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Benchmarking of best practice in the regulation of quality health care

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

May 2012

EXECUTIVE SUMMARY

The importance of providing quality health services is non-negotiable and better quality of care is fundamental in improving South Africa's current poor health outcomes. Better quality of care will restore patient and staff confidence in the public and private health care system. Quality in the health system can be defined as getting the best possible results with the available resources.

Whilst the root causes for the problems underlying the poor quality of service in the health sector maybe be varied and complex, the requirement for a quality assurance mechanism to improve health outcomes is largely uncontested. Such a mechanism to improve the quality of health care services in both the public and private spheres is central to the reform of the health system and the delivery of quality services in the health care sector.

This emphasis on ensuring better health outcomes is a key part of the Government programme and for the health sector these outcomes are contained in the Negotiated Service Delivery Agreement for Outcome 4.

In the light of the drive for better health outcomes, the health sector engaged in extensive discussions and consultations during the past few years to establish how best to achieve such outcomes. These deliberations led to the adoption and publication of a set of National Core Standards for Health Establishments in 2011. As part of this a number of areas were selected for fast track improvements and these included cleaner facilities, shorter waiting times and better patient safety and care. Although this led to some success and improvement in the quality of care it was clear that simply reminding health care staff of their basic duty was not enough.

In addition what was required is a mechanism to regulate and benchmark compliance of health facilities against these standards. A monitoring and compliance process whereby all facilities can be measured through independent inspections and or assessments will result in significant improvements in the effectiveness and quality of the health system as a whole.

Early on the National Health Council (NHC) indicated clear preferences for the establishment of a process and mechanism to respond to this challenge. It was clear that, effectively to respond, the establishment of an entity to monitor compliance with these standards and norms had to be independent – to engender the trust of both patients and health care staff; it had to be done in a manner that will ensure public accountability and credibility in terms of a single benchmark – to ensure that all are measured against the same yardstick; and to ensure compliance some element of consequences for non-compliance had to established.

With the publication of the draft National Health Amendment Bill for comment in early 2011 the first steps were taken towards the establishment of an independent health quality regulator. Simultaneously the National Department of Health embarked on a process to learn from other regulatory bodies and benchmark, review and analyse current practice in this area of work. All with a view to establish the best possible framework to setup a health establishment quality regulatory body as an independent entity, in line with 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. It provides the detail of the international and national benchmark studies and reviews of current practice.

The breadth of the thematic and comparative analyses of the studies conducted is presented here. These range from high level possible policy and legal approaches to be considered in the establishment of a quality regulatory body for health establishments, to the more practical considerations for the operationalisation of envisaged functions of such an independent entity.

The benchmarking studies were designed to examine three overall approaches to regulating quality in the health sector, namely the regulation of compliance, the monitoring and measurement of quality, and the investigation of complaints and recommendations on redress by an Ombud. To this was added the relatively new aspect of the importance of communication and stakeholder relations in regulatory practice.

In terms of regulating for compliance the issues ranged from the role and importance of designing an independent entity as regulator which is adequately and substantively independent; to the importance of coordinating regulatory activities with other regulatory bodies and institutions. In addition attention was paid the scope and extent of the enforcement powers vested in an independent health quality regulatory entity.

Amongst the issues considered with regards to the objective assessment of quality were the critical importance of the standards used in measurement and the purpose and methods of the process; the advantages and disadvantages of regular or routine as opposed to ad-hoc or unannounced inspections linked to strategies to monitor risk for prioritisation and early intervention; and the selection and location of inspectors.

In relation to the establishment of an Ombud function in the design of a health quality regulator the issues considered ranged from the communication and interaction with individuals which would like to make a complaint and handling of these complaints; jurisdiction and decisions to investigate; how to investigate and what to do with the results of the investigation; and lastly whether to make recommendations' and or determinations.

In designing the benchmarking work around these three overall approaches, specific areas were covered and these included the enforcement of regulations, the process of setting standards and norms, assessing whether standards and norms are met (inspections), risk profiling and knowledge management, complaints investigations, Ombud specific functions, and communication and reporting and stakeholder relations.

The last chapter explores the possible mandate, scope and structure of a South African independent entity to regulate the quality of care in health establishments in both the public and private sectors.

The results of the benchmarking exercises presented here enrich the debate about the necessity to institutionalise mechanisms to regulate the quality of health care 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. Such an entity should be formally established as an independent public entity with a legislative mandate and voted funds. The studies do not support a voluntary peer review model and propose that quality regulation be made mandatory for all health facilities. In order to ensure objectivity, the regulator would not be directly involved in, or responsible for, activities within the health system designed to improve quality or compliance.

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INTRODUCTION

A number of reform initiatives to improve governance of the health system and service delivery have been initiated by the National Department of Health (NDOH) over the last few years. One of the considerations, in terms of implementation, is that the various reform initiatives be efficiently co-ordinated and sequenced so that they collectively contribute maximally to the Government's vision of *"A Long and Healthy Life for All South Africans"* (as expressed in the Negotiated Service Delivery Agreement [NSDA] for Outcome 2, 2010).

The four strategic outcomes, in terms of the NSDA which was signed in October 2011, 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.

The renewed focus on the quality of care as part of the NSDA output 4 now forms part of one the key health reform interventions along with re-engineering the system towards a primary healthcare approach, improving infrastructure, better human resource production and management, improved supplies of drugs and equipment, and stronger health information support.

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, in April 2008 a set of "Core Standards for Health Establishments" was launched. The "core standards" reflected what were 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 National Core Standards in January 2011. These core standards 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 sub set of the of these standards, focusing on six critical areas of the most concern to patients, are being used as part of a Baseline audit of all public health facilities conducted over the period May 2011 to April 2012. The results of this audit are envisaged to provide a baseline measure of the current status of the quality of care in the public sector.

A draft National Health Amendment Bill was published for comment in January 2011 and tabled in Parliament in November 2011. It seeks to amend the National Health Act, 2003 (Act No. 61 of 2003), to empower the Minister to establish an independent public entity, called the Office of Health Standards Compliance (OHSC). This Office is intended to serve as an independent regulator of health establishments (broadly defined). The functions of the envisaged OHSC include:

- The inspection and certification of all health establishments as compliant with prescribed standards;
- The investigation of complaints from health establishment users;
- The Establishment of an Early Warning System (EWS) for mandatory reporting on indicators of risk; and
- Communication and advisory functions related to prescribed norms and standards, and quality management systems in general.

CONTEXT

1. Constitutional, Legislative and Policy Framework

A number of governing acts, regulations and policies influence the quality of healthcare in South Africa. Underpinning the entire healthcare system are the constitutional imperatives found in the Bill of Rights. Specifically, section 27 of the Constitution guarantees everyone the right of access to health care 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 (Section 27 (2) (RSA 1996).

Health care services are a functional area of concurrent legislative competence across national and provincial governments which mean that provinces can also legislate in the area of health care services. In the event of a conflict between national legislation and provincial legislation however, national legislation prevails where any of the conditions listed in section 146 of the Constitution is met. Section 41 of the Constitution requires all three spheres of government to work cooperatively to secure the well being of the people of the Republic and to preserve the peace, national unity and indivisibility of the Republic.

The National Health Act, 2003 (the Act) 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 ensures broader community participation in healthcare delivery from a health facility level up to national level. With respect to the sections now being amended, the Act provided for the creation within the National Department of Health of an Office of Standards Compliance with an Inspectorate unit. The Office of Standards Compliance as then envisaged would advise on health standards, carry out inspections and monitor compliance, report on non-compliance, issue or withdraw a certificate of compliance, and advise on strategies to improve quality; and included an Ombudsperson. The Act also provided for MEC's to establish provincial "Inspectorates of Health Establishments". Licenses to operate were linked to criteria of need as well as compliance with standards, and could be withdrawn on the recommendation of the Office.

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 identifies mechanisms for improving the quality of healthcare in both public and private sectors. The policy highlights the need to focus capacity building efforts and quality initiatives on health professionals, communities, patients and the broader health care delivery system (National Department of Health, 2007). Hence, the objectives of the National Policy on Quality were to:

- improve access to quality health care;
- 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 health care.

The *Ten Point Plan,* released in 2009, reinforces the government's commitments to quality of healthcare services made in the legislative and policy framework, and was developed to

prioritise reform within the sector. Priority number three in the ten 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 though the establishment of a well-capacitated and independent Office of Standards Compliance, an integrated plan for improving the quality of health services, and an Ombud function that would receive and investigate complaints.

In addition to health specific policies and legislation, Batho Pele principles should govern all healthcare delivery. Batho Pele, a Sotho translation for 'People First', is an initiative to get public servants to be service orientated, to strive for excellence in service delivery and to commit to continuous service delivery improvement. 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". 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 suitable informed decisions about their health and to complain if they have not received decent care.

2. National Health Insurance

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 it 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 Health Care.

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 raised about quality at public sector facilities lead to a preference for health services in the private sector and the majority of South Africans cannot afford to make the out-of-pocket payments required to access these 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 set 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 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.

3. National Health Amendment Bill 2011

The National Health Amendment Bill was tabled in Parliament on 16 November 2011, tagged as a Section 76 Bill and referred to the Portfolio Committee on Health. On completion of the work of the National Assembly the bill will be referred to the National Council of Provinces for processing.

This Bill as tabled envisages an OHSC of which the objectives 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 the non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

The OHSC is proposed 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 draft legislation the OHSC must:

- 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 without delay;
- 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.

In addition 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.

4. National Core Standards

South Africa has some 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 Establishments" in April 2008.

These initial standards have gone through successive phases of development based on input from the numerous stakeholders involved in the process and were finally approved by the policy-making body (the National Health Council) and issued by the Minister in February 2011.

The National Core Standards are based on the existing policy environment and tailored to South Africa's health care context, while also reflecting international best practice and a strong evidence base. The purpose of the 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."

They have been linked from the beginning to an audit tool which has been through successive stages of testing and revision.

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 Department. 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 changes to the 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 can enable

"...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. ...."

Both the report of the National Planning Commission and ongoing work and analysis done by the National Department of Health points to the challenges faced by the public health system in particular and the extent of the burden of disease in general. These challenges remain central to the quality of health care delivery.

2. A crisis of accountability and its impact on unsafe and unacceptable (quality of) health care

In addition to the realities of the burden of disease and an ailing health system, the Minister of Health has on more than one occasion stated that a crisis of accountability also directly impacts on the quality of health care in South Africa. This challenge relates directly to the proposals for the establishment of an independent quality regulator.

2.1 Origins of the crisis of accountability in health systems

In an article in The Lancet (vol 374, September 5, 2009) the authors advance a cogent argument that the roots of the current difficulties faced in the health system in South Africa can be traced to policies from earlier periods in South Africa's history. These include racial and gender discrimination, income inequalities, migrant labour, the destruction of family life, and persistent violence spanning many centuries but consolidated by apartheid in the 20th century.

Of particular interest are some of the reasons advanced for the lack of stewardship and management, which is a feature of the public service in general and with an especially acute impact on the heath sector. With regard to the nursing profession the article argues that the root of the relationship between nursing staff and patients, and the concomitant complex factors that impact on accountability, stems from:

"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 middleclass 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."

The authors also identify the failure to acknowledge the need 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 be demanded as this ability to manage and deliver was never developed through education and training. Or in some cases these skills and competencies may not have been required in terms 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,.

The authors argue that the challenges of accountability arise in this interplay between valid reasons for incapacity to manage and deliver; and the continuous manifestations of actions and values shaped by an inhumane and unjust past.

2.2 The erosion of accountability and authority structures

Accountability, and lines of authority or the lack thereof, has 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 might challenge or undermine the authority of managers also lead to the erosion of accountability, including at times the relationship between management and organised labour.

Efforts to improve performance of government departments in general and the health system specifically have been many, with the establishment of the Department for Performance Monitoring and Evaluation (DPME) at the apex of these. The objective with the establishment of the DPME has been to improve inter-departmental collaboration and increase accountability. However, it is important to recognise that measuring performance can only deliver results if there is a commitment to hold those responsible for services, accountable at each level of government.

2.3 Fragmented Responsibility and Accountability

The delivery of public services requires appropriate infrastructure, skilled personnel, functioning institutional structures and competent leadership, and this is equally valid for the health system. All these dimensions are required to ensure that the system 'works' and if shortcomings or challenges in any of the dimensions are experienced it has a knock-on effect on the others. The difficulties that arise when it is *'someone else's responsibility'* provide ample ground to defer or shift accountability.

After 1994 the institutional structure of the health system changed rapidly. Fourteen separate bodies were consolidated into one national department. Responsibility for health care is now divided between national, provincial and local government. This is in addition to the various different role players involved in ensuring a health establishment functions and delivers quality care.

On releasing the first set of National Standards in 2008, the National Department stated: " In South Africa, while formal standards exist in some areas, in many other areas expected practice is expressed in broad policies and guidelines. The system is a complex one. Standards or guidelines are developed by more than twenty programmes and units at the national level and in many cases their efforts are mirrored or adapted at provincial and even municipal levels. Professional bodies and even private organisations also develop standards and guidelines. These contributions are made in different formats and with differing monitoring systems; making the task of performance assessment, benchmarking and implementing effective and integrated corrective action at delivery level very difficult.

"Roles and accountabilities for establishing levels of performance against standards are also not well-defined between the significant role-players. This is the case both within

Departments, between different spheres of government, and between government and external bodies.

"Under such circumstances, the availability of comparable and credible information on the achievement of a single set of national core standards becomes imperative; and is indeed reflected in the National Health Act (2003), which states that "the Minister ... may prescribe ... a set of standards ..." and "the Director General must issue, and promote adherence to, norms and standards...." Information regarding compliance with core standards would assist in making managers of hospitals and districts accountable for taking forward the proposed plans and improving delivery."

The possible negative effects of these fragmented responsibility arrangements are well captured by Karl von Holdt's description, as quoted in the NPC Diagnostic Report, of the difficulties that arise when a lift in a large public hospital 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 manoeuvered 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."

Effective collaboration between the different arms of the public service, spheres of government and other role players is critical in addressing the possible erosion of accountability in a system with varied and fragmented responsibility.

3. Rationale for policy choices made

Whether the lack of accountability in the public health system in particular, or the public service in general, is traced back to its historical roots, based on the erosion of authority structures or due to the fragmented nature of responsibilities it remains a challenge to confront in the efforts to ensure better quality of care.

In terms of the public service and public health establishments the Department of Public Service and Administration, the Department of Performance Monitoring and Evaluation and the Public Service Commission have a role to play in measuring performance. In addition a regulatory framework for health establishments, and the standards and norms against which they are measured, has a central role to play in the scope of possible interventions to ensure better quality of care.

In light of this reality where the level of care does not meet the expectations of the public, where it is increasingly suspected that the South Africa receives a poor return on its health budget investment, where accountability is weak with few consequences when things go wrong, and which has led to a situation where ethics and professionalism have been eroded; the National Health Council made clear choices for the establishment of an independent entity to fulfill this health quality regulatory function.

In terms of these choices, an independent and national health quality regulator should be established to ensure public accountability and credibility, with a single benchmark and with consequences for non-compliance. In ensuring this, the regulator would be formally established as a public entity with a legislative mandate and voted funds, and would not be based on a voluntary peer review model but would make quality regulation mandatory for all health facilities. In order to ensure objectivity, the regulator would not be directly involved in or responsible for activities within the health system designed to improve quality or compliance.

4. Review of Current Practice

In the light of the publication of the proposed draft amendments to the National Health Act 2003 and cognisant of the range of challenges faced by the health sector as it relates to the quality of health care provision, the NDoH embarked on a range of studies to review the extent and scope of current practice. These benchmarking studies were designed better to understand best practice and focused on:

- conducting comparative analyses;
- providing international and national benchmarks in relation to regulatory bodies in general and health regulatory bodies in particular;
- determining the scope of work for possible units and divisions in a to-be-established Office of Health Standards Compliance; and
- engaging in the initial design of systems and processes to operationalise the work of such an Office of Health Standards Compliance.

A comprehensive list of the regulatory and other bodies engaged with during the process of concluding the separate benchmarking reports is attached as **Annexure A**.

REGULATORY APPROACHES

Improving the quality of health care delivery is an important global health priority and health care quality improvement initiatives have been developed in many countries around the world. The purpose of these initiatives is not only to improve health care quality and ensure patient safety but also to improve clinical effectiveness and promote public accountability.

Evaluation of the work of the Healthcare Commission (the predecessor of the Care Quality Commission) in England 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 health care, an independent and authoritative regulator is essential to enhance public accountability and to ensure value for taxpayers' money.

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 quality 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.

External assessment systems may have a number of different objectives that range from improving or maintaining quality, addressing national public health priorities, managing risk or establishing centres of excellence. Common models of external assessment include peer review, compulsory licensing or certification for regulatory purposes, voluntary accreditation, and International Organisation for Standardisation (ISO) certification.

1. Regulation in the area of quality

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 within health systems. Improving the quality of healthcare and health care establishments are central to the reform of health systems and service delivery.

Whilst striving for an improvement in the quality of health care 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.

Two different types of quality assurance systems evolved worldwide. The first involves ensuring the quality of health services through explicit regulation as practiced 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. The quality assurance body under this system does not have explicit enforcement powers but coordinates its actions with other agencies to deliver on regulatory outcomes.

The National Health Amendment Bill (2011) in its current iteration envisages a mandatory system of certification for healthcare establishments. The Bill empowers the Office of Health Standards Compliance to inspect and certify establishments, address complaints, monitor risks and in a limited way enforce compliance. In this iteration, the bill develops a hybrid system of regulation. It establishes a regulator in the traditional sense but restricts the extent of its enforcement powers.

1.1 Examples of different approaches to regulation and enforcement

The benchmarking work undertaken reviewed experiences in the field of health quality regulation in relation to a number of different aspects: examples of good regulatory practice; voluntary compliance or mandatory enforcement; coordinated regulation along the value chain; risk-based approaches; provisions for independence; and evolution over time in regulatory approaches.

1.1.1 United Kingdom

The United Kingdom 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 broader regulation programme of the UK Government. The CQC takes over the reins from its predecessor, the Healthcare Commission, which was responsible for licensing healthcare establishments by assessing their compliance with a set of national minimum standards.

The CQC regulates the quality of care provided by the NHS, local authorities, private companies and voluntary organisations in the United Kingdom and has combined regulation of health care 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.

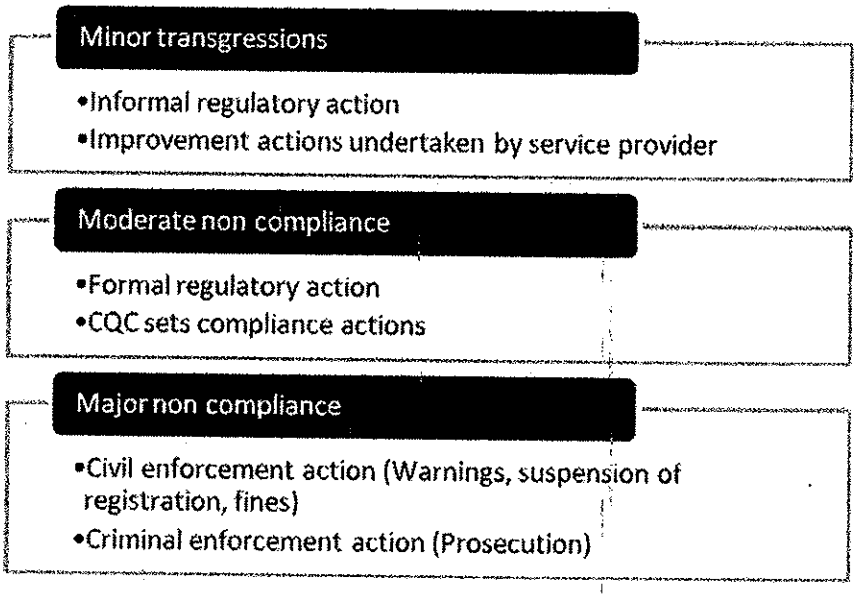
The regulatory approach adopted by the CQC has also moved away from compliance assessments that were process-orientated to an outcomes-focused system, and from the earlier "soft-touch" or risk monitoring approach to frequent on-site inspections for all units. The ability to adopt an outcomes focused 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.

The CQC enforces compliance against this set of essential standards by first registering all health and social care establishments (which is equivalent to providing a license to operate).; shift from soft touch/ data base to site visits and. The more recent approach reviews what is found not why, and is no longer giving advice to establishments on how to fix problems. Apart from the regular inspections, the CQC does through the minister have a legal mandate to "investigate serious concerns", which enables them to also do more in-depth investigative work Funding and resourcing of the CQC is increasingly based on cost recovery principles in order to enhance independence, however they do face a challenge in how to determine the appropriate level of user charges. The CQC is a

traditional regulator endowed with the power to inspect regulated entities, investigate concerns and enforce their decisions. In analysing the CQC, it is apparent that the legislative framework has evolved significantly to an independent regulator within the health sector. Based on previous experience, legislation and regulations now endow the CQC with greater enforcement powers. This allows the CQC to engage in civil and criminal enforcement action as the case warrants and reflects a certain level of maturity within the regulatory system in the UK. 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.

To enable the CQC to effectively discharge its regulatory mandate, the legislative and regulatory framework allows the CQC to initiate either civil or criminal action to enforce compliance with standards. These traditional enforcement powers are often seen as punitive and ideally are used only once other voluntary means are exhausted. Hence, CQC has developed an enforcement policy that presents a number of enforcement options. These options range from informal regulatory action for minor transgressions and thus encourage voluntary compliance, to litigation and enforcement action for more serious offences. Decisions are taken through a series of internal review processes where all potential problems are discussed and enforcement action agreed-upon. The figure below sums up this progressive approach to enforcement.

Enforcement approach adopted by the CQC



Source: Enforcement Policy (CQC, 2010)

In general with the NHS Trust, when concerns are raised, it then becomes a focused investigation that "picks them to pieces". It would do in-depth investigation into deaths or untoward incidents through assessing the quality risk profile (QRP) red dials after

which it would dig into the other standards or problems found. This is within their remit as the regulations state that "if directed by Secretary of State" i.e. Minister, the CQC can investigate serious concerns". The CQC does have some clinical advisors plus people they can call on in such situations. Compliance inspections of NHS Trusts are prepared / designed and based on these QRPs and may pull in specific expertise including patients, nurses and clinical advisors.

The comparative analysis of a range of regulators suggests that the relationship between enforcement and voluntary compliance is a dynamic one which can be influenced by the maturity of the entity as it develops over time.

1.1.2 France

In the case of Haute Authorite de Sante (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 health care and the financing of health care. Legislation creating the *Agence Regionale Sante (ARS)* – the health insurers – require 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.

1.1.3 South Africa

In an effort to explore the possible implementation of enforcement or compliance measures the benchmarking studies also looked at regulatory bodies with similar

responsibilities and their functional approaches in South Africa. In addition to work that was done with regard to the structure, scope and functional approaches of the Financial Services Board and the National Credit Regulator valuable lessons were drawn from an earlier 'Quality Assurance Best Practise Study within the Private and Public health sectors in South Africa' commissioned by the Department of Health in 2009.

The purpose of the 2009 study was to conduct a quality assurance best practice study in the private and public health sectors in South Africa, especially by reviewing the mandates of 5 selected institutions, which broadly operates in the field of "accreditation" in South Africa.

Evidence from the five selected case studies highlighted the need for institutional arrangements based on a clearly defined mandate. In this regard the South African National Accreditation System (SANAS), the South African Bureau of Standards (SABS) and the South African Council for Medical Schemes (CMS) have specific legislation which provides their clear legal mandates and to some extent also govern how they operate. The *Batho Pele Programme* derives its mandate from several White Papers and government policies. The affectivity of the programme is impacted on by the manner in which it is streamlined throughout the public sector. NGO's such as the Council for Health Service Accreditation of Southern Africa (COHSASA) on the other hand operates at the level of peer review and voluntary processes. These processes draw on professional, and or management, commitments to improve quality.

This study pointed to the importance of clearly setting out the mandate and scope of a quality assurance body in legislation, as this provides the impetus for the appropriate institutional arrangements to be set in place. In addition it confirmed that the core functions of such bodies should draw from local and international experiences but in the final instance it must be informed by local conditions.

a. The South African National Accreditation System (SANAS)

SANAS was established in terms of Section 21 of the Companies 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 and use international standards, mostly developed by the International Standards Organisation ISO and IEC. In addition SANAS use SABS standards where applicable and where required develop guidelines for such standards. SANAS do provide accreditation for health laboratories and formally list those which meet the standards.

SANAS charges fees for their services and these are prescribed by relevant regulations in the context of the dti.

b. The South African Bureau of Standards (SABS)

SABS is a statutory body that was established in terms of the Standards Act, 1945 (Act No. 24 of 1945) and continues to operate in terms of the latest edition of the Standards Act, 2008 (Act No. 29 of 2008) as the national institution for the promotion and maintenance of standardization 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.

The Department of Trade and Industry (the dti) benchmarked the SABS regulatory system internationally and concluded that the practice of having a standards body as a regulatory body is not optimal or 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 can not display the SABS certification logo.

The fees charged for SABS services are prescribed and reviewed regularly.

c. The South African Council for Medical Schemes (CMS)

The Council for Medical Schemes 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.

CMS monitors the impact of the Medical Schemes Act and recommend improvements. They also secure 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 and promote 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 of 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. This is similar to SANAS which has become almost an overarching accreditation body which accredits SABS and other bodies engaged in 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.

d. The Department of Public Service and Administration – 'Service Standards' (Batho *Pele*)

Batho Pele, a Sotho translation for 'People First', and is a government-wide approved Cabinet initiative to get public servants to be service orientated, 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 quality assurance standards and norms implemented and evaluated through the Batho Pele programme emanates from the Constitution and the White Paper on the Transformation of the Public Service. The Batho Pele programme investigate and evaluate the application of personnel and public administration practices, and report to the relevant executive authority and legislature. The programme can investigate public service employee grievances (specifically where it concerns official acts or omissions) and recommend appropriate remedies. In addition they monitor and investigate adherence to applicable procedures in the public service and advise national and provincial organs of state regarding personnel practices in the public service. This can include recruitment, appointment, transfer, discharge and other aspects of the careers of employees in the public service.

The enforcement mechanisms inherent in the programme appear toothless unless there is a clear violation of legislation.

e. The Council for Health Service Accreditation of Southern Africa (COHSASA)

The Council for Health Service Accreditation of Southern Africa (COHSASA) is a non-profit organisation that assists a range of healthcare facilities to meet and maintain quality standards. It does so by enabling healthcare professionals to measure themselves against standards and monitor improvements using quality improvement methods, international accreditation standards and a web-based information system.

The quality assurance norms and standards used by COHSASA are developed, implemented and evaluated in line with the principles for standards development as outlined by the International Society for Quality in Health Care (ISQua).This includes defining systems and processes required for safe and quality patient care in a full range of hospital services/areas of operation.

The COHSASA model clearly indicates that the consideration of local conditions in terms of the development of systems and processes is important.

COHSASA, as a voluntary accreditation institution, developed a partnership approach before, during, and after the quality assurance process. On receiving COHSASA accreditation, a 'member' continues to benefit from ongoing training, support, and quality improvement.

COHSASA charges fees for their services and it operates as a Section 21 company. The fees they charged are approved by internal mechanisms under the auspices of the COHSASA Board of Directors.

As a Section 21 Company COHSASA amassed extensive experience during the last 13 years where it relates to accreditation in the health sector.

As indicated earlier in this report, work undertaken as part of the benchmarking study also focused on two so-called new generation regulators for the purpose of evaluating their approaches to amongst others regulation, enforcement and stakeholder relationships.

f. The Financial Service 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 and enabling the early detection of potential problems and promoting the continuous management of risk to facilitate proactive supervision in line with global trends, 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 as well as 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.

g. 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 on 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 also 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 whom they work with. For example, great success has been achieved in the Eastern Cape in prosecuting registrants for non compliance with the Act because of the good relationship built between the NCR's investigator and the SAPS representative.

1.2 Regulatory Coordination and / or Collaboration

The British regulatory system is built on a system of coordinated enforcement. 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 Foundation 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.

The basis for the coordinated enforcement approach is a concordat signed between the CQC and 9 other organisations that regulate, audit, inspect and review elements of healthcare in England. Underpinning this approach to coordinated enforcement are a number of tools that enhance and deepen the regulatory landscape in the health sector.

The regulatory mandate of Haute Authorite De Sante of France (HAS) has expanded significantly moving away from a narrow focus on certification towards a comprehensive model of regulation of the health sector. The HAS now focuses on regulating the value chain in the health sector – that is people, processes and material. These changes are a good example of how regulatory schemes evolve over time to regulate value chains rather than a specific component. This understanding is particularly useful in the context of the implementation of the National Health Insurance System. Whilst the envisaged mandate of the OHSC is currently limited to certification, its role may indeed expand or change under a system of national insurance where the price of health care can be directly linked to quality.

Moving towards a system of value chain regulation eliminates the issues of concurrent jurisdictions. In the case of the HAS, while the organisation certifies health establishments, it is also responsible for accrediting health professionals. Any transgression by a health professional identified during the certification process may be referred to the appropriate commission within the HAS.

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 amongst 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.

Interestingly, the quality standards themselves are not regulated through legislation in France. Rather, the standards are published in a manual which is revised every few years.

1.3 Strategic Independence and Legal Precedence

The independence of a regulatory body is generally entrenched in law and, as is the case with the envisaged independent entity to regulate quality in the health sector, is considered critical for the functioning of a successful regulatory body.

From the comparative benchmarking studies there are four aspects of independence that are generally entrenched in the governing acts of regulators:

- governing legislation should provide security of tenure for the Executive Officer
- the entity should have control over the appointment of staff as well as the management of its own resources;
- the entity should be able to make decisions on its core functions without prior approval from oversight department; and

- the entity should be able to publish and report on its findings to the public.

In terms of South African legal precedence established in *Hugh Glenister versus President of Republic of South Africa & others* and its relevance to independence generally, the Constitutional Court identified two components to independence:

- Structural components
- 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 governing reporting, oversight and decision making of such an entity.

In terms of international approaches to the question there are ample examples where International literature sees regulatory independence as a structural concept. In addition, regulatory independence is seen as augmented by credible, transparent and consistent regulatory processes for government to deliver on regulatory accounts.

It could therefore be surmised that effectiveness as 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.

The CQC in the United Kingdom has a Board whose Chairperson is appointed by the Parliamentary Health Committee on the recommendation of the Minster of Health, and who reports directly to the Department of Health but indirectly may be called to report to Parliament. The UK Health Ombud is appointed by the Queen and reports to Parliament.

SETTING STANDARDS AND NORMS

The benchmarking exercise covered definitional issues as well the process of development of norms and standards to be used as part of a health quality regulatory approach. In addition some studies pointed to the importance and experience of clarifying issues related to maximum and minimum standards; accreditation and licensing; as well as the utilisation of own or international standards.

The use of standards for measuring the quality of health care is not a new concept but has gained momentum as there has been increasing advocacy for health care organisations to take accountability for the health care offered. Many countries recognise the need for standards, particularly for hospitals, and are pursuing their establishment.

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 standard 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".

A "standard" refers to "the level of quality or excellence attained by somebody or something, or a level of quality accepted as the norm or by which actual attainments are judged".

However, 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 health care, 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".

Norms are often defined in quantitative terms (e.g. 3 beds per 1000 population), 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 health care service (e.g. 80%). Input norms which refer mainly to health personnel, facilities or finances are usually tied to a common denominator (e.g. one clinic per 10 000 people). Process norms relate to care, service or management (e.g. all children should be fully immunised by the age of one year). However, it has been argued that meeting such norms does not mean that the institution is providing quality care.

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 are on standards, rather than on norms.

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.

2. Purpose of measurement and choice of approach

Relevant, objective, and measurable standards are essential if the expected improvement in health care 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 health care quality and therefore to the type of standards to be set have had broad health sector acceptance for many years: licensure, accreditation, and certification.

Standards used for **accreditation** most typically are set through a process of expert input and consensus at a maximum achievable level to stimulate voluntary improvement over time and address organisational rather than individual practitioner capability or performance. Criteria or standards used for **licensure**, on the other hand, are most typically set at a minimum level consistent with ensuring that the organization has the essential components required to provide care to patients in an environment with minimum risk to health and safety and are mandatory. **Certification** is an approach that may address individual practitioners as well as organizations or components of an organization (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 inked 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 health care organizations to continuously seek to improve quality while recognizing what is possible to achieve given potential resource limitations. These standards are typically developed by a consensus of health care experts, published, and reviewed and revised periodically in order to stay current with the state-of-the-art thinking about health and evolutions 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 organization's ability to achieve optimal performance. If the standards are set unrealistically high, organizations will feel demoralized 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.

3. Development of Standards and Norms

Two paths towards the development of standards have been indentified: 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 3 to 5 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, they inevitably reflect choices

that have been made 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 in different stages in their use of standards as a means for managing quality in health care, all started in a relatively small way and some such as the Quality Care Commission in the United Kingdom have become sophisticated and deeply entrenched in the health system as a whole and others 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 health care establishments have had standards for various legislated aspects of health care such as radiation management, medicine control and training of health care 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 the process to develop them is, practical difficulties will arise in their measurement, policies and health needs will change and new evidence will become available making it necessary for a review system.

Our international review showed us the 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 set by the Department of Health, but has recently proposed a focus on a sub-set 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, these standards cover both patients and staff, reflecting the value placed on staff and the importance of protecting staff capacity for care provision.
- The Health Information and Quality Authority (HIQA) in Ireland monitor standards approved by the Minister of Health and reflecting largely media concerns with quality. Standards are high level and outcome based (e.g. "effective leadership") but do include clinical management.
- Accreditation Canada generates the standards that they assess and reviews them every 3 years.
- In Australia, the Council on Health Care Standards sets standards that were originally based on the UK standards, through a process of ensuring expert inputs on and reviews them every 4 years.
- There is a separate body (the Australian Commission on Safety and Quality in Health Care) that has also set standards in the area of its specific remit through an expert working group process.
- 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 (supported by legislation or regulation) standards 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 care unless they are part of a quality management system.
- The purpose of having standards in a health care system may include an attempt to resolve problems by providing guidance to best practice, as well as a means to assessing compliance to legislation.
- Experts in the subject field as well as in the development of standards and measurement tools are needed to ensure credible standards.
- A robust and recognized 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 funding of the development of standards will vary depending on the purpose and whether they are mandatory or voluntary standards.

ASSESSMENTS AND INSPECTIONS

The benchmarking exercises for the implementation of external assessments and the concomitant inspections covered the different possible methodologies to implement assessments including appraisals, assessment, audits and inspections, and whether these should be voluntary or mandatory. It examined the weaknesses and strengths of announced and unannounced inspections as well as whether these should be approached on a prioritised basis or based on periodic routine visits. Lastly it also considered experiences and lessons for the recruitment, selection, placement and training and quality control of staff implementing the assessments / inspections.

1. Experience of External Quality Assessment

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 programmes are still located in high-income countries. Low- and middle-income countries (LMICs) with functional accreditation programmes include Malaysia, Brazil and Zambia. The Council for Health Service Accreditation of Southern Africa (COHSASA) has operated a voluntary hospital accreditation programme in South Africa since 1994.

Despite concerted efforts to look more closely at the experiences of implementing external quality assurance programmes in countries with similar economic, health and developmental challenges and profiles, this was not possible as such programmes and examples do not exist internationally.

From the benchmarking exercise the current international trends in implementing external quality assessments are 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 semi-regulatory systems and in 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 and increasingly health outcomes and patient satisfaction are prioritised over process norms and standards. All of these trends are leading to greater transparency and public accountability.

2. Scope of 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 health care organisations.

In terms of the possible models for quality assessment, licensing and certification are commonly used for both individuals and organisations but accreditation usually refers to health care organisations and or facilities.

A few mature accreditation programmes, such as that of the UK or Australia, cover the whole range of possible activities, although responsibilities are usually shared between different bodies. Typically the regulation of health professionals and health facilities is undertaken by different organisations, although the French Haute Autorité de Santé (HAS), for example, does both. The most common basic model for facility accreditation focuses on the voluntary accreditation of publically-funded hospitals. This has been the starting model for most countries in Europe and Latin America, and has been the COHSASA model in South Africa.

At a formal level, only Italy, France and Scotland have compulsory accreditation, but where accreditation is linked to the receipt of public funds (either directly from government or from a national health insurance type fund), voluntary systems are 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.

Some regulators, such as the Care Quality Commission (CQC) in England, had moved to systems based more on compliance monitoring than regular external inspections, but have recently re-introduced regular mandatory inspections.

NHSLA does not use self assessment as they have had very poor experience of this, due either to ignorance of the process, or even humility on the part of managers who mark themselves down.

Lastly, the health quality systems in many countries have particular programmes focused on patient safety, but these are typically operated by separate organisations such as the National Patient Safety Agency (NPSA) in England and the Australian Commission on Safety and Quality in Health Care (ACSQHC) in Australia.

The experience of the Healthcare Commission in England, the predecessor of the CQC, provides valuable lessons on 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: inspect 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.

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 use of a range of regulatory tools and approaches flexibly in relation to the risks in providing and commissioning health care;
- 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 Health Care (ISQua) have identified important lessons for the successful implementation of a national accreditation programme.

Lessons learned from national accreditation programmes reflect common problems identified and can be summarised as:

- the need to clarify whether the major purpose is internal improvement or external regulation;
- the need to match assessment approaches to purpose;
- insufficient involvement of key stakeholders and institutions;
- a failure to prioritise culture change through commitment, collaboration and team work; and
- government domination and protection of public sector weakness or conversely lack of sustained support and authority.

Other problems identified were the often unrealistic expectations of what such programmes are able to achieve with 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.

3. Inspections for Compliance

The international and local comparative analyses highlighted some important design elements and provided guidance for the implementation of an inspectorate function to implement external quality assessment in South Africa. In addition the studies shows that initially an inspectorate function to assess quality may take an "inspections in partnership approach" to assist with getting health establishments on board. Such an approach could evolve over time as the regulator matures.

3.1 Staffing Models

In terms of the staffing models for an inspectorate unit to implement the external assessments the geographic spread of health establishments is one key consideration in establishing teams of inspectors, together with the scope of work to be done and the available pool of independent experts.

Inspectors are found in different models to be based locally, regionally or nationally; and can be full-time, 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 health care 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 do offset this), as well as increasing the pool of available expertise, improving job satisfaction and strengthening local relationships. The UK has adopted a model of "home-working" by individual inspectors, driven by their model which includes a large number of small private local social care homes. In the Two key policy decisions determined the human resource strategy of the CQC, one relates to generic portfolios in local geographic areas as opposed to knowledge of the field in order to cover this very large number of small institutions.. The other linked issue relates to home-working – 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 criteria, then trains and supports them to conduct inspections close to their place of residence or work. This enables them to make best use of a small pool of expertise.

A nationally / centrally based team on the other hand enhances the objectivity and standardisation of the work done, enables sharing of skills in different areas, and more easily creates an ethos or culture of excellence and integrity within the team. Organisations do also grow and evolve over time, with a larger workload and greater degree of community linkage being linked to decentralisation. Monitoring of actions by health establishments to meet compliance notices for instance is a very time-consuming process and requires sufficient resources to make it effective.

3.2 Quality control and decision making

A draft report on findings is usually provided to the service being assessed both for their information and to give them a fair chance to respond and if necessary to clarify their findings. Before a report is finalised and a decision taken on the formal status, benchmarking studies indicated that clear decision-making processes are critical to ensure the validity and credibility of external assessments. As the outputs are difficult to assess objectively a robust peer review and organisational process will need to be set up to ensure inspector consistency and compliance with internal quality standards.

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 consistent, valid and complete reports are submitted to health establishments.

CQC has developed a Guide which assists them CQC in making a judgement on whether an establishment or part thereof is compliant or not. The call to make such a judgement goes through four stages. Stage 1: determining whether sufficient evidence exist to make a judgement about compliance; Stage 2: Checking whether the evidence demonstrate compliance with the regulations; Stage 3: Determining the impact on people who use the services and the likelihood that this will happen again (risk assessment); and Stage 4: validating the judgement.

Certain key points are considered in Stage 1 in determining the weight of the evidence at hand, whether the evidence is current, reliable, relevant, sufficient, includes users and specialists' inputs.

Demonstration of compliance with regulations in Stage 2 means a process is followed of checking any beach of regulated activities or standards and if any breach took place Stage 3 then looks into the impact of such breach on the users, impact maybe minor, medium and high and the likelihood of such occurrence may be unlikely, possible or almost certain.

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.

3.3 Phasing and prioritisation

Most of the regulators interviewed used some form of prioritisation mechanism.

Inspectors internationally use a variety of techniques to help them prioritise assessments and workloads, depending on the purpose of the programme. Some examples include:

- Focussing activities in a specific type of service or facility;
- Profiles for each health establishment based on monitoring of indicators to predict the risk of non compliance on important outcomes/standards using a combination of qualitative and quantitative data from various sources;
- Focussing on the high risk health establishments first and sampling the medium and low risk establishments such that all health establishments are assessed within a specific timeframe;
- Alternatively some programmes will accredit those establishments who apply once they are sure they can meet the standards;
- Evaluation of self assessments performed by health establishments to determine which standards to focus on in an inspection instead of assessing compliance with all; and
- Use of self assessment-type desktop reviews to assist in preparation and contextualisation prior to inspection or for determining compliance without necessarily inspecting.

In a situation 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 would be important. Many of these techniques increase the capacity of the inspectors and provide an ongoing assessment of compliance without always necessitating an onsite full inspection

3.4 Inspectors

The comparative analysis indicated that the competencies and skills of the staff implementing 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 providers they assess, work with and the other regulatory bodies and forums involved in delivering care to patients.

The competencies, roles, performance and training for inspectors should be tailored to the nature of inspections they will be performing and the degree of judgement they will have to exercise. An example of applying such considerations can be seen in the difference the Council for Medical Schemes indentified between 2 categories of "inspectors", namely compliance inspectors and investigators (e.g. of irregularities). Compliance inspectors are lower level, multi-skilled employees while those who are required to perform investigations would need to be more highly skilled and experienced evidence gatherers with competencies in auditing, investigations or law; and

Training was generally found to include a mixture of class room learning and on the job training under the supervision of a buddy or mentor to ensure competent inspectors. 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 inspector should include an element of 360 degree review by others in that inspector's team and their line manager, carried out with some frequency..

However, in a role such as this, technical competence is not sufficient. Ethical considerations and culture play an equally important role. Building an organisation from scratch would need to ensure this aspect is accorded the importance is deserves. The CQC faced a particular to build a new identity from the three different organisations and their process to develop and change the culture included:

- utilising a baseline staff survey as kick-off (which will be repeated in future);
- a framework for values and behaviour were developed by the staff and it feeds into the Performance Management System;
- a regular staff-nominated awards process reflecting these values;
- working towards a "professional Regulator" identity; and
- providing recognition for qualifications.

INFORMATION AND KNOWLEDGE MANAGEMENT

The benchmarking exercises examined quality reporting systems, the use of risk profiles to prioritise assessments and serve as a guide for intervention and also looked at the functions of an early warning system. Some attention was paid to the design approaches for establishing composite index-based specific and routine data reporting which could form the basis of quality risk profiles. The possibility, and international experience, of monitoring the trends of important outcomes such as mortality outliers as well as the use of complaints were reviewed in relation to an active surveillance or Early Warning system.

These exercises pointed to the requirements for sophisticated analysis and knowledge management capacity and the value and rich knowledge base which analyses across areas and categories can provide.

1. Monitoring, reporting and learning systems

In general, the most important function of a quality reporting or information management system is to use the results of inspections, complaints investigations and data analysis to formulate and disseminate recommendations for *systems change and quality improvement.*

A 2005 WHO review on national adverse event reporting and learning systems found that: existing national reporting systems aim to improve patient safety, but exhibit great variation in sponsorship, support, participation, and function; that reporting tends to be voluntary; and that a major issue for all reporting systems is confidentiality. The review also found that the ability of national reporting systems varies according to the sophistication of the analyses and that many countries do not have the human or financial resources to carry out the plans they make.

Consequently, the WHO identified key characteristics of successful quality reporting systems which can be summarised as systems which are non-punitive, responsive, ensures confidentiality, retains independence, utilises expert analysis, conduct analysis and make recommendations timely, have a strong systems focus and orientation and is supported by adequate financial and human resources.

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

The Healthcare Commission in England used information in two ways:

- To provide a view of risks in the system of health care and to give early warning of which 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.

Their key strategies for implementing information management included:

- 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.
- Communication to the national health system that it ought to know what it is doing; should be able to assess its own performance; and be held accountable on behalf of the public as the taxpayer.
- Limited deliberate and targeted 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'.
- Production of an annual rating of organisations' performance, starting with a post hoc audit of performance. The Annual Health Check involved the overall analysis of existing data, including the views of patients and the public, to provide an assessment of the extent to which there were risks that a service provider might not be able to deliver good outcomes.
- This analysis was backed up by targeted inspections, and was developed over the years.
- Gradual development of the capacity to engage in 'real time' surveillance of performance, through refining the information available, and providing an early warning system when things were going wrong so that action could be taken. From the perspective of the regulator, it meant that less emphasis needed to be placed on lengthy investigations of things that had already gone badly wrong and more on collaborative working between the regulator and others to identify problems early and work to resolve them. (It should be noted however, that this concept of "light touch regulation" has recently been replaced in the work of the CQC which succeeded the previous HCC.)

2. Early Warning System

An Early Warning System (EWS) is a surveillance system which collects information on specific events in order to trigger prompt improvement action. In this specific case, a health quality early warning system would detect risks to or breaches of quality standards in order to trigger quality improvement action.

The role of a national EWS is to conduct risk identification, monitor quality against a legislated set of core standards, and communicate alerts (report on quality). The key functions of such a national EWS should thus be to ensure the primary and secondary prevention of breaches in quality, specifically:

- Early identification of a risk to patient safety or quality to enable preventive action;
- Identification of risk to the certification status of a health establishment to enable preventive action;
- Early appropriate remedial action after a serious event or catastrophe.

Four main elements of an EWS are described by the United Nations, namely Risk assessment, Monitoring and predicting, Communicating alerts and Response. The application of these elements can be seen in the systems already developed in the UK which is now being expanded in other countries such as Australia and Canada. These elements serve to identify risks to

quality through drawing on multiple information sources in order to prioritise compliance action.

2.1 Risk assessment

This initial step involves identifying any risks to the patients' safety and risk to the compliance of the health establishment. In the UK system, several methods are sued to assess risk: through the creation of composite "quality risk profiles" (see below) using multiple sources of information; through analysis of key outcome data (such as mortality statistics) to identify unexplained outliers, and through statutory notifications of defined critical events.

2.2 Monitoring and predicting

This entails monitoring the events described in section above by relevant institutions through all of the prescribed reporting systems. The information provided can be converted into estimates of the potential risk.

2.3 Communicating alerts

The quality risk profile (QRP) database is updated monthly as new information becomes available and the updated summary is made available to each institution. The institutions are able to access the information through a web-based online system. To ensure that the institutions are able to use the QRP effectively, CQC produces detailed guidelines on how to interpret the QRP.

2.4 Response

The response may involve temporary closure of a ward or loss of certification status. Corrective action or concrete response to a breach in quality would be the function of the broader EWS and the health establishment. In response the following can be done:

- Categorization of the event according to its severity
- Undertake the root cause analysis of the organization.
- Publication of annual review of events

3. Risk Profiles

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

- *Quality 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* for developing and updating a risk profile should be used, whilst

acknowledging that each of these data sources has their limitations in terms of usefulness, completeness, comprehensiveness and accuracy;

In order to do this a Quality Risk Profile (QRP) of a health establishment is created, as described in detail below. Thus the QRP serves as a tool for risk assessment and is used by the regulator (in this case by the inspection teams) to guide the work of the inspectors. The QRP are created by bringing together existing information and also using information from a number of sources. Both qualitative and quantitative data is used in developing the QRP.

Each source of data is weighted according to the quality of data and its relevance to a particular standard. Using the QRP each health establishment is classified into one the risk categories called RAG (Red, Amber and Green).

The QRP database is updated regularly as and when more information becomes available. QRP takes into consideration the different types of risks namely:

- Inherent risk: The risk attributable to an organization by virtue of its case-mix
- Situational risk: The risk attributable to an organization 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
- The international literature suggests that an early warning system (EWS) 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".

A critical set of indicators can be further extracted from the EWS and these indicators will be monitored on a weekly basis, in order to identify immediately serious breaches in quality at health establishment level and those that are threats to the patients' safety. These indicators could serve as a sub-set of indicators that are treated as notifiable events.

The purpose of such a sub set of indicators is to facilitate prompt reporting on serious incidents, communicate alerts immediately, in order to prompt an immediate response that will prevent further harm or manage the risk or its consequence. These indicators will also inform the QRP.

CQC has surveillance **"Outliers" and Analysis Department**. This department uses mortality notifications provided by NHS Trusts and a private agency for analysis. Statistical time series techniques are used to identify where mortality data / figures are worse than expected (threshold set based on historical series). Despite this data is quite hard to analyse due to incomplete data sets and low reporting rates.

The CQC also review emergency re-admissions (within 28 days of discharge) for specific procedures; as well of maternity services.

If anything is found, an action plan is developed and implemented by the Trust; Inspectors will monitor this. In about 40% of cases the Trust does develop an action plan for improvement in response to alert. However nothing serious has been picked up over the past year or two. Now serious cases seem to be very rare. Trusts act proactively before investigation and this does seem to have worked, though sometimes investigations are needed.

- *Data sharing agreements* can secure access to required data. Information should be weighted according to the quality of data;
- A *quality risk rating* 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 technology becomes more sophisticated, new indicators can be used to create risk profiles and risk ratings;
- *Health establishment information* in an easily accessible format. Providers should be able to access and know what their risk profile is and how it was computed (with security and access levels clearly defined);
- The information contained in a risk profile is dynamic and should be updated on an on-going basis. Risk profiles and risk ratings to be updated regularly.
- Far more emphasis and resources and resources are now being channelled to supplement risk profiles with frequent and un-announced on-site inspections, as the only method of ensuring a full and objective picture of a facility

It is important to note that building credible, comprehensive and accurate risk profiles for health establishments is a long term investment and will take long to develop and refine. With time, as the system becomes more sophisticated and additional data sources, including NDoH routine statistics, become more reliable and are validated, information from clinical teams, morbidity and mortality meetings, specific conditions and how they are treated (for example diabetes and hypertension) and specific quality related indicators can be included.

In terms of the structure of risk profiles it should include both basic health establishment information as well as the actual risk ratings.

Certain events or occurrences are considered to be of major or immediate risk and as such are indentified

4. Knowledge management

The information collected in and for the quality risk profiles and early warning system would be a rich source of understanding of the health system, enabling 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 improve the quality.

Such data sets have enabled regulators to contribute to the understanding of the health system as well as to influence policy and planning. However the Health Care Commission also stated that the degree of influence they achieved on the UK National Health Service was less then intended or anticipated. The reasons for this would need to be examined.

COMPLAINTS MANAGEMENT

The international review showed that complaints management should include both considerations of patient rights and expectations as well as clearly documented complaints management procedures. In both cases the benchmarking studies provided valuable pointers for establishing complaint management procedures and systems.

In establishing complaints mechanisms the benchmarking exercises considered approaches where complaints are managed locally i.e. at the level of the institution or facility with the possibility of escalation levels if complaints are not resolved, and examples of complaints mechanisms that are operated as a completely separate channel and not linked to facilities. It also looked at the use of complaints systems as a form of active surveillance to identify system failures as well as the possibility of utilising a complaints mechanism as a whistle blowing channel

1. Complaints and patient expectations

The Netherlands Institute for Health Services Research noted that a common finding in several studies was patients' dissatisfaction with complaint handling in health care. While the reasons why were for the greater part unknown, they thought that an answer might be found in a better understanding of patients' expectations.

In a study published in 2006, they investigated patients' expectations of complaint handling in 74 hospitals in the Netherlands, regarding what they expected as a fair process and response. They found that "the predominant reason for complainants to lodge a complaint was to prevent the incident from happening again". Patients also expected to be treated respectfully, and to receive a response from the health professional and disclosure of any mistake that had occurred. Only a minority of complainants (7%) wanted financial compensation. The study concluded that "nearly all complainants want to prevent the incident from happening again, not out of pure altruism, but in order to restore their sense of justice, (as) complaint handling that does not allow for change is unlikely to meet patients' expectations".

The Health Care Commission in the United Kingdom (the predecessor of the current Care Quality Commission), focused on strengthening accountability in health services. They adopted a range of tools for measuring compliance and improvement including listening to users and to staff. This was done through surveys, focus or user groups but also through complaints. The HCC had the responsibility for reviewing cases where the complainant was unhappy with the response received from the NHS Trust, although local resolution remained the primary goal (with escalation through the Ombud office (see below).

Patients who approached the HCC in 2009 expressing dissatisfaction and requesting a review represented about 9000 of the total of 135 000 of complaints received by the NHS in one year. Of these the HCC conclusions upheld the patient's concerns in 30% of cases and supported the respective NHS Trust in 18%; while in 17% the HCC found that the Trust had not responded adequately to the patient and in 28% the patient had not first followed the required procedures at local level and their complaint was therefore not reviewed. In 43% of cases complaints were related to poor hospital care, mainly in relation to basic nursing care, while 11% were in relation to GPs with all the other types of services each receiving between 2-5% of the total. In terms of

the Healthcare Commission's feedback, the priorities in terms of improving the complaints systems were identified as:

- More focus on complainants and what they are seeking from a complaint;
- Identify better ways of learning from complaints;
- Improve access to more complaints investigators and clinical advisers; and
- Support and train staff and encourage less defensive responses.

2. Complaints Procedures

One of the most important results of receiving a complaint is an understanding of the issue the complainant wishes the Ombudsperson to consider. Therefore the **Guide for Ombudsman Institutions of the United Nations Development Programme** recommends that an initial fact-finding interview with the complainant is done. The following questions can be asked:

- What is the basis of his or her understanding of the complaint or grievance?
- What kind of relief does the complainant seek?
- Why does the complainant believe he or she is entitled to that relief?

In the case of the **Australian Commonwealth Ombudsman their Better Practice Guide** (1 April 2009) states: "Complaint handling is a predictable and necessary part of program and service delivery. Errors, misunderstandings, client dissatisfaction and unexpected problems occur in all administrative systems. Complaint handling can be effective in resolving a problem before it becomes worse, providing a remedy to a client who has suffered disadvantage, and nurturing good relations between government agencies and the public.

Complaints also provide agencies with information about program weaknesses and service delivery faults. Good administration involves regular review of existing programs, and the lessons learnt from complaints can feed into that process.

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The Better Practice Guide to Complaint Handling describes five elements on which a strong, effective complaint handling system should be built .These are:

- **Culture:** Agencies must value complaints as a means of strengthening their administration through improving the agency's accountability and transparency and improving their relations with the public as it reassures clients that the agency is committed to resolving problems.
- **Principles:** An effective complaint handling system must be modelled on the principles of fairness, accessibility, responsiveness, efficiency and integration.

- **People:** Complaint handling staff must be skilled and professional.
- **Process:** The seven stages of complaint handling—acknowledgment, assessment, planning, investigation, response, review, and consideration of systemic issues—should be clearly outlined.
- **Analysis**: Information about complaints should be examined as part of a continuous process of organisational review and improvement.

The **NHS Wales** use complaints handling as part of learning from patients' experiences with a view to using lessons to improve services as part of clinical governance.

The National Assembly for Wales (the Assembly) accepted this in March 2002 and endorsed the principles of:

- Ensuring that as many complaints as possible are resolved using Local Resolution;
- Making the complaints process faster and more independent of NHS organisations;
- Providing adequate support for people who may wish to complain and for those complained against; and
- Ensuring that the NHS in Wales learns from complaints.

The local and international benchmarking and research raised the following approaches and matters for consideration in establishing a complaints procedure:

- **Independence:** independent of the system of health care delivery and thus able to impartially investigate and report on complaints received;
- **Administrative as opposed to adjudicative:** not adjudicative to make determinations but take an administrative approach similar to the UK ex-HCC, designed to enhance (rather than ensure) the access of patients to fair and just redress in the case of un-resolved complaints in both public and private sectors;
- **Source of information:** Complaints can provide direct and real-time information on possible breaches of standards and compliance, as part of the process of quality risk profiling and prioritisation of establishments for investigation;
- **Accessible:** Mindful of the critical importance for patients of a caring and respectful response manage a toll-free call line to ensure patients can communicate their concerns and be heard. Develop other mechanisms of enhancing access for patients – most importantly for those who may not feel confident or able to use the call line, but also for younger or more sophisticated users who might make use of electronic media.
- **Adequate response:** For the patient, the final outcome would need to be a detailed response and explanation, provided in a suitably short period. The possible risk of admission of liability in the case of a legal claim will need to be assessed and issues of concrete "redress" beyond this explanation would be more complex, but in cases of clear harm to the patient, recommendations to the respective person accountable or accounting officer could include such alternatives as "medical undertakings" to provide needed care.

In South Africa, health sector related complaints are currently part of the remit of a number of bodies, including:

- The Health Professions Council of South Africa;
- The Allied Health Professions Council of South Africa (AHPCSA);
- The Hospital Association of South Africa (HASA); and

- The Council for Medical Schemes.

The **Council for Medical Schemes (CMS) complaints procedure** provide a useful departure point in considering what it would entail to establish and support accessible complaints procedures for a health establishment regulator. In terms of the CMS procedure, any beneficiary or any person who is aggrieved with the conduct of a medical scheme is allowed to submit a complaint to the CMS. Complainants may complete an online form, a letter, fax, or e-mail to lodge a complaint. Alternatively, complainants may also lodge a complaint in person at the CMS office. The CMS does however encourage complainants to use the CMS as the last resort after they have exhausted all the complaints mechanisms in place at the respective medical scheme.

After receiving a complaint, the Registrar's Office sends an acknowledgement of the complaint to the complainant within 3 working days. The complaint is then referred to the medical scheme for them to respond to the complaint within 30 days. Upon receipt of the response from the medical scheme, the Registrar's Office analyse the response in order to make a decision or ruling. Decisions / rulings will be made within 120 days of the date of referral of a complaint and communicated to the parties.

Any party that is not satisfied with the decision of the Registrar's Office may appeal to the Council's Appeals Committee, provided that the Registrar's decision was not made in consultation with the Council. The appellant has 30 days to lodge an appeal for a formal hearing.

If any party is still not satisfied with the decision of the Appeals Committee or Registrar in consultation with the Council, they have 60days to put forward an appeal to the Appeal Board at a cost of R2,000.00. This prescribed fee is however refundable if the Appeal Board sets aside the decision of the Council. Section 50 of the Medical Schemes Act provides for the establishment of an Appeal Board whose 3 members are appointed by the Minister of Health. One member is appointed based on their legal knowledge whilst the other two must be experts in the medical schemes industry.

The Medical Schemes Act (1998) does not remove a party's right to take their case to the Courts. As such, any member or creditor of a medical scheme may apply to the High Court for an order to investigate a scheme, or for the scheme to be placed under judicial management or closed. The applicant must however notify the CMS at least 15 days prior to lodging their application. Similarly a medical scheme may apply to the High Court for any of the above orders to be set aside, provided that the scheme can show that it is not in a financially sound position. If the CMS believes that it is in the interest of members or that there are material irregularities, it may also apply to the High Court for an order to investigate, or for the scheme to be placed under judicial management or closed. The CMS may also apply for the rules of a medical scheme to be altered in such a way as may be considered appropriate.

OMBUD FUNCTION

The benchmarking exercises explored the common use of the terminology which normally signifies a 'quasi court' with adjudicative or determinative powers which is used as an alternative dispute resolution mechanism. 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 terms of the questions regarding what an ombud can "do", the studies pointed to the importance of clarifying definitional issues 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), *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. This in turn showed up the possible major legal risks in relation to information that can be sued in a court of law.

1. Adjudication and Determination

From the international review it is clear that the Ombud Office is essentially an alternative to going to the courts. In this instance, there is someone who not only has an interest in the resolution of a dispute / complaint, but also has the legal authority to take decisive action and set a precedent, thereby building consistency, predictability and deterrence. For reference purposes, this is called an "Independent Authoritative Approach". The features of this approach are:

- the Ombud assumes an adjudicative role / function;
- Where the Ombud has both the investigative as well as the adjudicative powers, the office is so structured as to achieve a clear distinction between the investigation function(s) and the adjudication function(s);
- The independence of the Ombud is not only in respect of a Ministry or National Government Department, but also in respect of the external assessment function and the standards setting function. So much so that the Ombud is empowered to make a finding against the inspectorate or standards setting divisions of the same regulatory authority to which it is aligned;
- An Ombud to be so properly called must have **determinative powers**. Lesser than that, it cannot be an Ombud but may be a Commission (e.g. Human Rights Commission) or some other kind of institution; and
- 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.

Such an Independent Authoritative Approach is not conducive to where the disputants would continue to have a relationship after the dispute or complaint as it can severely strain the relations. Furthermore, it is not uncommon for the Independent Authoritative Approach to produce the very ills that one is trying to void from the normal court system such as delays occasioned by technical arguments.

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 the determination or adjudicative powers vested in such an office.

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. (It is administered together with the Parliamentary Ombud, similar in scope to our Public Protector, which functions under its own Act). Although the Health Ombud considers 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 (these are compliance related and are monitored through a 'hospital action plan'). 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 then 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 expressed by the Health Ombud remain unrealistic or misinformed expectations on the part of the public.

2. Investigations

From the international benchmarking and reviews, the importance of a clear brief or mandate was identified. This is important to ensure complainants do not direct complaints to the wrong entity with resultant frustration and de-motivation, as well as avoiding overload of the complaints system. The investigation of complaints as envisaged in the National Health Amendment Bill should therefore focus on the investigation of complaints received by the Ombud pertaining to breaches of standards. Not all complaints will or can be investigated due to the multiple regulators involved in the South Africa healthcare industry.

An Ombudsperson's credibility depends on being able to talk to everyone who has knowledge of the events being examined and looking at any documents or record that contain information that will help the Ombud Institution to determine the facts. The United Nations Development Programme has developed a guide for Ombudsman Institutions that details processes to be followed on finding facts.

An initial review of a complaint is usually done by an Ombud office to ascertain the merit of the complaint and establish jurisdiction, and 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 organization for appropriate or local resolution; or to further enquiries by the Ombud office.

An Ombud office should acknowledge a complaint promptly and formally. 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, to further enquiries including interviews with the concerned individuals. 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 would 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.

The UK Health Ombud complaints investigation 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 of40 days, their initial assessment must wil determine whether or not the complaint will be further investigated by the Ombud. Of the approximately 15 000 complaints received by the UK Health Ombud, only a quarter (3 750) were investigated, the rest were referred back to the NHS trust or other bodies.

The governing legislation lists specific reasons an Ombud may choose not to investigate or stop investigation. They include reasons 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.

Clear criteria assist investigation processes, based on four key questions, namely: i) Was there maladministration or service failure? ii) if so, did it cause injustice? iii) was the injustice remedied? and iv) what would further control intervention achieve? 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.

COMMUNICATION AND REPORTING

The benchmarking exercise covered the importance of communications in relation to the dissemination of information to users, regulated entities and the public. In terms of users this would largely focus on informing them of the basic standards, how to complain and what to expect at health facilities. 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, the importance of scientific rigour and respect for confidentiality of both patient and business information.

1. Purpose, functions and structure

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.

1.1 Regulators covered

The regulators selected for interviews comprised:

- *Regulators in the health sector.* These were prioritised because they operate in a similar environment to that which the OHSC will inhabit and deal with related, if not identical, matters. They communicate with many of the same stakeholders and audiences that the OHSC will need to reach.
- *Regulators with relatively high public profiles.* The fact that some regulators feature regularly in the media and on public platforms indicates that they invest in communication and outreach activities and would therefore be valuable sources of information.
- *A mixture of well established, relatively young, and very new regulators and ombud offices.* It was considered possible that the organisation's "vintage" might partly define its communication approach and that the variety might indicate how communication and stakeholder relations practices evolve with the maturation of the organisation.

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 (CMC), 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 Service (SARS) and with a Canadian public health monitoring expert. A lot 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.
- However, informants at the other organisations tended to present their objectives in terms of performing various functions – for example, communication, stakeholder relations, customer service, or education – in a well-planned and competent way.
- Useful and comparable information was provided on communication functions or major areas of work of the units in question.

1.2 Similarities and differences

The majority of the communication units 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 the all 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.

Communication and stakeholder relations (see below) 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/Ombud, although it is sometimes seen as part of an "education" function. The older regulators/Ombud either do not differentiate stakeholder interventions from communication interventions or else deal with it as a function of general management.

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 usually perform a whole range of communication functions.

2. Outsourcing of specific technical functions

From the reviews we learnt that certain specific technical functions are the most likely to be outsourced. These included the layout and design of publications, backend development and content management of websites, and independent research to inform or evaluate communication interventions.

The reasons given for outsourcing were cost-effectiveness: many of these functions require people with specific skills but the volume of work does not justify hiring staff in these areas. Occasionally the reason was simply the special nature of highly creative work needed, for example, in advertising.

In one instance outsourcing was used as a way of coping with the overload on unit staff who could have performed the work internally if there were more of them.

With the exception of the NCR, none of the organisations outsourced the more "political" aspects of the work namely media relations and stakeholder relations. The NCR outsources public relations, which includes media relations and such outsourcing requires very close management and control.

3. 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.

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 that 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.

Information of this nature is It was also clear that political considerations play no small part in this process, as between publication of information and findings and

STAKEHOLDER RELATIONS

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

There was at least as much to be learned from the particular emphases and unique features of communications 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 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 communications "recipe" for regulators. 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 are a wide range of public and private (non-profit) organisations and initiatives which focus 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 policy makers, professionals, clinicians, education and research institutions, user groups, consumer groups, patient advocacy and lobby organisations. Patient participation in informing safety and quality processes and ensuring that the patient voice serves as a central reference in patient safety 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. 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.

1. Users

From an international perspective 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.

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 health care 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 organizations 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 role being to "amplify local voices".
The CQC recognises that this programme has changed the culture of CQC and enhanced hto recognition by staff that their work is to protect patients. Close links with users at local level does improve input and "surveillance" by 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, but this needs resources

Also 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. A 2006 UK Department of Health report, entitled *Safety First: A report for patients, clinicians and healthcare managers,* sets out a series of recommendations of which the establishment of a National Patient Safety Forum constitutes one of the central recommendations. The NPSF 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 health care 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 Coalitions 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 health care. 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 Partnerships operates on pledged commitments from hospitals, physicians and nurses groups, consumer groups, and employers.

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 health care and the strengthening of the effectiveness of health care systems.

The purpose to a regulator is ultimately, to protect and ensure patients' right to quality health care, 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.

2. Regulated Entities

The nature of quality health care means that the regulated entities themselves (the managers and staff in health establishments) have a fundamental role to play in ensuring compliance with standards. The CQC for example recognises this through a close formal working relationship with the National Health Service and with the 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. Relationships with private providers including with the large number of independent GPs shortly to be brought into the regulatory scope of the CQC will offer us lessons going forward. The South African Revenue Service emphasised how critical it is to understand and take account of the operating model(s) of service delivery in order to effectively impact on the functioning of the system.

3. Other Regulators

Improving the quality of health care 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.

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 health care 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 on managing relations with other regulators. The objectives of such relations are identified as being 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.

LESSONS AND IMPLICATIONS

This concludes the benchmarking section of the report and in this section lessons learnt across the various areas of the benchmarking exercises and their possible impact these lessons could have for the establishment of a health establishment quality regulatory body as envisaged in the National Health Amendment Act are highlighted.

The lessons learnt from the benchmarking studies and comparative analyses as outlined in the previous section provide some guidance on considerations for establishing a South African external quality assessment regulatory body for health establishments.

A future independent entity to regulate external quality assessment of health establishments in South Africa could incorporate the following

A mandate clearly stated as being to **protect and promote the health and safety** of those who use health services by **monitoring** compliance by health establishments with national norms and standards that are contained in regulations and have the force of law; ensuring that **complaints** of non-compliance by health establishments with national norms and standards are properly **investigated** and dealt with expeditiously; and **inspecting** health establishments to ascertain whether they comply with national norms and standards, and taking **measures to secure compliance** where establishments fall short of the standards.

This entity should operate **outside** the National Department of Health but be **accountable** to the Minister of Health as the line department but have clear provision to protect its independence and lack of bias. It should have no links to provincial health departments, which are responsible for the running of public hospitals and clinics, or to any private healthcare providers.

In exercising general oversight of the entity, the Minister of Health might call on either a Board or an Advisory Committee consist of experts in the fields of healthcare, regulatory practice, consumer protection, and legal and financial matters; or both to assist him ad to guide the entity in its work.

The entity would differ from other regulators in the health sector in that it will focus not on individual health professionals but on **health establishments**, which are defined in the National Health Act as a wide range of health facilities, institutions and practices. Despite this distinction, there are potential overlaps of jurisdiction with other regulators. It is envisaged that the entity 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.

National **standards and norms** for health establishments should be designed to **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 – early 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 are already utilising the NCS to upgrade their services and this effort should contribute to their certification by the entity.

The entity should be vested with the **power to require regular, mandatory reporting** by health establishments on items related to health standards compliance. Regular monitoring by the entity can be designed to give it proactive capacity to avert serious problems in health service delivery by raising **"early warning"** signs of potential risks. This could include self-assessment as a means of raising the alert on possible problems. One of the key challenges of an entity will be the selection of reporting indicators that best reflect risks in-the-making. The monitoring unit of the entity can also compile and analyse relevant information gathered by other regulators and organisations.

The regular and continued inspections of health establishments to review their compliance with the prescribed standards should be a key function of the entity. 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 ethos will primarily be **corrective rather than punitive,** as the ultimate goal of inspections should be to improve quality of care. However, protracted failure to respond to compliance orders could result in the imposition of serious penalties. In addition to routine inspections, there may be inspections prompted by complaints or by the flashing of red lights on a monitoring and early warning systems.

An entity with this mandate should establish a **complaints investigation unit** under the powers and authority of an independent Ombud, to take responsibility for investigating complaints of failure to meet health standards and recommending appropriate action. This unit should not replace mechanisms that exist in health establishments, provincial health departments and private healthcare companies to address routine complaints. The entity can provide recourse where the more routine processes have failed or are inappropriate but should also have the power to subpoena individuals to collect evidence and to enter health establishments and obtain evidence. The unit should be empowered to act on complaints from any individual or organisation – including internal whistle blowers – and to take the initiative to institute investigations in at-risk areas without receiving specific complaints.

Such an entity should be mandated to **publish** any information related to prescribed norms and standards in the mass media or through other channels. This provision in legislation would allow the entity to follow the international practice of publishing the outcome 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.

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 an initial phase, the entity could focus on ensuring compliance across the public sector. However, the envisaged complaints function could receive and investigate complaints relating to *all* health

establishments right from the start. Monitoring and surveillance systems should be developed to include both public and private establishments as soon as feasible.

The role of the entity should be to **ensure that standards are observed**. It can not 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. The proximity and access of the entity to the Minister and MECs for Health and could generate requests for their intervention to address situations of particular urgency.

CONCLUSION

The information presented here provides a valuable source of information on how similar regulators function around the world and in South Africa. It provides some underpinning of proposals for how a future South African Office of Health Standards Compliance could be structured and how it could function.

ANNEXURE A – List of Organisations / Bodies

[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.]

INTERNATIONAL		
REGULATORY BODY / INDEPENDENT INSTITUTION	ACRONYM	BENCHMARKING COVERAGE
Accreditation Canada, Canada	AC	Quality Standards Development and Information / Warning Systems
Australian Commission on Safety and Quality in Healthcare, Australia	ACSQH	Quality Standards Development and Information / Warning Systems
Australian Commonwealth Ombudsman		Complaints and Ombud Role
Australian Council on Healthcare Standards, Australia	ACHS	Quality Standards Development and Information / Warning Systems
Care Quality Commission, England, United Kingdom (formerly the Health Care Commission)	CQC	Legal and Regulatory Approach Quality Standards Development and Information / Warning Systems Inspections, Investigations, Compliance and Enforcement Complaints and Ombud Role Communication and Stakeholder Relations
General Medical Council, United Kingdom	GMC	Quality Standards Development and Information / Warning Systems
Haute Authorite De Sante, France	HAS	Legal and Regulatory Approach Quality Standards Development and Information / Warning Systems

INTERNATIONAL		
REGULATORY BODY /INDEPENDENT INSTITUTION	**ACRONYM**	**BENCHMARKING COVERAGE**
		Inspections, Investigations, Compliance and Enforcement
Health Information and Quality Authority, Ireland	HIQA	Quality Standards Development and Information / Warning Systems
Institut de Veille Sanitaire, France	INVS	Quality Standards Development and Information / Warning Systems
Institute for Healthcare Improvement, United States of America	IHI	Quality Standards Development and Information / Warning Systems
Joint Commission International, United States of America	JCI	Inspections, Investigations, Compliance and Enforcement
Malaysian Society for Quality in Health, Malaysia	MSQH	Quality Standards Development and Information / Warning Systems
Netherlands Institute for Health Services Research	NIHSR	Complaints and Ombud Role

NATIONAL		
REGULATORY BODY /INDEPENDENT INSTITUTION	**ACRONYM**	**BENCHMARKING COVERAGE**
Board of Healthcare Funders	BHF	Inspections, Investigations, Compliance and Enforcement
Competition Commission	CompCom	Legal and Regulatory Approach Communication and Stakeholder Relations
Council for Health Service Accreditation of Southern Africa	COHSASA	Quality Standards Development and Information / Warning Systems Inspections, Investigations, Compliance and Enforcement
Council for Medical Schemes	CMS	Legal and Regulatory Approach Quality Standards Development and Information / Warning Systems

NATIONAL		
REGULATORY BODY/INDEPENDENT INSTITUTION	**ACRONYM**	**BENCHMARKING COVERAGE**
		Inspections, Investigations, Compliance and Enforcement Complaints and Ombud Role Communication and Stakeholder Relations
Council for Social Services of South Africa	CSSSA	Complaints and Ombud Role
Financial Services Board	FSB	Legal and Regulatory Approach
Gauteng Provincial Department of Health - Inspectorate		Inspections, Investigations, Compliance and Enforcement
Health Professions Council of South Africa	HPCSA	Communication and Stakeholder Relations Complaints and Ombud Role
Health Quality Assessment	HQA	Quality Standards Development and Information / Warning Systems
Hospital Association of South Africa	HASA	Quality Standards Development and Information / Warning Systems Complaints and Ombud Role
Medicines Control Council	MCC	Inspections, Investigations, Compliance and Enforcement
Medi-clinic		Quality Standards Development and Information / Warning Systems
National Consumer Tribunal	NCT	Complaints and Ombud Role
National Credit Regulator	NCR	Legal and Regulatory Approach
Netcare		Quality Standards Development and Information / Warning Systems

NATIONAL		
REGULATORY BODY / INDEPENDENT INSTITUTION	ACRONYM	BENCHMARKING COVERAGE
Office of the Ombud for Financial Services Providers	FAIS Ombud	Complaints and Ombud Role
Office of the Public Protector	PP	Communication and Stakeholder Relations
Ombudsman for Banking Services	OBSSA	Communication and Stakeholder Relations
South Africa Human Rights Commission	SAHRC	Complaints and Ombuds Role
South African Pharmacy Council	SAPC	Inspections, Investigations, Compliance and Enforcement Communication and Stakeholder Relations
South African Revenue Services	SARS	Quality Standards Development and Information / Warning Systems Communication and Stakeholder Relations
Tax Board and Court		Complaints and Ombud Role
Western Cape Provincial Health Administration		Inspections, Investigations, Compliance and Enforcement Complaints and Ombud Role

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 health care 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 Africa 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.

ANNEXURE C - Comparative analysis of Norms and Standards Development

Organisation	Norms and Standards Development
International Organisations	
Care Quality Commission (CQC) In 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 health care 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 health care settings. Onus is on health care providers to ensure compliance with standards. • Against a "stick" approach • Not keen on inspections are they are very labour intensive and expensive.
Accreditation Canada	• Standards are generated and reviewed on a 3-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 is 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 Health Care Standards (ACHS)	• Sets their own standards (blood products, infection control, consumer involvement etc.) which it reviews every 4 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 Health Care 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

Organisation	Norms and Standards Development
Malaysian Society for Quality in Health (MSOH)	• 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 2 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 3-4 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 Health Care (ISQUA). • Four sets of COHSASA standards, Primary Health Care 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 health care, finance etc. • Within each section, standards are also developed.
Medi-clinic	• Set by quality audit teams in consultative process with health care 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

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

ANNEXURE E - Lessons for the OHSC from the Quality Surveillance and Analysis Study

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 England. ▪ 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 programs (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.
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

Institution	Key Messages for OHSC	Key Messages for QSAD
South African Organisations		
CMS	▪ 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	▪ Link information requirements to registration and accreditation decisions. ▪ Integrated IT and database systems critical for effective functioning. ▪ Systems take a number of years to mature.
COHSASA	▪ 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.	▪ 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. ▪ Recruit highly skilled individuals
HQA	▪ Learn from the experience of similar organisations ▪ Utilise 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 provider's confidentiality is not maintained they are unlikely to report areas of weakness.	▪ 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 has a serious knock on effect. ▪ Outsource data analysis until capacity is built within the organisation ▪ Migrate from Access database to a web-based platform so that hospital or clinic loads data and it is immediately accessible to QSAD
Netcare & Medi-clinic	▪ 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	▪ User-friendly online data submission system ensures high reporting compliance ▪ Range of indicators, not only clinical indicators, included in senior management alert system
HASA	▪ 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	▪ EWS good idea but only choose very few red flag issues that have to be reported immediately
SARS	▪ Strong leadership & values ▪ Clear scope and purpose ▪ Enabling systems to ensure compliance ▪ Success rests on impeccable planning and swift execution that takes into account current realities.	▪ Standardisation of data. ▪ Strong and skilled team

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