application of quality standards by healthcare establishments across South Africa. However, Chapter 10 was never promulgated because of concerns around the lack of independence of the Office of Standards Compliance and its silence on the consequences of non-compliance.

In 2007, the National Department of Health published the Policy on Quality in Healthcare for South Africa (National Department of Health, 2007). The policy, based on work done from the early 2000s re-iterated the role of the Office of Standards Compliance in monitoring the quality of health services while decentralising the measurement functions to provincial departments. More generally, the policy emphasised structures and processes for quality improvement, with little attention given to the regulation of quality.

More recent policy reforms in South Africa were centred on creating a set of national standards that guide quality of health services. The multiplicity of different standards and guidelines has made it
difficult to measure performance against a common benchmark. For managers in the public health system, multiple sets of standards create additional administrative burden and impose additional resource demands on already constrained budgets. The launch of a set of “Core Standards for Health Establishments” in April 2008 was meant to address these problems by introducing a set of nationally accepted and evidence-based quality standards. The “core standards” reflected current national policies and guidelines, and were thus a reasonable statement of what was expected of management in health establishments.

The National Health Council (NHC) approved and published a set of revised National Core Standards in January 2011. These core standards and their assessment tools are now widely used in the public sector as a guide to what is expected, and as a basis for measuring the gap in the implementation and development of tailored quality improvement plans. A subset of these standards, focusing on six critical areas of greatest concern to patients, has been used as part of a baseline audit of all public health facilities conducted over the period May 2011 to April 2012.

Another important policy change in government was the introduction of the outcomes-based system aimed at enhancing accountability for the delivery of services. The country’s vision of “A Long and Healthy Life for All South Africans” is expressed in Outcome 2. The Negotiated Service Delivery Agreement (NSDA) agreed upon between the President and the Minister of Health breaks down this vision into four strategic outputs. These are:

- increasing life expectancy;
- decreasing maternal and child mortality;
- combating HIV and AIDS and decreasing the burden of disease from tuberculosis; and
- strengthening health system effectiveness.

Output 4, which sets out activities aimed at strengthening the effectiveness of the health system, renews the focus on the quality of care. Increasing patient satisfaction and improving the quality of health services now form part of one of the key health reform interventions, along with re-engineering the system towards a primary healthcare approach, improving infrastructure, enhancing human resource capabilities, improving the supplies of drugs and equipment, and better health information systems and establishing a system of national health insurance. The NSDA calls for a formal assessment of compliance by health establishments through an independent body, and signals the introduction of a new form of quality regulation within the health system.

1.3 The need for regulation

In its most basic form, regulation can be defined as “a government measure that seeks to change the behaviour of individuals or groups” (Frieberg, 2010). Government may choose to regulate a sector for a number of reasons. The most important among these is the “public interest” argument, where regulation is used to protect people against serious harm. This argument makes it clear why health is among the most highly regulated of sectors. It falls to government to protect the users of the health system from serious physical harm, by regulating the competencies of health practitioners, the safety of medicines and medical devices and the quality of care received.

The need for regulation also arises due to market failure, which typically happens for three reasons. First, competitive markets may fail to provide certain public goods -- parks and street lighting being among the most common examples cited. Public goods are generally characterised
by the properties of non-excludability and non-rivalry. Simply put, the consumption of a public good does not prevent another person's consumption, nor does consumption reduce the amount of the good available for others. An example of a public good in the health sector is “disease control”, which covers government’s efforts to stop the spread of communicable diseases such as malaria and tuberculosis.

Second, externalities are often the result of market failure. Externalities occur when the total cost of producing a good is not fully reflected in the price paid by the consumer. Pollution is a typical example of a negative externality. The last source of market failure is information asymmetry. In situations where the provider of services has significantly more information than the user, there is an incentive for the provider to manipulate the transaction to his benefit. Information asymmetry is the reason why medical practitioners in most countries are registered with professional councils and bound by rules of conduct, as users of health services are generally vulnerable when they seek out health services.

By the same token, regulating the quality of health services makes information on the extent to which health establishments met quality standards available to government and the public. Over time, the regulation of health services promotes more efficient use of resources and enhances public accountability.

The importance of providing quality health services is non-negotiable, and better quality of care is fundamental to improving South Africa’s current poor health outcomes. Regulating the quality of health services can help enhance overall health outcomes by safeguarding users against harm, ensuring reliable implementation of best-practice interventions, improving patient experience, and strengthening the confidence and trust of the public in the healthcare system.

Building a new regulatory scheme for the quality of health services requires enabling legislation, which sets out the institutional structures, processes and activities involved in quality assurance. The National Health Amendment Bill (2011) establishes the Office of Health Standards Compliance as an independent regulator, sets out its functions and empowers it to enforce compliance. By examining the objects of the Bill (2011), the intention of legislators is made clear. Accordingly, objectives of the OHSC are to protect and promote the health and safety of users of health services by:

- monitoring compliance by health establishments with norms and standards prescribed by the Minister in relation to the health system; and
- ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

### 1.4 Structure of this report

Given the changes introduced, a review of the options for South Africa was undertaken, the results of which are summarised in this report.

This document is structured as follows. Chapter 2 tracks the evolution of the policy and legislative framework, while Chapter 3 analyses the current situation. Chapter 4 develops a rationale for regulating the quality of health services, and discusses the different approaches to regulation. Chapter 5 provides an overview of regulatory structures internationally and in South Africa. Chapter 6 discusses the regulation functions of standard setting, compliance inspections, compliance monitoring and risk identification, investigations, reporting, and regulatory coordination and enforcement. Chapter 7 concludes with a summary of salient lessons from the experience of regulatory structures.
2. Policy and Legislative Framework

2.1 The Constitution

A number of governing acts, regulations and policies influence the quality of health services in South Africa. Underpinning the entire health system are the constitutional imperatives enshrined in the Bill of Rights. Specifically, section 27 of the Constitution guarantees everyone the right of access to healthcare services, including reproductive health services. The Constitution further requires the state to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.

The realisation of socio-economic rights has been tested multiple times by the Constitutional Court in relation to housing, social assistance and health rights. In the majority of these decisions, the Constitutional Court examined the reasonableness of government measures in realising these socio-economic rights (James, 2012). Put differently, the Courts focused on whether government had sufficient plans and policies in place to fulfil the obligations set out in the Bill of Rights. The regulation of the quality of health services charts a path for all health establishments to comply with policy priorities and minimum standards of care. In this manner, the regulation of quality contributes directly to government's progressive realisation of its constitutional obligations.

The constitutional imperatives set out in the Bill of Rights cannot be achieved without the collective efforts of all spheres of government. Hence, section 41 of the Constitution requires all three spheres of government to work cooperatively to secure the wellbeing of the people of the Republic, and to preserve the peace, national unity and indivisibility of the Republic. This principle of cooperative government is particularly important in health services, which are a functional area of concurrent competence across national and provincial governments as defined in Schedule 4 of the Constitution.

In other words, national government is responsible for developing and monitoring policies and legislation for the health sector. Provincial government can discharge their constitutional obligations by passing provincial legislation in the area of health services, but remain responsible for the implementation of national policy and legislation, while local government is responsible for municipal and environmental health functions. Section 44 of the Constitution gives the National Assembly the authority to pass legislation with regard to functional areas of concurrent competence and to prescribe minimum norms and standards.

2.2 The National Health Act (2003)

The National Health Act (2003) provides the overarching legislative framework for a structured and uniform national healthcare system. It highlights the rights and responsibilities of healthcare providers and healthcare users, and promotes broader community participation in healthcare delivery from a health facility level up to national level.

The Act re-affirms the constitutional rights of users to access health services and just administrative action. As a result, Section 18 allows any user of health services to lay a complaint about the manner in which he or she was treated at a health establishment. The Act, further obliges MECs to establish procedures for dealing with complaints within their areas of jurisdiction. Complaints provide useful feedback on the areas within health establishments that do not comply with prescribed standards or pose a threat to the lives of users and staff alike.
The Act regulates the quality of healthcare services by identifying the types of quality standards that the Minister may prescribe and thereafter developing structures to monitor the compliance of healthcare services and establishments with healthcare standards. Section 47 of the Act allows the Minister to prescribe quality standards relating to among others: human resources, health technology, equipment, premises, the delivery of health services, business practices, safety and any matter that influences the way users are accommodated and treated. This section of the Act, therefore, provides the legal basis for a set of national core standards.

Recognising that health is an area of concurrent national and provincial competence, the Act in its original form established the Office of Standards Compliance within the National Department of Health as well as an Inspectorate of Health Establishments within each province. Under this decentralised arrangement to regulation, each Inspectorate of Health Establishments was responsible for monitoring and evaluating the compliance of health establishments with norms and standards in its province.

The function of the Office of Standards Compliance included advising on health standards, setting new standards, monitoring compliance, reporting on non-compliance, and reviewing existing standards. In centralising the standard-setting function, the Act attempted to overhaul the existing situation where each province sets its own quality standards, which led to the inconsistent application of quality standards by healthcare establishments across South Africa.

The National Health Act (2003) formalises the regulation of quality through the creation of the Office of Standards Compliance, which was established within the National Department of Health and tasked with regulating the quality of health services, with the concomitant structural and operational attributes required for regulatory independence. Chapter 10 of the Act made no further mention of the enforcement powers of the Office, and only dealt with complaints through the establishment of an Ombud within the Office. Although Chapter 10 was never promulgated, it paved the way for amendments to the Act to strengthen the regulation of quality in the health system.

2.3 National Policy on Quality in Healthcare (2007)

A focus on quality assurance and quality improvement is not a new concept. A National Policy on Quality in Healthcare was initially developed for South Africa in 2001 and revised in 2007. The policy identifies mechanisms for improving the quality of healthcare in both public and private sectors. It highlights the need to focus capacity-building efforts and quality initiatives on health professionals, communities, patients and the broader healthcare delivery system (National Department of Health, 2007). Hence, the objectives of the National Policy on Quality were to:

- improve access to quality healthcare;
- increase patients’ participation and the dignity afforded to them;
- reduce underlying causes of illness, injury, and disability;
- expand research on treatments specific to South African needs and on evidence of effectiveness;
- ensure appropriate use of services; and
- reduce errors in healthcare.

While the policy sets out a comprehensive approach to quality improvement, it pays little attention to the role of quality assurance in the health system except to recap the provisions relating to the Office of Standards Compliance with the Act. The policy overlooked the importance of establishing a
quality assurance system to objectively measure compliance against norms and standards, ultimately providing the basis of effective quality improvement.

### 2.4 Batho Pele and the Patient’s Rights Charter (2007)

In addition to health-specific policies and legislation, Batho Pele principles govern all public services including healthcare delivery. *Batho Pele*, a Sotho translation for “People First”, is an initiative to get public servants to be service-oriented, to strive for excellence in service delivery, and to commit to continuous service delivery improvement. Batho Pele sets out eight principles to enhance the delivery of public services (Republic of South Africa, 2007). These include obligations on public agencies to:

- regularly consult with customers;
- set service standards;
- increase access to services;
- ensure higher levels of courtesy;
- provide more and better information about services;
- increase openness and transparency about services;
- remedy failures and mistakes; and
- give the best possible value for money.

The specific commitment of the health sector to this basic policy of government was the development and extensive promulgation of the “Patient’s Rights Charter” which is re-iterated in the National Core Standards. This specifies that the most critical rights of patients are to be respected and upheld, including the rights of access to basic care and to respectful, informed and dignified attention in an acceptable and hygienic environment. Patients should be empowered to make suitably informed decisions about their health, and to complain if they have not received decent care. The Patients’ Rights Charter specifies that the universal health rights of patients are to be respected and upheld, including the rights of access to healthcare by users and to be treated respectfully.

### 2.5 Core Standards for Health Facilities (2008)

South Africa has developed considerable experience in the development of quality norms and standards. The National Department of Health, in responding to concerns regarding the multiplicity of different standards and guidelines for managers throughout the health system and the consequent difficulty in measuring performance against a common benchmark, launched a set of “Core Standards for Health Facilities in South Africa” in April 2008.

The “Core Standards for Health Facilities in South Africa” was structured around seven domains of healthcare delivery within health facilities, covering: safety, clinical care, governance, patient experience of care, access to care, infrastructure, environment and public health. Each domain comprises a set of standards against which performance could be measured. These standards were piloted in both public and private facilities and learnings were used to inform the development of the National Core Standards.

### 2.6 Ten-Point Plan (2009)

The 10-Point Plan, released in 2009, reinforces the government’s commitments to quality of health services made in the legislative and policy framework, and was developed to prioritise reform within the sector. Priority number three in the 10-point plan augments the provisions of the National Health
Act by placing emphasis on the need to improve quality of service. This is to be achieved through the establishment of a well-capacitated and independent quality management body, an integrated plan for improving the quality of health services, and an ombud function that would receive and investigate complaints.

### 2.7 National Core Standards for Health Establishments (2011)

The “Core Standards for Health Facilities in South Africa” have gone through successive phases of development based on input from the numerous stakeholders involved in the process. In 2009, a working group was established to enhance and refine the original core standards. These standards together with the measurement tool were piloted in clinics, community health centres and hospitals in all nine provinces during March 2010, using provincial staff and national health staff who acted as assessors, together with technical assistance from partners of the NDoH. Following this extensive pilot, feedback was obtained from the assessment team members and from the health establishments themselves; and significant technical input was used to revise the assessment tool as well as some standards and criteria, using a risk-based approach and ensuring validation of the tool, given its intended use for audit and accreditation. An important part of the development process has been that sections of the standards have also been benchmarked against other accreditation systems. The resulting document is *The National Core Standards for Health Establishments in South Africa, version June 2010*.

These developmental processes in South Africa showed how powerful the knowledge of future regulation can be in driving interest and efforts to achieve compliance. They also seemed to confirm that the bulk of healthcare workers and managers welcome the guidance provided and the opportunity to provide good care for patients. Quality norms and standards indeed enable better care, reflect a certain set of values, and place a focus on accountability and leadership.

The process has, however, shown the importance of an in-depth knowledge of the business model of the services being assessed, if the standards themselves and the reports from assessing compliance are to actually make an impact. The mechanisms through which decisions are made, and the level at which problems can be solved are all critical aspects of this understanding, if the gap between intention and implementation is to be filled.

The “National Core Standards” were finally approved by the policy-making body (the National Health Council) and issued by the Minister in February 2011.

This set of standards is based on the existing policy environment and tailored to South Africa’s healthcare context, while also reflecting international best practice and a strong evidence base. The purpose of the National Core Standards is to:

- develop a common definition of quality care which should be found in all health establishments in South Africa, as a guide to the public and to managers and staff at all levels;
- establish a benchmark against which health establishments can be assessed, gaps identified and strengths appraised; and
- provide for the national certification of compliance of health establishments with mandatory standards.”

A subset of these standards, focusing on six critical areas of most concern to patients, has been prioritised throughout the public health system. These areas cover:

- values and attitudes;
• waiting times;
• cleanliness;
• patient and staff safety and security;
• infection prevention and control; and
• availability of medicines and supplies.

2.7 National Health Insurance (2011)

In August 2011, the National Department of Health (NDoH) published a policy paper on National Health Insurance in South Africa (NHI). The policy paper envisages the implementation of a health financing mechanism that covers the whole population of South Africa. In order for this to become a reality, the paper identifies four key interventions that need to be embarked upon simultaneously:
• a complete transformation of healthcare service provision and delivery;
• the total overhaul of the healthcare system;
• radical change of administration and management; and
• the provision of a comprehensive package of care underpinned by re-engineered primary healthcare.

The policy paper identifies the quality of care as a theme and central reality in terms of needed improvements towards the implementation of NHI. Despite significant improvements in health service access and coverage since 1994, there are still notable quality problems. Specifically, the concerns about quality and availability of health services at public sector facilities lead to a preference for health services provided in the private sector. Given the significant and growing costs of private healthcare, the vast majority of South Africans cannot afford to make the out-of-pocket payments required to access these health services.

In terms of the NHI policy paper, all health establishments (public and private) who wish to be considered for rendering health services under the NHI will have to meet stipulated standards of quality. These standards currently refer to the six priority standards. Although compliance with these core standards will only form one aspect of ultimate accreditation (used in the sense of “contracting”) to provide services under the NHI, it remains a critical part of the NHI accreditation process.

In this context, the envisaged OHSC will be primarily responsible for the certification of health establishments based on compliance with the prescribed quality norms and standards and monitoring the progress of facilities in this regard.

2.8 National Health Amendment Bill (B24-2011)

The National Health Amendment Bill was first published for public comment in January 2011. Comments were received from various stakeholders in the health sector, including public and private organisations as well as non-governmental organisations and private individuals. A revised Bill was subsequently tabled in Parliament on 16 November 2011, tagged as a Section 76 Bill and referred to the Portfolio Committee on Health. Since then, the Bill has undergone multiple changes to reflect comments received during the public participation process and guidance from the National Assembly and National Council of Provinces.

In the Bill tabled in Parliament in November 2011, the objectives of the OHSC were to protect and promote the health and safety of users of health services by:
• monitoring compliance by health establishments with norms and standards prescribed by the Minister in relation to the health system; and

• ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

The OHSC was to be established as an independent public entity, with a CEO appointed by and reporting to the Minister of Health, and an Ombud appointed by the Minister of Health but placed within the Office. In terms of the Bill, the mandatory functions of the Office were to:

• advise the Minister on matters relating to the determination of norms and standards to be prescribed for the national health system and the review of such norms;

• inspect and certify health establishments as compliant or non-compliant with prescribed norms and standards, or where appropriate and necessary, withdraw such certification;

• investigate complaints relating to the national health system;

• monitor indicators of risk as an early warning system relating to serious breaches of norms and standards, and report any breaches to the Minister immediately;

• identify areas and make recommendations for intervention by a national or provincial department of health or a health department of a municipality, where it is necessary, to ensure compliance with prescribed norms and standards;

• recommend quality assurance and management systems for the national health system to the Minister for approval;

• keep records of all its activities; and

• advise the Minister on any matter referred to it by the Minister.

The Bill also endows the regulator with discretionary powers. In terms of the Bill, the OHSC may choose to carry out these discretionary function as and when needed and within its resource capabilities. Thus, the OHSC may:

• issue guidelines for the benefit of health establishments on the implementation of prescribed norms and standards;

• publish any information relating to prescribed norms and standards through the media and, where appropriate, to specific communities;

• collect or request any information relating to prescribed norms and standards from health establishments and users;

• liaise with any other regulatory authority and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority in respect of (i) matters of common interest, or (ii) a specific complaint or investigation; and

• negotiate cooperative agreements with any regulatory authority in order to (i) coordinate and harmonise the exercise of jurisdiction over health norms and standards, and (ii) ensure the consistent application of the principles of this Act.

In the Bill’s original form, the Office has limited tools for enforcement. In the case of continued non-compliance, the Bill allowed the OHSC either to impose an administrative fine of up to R10 million, or to refer the matter to the National Prosecuting Authority for prosecution.

2.9 National Health Amendment Bill (B24B-2011)

After deliberation in the National Assembly, a revised version of the National Health Amendment Bill (B24B-2011) was released with amendments by legislators. This later version responds to
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concerns raised by stakeholders during the public consultation sessions around the independence of the office and its governance structure. During their deliberations on the Bill, legislators were also concerned about the limited enforcement powers given to the OHSC. Moreover, legislators envisaged a stronger role for the OHSC in reporting on the quality of health services.

Some of these concerns are now addressed in the revised version of the Bill. The OHSC now functions under the control of a board whose roles are to determine the policy and undertake the planning necessary for the office to discharge its legislative functions. The Bill describes in greater detail the composition of the board, as well as how it operates.

Regulation without good enforcement powers and capacity is limited in its effectiveness. The revised Bill now grants the OHSC additional progressive powers of enforcement. Hence, in the event of continued non-compliance, the OHSC may now:

- issue a written warning to achieve compliance within a set time period in a prescribed manner;
- require a written response from the health establishment regarding the continued non-compliance;
- recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance; or
- revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or part thereof that constitutes a serious risk to public health or to health service users.

2.10 National Health Amendment Bill (B24D-2011)

The National Health Amendment Bill with amendments (B24B-2011) was referred to the National Council of Provinces for provincial hearings, final mandates and voting. The NCOP proposed some minor changes to improve the clarity and legal rigour of the Bill. First, the Bill now designates the Board as the accounting authority of the office. The Board is therefore ultimately responsible for compliance with the Public Finance Management Act (1999). Second, representation from the nursing profession is now formally included on the Board reflecting its importance in ensuring better quality care. Third, the Bill enhances the independence of the OHSC by allowing the Board, after consultation with the Minister, to appoint the Chief Executive Officer. This contrasts with the previous iteration of the Bill, which empowered the Minister to appoint the Chief Executive Officer. Fourth, the Bill now obliges the Chief Executive Officer to act on the report and recommendations of the Ombud. In this way, the Bill ensures a level of mutual affinity between the Chief Executive Office and Ombud so that regulatory actions are coordinated and the objectives of the OHSC achieved. Finally, and crucially, in terms of the Bill, the Ombud reports to and is accountable to the Minister.

On an annual basis, the Ombud is required to prepare a report on the affairs and functions of the Ombud and submit it directly to the Minister (as opposed to the Chief Executive Officer in earlier versions of the Bill) for tabling in Parliament. These provisions safeguard the independence and decision-making autonomy of the Ombud within the broader regulatory scheme particularly where his/her decisions may differ with the findings of the OHSC. This final version now awaits final confirmation by Parliament prior to promulgation by the President.

In sum, the policy and legislative landscape governing the quality of health services has undergone significant changes over the past decade. In the earlier years, greater emphasis was placed on voluntary approaches to quality assurance and improvement within health establishments. However, the deteriorating situation within the health system in terms of the quality of care and patient safety (which is discussed in the next chapter) warrants an explicit form of regulation. This regulatory reform is driven by the establishment of a regulator in the form of the OHSC.
The changes made to the National Health Amendment Bill since its initial tabling in November 2011 reflect some of these discussions and changes in policy thinking particularly around the independence of the OHSC, its powers and functions as well as the autonomy of the Ombud as a complaint investigation and adjudication body.
3. Situational Analysis

In 2010, total expenditure on health was 8.9 per cent of Gross Domestic Product (GDP). Private sector expenditure accounted for around 55.9 per cent of total expenditure on health, with the remainder spent on public healthcare, which caters for roughly 85 per cent of the country’s population. South Africa’s expenditure on health as a percentage of its GDP counts among a set of similar developing countries, although South Africa’s spend per capita is very inequitable1. However, despite such high expenditure, South Africa’s health outcomes continue to deteriorate.

In its 2011 Diagnostic Report, the National Planning Commission describes the state of the public health system at that time and the burden of disease as follows:

“...Total deaths in South Africa have increased sharply, with the numbers approximately doubling in ten years up to 2008. The rise in total deaths, low life expectancy and high infant mortality are all evidence of a health system in distress. ...”

“... Our score on the United Nation’s Human Development Index shows the impact of South Africa’s quadruple disease burden on all aspects of society. The first burden is the HIV pandemic; the second is that of injury, both accidental and non-accidental; the third epidemic consists of infectious diseases such as tuberculosis, diarrhoea and pneumonia, which interact in vicious negative feedback loops with malnutrition and HIV; and the fourth burden of disease is the growing epidemic of lifestyle diseases related to relative affluence. ...”

“... While the country’s disease burden is rising, the health system is collapsing. ...”

“... Alongside the problems within the public health system, government has not managed the relationship with the private health sector effectively. ...”

“... The most severe of these policy lapses concerns the treatment of staff, particularly professional staff in the public health service. The status and role of professionals in the health system is undermined. The rise of silo-based management systems eroded discipline and management authority. ...”

“... In practice, though, the quality of care in the primary sector is unsatisfactory and clinics often run out of essential medicines. Legitimate public perceptions of substandard care also prevent people from using these clinics. As a result, the shift of resources out of the hospital system has not achieved better health outcomes or lower patient loads. ...”

“... Efforts to improve health outcomes have focused on two broad areas – improving the quality of care in the public sector, and introducing a national health insurance model. ...”

There are many reasons for the poor health outcomes seen in the country. The legacy of apartheid’s system of racial segregation and spatial planning continues to influence levels of poverty and income inequality and access to high quality services in the country. Since then, specific policy and programme changes for HIV and tuberculosis and maternal, neonatal, and child health, as well as for chronic illness, injury and violence have all contributed to an increase in life expectancy from 54 years in 2009 to 60 years in 2012 (TimesLive, 2012).

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1 See World Health Organization (2012)
Nonetheless, poor health outcomes can also be explained by institutional failures within the health system. These failures include, among others, poor accountability within the health system, inadequate management capacity, over-centralisation of decision-making, the lack of skilled personnel, and inefficient delivery of health services (von Holdt, 2010).

An analysis of anecdotal cases reported through various complaints systems, medico-legal claims and media reports reveals an unacceptably high number of cases of alleged negligence on the part of healthcare staff, outbreaks of healthcare-acquired infection, and many instances of uncaring and rude staff and dirty and unwelcoming facilities. In the private sector, quality concerns manifest themselves through over-servicing in certain geographical areas or clinical practices. Over-servicing refers to the “provision of services that may not be reasonably necessary for the adequate medical care of the patients concerned” (Palmer and Short, 2000). Over-servicing results in the inefficient utilisation of scarce resources and impacts on access (one of the dimensions of quality) to health services particularly in rural areas. In addition, the true level of other quality problems such as medical error or healthcare-acquired infections is un-reported and unknown.

Recent figures from baseline audits of public sector facilities show high levels of non-compliance with core standards, including those identified to be of the highest risk to the safety of patients and staff. The figures from earlier self-assessments showed compliance figures in the order of 30 per cent for staff attitude, 50 per cent for cleanliness, 68 per cent for waiting times, 34 per cent for patient safety and 54 per cent for the availability of medicines and supplies.

The causes of these institutional failures are multi-fold and varied.

3.1 **Understaffing and lack of skills**

Working conditions in the public healthcare system are often difficult, and can be hazardous for health practitioners. Karl von Holdt’s description captures the difficulties in working in a large public hospital when the lift stopped working:

“This meant that nurses had to carry meals and laundry, as well as patients, up and down stairs. On occasion, corpses too had to be manoeuvred down the steps. This problem resulted from the failure of the Department of Public Works to put in place a lift maintenance contract. This situation persisted for six months, as the Provincial Health Department and Public Works were in dispute over the tender process and to whose budget the item belonged. In the meanwhile, the nurses (not to speak of the patients) continued to battle with the consequences” (von Holdt, 2010b:245).

With the education system producing lower numbers of health professionals, the country faces severe shortages in personnel, compounded by the prevalence of HIV/AIDS among healthcare personnel, which translates into relatively higher attrition rates. As a result of these shortages, long working hours are often the norm for health professionals especially in the public sector and often lead to illness, high rates of absenteeism and lower productivity.

Private health establishments also face similar problems, with staff often working two shifts to accommodate increasing demand for private health services and an increasing drain on human resources in the public sector. In addition, difficult and risky working conditions in the public sector can demoralise health practitioners and create a sense of hopelessness.

The quality of healthcare is often compromised by inadequate skills among staff. According to von
Holdt in his research, nurses working in historically disadvantaged communities practiced nursing in abnormal conditions, and had never learnt the reliable practice of clinical care procedures such as “hand washing” (von Holdt, 2010a; 2010b).

Finally, the perceived disjuncture between effort and wages in the public sector has created incentives for moonlighting among public sector health personnel, who use this practice as a way to augment their earnings with additional income from private sector work. Moonlighting undermines the productivity of the public health sector and without adequate managerial controls is difficult to address.

### 3.2 Poorly maintained infrastructure and equipment

Poorly maintained infrastructure and dysfunctional equipment have a profound impact on the quality of care. In public health establishments, the patient’s experience is often compromised by poorly maintained facilities. Commonly cited examples include broken lifts and lavatories. Similarly, dysfunctional equipment places the patient at risk, particularly when emergency care is needed. For example, neonatal wards with no sterilisation equipment increase the likelihood of hospital-acquired infections in neonates.

In contrast, the private sector is well equipped with the latest medical technology. As the private sector has fewer incentives to contain costs, resource decisions may lead to the oversupply of certain types of equipment or luxury in accommodation. Ultimately, the cost of these types of resource decisions is passed on to the user, which drives up medical costs.

### 3.3 Operational inefficiencies

The public health system is plagued by operational inefficiencies, which arise as a result of inadequate systems within health establishments and poor managerial oversight, accountability and discipline. In particular, two specific problems are often raised by patients during surveys and illustrate these operational inefficiencies – long waiting times and unhygienic facilities.

Patients have voiced their discontent at the long waiting times they are forced to endure before receiving treatment. Often, patients wait for hours to get their files, to see the nurse or doctor, and then to get their medicines. There are frequent reports of patients having to return the next day to be seen; and even more shocking reports of patients who have died in the queues without being attended to. Long waits and queues limit patients’ access to much-needed care. Although, long waiting times at health facilities can in part be explained by staff shortages, organisational systems within health establishments to improve work processes are inadequate, with little effort made towards enhancing the operational efficiency. Long waiting times at facilities also have economic impacts – they increase the costs of obtaining care for low-income individuals and reduce worker productivity.

Patients and users view many hospitals and clinics as dirty, untidy and unhygienic. This situation may also lead to infections associated with healthcare, which place an additional cost on the health system and further compromise patient outcomes. The low levels of cleanliness in hospitals also suggest that staff and managers do not care for or respect their patients’ rights (or their own) to a clean and safe environment. Cleaning materials and equipment are often not adequately available, as these consumables are typically the first items to be cut when budgets are tight, illustrating poor judgement by managers. The cleanliness of facilities remains one of the commonest problems raised in media reports, in complaints, and by visitors.
3.4 Poor quality assurance processes

The delivery of health services is process-driven. Quality assurance systems monitor each step in the treatment of a patient within health establishments against certain norms and standards. Health establishments are primarily responsible for implementing quality assurance systems and improvement actions. The design of these systems is informed by policy and guidance from government. After 1994 the institutional structure of the health system changed rapidly. Fourteen separate bodies were consolidated into one national department. Responsibility for healthcare is now divided between national, provincial and local government.

The consolidation of separate and distinct bodies created a multiplicity of formal standards in some areas, and in other areas expected practice was expressed through broad policies and guidelines. Standards or guidelines are developed by more than 20 programmes and units at the national level, with in many cases their efforts being mirrored or adapted at provincial and district or municipal levels. Professional bodies and even private organisations also develop standards and guidelines. Collectively, all these disparate standards are not only confusing but also increase the administrative burden on health establishments.

With the release of the “National Core Standards”, a common national framework now exists with the potential to bring some coherence and create a common platform for delivery of health services that can be monitored against objective and verifiable standards.

3.5 Weak leadership and accountability within the health system

Accountability, and lines of authority or the lack thereof, have a direct impact on organisational performance. Effective mechanisms to ensure accountability are premised on managers or those higher up the authority structures taking responsibility for this, which often does not happen. In many cases this is exacerbated by a reluctance to devolve authority.

Similarly, practices which challenge or undermine the authority of managers also lead to the erosion of accountability, including at times the relationship between management and organised labour.

With regard to the nursing profession, the root of the relationship between nursing staff and patients, and the concomitant complex factors that impact on accountability, is alleged to stem from that fact that:

“Nurse training, from the earliest missionary days, was regarded as a socialisation process, initiating students into both an ethos and way of life. Groomed as a middle-class elite, the task of nurses was to ‘moralise and save the sick and not simply nurse them’. They were taught to see themselves as subordinate to doctors and as authority figures in control of the lives of their patients” (Chopra et al., 2009).

Chopra et al. (2009) also identify the failure to demand personal accountability as being due to the belief that people are a product of their past. In terms of this past, it is not fair and/or even possible to hold individuals accountable for actions and values that have been shaped through apartheid oppression. In addition, accountability cannot fairly be demanded, as this ability to manage and deliver was never developed through education and training. In some cases, these skills and competencies may also not have been required in terms of appointment.

The highly variable quality of care in public sector health facilities can better be understood in this complex environment of a lack of accountability and accompanying lack of leadership.
3.6 Unethical and unprofessional behaviour

The relationship between a health practitioner and a patient is premised on trust. In other words, the patient trusts that the health practitioner will act in a professional and ethical manner placing his/her welfare and safety first.

As is the case in most countries, the relationship between a health practitioner and the patient is regulated in South Africa through registration with or certification by professional councils. This form of regulation is, however, only effective when enforced consistently within the health profession. Hence, health practitioners are less likely to engage in unethical and unprofessional behaviour if the threat of likely punitive action exists, through deregistration or suspension and/or medico-legal claims.

Patient opinions consistently show that users of the health system perceive healthcare workers as being far too often rude and uncaring towards them. Unethical and unprofessional behaviour in South Africa is the product of multiple failures within the healthcare system. Sanctions in the public service in the form of dismissals are infrequent and may only happen after a long and drawn-out process. Deregistrations and suspensions by professional councils are also rare, and not perceived by health professionals as a sanction that is likely to be imposed.

In the private sector, the profit motive is a powerful incentive to increase the throughput of patients within health establishments and the cost of procedures. Hence, health practitioners may make inappropriate clinical decisions that maximise the revenue received from treating a patient.

Finally, widespread concerns exist regarding the failure of health professionals to respond appropriately to clinical warning signs often resulting in poor care or placing patients at risk. Even if patients are monitored, appropriate action often does not follow.

3.7 Stifling bureaucracy

Budgeting within the public health sector is still centralised. Budgets are usually developed at provincial and sometimes district level and imposed on health establishments such as hospitals and clinics. Where they have little or no say in the budgeting system, holding managers accountable for the utilisation of resources is more difficult (von Holdt, 2010a; 2010b). This centralised approach breaks the link between planning, budgeting and expenditure management, and reduces the accountability of managers for performance. On the whole, a centralised budgeting system creates a disincentive for managers to make efficient decisions around resourcing their health establishments.

Similarly, staff appointments in some provinces are managed centrally, even for very junior positions. The centralisation of recruitment in the public health sector, which was initially implemented to rein in spending and increase financial control has become an obstacle for managers seeking to effectively run their health establishments.

Additional examples of the inefficiencies arising out of rigid and centralised bureaucratic processes relate to the purchase and distribution of medicines. Shortages of medicines and supplies have become more and more common across the country. There are many reasons for this – from lack of payment or failure to place orders with suppliers due to poor contract management processes or budget cuts, to failure to distribute drugs to health facilities and pervasive problems with procurement. The net result is that patients are unable to receive the treatment they need on the day they come to collect it from the hospital or clinic.
In sum there have been major improvements in access to services for previously disadvantaged communities or patients, and in the implementation at scale of effective control programmes. However these advances are in part being undermined by poor-quality health services caused by unsafe clinical practices, severe resource constraints, lack of accountability, deteriorating infrastructure and operational inefficiencies. Finding solutions to these pervasive problems requires fundamental and sustainable reforms to the health system.
PART B: REGULATORY RATIONALE AND STRUCTURES
4. Rationale for the Regulatory Approach

The regulation of the quality of health services is one of the critical aspects of any health reform programme. Regulation comes in various forms and structures, ranging from voluntary regulatory approaches (such as accreditation) to more explicit forms of regulation (such as licensing). The decision to adopt a specific type of approach depends on the regulatory problem government seeks to address.

Two different types of quality assurance systems have evolved worldwide. The first involves ensuring the quality of health services through explicit regulation, as practised in the United Kingdom. Here, a traditional regulator with inspection and enforcement powers is established to regulate health establishments. The second involves a system of quasi-regulation where health establishments submit to accreditation and certification processes voluntarily or as required by legislation. Under this system, the quality assurance body does not have explicit enforcement powers, but may coordinate its actions with other agencies to deliver on regulatory outcomes.

In health systems where quality processes are well-developed, self-regulation might be appropriate. Under this approach, quality assurance functions are performed by the industry body that regulates the behaviour of its members. More explicit forms of regulation, such as certification and licensing, are needed when government seeks to safeguard the public interest and prevent harm. Explicit forms of regulation can also be used to achieve certain policy goals by attaching conditions to licenses or certification.

The National Health Amendment Bill, currently before Parliament, proposes a system of certification for the quality of health services. Certification is defined as “A system of formal or authoritative recognition that persons or organisations have ... met specified standards” (Frieberg, 2010).

By adopting this approach to regulation, the National Health Amendment Bill addresses the following systemic problems associated with the healthcare sector:

- **Harmful and unsafe practices**: Certification is seen as a preventative tool within a regulator’s toolkit. By certifying that an organisation meets certain prescribed standards, a regulator assumes that processes, systems and structures exist to mitigate risks and thus reduce or prevent harm to users. The National Core Standards specify quality nursing and clinical processes and ethical practice that reduce unintended harm to healthcare users or patients in identified cases of greater clinical risk, and prevent or manage problems or adverse events, including infections associated with healthcare. Over the long term, regulating the systems through which health services are delivered is an effective way of building capacity within health establishments to improve nursing and clinical care and reduce adverse events.

- **Lack of leadership and accountability**: The erosion of accountability and leadership within the health system means that managers are often not held accountable for their decisions and actions. Part of the problem is that there are no processes, systems or structures in place within the health system to hold managers accountable for their actions and the consequences thereof; or to reliably recognise and incentivise those who show effective leadership. Inspections, documentary reviews and risk profiling are regulatory tools that make the decisions and actions taken by managers of health establishments more transparent. By opening up the “black boxes” that are health establishments to public scrutiny or even management scrutiny, regulation enhances accountability and leadership.
• **Unethical and unprofessional behaviour:** Unethical and unprofessional behaviour by health practitioners undermines the credibility of the health system. Regulation can enhance professionalism in the health sector by regulating service standards, enforcing patient rights and promoting training and continuous professional development. In addition, regulated standards provide guidance to health professionals and managers by specifying what is acceptable and what is unacceptable practice (Frieberg, 2010).

• **Operational inefficiencies:** When designed well, regulation of the quality of health services can drive continuous quality improvement within health establishments. In particular, standards that regulate the management of operations and facilities within health establishments and in the systems that support them can promote efficiency and directly impact on the patient’s experience.

Regulating the quality of health services plays an important role in improving health outcomes by making the reliable and safe implementation of good clinical practices for every patient and on every occasion the norm. Equally important, a system of quality regulation enhances public accountability by putting in place sanctions for non-compliance. To implement this new explicit regulatory scheme, the National Health Amendment Bill proposes the establishment of an independent regulator with a legislative mandate and voted funds.

The functions of a regulator differ across jurisdictions, and are often tailored to the regulatory outcomes government seeks to achieve.

In the next chapters of this document, the function of regulators (and quasi-regulators) across a range of countries is benchmarked and discussed. In 2011, the NDoH commissioned a set of benchmarking studies to understand good practice in terms of the functions, structure and operations of regulators. In particular, a study of the Care Quality Commission in the United Kingdom provided additional and detailed insights into how a system of explicit regulation might work. Learnings from this analysis are distilled in the next chapters, and inform proposals on the design and structure of the OHSC.
5. Regulatory Structures

Regulators come in different shapes and sizes. When designed well, the structure of a regulator adheres to internationally accepted principles of good regulation, while taking into account the local context. The concept of regulatory independence has been widely debated in the literature. The consensus view is that regulatory independence refers to the right of regulators to make decisions within their legislated scope of responsibility without fear or favour (Eberhard, 2007).

Decision-making independence is based on three key aspects. First, all employees of regulatory agencies are entitled to security of tenure. Employees should be able to perform their duties diligently without fear of dismissal or retribution. Second, regulators should have control over their human and financial resources. This includes the right to appoint suitably qualified staff, and access to a secure stream of funding. Third, regulators should be able to plan and carry out their work without undue influence from government or the regulated sector. Regulatory independence is further enhanced when regulators are able to publish and report on their findings to the public. In the health sector, this reporting function is subject to confidentiality and privacy laws, which safeguard the information of users of the health system.

Legal jurisprudence gives some guidance around the application of the concept of independence in South Africa. In Hugh Glenister versus President of Republic of South Africa and others, the Constitutional Court identified two components to independence:

- structural components; and
- operational attributes.

The ruling indicated that an entity did not have to be set up as an independent body to achieve structural independence, and structural independence could be provided for through elements within legislation that governs reporting, oversight and decision-making of such an entity. In addition, regulatory independence is seen as augmented by credible, transparent and consistent regulatory processes that enable government to deliver on regulatory outcomes.

In contrast, international good practice often sees regulatory independence as a structural concept with regulators having clearly defined governance structures and lines of accountability. It could therefore be surmised that effectiveness of an independent regulator is based on both strong regulatory independence and strong regulatory processes.

The structural aspects of independence are largely a political decision, and more often than not this is codified in the legislation establishing the entity. This report highlights the different organisational structures adopted by a range of international and local regulators.

5.1. International regulators

5.1.1 Care Quality Commission (CQC)

The CQC was established in the United Kingdom in 2009 in terms of the Health and Social Care Act (2008). The Act set out to establish a single regulator for health and social care in the UK. The CQC regulates the quality of care provided by the NHS, local authorities, private companies and voluntary organisations in the UK, and has combined regulation of healthcare with that of social care with profound implications for their regulatory approach and staffing model. The regulator is also mandated to protect the interests of people whose rights are restricted under the Mental Health Act.
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The CQC has a Board whose Chairperson is appointed by the Parliamentary Health Committee on the recommendation of the Minister of Health, and who reports directly to the Department of Health, but indirectly may be called to report to Parliament.

The UK has a number of agencies and bodies that regulate the different dimensions of healthcare delivery. Recognising the complexities associated with this landscape, and in order to reduce unnecessary red tape, the Department of Health in the UK has streamlined a number of functions into the newly established Care Quality Commission (CQC) as part of the British government’s broader regulation programme. The CQC takes over the reins from its predecessor, the Healthcare Commission, which was responsible for licensing healthcare establishments by monitoring and assessing their compliance with a set of national minimum standards. Further reforms of the NHS are in the pipeline, but the role of the CQC and other regulators is seen as being strengthened through these changes.

5.1.2 Haute Autorité de Santé (HAS)

The Haute Autorité de Santé (HAS) or “National Authority for Health” was established in France through statute in 2004 as an independent public body with financial autonomy. HAS was designed to improve quality of patient care, and to promote equity within the healthcare system. The HAS’s regulatory powers include accreditation of health professionals and medical equipment, and the certification of health establishments. This implies that the HAS is a super-regulator focusing on regulating the value chain in the health sector – that is people, processes and material.

5.2 South African regulators

5.2.1 Health Professions Council of South Africa

The Health Professions Council of South Africa (HPCSA) is a statutory body, established in terms of the Health Professions Act (1974), and is a Schedule 3A public entity. The Council regulates the health professions in aspects pertaining to: registration, education and training, professional conduct and ethical behaviour, continued professional development, and compliance with clinical standards. The HPCSA is headed by a 32-member council made up of persons from, among others, professional boards, community representatives, NDOH and the tertiary education system. The Council oversees the regulation of the bulk of the health professions as well as the work of the health professional boards. The HPCSA consists of 12 boards representing each of the registered health professions covered. These boards register health professionals, and administer and enforce a code of conduct against individual practitioners in the event of a breach of the code including deregistration and disciplinary action.

5.2.2 South African Pharmacy Council

The South African Pharmacy Council (SAPC) is a regulatory body responsible for promoting the provision of pharmaceutical care which complies with universal norms and values in the public and private sectors, as well as safeguarding the rights of the general public in accordance with pharmaceutical standards. The Council is established in terms of the Pharmacy Act (1974) and is listed as a Schedule 3A entity under the Public Finance Management Act (PFMA). The SAPC is governed by a council of approximately 25 members whose functions are to develop standards for pharmaceutical services, promote ethics and professional conduct, and ensure the quality of pharmaceutical services in South Africa. The Council has a number of subcommittees which deal with key elements of pharmaceutical practice and services such as continuing education.
5.2.3 Medicines Control Council

The Medicines Control Council (MCC) is a statutory body established in terms of the Medicines and Related Substances Control Act (1965) to regulate the manufacture, distribution, sale, and marketing of medicines throughout South Africa. The Medicines and Related Substances Control Act is currently under review, with proposals for a new multi-product regulator being finalised.

5.2.4 South African Nursing Council

The South African Nursing Council (SANC) is a statutory body established to regulate the nursing and midwifery professions to ensure safe and quality practice. SANC is endowed with wide-ranging regulatory powers in terms of the Nursing Act (2005).

In relation to individual nurses, the Council is required to register nursing professionals and ensure that these practitioners discharge their duties in a manner consistent with the constitutional rights of the healthcare user. Where breaches of the ethical codes of conduct are identified, the Council may take steps to sanction or deregister a nursing professional.

SANC is also responsible for ensuring the quality of nursing education. As such, the Council is empowered to inspect and accredit nursing education institutions or programmes should they not comply with prescribed requirements.

The Council’s regulatory powers extend to the scope of practice and the conditions under which registered nurses may practice their profession and sets out the continuous professional development requirements that all nurses must comply with. Although, the council has yet to formalise continuous professional development requirements, their focus has been on regulating the competencies around nursing and specialist nursing practices.

5.2.5 The South African National Accreditation System (SANAS)

The South African National Accreditation System (SANAS) was established in terms of Section 21 of the Companies Act (Act 61 of 1973), registration number 1996/00354/08. On 1 May 2007, it became a public entity with the promulgation of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act 19 of 2006). SANAS is recognised by the South African Government as the single National Accreditation Body, and their certificates are a formal recognition of an organisation’s competence to perform specific tasks.

SANAS does not develop standards, but uses international standards, mostly developed by the International Standards Organisation (ISO) and International Electrotechnical Commission (IEC). In addition SANAS uses SABS standards where applicable and where required develops guidelines for such standards. SANAS does provide accreditation for health laboratories, and formally lists those which meet the standards.

SANAS charges fees for its services, and these are prescribed by relevant regulations in the context of the Department of Trade and Industry (dti). SANAS has become almost an overarching accreditation body which accredits SABS and other bodies engaged in accreditation.

5.2.6 The South African Bureau of Standards

The South African Bureau of Standards (SABS) is a statutory body that was established in terms of the Standards Act, 1945 (Act 24 of 1945) and continues to operate in terms of the latest edition of the Standards Act, 2008 (Act 29 of 2008) as the national institution for the promotion and maintenance
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of standardisation and quality in connection with commodities and the rendering of services. SABS publishes national standards which it prepares through a consensus process in technical committees, and provides information on national and international standards.

The SABS’ conformity assessment services include system and product certification, laboratory testing and inspection functions, with some covering health services (such as pathology) and a few specific management systems.

The dti benchmarked the SABS regulatory system internationally, and concluded that the practice of having a standards body as a regulatory body is neither optimal nor advantageous. After careful consideration of the benchmarking results and public input, the shareholder (the dti) decided that the SABS Regulatory Division should be a separate agency reporting to the dti. SABS accreditation is specific to a certain process or product, and where these do not meet the standards, they cannot display the SABS certification logo. The fees charged for SABS services are prescribed and reviewed regularly.

5.2.7 The South African Council for Medical Schemes

The Council for Medical Schemes (CMS) is a statutory body established by the Medical Schemes Act (131 of 1998) to provide regulatory supervision of private health financing through medical schemes. The governance of the Council is vested in a board appointed by the Minister of Health. The Council is listed as a Schedule 3A public entity under the PFMA.

CMS monitors the impact of the Medical Schemes Act and recommends improvements. It also secures adequate protection for beneficiaries by approving the manner in which medical schemes carry out business, and by monitoring their financial performance.

The CMS supports the work of trustees of medical aid companies and promotes public understanding of the way in which medical schemes function. It is empowered to take fair and timely enforcement actions, and it can investigate and resolve complaints by beneficiaries. Importantly, the CMS adopted an approach to develop strategic alliances with counterpart regulators and other bodies.

The CMS, as a statutory regulatory body, can legally enforce compliance through accreditation and de-accreditation.

Fees for the services of the CMS are prescribed through relevant regulations, and the Act enables CMS to carry out its mandate adequately in terms of financing and funding.

In summary, it can be seen that most regulators are creatures of statute established by way of a governing act. These acts set out the scope of regulation and confer upon the regulator specific powers and functions. While most regulators carry out an authorisation function, in the form of registration, licensing, accreditation or certification, many of them do not have direct enforcement powers.
PART C: REGULATORY FUNCTIONS
6. Regulatory Functions

Improving the quality of healthcare delivery is an important global health priority, and healthcare quality improvement initiatives have been developed in many countries around the world. The purpose of these initiatives is not only to improve healthcare quality and ensure patient safety, but also to improve clinical effectiveness and promote public accountability. Ultimately, regulation should contribute to universal healthcare coverage. While many definitions have attempted to define universal healthcare coverage, it is now widely accepted that the concept refers to the “right of every citizen to access good quality, affordable healthcare, not determined by the socio-economic condition of the individual.”

Evaluation of the work of the Healthcare Commission (the predecessor of the Care Quality Commission) in the UK found that regulation has made an important contribution to the overall system for improving the quality of care. Importantly, it has been argued that because of the huge investment of taxpayers’ money in healthcare, an independent and authoritative regulator is essential to enhance public accountability and to ensure value for money.

Though the challenges faced by the public and private healthcare markets may differ significantly, both require quality assurance mechanisms in order to improve health outcomes, promote patient satisfaction and improve efficiency and accountability within health systems. Improving the quality of healthcare and healthcare establishments is central to the reform of health systems and service delivery.

While striving for an improvement in the quality of healthcare is a laudable goal, delivering on such a goal can be difficult, particularly if health establishments are left to their own devices. Moreover, given that “quality” as a concept is often subjective and dependent on the viewpoints of the users of the healthcare system, regulating such an abstract concept is likely to pose a challenge for any government.

To resolve this problem, governments have sought to define “quality” through a set of measurable norms and standards, which once developed and adopted, can form the basis for the regulation of health services. By regulating the quality of health services, governments seek to influence the behaviour of individuals and organisations, thereby improving the quality and safety of health services.

Regulation is a complex exercise and involves different role players across government. In general, regulation can be broken down into six core functions illustrated on page 42:

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2 Definition derived from the “Seguro Popular” health insurance programme in Mexico.
This chapter presents the learnings from international and local experience in carrying out each of these regulatory functions. While regulatory functions are discrete, there is interdependence with performance of a particular regulatory function, often dependent on inputs from other functions within the regulatory structure or from another structure. For example, external quality assessment requires information on compliance and risk monitoring to develop an annual inspection strategy. In the same way, the communication function promotes voluntary compliance among health establishments and may reduce a regulator’s reliance on punitive enforcement action.

This chapter is structured in six different sections:

1. **Norms and standards** elaborates on the different definitions of norms and standards and reviews international experience in the process of developing norms and standards.
2. **External quality assessment** draws on international experience to identify the different approaches to assessing the quality of health services.
3. **Compliance and risk monitoring** assesses information that is used to monitor compliance with norms and standards and support regulatory activities.
4. **Complaints management, resolution and redress** discusses the mechanisms used to handle complaints and promote redress in instances where non-compliance has had a negative impact on users.
5. **Communication, stakeholder management and reporting** demonstrates how other jurisdictions promote voluntary compliance and enhance accountability through better reporting.
6. **Enforcement and sanctions** reviews the different approaches to enforcement adopted by both national and international regulators.
6.1 Norms and standards setting

The use of standards for measuring the quality of healthcare is not a new concept, but has gained momentum as greater emphasis is placed on health establishments taking accountability for the health services offered. Many countries recognise the need for standards, particularly for hospitals, and are engaging in developing these norms and standards.

Setting norms and standards is a difficult exercise, and raises questions around definitional issues, their purpose as well the process of development of norms and standards. In addition, some studies point to the importance and experience of clarifying policy choices between:

- using optimal or minimum standards;
- accreditation, certification and licensing; and
- the costs versus benefits of utilising national or international standards.

6.1.1 Definitions

The terms “norms and standards” are commonly used, and there are several definitions of these in the literature.

In general terms, a “norm” is defined as “the pattern of behaviour that is considered normal in a particular society, the usual situation or circumstances, or the required level of achievement and the range of functioning that can be expected of members of a particular population”. In public management, norms refer to the expected rate of delivery of a service or utilisation of a resource. Norms are often defined in quantitative terms and may refer to access, input (structure) and activities of health services. An example of an access norm is to specify what proportion of the population should be within two kilometres of a primary healthcare service (e.g. 80 per cent). Input norms which refer mainly to health personnel, facilities or finances are usually tied to a common denominator (e.g. nurse to patient ratio). Process norms relate to care, service or management (e.g. all children should be fully immunised by the age of one year).

Norms promote the efficient utilisation and equitable allocation of resources and are used in conjunction with standards to ensure that health establishments provide quality care. Governments can choose to set minimum norms to improve the efficiency of resources. In complying with these minimum norms, health establishments demonstrate that they have adjusted their capital and operational budgets to achieve the required resource utilisation rate. Having a minimum norm set by government does not preclude health establishments from identifying and setting appropriate performance targets for their organisations. Indeed, any norms framework should also encourage health establishments to pursue efficiency gains, once the minimum norm has been attained.

In general, a standard is a set of rules that ensures the quality and safety of a product or service. While standards have been used extensively in fields such as engineering and manufacturing, caution should be exercised in the context of quality of care discussions.

In 1981, Donabedian, arguably the most influential author in the field of quality in healthcare, proposed that standards, criteria and norms should be redefined to distinguish them from one another. At the time, Donabedian suggested that “quality assessment requires specification of: phenomena that are usually attributes of either process or outcome; a general rule of what constitutes goodness; and a precise numerical statement of what constitutes acceptable or optimal goodness with respect to these phenomena”. This definition is useful for two reasons. First, it suggests that all standards should be accompanied by some criteria that demonstrates how performance (or compliance) is
achieved. Second, it recommends that all standards should be inherently measurable against these criteria.

Although there are various definitions of standards, the definition provided in the National Core Standards of a “statement of an expected level of performance that forms the basis for providing quality care, as they set out the anticipated best-practice in a given context” will be used in the remainder of this document.

The comparative analysis found that, although norms and standards are often used interchangeably, in practice, the focus of external quality assessment bodies in almost all cases is on standards, rather than on norms. Where norms are used, they are linked to health financing or resourcing arrangements between the health establishment and the insurer and introduce aspects such as equity and efficiency into the assessment.

6.1.2 Development process

Two paths towards the development of standards have been identified: that of utilising international standards or of developing national ones. While the first path is much faster to initiate, the second can take anything from three to five years. However the dissemination and uptake of nationally-developed standards may then take less time as they reflect the local ethos and policies. There is also a debate regarding the extent to which “international standards” are appropriate within the resource availability and health system models of middle-income or developing countries. While standards must be evidence-based and are thus by implication “international”, they inevitably reflect choices that have been made locally with regard to expectations and approaches, and these would need to be taken into account if sustainability and ownership are to be assured.

While various countries in the world are at different stages in their use of standards as a means for managing quality in healthcare, all started in a relatively small way, and some, such as the Healthcare Commission and its successor the Care Quality Commission in the United Kingdom, have become sophisticated and deeply entrenched in the health system as a whole. The ability to adopt an outcomes-focused system may reflect the evolution in the British healthcare system that now emphasises the experiences and views of patients, as CQC regulations cover 28 outcomes, and the focus is mainly on meeting people’s needs or expectations/experience.

Other regulatory regimes are beginning the journey with statements of intent and proposals such as those recently issued by the government of Bangladesh. Even those who have recently commenced developing comprehensive standards for healthcare establishments have previously had standards for various legislated aspects of healthcare such as radiation management, medicine control and training of healthcare professionals.

The comparative analysis found that the development and establishment of national standards is a difficult and time-consuming task that requires the appropriate use of evidence, consultation and consensus-building with numerous stakeholders, piloting and field-testing, monitoring and evaluation, and periodic and ongoing revision. However rigorous is the process to develop them, practical difficulties will arise in their measurement, policies and health needs will change, and new evidence will become available, making it necessary to have a review system.

The international review undertaken demonstrated many different ways used in determining a set of national standards. These include:

- The CQC in the UK uses a set of 28 outcome standards reflecting the experience of patients and
is set by the Department of Health, but has recently proposed a focus on a subset of these in response to public concerns. These standards have evolved over a long period of time to reflect a changing policy environment.

- The UK National Health Service Litigation Authority (NHSLA) also has Risk Management Standards covering both patients and staff, reflecting the value placed on staff and the importance of protecting staff capacity for safe care provision and the avoidance of medical errors.
- The Health Information and Quality Authority (HIQA) in Ireland monitors standards approved by the Minister of Health and concerns itself largely with media coverage relating to quality. Standards are high-level and outcome-based (e.g. “effective leadership”), but include clinical management.
- Accreditation Canada generates the standards that it assesses and reviews them every three years.
- In Australia, the Council on Healthcare Standards sets standards that were originally based on the UK standards, ensures expert inputs and reviews them every four years.
- There is a separate body (the Australian Commission on Safety and Quality in Healthcare) that has also set standards in the area of its specific remit through an expert working group.
- In Malaysia, the Malaysian Society for Quality in Health used the Australian standards and adapted them through an extensive process of consultation and expert input.

Some lessons learned from international experience during the early processes to develop standards and norms for the South African context and the institutional comparisons showed that:

- It is important to distinguish between mandatory standards (supported by legislation or regulation) and voluntary standards, as they are used for different purposes.
- Requirements to comply with standards will not bring about meaningful improvement to patient outcomes and quality of care unless they are part of a holistic quality management system.
- The purpose of having standards in a healthcare system may include an attempt to resolve problems by providing guidance on good practice, as well as a means to assessing compliance to legislation.
- Experts in the specific subject field as well as in the development of standards and measurement tools are needed to ensure credible standards.
- A robust and recognised system of development based on expert committee consensus and best-practice evidence is the most widely accepted method of developing standards. This must be followed by a system of formal approval before being used in the public domain.
- The results of external quality assessment can be gainfully used to improve and revise existing standards.
- The funding of the development of standards will vary depending on the purpose and whether they are mandatory or voluntary standards.

6.1.3 Choice of regulatory instruments

Relevant, objective and measurable standards are essential if the expected improvement in healthcare quality is to be achieved. Clarifying the purpose of setting and measuring the norms and standards is critical, and in general standards should reflect or be coherent with existing policy. Three primary approaches to the standards-based evaluation of healthcare quality are recognised: licensure, accreditation and certification.

Typically, standards used for accreditation are set through a process of expert input and consensus on the optimal achievable level of quality. The main aim of accreditation is to stimulate voluntary improvement over time and address organisational performance. Standards used for licensure, on the
The other hand, are most typically set at a minimum level consistent with ensuring that the organisation has the essential components required to provide care to patients in an environment with minimum risk to health and safety. Certification is an approach that may address individual practitioners as well as organisations or components of an organisation (e.g., laboratory or radiology services), such as the ISO 9000 standards which evaluate conformance to design specifications.

The recent expansion in mandatory accreditation programmes backed by government policy or legislation and at times linked to funding mechanisms has, however, begun to blur these classic definitions, with approaches and standards that are more of a hybrid in terms of scope and process.

Accreditation-type standards, unlike minimum licensure standards designed to protect public safety, must encourage healthcare organisations to continuously seek to improve quality while recognising what is possible to achieve given potential resource limitations. These standards are typically developed by a consensus of healthcare experts, published, and reviewed and revised periodically in order to stay current with the changing dynamics within the health sector and evolution in the policy environment.

The philosophy of “doing the best, given available resources” is especially important to consider in developing countries where resource limitations can significantly impact an organisation’s ability to achieve optimal performance. If the standards are set unrealistically high, organisations will feel demoralised and unmotivated to work towards meeting them; however, incremental improvements may be possible and should be rewarded. Issues of inequity in resource allocation are also critical to consider if mandatory compliance is envisaged.

**Box 1: Service standards in South Africa**

*Batho Pele*, a Sotho translation for “People First”, is a government initiative to get public servants to be service-oriented, to strive for excellence in service delivery, and to commit to continuous service delivery improvement. It is meant to be a simple and transparent mechanism, which allows citizens to hold public servants accountable for the level and quality of services they deliver.

The Batho Pele initiative requires all departments to develop a service delivery improvement programme which sets out: existing levels of services and the proposed service standards, the approach to monitoring service standards and how the complaints-handling and management system will be used to rectify service delivery failures. Each department’s service delivery improvement programme must be approved by the relevant executive authority.

The DPSA together with the Public Service Commission are jointly tasked with monitoring the implementation of the Batho Pele initiative.

Source: DPSA (1997)

### 6.2 External quality assessment

In the development of national health quality systems, increasing use is being made of external assessment, which involves the regular evaluation of health facilities by external assessors against defined standards. External assessment is but one element of a country’s broader health system, and is intended to complement internal quality improvement initiatives such as clinical audits, clinical
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governance, and the surveillance of adverse patient events and avoidable deaths, as well as routine monitoring and evaluation systems within health establishments.

External assessment systems may have a number of different objectives that range from improving or maintaining quality and addressing national public health priorities, to managing risk or establishing centres of excellence. External assessment systems also play a critical role in strengthening complaints-handling and monitoring systems within health establishments. Common models of external assessment include peer review, compulsory licensing or certification for regulatory purposes or voluntary accreditation.

Prior to 1990, there were only eight countries with national health facility accreditation programmes, of which those in the United States of America, Canada and Australia were the most developed. A global survey by the WHO in 2000 identified 24 operational national accreditation programmes. The major expansion in external accreditation has occurred in Europe, and the most recent European survey identified 18 active national accreditation organisations in that region. The most developed accreditation programmes are still located in high-income countries. Low- and middle-income countries with functional accreditation programmes include Malaysia, Brazil and Zambia. The Council for Health Service Accreditation of Southern Africa (COHSASA) established as a not-for-profit organisation has operated a voluntary hospital accreditation programme in South Africa since 1994.

Findings from the benchmarking exercise suggest that there is an increase in the number of programmes managed by governments rather than non-governmental organisations (NGOs), with an associated increase in state contributions to the financing of national programmes. In general, there is a shift from the traditional collegial peer-review model to quasi-regulatory systems, and an increase in the number of systems with mandatory accreditation rather than voluntary accreditation.

The larger the number of facilities participating in national programmes, the bigger the resource and capacity requirements of the accrediting organisations. Accreditation programmes are expanding beyond hospital accreditation to include primary care and community-based services. The focus of accreditation programmes is now increasingly on health outcomes and patient satisfaction as opposed to exclusively process norms and standards. These changes are in line with the move towards outcomes-based monitoring in the public service.

6.2.1 Approaches to external quality assessment

Although external quality assessment programmes have been established in a number of countries, they vary considerably in the scope of their activities. Quality assessments have been applied to both health practitioners and healthcare organisations.

In terms of the possible models for quality assessment, licensing and certification are commonly used for both individuals and organisations, but accreditation is usually applied to the services rendered by health establishments. In contrast to certification and licensing, the need for accreditation is often not legislated, and may not have any consequent sanctions for non-compliance other than the reputational damage for those organisations that fail to receive accreditation.

A few mature accreditation programmes, such as that of Australia, cover the whole range of possible activities, although responsibilities are usually shared between different bodies. In Australia, quality assurance functions are decentralised to states and territories, with each of these sub-national governments having a separate body to promote compliance with standards. The advantage of this
decentralised approach lies in being able to prioritise risks specific to local conditions during external quality assessments. This approach, however, may give rise to differences in the quality of health services across different state lines. Where a national health insurance system exists that depends on the accreditation status of health establishments, a decentralised system of quality assessment may disadvantage states with more mature (and strict) regulatory processes.

The most common basic model for facility accreditation focuses on the voluntary accreditation of publicly funded hospitals. This has been the starting model for most countries in Europe and Latin America, and has been the model for COHSASA in South Africa.

At a formal level, only Italy, France and Scotland have voluntary accreditation, but since accreditation is linked to the receipt of public funds (either directly from government or from a national health insurance-type fund), it is essentially compulsory in practice. The major increase in external quality assessment programmes during the past decade is driven largely by government-led mandatory or regulatory approaches that fall largely into this group.

Traditional regulators have adopted a model of explicit regulation where registration and inspections are mandatory for all regulated entities. The CQC and its predecessor, the Healthcare Commission, offer some interesting insights on the consequences of different approaches to external quality assessment. The Healthcare Commission was established as an independent body on 1 April 2004 and replaced the Commission for Health Improvement. Its key functions were to: assess the quality and value for money of healthcare and public health; equip patients with the best possible information about the provision of healthcare; and promote improvements in healthcare and public health.

In line with the government-wide move towards deregulation in the UK, the Healthcare Commission adopted a ‘light touch’ approach to regulation. This meant that the regulator relied on self-reporting, risk profiling and compliance-monitoring over more traditional methods of external quality assessment, such as inspections. In response to a number of high-profile scandals which demonstrated the shortcomings of this approach, the CQC has since revised its strategy to include more on-site inspections and visits and reduce its reliance on self-reported information by health establishments in developing a risk profile.

As it ceased to exist in 2009, the Healthcare Commission documented its main lessons in the implementation of its vision for modern regulation of health and healthcare. These are summarised below:

- the flexible use of a range of regulatory tools and approaches in relation to the risks in providing and commissioning healthcare;
- holding organisations to account for the quality of care they provide and the outcomes for service users;
- working with patients and the public;
- involving clinicians and clinical bodies in measuring what matters;
- promoting equal citizenship and giving particular emphasis to the rights and entitlements of those who find themselves more vulnerable;
- making effective use of existing information;
- improving the information available on the outcomes of care and the experience of patients;
- providing accessible and relevant information on the quality of care;
- ensuring robust intervention and investigation in tackling poor performance;
- taking a “whole system” view;
• working in partnership and aligning regulation with other mechanisms for achieving the Government’s wider goals in the system; and
• building the capability of the regulator to do its job.

Unfortunately, not all new national programmes to implement external quality assessment have been successful – a number have failed for technical, political or economic reasons. The recent review of European initiatives noted that many were not thriving. Analyses of the international experience by the World Bank and the International Society for Quality in Healthcare (ISQua, 2007) have identified important lessons for the successful implementation of a national quality assessment programme.

These lessons learned from national quality assessment programmes reflect common problems identified, and can be summarised as the need to:
• clarify whether the major purpose is internal improvement or external regulation;
• match external assessment approaches to purpose;
• promote a culture change through commitment, collaboration and team work; and
• use the appropriate levels of onsite inspections and compliance-monitoring to maximise the effectiveness of regulation.

Other critical problems identified were often the unrealistic expectations of what such programmes are able to achieve, a lack of prioritisation, the absence of clear, transparent and credible procedures backed up by sustainable funding and adequate resources for the size of the task, and failure to learn from other efforts internationally.

6.2.2 Inspections as a form of external quality assessment

Inspections are an important form of external quality assessment. By directing inspections towards high-risk areas of the health system, a regulator can maximise the impact it has on the quality of health services delivered. It is important, however, to acknowledge that inspections are costly exercises, and an inspectorate strategy should maximise the benefit of regulatory action within the available resource envelope. International and local comparative analyses highlight some important design considerations for the establishment of an inspectorate function within the OHSC.

6.2.2.1 How are inspectorates resourced?

Inspectors use structured and evidence-based methodologies to assess compliance of health establishments with norms and standards. Through a combination of documentary reviews, data collection and psychical visits, inspections provide a holistic view of compliance by a given health establishment. A dedicated and well-resourced inspectorate is critical for the overall effectiveness of a regulator.

Inspections are a labour-intensive and costly function within a regulator – nonetheless, learnings from international experience can help design efficient and effective inspectorates. In terms of the staffing models for an inspectorate unit, the geographic spread of health establishments is a key consideration in establishing teams of inspectors, together with the scope of work to be done and the available pool of independent experts.

Inspectorates follow different models, with teams of inspectors based locally, regionally or nationally. Inspectors themselves can be employed full-time or part-time, or seconded for periods of time from other bodies such as universities or from the health services themselves. They usually (but not always) work in teams, and may be from the field of healthcare or with more generic skills.
Locally or regionally based teams (whether full- or part-time) have the advantage of reducing travel time and therefore costs (although office costs may offset this), as well as increasing the pool of available expertise in specific areas, improving job satisfaction and strengthening local relationships.

The Australian Council on Healthcare Standards, Australia’s leading accreditation body, employs about 400 surveyors, who in general are senior healthcare practitioners with broad experience in healthcare and knowledge of the National Safety and Quality Health Service (NSQHS) standards. Most surveyors are employed by the healthcare industry and receive permission and support from their employer to survey for the ACHS in addition to their normal work. Alternatively, surveyors can be paid an honorarium for their services by the ACHS. For each inspection, the surveyor will be supported by contracted coordinators (ACHS, 2012).

In the US, the Joint Commission was established as an independent not-for-profit organisation. The commission accredits and certifies more than 20 000 healthcare organisations and programmes in the US. The Commission inspects health establishments (ambulance services, mental health services, hospitals, rehabilitation centres and laboratory services) against a set of standards once every three years (or once every two years for laboratory services). The Commission employs 1 000 salaried surveyors who travel to the facility to complete the inspection (Joint Commission, 2013).

In the UK, the human resource strategy of the CQC is determined by the scope of their work. The very large number of small institutions (over 22 000 local private care homes and a much smaller number of National Health Service Trusts) led to a policy decision to use individual inspectors with generic skills covering a range of institutions in a small geographic area. A linked issue relates to “home working” – given their very dispersed placement, all inspectors and many other staff work from home using integrated IT systems and electronic communication.

Malaysia’s programme appoints part-time inspectors who meet their qualifying criteria, then trains and supports them to conduct inspections close to their place of residence or work. This enables them to make the best use of a small pool of expertise.

There are advantages and disadvantages to different resourcing models. A nationally or centrally based team enhances the objectivity of inspectors, standardises approaches to inspections, enables sharing of skills in different areas, and more easily creates an ethos or culture of excellence and integrity within the team. On the other hand, as organisations grow and evolve over time, workloads increase and communities become more involved in the delivery of health services, decentralised inspectorates may be more cost-effective. It is, however, apparent from the review that the resourcing models adopted by the inspectorate is likely to change as the regulatory scheme evolves.

### 6.2.2.2 Inspection processes

A regulator is only as strong as the weakest of its regulatory processes. Most regulators also know that their regulatory findings (particularly adverse ones) will be subject to intense public scrutiny. This is why regulators have strong internal quality control and assurance processes to test and validate their findings and reports.

Therefore, all inspections must be carried out in a structured and consistent manner based on approved methodologies. Once an inspector has completed his/her inspection, their findings are drafted into a formal report. Benchmarking studies and internal rules and operating procedures ensure the validity and credibility of inspections before a report is finalised and a decision taken.
on compliance of the health establishment. As compliance against standards is often difficult to assess objectively, robust peer review and quality control processes are set up to ensure consistency and compliance with internal rules and procedures. Such processes should ideally include a formal validation and quality control process both within and between teams and across management units, as well as review by an executive governance structure, to ensure that consistent, valid and complete reports are submitted to health establishments.

In line with the principles of good regulation, a draft report on findings is usually provided to the health establishment being assessed, to give them a fair chance to respond and if necessary to clarify the findings.

An example of a decision-making framework comes from the CQC, which has developed a guide to assist inspectors in making judgements on whether or not an establishment or part thereof is compliant. The call to make such a judgement goes through four stages, as illustrated in Figure 2.

**Figure 2: CQC Judgement Framework**

- **Stage 1**
  - Determining whether there is enough evidence to make a judgement

- **Stage 2**
  - Making a judgement about whether the evidence demonstrates non-compliance with one or more regulations

- **Stage 3**
  - Determining the level of impact of non-compliance on people

- **Stage 4**
  - Determining the regulatory response (which includes referring to the enforcement policy)

Source: CQC website 2012 (www.cqc.org.uk)

In Stage 1, inspectors would determine whether sufficient evidence exists to make a judgement about compliance. Certain key points are considered in Stage 1 in determining the weight of the evidence at hand, i.e. whether the evidence is current, reliable, relevant, sufficient, and includes inputs from users and specialists.

Stage 2 involves checking whether the evidence demonstrates non-compliance with the regulations. This represents a shift in the focus of the CQC’s inspection strategy to actively identifying instances of non-compliance with regulations rather than merely assessing the extent of compliance by health establishments. In Stage 3, an assessment of the impact of non-compliance on users of health services is made. In addition, inspectors assess the likelihood of non-compliance recurring. Where the likelihood of recurrence is high, the CQC can choose to commence enforcement processes.

In Stage 4, the judgement is validated by managers within the organisation. Final decisions on regulatory and enforcement actions are usually made through some form of executive governance.
structure (a Board) or through a Committee of senior staff (as for the CQC), which may bring in outside expertise and sometimes representation from the health services themselves.

### 6.2.2.3 A prioritisation framework for inspections

Most regulators do not have the resources to inspect all health establishments regularly. Moreover, the purpose of inspections is to assess compliance of health establishments against standards during regular operations. Hence, a decision has to be made regarding the balance between announced and unannounced inspections. Unannounced inspections often have the advantage of not allowing health establishments enough time to “game” the system.

Inspectorates internationally use a variety of techniques to help them prioritise inspections and workloads. The framework for prioritising inspections depends on the regulatory outcomes that the regulator wants to achieve. Hence, an inspectorate may choose to select:

- a specific type of service or facility because of a particular area of risk, or because the health service is seen as a policy priority;
- a health establishment based on its risk profile in terms of a set of indicators to use to predict the future risk of non-compliance;
- high-risk health establishments first, and sampling the medium- and low-risk establishments, such that all health establishments are assessed within a specific timeframe;
- health establishments who have applied for accreditation/certification once they are sure they can meet the standards; and/or
- health establishments on the basis of the results of their self-assessments.

In newly established regulators, with a large initial workload of inspections and a relatively small number of compliance officers to commence inspections, prioritising which health establishments to assess and in what detail is important.

### 6.2.2.4 Competencies and attributes of inspectors

The competencies and attributes of the staff in carrying out external quality assessments are crucial, as the credibility of their findings rests on this. Inspectors would generally also have a relationship-building, ambassadorial role in relation to the health establishments they assess, working with them and with other regulatory bodies and forums involved in delivering care to patients. Inspectors have to maintain an arms-length relationship with health establishments in order to maintain their objectivity. As the public face of the regulator, inspectors are generally bound by strict codes of conduct to assure the integrity of the organisation. Therefore, screening procedures for inspectors should also flesh out attributes in potential candidates that conform to the principles and values of the regulator.

The competencies, roles, performance and training of inspectors should be tailored to the nature of the inspections they will be performing and the degree of judgment they will have to exercise. An example of applying such considerations comes from the Council for Medical Schemes, which identifies two categories of “inspectors”: compliance inspectors and investigators (who investigate irregularities). Compliance inspectors are lower-level, multi-skilled employees with an excellent knowledge of standards and inspection methodologies. On the other hand, investigators are more highly skilled and experienced evidence gatherers with competencies in auditing, investigations or law, based on the nature of expected irregularities.

The international review found that training for inspectors was generally a mixture of classroom
learning and on-the-job training under the supervision of a buddy or mentor. Ongoing peer review ensures that inspectors maintain their competence, and that the standards are maintained at a higher level.

Established bodies revealed that performance management systems for inspectors include an element of 360-degree review. All inspectors are reviewed by their team and their line manager, and performance reviews are carried out with some frequency.

In addition to technical competences, all inspectors are trained in ethical behaviour and are asked to subscribe to a code of conduct. In particular, new regulators should ensure that a code of conduct and ethics is developed and signed by all inspectors. Following the merger of three organisations into the CQC, the regulator adopted a structured approach to inculcating the right ethical behaviour and values in its staff. Interventions included:

- utilising a baseline staff survey as kick-off;
- developing a framework for values and behaviour and integrating it into the Performance Management System;
- holding a regular staff-nominated awards process reflecting these values;
- working towards a “professional regulator” identity; and
- providing recognition for qualifications.

6.3 Compliance and risk monitoring

Compliance and risk monitoring covers the collection, analysis and synthesis of the information needed by regulators to discharge their other regulatory functions. This form of informational regulation is increasingly popular among regulators as a way of managing risk within the sector. With a wealth of data at their fingertips, regulators are increasingly using statistical methods to predict risky behaviour, making regulation more pro-active and better targeted. Moreover, by collecting the right types of information, analysing and publishing it, regulators are able reduce the information asymmetry between users and health establishments, thus allowing users to make more informed choices about health services.

The benchmarking exercises examined compliance monitoring systems, and the use of risk profiles to prioritise assessment and serve as a guide for intervention including enabling an urgent response where needed. Some attention was paid to the design approaches for establishing composite, index-based, specific and routine data reporting which could form the basis of profiles of risk to quality. The possibility, and international experience, of the use of complaints, the monitoring of specific incidents as well as of health indicators such as mortality outliers were reviewed in relation to an active surveillance or Early Warning system.

The findings of these studies all point towards the need for sophisticated risk assessment, data analysis and knowledge management capacity to be built within regulators to focus and prioritise inspections in order to maximise their use of costly human resources in the field and encourage regulated entities to address risks to quality.

Compliance and risk monitoring systems are becoming a key aspect of effective regulation. In general, these systems gather information from various sources and collate and analyse this information to formulate and disseminate timely recommendations for further regulatory action. Recommendations may highlight the need for a follow up inspection, urgent action or increase the frequency of reporting from a specific regulated entity.
Sources of information used to monitor risk are diverse and range from inspection reports and self-assessments, through routine reported information, to complaints and media reports – with the sophistication of the risk profiling system dependant on the amount and reliability of information available. Results of community-based monitoring systems are nowadays given greater weight in compliance and risk monitoring systems. The risk profiling systems can also make use of real time surveillance information so as to issue timely alerts around serious breaches of norms and standards. Hence, as Figure 3 illustrates, surveillance systems are a subset of the broad risk profiling activities.

Whatever the form of the compliance and risk monitoring system, specialised analytical capability is needed to ensure that they operate effectively and support regulatory action. This requires not only significant investments in information and communication technology but also a highly skilled complement of staff to operate the compliance and risk monitoring system.

**Figure 3: Compliance and risk monitoring systems**

The review revealed very little published literature on the organisation of information management within regulators. Such information had to be obtained directly from accreditation organisations as part of the institutional comparison.

### 6.3.1 Risk profiles

Risk profiling has long been used in the financial sectors to identify and mitigate systemic risks. Similar techniques are gaining acceptance in the health sector, as data collection and analytical capabilities improve. In simple terms, a risk profile outlines the types, severity and likelihood of risks faced by an organisation. Statistical advances mean that the likelihood of occurrence and their impact on an organisation can now be quantified by analysts.

The concept of risk in the field of healthcare quality has been much enhanced by a risks management and mitigation framework developed in Australia to categorise such risks and rank them. It defines risk as
“...the possibility of something happening that impacts on the objectives of the system... It is measured in terms of likelihood and consequence.”

The framework has been adapted to the health sector recognising the four dimensions to risk within health establishments, namely: patient care and safety, healthcare processes, financial sustainability and reputation. It goes further to categorise risk into insignificant, minor, moderate, major and catastrophic based on a matrix that rates each aspect being considered with respect to its impact and likelihood.

Risk profiles are increasingly critical to the regulatory process as they provide a way for regulators to collect regularly produced and routine information and formulate an assessment of risk.

From the interviews and benchmarking discussions with the CQC, it is clear that the development of any risk profiles should be guided by the following broad principles:

- **Risk profiles** are created by primarily bringing together *existing* information, from a number of different data sources.
- Both quantitative and qualitative data on the health establishment is important. A *wide range of data sources* should be used to develop and update a risk profile, while acknowledging that each of these data sources has its limitations in terms of usefulness, completeness, comprehensiveness and accuracy.

Risk profiles should take into consideration the different types of risk.

**Box 2: Types of risks**

There are various types of risks within the health sector. Some are exogenous and relate to the burden of disease or characteristics of the local population. Others arise from within health establishments. Each of these risks warrants different mitigation measures. In general, the four types of risks faced within the health sector are:

- **Inherent risk**: The risk attributable to an organisation by virtue of its case mix.
- **Situational risk**: The risk attributable to an organisation by virtue of its context.
- **Population risk**: Features in the local population that have been shown to affect care outcomes or access to care.
- **Uncertainty risk**: Assessment of the completeness of the above types of risks.

Source: CQC (www. CQC.org.uk)

The CQC’s approach to developing their quality risk profiles is as follows:

- Data sharing agreements can secure access to required data. Information is weighted according to the quality of data to ensure that the analysis is not biased.
- A quality risk rating is developed for each facility. This risk rating may be a single metric for risk, or a risk rating may be developed for a number of different categories of risk.
As new data sources are identified, validated and evaluated, and as technology becomes more sophisticated, new indicators are used to create risk profiles and risk ratings.

- Health establishment information is made available in an easily accessible format. Providers are able to access and view their risk profile, as well as understand how it was computed (with security and access levels clearly defined).
- The information contained in a risk profile is dynamic, and is updated on an ongoing basis. Risk profiles and risk ratings are updated regularly.
- Far more emphasis and resources are now being channelled to supplement risk profiles with frequent and unannounced on-site inspections, as the only method of ensuring a full and objective picture of a facility.

To complement other forms of routine data collection, the CQC’s “Outliers and Analysis” Surveillance unit uses mortality notifications provided by NHS Trusts and a private agency for analysis. Statistical time series techniques are used to identify where mortality data are worse than expected, by comparing actual occurrences to the statistical threshold of expected mortality based on historical series. The CQC also reviews emergency re-admissions (within 28 days of discharge) for specific hospital procedures, and maternity services. If statistical anomalies or breaches are detected by the CQC, an action plan is developed and implemented by the hospital. In about 40 per cent of cases, the hospital develops an action plan for improvement itself in response to the alert, without the need for outside intervention.

Inspectors then monitor the implementation of the action plan. In rare cases, an investigation is needed and undertaken by the regulator.

From the perspective of the regulator, the use of risk profiles relating to quality meant that less emphasis needs to be placed on lengthy investigations of things that had already gone badly wrong, and more on collaboration between the regulator and others to identify problems early and work to resolve them. However, the reliance on self-reported information by health establishment can introduce bias in the risk profiles and limit the regulator’s ability to detect severe non-compliance. This has led to a move away from reliance on “soft touch regulation” that saw quality monitoring as a substitute for external quality assessment.

### 6.3.2 Surveillance or Early Warning systems

The concept of an “early warning system” is well known in the field of weather or disaster forecasting, or famine early warning systems, where large amounts of data are monitored and analysed in real time in order to detect a pattern that might predict an imminent weather event or disaster. An Early Warning System (EWS) as applied to the area of quality risk monitoring is in effect a surveillance system which collects information on specific events in order to trigger prompt improvement or enforcement action.

Surveillance is a commonly accepted concept in healthcare and is defined by the WHO as “the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice” (WHO, 2006). However, in the case of communicable disease surveillance where there is an immediate risk to public health, this definition is augmented by reference to an early warning system that is designed specifically to lead to control and prevention.
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Surveillance systems in the context of quality therefore exist to serve as an early warning system to identify serious breaches of norms and standards, guide any immediate action to resolve the breach, document the impact of the breach and maintain a concerted and targeted monitoring process.

Four main elements of an EWS are described by the United Nations, namely risk assessment, monitoring and predicting, communicating alerts, and response.

The purpose of using a surveillance system and regulating notifiable events is to facilitate prompt reporting on serious incidents, and to communicate alerts immediately, in order to allow for an immediate response that will prevent further harm or manage the risk and its consequences.

An Early Warning surveillance system would monitor a critical set of safety and quality indicators on a real-time basis, in order to identify serious breaches at health establishment level. The most critical success factor in an effective surveillance system is the completeness of reporting, but it is also one of the most common weaknesses. Given that the purpose of an early warning system is to ensure prompt corrective or regulatory action, incidents pointing to potential or actual serious risks can be treated as notifiable events and hence regulated. For example, the state of Victoria in Australia has established a surveillance system for “sentinel events that occur independently of a patient’s condition, commonly reflect hospital system and process deficiencies” that results in harm to patients (Department of Health, Victoria, 2012).

The selection of the actual data to be monitored would depend on the realities of each specific situation, the risks that are more critical at any time, and the capacity and systems for reporting on them. Given its wide scope, international literature suggests that an early warning or quality surveillance system is “not the responsibility of a single organisation or reliant on a single process, but that its success depends on the culture within and between organisations which, in turn, needs to be underpinned by robust systems and processes and clarity around roles and responsibilities”.

6.3.3 Regulatory information management

Most regulators tend to collect and generate a wealth of information. The information collected in and for the quality risk profiles and early warning system will be a rich source of understanding of the health system. This information would enable analysis across standards, across establishments, across services, across geographical regions and across user groups. The added advantage is that mandatory reporting may improve the completeness of the data, while on-site verification, if present, is an opportunity to enhance and validate the data quality.

Such large data sets have enabled regulators to contribute to the understanding of the health system as well as to influence policy and planning. However, the Healthcare Commission also stated that the degree of influence they achieved on the UK National Health Service was less than intended or anticipated. The reasons for this would need to be examined to determine how regulatory information can best be leveraged to improve health outcomes. In a recent strategic review, the CQC put the effective use of their information to influence change as their number one priority (CQC, 2012).

The Healthcare Commission in the UK (the predecessor to the CQC), used information gathered on the quality of care in two ways:

- To provide a view of risks in the system of healthcare, and to give early warning of which risks required some form of action, including intervention.
• To report publicly on the performance of organisations, services and those managing pathways of care, so as to enable people to make better-informed decisions.

Information was used to target the use of inspections, informed by a risk analysis – particularly in areas where a range of additional sources of information was lacking (such as the quality of services for those with learning disabilities, or the treatment of older people in hospital); where information suggested that questions needed to be asked which could only be answered by visiting; and on a more random basis, and unannounced on occasions, to “keep the system honest”.

Over time, they gradually developed the capacity to engage in “real-time” surveillance of performance, through refining the information available, and introducing an early warning system so that immediate action could be taken. Hence, it seems that the ‘early warning system’ evolved from the quality risk profile work which, in turn, was made possible by extensive technological and analytical infrastructure and capacity.

Their key strategies for implementing information management included the:
• adoption of an information-led, risk-based approach to regulation;
• significant investment (amounting to some £16 million) to create its analytical and technological capability;
• establishment of benchmarks for performance;
• utilisation of existing data generated by the NHS and others to answer questions about quality;
• use of information to communicate to the NHS its performance in key areas; and
• production of an annual rating of organisations’ performance, starting with a post hoc audit of performance.

6.4 Complaints management, resolution and redress

Complaints are a way for users to express dissatisfaction with health services in both the public and private sector. Apart from the obvious and primary objective of responding effectively and timeously to the immediate concerns of the individual user, without proper complaints handling and management systems, this valuable source of feedback from users would be lost within the bureaucracy, further frustrating them and undermining the reputation of the service provider. However, when used effectively, complaints yield useful insights into areas of service delivery where major challenges exist.

In the health sector, complaints from users are particularly important as they can relate to poor service standards or system failures but may also denote more serious and life threatening issues such as medical errors or dangerous practices/conditions within health establishments.

The Netherlands Institute for Health Services Research found that patients were generally dissatisfied with the way their complaints were handled. The research found that, contrary to popular belief, the predominant reason cited by their study population for lodging a complaint was to prevent the incident from recurring, rather than that of seeking compensation or financial redress. In effect, users sought to restore their sense of justice by laying a complaint in the hope that a response and explanation would be forthcoming from the health professional or that any medical error might be uncovered and thus avoided in the future (“I don’t want this to happen to anyone else”) (Friele and Sluijs, 2006).
Complaint handling and management system can often resolve a problem before it worsens and impacts negatively on the quality of health services. Specifically, complaints can provide managers with information about service delivery failures or breaches of standards. Second, these systems can provide a remedy to a client who has suffered disadvantage by way of a simple gesture such as an acknowledgment or apology or in the extreme through financial compensation. Finally, government departments and agencies that handle, respond, and resolve complaints are able to foster a more open relationship with users and members of the public.

It is for this reason that complaints handling and management systems are found at all levels of government so that users may report their complaints at the point of service. Throughout the world, most governments prescribe some form of complaints handling and management system through legislation, policy or guidance. In the UK for example, the Department of Health and NHS have developed regulations governing the design and operations of complaints management systems (NHS, 2012).

From the perspective of the regulator, complaints can provide information on possible breaches of norms and standards and are a critical source of data for quality risk profiles. In addition, regulators review, test and validate the complaint handling and management systems within health establishments to ensure that they are operational and fit for purpose.

In certain cases, health establishments or government agencies may be unable or unwilling to resolve a complaint. Where this occurs, most governments have established Ombud offices to record and investigate and/or adjudicate complaints.

Ombud offices have been established worldwide and serve as a channel for consumers or users to complain about the quality of services received and/or to report unfair treatment at the hands of organisations in either the public or private sector. Ombuds are normally established as independent and impartial offices with the task of resolving complaints and disputes between consumers and service providers in a way that is fair but also quick. The speedy resolution of complaints and disputes is one of the main reasons for the establishment of an Ombud. Ombuds offer an effective alternative to more expensive, onerous and time-consuming legal process for aggrieved consumers.

The benchmarking exercises explored the common use of the terminology around an Ombud (which normally signifies a “quasi-court”) with adjudicative or determinative powers. It covered the critical issues of independence and impartiality, as well as the importance of clarifying the mandate and/or scope of an Ombud in the light of the expectations of complainants.

In establishing an Ombud, the studies pointed to the importance of clarifying definitional issues upfront within legislation in relation to redress (compensation for or correction of a wrong or violation of rights), remedy (to recover a right or to prevent or obtain redress for a wrong), and resolution (solving a problem or violation of rights), as well as whether compensation and/or restitution would form part of the scope of possible remedies.

6.4.1 Adjudication and determination

From the international review it is clear that an Ombud Office is essentially an alternative to going to the courts. An Ombud not only has an interest in the resolution of a dispute or complaint, but also has the legal authority to either take a decision or make a recommendation depending on the
powers endowed on the Ombud through its governing act or agreed terms of reference. Traditionally, for an Ombud to be properly so called, he/she must have *determinative powers*. In other words, an Ombud must have the ability to make binding decisions on measures to achieve redress, remedy, compensation or restitution.

In the past, a role-player with lesser powers was not automatically seen as an Ombud, but could be established as a Commission (e.g. the Human Rights Commission) with the power to make administrative decisions. These types of institutions assumed an adjudicative role where administrative determination is made in respect of the dispute.

However, as more ombuds have been established, a range of typologies have emerged. This spectrum ranges from ombuds with both adjudicative and determinative powers to those created with solely adjudicative powers (power to make a finding and recommend action).

The emergence of primarily adjudicative ombuds offers more flexibility in situations where the disputants have to continue to have a relationship after the dispute or complaint. These types of Ombud can make recommendations on a matter to benefit the complainant while minimising any financial costs to the respondent and without unnecessarily straining relationships between the two parties. This approach contrasts with the notion of an adjudicative and determinative Ombud which can in fact produce the very ills that one is trying to avoid in the normal court system, such as delays occasioned by technical arguments.

The involvement of the Ombud is often preceded by escalation processes such that the volume of matters coming to the Ombud office is generally lower than they would actually be expected. Put differently, for an Ombud in the health sector to be effective, health establishments themselves should have their own complaints handling and management systems in place to resolve the majority of disputes, and complaints not yet dealt with at this level might be referred back as a first step.

Where the Ombud has both the investigative as well as adjudicative powers, the office should be structured so as to achieve a clear distinction between the investigation function and the adjudication function, in order to avoid compromising the impartiality of the final findings.

The benchmarking exercise showed that considerable care should be taken in setting up an Ombud office, with clear frameworks for both the scope of the complaints that can be considered, as well as for the determination or adjudicative powers vested in such an office.

**6.4.2 Investigation process**

The international benchmarking studies identify the importance of a clear brief or mandate for such an ombud. The scope of work of an ombud must be made clear to all complainants and health establishments, so that complaints are not directed to the wrong entity or so that complaints can be swiftly channelled to where they are best resolved. Ineffective or inefficient referral systems are likely to frustrate and demotivate complainants and overload the complaints system.

An Ombud’s credibility depends on his or her ability to gather evidence (whether documentary, verbal or scientific) that will help determine the facts associated with the complaint. To achieve this, the Ombud needs qualified investigative staff as well as rigorous processes.

The United Nations Development Programme has developed a good practice guide for Ombud’s
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that details processes to be followed prior to making a determination. The process can be broken down into three phases.

6.4.2.1 Complaints filtering
An initial review of a complaint is usually carried out by an Ombud office to ascertain the merit of the complaint and establish jurisdiction, and to ensure that all requirements as set out in the policy and procedures of the Ombud office are adhered to. Such an initial review can lead to the complaint being rerouted to the appropriate regulator or organisation for appropriate or local resolution, or to further enquiries by the Ombud office.

6.4.2.2 Evidence gathering and investigation
An Ombud office should acknowledge a complaint promptly and formally once the decision is taken to investigate it. This can then be followed by immediate assessment of the seriousness and urgency of the matter, and referral to a case investigator. The case investigator may request all reports pertaining to the complaint from the appropriate authority, as well as all documentation the complainant has regarding the complaint. Reviewing these documents will either lead to closure of the case, or to further enquiries including interviews with the concerned individuals.

6.4.2.3 Determination
From the assembled information, the Ombud must then reach a finding regarding whether the complainant was indeed harmed, and if so in which way. The Ombud could further be expected to determine if any individual was responsible for what happened. The findings of the Ombud could be in the form of a determination regarding measures for redress including compensation, or in the form of a recommendation.

6.4.3 The experience of the UK Health Ombud
As an example, the UK Health Ombud is empowered by the Health Act with functions that relate to process and include considerations of clinical judgement. Although the Health Ombud does consider the actions of individual practitioners, individual negligence cases are handed over to the General Medical Council to handle. The Health (and Parliamentary) Ombud Offices see facilitation of sharing and learning across government as a whole as a core objective.

The UK Health Ombud has a complement of more or less 300 staff members that includes customer services, complaints assessment, complaints investigation as well as legal services, communication and corporate resources.

The recommendations issued by the UK Health Ombud range from an apology, to recommendations for system changes. In a limited number of cases, the Ombud awards relatively small compensation payments. During 2010, this amounted in total to no more than £0.5 million.

The Ombud is not allowed to publish reports on individual investigations and/or recommendations. They publish an Annual Report, and from time to time thematic reports of case studies. They make use of customer satisfaction surveys to evaluate and reflect on the services that they have provided. Complainants participate in these surveys once their complaint has been closed. Major challenges identified by the Health Ombud remain unrealistic or misinformed expectations on the part of the public.

Their complaints investigation process is based on the principles of good administration and general
best-practice implementation. Complainants access a well-resourced call centre where call takers record all details for subsequent review by a team of assessors. Within a period of 40 days, their initial assessment must determine whether or not the complaint will be further investigated by the Ombud. Of approximately 15 000 complaints received by the UK Health Ombud, only about one quarter (3 750) were assessed, the rest being referred back to the NHS Trusts or other bodies. Of these, only 350 of these complaints were fully investigated by the Ombud, with the remainder receiving a response and explanation.

The governing legislation lists specific reasons an Ombud may choose not to investigate, or to stop investigation, such as:

- the complainant knew or ought to have known of the alleged violation more than a year before contacting the Ombud institution;
- the complainant does not have sufficient personal interest;
- the person aggrieved has not pursued an available and adequate remedy;
- the complaint is frivolous, vexatious, trivial or not made in good faith; further investigation is not necessary; or
- an investigation would not benefit the complainant or aggrieved person.

Box 3: Criteria for determining whether investigation is needed

Clear criteria assist investigation processes, based on four key questions:

1. Was there maladministration or service failure?
2. If so, did it cause injustice?
3. Was the injustice remedied?
4. What would further control intervention achieve?

Source: UK Health Ombud

Investigators have strong powers to collect all relevant information from all relevant parties and may call on any further needed expertise in order to arrive at a conclusion, and produce a report with recommendations.

Decisions on which cases to investigate, as well as final decisions on the report and recommendations, are made through collective processes or review panels. A final investigative report is normally prepared when a full investigation is completed. Investigative reports provide accountability and a degree of transparency to the public for the office. According to the Guide for Ombudsman Institutions from the United Nations Development Programme, each report should be structured and written based on the investigation done.

6.4.4 The Public Protector

The institution of the Public Protector was established by the Public Protector Act, 1994 as a “Chapter 9” institution in terms of the Constitution. The actual office was established in 1995, with jurisdiction over all organs of state, any institution in which the state is the majority or controlling shareholder and any public entity as defined in section 1 of the Public Finance Management Act (1999). The Office has a large team of investigators, but the findings and recommendations are decided and issued by the Public Protector or his or her deputy.
The core business of the Public Protector is

“To investigate any conduct in State affairs or in the public administration in any sphere of government that is alleged or suspected to be improper or to result in impropriety or prejudice.”

The Public Protector is accountable to the National Assembly and must report at least once a year; although he/she may submit a report on a particular investigation when he/she

“deems it necessary; …deems it in the public interest; .. requires the urgent attention of, or an intervention by, the National Assembly, or .. is requested to do so by the Chairperson of the national Council of Provinces.”

Any report issued by the Public Protector must be open to the public unless there are clear reasons for it to be kept confidential (Public Protector, 2009).

6.4.5 The experience of the FAIS Ombud

The Financial Advisory and Intermediary Services (FAIS) Ombud ranks among the older and more entrenched ombuds in South Africa, and offers some valuable lessons regarding the relationship between a regulator and sector Ombud. The FAIS Ombud is aligned to the Financial Services Board (FSB), an independent regulator in the financial sector. The Ombud is appointed by the Minister of Finance on recommendation of the FSB and reports to the board of the FSB. Both the Ombud and Executive Officer of the FSB are *ex officio* members of the Board. The Act empowers the Ombud to make a determination against the service provider and/or consumer as well as the FSB.

To manage concurrent jurisdiction between the FAIS Ombud and other ombud schemes in the financial services sector, the Financial Services Ombud Schemes Act (FISOS) provides that where none of the ombud schemes has jurisdiction, the FAIS Ombud will be deemed to have jurisdiction and also where all the ombud schemes have jurisdiction, the FAIS Ombud will take precedence. Furthermore the FISOS empowers the FAIS Ombud to set the standards with which the other ombud schemes must comply. This is a very clear and decisive tool to manage regulatory capture or “forum shopping”.

The Financial Advisory and Intermediary Services Act requires every registered service provider to have a Compliance Officer who also acts as the point of contact between the service provider and the Ombud. The FAIS Ombud presents a good example of the separation between investigations and determination. Investigations are carried out by qualified and trained case managers. Determinations are made by either the Ombud, his deputy or an assistant Ombud who consider the investigation recommendation made by the case administrator and make a final determination.

The FAIS Ombud is created within the Financial Services Board although the governing legislation assures its independence. The decision to align the Ombud with regulators is generally made for cost-saving purposes. Often the work of a regulator and Ombud may allow for economies of scope and cost savings. But as practical experience shows, the alignment of the Ombud with a regulator can also create tensions.

This integrative approach was tested in courts through the *Leader Guard* matter. Initially the FAIS Ombud reported to the Executive Officer of the FSB. In its determination, the Ombud made a finding against the FSB (that the FSB was negligent in authorising a particular Financial Services Provider, and therefore that the FSB should be held liable for the loss suffered by the consumer). The determination created tensions between the FAIS Ombud and the FSB.
During the amendment to the FAIS Act, legislation was amended so that the FAIS Ombud no longer reports to the Executive Authority but to the Board of the FSB. As a result of these amendments, the Ombud is now listed separately as a Schedule 3 public entity under the Public Finance Management Act. The Ombud accounts to the FSB Board / Parliament on governance and financial management, but not on the decisions the Ombud makes on cases.

In summary, regulators can use information on complaints to improve the rigour of their quality risk profiles or to identify potential breaches of norms and standards. Regulators are not directly involved in investigating complaints but may support the work of an Ombud. The overall effectiveness of an Ombud is influenced by the current complaints handling and management mechanisms within health establishments. Where strong complaints management systems exist, a smaller proportion of complaints are escalated to the Ombud to review and resolve. Ombud offices generally have determinative powers which allow them to make binding rulings on all parties; however in some situations they have only adjudicative powers to make an administrative finding.

6.5 Communication, stakeholder engagement and reporting

As the practice of regulation has evolved, it has become apparent that the non-traditional regulatory functions such as communication and stakeholder engagement play an important role in promoting voluntary compliance by regulated entities, strengthening the credibility of regulators and educating the public about their rights and about the recourse available to them. Many regulators now have strong communications arms which work in tandem with their core regulatory functions to achieve better compliance within sectors.

The benchmarking exercise reviewed a number of national and international regulators in order to understand better their communication and stakeholder relation functions. The research covered the importance of communications in relation to the dissemination of information to users, regulated entities and the public. In terms of users, the communication function focuses on informing them of the basic standards, how to complain and what to expect from health services. In relation to regulated entities, the areas covered were advice on how to comply and information on the broad patterns, problems or actions needed. In addition, the benchmarking exercise also provided information on the importance of a communication function with respect to informing the public of findings and lessons learnt. With regard to the relationship between regulators and the various stakeholders, the studies noted that regulators relate in a more or less structured way to broad categories of stakeholders; namely the users of the services they are regulating, the entities they regulate and other regulators operating in the same field or with similar objectives.

6.5.1 Lessons from other regulators

In the area of communication, interviews were conducted with other regulators to explore their views on the strategic purpose of communication and stakeholder relations, their definition of the practical functions of units dealing with this area of work, the structuring and resourcing of relevant units and the audiences they endeavour to reach. These interviews focused more on South African regulators because of the importance of the specific social, economic, political and cultural environment to communications and stakeholder work.

The regulators interviewed in a structured manner were: the Health Professions Council of SA (HPCSA), the SA Pharmacy Council (SAPC), the Council for Medical Schemes (CMS), the Competition Commission (CC), the Public Protector, the National Credit Regulator (NCR), and the Ombudsman for the Banking Sector. Less structured interviews were conducted with the South African Revenue
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Service (SARS) and with a Canadian public health monitoring and advocacy expert. A great deal was learned from the UK Care Quality Commission (CQC) and the UK Health Ombud.

From these interviews it is clear that:

- The newer regulators (CC, NCR and Public Protector) as well as SARS tended to view communications strategically, as a significant tool in securing compliance with relevant legislation – that is, in fulfilling the core regulatory mandate of the organisation.
- They described education and advocacy aimed at individuals and organisations that are subject to regulation as a means of securing “voluntary compliance”. This reduced the need for action by the enforcement arm of the regulator, and made for more efficient regulation.
- They also viewed public education and interaction with consumer bodies as strategies designed to empower consumers to hold service providers or companies accountable. Once more, this was seen to contribute to voluntary compliance and reduce the need for enforcement.
- The Banking Ombudsman, which is mainly a complaints-driven service, also viewed communication as critical to eliciting complaints and improving the organisation’s ability to address the service problems in the sector.

6.5.2 Communication

The majority of the communication units within the regulators interviewed undertook the following functions:

- media relations;
- production of publications, including newsletters;
- corporate branding and identity management;
- communication to a range of external stakeholders;
- communication to internal stakeholders;
- writing or editing content for the website;
- community outreach and awareness-building;
- education and/or training;
- road shows across several provinces; and
- stakeholder events.

The fact that certain communication functions were not performed by all the units interviewed did not mean that the regulator as a whole neglected the specific function. For example, it was quite common for high-level and sensitive communication interventions to be undertaken by the head of the organisation. The CMS, on the other hand, invested a lot of time and effort in education of stakeholders and the public, but this was undertaken by a dedicated education and training unit.

Where communication units are responsible for stakeholder relations and do not have specific staff for this aspect of their work, very little focused stakeholder work seems to take place. However, the converse does not apply. Divisions and even units with titles that make no mention of communication may perform a whole range of communication functions.

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4 Although SARS is not a regulator, their communication campaign offers some useful lessons around communicating with users and promoting voluntary compliance.
6.5.3 Stakeholder relations

The benchmarking exercises in relation to stakeholders, and the relationships a health regulatory body could establish with these stakeholders, included the critical requirement to incorporate the needs and/or mandates of various stakeholders into the operations of the regulator. The stakeholder groupings reviewed were the users of services, the regulated entities and other regulators.

The international and local comparative analysis revealed that communication and stakeholder relations do not invariably fall into the same unit, or even into the same accounting or reporting line. It was noted that specific stakeholder relations capacity is a feature of the newer regulators/ombuds, although it is sometimes seen as part of an “education” function. The older regulators/ombuds either do not differentiate stakeholder interventions from communication interventions or else deal with it as a function of general management.

There was at least as much to be learned from the particular emphases and unique features of stakeholder relations in each organisation as there was from the profile of common functions:

- The SA Pharmacy Council partners with pharmacies (“the regulated”) to achieve a low-cost annual public education campaign to mark Pharmacy Week.
- The Council for Medical Schemes invests time and effort in educating and empowering trustees of medical schemes (“the regulated”) to assist them to fulfil their fiduciary duty to the membership of schemes.
- The Competition Commission consciously provides platforms for consumer bodies such as the National Consumer Forum and the Black Sash in order to strengthen their capacity as civil society watchdogs.
- The National Credit Regulator forms partnerships with traditional leaders and the SA Social Security Agency to identify unscrupulous microlenders.
- The Public Protector seeks not only to investigate complaints against local authorities but to mediate between them and disaffected communities where relationships could easily deteriorate into violent confrontations.

The above indicates that there is no single “recipe” for regulators in so far as stakeholder engagement is concerned. They form partnerships and target communication in ways that will yield the best results in terms of compliance in the particular fields they regulate.

Internationally, there is a wide range of public and private (non-profit) organisations and initiatives focusing on bringing together stakeholders concerned with quality of care and patient safety – each with a distinct set of objectives and goals. Stakeholders involved in the broad range of different initiatives include policymakers, professionals, clinicians, education and research institutions, user groups, consumer groups, patient advocacy and lobby organisations.

With regard to the regulated entities and their management systems, attention was paid to how these relationships could make enforcement action more effective through understanding their operations. In the case of other regulators, the exercise included a look at overlapping and/or complementary mandates and how value could be added by including these as part of a business model for the health quality regulator.
6.5.4 Engaging with patients and users

Patient participation in ensuring that services are safe and acceptable to users and ensuring that the patient voice serves as a central reference in key decisions is in line with internationally recommended practice. The value of the input of the users of services for design and methodology were explored more broadly in relation to quality and safety as a whole. Patient safety is defined as “the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum” (WHO, 2009). Patient safety and quality groupings take a number of different forms, with a range of different purposes. However, one common theme is the recognition that patient involvement in patient safety and quality processes is not only important, but absolutely necessary in ensuring greater access to safe and high-quality care. This concept is underpinned by an understanding that patients are not just victims but important contributors to the continued development of the quality and improvement of patient safety. In some instances, this understanding has also been applied to the work of regulatory bodies.

In the United Kingdom the National Patient Safety Agency (an arm’s length body of the Department of Health) includes the involvement of and communication with patients and public. The National Patient Safety Forum on the other hand is seen as a vehicle to harness the skills and expertise of a number of organisations, agencies and stakeholders which are making a significant contribution to patient safety, to bring together key organisations, agencies and stakeholders at national level, as well as other key players, with responsibilities for patient safety, to influence the development of the patient safety agenda and facilitate its delivery and become the national conscience of patient safety. The NPSF is further given the responsibility to oversee the design and implementation of a national patient safety campaign-focused initiative, with the objective of engaging, informing and motivating clinical staff and healthcare providers to address the challenge of providing safer healthcare.

Whereas the UK model is a government driven initiative, the German Coalition for Patient Safety is an example of a Ministry of Health-supported initiative. The Coalition is a non-profit association established by a collective of healthcare professionals, institutions and patient organisations. The Coalition is a multi-professional (inter-disciplinary) umbrella organisation headed by an executive committee elected in the general meetings. The Coalition involves itself in practical safety projects undertaken by a special expert group. Results of these special projects are published as recommendations. The Coalition has the responsibility for directing national and international cooperation with assemblies, medical associations, research institutes, health insurance companies, non-government organisations and patient organisations.

In 2011 the Government of the United States of America launched the Partnership for Patients: Better Care, Lower Costs – a public-private partnership aimed at improving the quality, safety, and affordability of healthcare. The partnership brings together leaders of major hospitals, employers, health plans, physicians, nurses, and patient advocates along with State and Federal governments in a shared effort to make hospital care safer, more reliable, and less costly. The Partnership operates on pledged commitments from hospitals, physicians and nurses groups, consumer groups, and employers.

From the specific point of view of a regulator, the CQC in the UK has developed and wide range of ways to interact in a structured and formal way with those whose interest it serves, namely patients and healthcare users. A user database of groups and individuals has been established to provide input for all policy and methodology development work, including a “Speak-out” network of hard-to-reach groups, contracted to provide specific input. The regulator goes a step further however, with
its “Acting together” programme, through which “experts by experience” or health service users, can be included in selected inspection visits through a formal process whereby organisations are contracted to recruit, train, supply and support them for this work. Local improvement networks of volunteers operating under Local Authorities already have the power to “enter and view” and report, and work in close touch with inspectors; this programme is to be expanded and given a lot more resources and powers through the new “Health Watch England”, which will be accountable to CQC but independent, with its role being to “amplify local voices”.

The CQC recognises that this focus on users has changed the culture of CQC and enhanced the recognition by staff that their work is to protect patients. Close links with users at local level does improve input and “surveillance” of service providers through providing on-site direct feedback. It does however require careful management of users’ expectations that all suggestions they make will be taken up. The regulator needs to ensure respectful engagement and an explanation if user feedback is not taken up; however this needs specific resources in order to function well. From the these examples it is clear that the involvement of users and patients can contribute to the achievement of better quality care through broadening and deepening their involvement in healthcare and the strengthening of the effectiveness of healthcare systems and of regulation.

The purpose of a regulator is ultimately, to protect and ensure patients’ right to quality healthcare, and it should have a role to play in the education of the consumer / users, general awareness raising and capacity-building of civil society organisations to engage in the process to articulate and act upon their demands. It is critical however to recognise the role of existing community groupings and not be seen to co-opt or undermine them.

6.5.5 Relationship with regulated entities

The nature of quality healthcare means that the regulated entities themselves (the managers and staff in health establishments) have a fundamental role to play in ensuring compliance with standards. This is equally the case with the governance, management or support structures that might be in place in the specific health system and within which the establishments function. Key policies, decisions and resources needed to ensure quality and compliance may in fact be managed at this level.

The CQC for example recognises this through a close formal working relationship with the National Health Service and with the sub-national Strategic Health Authorities in relation to the standards that are prescribed, the process of inspections and risk profiling, and the response to areas found to be of concern. These relationships are guided at a very senior level but reinforced through formal working relationships at other levels.

6.5.6 Relationships with other regulators

Improving the quality of healthcare is by its nature a cross-cutting challenge. This has meant that a coordinated approach to regulation is generally accepted as necessary. The HAS in France has designed their model around this, while in the UK, the CQC is part of a number of regulators that have signed an agreement on roles and powers. Effective coordination is important in order to reduce the regulatory burden, to enhance efficiency in the use of public resources, and to ensure the most effective enforcement powers should the need arise.

The British regulatory system offers some valuable lessons on regulatory coordination. In cases, where other government agencies or a regulatory agency have the power to take action, the CQC will work with them to coordinate their actions in order to avoid duplication. In particular, the CQC works
with other regulators such as the UK Health Ombud and the Regulator for NHS Trusts to coordinate enforcement actions, as well as with the professional Councils. Moreover, the CQC reports all non-compliance to the National Health Service and their sub-national structures (the Strategic Health Authorities), to the local authorities (who in the case of social care, agree with providers on service standards), and other relevant authorities.

6.5.7 Reporting

This is one of the most critical and challenging functions of regulators, as they operate generally on behalf of the public and to protect public interest and safety. As such, making their findings public is a critical part of their duty, as opposed to quality improvement activities undertaken on a voluntary basis and where contracting parties often sign specific undertakings that all information is entirely confidential.

As a regulator in a developed country with widespread internet access, the CQC makes extensive use of their website to report on their findings to the public and communicate with regulated entities. Their public reporting strategy is two-pronged. First, the CQC uses their website to facilitate consultation on their strategies and report on their operations. Second, the regulator uses their website to provide information to the general public on the extent of compliance with standards. The regulator has developed user-friendly summary reports, which are posted on their website following the completion of an inspection at a health establishment. These reports allow users to check the extent to which specific hospitals, dental and GP practices meet essential outcomes. Importantly, these summary reports are concise, written in clear and plain English and easy to grasp. In most cases, these summary reports are accompanied by the inspector’s report, which can be downloaded for a more detailed assessment of compliance.

Given the highly technical nature of the information collected, and the fact that a lot if it is indeed confidential (patient information, business information, personal staff information), it was clear from the benchmarking exercise that a balance needs to be found between competing “rights”. Accurate, validated, findings can be presented only once management has been given adequate opportunity to respond (or even to correct problems); and if this is presented in such a way that the public benefits from the information in terms of exercising their choice or holding public services to account.

6.6 Enforcement and sanction

Enforcement action is often seen as central to the credibility of a regulatory scheme. Without the ability to enforce compliance and impose sanctions, regulators are largely ineffectual. Enforcement refers to the variety of measures that regulators can take to compel compliance with regulation or punish non-compliance (Frieberg, 2010). In South Africa, regulators have traditionally relied on civil sanctions (such as compliance notices, administrative warnings, suspension or deregistration) to enforce compliance. Less use is generally made of criminal sanction such as imprisonment, with cases involving pervasive non-compliance infrequently reaching the courts.

Enforcement action is a powerful tool in the hands of a regulator, and should be used consistently and predictably. Checks and controls to prevent its abuse are important, and most regulators tend to publish an enforcement policy which details how and when enforcement actions will be taken.

The benchmarking studies examined the approach to enforcement and sanctions used by international and local regulators. Some key lessons around enforcement are as follows:
Enforcement action is punitive, and should be used judiciously after taking into consideration the seriousness of non-compliance and the severity of the harm incurred by users.

Transparency in relation to enforcement action is central to maintaining the credibility of regulators. Hence, all regulators should adopt and publish an enforcement policy which sets out their approach to enforcement action.

The regulator within the specific sector who is in the best position to enforce compliance should lead enforcement actions, supported by other regulators in that and other sectors.

A progressive approach ensures that enforcement action is administratively and procedurally fair, and ensures that regulated entities are given adequate time to explain and remedy non-compliance.

### 6.6.1 International experience

#### 6.6.1.1 United Kingdom

The CQC has the power to inspect regulated entities, investigate concerns and enforce their decisions. As the legislative framework regulating the quality of health services evolved in the UK, so too have more enforcement powers been conferred on the regulator. Under the Health and Social Care Act (2008), the CQC is allowed to engage in civil and criminal enforcement action if the case warrants it, to enforce compliance with standards.

These enforcement powers are often seen as punitive, and ideally are used only once other voluntary means are exhausted. Hence, the CQC has developed an enforcement policy that presents a number of enforcement options. These enforcement options begin with formal regulatory action, which requires a health establishment to undertake compliance actions within a defined timeframe to address transgressions. Where health establishment remains non-compliant, the CQC will issue a warning notice giving the health establishment a final opportunity to comply with essential standards before civil or criminal enforcement measures are initiated.

Failure to comply with the warning notice serves as the basis for more severe enforcement action. In these cases, the CQC may choose to initiate either criminal or civil enforcement action or both if continued non-compliance poses a serious threat to users of the service. Criminal enforcement action ranges from issuing a fixed penalty notice to referring the case to the crown prosecutors for criminal prosecution. Civil enforcement action by the CQC may include varying, removing or imposing conditions of registration or at worse cancelling the registration of the health establishment altogether.

Figure 4 sums up this approach to enforcement.
However, despite being given these strong enforcement powers, the CQC works in collaboration with other organisations (as well as with the National Health Service itself and its sub-national authorities). Where other regulators are in a better position to prosecute an offence, the CQC is likely to defer to the powers of the other regulator. Underpinning this coordinated enforcement approach is an extensive number of agreements and information-sharing protocols that allow regulators to coordinate their activities. The basis for the coordinated enforcement approach is a concordat signed between the CQC and nine other organisations that regulate, audit, inspect and review elements of healthcare in the UK.

**6.6.1.2 France**

In the case of Haute Autorité de Santé (HAS) in France, no explicit enforcement powers have been conferred through legislation. Rather, the French Quality Programme relies on a system of coordinated enforcement. Under this approach, the HAS relies on the Ministry of Health, Health Insurers and other sector regulators to enforce compliance with standards.

Enforcement therefore begins during the certification process, when the HAS is required to engage with other key players to obtain information on problem and risk areas for review during certification. During the certification process, these problem areas are investigated and reported on. At the end of the certification process, the HAS issues its results. The HAS may certify an organisation as being:

- fully compliant;
- with recommendations;
- subject to conditions; or
- non-compliant.

Should the HAS identify serious transgressions of standards or any matter that may pose a grave public health risk, then it is required to notify the Minister of Health. The Minister of Health may then,
depending on the seriousness of the transgression, take the necessary steps to enforce compliance. The Minister of Health has the power to close down a health facility should it pose a serious health risk. In the event of gross non-compliance, the HAS is also required to notify immediately other sector regulators, the National Health Insurance as well as any professional bodies.

Worth noting is the strong link between the quality of healthcare and the financing of healthcare. Legislation creating the Agences Régionale Santé (ARS) (“Regional Health Agencies”) – the health insurers – requires them to use the results of the certification process in their multi-year contracts. These health insurers are empowered through legislation to impose financial sanctions on health establishments which fail to comply with quality and patient safety standards. Legislation also allows health insurers to use the results of the HAS to require health establishments to conclude a “quality improvement agreement” with their surrounding communities.

The HAS approach shows that a system of coordinated enforcement may avoid duplication of resources and be effective in achieving the regulatory outcome of quality improvement. Coordinated enforcement is founded on two cornerstones.

- First, a mature system of data collection and information sharing among government agencies and regulators is required for the quality regulator to identify instances of non-compliance.
- Second, clear and defined responsibilities between the regulator and other government agencies are required for the system of coordinated enforcement to work. In other words, legal agreements, systems and processes have been developed that allow the HAS to communicate effectively with the relevant government agency. For example, the HAS and ARS (National Health Insurer) have developed a “mission et travaux” (protocol) that details how the two organisations should work together.

### 6.6.2 South African experience

#### 6.6.2.1 The Financial Services Board (FSB)

The FSB initiated a new supervisory framework in 2005. This approach moved from a compliance-based to a risk-based approach. The risk-based approach is in line with international trends, allowing for proactive supervision, enabling the early detection of potential problems, and promoting the continuous management of risk to facilitate proactive supervision, known as Risk-Based Supervision.

Where the FSB uncover non-compliance a number of enforcement measures can be undertaken, including:

- Debarment of individuals, effectively prohibiting them from practicing in the industry.
- Administrative penalties, relating to the late submission of the required documents and reports as well as the late payment of levies. In addition, overdue levy payments can be enforced through court orders.
- Recovery plans can be issued to a non-compliant firm, outlining the actions that the firm is required to take to comply with the FSB regulations. These can include management changes, the hiring and firing of staff, and operational changes.
- Licence suspension / withdrawal / provision changes. Here a notice of suspension is issued to the firm, providing the institution with a period in which to undertake corrective action. Where the firm fails to comply, a notice of intention to withdraw the licence is sent to the firm. More
time is given to the institution to undertake corrective action before the license is withdrawn. The registrar is empowered to suspend or withdraw a licence for non-compliance, incomplete disclosure and non-payment of levies.

- Curatorship / Liquidation. The FSB may make a court application for the curatorship or liquidation of an institution where there is sufficient evidence of financial mismanagement and risk.
- Punitive penalties. The registrar of the various divisions may refer a case to the enforcement committee for punitive penalties against a serious offence.

The FSB is implementing an innovative approach to enforcement in the form of an Enforcement Committee which collectively considers and decides on relevant actions. This has been done in a phased manner, migrating selective enforcement measures to the Committee and assessing the effectiveness of the Committee before making a decision on whether to migrate additional responsibilities. The FSB indicates that the Enforcement Committee has provided the regulator with a significant tool in enforcing regulation speedily and effectively. A similar model may prove useful in the health sector.

6.6.2.2 The National Credit Regulator (NCR)

The NCR has a variety of enforcement tools at its disposal. These include:

- Entering into a formal undertaking with the non-compliant registrant. This formal undertaking is a consensual legal agreement between the NCR and the registrant to implement certain actions to achieve compliance within a certain timeframe. The investigations and prosecutions unit is responsible for conducting follow-up site visits to ensure that the registrant is indeed complying with the terms of the formal undertaking.
- Issuing a compliance notice. The NCR uses compliance notices following the conclusion of an investigation. A compliance notice may be used where a registrant that has either failed to comply with a provision of the Act or alternatively is engaging in an activity that is inconsistent with the provisions of the Act.
- Referring a matter to the National Consumer Tribunal to obtain an order. The NCR may apply to the Tribunal for an order against a registrant. The Tribunal may either confirm or set aside the decision of the NCR. Should the Tribunal confirm the decision, then it may engage in High Court action.
- Engaging in High Court action. The Act allows the National Credit Regulator to enter into civil enforcement action. This has occurred in the past where the regulator and Tribunal have differed, or alternatively where the NCR has sought a declaratory order to clarify the interpretation of the law or declare a conduct prohibited in terms of the Act. The NCR has also sought liquidation orders against registrants in order to recover monies on behalf of consumers.

The NCR works closely with other regulators and law enforcement agencies. Cases of fraud and criminality are investigated and referred to the SAPS. The effectiveness of the relationship between SAPS and the NCR is, however, largely dependent on the person with whom they work. For example, great success has been achieved in one province in prosecuting registrants for non-compliance with the Act because of the good relationship built between the NCR’s investigator and the SAPS representative there.

6.6.2.3 Council for Medical Schemes (CMS)

The CMS protects the interests of scheme members by setting standards for medical schemes, securing appropriate levels of protection for beneficiaries, as well as monitoring the financial
performance and soundness of schemes. Therefore the CMS ensures compliance with standards, investigates complaints and facilitates the settling of disputes in relation to the affairs of medical schemes.

As the CMS requires that all medical schemes be accredited and registered with the CMS, the failure to comply with the governing Act could in an extreme case result in the withdrawal of the medical scheme’s licence to operate. Due to the immense disruption that such an action may cause on the operations of a scheme and policy holders, the CMS only uses this enforcement mechanism in extreme cases where all other avenues have been exhausted.

As part of the CMS’s mandate to ensure that medical schemes remain financially sound, Section 37 of the Medical Schemes Act requires that within four months after the end of a financial year, a medical scheme must furnish copies of the scheme’s audited financial statements together with a report from the Board of Trustees to the Registrar. These financial statements are used to ensure that all registered medical schemes are compliant with the financial obligations placed upon them by the Act such as maintaining a minimum solvency level of 25%.

A formal compliance investigation may be triggered by either a complaint or the CMS’s compliance monitoring systems. In terms of the monitoring system, the CMS has developed compliance profiles (essentially risk profiles) for medical schemes. The data used to generate the compliance profiles is obtained from information supplied during applications for registration and accreditation, other submissions, inspections and through desktop research. All this information is stored in a database which may be used to filter high impact schemes (i.e. large schemes or high risk schemes that persistently do not comply with the Act) from low impact schemes. So for example, a scheme that does not consistently comply with the 25% solvency level or any other key provision is considered to be of greater risk and should therefore be monitored more closely and inspected more often.

The CMS currently uses an enforcement manual to illustrate what sanctions it is likely to propose in the event of a contravention of the Act especially in instances where the Act itself is silent. The Medical Schemes Act does not have any prescribed standards nor does it specifically empower the CMS to issue circulars and directives containing updated standards. The legality of such a sanction is often challenged.

In terms of enforcement tools, the CMS’s arsenal of “tools” have proven to be too limited. The R 000 per day penalty is relatively insignificant especially for the large schemes. Alternatively the CMS can withdraw accreditation and therefore the licence to operate, but this may be too severe especially for smaller infringements. This leaves applying to the High Court as one of the only enforcement tools that the authority has for ensuring compliance. This however comes at a high cost as cases may be drawn out over a long period.
PART D: LESSONS AND CONCLUSIONS
7. Lessons and conclusions

The benchmarking section of this report contains valuable insights into the structure and functions of international and local regulators. In this chapter, lessons learnt across the various areas of the benchmarking exercises are summarised, and their implications for the establishment of a new regulator as well as the legislative amendments currently underway are discussed. The lessons learnt from the benchmarking studies and comparative analyses outlined in the previous chapter provide some guidance on considerations for establishing a regulator for the quality of health services rendered by health establishments. The lessons learnt cover three key areas:

- regulatory mandate and approach;
- structural and governance considerations; and
- regulatory functions.

7.1 Regulatory mandate and approach

Over the long term, improvements in the quality of health services will contribute to better health outcomes. The pursuit of better-quality outcomes requires the collective efforts of all role-players in the health system. This implies that policy makers, implementing agencies, health establishments, individual health practitioners and regulators all have responsibilities towards improving the quality of health services in the country.

In general, government chooses to regulate persons or activities because it is in the “public interest” to do so. In particular, one of the main aims of regulation is to protect users of a service from serious harm. Regulation is administered by regulators who are conferred the legislated powers they need to achieve the intended outcomes. For regulators to be effective, their mandate and the scope of regulation should be clearly defined.

The mandate of most of the health sector regulators surveyed over the course of this study has two clear elements. The first element relates to the protection of the safety of users of health services, while the second element focuses on ensuring that the quality of care meets national standards. These two elements are undoubtedly applicable in the South African context. The National Health Amendment Bill (B24D-2011) reflects both of these elements clearly, stating that the: “objectives of the Office are to protect and promote the health and safety of users of health services”. The Bill further specifies that this object will be achieved by “monitoring and enforcing compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system” (as well as investigation and disposal of complaints).

Evidence on the regulatory approach is varied. While the CQC in the UK is constituted as a traditional regulator, other quality assurance bodies were voluntary or government-sponsored such as in the case of the ACHS in Australia or the Joint Commission in the United States. The question thus revolves around whether to adopt a form of explicit regulation through the adoption of mandatory norms and standards, or to allow for forms of quasi-regulation. The final decision depends on two key factors: (1) the policy imperatives of government, and (2) the maturity of the health system.

In order to redress the dire problems around quality of health services, national government has adopted a policy reform agenda through the 10-point plan and the National Service Delivery Agreement, which calls for the introduction of a new regulatory scheme.
Moreover, within the context of pervasive non-compliance with norms and standards, voluntary forms of regulation are unlikely to have a profound and lasting impact on the quality of care. This implies that an explicit form of regulation is needed and appropriate for the South African health system. The National Health Amendment Bill (B24D-2011) has adopted a form of explicit regulation. The Bill establishes the Office of Health Standards Compliance as regulator with the power to certify compliance with norms and standards and to make recommendations for corrective interventions or progressive sanctions.

To ensure fairness and justice, the regulatory powers of the entity should apply equally to public and private health establishments, as well as those run by non-profit organisations. In terms of the bill, the Office of Health Standards Compliance is empowered to inspect and certify health establishments which by definition in the National Health Act (2003) means “the whole or part of a public or private institution, facility, building or place... that is operated or designed to provide inpatient or outpatient treatment...”.

### 7.2 Structural and governance considerations

Many of the regulators reviewed were creatures of statute established in terms of enabling legislation with clear governance arrangements. Regulators were governed by either a board or council, with an executive officer in place to manage the day-to-day operations of the organisations. The introduction of a board enables the regulator to maintain its decision-making independence. Most of these boards or councils were directly accountable to a government Minister, and reported to Parliament (through the Minister). Members of these boards were appointed on the basis of their expertise in the fields of healthcare or the equivalent in other sectors, regulatory practice, consumer protection, and legal and financial matters. Moreover, the benchmarking studies showed that many of the regulators were listed by the PFMA as Schedule 3A public entities.

The Bill reflects a number of good practices in relation to structure and governance. Section 77(1) establishes the Office of Health Standards Compliance as a juristic person funded through monies appropriated by Parliament or fees received for services rendered. The Office functions under the control of a seven-member board that is designated as the accounting authority of the Office. In this capacity, the board has to determine the policy and undertake the planning necessary to discharge the Office’s legislative mandate. By vesting the policy and planning responsibilities with the board, the Act strengthens the independence of the Office of Health Standards Compliance.

The decision-making autonomy of the board extends to the appointment of the chief executive officer. Therefore, in terms of Section 79H of the Bill, the board must, after consultation with the Minister, appoint a fit and proper and suitability qualified person as Chief Executive Officer. Put differently, the board has free reign to determine the qualifications and attributes of potential candidates for the position of Chief Executive Officer.

### 7.3 Regulatory functions

#### 7.3.1 Norms and standard setting

National standards and norms for health establishments can be designed by the National Department of Health to provide guidance to all health establishments on the expected levels of performance they should achieve. These standards should reflect policy priorities and contribute to the achievement of particular health outcomes. There is however a difference between standards and norms set for policy or planning purposes and those that are mandatory, and it is this distinction that is reflected
in the Bill which tasks the Office with advising the Minister on this specific subset of standards and norms.

While the Office’s role is primarily to monitor and enforce compliance, Section 79(1) of the Bill requires the Office of Health Standards Compliance to advise the Minister on matters relating to the determination of norms and standards. This provision ensures that the development or revisions to norms and standards to be prescribed are made after taking into account the evidence and information collected during regulatory activities.

A subset of these norms and standards may gain the force and effect of law once they are embodied in regulations made in terms of the proposed National Health Amendment Act. Such a first set of regulated health standards could be based on the National Core Standards (NCS) that were adopted as policy by the National Health Council – that is, the Minister of Health and his provincial counterparts – late in 2010 and published in 2011.

The NCS were developed on the basis of local needs and informed by international experience. The set of standards that emerged strongly resembles those developed in other countries, where standards are used as an instrument for improving the quality of healthcare. The present standards are seen as relevant and realistic. Alignment between these and the first regulated standards is important, as many health establishments (including those in the private sector) are already utilising the NCS to upgrade their services, and this effort should contribute to their certification by the entity. The inputs required to deliver on these standards remain a contentious issue, reflected in ongoing arguments about lack of equity in resources on the one hand and lack of efficiency in the use of comparable resources on the other hand. Judgements to be made on the compliance status of establishments and recommendations for intervention will need to recognise these considerations.

Further norms and standards will be developed as the regulatory scheme for quality evolves, and may incorporate other health establishments such as general practitioners and emergency services. In developing these standards, experts in the subject field are needed to ensure credible standards, and processes are needed to ensure that standards are developed in a structured and consultative manner.

### 7.3.2 External quality assessment

International literature suggests that the regular and continued inspections of health establishments to review their compliance with the prescribed standards should be a key function of any regulator. As such, its inspectors should have the necessary powers to enter health establishments, question individuals, request information and records, and take copies or samples of evidence.

Inspections may be of a routine nature, where the intention is to certify the institution as compliant with standards or to issue a notice of compliance; or be conducted on an *ad hoc* or unannounced basis, which has significant advantages. A notice of compliance should in effect be an instruction to the health establishment to take specific actions to ensure compliance. The whole aim of inspections would be to secure improvements in quality of care, so that compliance notices are withdrawn and the establishment becomes eligible for certification.

The Bill empowers the Office to ‘inspect and certify’ health establishments and confers on inspectors a set of wide-ranging powers to enter and search health establishments with or without a warrant. Nonetheless, in the case of routine inspections, entry and search provisions contained in Section 84(1) do not necessarily need to be invoked if permission for the inspection has been obtained from the owner of the health establishment as defined in Section 88(1) of the Bill.
In addition, a framework for the prioritisation of inspection should be developed by the regulator. This framework will guide the approach to selecting and inspecting health establishments to promote transparency, create certainty for the Office and maximise the impact of inspections as a key instrument in improving the quality of care. Prioritisation frameworks should be informed by the risk profiles and surveillance systems.

The role of the entity should be limited to ensuring that standards are observed. It cannot be directly responsible for quality improvement programmes at health establishments. This should remain the responsibility of healthcare managers at individual establishments and at higher levels in corporate or government structures.

### 7.3.3 Compliance and risk monitoring

Investment in compliance and risk monitoring systems is needed from the outset. Regular and well-established risk profiling processes can avert serious problems in health service delivery by identifying potential risks within the health sector. Risk profiling synthesises information from a variety of sources to develop a risk assessment of a particular health establishment and may include information from self-assessments or routine reports as a means of raising the alert on possible problems. Hence, when developing risk profiles, one of the key challenges for the regulator lies in the selection of reporting indicators that best reflect risks in-the-making. Surveillance or early warning systems are a subset of risk profiles and aim to provide timely alerts of serious breaches in order to trigger prompt control, improvement or enforcement action.

Two sections of the Bill are relevant to the compliance and risk monitoring function. Section 79(1)(d) of the Bill requires the Office of Health Standards Compliance to monitor indicators of risk as an early warning system. Once a serious breach is identified, it must be reported to the Minister without delay. The power to collect or request information is set out in S79(2)(b) and enables the Office to obtain the data necessary to populate risk profiles.

Moreover, the Office is empowered to recommend quality assurance and management systems for the national health system to the Minister, which could include guidance around regulatory reporting by health establishments.

### 7.3.4 Complaints management and the Ombud

From a regulatory perspective, complaints can provide information on possible breaches of norms and standards. They are fundamental in protecting and promoting the health and safety of users and are critical source of data for quality risk profiles. Clear regulatory processes are therefore needed to ensure that critical complaints information feeds into the compliance and risk monitoring function of the regulator.

International experience demonstrates that functional complaints-handling and management systems at health establishment-level are an important foundational element of any Ombud scheme. The Ombud does not replace mechanisms that exist, for instance, in health establishments, provincial health departments and private healthcare companies to address routine complaints. However, as an alternative channel for complaints, structured investigation and adjudication processes are needed to maintain the credibility of the Ombud’s office. Most Ombuds are constituted as independent entities with decision-making autonomy.

It is evident from the international review that the jurisdiction and powers of the Ombud should...
be clarified within legislation. Where the Ombud is located within the regulator, the relationship between these two entities should be clearly defined to avoid any potential conflict.

The National Health Amendment Bill (B24B-2011) requires the Minister, after consultation with the Board of the OHSC, to appoint a suitably qualified and experienced person as an Ombud. In line with the provisions of the Bill, the Ombud may, on receipt of a written or verbal complaint relating to norms and standards, or on his/her own initiative, consider, investigate and dispose of the complaint in a fair, economical and expeditious manner.

Aspects of the legislative provisions governing the work of the Ombud influence the design of the Ombud’s office and are worth highlighting. First, the Bill allows the Ombud the discretion to determine whether or not to consider a complaint. This implies that the Ombud should establish a complaints-filtering mechanism to determine whether a complaint should be considered. Second, the Act limits the scope of the Ombud to complaints relating to norms and standards. The Bill specifically states that most complaints to be investigated should relate to breaches of norms and standards and their impact on a user. A question exists regarding whether the Ombud will develop his/her own risk identification framework or use that of the OHSC.

The investigation of complaints as envisaged in the National Health Amendment Bill focuses, therefore, on the investigation of complaints received by the Ombud pertaining to breaches of norms and standards. Complaints not relating to breaches of norms and standards should be referred to the appropriate regulators or authorities in the South African health sector. This will require a significant degree of coordination as provided for in several places in the Bill, but lessons from the FAIS ombud regarding respective mandates may be relevant here.

Moreover, the Bill allows the Ombud to “on his/her own initiative” consider and investigate a complaint. This implies that the Ombud can play a proactive role and respond promptly to serious breaches of norms and standards. For the Ombud to be able to respond to breaches of norms and standards promptly, a surveillance mechanism (for example, media monitoring capabilities; or the early warning system of the Office) is needed.

Finally, the Bill also ring fences the Ombud’s sources of revenue from that of the OHSC to enable the Ombud to remain independent and safeguard decision-making autonomy.

7.3.5 Communication, stakeholder engagement and reporting

Communication, stakeholder engagement and reporting are all important functions for this regulator, and should be given due consideration in the entity’s organisational structure. The Office of Health Standards Compliance differs from other regulators in the health sector in that it will focus not on individual health professionals but on health establishments. As such, the scope of the Office should be widely publicised from the outset through public education campaigns and engagements with users and health establishments. It is envisaged that the Office will work with other regulators to create formal mechanisms for cooperation and to eliminate duplication. It is recognised that duplication is not only inefficient for regulators, but imposes an undue burden on the individuals and organisations subject to regulation.

The Bill requires the Office to publish any information related to prescribed norms and standards in the mass media or through other channels, and during the Parliamentary hearings on the Bill, this function was made mandatory. This provision in legislation adheres to international practice of publishing the outcomes of inspections and complaint investigations, as well as trends emerging
in the course of monitoring health establishments. The transparency of health regulators in other countries has been a critical factor in strengthening the hand of health consumers and improving quality of care. In the course of publication by health regulators, confidential information relating to patients or business undertakings is always protected. Hence, section S86A of the Bill guarantees the constitutional right to privacy.

### 7.3.6 Enforcement and sanction

International learning suggests that enforcement action be *corrective rather than punitive*, as the ultimate goal of inspections should be to improve quality of care. Hence, progressive approaches to enforcement can be adopted to allow health establishments sufficient time to remedy non-compliance. However, protracted failure to respond to compliance orders could result in the imposition of serious administrative penalties and ultimately criminal prosecution. The Bill sets out a progressive approach to enforcement. Specifically, Section 82A(4) of the Bill now contains a set of measures to address non-compliance. These include:

- issuing a written warning;
- requiring a written response from the health establishment;
- recommending appropriate and suitable action to the relevant authority;
- revoking the compliance certificate and recommending to the Minister temporary or permanent closure of the health establishment or part thereof;
- imposing a fine; and
- referring the matter to the National Prosecuting Authority.

Reflecting the over-arching nature of “quality”, the scope of the existing National Core Standards in South Africa, seen as the basis for future prescribed or regulated standards, was deliberately comprehensive, covering the range of inputs, activities (processes) and outputs that together comprise the complex business of healthcare provision. Within the complete set of standards, areas of concurrent jurisdiction will arise, and international experience reflects that this situation will require a specific and concerted focus in coordinating regulatory actions with other regulators. The objectives of such collaboration are to identify which specific regulator has the most effective mechanisms or powers in specific situations; to enhance communication and the exchange of information; and to enhance and formalise a positive working relationship.

### 7.4 Conclusion

Regulation can be a powerful force for change when designed well and administered effectively. Designing new regulatory schemes is a complex exercise that should take into account the legal, economic, social and political context faced by a country. Regulatory good practice from national and international regulators is a valuable resource, and provides guidance on how similar regulators function around the world and in South Africa.

This document summarises extensive research carried out by the National Department of Health, and provides some underpinning of proposals for how a future Office of Health Standards Compliance could be structured and how it could function. Regulation itself forms one of the first steps in the long and difficult process of improving the quality of care in South Africa.
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Care Quality Commission (2010b). *Quality and Risk Profile, South West London and St George’s*. Newcastle on Tyne: Care Quality Commission.


Regulating the Quality of Health Services


Regulating the Quality of Health Services


The Technical Work streams, in executing the international / national review and benchmarking exercises, interacted with, studied and recorded best-practice models from a range of international and national regulatory-type bodies, independent institutions and stakeholders. The following table provides a list of the regulatory-type bodies and independent institutions included in the exercise with an indication of the functional areas / themes explored at each of the listed regulatory bodies / independent institutions for the purposes of the benchmarking studies.

<table>
<thead>
<tr>
<th>INTERNATIONAL</th>
<th>Acronym</th>
<th>Benchmarking coverage</th>
</tr>
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<tbody>
<tr>
<td>Accreditation Canada, Canada</td>
<td>AC</td>
<td>Quality Standards Development and Information / Warning Systems</td>
</tr>
<tr>
<td>Australian Commission on Safety and Quality in Healthcare, Australia</td>
<td>ACSQH</td>
<td>Quality Standards Development and Information / Warning Systems</td>
</tr>
<tr>
<td>Australian Commonwealth Ombudsman</td>
<td></td>
<td>Complaints and Ombud Role</td>
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<tr>
<td>Australian Council on Healthcare Standards, Australia</td>
<td>ACHS</td>
<td>Quality Standards Development and Information / Warning Systems</td>
</tr>
<tr>
<td>Care Quality Commission, England, United Kingdom (formerly the Healthcare Commission)</td>
<td>CQC</td>
<td>Legal and Regulatory Approach&lt;br&gt;Quality Standards Development and Information / Warning Systems&lt;br&gt;Inspections, Investigations, Compliance and Enforcement&lt;br&gt;Complaints and Ombud Role&lt;br&gt;Communication and Stakeholder Relations</td>
</tr>
<tr>
<td>General Medical Council, United Kingdom</td>
<td>GMC</td>
<td>Quality Standards Development and Information / Warning Systems</td>
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<tr>
<td>Haute Autorité de Santé, France</td>
<td>HAS</td>
<td>Legal and Regulatory Approach&lt;br&gt;Quality Standards Development and Information / Warning Systems&lt;br&gt;Inspections, Investigations, Compliance and Enforcement</td>
</tr>
<tr>
<td>Health Information and Quality Authority, Ireland</td>
<td>HIQA</td>
<td>Quality Standards Development and Information / Warning Systems</td>
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<tr>
<td>Institut de Veille Sanitaire, France</td>
<td>INVS</td>
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<tr>
<td>Institute for Healthcare Improvement, United States of America</td>
<td>IHI</td>
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<td>Inspections, Investigations, Compliance and Enforcement</td>
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<td>NIHSR</td>
<td>Complaints and Ombud Role</td>
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## Annexure A – List of Organisations / Bodies

<table>
<thead>
<tr>
<th>NATIONAL</th>
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<tbody>
<tr>
<td><strong>Regulatory body / Independent institution</strong></td>
</tr>
<tr>
<td>Board of Healthcare Funders</td>
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<tr>
<td>Competition Commission</td>
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<tr>
<td>Council for Health Service Accreditation of Southern Africa</td>
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<tr>
<td>Council for Medical Schemes</td>
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<tr>
<td>Council for Social Services of South Africa</td>
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<tr>
<td>Financial Services Board</td>
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<tr>
<td>Gauteng Provincial Department of Health – Inspectorate</td>
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<tr>
<td>Health Professions Council of South Africa</td>
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<td>Health Quality Assessment</td>
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<td>Hospital Association of South Africa</td>
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<td>Medicines Control Council</td>
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<td>Medi-clinic</td>
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<td>National Consumer Tribunal</td>
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<td>National Credit Regulator</td>
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<td>Netcare</td>
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<tr>
<td>Office of the Ombud for Financial Services Providers</td>
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<tr>
<td>Regulatory body / Independent institution</td>
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<tr>
<td>Office of the Public Protector</td>
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<tr>
<td>Ombudsman for Banking Services</td>
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<td>South Africa Human Rights Commission</td>
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<td>South African Pharmacy Council</td>
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<td>South African Revenue Services</td>
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<tr>
<td>Tax Board and Court</td>
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<tr>
<td>Western Cape Provincial Health Administration</td>
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</table>
Annexure B – Existing Health Sector Regulators

A number of statutory bodies have been established to regulate different aspects of healthcare but with a focus on healthcare professionals (the “providers”) and on the private sector. The OHSC will in terms of a cooperative / coordinated regulatory approach need to consider some form of formal working relationship / memoranda of understanding with these bodies:

- The Health Professions Council of South Africa (HPCSA) is a statutory body, established in terms of the Health Professions Act (1974). The Council regulates the health professions in aspects pertaining to: registration, education and training, professional conduct and ethical behaviour, continued professional development, and compliance with healthcare standards.

- The Pharmacy Council is a regulatory body responsible for promoting the provision of pharmaceutical care which complies with universal norms and values in the public and the private sector, as well as safeguarding the rights of the general public in accordance with pharmaceutical standards.

- The Medicines Control Council is a statutory body established in terms of the Medicines and Related Substances Control Act (1965) to regulate the manufacture, distribution, sale, and marketing of medicines throughout South Africa.

- The Council for Medical Schemes is a statutory body established by the Medical Schemes Act (1998) and aims to protect the interest of members of medical schemes and ensure fair and equitable access to private healthcare financing.

- The South African Nursing Council is a statutory body established to regulate the nursing and midwifery professions to ensure safe and quality practice. They do this by regulating the quality of nursing programmes and educational initiatives, registering individual nursing professionals and licensing nursing agencies.
<table>
<thead>
<tr>
<th>Organisation</th>
<th>Norms and standards development</th>
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<tbody>
<tr>
<td><strong>International organisations</strong></td>
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</table>
| Care Quality Commission (CQC), UK | • QRP unit uses a comprehensive data plan to suggest possible data sources and indicators to include in the QRP.  
• These are discussed and evaluated by the broader Intelligence Directorate on a regular basis. |
| Health Information and Quality Authority (HIQA), Ireland | • Standards for healthcare sector are currently with the Minister of Health for approval.  
• To date the organisation has only been monitoring a minimum set of standards: Hygiene; Infection control; Symptomatic breast disease – management.  
• These areas were selected as they were priority areas in the media – not necessarily highest risk to patients but needed to be seen as doing something.  
• Standards are high-level, outcome-based and not disease-specific (which they used to be). An example would be standards around effective leadership.  
• Standards designed for all healthcare settings. Onus is on healthcare providers to ensure compliance with standards.  
• Against a “stick” approach.  
• Not keen on inspections as they are very labour-intensive and expensive. |
| Accreditation Canada | • Standards are generated and reviewed on a three-yearly basis.  
• On-line questionnaires are sent out, a national client services team coaches the institution to assist them to meet the standards, self-assessments are done and when the institution believes themselves to be ready, audits are carried out against the standards by the assessors, and a report sent to the institution with findings and recommendations for improvement.  
• All the data are captured electronically and collated to provide aggregated information about trends which is shared by means of an annual report, focused reports on specific areas of interest such as governance and patient safety, and national reports on particular areas of service e.g. the link between patient safety and organisational practices. |
| Australian Council on Healthcare Standards (ACHS) | • Sets their own standards (blood products, infection control, consumer involvement etc.) which it reviews every four years.  
• Current version is EQUIP 5.  
• Standards are reviewed by working groups which involve healthcare users, academic institutions, experts and clinicians.  
• A Standards Committee correlates information from working groups and makes recommendations, which need to be approved by the Council.  
• Once approved, they are pilot-tested and changes made where necessary. |
| Australian Commission on Safety and Quality in Healthcare (ACSQHC) | • The ACSQHC role is to ensure providers have standards, that the standards are maintained, and that they develop tools, support systems and implementation mechanisms.  
• The process for standard development consists of the following: establishment of a technical expert group to define the problem, develop a practical set of standards, including issues of governance; develop implementation guidelines, involvement of patients, defining need for research; and testing and piloting of the standards.  
• The entire process can take up to 2.5 years.  
• The ACSQHC has developed a set of 10 core standards, ranging from governance, infection control, preventing medication errors to recognising and responding to clinical deterioration.  
• The ACSQHC used the UK quality processes and adapted it. |
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<tr>
<th>Organisation</th>
<th>Norms and standards development</th>
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</table>
| Malaysian Society for Quality in Health (MSQH) | • The Malaysian Hospital Accreditation Standards are intended to stimulate continuous, systematic improvement in an organisation’s performance and the outcomes of care.  
• The Malaysian Standards were adapted from the 1994 version of the Australian Council for Healthcare Standards set (which in turn used the UK standards).  
• The Australian Standards were customised to the values, practices and context of Malaysia and took two years to convert into a Malaysian set of standards.  
• The standards development process was inclusive and participatory and national consensus was reached by all relevant service providers.  
• The standards were also published for consumer input and consensus.  
• Primary healthcare standards including GP practice standards were also developed (2009-2011) in consultation with the Academy of Medicine and were submitted for to the Ministry of Health for approval.  
• The standards were developed using the Donabedian framework of structure-process-outcome and are revised every three-four years.  
• There is an attempt to include outcome indicators for each of the clinical services covered. |
| South African organisations | |
| Council for Medical Schemes (CMS) | • Standards have been established for the registration of medical schemes and the accreditation of medical scheme administrators, managed care organisations, and brokers.  
• Standards are produced as regulations in terms of the Medical Schemes Act following the process prescribed in the Act.  
• Current standards are version 4 for administrators and version 2 for managed care organisations. |
| COHSASA | • COHSASA standards are developed according to, and accredited by the International Society for Quality in Healthcare (ISQUA).  
• Four sets of COHSASA standards, Primary Healthcare Services Standards, Emergency Medical Services Standards, COHSASA Hospital Standards and COHSASA Hospice Palliative Care Standards.  
• There is a formal policy to review and update standards at regular, prescribed intervals with input from professionals and their representative organisations.  
• Professional bodies in SA have assisted with the development and refinement of the standards and input is solicited from clients, professional field staff and the public.  
• When further refinements are made to standards, COHSASA takes into account the feedback from over 500 facilities that have been in its programmes. |
| Health Quality Assessment (HQA) | • Not involved in any standards development. |
| Netcare | • Standards for each department are set by people in Head Office in consultation with institutional managers. Several departments at head office – human resources, nursing care, primary healthcare, finance etc.  
• Within each section, standards are also developed. |
| Medi-clinic | • Set by quality audit teams in consultative process with healthcare providers and institutions. |
| HASA | • Prohibited from doing this by the Competition Commission who views it as a restrictive business practice. |
Annexure D – Lessons for successful Implementation of National Accreditation Programmes

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<tr>
<th>Area</th>
<th>Common problems</th>
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<tr>
<td>Clarity of purpose</td>
<td>Failure to identify a balance between the objectives of <em>improvement</em> (internal organisational development) and <em>regulation</em> (external control) within an overall policy for quality in the healthcare system.</td>
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<td>Appropriate technology</td>
<td>Failure to differentiate the methods of accreditation, licensing and regulation, and to match them to the defined objectives.</td>
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<td>Quality culture</td>
<td>Failure to identify stakeholders and involve them in the design and direction of the accreditation programme.</td>
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<td>Unwillingness to share information, authority and responsibility.</td>
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<td>Motivation</td>
<td>Reliance on directives and sanctions rather than internal organisational commitment to self-improvement, preferential funding and recognition of professional development.</td>
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<td>Perverse incentives for superficial compliance with standards.</td>
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<td>Unwillingness of managers to release staff to become accreditation surveyors.</td>
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<td>Unwillingness of surveyors to work without additional pay.</td>
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<td>Independence</td>
<td>Government domination of programme direction, leading to conflict of interest in assessment of public services.</td>
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<td>Demotivation of other stakeholders and vulnerability to short-term political change.</td>
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<td>Failure to authorise and support (by legislation if necessary) an independent governing body.</td>
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<td>Scope of responsibility</td>
<td>Unrealistic expectations that the accreditation programme would resolve issues for which it was not designed or resourced, e.g. facilities licensing, professional registration, healthcare financing.</td>
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<td>Failure to identify <em>priority concerns</em> (e.g. patient safety, clinical performance) and <em>priority sectors</em> (e.g. primary care, hospitals, and the continuity between them).</td>
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<td>Clear relationships</td>
<td>Lack of mechanisms to cooperate and communicate with related professional, academic, independent and governmental bodies, e.g. professional chambers, teaching institutions, health insurers, ISO certification bodies and local government inspectorates.</td>
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<td>Objectivity and probity</td>
<td>Lack of (or failure to comply with) defined and transparent procedures for the assessment of facilities and decisions on accreditation awards.</td>
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<td>Failure to separate independent functions of facilitation, assessment, awards and payments - leading to bias, lack of credibility and possible corruption.</td>
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<td>Sustainable resourcing</td>
<td>Underestimation or underfunding of the time, personnel and skills needed to establish a new programme.</td>
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<td>Unrealistic expectations of the rate of uptake by health facilities and the capacity of the programme to generate income from them.</td>
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<td>Lack of long-term government commitment.</td>
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<td>External technical assistance</td>
<td>Failure to learn from the experience of accreditation in other countries which is available from publications, from technical consultancy and from the International Society for Quality in Healthcare.</td>
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Institution | Key messages for OHSC | Key messages for QSAD
---|---|---
**International organisations**

| CQC | It has taken many decades for the quality accreditation system to mature in the UK. Implementation of new CQC systems is happening through phased implementation over a number of years. Main decision-making about accreditation decentralised to local inspectors. | Integrated Intelligence Directorate to coordinate information function very similar to QSAD. QRP system focuses on accreditation monitoring. Risk profile continuously updated as new information becomes available. Requires a large skilled workforce. |

| HIQA | It takes a number of years to get established. Scope includes health technology assessment. | Accreditation cannot be based on routinely collected data which is of questionable quality. Patient discharge records may be a source of information. |

| Accreditation Canada | Be realistic about what can be achieved. Importance of independence and credibility. Need skilled individuals. Require significant resources to do properly. | Need phased approach rather than trying to do everything at once. Requires expertise regarding health sector, information and knowledge management, data analysis. Require significant resources to do properly. |

| ACHS | Partner with research institutions to continuously evaluate impact of OHSC programmes (e.g. Quality Services Research Group). Make provision for a “corrective improvement phase” after non-compliance is identified before facilities are penalised and undertake root cause analyses where necessary. | Constitute a panel of experts for indicator development and refinement to ensure acceptability, validity and reliability. |

| ACSQHC | Important to focus on patient safety and quality monitoring. Phased approach and optimising existing opportunities within health system. | Information strategy unit works across other units and programmes. Prioritise safety and quality in high risk areas. Consultation with stakeholders is critical success factor. |

<p>| MSQH | Phased, inclusive and participatory approach. Ensure standards stimulate continuous, systematic improvement in an organisation’s performance and the outcomes of care. Training and capacity building support to health establishments. Include both public and private sector. | Manual and elementary risk profiling systems are also useful. |</p>
<table>
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<tr>
<th>Institution</th>
<th>Key messages for OHSC</th>
<th>Key messages for QSAD</th>
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<tr>
<td>South African organisations</td>
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<tr>
<td>CMS</td>
<td>Effective health regulatory body in South Africa requires significant professionalism and competence. Requires strong leadership and need to attract a diverse mix of highly skilled staff.</td>
<td>Link information requirements to registration and accreditation decisions.</td>
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<td></td>
<td></td>
<td>Integrated IT and database systems critical for effective functioning.</td>
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<td></td>
<td></td>
<td>Systems take a number of years to mature.</td>
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<td>COHSASA</td>
<td>Use and adapt existing information systems where possible e.g. CoQIS. The COHSASA information System has a wide range of functions which allow not only gap identification but also a functionality to monitor implementation of improvements and trend analyses over time.</td>
<td>Follow the ISQUA principles for information management, to ensure that information systems are built on a solid platform, high quality data and credibility, particularly if data will be used to implement incentives and sanctions.</td>
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<td>Recruit highly skilled individuals.</td>
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<td>HQA</td>
<td>Learn from the experience of similar organisations. Utility assistance offered by organisations who are already working in the Quality Measurement field. Ensure confidentiality and never name and shame providers. HQA de-identifies all comparative reports. Data submission is based on trust between the provider and the quality measurement organisation. If providers’ confidentiality is not maintained they are unlikely to report areas of weakness.</td>
<td>A red flag event should be something very serious – otherwise the Office will have to respond to an unmanageable number of events. Ideally an EWS should be based on reporting indicators which have a serious knock on effect. Outsourced data analysis until capacity is built within the organisation. Migrate from Access database to a web-based platform so that hospitals or clinics load data and it is immediately accessible to QSAD.</td>
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<td>Netcare and Medi-Clinic</td>
<td>Learn From existing quality monitoring systems in the private health sector in South Africa. Link between internal self-assessment and independent external audit. Importance of feedback and follow-up action.</td>
<td>User-friendly online data submission system ensures high reporting compliance.</td>
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<td>Range of indicators, not only clinical indicators, included in senior management alert system.</td>
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<td>HASA</td>
<td>Confidentiality and publication of aggregated data. Incentives for health establishments to send data and to comply. Be careful of the quality of the data one gets – rather a little good quality data than asking for a lot and getting useless information.</td>
<td>EWS good idea but only choose very few red flag issues that have to be reported immediately.</td>
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<tr>
<td>SARS</td>
<td>Strong leadership and values. Clear scope and purpose. Enabling systems to ensure compliance. Success rests on impeccable planning and swift execution that takes into account current realities.</td>
<td>Standardisation of data. Strong and skilled team.</td>
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