ACCREDITATION AND OTHER EXTERNAL QUALITY ASSESSMENT SYSTEMS FOR HEALTHCARE

Review of experience and lessons learned
May 2003

Dominic Montagu

Health Systems Resource Centre
27 Old Street
London EC1V 9HL
Tel: +44 (0) 207 253 2222
Fax: +44 (0) 207 251 9552
E-mail: enquiries@healthsystemsrc.org

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Dominic Montagu is a researcher in Public Health at the University of California at Berkeley. His work is primarily in research and project design related to private sector delivery of health care in developing countries, focusing particularly on transactional economics and provider networks. In this role he has undertaken research projects and consultancies related to health franchising and private sector regulation in Vietnam, Nepal, Indonesia, Kenya, Pakistan and India.

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Author: Dominic Montagu

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ACRONYMS

AABB:	American Association of Blood Banks
ALPHA:	Agenda for Leadership in Programmes for Healthcare
COHSASA:	Council for Health Service Accreditation of Southern Africa
CQI:	Continuous Quality Improvement
EQA:	External Quality Assessment
ISO:	International Standards Organisation
ISQua:	International Society for Quality in Healthcare
JCAHO:	Joint Commission on Accreditation of Healthcare Organisations
QAP:	Quality Assurance Project
TQM:	Total Quality Management

NOTE: Accreditation is one form of External Quality Assessment. However the close similarity between accreditation programmes and other certification schemes which also employ external reviews of quality has led to Accreditation and EQA being used interchangeably in many cases. Because the focus of the review was on accreditation programmes, the paper refers to both accreditation and EQA, which while technically incorrect serves to illustrate that the lessons drawn can be ascribed to more than one type of quality assessment system.

EXECUTIVE SUMMARY

This review of experience in accreditation and external quality assessment systems was produced at the request of the UK Department for International Development in India. The purpose of this review is to describe where External Quality Assessment (EQA) fits in the broader set of levers that exist for engaging with health care providers and organisations in developing countries in order to improve quality and affordability of care. This information is partially based on theory, but primarily presents lessons learned and experience with accreditation and other assessment methods in both OECD and developing countries.

Since the early 1990s healthcare reforms in developed and developing countries have led to increased privatisation, moves to greater organisational autonomy and outsourcing of goods and services. This has coincided with increased interest in achieving increased efficiencies and quality improvements in both public and private settings (Mills, Brugha et al. 2002). One result has been a rapid growth in the use of External Quality Assessment (EQA) by government as a way of improving the quality of services provided by healthcare organisations in both developing and OECD countries.This has been helped by the growing availability of well tested standards for a wide range of healthcare facility types which can be adapted to local conditions with relative ease and rapidity.

Because of overlapping use of the terms for different quality assessment methods the World Health Organisation (WHO) has recently begun using the term 'External Quality Assessment' to refer to all kinds of organisational review which use written standards. Accreditation is one of the most attractive forms of EQA for healthcare organisations, and therefore is the focus of much of this report.

Accreditation is an external review of quality with four principal components:

- It is based on written and published standards
- Reviews are conducted by professional peers
- The accreditation process is administered by an independent body
- The aim of accreditation is to encourage organisational development.

Accreditation and other EQA programmes provide achievable quality standards, supportive consulting, and benchmarking scores, all of which assist facilities to improve the quality of their operations. This is complementary to, but different from, the minimum standards needed to operate a healthcare facility, which must also exist and be enforced for accreditation programmes to have a significant nationwide quality impact.

The relationship between accreditation and regulation is close and ongoing for most programmes. Because accreditation, unlike licensure, is voluntary, adapting it to the level of quality and ability of participating organisations should be seen as an acknowledgement of reality, rather than a 'dumbing down' of standards. Accreditation programmes are already setting sights higher than the minimum; to be relevant to the accredited organisations, the standards must be achievable.

Accreditation programmes are most effective when they combine both evaluation and supportive consultation in order to assist hospitals and technical medical facilities to

improve their quality. As a result, mandated EQA is less effective than voluntary programmes. The effectiveness of accreditation is dependent on its voluntary nature, non-threatening process, and interactive process with external reviewers as a means of effecting and ratcheting up quality improvements.

Accreditation programmes, if undertaken with careful planning, strong government support, and organizational commitment have the potential to improve the quality of care available in hospitals and medical laboratories in many developing countries. While outside financial support is necessary during the initial years of programme development, financial independence is possible given the right circumstances. Where understanding and support exists, accreditation programmes and other external quality assessment methods are desirable and sustainable ways of improving care in developing countries.

EQA has significant potential for social benefits that are greater than its costs. As such, the support of independent quality assessment programmes, their development and continued existence, should be of interest to governments. To the extent that accreditation or EQA programmes communicate their results, they provide information on quality that is almost impossible to find out otherwise. In healthcare, informational asymmetry has an important role in raising the cost of transactions and making the procurement of health services inefficient, both for large contractors and individuals.

Accreditation can play an important role in communicating quality information to collective and individual purchasers and increasing efficiency in the health sector. When sufficiently widespread, accreditation serves to increase the overall quality of the health sector by providing both information on quality and feedback on structures necessary to achieve quality in a form that promotes benchmarking and internal organisation improvements. Such a scheme can benefit poorer users as well as richer ones.

The experience in developing countries, particularly in South Africa with the independent, but publicly financed Council for Health Service Accreditation of Southern Africa (COHSASA) programme, is that accreditation programmes are able to increase equity, by raising the standards for care in incremental stages. The success of EQA programmes in increasing equity is largely due to the commitment of purchasing organisations (NGOs, individual facilities or governments) to support participation by smaller facilities serving marginalized populations, in rural and urban areas.

Larger organisations are likely to value accreditation more than small facilities. Small facilities will find the costs of surveys and compliance more onerous than large facilities in proportion to their budgets. The commitment of direct funding or subsidy of assessments is therefore more important for small facilities than large ones. With that support, smaller institutions are often likely to benefit highly from EQA, particularly from accreditation, with resulting increase in quality of care, including drug availability and price transparency, and staff morale, making significant differences for the populations they serve.

Most healthcare organisations in developing countries, that do not serve the wealthy or have a strong driving moral mission, are unlikely to seek out accreditation unless the costs of participation are subsidized and/or there is another strong external incentive to join an accreditation process.

Accreditation of individual providers has tended to be ineffective. Franchise programmes, such as Green Star in Pakistan, Janani in India, or CFW Shops in Kenya, have been able to achieve measurable quality improvements at the level of private providers, but only through a much more intensive involvement with the providers than straight forward EQA programmes. This in turn has been possible only through significant donor support. While there may be an intermediary level of quality accreditation at the provider level, it will inevitably require external funding, and as yet no established model exists. Another option is the possible application of a certification-style intervention at the provider-level as a means of improving quality when linked to a payment mechanism (eg. vouchers). Although the terms accreditation and certification are often used interchangeably, accreditation usually applies only to organisations, while certification may apply to individuals, as well as to organisations. Certification usually implies that a provider has received additional education and training, and has demonstrated competence in a specialty area beyond the minimum requirements set for licensure (e.g. a physician who receives certification by a professional specialty board in the practice of obstetrics).

For governments interested in promoting accreditation as a means of stimulating quality improvements, there are some key issues that must be addressed:

- An accreditation organisation must be independent in order to avoid conflict of interest and to assure both the objective and non-policing nature of the assessment process. However, to be effective, they need the support of governmental licensing and health service bodies. Ministry of Health representation on accreditation boards is common, as is financial subsidy.
- Without intervention by governments or donors, accreditation/EQA will be likely to remain attractive only to high-end facilities and will not improve healthcare quality at the national level.
- Governments and/or international donors should be prepared to provide a minimum of three years of financial support to a nascent accreditation programme, including costs to develop, test, and disseminate standards. In poorer countries, longer support should be planned.
- The most effective means of providing long-term support for an accreditation programme are indirect, by establishing financial incentives for organisations to participate. Possible ways of doing this include:

    - Preference in contract selection with the government or other payers
    - Preferential or pre-approved payment rates for certified facilities by government or other payers
    - Governmental direct contracting for accreditation of public facilities
    - Strong enforcement of licensing standards which are aligned with accreditation/EQA standards
    - Advertising campaigns to generate public demand for certified facilities

- Accreditation or other EQA programmes are most likely to successfully improve quality if they are voluntary and exist in conjunction with enforced governmental licensure that assures minimum standards. Accreditation cannot replace licensure of substitute for effective monitoring of minimum operating standards – it is not a low cost substitute for regulation.

- International and local accreditation have proven effective in developing countries. However, international accreditation is expensive and can lead to market capture by a few leading institutions that serve the wealthy. Local schemes can serve a broader range of organisations and develop standards appropriate to local conditions.

1 BACKGROUND AND INTRODUCTION

This review of experience in accreditation and external quality assessment systems was produced at the request of the Department for International Development in India. The purpose of this review is to describe where External Quality Assessment (EQA) fits in the broader set of levers that exist for engaging with health care providers and organisations in developing countries in order to improve quality and affordability of care. This information is partially based on theory, but primarily presents lessons learned and experience with accreditation and other assessment methods in both OECD and developing countries.

Accreditation and external assessments are examined in terms of what they do, and the pros and cons of alternative methods of their application. A framework is described for understanding the implications for national governments or donor support of accreditation and assessment programmes in developing programmes, based on the potential effectiveness, sustainability, and ability to improve quality of care for users at differing levels of income. Finally, issues related to specific application of accreditation and EQA are set out in broad terms.

Quality standards for hospitals and other medical facilities were first introduced in the USA in 1917. After World War II, increased world trade in manufactured goods led to the creation of the International Standards Organisation (ISO) in 1947. Building on successes in Japan, Total Quality Management (TQM) and Continuous Quality Improvement (CQI) have become common in manufacturing industries throughout the world, and are increasingly part of the strategies of healthcare organisations.

Since the early 1990s healthcare reforms in developing countries have led to increased privatisation and outsourcing of goods and services. This has coincided with increased interest in achieving increased efficiencies and quality improvements in both public and private settings (Mills, Brugha et al. 2002). One result has been a rapid growth in the use of External Quality Assessment (EQA) as a way of improving the quality of services provided by healthcare organisations in both developing and OECD countries.

Assessment methods have been applied both by governments and non-governmental organisations, as stand-alone quality improvement programmes, and in conjunction with other strategies to address service costs, accessibility, information, and compliance incentives. Most common among these have been programmes for service vouchers, social marketing, social franchising, and service contracting (see Box 1). Each of these interventions seeks to leverage benefits to providers (subsidized supplies, performance-based payments, or increased client load) in order to improve quality. Quality assessment then, becomes integral to the programs as a way of tracking provider improvement and conformity. EQA is the gold standard for this assessment, and in some cases, in franchises or networks such as Planned Parenthood, accreditation becomes a tool for improvement, as well as an instrument for compliance verification.

A number of assessment mechanisms have been used to address quality in medical care organisations. The most common are certification, accreditation, and licensure (see box 2 for definitions).

Because of overlapping use of the terms for different quality assessment methods the World Health Organisation (WHO) has recently begun using the term 'External Quality Assessment' to refer to all kinds of organisational review which use written standards.

Accreditation is one of the most attractive forms of EQA for healthcare organisations, and therefore is the focus of much of this report.

Box 1: Common ways of working with private providers

- **Vouchers** programs are used to subsidize either specific services or specific groups through distribution of chits. Because vouchers can only be redeemed at pre-certified medical providers the promise of new clients is an incentive for providers or organizations to seek certification.
- **Social Marketing** addresses information about service availability and quality by providing subsidized advertising to inform potential clients that certain providers or organizations have been assessed and certified to have high quality and/or provide certain services.
- **Social Franchising** works like social marketing, advertising the quality of certified providers or organizations, but also provides for an ongoing relationship between providers/organizations and the franchisor, assuring more control over the ongoing quality.
- **Service Contracting** works with quality assessment programs by providing incentives to providers or organizations to participate in EQA programs, either as a criteria for contracting, or in order to receive a higher reimbursement rate.

Accreditation is an external review of quality with four principal components:

- It is based on written standards
- Reviews are conducted by professional peers
- The accreditation process is administered by an independent body
- The aim of accreditation is to encourage organisational development.

The distinction between this and licensure is significant: individuals or organisations are licensed by a government because they meet ***minimum*** standards for operation. Accreditation measures the same organisation against the ***ideal achievable*** standard of quality.

Accreditation usually involves: 1/ measuring an organisation against other equivalent organisations, and 2/ providing feedback to the accredited organisation on progress towards quality goals, and areas requiring greatest attention. This is known as 'benchmarking' and is recognized as a significant incentive for organisations, as they measure their own performance against others.

As organisations in an accreditation network improve, the overall standards of 'achievable ideal quality' rise. This incremental raising of standards is called 'ratcheting'. Benchmarking and ratcheting of standards are not built in to other

Box 2: Definitions of licensure, accreditation, and certification

Licensure is a process by which a governmental authority grants permission to an individual practitioner or health care organization to operate or to engage in an occupation or profession. Licensure:

- Exists to ensure that an organization or individual meets minimum standards to protect public health and safety
- Is usually granted after some form of examination or proof of education
- May be renewed periodically through payment of a fee and/or proof of continuing education or professional competence
- Organizational licensure is usually granted following an on-site inspection to determine if minimum health and safety standards have been met
- Maintenance of licensure is an ongoing requirement for the health care organization to continue to operate and care for patients

Accreditation is a formal process by which a recognized body, usually a non-governmental organization (NGO), assesses and recognizes that a health care organization meets applicable pre-determined and published standards. Accreditation standards are:

- Optimal and achievable
- Designed to encourage continuous improvement efforts within accredited organizations
- Accreditation is granted following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years
- Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation

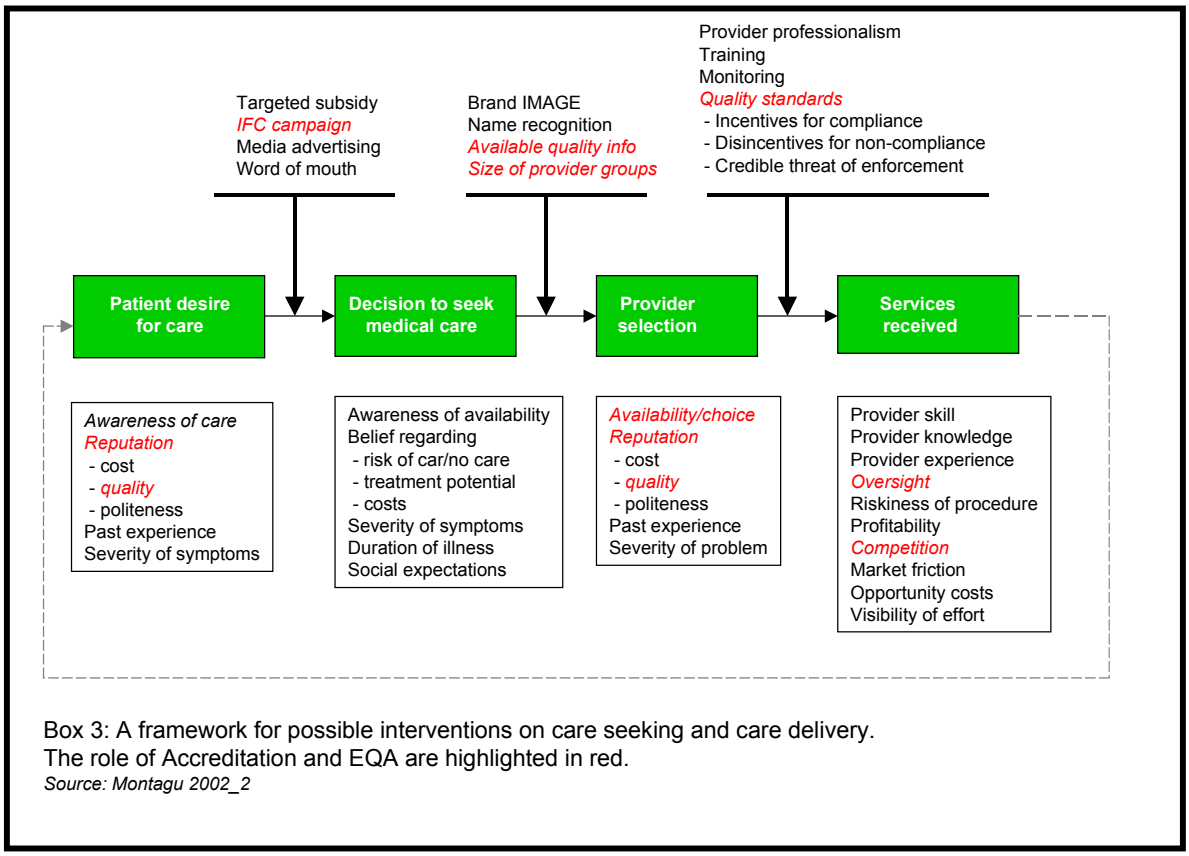
Certification is a process by which an authorized body, either a governmental or non-governmental organization, evaluates and recognizes either an individual or an organization as meeting pre-determined requirements or criteria. Although the terms accreditation and certification are often used interchangeably, accreditation usually applies only to organizations, while certification may apply to individuals, as well as to organizations. Certification usually implies that a provider has:

- Received additional education and training
- Demonstrated competence in a specialty area beyond the minimum requirements set for licensure (e.g. a physician who receives certification by a professional specialty board in the practice of obstetrics)

Facility certification usually implies that the organization has additional services, technology, or capacity beyond those found in similar organizations.

Source: Rooney and Ostenburg 1999)

assessment processes[1]. How accreditation affects clients is shown in Box 3.



Box 3: A framework for possible interventions on care seeking and care delivery.
The role of Accreditation and EQA are highlighted in red.
Source: Montagu 2002_2

This report addresses accreditation and external assessment programmes for all healthcare organisations. However, health service organisations and laboratory organisations operate quite differently and should generally be considered independently. Laboratory services, such as haematology wards, blood banks, radiology, and medical engineering have less variability in their processes than service organisations. In medical services there is a great deal of inherent uncertainty, which is difficult to quantify, because of individual provider skills and co-morbidity of the different diseases. As a result, the standards for certification of laboratories and the standards for accreditation of laboratory processes can be similar. However, for medical services the standards of certification and accreditation must be different in important ways, which will be described below.

[1] Although there is increasingly a move in this direction, particularly in the ISO 9000-2000 process standards and the European *Visitatie* programme (Heidemann 2000; Shaw 2000)

2 THEORIES OF EQA AND HEALTHCARE QUALITY MANAGEMENT

EQA is a potentially effective way to improve the quality of services in healthcare organisations. What makes an EQA programme effective or not, and what specific indicators of quality are measured, varies from service to service, and programme to programme.

Box 4: Examples of indicators from different evaluation methods

Inputs
- Facilities
- Equipment
- Number and training of personnel
- Stocks of materials

Outcomes
- Incidence of infection
- Number of procedures performed/year
- Patient satisfaction
- Continuity of care
- Accuracy of physician diagnosis

Process
- Documented procedures (eg how to check-in new patients or a list of screening questions for potential blood donors)
- Chain of responsibility for all activities
- Regular meetings to bring up and address quality issues

Evaluations measure inputs, outputs, or process (Box 4). Inputs refer to the facilities, the equipment, training and number of personnel, and material used in providing care or conducting health-related activities. Outcomes can be both quantity and quality measures, reflecting the incidence of infection, number of procedures performed per year of a certain kind, patient satisfaction and knowledge, continuity of care, accuracy of diagnosis etc.

2.1 Process measures

In the past two decades there has been a shift towards evaluation of process measures as well as inputs or results. Sustainability of results has been tied to effective quality management processes.

Within a process focus, attention in recent years has shifted towards an emphasis on quality improvement, rather than just quality attainment (Rooney and Ostenburg 1999). ISO's most recent standards for service organisation now measure more than just quality and quality management; the ISO 9000:2000 standards also evaluate an organisation's structures to facilitate adaptation and quality improvement. There has been a evolution in accreditation programmes from Total Quality Management (TQM) towards Continuous Quality Improvement (CQI), where employees and organisations are judged on their ability to not just meet a standard, but surpass it (Viswanathan and Salmon 2000).[2]

Although this trend exists in industry EQA systems, the application of process measures to healthcare has been slow. Accreditation programmes generally come closest.

[2] The main criticism of TQM systems is that they inhibit innovation and are limited to box-ticking as each indicator is met. CQI has the potential to both assure quality, and quality improvement.

Box 5: Potential benefits of participation in accreditation programs

- Assistance in improving organizational quality
- Increased reputation among end-users
- The right to participate in re-imbursement programs
- An approved supplier status for some clients
- De-facto licensure in some countries
- Higher reimbursement from payers
- Information about competitors' relative quality

2.2 Incentives and disincentives

Licensure systems are required for participation in an industry. EQA programmes work because the hospitals, laboratories, blood banks, and clinics who are assessed find it worth their while to participate. This can be for a number of reasons, both financial and non-financial (Box 5).

At the same time there are disincentives to participate in accreditation programmes, as illustrated in Box 6.

Box 6: Potential costs of participation in accreditation programs

- Added workload for staff and administration
- New instrumentation needed to meet standards
- Stress associated with compliance efforts
- Cost of survey
- Cost of membership
- Risk to staff morale if not accredited
- Risk for sales or reputation if knowledge of non-accreditation becomes widespread
- Risk that purchases/clients will shift away from a facility if a low grade is given

Accreditation programmes in OECD and developing countries have worked to alter the cost-benefit balance in a number of ways, often through intervention by governments or international donor agencies (Box 7). Governments that are purchasers of medical services can link purchasing to accreditation as mentioned above. More directly, governments or donors can subsidize all or some of the cost of accreditation membership and survey expense. Start up costs of accreditation organisations have been subsidized in a number of cases by bilateral and multilateral aid agencies.

In order to be more attractive to potential participants some programmes reduce the risk of receiving a poor evaluation score. Accreditation programmes have been accused of lowering standards or extending deadlines to reduce the risk of non-accreditation: organisations don't fail, they simply never complete the process.

Box 7: Ways of increasing benefit of participating in an accreditation program

- Accreditation is a pre-requisite for contracts
- Subsidy of membership
- Subsidy of survey expense
- Organization support during start-up years
- Adjusting standards so no organizations fail
- Optional publication of accreditation results

Finally, many accreditation programmes do not publish or otherwise disseminate rankings – so while a facility may have a graded score representing poor quality, what will be made public is only a certificate demonstrating accreditation.

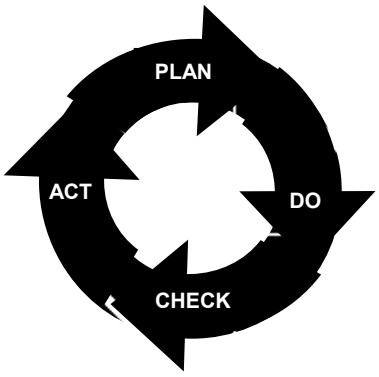
Because accreditation, unlike licensure, is voluntary, adapting it to the level of quality and ability of participating organisations should be seen as an acknowledgement of reality, rather than a 'dumbing down' of standards. Accreditation programmes are already setting sights higher than the minimum; to be relevant to the accredited organisations, the standards must be achievable.

2.3 Ratcheting quality standards

Accreditation programmes improve quality in a number of ways, building upon existing organisational strengths. Strong management, motivated staff, community awareness and 'buy-in' to the process at all levels have been shown to be critical in achieving and retaining the quality improvements associated with meeting programmes standards (WHO 2002 - draft; Ginsburg and Hammons 1988).

In the most successful accreditation programmes quality improvements take place in the context of a consulting process that is designed to assist the organisations in meeting their own goals for quality care or quality service.

Box 8: PDCA: a model for continuous improvement



It is this process of evaluation, prioritization, action, and re-evaluation, the cycle of Plan Do Check Act (PDCA), which is central to quality improvement over time (Box 8). The actual processes of implementation in healthcare assessments are more complex, and exist in incrementally more detailed versions. One example of a more complete PDCA process adapted to healthcare is shown in Box 9. It is a variation on processes used by the US accreditation programme JCAHO, and by ISO 9000:2000.

BOX 9. A sample Quality Assurance Process for healthcare

1. *Planning* for quality assurance
2. *Developing guidelines* and setting standards
3. *Communicating* standards and specifications
4. *Monitoring* quality
5. *Identifying problems* and selecting opportunities for improvement
6. *Defining* the problem operationally
7. *Choosing a team*
8. *Analyzing* and studying the problem to identify its root causes
9. *Developing solutions* and actions for improvement
10. *Implementing and evaluating* quality improvement efforts

Adapted from: Quality Assurance Project (Brown et al.)

2.4 Relationship to government regulatory bodies

In theory, accreditation is supplemental to government licensure. In practice, that is not always the case, but when accreditation programmes are set up to replace licensure, conflicts of interest are inevitable.

Accreditation or other voluntary EQA programmes have three potential advantages over mandated requirements.

First, they can support an improvement process, through non-punitive consultations. Second, by setting standards at an 'achievable' level, rather than a 'minimum' level, accreditation can be a target for improvement. Finally, because accreditation standards are not intended to be fully achieved, they allow for ranking of participating organisations against one another, much in the way that hotels or restaurants are ranked in many countries (Box 10).

Box 10: Advantages of voluntary accreditation

1. Support improvement process
2. Provide standards to serve as achievable goals
3. Allow comparisons between organizations

With all of that said, the relationship between accreditation and regulation is close and ongoing for most programmes. In the United States JCAHO accreditation is a pre-requisite for government reimbursement under Medicare and Medicaid. As a result it is effectively mandatory for most hospitals. The AABB accreditation standards for blood banks have been adopted by the state of California as state licensure standards. In Europe as well also some accreditation programmes are mandatory (Shaw 2000; Scrivens 2002).

In general, however, while governments have often been active in encouraging the development of accreditation programmes, they have also recognized the benefit of having the programmes be independent.

If an accreditation programme is initiated as a result of government interest it must have a broad base of support in the health, justice, and finance ministries in order to be viable.

In many cases the push for an accreditation programme can be attributed to an individual or a small number of active individuals within or associated with the ministry of health (Whittaker and Rooney 1999; Nizankowski 2001). While this is often effective at starting a programme, it creates liabilities for sustainability. If these individuals leave office, lose interest, or are unable to generate enthusiasm to support the programme before it attains financial self-sufficiency (at least three to five years) there is no assurance that a programme will survive (Rooney and Ostenburg 1999; WHO 2002 - draft).

Accreditation programmes in both Brazil and Zambia have had significant problems due to overdependence on government involvement (Bukonda et al. 2002). In both instances accreditation programmes were developed at the request of government bodies, with international assistance, but had not achieved independent status before changes in government decreased the support provided to the organisations. The continuation of those programmes is in some doubt as a result.

In countries where the government operates all or some hospitals (or other healthcare organisations) the relationship between government and assessment organisation is more complex. There is some experience, from France, Belgium and Scotland, of governments mandating accreditation of hospitals and creating independent accreditation organisations to implement the process. Because the government owns the hospitals, they are the purchasers of accreditation services, and this has worked.

In South Africa districts have contracted with COHSASA, a non-profit accreditation organisation, to accredit government hospitals and clinics. The direct costs of participation are borne by the district, making participation more attractive to the hospitals. The experience in Canada is similar to South Africa, with the government contracting with CCHSA, an independent body, for accreditation of federal hospitals.

2.5 Economic models

Purchasing any good or service involves transaction costs. These costs are the unavoidable expenses incurred to research potential transactions, produce written or verbal contracts, and enforce compliance. The greater the information differential between purchaser and seller, the greater the transaction cost because of the increased difficulty for the purchaser of assuring that they receive value for money, and correspondingly increased risk of not receiving the correct value for their payment (Williamson and Winter 1993).

Healthcare has a high 'information asymmetry' because clients and payers cannot easily judge the quality of what they purchase.

Accreditation programs can make markets more efficient by allowing payers to better judge what they pay for.

In an efficient market, where quality is indicated by accreditation, quality-based competition will result, and quality will improve.

Competition is often put forward as a driver for quality improvements, but competition will only lead to greater quality where purchasers have information about the services they buy (Ginsburg and Hammons 1988). Where little or no information about quality exits, providers compete only on price, and quality suffers because all incentives are to reduce

costs in order to lower prices. Accreditation or other quality assessments have the potential to greatly reduce transaction costs by giving credible information about organisational quality (Viswanathan and Salmon 2000).

There are health related products and services which are more or less adapted to outsourcing by governments (Preker, Harding et al. 2000). Whether a government produces or purchases healthcare services, the need to evaluate quality levels reliably in order to price them is similar. The potential benefit of an external assessor of quality is unchanged.

The extent to which accreditation programmes do, in fact, reduce market asymmetry is dependent upon their ability to measure quality in ways that are actually relevant to outcomes. To assure this happens it is important to chose the right model of assessment, and assure the reputation of the assessing body. Corruption or the risk of manipulation of assessment results will lower the value of accreditation as an indicator of true quality, and must therefore be planned for and guarded against in situations where corruption is endemic.

2.6 Who benefits

When quality improves, patients benefit. This is true if the improving organisation is a hospital, clinic, homecare provider, or blood bank. In a review of twelve experiences with external quality assessments in eight countries, WHO found that in most cases there was evidence that the quality of services did improve (WHO draft 2002). An unpublished quasi-experimental study of COHSASA, the South African hospital accreditation programme, also found statistically significant improvements on a number of quality indicators resulting from accreditation participation.

Providers benefit from accreditation indirectly: from the pride of association with a recognized institution of quality, from satisfaction with better outcomes, and probably from greater efficiency in the operation of their support staff. If directly involved in accreditation-related facility improvements, their personal skills may be enhanced through participation. However, the available evidence indicates that they may work harder and be constricted by more pre-set processes, and the effort to make quality improvements and achieve accreditation involves a significant additional workload for medical personnel. The reaction of providers to accreditation is likely to be mixed, depending upon what results from the improvement and evaluation process, as well as their personal and group buy-in to the procedures.

How staff view accreditation appears to depend to a large extent upon the particular instances of the process, its introduction and management, and the support given by administration. In nearly all of the WHO review cases staff felt a significant additional burden as a result of the accreditation process. One conclusion of accreditation experience in developing countries is that the quality can be improved through better processes, and without significant additional financial resources. However, time and effort from administrators, medical personnel, and support staff are always necessary. The extent to which staff find this investment worthwhile depends on their early involvement in the quality improvement process and pride in accreditation or certification as a visible result of their effort.

Box 11: Who benefits

Patients
- Benefit from improved quality

Providers
- Benefit from association with a reputable facility
- Suffer from increased workload

Staff
- Benefit from job satisfaction and pride if involved in process
- Suffer from increased workload

Organizations
- Benefit if…
  - Larger organization
  - serve high-end of market, or
  - quality conscious
- Suffer if…
  - Small organization
  - Serves middle or low-end of market where clients less willing to play extra for quality

The value of EQA to a healthcare organisation depends to a great extent upon the economic incentives described in section 2.5 above. For high-end facilities, where potential clients are willing and able to pay a premium for quality care, accreditation is likely to be beneficial. Likewise, accreditation or other EQA offers a valued and unique opportunity for organisations which are highly quality conscious because of inspired leadership, organisational mission, or supra-facility priorities. It provides the means to use professional guidance not only to self-evaluate against accepted quality standards, but to plan how to move from an existing quality level to a higher one.

Because appreciation of the potential benefit of accreditation requires a level of abstraction from day-to-day operations, larger organisations are likely to value accreditation more than small facilities. In addition, while the costs of surveys are adjusted to facility size, in developing countries in particular, transportation is a significant part of that cost, so while the direct cost of accreditation may shrink in proportion to the facility size, the total costs will not decline as much. Small facilities will find the costs of surveys and compliance more onerous than large facilities in proportion to their budgets.

Accreditation of individual providers has not been effective. An attempt in the United States in 1998 failed after two years, despite being supported by both JCAHO and the American Medical Association. A pilot program in Cambodia set up by the London School of Hygiene and Tropical Medicine and Options Consultancy Group was never able to sustain provider interest. In New Zealand, the Te Wana Quality Programme has had some success in accrediting community based health services, but its finances remain uncertain.

Franchise programmes, such as Green Star in Pakistan, Janani in India, or CFW Shops in Kenya, have been able to achieve measurable quality improvements at the level of private providers, but only through a much more intensive involvement with the providers than straight forward EQA programmes. This in turn has been possible only through significant donor support for the programs. While there may be an intermediary level of quality accreditation at the provider level, it will inevitably require external funding, and as yet no established model exists.

Most healthcare organisations in developing countries, that do not serve the wealthy or have a strong driving moral mission, are unlikely to seek out accreditation unless the

costs of participation are subsidized and/or there is another strong external incentive to join an accreditation process.

3 EXPERIENCE IN INTERNATIONAL ACCREDITATION / EQA

Most international experience in accreditation is from OECD countries. However the number of developing countries with accreditation programmes is increasing, and resources, included draft standards, are available from many countries. Links to specific accreditation programmes can be found in ANNEX A and to research resources in ANNEX B.

For the majority of healthcare organizations in developing countries, which do not serve the wealthy or have a strong driving moral mission, if there is no strong external incentive to join an accreditation process, it is unlikely they will seek it out unless the costs of participation are subsidized.

A forthcoming ISQua/WHO report on 36 accreditation programmes includes summary information about accreditation programmes, their relationship to governments and their development. The report found a strong degree of similarity among programmes, and a significant increase in the pace of programme development. A selection of findings is presented in Box 12.

Because the accreditation experiences and issues are so different for health services and for laboratory-based facilities, this paper reviews experience of the two categories independently. However, in practice, there is overlap in organisations that accredit both types of facility, and often both types exist in one single institution – so hematology departments of hospitals are accredited in the context of the full hospital, and blood banks are accredited based on their service components insofar as they draw and distribute blood and blood products.

3.1 OECD experience

Accreditation organisations exist on a national scale in many OECD countries. A number of countries (USA, Australia, UK, France, etc) have more than one accreditation system for hospitals. Accreditation for blood banks in the US is done through AABB. In Europe blood bank accreditation is primarily done by ISO for reasons discussed below.

OECD experience in accreditation demonstrates the viability of the accreditation system, at least in wealthy countries, but more importantly the OECD accreditation programmes have produced a plethora of standards, many of which have already been adapted to developing country settings.

The International Organisation for Standardization (**ISO**) grew from manufacturing industry into service assessment, addressing specific issues in healthcare beginning in 1987 with the introduction of ISO:9000 -- a ‘generic management system standard’

focusing not on specific industries, but on processes of quality assurance. ISO:9000 series standards have been used as a basis for certifying quality at hospitals in a number of European countries, particularly in Germany and Switzerland. Because of the focus on process, rather than outcomes, many people believe that ISO standards are better suited to laboratory, radiology or similar technical departments, rather than to whole healthcare facilities. The 2000 revisions have addressed some of these concerns, but experience with ISO certification remains primarily in technical rather than clinical areas.

Box 12: International experience in accreditation program development – excerpted from a WHO/ISQua survey of 36 programs worldwide.

- Although 11 countries report legislation related to accreditation most programs are not based on government mandate. Only France and Italy make hospital accreditation compulsory.
- Half of the programs are partially funded or managed directly by governments; except for Taiwan, the long-established programs are independent of government.
- Accreditation is becoming more popular: in the 32 years up to 1990 five responding programs started operations. In the subsequent five years, six more programs began, and 13 in the five years after that.
- Most programs established in the last five years are government sponsored; accreditation is increasingly used by government as a means of regulation and public accountability, rather than for voluntary self-development.
- Developing the accreditation programs took between 1 and 15 years, averaging 3.5. Some programs (Canadian CCHSA and Australian QIC) grew from existing organizations.
- Most programs focus on secondary and tertiary care. There has been a shift in recent years towards accreditation of primary care, particularly in developing countries, presumably a result of both growing attention to population-based medicine, and donor interest in primary care.
- Approximately half of the programs provide their standards free or at minor cost.
- Nearly three quarters of the programs acknowledge that standards were influenced by a specific external model, most commonly the USA, Canada, or Australia.

Source: Shaw 2002. Draft

Since 1995 the Australia-based International Society for Quality in Healthcare (**ISQua**) has served as an information exchange for national accreditation programmes. Among ISQua activities is their Agenda for Leadership in Programmes for Healthcare Accreditation (**ALPHA**), which has developed standards for the activities of accrediting bodies. It is essentially an accreditor of accreditation organisations. Participating organisations represent both OECD and developing countries.

A description of the major OECD accreditation programmes can be found in ANNEX A.

Box 13: Lessons from OECD accreditation programs

- International standards exist for the operation of accreditation organizations (ISQua)
- Numerous standards exist for free or to purchase for nominal fees
- Costs for accreditation decline as volume increases: successful programs have many members
- ISO certification of blood banks works in Europe and is similar to AABB standards in the U.S.
- Accreditation of providers has proven difficult on a large scale

3.1.1 Focused accreditation

Focused accreditation refers to a selective review of one or more functions in a healthcare organisation (Silimperi 1999). Carried out by assessment teams, which often include community representation, focused accreditation is increasingly common in primary care settings.

Internationally the best-known focused accreditation programmes are WHO/UNICEF's Baby Friendly and Mother Friendly Hospital initiatives. The Baby Friendly Initiative has been successful in accrediting hospitals with regard to their breastfeeding promotion activities. However standards, payment mechanisms, and both international aid and government support vary from country to country, raising questions about the sustainability of these as models.

In the United States the Planned Parenthood Federation of America (PPFA) has 128 member affiliates, all of which are accredited regularly as a condition to Federation membership and use of the Planned Parenthood logo. Within the PPFA organisation, accreditation of affiliates is located in the Affiliate Consulting division: consulting is free to affiliates, which makes the accreditation process more supportive than combative.

Box 14: Focused Accreditation

- Looks at specific functions of a healthcare organization
- Example: Baby Friendly Initiative – Certifies hospitals as breastfeeding-supportive
- Easier to involve communities
- Inefficient way of improving overall quality

3.1.2 Technical accreditation experience

Technical healthcare organisations or hospital divisions such as transport, radiology, laboratories, transfusion and blood banking, and medical engineering are well suited to

focused accreditation. These functional areas are often accredited by their own accreditation professional bodies in addition to or independent of overall medical organisation accreditation.

In the US this means that while JCAHO accredits transfusion departments, the American Association of Blood Banks (AABB) also accredits these departments. In Europe ISO certification of technical hospital departments or of independent laboratories is the most common application of EQA of any sort.

The AABB accredits the majority of blood banks and transfusion centers in the United States. This is partly because AABB accreditation is inexpensive in proportion to the scale of centralized blood banking services in the US, and partly because the benefits of accreditation are especially significant in demonstrating that every effort has been made to assure the safety of blood and blood products. FDA licensing of blood banks in the US is very strict; as a result, the AABB process is seen by blood banks as useful to assist in preparation for FDA review. That AABB, rather than ISO, is the standard in the US is at least in part the result of this strict FDA oversight of the industry, which provides strong incentives for continuous improvement of blood banking facilities.

3.2 Developing country experience

Accreditation and EQA experience in developing countries is less extensive and less well established than in the OECD, however in the past decade programmes have started in a number of countries which serve to provide lessons on models, standards, and the process of application.

A significant difference between accreditation programmes in developing countries and those in OECD countries is in the use of strictly volunteer assessment teams. In the OECD there is some movement away from volunteer-only accreditation programmes as a result of the increasingly complicated technical training expected of evaluators. Nonetheless volunteers are significant in most programmes.

In developing countries accreditation by volunteers is rare. In part this may be due to the comparative youth of most programmes, and their subsequent need to prove their professionalism. Another possible explanation for more professional assessments is the issue of quality assurance in the accreditation process and the risk of corruption.

The forthcoming Shaw and Portela/Mehaffay WHO/ISQua publications give a comprehensive overview of accreditation programmes in developing countries. Listed below are a sampling of global experiences.

The Council for Health Service Accreditation of Southern Africa (**COHSASA**) grew from a university-based pilot project in 1992 and became a registered non-profit accreditation organisation in 1995. COHSASA accredits both government and private hospitals through a multi-visit consultative process. COHSASA's 3,500 standards were developed independently, with post-facto alignment with JCI/JHACO standards. When accrediting government hospitals it is the district which pays, rather than the hospital itself. An average accreditation cost is US$15,000 of which half is attributed to travel expenses.

In Malaysia the Ministry of Health initiated development of the Malaysian Society for Quality in Health (**MSQH**), now an independent non-profit organisation. MSQH was

registered as a legal entity in 1997, and worked with a WHO consultant to adapt Australia standards to Malaysia. Since 1999 MSQH has provided quality management training to 70 hospitals, and accredited 1 private and 22 public hospitals (up to April 1, 2002).

With support from the USAID-supported Quality Improvement Project (QIP), the Egyptian Ministry of Health and Population created a series of 'centers of excellence' among the government family planning clinics. Clinics are evaluated by the MOH. Those that meet quality standards are certified as 'Gold Star'. A well-funded advertising campaign has promoted Gold Star centers as providing high quality, resulting in greater client demand, and provider desire to associated with a recognized quality clinic. The Gold Star system has been duplicated in a number of countries. It is fully government/donor funded.

In 1996 the State Secretariats of Health of Bahia and Ceara collaborated with Management Science for Health (MSH), Johns Hopkins University/Center for Communication Programmes, and JHPIEGO, to develop a quality assessment programme with documented standards. Like the Egyptian Gold Star programme, **PROQUALI** standards are assessed by the State Health Secretariat, and are applied only to government facilities. Reports of PROQUALI suggest that quality improved, but that staff motivation was uneven, and quality improvements were not always sustained after the external assessment.

At the request of the Zambian MOH, USAID supported the Quality Assurance Project (QAP) to assist in developing a national accreditation programme for the 77 public and 3 private hospitals in the country beginning in 1997. An advisory board, the Zambia Health Accreditation Council (**ZHAC**) was formed with participation from a wide range of professions. Process-focused surveys were developed by the ZHAC and QAP and pilot tested in 1998. Although it was planned to introduce legislation creating an independent, non-governmental, accreditation organisation, this did not happen, and the accreditation process remains under the MOH. Since the end of USAID funding in 2000 anecdotal reports suggest a decline in programme momentum.

MSS, the Pakistan affiliate of Marie Stopes International (MSI), provides a range of reproductive health services through a network of 30 clinics in urban areas throughout the country. All MSS clinics have been ISO 9002 certified since 1999. Certification assessments were conducted by the UK-based United Registrar of Systems, with ongoing surveillance audits planned every six months. Although there have been complaints about the additional workload, there is agreement by staff that quality improved as a result of the certification process. MSI Sri Lanka has recently decided to seek ISO certification.

3.2.1 International quality assessment of developing country organisations

There are many hospitals, blood banks, laboratories, and medical systems in developing countries that are assessed by OECD-based EQA programmes. Most important in international EQA have been ISO and JCI, the international branch of JCAHO. The UNICEF/WHO Baby Friendly Initiative programme, AABB, and other organisations have also provided assessments to facilities, particularly in Asia and South America.

Assessment and certification of this kind is not the focus of this report. In general the assessed facilities are exceptional performers – either high-end hospitals (eg: Bumrungrad Medical Center in Thailand, Hospital Israelita Albert Einstein in Sao Paolo Brazil), facilities from wealthy but non-OECD countries such as Saudi Arabia, or facilities with a unique concern for quality (MSI Pakistan, Jeevan Blood Bank in Chennai, India).

While the experiences of these facilities are important in evaluating accreditation and EQA in an international context, they do not provide models for widespread accreditation of healthcare facilities in specific countries. International EQA is expensive, uses high level standards relative to national quality levels, and does not address the different incentives between high and low end facilities and the lack of national incentives associated with accreditation.

3.3 Lessons learned: what works in developing countries

As has happened with all service and manufacturing assessments, healthcare EQA has shifted from assessment of quality (TQM) to assessment of quality management processes (CQI).

Experiences from twelve accredited organisations in eight countries led WHO to a conclusion similar to that reached by the manufacturing industry as a whole: facility-level process involvement is integral to successful quality improvement. Personal and continued investment of staff in quality as a continuing process is necessary for quality changes to be sustained. This only happens if the quality assessment programme is also sustained.

Box 15: lessons from developing country accreditation programs

- Trend to professional or professional / volunteer mix for surveys (no volunteer only programs)
- Programs usually accredit both private and public hospitals
- Standards can be adapted from existing models or locally developed
- Locally developed standards tend to align over time with international standards
- Government / donor funding is common
- Sustainability is determined by:
  - Credible business plan for accreditation income to cover costs
  - Sustained government support
- Government support can be:
  - Direct organization support
  - Purchasing of services
  - Incentives for private organizations to participate in accreditation

For accreditation/EQA programmes to be effective, they must have the support of governmental licensing and health service bodies. Ministry of Health representation on accreditation boards is common and desirable. More importantly, MOH commitments to paying for accreditation of facilities is common, and probably key, to the acceptance of accreditation in countries where health facilities are commonly government operated (eg Zambia, Brazil, South Africa, New Zealand, Taiwan).

In many instances, particularly in developing countries, it has been MOH interest that has driven the development of accreditation bodies. This has risks. Political changes, shifting personnel, or more immediate needs can undermine the support of an accreditation programme by either removing financial backing, or simply indicating to participating hospitals that

the ministry does not take the process seriously (Brazil, Zambia).

Support to the creation of accreditation organisations by international agencies has involved technical assistance in the adaptation of established standards to local conditions. In the best of cases this has involved extensive consultation with local experts and the public. Direct financial support for newly created accreditation bodies has also occurred. This is needed, as it is unlikely that any medical accreditation body can achieve financial self-sufficiency in less than three years. Experience from Zambia's hospital accreditation programme shows the risk in not planning for organisational independence, both financial and political. Community involvement in development of accreditation or EQA standards is important, particularly in primary care service. It is necessary in order to prioritize the types and grading of measures addressing client treatment, processing, and satisfaction in all levels of service involving direct patient care.

Having appropriate and credible measures is critical to the reputation of the accreditation programme among end users. Community involvement in standard creation is not as important an issue for blood banks, laboratories and other technical service areas.

4 PUBLIC-PRIVATE INTERACTION IN QUALITY MANAGEMENT

EQA exists at the intersection of public and private interests in the healthcare service industry. As an external process, accreditation and other quality assessment systems provide a degree of objective reporting on the healthcare sector that is difficult to obtain otherwise.

Government over-involvement in accreditation programmes is dangerous because of the conflict of interest inherent in the MOH conducting evaluations of its own activities. At the same time, government interest in, and support for, accreditation is the result of desire to improve the quality of both public and private healthcare organisations, and is often instrumental in developing an accreditation programme.

The benefit of accreditation may justify government support:

- **Increased awareness of quality**
- **Ratcheting upwards of average quality**

The benefits of an accreditation programme are significant enough to justify governmental support in many cases. Objective ranking of quality among facilities provides an aid to health ministries for a number of reasons. It increases awareness within the facilities of their quality standards vis-à-vis comparable organisations, which has a ratcheting effect. It can increase awareness of quality issues – both good and bad – among both the general public and government funding agencies, producing public support for facility improvement, oversight funding, or the continuation of well operated MOH programmes.

Accreditation programmes can help governments (and individual clients) select healthcare organisations on the basis of their quality – for funding, increased regulatory oversight, closure, or contracts. Licensure does not achieve these goals, and although an effective licensing programme, with its concomitant site visits and evaluations, has many similarities to accreditation. Neither one can be a substitute for the other.

4.1 Mandated versus voluntary accreditation programmes

Voluntary participation in an accreditation or EQA programme has the advantage of buy-in and commitment on the part of assessed organisations, which appears to be integral to the effectiveness of programmes in promoting a culture of improvement, necessary for sustaining quality advances. When participation is mandated, accreditation or other EQA systems become another form of licensure, with more weight on the threat of failure, and correspondingly less likelihood to use the process as an outside consulting experience to assist in in-house improvements, as is the case in the best accreditation programmes.

Box 16: Benefits of voluntary participation in EQA

- 'Buy in' by participating organizations
- Consulting to assist in positive change
- Credibility

Mandated and voluntary assessments have different goals, different incentives for the assessed organisations, and as a result are likely to achieve different results.

4.2 Local versus international accreditation

International and local accreditation have both proven effective in developing countries. However, even the organisations most involved in international accreditation feel that local ownership is more sustainable and therefore a desirable goal. The cost of international accreditation is high in most experiences and likely to remain so except for rare cases when demand for accreditation is strong enough to support an established local branch-organisation or subcontractor, as is the case for many ISO manufacturing programmes, but not yet for health-specific programmes.

The credibility of international assessment organisations is often higher than local equivalents, which justifies the additional expense. The reputation established over years, and in an OECD country, cannot easily be recreated. Reputation has driven the popularity of ISO 9000 series licensure among manufacturers, for both export goods and locally consumed products.

Box 17: Local vs. international accreditation

- Less expensive
- Lower credibility – confers less 'market advantage' to participating organizations
- Serve broader range of organizations
- Standards appropriate to local conditions

Involvement of international accreditation organisations in the development of new programme standards therefore has a credibility value beyond the immediate benefit of rapid ramp-up due to experience and adoption of base standards. Association with an international accrediting assessment body such as ALPHA would also help establish this credibility.

The importance of this depends on the degree to which: consumers of healthcare services (either individuals or purchasers, from governments or insurance companies) are sceptical of their provider choices; educated about local and international standards;

willing to adjust purchasing behavior in response to quality information; as well as the existence of competition in the healthcare industry in general.

One argument for local, rather than international accreditation programmes, particularly for healthcare, is the positive experience of context-specific adaptation of international standards to local conditions. The adaptation can be local (e.g. New Zealand), or technical (AABB experience in the Caribbean). Adaptation can be specific (e.g. parental consent for certain services) or more general alignments to existing quality levels so as not to create standards that are unachievable by the majority of participants.

4.3 The potential roles for government in accreditation programmes

Government involvement in accreditation programmes can happen in a number of ways, specific to the structure of the medical industry of each country. Government support for accreditation programmes is often direct: funding the creation of the organisation, paying for international consultants in order to assist in adapting established standards, training of assessor, and structuring assessments and rankings. In a number of instances this support has been provided primarily through donor funds.

The independence of the accrediting organisation and a timeline for projected funding sources and ultimately for financial self-sufficiency are critical. Without this, or where uncertainty exists about the market demand for accreditation among healthcare providers, governments and donors wishing to support accreditation programmes must make a commitment for continued support over a long period. They must also think through a programme to promote market demand.

Box 18: Potential role of government

- Support organizational development
- Subsidise membership
- Increase licensure enforcement and harmonize licensure and accreditation standards
- Purchase accreditation for public facilities
- Make accreditation a condition/priority for contracts with public sector
- Work with insurers and other large purchasers to make accreditation a condition/priority for contracts
- Provide other benefits for accredited organizations, such as streamlined payments, priority re-licensure, etc.

4.3.1 Intervening to build market demand for accreditation

An MOH can intervene as a purchaser of medical services, making accreditation of suppliers either a requirement or a basis for higher reimbursement rates or faster reimbursement. Where governments are large contractors of healthcare this is the most important possible intervention. To support this, a government might coordinate with large purchasers of healthcare – insurers, private pensions, or other groups - to link payments to accreditation. This could be used for all types of services including laboratories, hospitals, or hospital groups.

Where governments are providers of services rather than purchasers, accreditation can be recommended to sub-national administrative levels, and the cost of accreditation borne fully or partially by federal or provincial ministries. This has worked in Brazil and

South Africa. It is important that hospitals receive support to participate in what can be a time taking and difficult process, and that they receive administrative recognition when accredited.

Where governments are neither purchasers nor providers of services, intervening to build a market is more complicated, and probably needs to take the form of a commitment to subsidized advertising and information campaign. This will inform service purchasers (individuals, companies, pension plans, or insurers) of the existence, value, and usefulness of accreditation so that being accredited becomes a worthwhile business proposition for healthcare facilities: public demand for accredited services will increase their client-load or allow them to charge a premium or both.

Finally, as is the case with blood banking in the United States, licensure requirements and accreditation standards can be aligned over time. However, this can only be effective where strong enforcement of licensing standards exits.

4.4 Justification for government intervention in accreditation programmes

EQA has significant potential for social benefits that are greater than its costs. As such, the support of independent quality assessment programmes, their development and continued existence, should be of interest to governments. Judging by the recent growth in accreditation programmes around the world, commonly with legislative or regulatory support, this is the view of many governments.

To the extent that accreditation or EQA programmes communicate their results, they provide information on quality that is almost impossible to find out otherwise. In healthcare, informational asymmetry has an important role in raising the cost of transactions and making the procurement of health services inefficient, both for large contractors and individual.

Accreditation can play an important role in communicating quality information and increasing efficiency in the health sector. When sufficiently widespread, accreditation serves to increase the overall quality of the health sector by providing both information on quality and feedback on structures necessary to achieve quality in a form that promotes benchmarking and internal organisation improvements.

4.4.1 Equity

The experience in developing countries, particularly in South Africa with the COHSASA programme, is that accreditation programmes are able to increase equity, by raising the standards for care in incremental stages. This is most important for facilities serving the urban poor or rural areas. Funding available for management of quality assurance systems (stock verification, process monitoring, etc) is particularly low in these facilities. The COHSASA experience has shown that small facilities serving marginalized populations often benefit the most from the consulting support and achievable standards which accreditation incorporates.

Similar experience has been documented in Pakistan where the quality of services targeting low-income populations has been improved through EQA, and in New Zealand where small facilities have benefited from the adaptability of accreditation norms.

The success of EQA programmes in increasing equity is largely due to the commitment of purchasing organisations (NGOs, individual facilities or governments) that either fully or partially subsidize the participation by smaller facilities serving marginalized populations. The commitment of direct funding or subsidy of assessments is more important for small facilities than large ones. With that support, smaller institutions are often likely to benefit highly from EQA, particularly from accreditation, with resulting increase in quality of care, including drug availability, making significant differences for the populations they serve.

COHSASA's experience provides an example of how standards and the consulting support of an accreditation program can improve the availability of quality care for the poor. One of the essential functions evaluated by COSASA is that each facility should be guided by a mission, adequate funds should be assured to accomplish that mission, and regular internal checks and clear chains of responsibility should exist at every level of the organization. These are simple enough steps, but assisting smaller and poorer facilities to put these functions in place and assuring their application often makes a tremendous difference in quality. First, it can highlight where facilities are underfunded, and second, it can assure that available funds are used as strategically as possible, maximizing the efficiency of all facilities and evaluating the appropriate level of services offered in comparison to equivalent health centers.

While COHSASA's accreditation programs do not explicitly address issues of equity within an institution – for example access to services by poor users – if proving access to all clients is part of an institution's mission, COHSASA or equivalent accreditation programs will evaluate how well an institution is able to carry out this aspect of its mission, and provide guidance on improving this area of service provision. Equity is a byproduct of efficiency improvements when there is an organizational desire for addressing equity issues.

4.5 Risk of government intervention in accreditation programmes

Accreditation cannot replace licensure or substitute for effective monitoring of minimum operating standards – it cannot be a low-cost escape from regulation. The effectiveness of accreditation is dependent upon its voluntary nature, non-threatening process, and positive consulting as a means of effecting quality improvements. As a result, some organisations will not participate.

If the incentives to participate are not strong enough, government-supported local accreditation will act like international EQA: attracting only the exceptional centers with a special concern for quality and those serving the wealthy. This could have a negative effect on overall care: pulling the best providers away from mid-level organisations, and increasing the differences in quality between high-end facilities and the rest. If only a small percentage of organisations participate in an accreditation programme, the result may be a misuse of government subsidies and energy.

5 APPLICATION IN DEVELOPING COUNTRIES

The most likely application of accreditation or other quality assessments programmes will be hospitals and blood banks as they are the health organisations large enough to be able to justify the costs of accreditation.

5.1 Hospitals

An increasing number of hospitals in developing countries are seeking ISO 9000 certification. While significant, ISO certification remains attractive only for hospitals in competition for wealthy private clients. Seeking ISO certification has not become commonplace among hospitals and has not been encouraged for government facilities in any developing country. As such, it is not likely to be a model for overall improvements among hospitals in general.

Local accreditation programmes in some developing countries, most notably South Africa and Malaysia, have been successful in creating standards that are achievable, and appear to have made a difference in both quality and client perception. These programmes have become sustainable due to the willingness of governments and participating facilities to pay for the services.

5.2 Blood Banks

In some countries blood banks have received overseas certification or accreditation. In India some of which report having received AABB accreditation in 1985, and blood banks have ISO 9000 certification in many countries. Nonetheless the numbers are small relative to the scale of the blood banking industry. The trend, rather, is towards local accreditation. In Brazil, the Caribbean, and elsewhere, independent blood banking accreditation programmes exist or are being created.

5.3 Preconditions for new accreditation programmes

Incentives for participation in any EQA programme must be built into an effective licensure and oversight programme. The effectiveness of these incentives must address the cost of participation, both in terms of changes and effort needed to comply, and any annual and survey related fees.

To be sustainable, an accreditation program must be able to generate income through fees.

The sustainability of accreditation programmes or organisations is closely linked to their ability to raise their own funds through fees. Long-term dependence on subsidy leaves an accreditation programme overly reliant upon foreign donors and the continuity of political parties, individuals, and attention. In order to assure sustainability a programme must have a planned schedule for eventual organisational support through fees, which would be applied equally to government, private, and NGO blood banks.

Any accreditation programme should have a mix of professional and volunteer surveyors, the former being a requirement for professional evaluation, the latter offering potential to provide transfer of experience quickly in an industry where operations and supply are often highly fragmented and varied by geographic locale.

Random overlap of accrediting visits will further assure rapid dissemination of standards and equality of survey scoring, while protecting the reputation of the programme from accusations of corruption. To further support this any accreditation programme should apply for membership in ISQua's ALPHA programme or regional bodies such as the Asia-Pacific Laboratory Accreditation Cooperation, ILAC.

Box 19: Attributes for an effective accreditation programme

- Independent of government
- Generates revenue through fees
- Has a business plan prior to receiving government/donor support
- Mix of professional and volunteer surveyors
- Wide dissemination of standards
- ALPHA or regional certified
- Adapts standards from existing published standards
- Accreditation supported by increased government oversight of licensure standards

Accreditation standards must be higher than those of mandatory licensure. For instance blood bank standards might require testing for Hepatitis C, not currently required of blood banks in many countries.

Standards must be adapted to the local context, but need not be written from scratch. Building on the 'CORE' standards developed by AABB and adapted by PAHO for use in Latin America or on ISO 17,025 laboratory standards is likely to save time in ramping up a blood bank accreditation programme. For hospitals the many standards developed by JCI or ALPHA member programmes provide templates from which to develop locally appropriate standards.

The final advisory group for any accreditation programme should include a broad geographic representation as well as community representatives. This is necessary assure credibility and support throughout a broadly defined stakeholder group. The credibility of any accreditation programme is its main asset and must be carefully planned for.

5.3.1 Cost recovery and duration of subsidy

Shaw estimates, based on a review of 36 accreditation programmes, that financial self-sufficiency from fees cannot be expected in less than three years and may take much longer (Shaw 2002 - Draft Document). Experience of the AABB, which is assisting the development of a blood-bank accreditation project in the Caribbean, suggests that self-sufficiency may take much more than three years. In South Africa, COHASA became self-sufficient in approximately three years, but the programme in Zambia still requires outside funding five years after its initiation.

Further price information is given in ANNEX C.

5.4 Steps for the development of a national accreditation organisation

If a decision is made to develop an accreditation programme for hospitals or blood banks, issues of funding, legal structure, mandates and enforcement, and relationship to the government, particularly existing health care quality, AIDS and Blood Testing programmemes must be addressed. A working group will need to be established, preferably based outside of the government, in a professional organisation, existing standards accreditation body, non-governmental organisation, or academic institution.

Box 20: Steps in the creation of an accreditation organisation

- Establish a working group outside of the government, with donor, MOH, or private funding
- Evaluate the legislative changes needed to create a viable accreditation programme, beginning with existing policies towards private sector quality, and focusing on incentives for voluntary participation
- In collaboration with relevant oversight programmes and the MOH, draft policy and legislative changes needed
- Prepare a field-tested business plan with a timeline for financial sustainability
- Apply for start-up funding support based on recommended policy changes, and organisational business plan

With funding from government, donors, or local hospital and blood banking organisations, this working group will need to develop the legal framework and business model for an accreditation organisation. This accreditation programme must have sufficient incentives to assure high levels of participation among hospitals and blood banks, and sufficient income to assure financial independence from the government in a realistic time frame.

Finally, the credibility of the business plan must be tested through surveys of medical facilities of varying sized. Once established, a proposal from the working group for government or donor funding, and non-profit incorporation, can lead to the establishment of a fully independent accreditation organisation.

The work of adapting standards, setting prices, developing an advertising campaign and creating a curriculum for training assessors will begin once the organisation is established. These elements should of course be outlined and budgeted in the proposal, and may be well advanced during the working-group stage.

ANNEX A: ACCREDITATION ORGANISATIONS

This appendix provides review of some of the important accrediting and assessment organisations with contact information. More complete listings can be found at the website for ALPHA (listed below), in the draft ISQua/WHO report of 36 accreditation programmes by Shaw, and the article on Licensure, Accreditation, and Certification by Rooney and van Ostenberg, which can be found at www.qaproject.org.

In the United States the Joint Commission on Accreditation of Healthcare Organisations (**JCAHO**) is the oldest established hospital accreditation organisation, now also assessing homecare, laboratories, and a number of other service areas. Because accreditation is a requirement for reimbursement of hospital services under the US government Medicare and Medicaid programmes, and is a de-facto requirement for private insurance reimbursements, 95% of hospitals in the country participate in accreditation programmes (Bergman 1994).

JCAHO has a subsidiary, the Joint Commission International (**JCI**), which does consulting and standards development and adaptation, as well as direct facility accreditation, throughout the world, in both developed and developing countries. JCI publishes its international standards.

The American Medical Accreditation Programme (**AMAP**) was developed in 1998 as a joint project of JCAHO, the National Committee for Quality Assurance (**NCQA**) and the American Medical Association. The goal of AMAP was to accredit physicians and office practices, using criteria that would address both process and patient outcomes. It was hoped that AMAP would eventually replace the patchwork of state and local licensure and accreditation plans with a national standard. There was strong resistance by both providers and hospital plans, and AMAP was discontinued in 2000 with less than 3500 participating physicians.

The Canadian Council on Health Service Accreditation (**CCHSA**) grew out of the American accreditation movement but operates with greater emphasis on education and self-improvement than the former. This is possibly cultural or the result of the differing incentives that drive accreditation in Canada where facilities are all government operated.

The Australia Council on Health Care Standards (**ACHCS**) was created in 1974 and operates in a manner similar to JCAHO and CCHSA. The Quality Management Services (**QMS**) programme was established in 1990 to accredit healthcare human service organisations. The Australian General Practice Accreditation Limited (**AGPAL**) was incorporated in 1997 and accredits 80% of the general practitioners in Australia.

In the UK accreditation is conducted primarily by the Health Quality Service (**HQS**), formerly the Kings Fund Organisational Audit (**KFOA**) scheme, set up in the early 1980s. Based on the Australian and Canadian models, the UK programme differs by focusing primarily on process rather than outcomes, and on education for improvement without the implicit policing functions in the US model (where accreditation is associated with eligibility for federal funding). Clinical audits are not part of the HQS review, and unlike

other OECD countries a number of competing accreditation or self-accreditation programmes exist in tandem to HQS. The influence of the HQS on quality at a national level is therefore less clear than in some other countries.

The Japanese Council for Quality Health Care (**JCQHC**) was established in 1995 with funding primarily from the MOH. JCQHC accredits both private and public hospitals. Similar to the US model, the JCQHC seems to focus on assessment more than education.

New Zealand's **Te Wana Quality Programme** is a community health center accreditation programme developed by a non-profit provider network, Health Care Aotearoa, in conjunction with the Australian Quality Improvement Council (QIC). The programme accredited its first health service only in November 2002, however if effective it will be significant for the degree of involvement by community members in developing accreditation standards.

In the European Union France, Switzerland, Germany, Italy, Ireland, Portugal, and Scotland have all begun accreditation programmes in the past five years.

Below is a more complete summary of the major accreditation organisations with contact information:

Joint Commission on Accreditation of Healthcare Organisations (JCAHO) www.jcaho.org	JCAHO is the oldest healthcare accreditation organisation in the world, having its roots in the 'Minimum Standard for Hospitals" developed by the American College of Surgeons in 1917. In 1951 the American Medical Association, the Canadian Medical Association and the American College of Surgeons created the Joint Commission of Accreditation of Hospitals, later expanded to accreditation of healthcare organisations. JCAHO is a non-profit, non-governmental body. It accredits and advises approximately 20,000 healthcare organisations and programmes, all inside the USA. JCAHO accredited hospitals are considered to be in compliance with federal standards and *defacto* approved for reimbursement by federal programmes (Medicare, Medicaid). On-site surveys take place at least once every 3 years. Costs are borne my participating organisations, who pay membership fees and additional fees for each survey. **Target:** Hospitals, home health, long-term care, behavioral healthcare, clinical labs,

	ambulatory care, health networks. An attempt in the late 90's to accredit physicians in collaboration with the AMA failed due to resistance from providers, competing accrediting groups, and hospitals. **Resources:** numerous standards for differing types of medical organisations.
Joint Commission International (JCI) www.jcrinc.com	Established by JCAHO in 1992, JCI is now a programme under Joint Commission Resources, Inc., an income generating subsidiary of JCAHO. JCI oversees international accreditation of hospitals and other organisations, primarily in the Europe and the Persian Gulf. JCI has also accredited hospitals in Thailand, India, Turkey, and Brazil. **Resources:** JCI has developed international accreditation standards (eg. the 2003 JCI International Standards for Hospitals), and consulted to USAID and other organisations on international accreditation efforts.
International Society for Quality in Health Care (ISQua) www.isqua.org.au	Since 1995 the Australia-based International Society for Quality in Healthcare (**ISQua**) has served as an information exchange for national accreditation programmes. Among ISQua activities is their Agenda for Leadership in Programmes for Healthcare Accreditation (**ALPHA**), which has developed standards for the activities of accrediting bodies. It is essentially an accreditor of accreditation organisations. Participating organisations represent both OECD and developing countries.
Agenda for Leadership in Programmes for Healthcare Accreditation (ALPHA) www.isqua.org.au/isquPages/Alpha.html	An umbrella organisation, under ISQua, which offers accreditation to individual accreditation organisations based on standards of operation. Member organisations represent accreditation organisations in a dozen countries, including Japan, Finland, Malaysia, Argentina, South Africa and others. **Resources:** International Accreditation Standards - International Principles for Healthcare Standards – a framework of requirements and principals needed to structure delivery standards.

Australian Council on Healthcare Standards (ACHS) www.achs.org.au	Started in 1974, ACHS accredits facilities through Australia. Accredited organisations are listed on the ACHS website.
Canadian Council on Health Services Accreditation (CCHSA) www.cchsa.ca	CCHSA became independent from the American JCAHO in 1958. CCHSA accredits both public and private hospitals in Canada. CCHSA standards have been used as templates for new programmes in France, Australia, and elsewhere.
International Organisation for Standards (ISO) www.iso.org	A network of national standards organisations. ISO began as an arbiter of manufacturing standards, however with the publication of ISO9000 series standards in 1994 they established criteria for evaluation service organisations based on processes and principals of quality management.
US Agency for Healthcare Research and Quality http://www.ahrq.gov/	Researches and publishes standards for clinical care.
French National Organisation on Accreditation and Evaluation in Health www.anaes.fr	Accredits healthcare facilities in France and French dependents. Standards available
Council of Health Services Accreditation of South Africa (COHSASA) www.cohsasa.org.za	Independent accreditation body in South Africa, evaluating both private and public facilities. Currently developing standards to accredit HIV/AIDS care and counseling services
Health Quality Service, UK (HQS) www.hqs.org.uk	Formerly the Kings Fund Organisational Audit (KFOA), the HQS is Europe's oldest healthcare accreditation organisation. An independent non-profit since 2000, HQS also has an international consulting branch for development of standards for a range of services, and advising of governments and accreditation programmes, both in developing and OECD countries.

ANNEX B: RESEARCH ORGANISATIONS

A partial list of research and consulting organisations in international accrediation and assessment work.

Joint Commission International (JCI) www.jcrinc.com	JCI has developed international accreditation standards (eg. the 2003 JCI International Standards for Hospitals), and consulted to USAID and other organisations on international accreditation efforts.
Quality Assurance Project (QAP) www.qaproject.org	A USAID-funded project focused in training and research to improve quality of healthcare and healthcare services in developing countries. QAP has been instrumental in a number of recent quality assessment and accreditation programmes. Numerous publications available online.
International Society for Quality in Health Care (ISQua) www.isqua.org.au	Since 1995 the Australia-based International Society for Quality in Healthcare (**ISQua**) has served as an information exchange for national accreditation programmes. With funding from WHO, ISQua has conducted research on international experiences in accreditation.
Clinical Accountability, Service Planning and Evaluation (CASPE) www.caspe.co.uk	A private research unit based in the UK. CASPE focuses on development in outcome and service indicators for quality measurement, and research into comparative peer review techniques in Europe. Recent activities have involved them more in international comparisons.
Johns Hopkins University Center for Communications Programme (JHUCCP) www.jhuccp.org	A large research group affiliated with Johns Hopkins University in the US. JHUCCP has worked on a number of USAID funded project involving the introduction of quality systems. Their focus is often on the IEC side of quality awareness development.
Management Sciences for Health (MSH) www.msh.org	US based research and consulting group with considerable experience, particularly in organisation development and economic analysis.

ANNEX C: INTERNATIONAL EXPERIENCE IN ACCREDITATION COSTS

Actual prices for accreditation experiences are not always easily available. AABB charges a base annual fee of US$800 plus charges for volume and direct expenses related to site surveys. The final fees range from $2,000 to $8,000 per year for facilities in the United States. In India, the Rakjot Blood Bank reports having been AABB accredited under an international clause in the late 1980s but dropped out of the system when the annual fees became too high (close to $10,000). Rakjot is now ISO certified and expects to pay approximately $2,000/year for that.

In Pakistan Marie Stopes International pays approximately $800/clinic per year for ISO 9000 certification of its 30 medical clinics. In South Africa COHSASA charges an average of $15,000 per hospital survey, half of which is directly attributable to transportation costs. In Zambia it costs an estimated $10,000 per hospital; most of this paid by donors. All of these organisations are non-profits and so set prices to be equal but not exceed total costs including overhead and amortization. In Canada annual CCHCA fees are approximately 0.0001 (1/10,000) of facility budget, with additional survey fees aligned to actual costs. Further data on costs are available in the forthcoming Shaw/WHO review of 36 international accreditation programmes.

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