International Health Care Accreditation
Models and Country Experiences:
Introductory Report on Options for
The Republic of South Africa

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<th>Description</th>
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<tr>
<td>COHSASA</td>
<td>Council on Health Services Accreditation of South Africa</td>
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<td>CQI</td>
<td>Continuous Quality Improvement</td>
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<td>DNV</td>
<td>Det Norske Veritas (Norway)</td>
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<td>DOH</td>
<td>Department of Health</td>
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<td>EC/EU</td>
<td>European Commission/European Union</td>
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<td>HCI</td>
<td>USAID Health Care Improvement Project</td>
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<td>IAP</td>
<td>International Accreditation Programme (ISQua)</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>ISQua</td>
<td>International Society for Quality in Health Care</td>
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<td>NGO</td>
<td>Non-governmental Organisation</td>
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<td>NHI</td>
<td>National Health Insurance</td>
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<td>NHIF</td>
<td>National Health Insurance Fund</td>
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<td>NIAHO</td>
<td>National Integrated Accreditation for Healthcare Organisations</td>
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<td>OECD</td>
<td>Organisation for Economic Co-Operation and Development</td>
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<td>OSC</td>
<td>Office of Standards Compliance</td>
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<td>QI</td>
<td>Quality Improvement</td>
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<td>QM</td>
<td>Quality Management</td>
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<td>RSA</td>
<td>Republic of South Africa</td>
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<td>SAAA</td>
<td>South Africa Accreditation Authority</td>
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<td>USA</td>
<td>United States of America</td>
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<td>USAID</td>
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<td>URC</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WHO</td>
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Executive Summary

The purpose of this paper is to review and analyze international experiences on health care accreditation, especially in middle-income countries, as they relate to the present South Africa accreditation environment. The paper is the first phase of a two-phase project to provide advice and recommendations on how to proceed with the proposed accreditation programme. This paper reviews what is “known” and what is not known about health care accreditation programmes internationally. While a few European regional studies have been completed, only one international survey (2001) of health care accreditation programmes has been done, although a new survey has recently just been commissioned but will not be available until 2011. Relatively little is known or published about health care accreditation in middle income countries, as relatively few programmes have been established or are successful. This paper documents what information is presently available on these country programmes.

There has been considerable growth internationally of health care accreditation programmes over the last two decades, with the number of programmes doubling every five years. Much of this growth has come in the European region as former Communist and Socialist countries have moved toward establishing market mechanisms in the health care sector. Most of the former central and eastern European countries have established Health Insurance Funds, which usually require that health facilities must be “accredited” in order to be paid for services. This is the case in the Republic of South Africa (RSA), as a National Health Insurance (NHI) programme is in the developmental stages. The health insurance requirement plus the general globalization of health services and the movement of more countries into middle income economies, are the main reasons for this growth in health care accreditation programmes.

South Africa has made major economic improvements over the last decade and is now classified as an upper-middle income economy. Significant improvements have been made in the health care environment, but in general the facilities, services, and quality are considered inadequate by much of the population. While accreditation programmes are not new to South Africa, the process of taking on a country-wide accreditation programme for both hospitals and primary care facilities will require major resource investments, large amounts of education and training of health system personnel, inspired leadership, and improved management at all levels.

Internationally, a number of accreditation programmes are struggling or have failed. International experience has shown that most new programmes take two years before doing their first facility survey and that it takes five years to fully establish an accreditation programme and ensure its financial and organisational sustainability.

This paper will outline the lessons learned from other countries as well as the success factors and areas of possible failure that other countries have experienced on the road to better quality management. This paper recommends a thorough review and analysis of policy, organisational, methodology, and costing plans and strategies. It is most important to take a graduated and “step by step” approach to implementation. Experience has shown it is important to begin on a small scale and build the programme over many years as both management and personnel begin to understand how to apply the benefits effectively. While accreditation programmes have been successful in the higher income countries, much of this is due to 30 years of learning and experience, and applying quality management principles in health care over the long term. As international experience has shown, trying to do too much too quickly is usually not successful.
I. Introduction

The purpose of this paper is to review the international experiences on health care accreditation, especially in middle-income countries, and to make recommendations on possible models for South Africa. In order to accomplish this task the paper will review what is known and what other countries have done in health care accreditation. The paper will also outline the specific experiences, various organisational and political processes, and the success and failures of accreditation programmes internationally. After a review of what is available from a thorough literature search, the paper will present specific key issues which need to be reviewed and discussed prior to any serious decision taken with regard to designing and implementing changes to the existing accreditation programme. The specific tasks to be undertaken in this paper are as follows:

1. To review the experience internationally (and especially in middle-income countries) with respect to the functions, structure, and roles in national quality programmes, covering the core areas of standard setting, accreditation and licensing, and quality improvement;

2. In the light of international experience, to make recommendations on suitable operational model(s) for quality assurance and quality improvement for South Africa based on the plans and review process already underway and to include capacity issues, resource requirements and risks; and

3. In the light of international experience, to make recommendations on a suitable process for international accreditation / endorsement of the South African national core standards based on the plans and review process already underway, as well as for the standard-setting function and role in the future.

This paper will present various models and options for South Africa, along with the advantages and disadvantages of each option which should be reviewed and discussed prior to any final decision on developing and implementing a national accreditation programme.

II. Background

In South Africa, an “Office of Standards Compliance” (OSC) already exists in rudimentary form within the National Department of Health and is empowered by the existing National Health Act to conduct inspections of all public and private health establishments and agencies every three years and recommend closure in cases of serious non-compliance. The Office has produced a set of national “core standards” as the basis for accreditation of health facilities; these standards have undergone one round of testing and subsequent review, which is currently being finalized and will be approved by the National Health Council (the highest decision-making body) for use as the basic statement of expected performance. The measurement tools will be tested in parallel with this process in public hospitals and primary health care facilities during the first three months of 2011. The OSC has discussed that it may also seek some form of international endorsement of the “core standards”.

With respect to measurement and benchmarking along with accreditation and licensing, it has been discussed that in the interests of objectivity and legitimacy, the accreditation function will be shifted from its current location in the National and Provincial Departments of Health to an “independent quality management and accreditation body” to report directly to the Minister of Health and to the Parliament, with the necessary amendments to the Health Act. The political leadership would like this independent function to start in April 2010. The core standards will form the basis for regular inspections in the public and private sectors and the issuing of accreditation certificates and for funding flows through the National Health Insurance Fund, to be set up in the coming years.

The internal management functions of improving quality currently included in the National Health Act will remain within the Department of Health (at all levels) and will also need to be revised. A number of different operating models have been provisionally identified. The Department will secure support from the National Treasury to assist in a review of the current situation (including interviews with Provincial Departments of Health and key national departments or bodies involved
in standard setting or quality assurance). The Treasury will guide strategic-level decision-making and assist in the development of a business case for the selected option. What is presently missing is an international perspective on quality assurance and accreditation, especially from the point of view of functions and structural/institutional arrangements, in order to inform thinking and planning functions. Expertise is therefore sought to provide this perspective to the accreditation process.

The implementation of NHI will bring new funds and new programmes and services to both the public and private sectors in health care. Patients are demanding improved services and higher levels of quality, and an effective accreditation programme is one method of reaching this goal. The challenges, threats, and opportunities of designing, developing, and implementing a new national accreditation process for RSA under the umbrella of a new NHI programme, will require inspired leadership, enlightened management, and a large commitment of resources at all levels. This paper and the follow up visit to South Africa has provided the basis for improved decision making with regard to establishing and managing a national accreditation programme in RSA.

III. Key Definitions

In the field of “Quality Management” (QM) in health care there are a number of key definitions and concepts which need to be clearly understood before design and implementation of any health care accreditation programme. There is often confusion and misunderstanding among various stakeholders on these key definitions. Outlined below are the major health care definitions and concepts as they apply internationally and as they will apply to the South African environment:

**Licensure** is a process by which the government authority grants permission to an individual practitioner or health care organisation to operate or to engage in an occupation or profession. Licensure regulations are generally established to ensure that an organisation or individual meets minimum standards to protect public health and safety. Maintenance of licensure is an ongoing requirement for the health care organisation to continue to operate and care for patients. Licensure is always mandatory and most commonly carried out by the state or a recognised professional organisation. Licensure is mostly concerned with patient safety issues and usually has a minimal number of standards, often structural standards with respect to health facilities.

**Accreditation** is a formal process by which a recognised body assesses and recognises that a health care organisation meets applicable pre-determined and published standards. Accreditation standards are regarded as optimal and achievable, and always involve a large number of standards. Accreditation is usually a voluntary process in which organisations choose to participate rather than one required by law and regulation. However, this “voluntary” nature of accreditation has been changing over the last decade, and a number of countries now have mandatory accreditation (see later discussion).

A more generalized definition of accreditation is as follows: “Accreditation is a process in which certification of competency, authority, or credibility is presented. Organisations that issue credentials or certify third parties against official standards are themselves formally accredited by other accreditation bodies. The accreditation process ensures that their certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically, and employ suitable quality assurance.”

**Certification** is a process by which an authorized body, either a governmental or non-governmental organisation, evaluates and recognises either an individual or an organisation as meeting pre-determined requirements or criteria. Certification usually involves a larger number of standards than licensure, but a fewer number of standards than accreditation.

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1 Taken from NDOH and OSC documents.
2 Taken from a variety of QM documents and modified to fit the objectives of this paper.
3 Accreditation definition taken from Wikipedia.
IV. Types of Health Care Accreditation

The various types of health care accreditation have evolved over the last few decades. In the health care field, hospitals have traditionally been the major focus of accreditation programmes, but in the last decade primary care facilities have increasingly been included in accreditation (see later discussion). Internationally, the literature review and experience has revealed four commonly utilised models for health care accreditation:

**Traditional Accreditation Model:** Under the traditional model, a variety of standards (structural, process, outcome) are developed for the health care facilities, both at the departmental level as well as with a number of quality assurance processes. The focus under this model is on inputs and processes. This model could be easily adapted in South Africa as most standards for service delivery have already been developed. However, many facilities may not be able to meet the inputs/process standards and significant investment in education, training, and development of personnel and facilities would need to be implemented to ensure that these standards can be met.

**Focused Accreditation Model:** Under this model, the focus of accreditation is initially limited to a few key high risk/high priority areas such as surgical theatres, accident and emergency units, laboratories, child health services, and related departments and services, including blood banks, radiology, pharmacies, etc. The World Health Organisation (WHO) programme on “Baby Friendly” Hospitals is an example of a focused accreditation model, as well as the “Adolescent-Friendly” Clinic Initiative in South Africa.

**Outcome-based accreditation:** Under this model, health outcomes are used as a measure to assess the quality of care provided by a facility. However, outcomes are not only determined by the quality of care but by also type of patients admitted (stage of disease) to the facility. The facilities use continuous quality improvement (CQI) tools and approaches to improve the health outcomes through changes in the processes of delivering care.

**Other approaches:** There are a few other approaches for accreditation of health care facilities available internationally (e.g., ISO 9001:2000). The International Organisation for Standardisation (ISO) is by far the largest and best known of these organisations. In the health care field, most of these are in the non-health care areas of business and various specific industries. The ISO is the largest and best known of these organisations. In the health care field, the two major organisations are as follows:

**The International Society for Quality in Health Care, Inc. (ISQua)**

In health care there are many country accreditation programmes as well as a few regional organisations (see later discussion), but the one most recognised “internationally” in the health care field is the International Society for Quality in Health Care (ISQua), now based in Dublin, Ireland. A description of ISQua follows:

**History:** ISQua began in 1985 with a group of health professionals meeting in Italy to discuss the issues of quality assurance in medicine. The group later became international in 1986; the Secretariat was moved to Australia in 1995 and was relocated to Dublin, Ireland in 2008. ISQua is a

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4 This discussion is taken from URC documents and other Quality Management publications.

5 Taken from the ISQua website, http://www.isqua.org.
non-profit, independent organisation, managed by an Executive Board. ISQua offers both affiliated and institutional memberships.

Programmes: ISQua’s International Accreditation Programme (IAP) was launched in 1999 and is the only international programme that “Accredits the Accreditors”. ISQua accredits 1) organisations, 2) sets of standards, and 3) surveyor training programmes under the IAP framework. ISQua is the “gold standard” of international health care accreditation programmes, offers international recognition of country programmes, and is universally recognised as the leader in the field of health care accreditation. The programme approval process can take a number of years to accomplish successfully. The approval process is in reality three separate programmes: 1) review and approval of the agency’s standards; 2) review and approval of the agency’s surveyor training programme; and 3) review and approval of the organisation. The first two are done by submission of documents only, and the third requires a site visit and survey by the ISQua staff surveyors. As of December 2009, ISQua has accredited 19 sets of standards, 5 surveyor training programmes, and 16 organisations. The list of organisations includes accreditation programmes in Australia, New Zealand, UK, Ireland, USA (JCI), Colombia, Netherlands, Taiwan, Jordan, and South Africa (COHSASA). ISQua accredits a variety of programmes, including governmental, quasi-governmental, and NGO programmes, for a wide variety of services, including blood banks, facilities for the aged, hospitals, primary care, and others. ISQua has accredited governmental programmes in France, Ireland, and Denmark.

Key Documents: The ISQua principles and requirements are included in two key documents. International Accreditation Standards for Health Care External Evaluation Organisations, Third Edition: This document outlines the various organisational issues which need to be addressed and include: 1) Leadership: Governance, Strategic, Operations and Financial Management, Risk Management & Performance Improvement; 2) Support Services: Human Resources Management, Information Management; 3) Service Delivery: Assessor Management, Assessment Management, Accreditation Awards. International Principles for Health Care Standards, Third Edition: This document includes the major Principles and Guidelines for standards development, regardless of the type of organisation.

International Organisation for Standardisation (ISO)\(^6\)

The ISO is a network of the national standards institutes of 163 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organisation (NGO) that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries or are mandated by their governments. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnership of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirement of business and the broader needs of society.

ISO is the world’s largest developer and publisher of international standards. Between 1947 and the present day, ISO has published more that 17,500 International Standards, ranging from standards for activities such as agriculture and construction, to mechanical engineering, to medical devices, the newest information technology developments. The ISO has three categories of member bodies: full member, correspondent member, and subscriber member. ISO has a large number of publications and extensive training and education programmes. ISO is a certification programme and not a formal accreditation programme.

The utilisation of ISO 9001:2000 has been much debated in the health care field and is presently in competition with the Joint Commission in the USA. One major weakness of the ISO model is that the standards and the results are not in the public domain, and as a result, no one knows how many hospitals or hospital departments are using it or how many hospitals have been certified.

\(^6\) Taken from the ISO website, http://www.iso.org.
VI. Surveys and Studies of Health Care Accreditation Programmes

Over the last decade, a number of surveys and studies have been completed to assess the development of health care accreditation programmes both regionally and internationally. These studies have been commissioned by WHO, the World Bank, ISQua, and others. As most of the programme growth has been in Europe, this has been the focus of major surveys. Little information on the “emerging” programmes in Africa and Asia is available, and what information that is available has been included in a later section of this report. At present there is no central source for the collection and dissemination of the data and information of health care accreditation programmes in various countries. However, there is a “contact list” for programmes in various countries internationally which is listed in the bibliography of this paper, and this is the source of information on most of these country accreditation programmes. The major author of all of these studies (and the contact list) is Dr. Charles D. Shaw, an independent health care accreditation consultant living in the United Kingdom. At the present time, a new study of health care accreditation programmes internationally has just been commissioned, but the results will not be available for at least another year. The issues highlighted in these studies have direct relevance to the South African environment and are presented below to identify key issues for discussion. A later section of this report will outline which of these issues are most important for South Africa. The major surveys or studies, presented chronologically are as follows:

A. National Accreditation Programmes in Europe (February 2001)

This was the first survey which covered 25 countries in the European Region of WHO using 1999 collected data. The survey covers a number of areas including the status of accreditation programmes, enabling legislation, relationships to government, government sponsorship, public access to standards, number of completed surveys, number of trained surveyors, expenditures, fees for a survey for 100 bed hospital, and main sources of income for the accreditation programmes. The general conclusions of the survey are as follows:

“Programme Growth: 1) The number of programmes around the world has doubled each five years since 1990. This growth is most marked in Europe; 2) Public Agenda: One programme in three is enabled by national legislation, particularly since the late 1990s; voluntary accreditation is becoming statutory. Most newer programmes are government “sponsored”; accreditation is moving from a collegial tool of self-development to a “regulatory tool” of public accountability.”

The link to the licensing function is unclear in this paper, but from the consultant’s experience the two QM programmes (licensing and accreditation) are always “separate” programmes, and accreditation is seen as a higher order QM activity, and not an extension of licensing. The two functions (licensing and accreditation) have different objectives, rewards/punishments, organisations, staff, and reporting structures. The consultant is unaware of any country that had successfully combined the licensing and the accreditation functions under one organisation, and a least one large failure in this model has been documented. However, there is a movement, as least in Europe, towards “certification” of safety on a mandatory basis. This has been introduced in France and is being worked on in Ireland and being considered in Serbia. Currently in RSA, there are requirements for registration and licensing of private providers according to structural norms, but there is no mechanism for licensing the operation of health care institutions in the public sector. Certification could provide RSA with a mechanism for stewardship which would have a much greater and more rapid impact on the health care system than the voluntary uptake of accreditation against standards of excellence.

7 Taken from the Survey Results and modified slightly.

8 Consultant has taken this from discussions with Dr. Charles Shaw in February 2010, the foremost international authority on accreditation programmes; the documented failure of combining a licensing and an accreditation programme under one organisation occurred in Central Asia under a USAID and World Bank funded project during the period 1997-2000.

“3) Transparency: The move towards statutory and governmental endorsement is associated with freer access by the public to the standards, processes and findings of accreditation; half of the responding programmes make their standards available at little or no cost; some make full reports available also. Governments argue that standards should be available in the public domain for the sake of transparency and public accountability; but many accreditation programmes cannot afford to give away a source of income and intellectual property which has taken years to develop; 4) Distribution of workload: Many programmes have yet to reach a critical mass of work and income (and nor has this survey identified where that threshold is), but this is likely to change rapidly as programmes of “new accreditation” multiply and flourish with the political, if not financial support of governments. 5) Costs and benefits: Many users and most providers of accreditation services proclaim its many benefits, even though there is a dearth of robust research evidence for them. Despite lack of detail to define comparable prices for a single common product, it does suggest that more information would be valuable about the costs of accreditation to governments, communities and providers. Data on both costs and benefits may be increasingly critical to governments and paying agencies when making decisions over whether to invest in quality improvement and, if so, whether to adopt accreditation (rather than ISO certification or industry awards, for example) and, if so, whether to buy services from the local or international market; 6) Summary: In short, this review shows that demands for accreditation are increasing and changing rapidly within Europe. Traditional accreditation must adapt to survive and to thrive as a vehicle to link internal self-development with external regulation.”

B. Health Service Accreditation Programmes - International (June 2001)

This was the first “international” study and was commissioned by WHO for ISQua to review the development of quality improvement in health care worldwide. This report focuses on the use of accreditation at a national level as a tool for organisational development and for external assessment of health services. The survey was undertaken in late 2000 of “known” national accreditation programmes (excluding those which were specialty-based, or sub-national, or which relate to certification under ISO). A one-page questionnaire, previously piloted in Europe, was designed to obtain objective descriptions of each programme, using existing data. The survey was distributed by e-mail or fax to 36 known programmes in 33 countries, and to academic or governmental contacts in 32 other countries. Twenty-eight programmes completed and returned the survey. Six of the remaining eight known programmes are based in the USA. Additional data were gathered opportunistically from multiple sources including the literature and Internet searches which were undertaken. These provided basic but unsystematic descriptions of the state of accreditation in 46 countries.

The findings\textsuperscript{10} of this study are as follows: 1) Programme growth: two thirds of all respondents were from Europe. The number of programmes around the world has doubled each five years since 1990. 2) One programme in three is enabled by national legislation, particularly since the late 1990s; voluntary accreditation is becoming statutory and most new programmes are government-sponsored. 3) Gestation: most new programmes take \textit{two years to prepare for their first survey} and certainly longer before they are self-sufficient. 4) Shifting focus: programmes now focus their standards and assessments increasingly on integrated pathways; they follow patients and disease processes (horizontally) rather than management units (vertically). This item is not related to the outcomes-based model, but is concerned with following the patient (e.g., the patient’s medical record) across various departments and not just only one department as was common in earlier programmes. 5) Transparency: The move towards statutory and governmental endorsement is associated with freer access by the public to the standards, processes and findings of accreditation. 6) Distribution of workload: eighty percent of the world’s reported surveys are done by twenty percent of the programmes. Many programmes have yet to reach a critical mass of work and income. 7) Costs and benefits: more evidence would be valuable about the costs and benefits of accreditation to governments, communities, and providers. Such data may be increasingly critical to governments and paying agencies when making investment decisions. 8) Summary: This review shows that demands for accreditation are increasing and changing rapidly around the world.

\textsuperscript{10}Taken from the study results and modified slightly.
Traditional accreditation must adapt to an increasingly public agenda if it is to survive and to thrive as a vehicle for internal self-development.

C. Health Care Accreditation Programmes in Europe (2009)

This is the most recent regional survey of accreditation programmes in Europe and has yet to be completed and published. The 2009 survey was the first to be web-based; and will be adapted for “global” use later in 2010 by refining the questionnaire and analysis in the light of experience in Europe. States within or bordering the European Union were included, but the wider WHO definition of Europe would have included also programmes which exist in Kyrgyzstan and Kazakhstan. Programmes were included if they were available nation-wide or internationally; this excluded the regional programmes, such as in Spain and Italy. This study has not yet been published but a few general conclusions are listed below:

“Health care accreditation has grown rapidly since the 1980s but critics question the value of investing in accreditation rather than certification or inspection. Research has focused more on evidence of impact on provider institutions than on health systems; little has been published on the determinants of growth or decline of accreditation programmes. The objective was to describe the development of current national accreditation programmes in Europe in relation to incentives, funding and market position; to identify trends over time using data from previous surveys. Known contacts in 24 countries were invited to complete a web-based survey comprising 183 questions seeking numerical data or posing multiple choice options. The results of the survey identified 20 national accreditation programmes in Europe. Older programmes tend to be independent, profession-dominated and self-financing; they have shown little growth in activity and coverage of the potential market. Newer programmes have broad stakeholder governance, support from government policy and growth sustained by legal or financial incentives – giving wide coverage across the health care system. The traditional collegial model of accreditation is moving towards a semi-regulatory model of external assessment which could integrate minimal standards of licensing, public safety and accountability with aspirational standards for organisational development and improvement. It was concluded that the principal challenges to accreditation programmes appear to be market size, consistency of policy support, sustainable programme funding and financial incentives for participation. The results offer food for thought and agenda items for discussion by the international community.” The semi-regulatory model of external assessment may be the preferred model that South Africa is striving to develop in the present environment.

D. Health Care Accreditation Programmes in Low and Middle Income Countries

Traditionally, health care accreditation has been carried out mainly in high-income and OECD member countries, but with the enlargement of the European Union (EU) to 27 countries, and the movement of more countries into the middle and upper-middle economies classifications, the expansion of health care accreditation has been significant, as discussed above in the European context as well as internationally. Little information is available internationally about these newer accreditation programmes in low and middle income countries. Hopefully, the new survey just commissioned by ISQua in 2010, will provide more details on these programmes, but this is just being developed and it will be 2011 before this is available.

The World Bank (WB) classifies South Africa as an “upper-middle-income economy”. The WB list of some 210 countries globally, includes some 46 countries as upper middle income economies. These 46 countries include 10 countries (Argentina, Brazil, Chile, Colombia, Kazakhstan, Lebanon, Malaysia, Mexico, Serbia, Turkey, and South Africa) which have begun planning, just started, or have established accreditation programmes in health care in various stages of development. Unfortunately, little is known about these programmes and what is known is only anecdotal, as little

11 Taken from the unpublished study and summarized in discussions with Dr. Charles Shaw, January, 2010.
12 Taken from The World Bank Website/External/Data/Statistics, January, 2010.
13 Taken from recent list of contacts for international health care accreditation programmes (C. Shaw 2009) and may not be accurate with respect to the status of the various country programmes.
is published. What information that is available is hidden in various reports of international donors and not readily accessible.

Some of the upper middle income economy programmes are still in the beginning design and development stages (Kazakhstan), some are new and just starting (Serbia and Turkey), and others (Lebanon) are simply extensions of licensing programmes and focus mainly on non-clinical areas. South Africa has had both public and private accreditation programmes\(^\text{14}\) for a number of years. Accreditation has also moved into some low-income economies (Zambia\(^\text{15}\) and Tanzania) and also into some lower-middle income economies (Albania and the Philippines). Jordan is the one best example of a middle income economy with a new health care accreditation programme (see discussion below).

Some of the other low and middle income economy programmes have had very limited success (Zambia\(^\text{16}\)) and little is known or published about some of the others (Tanzania and Malaysia). Most of these new programmes have been supported in the start up and development phases by international donors (USAID, EC/EU, WB, etc.). The most recent new health care accreditation programme in a middle income country is Jordan, but USAID has provided funding of approximately $7 million over five years to assist this programme reach organisational and financial sustainability\(^\text{17}\). This amount of funding does not include the WB loans and donor funds that were utilised over many years to upgrade the physical facilities of the hospitals and clinics in Jordan. This $7 million is the approximate resource commitment that is required to design, develop, and implement a health care accreditation programme at the country level for both hospitals and primary care facilities if sustainability is the desired goal. Investments in upgrading facilities in South Africa would be significantly larger.

“As we know from international experience, health care accreditation programmes are expensive to design, to develop, and to operate and this can only be done efficiently in a growing and vibrant health care economy, with both public and private health care services. The good and bad experiences of these other middle income countries can be critical to the success of the programme in South Africa. As South Africa moves forward with its accreditation programmes, consideration should be given to visiting some of these other countries (especially regional programmes) to find out the critical success and failure issues and lessons learned from other country programme experience.”

“In reality, the improvement of the health system will be limited not by the capacity of the Agency to identify institutional compliance with standards, but by the capacity of institutions - and municipalities and the National and Provincial DOH - to respond by adapting or developing more effective systems for planning, organisation, direction and control. All of these elements should be visible in the national strategy for quality improvement, together with a realistic timescale for achievement of health care reform. Experience from many countries confirms that all accreditation programmes face threats to their sustainability, including:

- Unrealistic business planning and timescales
- Delay, or failure of financial incentives for institutions to participate
- Premature or untapered end of core funding by international donors
- Resistance from academic institutions to participation


\(^\text{16}\) Some data on the cost of the Zambia project is available, but it does not appear to be a comprehensive analysis.

\(^\text{17}\) There is no available breakdown of the expenses under this programme.
• **Change of government, minister or policy**

In short, political and financial support needs to be consistent beyond the term in office of most health ministers and many governments.\(^{18}\)

**VII. Key Developmental Tools for Accreditation Programmes**

Over the last decade there has been a large increase in the number of countries setting up health care accreditation programmes, with the number doubling every five years, as highlighted in the surveys reviewed above. With impetus from the World Bank, significant efforts have gone into documenting and publishing the key variables in setting up and operating an effective country-wide programme. Outlined below are the two major studies, now called guides or “Toolkits” that have been developed, primarily with the assistance of Dr. Charles Shaw, ISQua, and others in the international health care Quality Management (QM) field:

**A. Developing Hospital Accreditation in Europe (July 2003)**

This development guide was commissioned by WHO Barcelona, and was the first attempt to begin to clearly document some of the key variables in establishing a successful accreditation programme. The document was written by Dr. Charles Shaw and was completed in 2004.

“The chapters of this guide to accreditation outline some of the activities and steps which lead to a sustainable programme. These steps are an amalgam of the discussions, activities and results of many countries; no one country has followed them all. The following stages therefore act only as a guide: 1) Analysing the national context - take stock of values and mechanisms relating to quality and safety in health care; develop government policy framework for regulation and reform of the health care system; 2) Defining the guiding principles - choose a national strategy for accreditation; establish a working group to define and recommend options for adopting or adapting a model of accreditation; design and enable a national accreditation agency; 3) Establishing a national agency – authorise agency and terms of reference working group enables establishment and hands over to new agency; 4) Developing and launching accreditation systems - develop standards and assessment process, surveyor selection and training, pilot testing and education, revision of standards and methods; first “live” surveys, first accreditation decisions; performance measures; sustainability.”\(^{19}\) This guide was later expanded into a major Toolkit as highlighted in the next section.

**B. Toolkit for Accreditation Programmes: Some issues in the design and redesign of external assessment and improvement systems, Charles D. Shaw, ISQua, for the World Bank, 2004**

This toolkit was commissioned by the World Bank to outline the various key factors in developing health care accreditation programmes and is a major effort in the design, development and operation of the programmes. As quoted below the key issues to consider in design of an accreditation programme are as follows:

“In many countries, accreditation has developed as an effective strategy for continuous improvement of health care institutions and systems, with benefits to consumers, regulators, managers, professions and other stakeholders. But, when the technology of accreditation is transferred to other countries and settings, the same benefits do not automatically follow. The commonest issues which may become barriers to this transfer may be summarised as:

1. **Clarity of purpose**: failure to identify a balance between the objectives of internal organisational development (improvement) and external control (regulation) within an overall policy for quality in the health care system.

2. **Appropriate technology**: failure to differentiate the methods of accreditation, licensing and regulation, and to match them to the defined objectives.

\(^{18}\) This section is compliments of Dr. Charles Shaw and recent experiences and research findings.

\(^{19}\) Taken from the guide and modified slightly.
3. **Quality culture:** failure to identify stakeholders and involve them in the design and direction of the accreditation programme; unwillingness to share information, authority and responsibility.

4. **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.

5. **Independence:** government domination of programme 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.

6. **Scope of responsibility:** unrealistic expectations that the accreditation programme 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).

7. **Clear relationships:** lack of mechanisms to cooperate and communicate with related professional, academic, independent and governmental bodies, e.g., professional chambers, teaching institutions, health insurers, ISO certification bodies and local government inspectocrates.

8. **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.

9. **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 programme to generate income from them; lack of long-term government commitment.

10. **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 ALPHA programme of the International Society for Quality in Health Care.

The ISQua Toolkit aims to illustrate the key factors to be considered before starting an accreditation programme, and some options to be adopted or avoided. It could be used to scan the health care environment to identify what is already available, to define options for discussion with ministers and other agencies, and to outline practical implications for organisation, management, and funding. It is not intended to be a definitive manual, but a reasonably balanced collection of facts and opinions from informed people around the world.”

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20 Taken from the ISQua Accreditation Toolkit document, which is available at: [http://www.hciproject.org/node/1175](http://www.hciproject.org/node/1175).

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**VIII. Discussion of Accreditation Models and Key Issues**

As outlined in the above section on “Definitions” there are a number of international models/options for quality assurance and quality improvement in the health care field which South Africa should consider. Beginning with “licensure” programmes (most developed and developing countries have a registration or licensure programme for both health professionals and health...
facilities) many upper-middle income and high income countries have moved from just licensure into more extensive programmes of quality management, including certification and accreditation.

As outlined above there has been large growth in traditional accreditation programme over the last decade, with the number of programmes doubling every five years. Ten (10) of the forty-six (46) countries on the WB list of upper-middle income countries have either established or are establishing accreditation programmes. One issue not highlighted above is that a major reason for the establishment of many new accreditation programmes is that many countries have established National Health Insurance Funds (NHIF), and traditionally NHIFs have required that health facilities can only be “reimbursed” for services if the facility is “accredited”. There is no available list of which countries have established NHIF’s, but in the consultant’s experience, it is the larger majority of countries that have established the traditional model of accreditation, as this has become the “driver” for accreditation programmes in many countries. NHIFs normally have had a general rule that each facility should have in place a Continuous Quality Improvement (CQI) programme (usually meaning accreditation) to ensure improving levels of quality for patients, before paying for patient services. This requirement is one reason for the growth in numbers of accreditation programmes, especially as countries have moved away from former Communist/Socialist economic models to more western and market-oriented health insurance and health delivery systems with both public and private health services.

A. Traditional versus Focused Accreditation Organisations and Programmes

There are major differences between the traditional and the focused accreditation model, as previously outlined. The focused accreditation model is limited to a few major programmes (e.g., Baby-Friendly and Adolescent-Friendly Hospitals) and not the whole institution, are often conducted by international organisations like the WHO. Under this model, the focus of accreditation is initially limited to a few key high risk/high priority areas such as surgical theatres, accident and emergency units, laboratories, child health services, and related departments and services, including blood banks, radiology, pharmacies, et al.

The traditional model has some 50-60 years of developmental experience, beginning with hospitals in North America in the late 1950-60s and then moving rapidly around the world as major OECD countries improved their health systems, and later middle income countries followed this traditional model. Most accreditation programmes are independent, non-profit, professional organisations doing nothing but accreditation, mainly for hospitals (more recently in primary care), are instituted by medical professionals, have voluntary participation by facilities, are transparent with respect to publishing results and standards, and are funded mainly through fees charged to member facilities. However, as previously outlined, this model is changing with more government involvement and funding and more countries making accreditation mandatory. One major concern with traditional accreditation systems are that they are expensive to set up and to operate. The recent study (2009) reviewed above for European countries outlines that the accreditation survey fee for a 100 bed hospital is Europe ranges of a low of 1000 Euro (Bulgaria) to a high of 12,000 Euro (Switzerland) depending on the type of funding and various government subsidies, and the fee in some countries can be as much as US$ 50,000 for a one-time accreditation survey fee for the traditional three day visit by a three-person survey team. The cost of the survey visit is usually the single largest expense in an accreditation programme, and the real cost of the survey needs to be accurately determined and built into the cost structure of the new accreditation organisation.

B. The ISO Model and ISO Hybrid Model

As highlighted in the definitions section above, the International Organisation for Standardisation is by far the largest standards/certification type organisation, with the ISO Model 9001:2000.

21 From the consultant experience most of the countries establishing some type of National Health Insurance (NHI) Programme has drafted legislation that requires that facilities be “accredited” in order to receive funds from the NHI organization.

22 Licensing of facilities is assumed to be present before an accreditation process is developed.
However, the ISO model has been utilised mostly in business and industry and has had less application in health care. The ISO model has developed many standards in the non-clinical departments (housekeeping, maintenance, etc.) but ISO has made fewer inroads into the clinical departments, with the exception of laboratory, where many standards have been developed. ISO is a "standards" and certification organisation, and is not a formal accreditation organisation. One criticism of ISO is that the results are not available to the public so it is not possible to know how many hospitals are using it.

Another model is a “hybrid” approach that utilizes some of the traditional model components, but utilizes primarily the ISO 9001:2000 standards as the major component for hospital accreditation. This is a new model in the accreditation field and has been making inroads internationally, and has 22 hospitals in the USA, and is accepted by many third party payers as an acceptable model. The organisation is a Norwegian Group, Det Norske Veritas (DNV), marketing accreditation programmes internationally, under the name: National Integrated Accreditation for Healthcare Organisations (NIAHO). This model is much less expensive that the traditional model (no estimates available) and the model is still in-process, testing, and implementation stages in many health care facilities.

C. Key Issues in Setting up an Accreditation Programme

The experience of the last decade shows that accreditation has been a valuable technology for quality improvement in many settings. But the effectiveness of an accreditation programme, as well as its affordability and whether it will be “sustainable”, depends ultimately on many variable factors, in particular the health care environment of the country or organisation involved. It also depends on the kind of programme concerned and how it is implemented. International experience has also shown that setting up accreditation as an extension of licensing or combined with a licensing programme has not been effective and has failed in a number of countries.

In the ISQua Accreditation Toolkit, these variables are addressed under four principal headings:

Policy:
- What is the purpose of the proposed programme?
- How might it complement or replace alternative mechanisms, such as licensing and certification?
- How would it match the culture of the population and professions concerned?
- What incentives would encourage participation?

Organisation:
- How would the people most likely to be affected (“stakeholders”) be identified and involved?
- How would the programme be governed?
- How would it ensure compatibility with associated regulatory and independent agencies?

Methods:
- How will standards be made valid?
- Who will develop standards?
- How will assessments be made reliable?
- How will assessors be trained and re-validated?
- How will procedures and results be made transparent and fair?

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23 Taken from the Introductory Section of the ISQua Toolkit 2004.
24 These four key issues are discussed in more depth in a Section IX of this paper.
Resources:

- What are the implications for data, information and training?
- What are the costs to participating institutions?
- How long does it take to set up a sustainable programme?
- What does it cost to set it up?

Outlined above are the key questions and issues that need to be clearly reviewed and discussed before South Africa moves into a decision making process with regard to selection of an accreditation programme. These issues are discussed more extensively in Section IX with regard to the RSA environment. Table 1 outlines some of the advantages and disadvantages of each of the various accreditation models.

**Table 1. Comparison of Various Models: Strengths/Advantages/Incentives and Weaknesses/Disadvantages/Consequences**

<table>
<thead>
<tr>
<th>Model</th>
<th>Strengths/Advantages/Incentives</th>
<th>Weaknesses/Disadvantages/Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional</td>
<td>Well developed over 50 years in 30+ countries with thousands of successful facilities being accredited Standards and results are usually in the public domain - more transparency International organisation (ISQua) which accredits country standards, surveyor training, and the organisational programme Standards exist for every department and function Application of principles will increase levels of continuous quality improvement over the long term</td>
<td>High expense to develop, implement, and operate Can be over-developed and become too complex and too costly to operate Needs a critical mass of the number of facilities to be optimally implemented Long development time with two years to do first surveys and five years to become organisationally and financially sustainable Government must be committed to long term development and implementation with focus on results over many years May need donor assisted funding to get it designed and developed</td>
</tr>
<tr>
<td>Focused</td>
<td>Focus on high priority areas Lower expense than traditional model to develop and to operate Good experiences in many countries over many years with good results Can be developed and implemented quickly as compared to traditional method</td>
<td>Limited number of applications available and does not cover the whole organisation nor the total continuous quality improvement process</td>
</tr>
<tr>
<td>ISO 9000: 2001</td>
<td>Well-developed international organisation (ISO) Well-developed standards in non-clinical areas: housekeeping, maintenance, dietary, laundry, etc. Large international organisation for support, backup and education Has proven successful in limited number of facilities as compared to traditional model</td>
<td>Certification Programme and not an Accreditation Programme Standards and results not in the public domain means less transparency and no knowledge of how many facilities are using the standards Only one clinical department (Laboratory) has ISO developed standards and not well developed in most of the clinical departments; Development costs are high at the beginning but less to maintain over the long term</td>
</tr>
<tr>
<td>Hybrid ISO</td>
<td>Lower cost than traditional model New accreditation model with new ideas and approaches</td>
<td>Still unproven and still being fully tested internationally Actual cost not known</td>
</tr>
</tbody>
</table>
IX. Review of Key Issues and Recommendations

An NHI programme is a high priority and is in the developmental stages in the RSA. Developing and implementing a nationwide accreditation programme under the Office of Standards Compliance (OSC) will take many years and require significant financial and human resources at both the organisational development level and also with the training of staff, and in upgrading of facilities. This section will outline the key issues, as identified internationally, and will propose some suggestions and recommendations for South Africa. This list is not meant to be comprehensive, but outlines some of the major concerns, and a comprehensive review can come in phase II of this report which includes a visit and a review of accreditation plans as well as a Business Case for development.

A. Policy Concerns

As highlighted in the ISQua Toolkit, with any new programme, there are many “policy” issues that need to be discussed and clearly documented. What is the purpose of the proposed programme? Is this clearly outlined in a mission and vision documents. Has a strategic planning process been conducted with major stakeholders to assess all of the policy issues? How might the new programme complement or replace alternative mechanisms, such as licensing and certification? How will the new accreditation match the culture of the population and professions and professional organisations concerned? What incentives will be need to encourage participation by facilities, management and professional organisation? It is unclear whether all of these questions have been answered or considered.

B. Organisational Concerns

As previously highlighted in various international studies and the ISQua Toolkit, there are various organisational questions which need to be reviewed and discussed including: How would the people most likely to be affected (“stakeholders”) be identified and involved? How would the programme be governed and will the organisation have a board of directors? How would it ensure compatibility with associated regulatory and independent agencies?

The organisational form of the accreditation agency is one of the critical determinants to its future success. International experience has shown that governmental accreditation programmes as an extension of a governmental “licensing” system are not effective. Most new accreditation programmes started during the last decade have set up semi-autonomous organisations that have managerial, technical, and professional autonomy, but still are dependent on the state budget for some or all of their funding. There are a great many variations and organisation forms depending on legal, legislative, and political structures. There is no one “best” model and each country has taken their own path, but most successful programmes have had autonomy as well as their own board of directors. However, it is most important that the organisation model adopted allow the accreditation agency to direct an “external assessment” process, to have both professional and technical objectivity and transparency as well as some autonomy and independence; otherwise, the agency is simply an extension of “licensing” and could be utilised as a “punishment” vehicle rather than a positive QI and CQI mechanism to improve quality management over the long term. Without this external evaluation process and the required autonomy, objectivity and transparency, the agency would be carrying out an extension of the licensing function and not an accreditation function. Accreditation internationally is seen as a higher order QM process and is meant to be positive and helpful, rather than punitive and punishing. This is one reason why the term “survey” is utilised in the accreditation process and not “inspection,” and the assessors are “surveyors” and not “inspectors”. It is unclear in the South Africa accreditation process will allow a level of autonomy, objectivity, and transparency, and if the agency will really be an “external” assessment process and not an extension of licensing. Finally, there is the issue of international recognition of the South Africa programme by reputable and recognised international accrediting organisations, like ISQua or ISO.
C. Methodology Concerns

There are also many methodological issues that should be reviewed and discussed prior to development and implementation. Who will develop standards? Will standards be available in the public domain and will the public as well as facilities be able to review, criticise, and suggest changes? How will standards be made valid and how will they be recognised or validated internationally? In many of the new country programmes, a variety of stakeholders develop standards. These could be the accreditation agency, professional bodies, expert panels, or the government itself using various specialists from various specialty areas. In the consultant’s experience, the newer traditional accreditation programmes developed over the last ten years, have tried to get international validation by applying to ISQua for review and recognition. Little is known about ISO validation, as results are not in the public domain. The development of standards is a major concern of all programmes, and in RSA the OSC has developed “core standards” with the input and assistance of various stakeholders. These core standards are a result of a consensus of all key stakeholders, and will be piloted, and are designed to meet local needs and conditions in all nine provinces.

Another major methodological issue is the selection, training, and development of surveyors. This is often done in conjunctions with the development of the standards. How will assessors be trained and re-validated? Will the surveyors be paid and full-time staff or part-time and volunteers or seconded personnel (as happens in many countries, whereby health professionals from various institutions are utilised to do the surveys and then return to their own institutions to do further education and training of staff)? Has surveyor selection and development been discussed and decisions taken?

The entire assessment process, including an institutional “self-assessment” process, is utilised in most accreditation programmes. How will assessments be made reliable? How will assessment and procedures and results be made transparent and fair? What will be the scoring system for standards compliance or non-compliance, and what will be the reporting and reward systems or non-reward and probation system? All of these are critical methodology design concerns and should be addressed.

D. Costing and Resource Concerns

The cost of the survey is usually the single largest expense in an accreditation programme, and the real cost of the survey needs to be accurately forecasted and built into the cost structure of the accreditation organisation. How long will the survey take and how many surveyors are needed for what amount of time? What are the costs to participating institutions? How long does it take to set up a sustainable programme? What does it cost to set up the new programme? Another important variable, and one that is not apparent, is that there are a host of resources issues that need to be addressed and estimates determined, including: What are the implications for data, information and training, both at the agency level and at the facility level? Most important, is the cost of upgrading some of the facilities in order to meet the new core standards, what are the estimates of these costs, as well as the ongoing cost of educating and training the staff at each facility on the new accreditation process? As NHI is a government priority, the cost of setting up an effective accreditation programme will need to be clearly outlined.

E. International Recognition and Validation

Finally, there is the issue of international recognition and validation of the South Africa programme by reputable and recognised international accrediting organisations, like ISQua or ISO. ISQua accredits both governmental and non-governmental programmes. The ISQua programme has three levels of review and validation. The first is usually the review of standards and the second is a review of the surveyor training programme. Both of these can be done by a document submission process. The third review is of the institution itself and requires a survey visit from ISQua with the various surveyors coming to review all of the governance, organisation, policy, methods and various management and operational programmes, policies and procedures. This whole process can take 5-7 years of effort to accomplish effectively.
International recognition is difficult to attain and to hold on to, as the organisation, standards, and surveyors must be highly effective and well documented.

F. Recommendations

The purpose of this paper was to review and analyze the international experiences on health care accreditation, especially in middle-income countries, as they relate to the present South Africa accreditation environment. The paper is the first phase of a two-phase project to provide advice and recommendations on how to proceed with the new accreditation programme. This paper reviews what is “known” and what is not known about health care accreditation programmes internationally. The following recommendations are only preliminary and the result of a desk review of documents from South Africa and a thorough literature search. A more thorough set of recommendations will follow after a visit to further assess the environment and what is needed. Preliminary recommendations are as follows:

1. A strategic planning process for accreditation should be initiated if it has not already been completed. This should include all key stakeholders and should develop the usual strategic planning process (Vision, Mission, Environmental Assessment, Critical Issues, Goals, Strategic Objectives and Action Plans) to allow a thorough involvement of all stakeholders as well as an understanding and communication of the programme goals, objectives, and strategies. The strategic plan should include a Business Plan (Business Case) to effectively outline all of the key strategic issues, costs, and benefits of the new programme. Once the decision is taken of the organisational form of the new accreditation body, a more detailed Business Plan would need to be developed for implementation purposes.

2. Serious consideration should be given to visiting some of these other countries (especially regional programmes) to find out the critical success and failure issues and lessons learned from other country programme experience. This should include Zambia and Tanzania programmes, as well as the Malaysia and Jordan programmes, and possibly France, Ireland, and Denmark (which have governmental accreditation programmes).

3. The ISQua Accreditation Toolkit for design of health care accreditation programmes, along with the key ISQua guidelines on standards and external organisations, should be reviewed in-depth by the programme designers to ensure the advantages of international experience is utilised in the design of the programme. The questions and concerns as highlighted in this report should be reviewed to ensure that the “Policy, Organisation, Methods, and Costing” areas are thoroughly reviewed and discussed for specific application to RSA. Additional consulting assistance may be needed to further develop plans in these areas.

4. South Africa should seriously consider becoming a member of one of the international organisations to ensure international recognition of the Republic of South Africa programme by reputable and recognised international accrediting organisations, like ISQua or the ISO.

5. Finally, this paper recommends a gradual “step by step” approach to the design, development, and implementation of any new programme. As international experience has shown, it is important to begin on a small scale and build the programme over many years as both management and personnel begin to understand and implement the QI processes.

In summary, the challenges, threats, and opportunities of the designing, developing, and implementing a new national accreditation process for RSA will require inspired leadership, enlightened management, and a large commitment of resources. The implementation of NHI will bring new funds and new programmes and services to both the public and private sectors in health care. Patients are demanding improved services and higher levels of quality, and an effective accreditation programme is one method of reaching this goal.
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23. Evolution of the National Adolescent-Friendly Clinic Initiative, WHO.

24. The functions of the Office of Standards Compliance (OSC) as set out in the National Health Act No. 61, 2003, and other documents on the OSC and the Directorate of Quality Assurance.