

Quality in Health Care



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1 Introduction

1.1 Aim and purpose of this report

This report presents a description of the Norwegian governmental model of supervision and monitoring to ensure quality in health care and a discussion on its possible usefulness for the health sector in Sub-Saharan Africa.

There has been a trend in development cooperation towards joint approaches to programming of resources. Instead of vertical programmes supported by different donors, emphasis is increasingly put on horizontal approaches comprising the totality of health systems. The essence of these sector wide approaches (SWAPs) is that, “under government leadership, a partnership of funding agencies agrees to work together in support of a clear set of policy directions, often sharing many of the implementation procedures, such as supervision, monitoring, reporting, accounting and purchasing”¹. Enabling governments’ own priority setting is a key feature of SWAPs that implies increasingly stringent demands for dialogue between ministries, donors, NGOs, private sector and the public.

Quality Assurance and supervision may be important tools towards improved health systems performance within the SWAP framework. The need for reliable regulatory mechanisms increases with decentralisation and privatisation, elements that are some of the most common in current health sector reforms in Sub-Saharan Africa.

Quality is the result of a variety of complex and interlinked processes. Some are initiated on “the floor” as a result of staff initiative and competence. Other are initiated by management or by requirements from customers or

government agencies. Government plays an important role in enabling and supporting bottom-up initiatives for improvement.

The focus of this report however is on the *role of government* in ensuring external quality mechanisms in health care.

1.2 The concept of Quality Assurance

In this report the concept quality assurance (QA) is chosen as a generic description to represent all common approaches going by a diversity of names such as: Total Quality Management, Continuous Quality Improvement, Quality Assurance etc. We do not attempt to describe these various approaches to quality. Their common factor is a systematic approach to quality improvement.

Quality is defined as the “*degree to which a set of inherent characteristics fulfils requirements*”². Quality in health care is about health facilities and providers, clinicians and other professionals, providing the ‘right’ care for the ‘right’ people at the ‘right’ time and in the ‘right’ amount³. The provider must recognise internal and external requirements and deliver according to them. QA implies that it is the provider’s own duty to establish systematic management mechanisms to ensure and document conformity to requirements.

Quality assurance is however also linked to external mechanisms that contribute to “defining, designing, assessing, monitoring and improving the quality of health care, such as developing and communicating standards, measuring the level of compliance with standards, and applying quality management methods to continually improve quality”⁴. Such external mechanisms can in principle be

voluntary (such as various accreditation arrangements) or statutory whereby government (through legislation or other regulatory arrangements) sets standards and monitors performance.

2 Background

2.1 Aims of health systems

Aims of health care systems forms the foundation of policymaking within health care. Key objectives of most health care systems are those of equity, efficiency, choice/responsiveness and quality. What dimensions of quality that are emphasised in a country's health care depends on weighting between competing aims.

2.1.1 Equity

Equity is about justice and fairness. Equity is not the same as equality. Genetic differences, unpreventable and untreatable diseases will always result in inequalities in health states in the population. Inequities are those inequalities or differences that are *unnecessary* and *avoidable* and judged to be *unjust* and *unfair*⁵. Since the majority of health determinants are to be found outside the health sector, the most important efforts to achieve equity of outcome must be put in policies for education, housing, gender, labour etc. Ensuring equity when delivering health services implies providing equal treatment opportunity for equal need. Goals of universal coverage means working to ensure equality of access across geographical areas, ethnic groups, social classes, educational and employment status, income groups and gender.

2.1.2 Efficiency

Aims of efficiency comprise both macro and micro efficiency. Macro efficiency concerns the proportion of national resources devoted to health care. Micro efficiency relates to the ability to use these resources to maximise effect both between and within different services.

Allocative efficiency concerns how funds are distributed to different services according to public need or highest value for society. Within the service the production is efficient if a maximum output is produced with a given level of input at lowest possible cost.

2.1.3 Choice/responsiveness

Responsiveness concerns the capability of the health system to respond to and to meet the populations' expectations. Choice and responsiveness are important in the perspective of people's rights and in the perspective of legitimacy and credibility in health care systems.

2.1.4 Aim trade-offs and implications for quality requirements

Designing good health systems always implies contradictions between aims. Arrangements that in economic terms are efficient may diverge from the goal of equity. Free choice for powerful, outspoken patients may be at the expense of vulnerable groups and thereby jeopardise equity. The gist is that the quality requirements to which health services must conform to, will always reflect trade-offs between competing goals of health care delivery.

2.2 Trends of health sector reforms and role of governments in development of criteria and standards for the assessment and monitoring of performance in health care services

The recession during the mid-70s and 80s, particularly in developing countries, resulted in a declined resource base for governments. Influenced by new views on the role of

governments in the developed countries and concern about the cost and equity of health care systems led to pressure for health sector reform.

Health sector reform can be described as “a sustained, purposeful change to improve the efficiency, equity and effectiveness of the health sector”⁶.

The most common elements of current health care reforms are:

- “Restructuring of public sector organisations (including decentralisation, and bureaucratic commercialisation whereby publicly-owned facilities are restructured so that they run more along the lines of privately-owned establishments: in the health sector this is usually termed hospital “autonomy” or “corporatisation”);
- Changing the way in which resources are allocated and paid to both organisations and individuals – generally with the aim of creating a clearer link between performance and reward;
- Encouraging greater plurality and competition in the provision of health care services through policy measures such as liberalising the private health sector, and contracting with or subsidising private health providers;
- Seeking increased financing for health care from non-tax revenue sources such as user fees, social health insurance and private health insurance;
- Increasing the role of the consumers in health systems through enhancing the power and scope of consumer choice and making health providers more accountable to community-based organisations such as hospital boards.”⁷

The majority of the countries in Sub-Saharan Africa have undertaken some reform of the system of health financing and many have embarked upon organisational reforms within public sector. There are no universal packages applied, but often the reforms can be linked to the ideologies of *New Public Management* (NPM). The essence of NPM has been described as government moving from “a concern to do, towards a concern to ensure that things are done”⁸. A key feature is a more market-oriented approach to the provision of health care services.

The desirability and feasibility of NPM in developing countries are matters of considerable debate and dispute^{9 10}. It is however not disputed that governments need to strengthen capacity in policy making and regulation of health care provision. Whether provision is given within structures that are fully state owned, decentralised public structures, private public partnership or private markets there is a need for explicit standards for assessing performance and mechanisms to monitor and ensure that health services provide services according to the standards or requirements. There is currently a focus on strengthening this governmental role both in developed and developing countries.

3 The Norwegian Government Strategy for Quality in Health Care

Quality assurance has its roots in manufacturing industries that introduced quality improvement methods in the 1930s. This was based on the recognition that reliance on inspection was less effective than strengthening the production process¹¹. Traditional inspections may reveal non-conformity. The weakness of traditional inspections is the lack of attention to why non-conformity appeared in the first place. Only by looking at the process leading to an output, may the underlying causes of a problem be revealed. In the 80s and 90s many European countries initiated programmes of quality assurance in health care provision.

The quality influence reached Norwegian health authorities in the early 90s. In 1994 national policies for QA in health care were established. Partly this was a follow up of the WHO strategy "Health for all by the year 2000". The European version Target 31 prescribes the development of effective mechanisms for ensuring patient care within their health care systems. Norwegian authorities recognised that one of the major challenges of health care was to start focusing on the totality of the health service process, rather

than on isolated activities in closed areas¹². Focusing on events of non-conformity without investigating errors in the process leading to the output would not lead to sustainable improvement of health care services.

3.1 The role of government

The Norwegian health care system aims at providing, in an efficient way, high quality services with equal access for the whole population¹³. Important quality dimensions are effectiveness, safety, technical competence, continuity, responsiveness and amenities, equity and efficiency.

3.1.1 The large quality circle

Quality assurance covers the 4 main steps made well known by W. Edwards Deming: Plan, Do, Check, Act¹⁴. Quality assurance institutionalised within the health system mirrors these 4 steps and gives authorities and providers mutual responsibilities. Schematically this may be illustrated in the following figure:

<i>Provider responsibility for quality improvement</i>	<i>Step</i>	<i>Stewardship role of government in quality improvement</i>
<i>Define</i> quality: Plan systematic management to ensure compliance with requirements	1 “Plan”	Establish requirements to the quality of health care according to public interest and user needs (policy goals, legal requirements etc).
<i>Perform</i> and maintain services.	2 “Do”	Dissemination – Advice/guidelines, establish organisational frameworks, create economic incentives, point out action areas through action plans etc to support compliance to requirements.
<i>Monitor</i> quality: Internal control with quality system/assurance	3 “Check”	<i>Supervise, monitor and see to it that the provider complies with requirements.</i>
<i>Improve</i> quality: Revise systems and processes and improve service provision.	4 “Act”	Disseminate supervision and monitoring experiences (among others as basis for adjustment of requirements and advice)

Box 1. The Large Quality Circle

Supervision (step 3) is thus one of the government stewardship roles in assuring quality of care. The provider is obligated to implement systematic management to ensure compliance with requirements.

3.1.2 Regulating quality requirements

Primary health care services in Norway are decentralised through *devolution* (transfer of authority to substantially independent local governments¹⁵). There exists no direct command and control line from central authorities down to the municipalities who are responsible for primary health care.

Until June 2001 hospitals were owned and run by the 19 Norwegian counties. After a hospital reform these hospitals are now operated as *health enterprises* wholly owned by central government. The hospitals are thereby separate legal subjects and thus not an integral part of the central government administration.

Because of the high degree of decentralisation, standards and quality requirements for the health service provided in the Norwegian health care system are to a large extent specified through legislation.

It has been claimed that quality in the meaning of “conformance to requirements” is old fashioned because it does not take into account the implied needs of the customer and commitments of continuous improvement¹⁶. The fallacy of this argument may be that it is impossible to argue that “conformance to requirements” will give insufficient quality without analysing what the contents of the

requirements are. The contents of the requirements might precisely be (and are in Norwegian legislation) that the health care provider shall commit to continuous improvement and systematic management according to customers or patients needs.

Quality requirements can be set within several dimensions:

- Technical competence
- Equity (equality of access and equal treatment for equal need)
- Effectiveness
- Safety
- Interpersonal relations/responsiveness
- Efficiency
- Continuity
- Amenities

Together user requirements (individual perspective), regulatory requirements (society perspective) and the organisations’ own requirements cover all these dimensions. The different actors may however emphasise the dimensions differently. The user or patient may for example put high value on interpersonal relations while governments also have to focus on efficiency. Health care markets differ from other markets in the sense that it in most cases the government acts on behalf of the patients in the purchasing situation. Hence patients initially do not have the same possibilities to express tastes and preferences and purchase according to these. It is therefore of utmost importance to ensure mechanisms to incorporate user requirements into quality assurance systems. In Norway this is done through legislation. This means

that, in principle, Norwegian regulatory requirements of quality in health care cover both individual user requirements and society requirements within all the above mentioned dimensions of quality. (The use of patient experiences is a legal requirement.)

3.1.3 Supervision and monitoring mechanisms

Governments may take different roles in mechanisms to ensure quality of health care. Some governments chose to give little direction on organisational health service standards. Quality assurance initiatives may be a concern between the health care provider and accreditation or certifying bodies. In fully state owned integrated systems the hierarchical command and control system has been the mechanism relied on to ensure the maintenance of quality standards¹⁷. Other governments legislate the use of supervision and monitoring mechanisms to measure the quality of service provision.

Supervision and monitoring of quality of care are regarded as important and legitimate parts of the government's stewardship role. The Norwegian Board of Health together with 19 County Medical Officers (CMOs) have the overall responsibility for supervision and monitoring of health services in Norway. The Norwegian Board of Health co-ordinates supervision activities carried out by CMOs in each county.

An important driving force behind initiatives to improved supervision and monitoring of quality assurance in health care is to ensure confidence in the public health care system. It is seen as a prerequisite for such confidence that the formal supervision body has both:

1. tools to supervise and monitor how services are provided, with the purpose to call attention to improvement areas and conditions or practices that do not conform to good practice; and
2. authority to take legal action when necessary.

When Norway embarked on a quality strategy in health care, it was natural that national and regional authorities took a strong role of implementation of quality assurance. In 1994 requirements for quality assurance were laid down in the National Supervision Act. When QA became a legal requirement, health care providers had to establish their own quality circles (See Annex no I).

Along with the requirements for quality assurance, the authorities changed supervision methodology accordingly from inspections to "system audits". It was acknowledged that traditional inspections did not really contribute to a sustained quality improvement. By inspections the authorities focused on single events of non-conformities. This enabled the provider to correct the identified failure. Corrections of isolated failures do, however, not support the provider in preventing failure to arise again. This can only be accomplished by scrutinising the causes of failure in the organisation's processes and management system. Such a focus is precisely the key feature with system audits.

In addition to, and complementing, this focus on organisational processes to ensure quality and continuous improvement there is an increasing emphasis on monitoring of results and capacity in relation to national goals and population needs. This implies identifying criteria for monitoring and comparison between services as well as analysis of aggregated data on service performance and output on a national level. These activities are intended to support the individual provider's own systems of monitoring results and to enable national level planning and adjustment.

3.1.4 Supervision in the context of regulation

Supervision of QA in health care provider institutions should be understood in a wider framework of regulation of health care providers. Regulation may be defined as – "*action to manipulate price, quantity (and distribution) and quality of services*"¹⁸

Regulation can broadly be divided into the two mechanisms of:

1. Incentives – financing of programmes, subsidies, tax relief, incentive structures in payment methods.
2. legal restrictions/control mechanisms

Regulation of price, quantity and quality is interconnected and should not be viewed isolated from each other. Providers might for example compensate for caps on provision of certain services by increased price on the same or other services. Price caps might be compensated by reduced quality etc. It is important to be aware of this so-called "balloon effect" in the regulation of health care providers.

Quantity	Quality	Price
<ul style="list-style-type: none"> • Licensing • Cap on education • Global budgets • Equipment – Certificate of need • Staff levels • Patient quotas • User fees (demand side measure) • Prospective payment (provider side measure) 	<ul style="list-style-type: none"> • Professionalism • Licensing • Self regulation • Quality registers • Quality assurance enforced by law combined with authorities' external supervision • Accreditation • Complaint mechanisms 	<ul style="list-style-type: none"> • Fixed charges • Negotiated salaries • DRGs • Reference pricing

Box 2: Examples of regulatory mechanisms

Quality assurance enforced by law combined with authorities' external supervision is thus one tool from a larger tool kit of regulatory mechanisms that influence quality of care. Licensing with reliable registration procedures for staff may be seen as the first step to regulate quality of health care. The need for reliable regulatory mechanisms increases with decentralisation and privatisation.

3.2 Supervision tools

In supervision context the health system may be divided into three levels that together constitute the totality of services provided to the population:

1) *Health personnel level.*

Health personnel constitute "basic building blocs" of a well functioning health system.

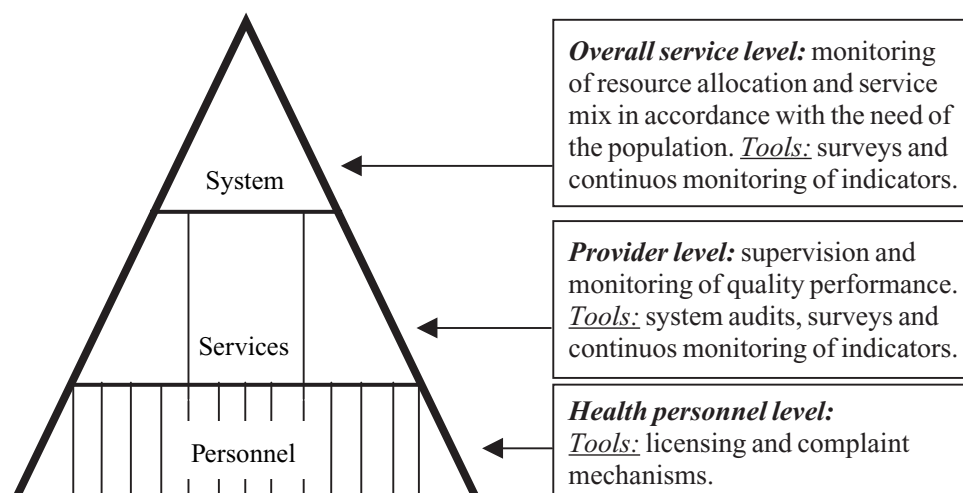
2) *Provider level.*

The various providers of primary and secondary health services, prevention/promotion services etc may be seen as the next level.

3) *Overall service level.*

This third level constitute the total "service package" provided in the Norwegian health care system according to population need. This includes how the services are run according to health policy and exertion of influence through regulation, advocacy, plus collecting and usage of information to ensure that health systems as a whole are oriented towards achieving goals that are in the public interest.

Supervision and monitoring methods or tools directed towards the "levels" differ accordingly. The pyramid below may illustrate how different supervision tools are directed to-



wards the three levels of the health system.

The methods of supervision described below are adapted to the three different levels in the pyramid. There are however clear links and emphasis on using information from each supervisory activity to inform other such activities.

One such example is the reporting of failure or adverse events. Health care providers are required to establish internal systems for reporting, monitoring and using adverse events to improve services. CMOs will in their supervisory activity inquire whether such systems are in place. There are also legal requirements to report adverse events to CMOs to enable local and national monitoring, comparison and intervention on an overall basis to ensure appropriate quality of health care.

3.2.1 Health care personnel

Licensing of health personnel is a basic regulatory mechanism to ensure quality of care. For licensing to function appropriately there must also exist possibilities for withdrawal of licence. A personnel supervision case is initiated by patient complaints or reports about suspected failure through other formal or informal channels. If the Norwegian Board of Health finds serious failure or indefensible neglect of duty the personnel receives a *warning* or in particularly serious circumstances withdrawal of licence. An important principle, however, is that individual cases should be judged in the context of the health service where the particular health personnel is just one input factor. It is important to disclose whether or not it is a system error that has led to personnel failure. Individual blame may be wrong if the institution's management of personnel resources is insufficient. A case may start as an investigation of an individual and end with establishing fault in the responsible management of the service in question.

3.2.2 Health care providers

Systematic quality assurance is a legal requirement in Norway. Supervision of providers is consequently increasingly targeted at establishing whether systems of internal control have been implemented and at whether they function as required. In annex no II we have provided a more in-depth description of the requirements and of the method of system audit that is currently used.

The system audit is based on NS-ISO 10011

(1992) *Guidelines for auditing quality systems*. The audit focus is on how the provider ensures the appropriate quality of service, which routines and procedures that are in place and how these are implemented and monitored to ensure continuous compliance and, when necessary, improvement. The audit standard describes the steps of:

- Planning which includes defining the topics and the relevant standards to be reviewed, informing the service provider well in advance of both scope, topic and method, and of reviewing relevant documents provided by the service.
- Site visit which includes meeting all the relevant informants to describe the scope and purpose of the audit, interviewing staff and verifying findings and closing with a meeting to ensure that the findings are in accordance with reality.
- Reporting in writing on findings and whether the findings are in compliance with the requirements in question. The Board of Health has the legal authority to impose compliance.

3.2.3 Overall service level

Supervision of individual providers does not give a complete picture of the health system's provision of services. There may for example be individual providers that provide their service right without providing the right service. Supervision on the overall service level implies monitoring of provision performance (including service mix) and assesses whether the population's needs are met. By continuous monitoring of health status data and health service indicators, gaps in coverage may be revealed. Additionally special focus areas are picked out on a yearly basis for more in-depth appraisal often based on surveys. An example of a topic for appraisal is patient flow between providers and collaboration between primary and secondary care for one particular disease category. This may reveal possible obstacles for proper quality, efficiency and equity of care.

This overall level also includes monitoring of information provided through the other two levels. Systematic reviews of patient complaints and cases against individual health care workers may reveal vulnerable points for intervention or further investigation. Assessing information collected in audits of individual providers will in the same way give indications of reasons for lack of quality that linked to

factors outside the service in question.

3.2.4 Other support towards health care services in their bottom-up QA work

It is an important aspect of the Norwegian quality strategy to motivate and facilitate bottomup initiatives for quality improvement within services and institutions. Financial and technical support has been given both to management level and to individual units or groups of staff as incentives to change.

These may be summed up in the following points:

- Quality improvement education (courses and training)
- Economic and technical support to quality improvement projects
- Quality advisor program in hospitals
- Quality advisor program in primary health care
- Quality networks
- Systematic collection and distribution of laws and regulations relating to health care

It is beyond the scope of this report to elaborate on this point, but other documentation is available from Norwegian health authorities.

4 Quality Assurance and supervision in Sub Saharan Africa – activities and experiences

The recession during the mid-70s and 80s resulted in a decreased resource base for governments followed by decline in the quality of services in many developing countries¹⁹.

Although quality is an expressed aim for most health system policies, action to address the aim has been insufficient. A management-by-results approach is a common strategy for improving health care services, for example by setting quantitative coverage targets for specific interventions combined with inspection-oriented supervision²⁰. National QA Programmes constitute one framework for improved quality of care.

Annex no III gives a brief summary of information available on QA and supervision activities in Sub Saharan Africa. The summary is brief because sources of such information are limited. Furthermore QA initiatives within the health services are not always closely linked with national supervision and monitoring mechanisms like in the Norwegian model. In some countries voluntarily entered accreditation is introduced as an alternative to governance by a civil service approach. QA initiatives may also take place within one region of a country with little involvement of central or regional authorities. Documentation that covers both QA activities within services and the role of government in supervising and monitoring quality of care is thereby sparse. The overview in annex III is thus not exhaustive but gives:

- examples of activities that are taking place,
- examples of project approaches,
- information about some agencies and donors that engage in QA activities.

In 2001 WHO undertook a global study in order to provide an overview of QA activities in countries, identify methodologies in use, and describe the various efforts in developing health services and hospital accreditation. The study is finished and is currently in the process of approval, editing and printing²¹.

Norway has a co-operation with Botswana on quality assurance. Consequently the description of this country's QA strategy experience goes more in-depth than the description of the other country experiences (Annex no IV). In summary this experience has proved valuable to both countries and indicates that the methods used in Norway can be adapted and implemented elsewhere.

In addition to searching for information on QA in developing countries we have tried to identify key international actors that have supported such activities. This information has been equally difficult to obtain, but annex V provides some information about WHO, USAID, DANIDA and Liverpool Associates in Tropical Health.

5 Desirability and feasibility of institutional collaboration on quality in health care – discussion and conclusion

It may be argued that QA strategies are expensive. Developed countries have experiences with resource demanding methods of developing, implementing and monitoring clinical guidelines.

On the other hand it is questionable whether a government can afford not to direct efforts towards building up a systematic national approach to quality in health care. “Although lack of resources is a key constraint to improve performance of government health services, efficiency and quality improvements should accompany, if not precede, any policies that seek to expand the pool of resources devoted to government-provided health care”²².

It can be argued that it is not a question of whether there should be government supervision of quality or not, but a question of to what extent and with which methods. Methods of service provision change because morbidity patterns change, health technology changes (improves), financial constraints are increased or reduced or the role of government changes. Some form of government involvement in health service performance is evident virtually everywhere.

The challenge is to find solutions or models that are appropriate in a specific country context. National administrative cultures are unique and distinctive. Situational, structural, cultural and external factors might facilitate or impede change.

Situational factors – impermanent factors that have impact on policy (war, media events)

Structural factors – relatively unchanging elements of society (economic base, labour market)

- Macroeconomic situation – strength of national economy. In situation of economic contraction there is less room for manoeuvre.
- Political environment – structure of political institutions, extent of decentralisation – relative power to implement change

Cultural factors - Societal values - among policy-makers, professionals and the public (solidarity ideal, corruption etc)

External (exogenous) factors – structures/values/events outside political system - globalisation

Box 3: Framework for understanding contextual factors when implementing policy change²³.

There is no single right structure or way of implementing QA in any country²⁴. The notion of a universal QA-package might seem alluring but should be rejected. Because changing health service culture is a prerequisite for implementation of QA, ownership of the QA programme by health personnel themselves is vital²⁵. This is unlikely to happen if blueprint packages are implemented in a top-down manner.

The Norwegian model is for example based to a large extent on regulating through legislation. Legislating is however not specific to Norwegian health care, it is an approach chosen (not without political debate) on most sectors of society in this country. Whether legislation or other methods of regulating, for example by incentives through a system of contractual arrangements, are chosen, some form of standards and of a systematic approach to investigating compliance with standards, is needed.

It has been argued that quality initiatives run a high risk of stagnation caused by lack of managerial capacity²⁶. Capacity may be defined as ability to perform appropriate tasks effectively, efficiently and sustainably (ref: Grindle and Hildebrand). The question is whether a well designed QA-project can contribute to strengthening of government capacity. The Norwegian experience is of adapting national and international experiences to suit our own needs and resources. We can not claim that all the approaches described function as intended or that all are equally relevant even in our own context. The process of continuous improvement, including monitoring of results, is ongoing and complex.

We can however claim to have **improved** our systematic approach to defining standards of quality and our methods of supervising and monitoring the attainment of our standards.

In conclusion, the experience of The Norwegian Board of Health in defining and implementing a role and several interlinked methods in government supervision and monitoring is in our view of relevance to countries with different legal frameworks and less resources. Many approaches to monitoring requires skills that most health professionals already have. Training in managerial skills is available in all regions. Retraining of government staff is already on the agenda in many countries. Resources for training in systematic audits are available in Southern Africa.

Norway should be able to provide meaningful collaboration on good government stewardship in this area by establishing institutional cooperation and recognising that the structure and resources of other countries do not correspond to those of this country. The Norwegian Board of Health can provide staff

Quality Assurance of health care provision – requirement for management systems in Norway

When QA became a legal requirement in the National Supervision Act, health care providers had to establish their own quality circles.

*“Anyone providing health care shall establish an internal control system and ensure that the health care facility and services are planned, performed and maintained in accordance with generally accepted professional standards and requirements laid down pursuant to laws and regulations”.*²⁷

In practice the obligation to establish QA constitutes a requirement for management system. It is useful to distinguish between requirements for management systems and requirement for products. Requirements for products are specified through patients/users directly or indirectly through regulation. As described in chapter 3.1.2 standards and quality requirements for the health service (product) provided in the Norwegian health care system are specified through legislation. It is self-evident that health care providers always have been expected to conform to this legislation. The introduction of requirements for quality assurance does thus not imply new quality requirements for the product/service. QA establish the principle that it is the providers’ *own* responsibility to show that requirements are understood, interpreted and followed in a systematic manner. Systematic management to ensure conformity to requirements implies not only ability to show that a service that already has been provided is of right quality, but that routines are in place to ensure that services will conform to the requirements in the future.

In practice QA implies that the health care provider takes the following questions under consideration:

- What requirements (internal, external) do we have to conform to?
- How do we need to work in order to fulfil these requirements?
- Who is responsible for doing what?
- How do we ensure that non-conformities are discovered?
- What measures are put in place in order to

take corrective action and improve quality?

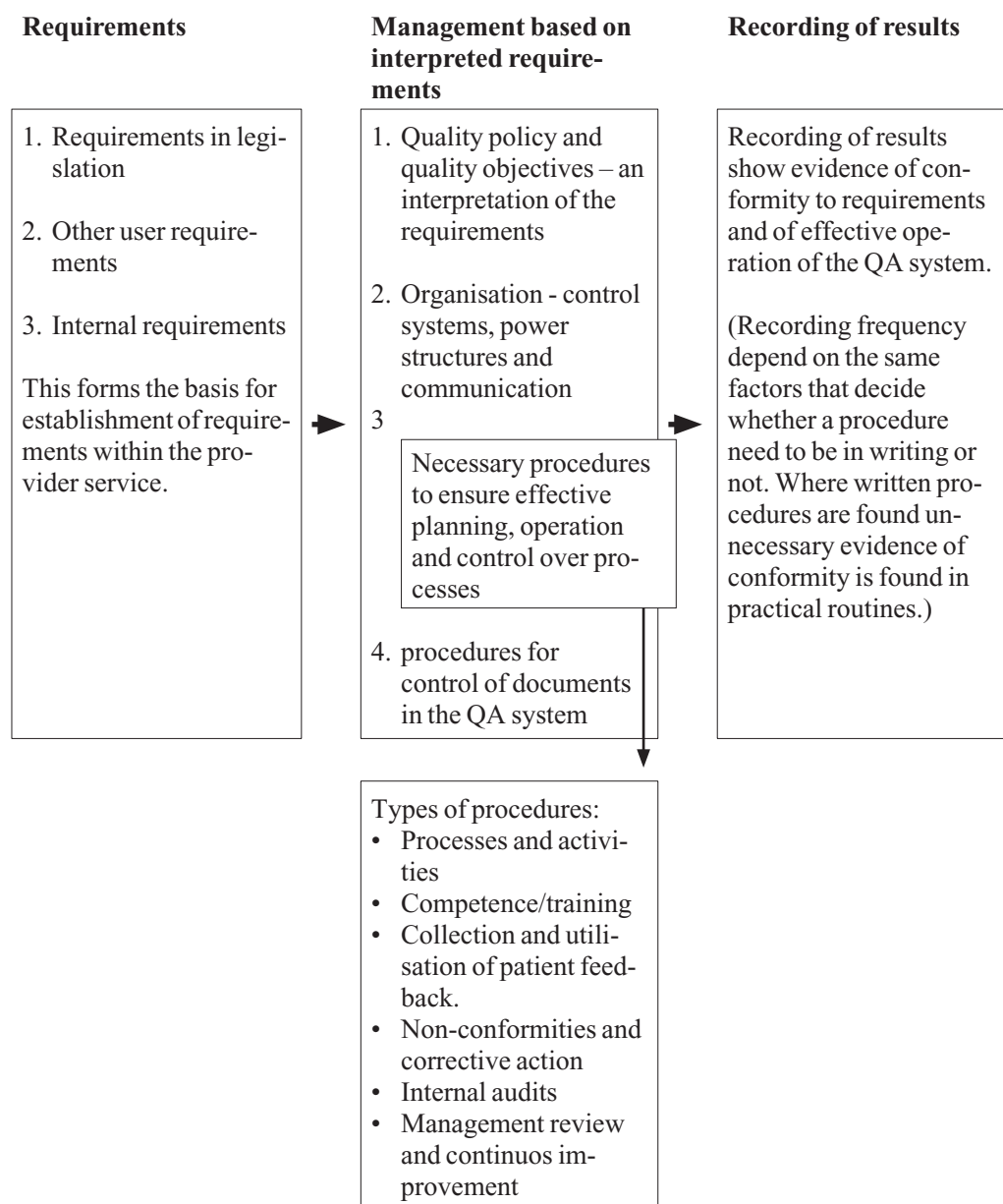
By introduction of quality assurance, health care providers easily tend to overestimate the requirement for written documentation. Exaggerated use of written procedures for activities that are simple, well known and implemented with clear allocation of responsibility, may make management unnecessarily rigid. It is thus important to emphasise that quality assurance is a way of managing organisations, and not a duty to develop complicated collections of procedures. A golden rule to test whether or not a procedure needs to be in writing or not is to ask the question: does the absence of a written procedure reduce the sustained quality of this service or process? The answer to this question will depend on factors such as: size of provider, type of activity, complexity of the process, competence of personnel, stability of personnel (turnover) etc.

The overall goal of quality assurance is to satisfy the requirements, needs and expectations to the user in a systematic manner. User refers to the health care provider’s target population, whether it is curative, preventive or promotion services.

Summing up quality management is characterised by:

- focusing on user perspectives and needs
- systematic improvement of processes and systems
- decisions based on facts and
- employer involvement with focus on organisational learning.

Schematic presentation of key elements of quality assurance:



The Norwegian approach to system audits in health care

System audits are based on the principle of quality assurance. The method used in Norway is in compliance with ISO-standard: NS-ISO 10011 (1992) Guidelines for auditing quality systems. The audit method is transparent and focuses on the providers' systematic management to assure right quality of care.

System audits constitute:

1. support to the provider institution in its own quality assurance work and
2. a public's safeguard against unsafe services by execution of authority

System audits are run as a three-phase process of planning, site visit and follow-up by an audit team of 3-5 auditors.

Planning

The scope of an audit describes the extent and boundaries of the audit in terms of physical location, activities and legal requirements. The audit team must thoroughly clarify what requirements the service has to conform to. The provider is notified about the system audit 2-3 months before the actual site visit. There is no intention to surprise the provider by an unnotified visit since the visit focuses on long term management systems and not isolated incidents.

In the notification letter the provider is informed about scope of the audit, which key-persons they expect to be present at the visit and what documents the audit team want to review in advance of the site visit. The provider is also asked to appoint a contact person for the audit.

By reviewing documentation beforehand the audit team is able to get a picture of how the provider has interpreted requirements into action and how the management system is intended to work. It is important to be aware that documentation is only one source of information to find out whether a provider works systematically with QA. An exaggerated reliance on documentation may give a wrong picture of the real activity in the provider organisation. On the one hand performance may be overestimated. Written

procedures may for example indicate good quality management, but may not be implemented into practice. On the other hand performance may be underestimated if procedures are not written down, but requirements are well known and appropriate routines are put in place in the day to day activities in the provider organisation.

The most important information is obtained in the meeting with employees at the site of the provider organisation. On the basis of the documents provided the audit team prepares questions to be used during interviews with the providers management and employers.

Site visit

When the audit team arrives at the site an opening meeting is arranged. The purpose of the opening meeting is to introduce the audit team, give an account of the scope of the audit and audit method, agree on the audit timetable and promote active participation by the provider management and employees.

It is important to assure the interviewees that they may speak to the audit team in confidence. An audit is not a search for actors to blame for adverse events. People should feel free to admit mistakes without fear of retribution in order to create a system in which lessons are learnt and shared. Instead of blaming the people working in the systems for poor performance, the audit involves people in detection of problems within processes or systems. The interviews are not a knowledge test of individual employees, but a methodologically systematic conversation to reveal the facts about how procedures (specified way to perform an activity) are known and interpreted in a common consistent manner. Therefore an answer "I do not know" is a perfectly acceptable reply, if that is indeed the fact. If interviews give information which need verification, a note should be made in order to enable the team to follow this up.

At a closing meeting audit findings are presented, expressed in terms of the observations made. The purpose of the meeting is to obtain the provider's clear understanding and acknowledgement of the factual basis of the findings. The lead auditor provides infor-

mation about what happens after the visit, i.e. that the provider will be sent a draft report they may comment on before the final report containing observations and possible non-conformities is issued. Finally the lead auditor informs the provider that if non-conformities are not followed up within the time stipulated, the case may be sent The Norwegian Board of Health for legal follow-up.

Follow-up

Immediately after the site visit the audit team prepares a draft report, which specifies the results of the audit and the conclusions that can be drawn from the observations. The provider may comment on the report within three weeks before a final report is issued, normally within 6 weeks. If non-conformities are discovered, the audit team requests a plan of action for dealing with the listed non-conformities. If the provider does not come up with a satisfactory plan for follow-up, the Norwegian Board of Health may be brought in and decide upon legal resolutions. In most cases there is agreement on the findings and the management of services will implement the necessary changes.

QA initiatives in some SSA countries

Searching for information on QA on the web and databases of relevant journals has revealed that such information is limited. Some descriptions of improvement activities are available but little or nothing on role of government supervision and monitoring quality and quality improvement. This overview is therefore fragmented. Where possible we have given name of contact persons or references to web sites for further information.

South Africa

In South Africa, Provincial Health Departments and local authorities provide 80% of the public health services to the population, including hospitals, primary health care, laboratory and ambulance services. The remainder is provided by the private sector.

QA initiatives in South Africa started with a pilot accreditation programme launched by the University of Stellenbosch in 1994²⁸. The South Africa program was inspired by the King's Fund Organisational Audit Programme and The Bristol Hospital Accreditation Programme in the UK. In 1995 the Council for Health Service Accreditation of South Africa (COHSASA), a not-for-gain organisation, was established to run the programme. Today COHSAS is the only body in South Africa implementing accreditation of health care facilities.

193 private and public facilities have entered COHSAS accreditation programmes in the period between May 1996 and February 2000. Current experience indicates that the accreditation process enables improved provision of quality. In one of the province of KwaZulu Natal a joint USAID funded South African and American research project is underway to measure the impact of the accreditation programme.

The accreditation scheme is voluntary. However, the government has since the accreditation program started appointed Provincial Health Departments to control the quality of all health services and facilities. This was stated in The White Paper for the Transformation of the Health System In South Africa (Government Gazette No 17910). Such a formal inspectorate has, however, not yet materialised.

Zambia

As part of health reform the Ministry of Health in Zambia started to focus on QA²⁹. In 1993 a central Health Reforms Implementation Team (HRIT) established a QA unit responsible for promoting QA by exposing MOH Provincial Medical Officers, the Steering Committee and district staff to QA concepts and approaches. Later the unit expanded activities to training of local staff in four districts. By 1996 the HRIT and implementation of QA activities had become a responsibility of the Central Board of Health. Tolls of implementation were setting standards for health services, monitoring indicators of achievement and solving problems in teams. This work evolved into the creation of the Zambia Health Accreditation Council to oversee the setting of standards and develop a national accreditation program.

In this programme central level activities including development of clinical standards took place parallel to district level activities. The initial focus of the QA initiative was primary health care. Local focus was a natural part of the reform that was aiming to transform centralised management with a focus on curative care delivery to a decentralised system that emphasised preventive care. Later focus has shifted towards hospitals and 49 performance standards have been developed.

In 1998 the programme was evaluated particularly with the aim of providing information and guidance for the MOH to design the next steps for improving the quality of health care in Zambia³⁰. One of the recommendations was a call for strengthened leadership from the central level in developing policy, management structures, and resources for the QA Project.

Uganda

A National Quality Assurance Programme was established in Uganda in 1994. Development and dissemination of standards of guidelines, determining the needs of patients and their families, strengthening communication between health care providers and users, and using data to identify gaps in coverage.

Malawi

A National Family Planning Quality Steering Committee was established in late 1995 to guide efforts to improve the quality of family planning programs in Malawi³¹.

The USAID funded QA Project is providing technical assistance in quality assurance and quality management to six districts through the Community Health Partnerships Project (CHAPS). The QA project are “strengthening EDHMT team management and improving Maternal and Child Health services through the integration of QA principles and methods as well as assisting the Ministry of Health to implement and operationalize the QA components of the National Health Plan (NHP) within the targeted districts and the district health management”³².

Niger

A joint project on Quality Assurance and Basic Support for Institutionalising Child Survival (QA/BASICS)³³. The project created trained supervision teams to provide technical support to health facility staff.

In a project in the Tahoua region (ref USAID institutionalization paper p. 17) emphasis was put on developing quality improvement teams for solving pressing problems of low quality care, for example malaria treatment. Quality was measured by patient satisfaction surveys. There was not a parallel focus on defining and assessing quality (standard setting), but standards were developed for Integrated Management of Childhood Illness. These were later adopted by MOH.

Through the QA project there was a change in supervision system as a response to needs. “the concept of coaching helped transform the traditional authoritarian style of supervision into a supportive, problem-solving approach”³⁴.

Kenya

Kenya has just re-launched its department for health standards and regulatory services. They are taking a very strong lead at national level and are currently training staff across the country such that provinces and districts can support health centres in improving quality and also safeguard against dangerous practice in public and private sectors³⁵. (Contact person in Kenya: Dr Tom Mboya dsrs@africaonline.co.ke.)

Zimbabwe

The USAID funded QA Project “studied supervisor-provider communication related to delivery of family planning services. More specifically, supervisors’ interactions with service providers, and how supervisors affect the quality of providers’ interactions with clients. We found that on a scale of 11-110, supervisors rated 14-65. The strongest areas were in giving feedback and analyzing data; the weakest areas were in continuity, being proactive, and promoting participation of the supervisors.” (ref: <http://www.qaproject.org/index1.html>)

Eritrea

The USAID funded QA Project is working with the Ministry of Health to institutionalize QA. Activities include:

- QA training
- development of hospital standards
- development of a related monitoring system
- introduction of accreditation, licensure, and certification.

(ref: <http://www.qaproject.org/index1.html>)

Rwanda

The USAID funded QA Project “is working on promoting and strengthening a client-oriented approach among health workers in the provision of curative, preventive and primary health care; and improving efficacy and cost-effectiveness of health services provided by health workers through extensive training in quality improvement methods and tools at the facility level and hospital level.” (ref: <http://www.qaproject.org/index1.html>)

Mali

The USAID funded QA Project is “studying approaches to improve access and quality of care through a cross-project collaboration between QA Project and the USAID-sponsored Partnerships for Health Reform (PHR) Project. The study’s two main objectives are: to examine the relationships between quality of health services, client satisfaction and utilization in Mali (which has one

of the lowest per capita healthcare utilization rates in the region) and to develop and test an approach for using quality assessment data to improve quality of health services in public and private providers.”
(ref: <http://www.qaproject.org/index1.html>)

Ghana

In Ghana national policy statements on QA was made in late eighties and early nineties. In practice QA initiatives have been bottom – up, funded by DANIDA in one region and LSTM in another³⁶.

LATH has been engaged in establishing Quality Indicators for Hospital Out Patient Departments in Ghana:

LATH “spent six months working with OPD staff and patients in Ghana to define and construct a database for Quality Indicators that employed routine data and Exit Survey data to monitor quality at the OPD. This work underpinned the introduction of initiatives to improve quality of care at these OPDs.

Employing the experience gained over three years in Ghana and elsewhere, Vicki Doyle produced and tested training packages for Hospital and Health Clinic staff in QA techniques and strategy. These manuals are now in wide spread use throughout Ghana and have been adapted and redesigned for use in Central America and India³⁷.

(Contact person in Ghana: Dr Kwame Adogboba moh-icd@africaonline.com.gh)

An evaluation of the QA strategy for Ghana was carried out by The Ministry of Health, Ghana, in collaboration with Liverpool School of Tropical Medicine in 1998. A summary report may be found at:
<http://www.liv.ac.uk/lstm/qainfo.html>

Mozambique

Mozambique is currently establishing QA systems as part of their sector wide approach³⁸.

(Contact person: Herve herve@tropical.co.mz)

Tanzania

The majority of regulations in Tanzania focus on entry (licensing). A minimal level of quality is specified below which individuals and organisation cannot enter the market³⁹. The vast majority of the regulatory mechanisms towards the health sector are legally based.

Strengthening the MOH and central support systems are components of a health sector development project in Tanzania. The project document states that “the MOH will shift its role from a direct provider or implementer to a facilitator, whose mandates will be: policy

development and analyses; quality assurance through appropriate legislation and regulations, as well as setting up of standards; and monitoring and evaluation”⁴⁰.

In the Mbeya Region there has been a project to improve quality and uptake of reproductive health. District Co-ordinators have developed local clinical standards that are disseminated and monitored throughout the region. A QA method specific to family planning services has been introduced in the form of the Client Oriented Provider Efficient system. A formal evaluation of service needs at health facilities has been developed and is now practised regularly in all health districts⁴¹.

The Botswana Quality Strategy experience

In 1994 Botswana started to develop a National QA Policy. One of the conclusions from a NORAD/WHO evaluation of the decentralisation reform in Botswana was that the Ministry of Health (MOH) needed to start developing supervision mechanisms within health care⁴². Botswana adopted a National Health Policy in August 1995.

The National Health Policy stated that: “All the health services, whether public or private, shall establish internal control systems, and ensure that their services and activities are planned, executed and maintained in accordance with generally accepted technical and professional standards, with existing legislation and such guidelines as may from time to time be issued by the ministry.” (section 3.6.4)⁴³. Accordingly the Ministry of Health became responsible for “systematic and independent audits” (section 3.5.6).

Aims

The main focus of the project in collaboration with Norway was capacity building, more specifically development of:

1. quality management within the health services in Botswana and
2. a system for external quality audits (supervision)

The project was formally integrated within a Health Sector Agreement between Norway and Botswana in June 1996. The contract stated that:

- The project *aims* at developing and strengthening the capacity of the Ministry of Health over a 5 year Period, starting in 1996
- The *goal* is to improve the quality of health services in Botswana
- The *purpose* of the project is to assist in developing and strengthening capacity on quality management⁴⁴.

Specific objectives included:

- “To produce a Botswana national strategy for quality development in health care

- To train a core group of supervisory health personnel on the development of quality systems in health care.
- To set up quality audit capability in the Ministry of Health, Local Authority Health Departments, and in various health institutions
- To introduce quality management principles at hospital and district levels
- To set up the information system needed to mediate experience generated in the quality system and from quality audits, from information collection to analysis and presentation.
- To set up a system for regular monitoring of public opinion, receiving public complaints and responding to them.”⁴⁵

Implementation

In 1995 representatives from the country’s hospitals, District Health Teams (DHT = primary health care services), National Institute and Health Sciences and the MOH Headquarters participated on a 2-day conference to launch the National QA strategy.

In June 1996 a Quality Management Unit was established in the Ministry of Health. A Quality Officer staffed the office, reporting directly to the Permanent Secretary. By 1998 all hospitals had been visited by the Quality Officer, addressing the objective of introducing quality management principles.

Training

A core component of implementation has been training according to the two approaches for capacity building:

1. *Quality management systems within the health services*
This training has taken place both on site and by several courses targeted at various levels within the Ministry of Health and the Ministry of Local Government Lands and Housing.
2. *Quality audit methodology to build the external audit mechanism.*

Auditors have undergone a two-year training programme. Because several of the trained auditors come from various health services throughout the country, they represent competence to build up the services own management systems. The auditors help training people and will take part in internal audits in their own facilities⁴⁶.

By 1998 a total of 279 health personnel had been trained in quality management systems and quality auditing principles.

Development of guidelines for quality management systems within the health care services

To support systematic work to establish quality systems and encourage continuous quality improvement within the health care services, the MOH has been in process of developing national guidelines for quality systems to assist the health services in their work. Draft guidelines have continuously been discussed on training courses and workshops.

Accordingly the MOH has developed guidelines for quality auditors. The following is a summary of minimum requirement for quality systems that can be derived from the National Health Policy⁴⁷:

1. The facility has a master list of documented procedures which covers all basic processes of the facility, including a procedure to ensure control of documentation.
2. All internal quality documents are dated and signed and marked with planned date for review
3. There is a description of the facility with functional units, and of the customers whom they serve. The description of the facility can take the form of a functional organisational chart.
4. The facility has a Master list of all documents which contain requirements relevant to the facility (and its various functional units) and the services produced, with a description of how members of staff can read about these requirements.

5. Audit or verifications in thematic areas show that the facility has systematic control of the conditions which are necessary for the required service delivery.
6. Existence of records or statistics that show how high-risk processes are being monitored and how performance is being controlled and maintained.
7. Prompt submission of annual reports. Annual reports for the last 4 years should be available in the library.
8. Existence of well-known and fully documented procedures for detection, control, and elimination of non-conformities.
9. At least one WIT active on a project at the time of audit.
10. Systematically making the Setswana version of the "Patients' Charter" available to all users of the facility.
11. Documentation of the processes used to receive input from users, procedures to respond to input from user, and procedures for solving problems and implementing improvements to meet users needs.
12. Evidence of management commitment documented in minutes of meetings and reports from working groups
13. The members of staff have the competence required for the jobs they are doing. They are familiar with their own role in the internal control system, with the way in which responsibilities and authority have been delegated, and how to communicate effectively with management.
14. Quality documents are well known to all heads of departments and their deputies.
15. Quality objectives and procedures, which are relevant to their own jobs, are well known to members of staff.

Performance of quality audits

The first audit was performed already in 1995. A national procedure for quality audits was developed, describing a methodology that is very similar to the Norwegian procedure described elsewhere in this report.

By 1998 eighteen audits had been performed, 3 in referral hospitals, 6 in district hospitals and 3 in primary hospitals. From 1998 and onwards 15 audits have been arranged each year⁴⁸. The aim is to cover each hospital, each District Health department and each Institute of Health Sciences every 3 years.

The scope of the audits has included assessments of⁴⁹:

- “functioning of quality systems in hospitals
- functioning of quality systems for implementing specific programmes
- organisation and management of outpatient departments in hospitals
- systems for observing, recording and reporting vital signs
- aspects of the Safe Motherhood Initiative
- rights of patients during admission and inpatient stay in the Lobatse Mental Hospital”

Discussion

The Botswana National QA Policy will be reviewed as part of the overall report on the Health Sector Agreement between Botswana and Norway. There is currently no comprehensive evaluation available on the effects of this effort. The following brief discussion is based on the (draft) report of the Mid Term Review (MTR) in 1998, on documents produced as a result of the recommendations given by the Mid Term Review Team and on anecdotal experiences of individual Norwegians involved in the programme.

The MTR states that the programme is relevant to and will potentially make significant contributions to the quality of health care in Botswana. The report emphasises that crucial to effect and sustainability will be the capacity and competence on quality management and on quality audits in the Ministry of Health and in the health service. Political commitment in the MOH is another essential prerequisite.

It would seem that achievement and sustainability is linked to the relationship between quality management activities in hospitals and the audits that have now (2002) been performed twice in several facilities. Anecdotal evidence indicates that there is improvement between the first and the second audits. As a result of audits and of the MTR the Ministry of Health has provided increasingly clear and possibly more relevant guidelines for quality management in the individual health care facility.

It is difficult to assess to what extent any factors relevant to successful implementation are specific to Botswana or to what degree experiences from Botswana are relevant to other countries.

Compared to other countries in the region Botswana is economically well off, has stable and good governance and a well functioning health care system with skilled staff. Training and external quality auditing has been made possible by increasing government commitment to improving quality in health care.

These are indeed important factors in any effort to implement any programme for improvement. Without more experience from systematic efforts on QA in other countries conclusions can only be speculative. There can however be no question that success is linked to the fact that the QA approach builds on systems end experiences already in place.

The MOH in Botswana has a legitimate role in issuing guidelines and controlling the follow up in publicly owned hospitals. The hospitals already had another systematic approach to continuous improvement in place (Work Improvement Teams – WITs) that could easily be adapted to follow up on non-conformities disclosed through audits.

When the final report on the Health Sector collaboration between Botswana and Norway is available, we will have an important source of knowledge on the factors influencing success or failure in Botswana. Lessons learnt thorough this experience must be included in any effort in other countries.

Even before we have this final report however it is possible to assume that the most important lesson will probably be to assess the mechanisms already in place in any given country before embarking on developing guidelines, training programmes or audits.

Key international actors on QA in developing countries

WHO

In 1982 the WHO Regional Office for Europe published “Quality Assurance of Health Services: concepts and methodologies”. In 1993 a Consultation for Developing Countries was held in Maastricht, Netherlands, proceeding a ISQUA Meeting, for the first time in collaboration with DANIDA and USAID. Since then several such pre-ISQUA meetings have been held.

The WHO programme is focusing on a systematic development of the managerial aspects of service delivery. Quality assurance of specific items, agents (e.g. blood safety), equipment and supplies (e.g. drugs, vaccines) is left to “technology” and “vertical” programmes.

QA of service delivery covers: introduction, motivation, training and assistance in implementation and review of activities at the levels of:

- *Development and improvement of the organization and management of the execution of health care procedures (classical or “Donabedian” QA)*
- *Development and improvement of local or district health systems’ behaviour (interaction between intramural and ambulatory services, coordination of care aimed at individuals and aimed at collectivities along the lines of Total Quality Management, TQM)*
- *Development and improvement of the central levels of national health services, mainly: strategic services planning, organization, evaluation, development and adjustments. This area of activities covers the managerial process of national health services development, including appropriateness of services in relation to patterns of morbidity and mortality, referral arrangements with an emphasis on governance of service delivery by the public and private sectors, regulatory activities (licensing, credentialling, etc.), and national accreditation as an alternative to governance by a civil service approach.*

<http://www.who.int/health-services-delivery/performance/accreditation/index.htm>

In 2001 WHO undertook a global study in order to provide an overview of QA activities in countries, identify methodologies in use, and describe the various efforts in developing health services and hospital accreditation. The study is finished and is currently in the process of approval, editing and printing⁵⁰.

USAID and the QA Project

Among donors who support Quality Assurance initiatives in developing countries, U.S. Agency for International Development (USAID) has a leading role by funding The Quality Assurance (QA) Project (1990). The QA Project was initiated “to develop and implement sustainable approaches for improving the quality of health care in less developed countries”⁵¹.

The project mission is “to provide the technical assistance to build local capacity for establishing standards of care, assessing the quality of services, and undertaking actions to strengthen healthcare programs and systems”⁵². A major focus for the QA Project has been approaches for quality improvement methodology within health care services.

The African countries where the QA Project has engaged in QA initiatives are Eritrea, Kenya, Malawi, Mali, Niger, Rwanda, South Africa, Uganda, Zambia and Zimbabwe⁵³.

DANIDA

In DANIDA’s sector policy for health the organisation states that it has moved “from being concerned with health care services at the primary level - to trying to address systems issues as well”⁵⁴. QA is seen as one tool in this respect. Thus, DANIDA will promote the QA concept by “assisting health agencies and bilateral partners in developing QA/QM for practical use in developing countries, including the design, piloting, validation, by assisting in communicating experiences, and, where applicable, by assisting national implementation in the context of health sec-

tor support programmes”.

Together with WHO, DANIDA has among others been involved in a QA project in Zambia⁵⁵ and Ghana (information by Vicky Doyle, LATH).

Liverpool Associates in Tropical Health (LATH)

LATH is an international health care consultancy company owned by Liverpool School of Tropical Medicine (LSTM). Funded by the UK government’s Department for International Development (DFID), LATH is engaged in various QA activities around the world. In Africa collaborating countries are Ghana, Kenya, Uganda and Mozambique.

Currently the programme is involved in QA activities in Ghana, Kenya, Uganda and Mozambique⁵⁶.

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Rapport fra Helsetilsynet

Utgivelser 2002

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2/2002 Tilsyn ved regionsykehusene i 2001 – oppsummeringsrapport (februar 2002)

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4/2002 Fylkeslegenes tilsyn med helsetjeneste i fengsler 2001 – oppsummeringsrapport (mars 2002)

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8/2003 Helsetilsynets bidrag til statusrapport om fastlegeordningen (september 2003)

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