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Accreditation

Guidance on Designing Healthcare External Evaluation Programmes including Accreditation

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2015

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Acknowledgements

This document is based on the Toolkit for Accreditation Programs, 2004 developed by Charles Shaw. The International Society for Quality in Health Care would like to thank the following for their contributions to the development of this document:

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Mark Brandon, AACQA - Australia
Stephen Clark, AGPAL - Australia
Heleno Costa Junior, CBA - Brazil
Carsten Engel, IKAS - Denmark
Eric de Roodenbeke, International Hospital Federation
Carlos Goes de Souza, CHKS - UK
Helen Healey, DAP BC - Canada
Salma Jaouni, HCAC - Jordan
Thomas Leludec, HAS - France
Hung-Jung Lin, JCT - Taiwan
Lena Low, ACHS - Australia
Kadar Marikar, MSQH - Malaysia
Wendy Nicklin, Accreditation Canada
BK Rana, NABH - India
Charles Shaw, Independent Consultant
Paul van Ostenberg, JCI - USA
Kees van Dun, NIAZ - The Netherlands
Stuart Whittaker, COHSASA - South Africa
Hongwen Zhao, WHO
Nittita Prasopa-Plaizier, WHO
Akiko Maeda, World Bank
Dinesh Nair, World Bank
Rafael Cortez, World Bank

A special acknowledgement to Akiko Maeda and the World Bank for supporting this project.

Foreword

Accreditation is an important tool for improving the care delivered by healthcare systems, and one of the key roles of the International Society for Quality in Health Care (ISQua) has been to accredit the accreditors. However, accreditation has to evolve to be beneficial. An increase in requests - especially from developing economies - for advice on establishing an accreditation programme prompted ISQua to review two of its major tools: the Toolkit for Accreditation Programs, 2004 [1], and Checklist for Development of New Healthcare Accreditation Programs, 2006 [2]. The last decade has seen considerable changes, worldwide, to healthcare systems and external evaluation programmes. To reflect these changes, a revision to the existing guidance was deemed inadequate and this new Guidance manual was therefore developed. We believe this document will be suitable for a much wider audience; it is designed for countries, governments and policy makers within public or private, primary, secondary or tertiary healthcare systems. It is also intended as an aid for funding and development agencies such as the World Bank, international aid agencies, the World Health Organization (WHO), Ministries of Health, other government agencies, groups and organisations who want to improve the quality and safety of healthcare in their country, region or specialty area.

It has now been almost 100 years since the first external evaluation programme, known as accreditation, was established. Nearly every country currently has some form of external evaluation, whether voluntary or mandatory. There are both "aficionados" and critics of healthcare accreditation. Anyone who has dealt with accreditors coming into their site has likely felt that they were arbitrary, or focused on things that were less than important. However, accreditation gets organisations to pay attention to things they might otherwise prefer to ignore or put off. While it is sometimes voluntary, following a series of adverse events policymakers then change it to mandatory in response. While traditionally accreditation was a programme for developed economies, developing countries are now equally as interested. This document has extended its scope beyond healthcare accreditation programmes to include other external evaluation programmes such as certification and licensing as they apply to organisations, not individual practitioners. These programmes have different scopes and organisational coverage but are based on the same principle of evaluating and improving performance against a defined set of standards, using external evaluators, to improve the safety and quality of health services for the public.

Accreditation is not a panacea to address all quality improvement issues but it can provide a systematic approach that identifies areas where improvements are necessary, and when mandatory, can "lift all the boats", including some of the less strong entities within our healthcare systems. When used with tools such as checklists and supported by technology, it can become a powerful instrument for healthcare reform.

Developing an external evaluation system is a process that should be designed according to each countries' profile. Firstly, the purpose should be clear and secondly, depending on the desired outcome, a decision should be made as to whether a voluntary or mandatory system is appropriate. This document is not designed as a rigid guideline, rather as a diverse range of practices which should be discussed. It includes advice on best practices for governance, developing standards and assessment methodologies. It also includes real case studies from both developed and developing countries.

Healthcare continues to evolve; some of the key changes occurring today are that populations are ageing, while technology is becoming smarter and the relationships between providers and patients are tilting so that patients are much more empowered, and they are becoming our partners. We all need to strive to reach country specific and global goals such as the World Health Organization's mandate on Universal Health Coverage (UHC) by 2020.

Governments will ultimately be responsible for providing UHC and they will be required to demonstrate efficient use of limited public funds while providing safe quality healthcare. External evaluation systems can provide this assurance.

ISQua believes that accreditation can continue to be a powerful force for improvement in the quality of care that is delivered. However, like all quality improvement initiatives, it must evolve with the times to reflect the needs of our healthcare systems.

Professor David W. Bates
President International Society for Quality in Health Care
August 2015

Foreword

World Bank and the World Health Organization

The public has a growing awareness of and expectation for their healthcare to be accountable, safe, of high quality and responsive to their needs. Globally, healthcare costs are rising, putting increasing burdens on both governments and healthcare organisations, as they try to meet the growing challenges with limited resources. Governments are working towards Universal Health Coverage (UHC) as a way to ensure that their populations have equitable access to safe, high quality services, without suffering financial hardship. The critical question remains: how can countries maximise access whilst maintaining safe and quality services within affordable margins?

External evaluation programmes, which include accreditation, certification and licensing of healthcare institutions, are among measures that can help improve organisational efficiency and effectiveness as well as the safety and quality of services. However, implementation of these programmes is not uniform. This may be due to a lack of resources or expertise or, importantly, due to a lack of operational 'know-how' on the implementation of such programmes.

This report aims to provide a practical guide for setting up an external evaluation programme at both a national and an organisational level. It will help governments and policy makers to identify and determine health systems' priorities and gaps, so they can re-orient healthcare systems and policies to meet such growing challenges. The report offers a range of approaches and practical steps on the setting up of external evaluation programmes, including creating an enabling environment and developing human and system capacities.

Better implementation of external evaluation programmes can contribute to improved safety by requiring services to meet standards, and by encouraging quality improvement through organisational and individual professional development. Such programmes, if adopted and implemented appropriately and consistently, will contribute to a more resilient, more accountable, and more effective healthcare system in the long run.

It is hoped that this report will encourage governments and healthcare organisations to adopt and implement external evaluation programmes in order to achieve safe, high quality, resilient and sustainable health systems and services.

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Glossary of Terms

Accountability	Responsibility and requirement to answer for tasks or activities. This responsibility may not be delegated and should be transparent to all stakeholders.
Accreditation	A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system.
Assessment	Process by which the characteristics and needs of patients, groups, populations, communities, organisations or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or action.
Assessor	Person who evaluates characteristics and needs. For external evaluation, an assessor identifies and evaluates evidence that set criteria are being met and makes recommendations for action to address any gaps. Also auditor, surveyor, external evaluator.
Benchmarking	Comparing the results of services' or organisations' evaluations to the results of other interventions, programmes or organisations, and examining processes against those of others recognised as excellent, as a means of making improvements. Also benchmark.
Certification	Process by which an authorised body, either a governmental or non-governmental organisation (NGO), evaluates and recognises either an individual, organisation, object or process as meeting pre-determined requirements or criteria. The pre-determined requirements are set out in standards which are developed specifically for the purpose of assessment. The standards assess the performance of the organisation, object, process or person, may focus on specific aspects of performance and may address more than legal requirements.
Clients	Individuals or organisations being served or treated by the organisation. Also patients, consumers, service users.
External evaluation	Process in which an objective independent assessor gathers reliable and valid information in a systematic way by making comparisons to standards, guidelines or pathways for the purpose of enabling more informed decisions and for assessing if pre-determined and published requirements such as goals, objectives or standards have been met. An organisation, object, process or individual may be assessed and evaluation may be undertaken by peers, including organisations and professionals, private professional auditors or consultants, purchasers / funders / insurers, consumers / patients or governments.
Health Outcome	Health state or condition attributable to treatment, care or service provided.
Leader	An individual who sets expectations, develops plans and implements procedures to assess and improve the quality of the organisation's governance, management, clinical and support functions and processes.
Leadership	Ability to provide direction and cope with change. It usually involves establishing a vision, developing strategies for producing the changes needed to implement the vision, aligning people, motivating and inspiring people to overcome obstacles.

Licensing	Process by which a governmental authority grants permission to an individual practitioner or health and social care organisation to operate or engage in an occupation or profession. Licensing regulations are generally established to ensure that an organisation or individual meets minimum standards to protect health and safety. The output of licensing is the awarding of a document or licence allowing an organisation or person to provide a service within a specified scope.
Medical tourism	Travel of people to another country for the purpose of obtaining medical treatment in that country.
Organisational peer assessment	A process whereby the performance of an organisation is evaluated by members of similar organisations. Also peer review.
Outcome standards	Standards which address the results, consequences or outcomes of the performance and measurement of activities, systems and functions.
Patient centredness	Focus on the experience of the patient / client from their perspective, minimising vulnerability and maximising control and respect. Also patient / client focus.
Patient / Client journey	The patient / client path through the care or treatment process – entry, assessment, planning, delivery of care or treatment, evaluation, follow-up and across services and providers. Also client continuum of care.
Process standards	Standards which address the interrelated processes of different organisational and clinical functions and activities.
Quality improvement	Ongoing response to quality assessment data about a service, in ways that improve the processes by which services are provided to clients. Also continuous quality improvement (CQI).
Regulation	Is a form of external evaluation by which a body, who is authorised by law, assesses an organisation or a person against pre-determined requirements. The pre-determined requirements are derived from legislation and therefore, the regulator may take a number of actions in the event of non-compliance.
Risk mitigation	A systematic reduction in the extent of exposure to a risk and / or the likelihood and consequences of its occurrence.
Self-assessment	A process by which an organisation evaluates its own performance against set criteria or standards, identifies strengths and gaps, and plans actions for improvement.
Standardisation	Process of developing and implementing technical, service or other standards; that can help to maximize compatibility, interoperability, safety, repeatability or quality.
Structure standards	Standards which address the relatively stable characteristics of healthcare providers, their staff, tools and resources, and physical and organisational settings.
System	A set of interacting or interdependent processes forming an integrated, whole function or activity.
Transparency	Operating in such a way that it is easy for others to see what actions are performed; a principle that allows those affected by administrative decisions, business transactions or charitable work to know not only the basic facts and figures but also the mechanisms and processes. Usually requires documented policies and procedures.
Universal health coverage	The goal of all people having access to and obtaining health promotion, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, without suffering financial hardship to avail of them.

Introduction

The purpose of this document is to guide countries, agencies and other groups in the process of setting up new health or social care external evaluation organisations or programmes. It is also intended as an aid for funding and development agencies such as the World Bank, international aid and technical cooperation agencies, World Health Organization, Ministries of Health, other government agencies, groups and organisations who want to improve the quality and safety of healthcare in their country, region or specialty area. It revises the International Society for Quality in Health Care (ISQua) Toolkit for Accreditation Programs, 2004[1], and ISQua Checklist for Development of New Healthcare Accreditation Programs, 2006[2]. This document has extended its scope beyond healthcare accreditation programmes to include other external evaluation programmes such as certification and licensing as they apply to organisations, not individual practitioners. These programmes have different scopes and organisational coverage but are based on the same principle of evaluating and improving performance against a defined set of standards or criteria, using external evaluators, to improve the safety and quality of health services for the public.

Accreditation can be defined as a self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system. Certification is a process by which an authorised body, either a governmental or non-governmental organisation, evaluates and recognises an organisation as meeting pre-determined requirements or criteria. Licensing is a process by which a governmental authority grants permission for a healthcare organisation to operate. Licensing regulations are generally established to ensure that an organisation or individual meets minimum standards to protect health and safety. For the purpose of this document we will refer to an accreditation body but this includes any external evaluation programme as the principles remain the same.

The document refers mainly to healthcare organisations but is also applicable to social care organisations. In it, the term external evaluation is used to cover accreditation, certification, licensing and other standards based assessment programmes. The term survey is used to refer to survey, assessment and audit. The term surveyor is used to include surveyors, assessors and auditors.

Research and experience have identified the benefits of external evaluation programmes such as improved organisational efficiency and effectiveness, improved safety and quality, better risk mitigation, improved leadership, reduced liability costs, better communication and teamwork, increased satisfaction of users and staff, and better patient care. However, there are challenges in setting up these programmes. The principal threats to new external evaluation programmes appear to be inconsistency of government policy, unstable politics, unrealistic expectations and lack of professional / stakeholder support, continuing finance and / or incentives. The effectiveness and sustainability of an external evaluation organisation or programme depends ultimately on many variable factors in the particular healthcare environment of the country or organisation involved. It also depends on the kind of programme concerned, and how it is implemented.

To be sustainable, external evaluation programmes need ongoing government and / or private support, a sufficiently large healthcare market size, stable programme funding, diverse incentives to encourage participation, and continual refinement and improvement in the external evaluation organisation's operations and service delivery.

This guide addresses the variables of policy, organisation, methods and resources. It outlines the reasons why an external evaluation programme might be developed, describes the different models, and highlights the benefits and challenges associated with external evaluation.

It then provides guidance on the steps that need to be taken in establishing a new external evaluation organisation including:

- Establishing the fundamentals of scope and purpose, and defining the important roles of government and incentives in the external evaluation organisation / programme.
- Setting up of the external evaluation organisational structure including: establishing an advisory committee; developing relationships with stakeholders; designing a governance framework; embedding the values of fairness and transparency; and getting outside assistance and funding.
- Establishing governance and management systems including: staffing; financial and information systems; and risk management and performance improvement systems. It also highlights the importance of allowing enough time for these stages.
- Developing the standards to be used by the organisation and the system for measuring their achievement.
- Developing the surveyor and survey management systems including: the selection and training of surveyors; the designing of processes and technology for managing surveys and other events; developing and establishing education services; and determining and establishing the process for awarding accreditation or certification status.
- Integrating into all these systems and processes ways of measuring and evaluating performance.

This document reflects the best practice guidelines and standards developed by the International Society for Quality in Health Care (ISQua) as part of its International Accreditation Programme (IAP): ISQua Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1, 2014[3]; ISQua Guidelines and Principles for the Development of Health and Social Care Standards, 4th Edition Version 1.1, 2014[4]; and ISQua Surveyor Training Standards Programme, 2nd Edition 2009[5].

The appendices include case studies outlining how three different healthcare external evaluation organisations were established. Two of the organisations featured are accreditation organisations. The third featured organisation is an assessment organisation established primarily to assess against government-mandated standards for compulsory certification. Appendix 1d describes an Australian Practice Incentive Programme that demonstrates how accreditation can be used as a lever to encourage quality improvement.

Chapter 1: Why develop an external evaluation programme?

This chapter introduces what a healthcare external evaluation programme is; describes some of the different models of external evaluation; outlines the benefits of such programmes; and highlights the challenges which may be encountered in establishing such programmes.

1.1 The growing demand for external evaluation in health and social care

There is growing worldwide demand, concern and focus on quality and safety in healthcare. UUniversal Health Coverage (UHC) is now a key agenda item for the World Bank and the World Health Organization and many countries have adopted or are about to adopt this system of equal healthcare for all. The goal of universal health coverage is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them. This requires:

- A strong, efficient, well-run health system with good governance
- A system for financing health services in an efficient and equitable way
- Access to essential medicines and technologies and good health information systems
- A sufficient capacity of well-trained, motivated health workers[6].

There is increasing support from governments, and from funding agencies, for mechanisms, such as accreditation, to support UHC. Governments will ultimately be responsible for providing UHC and they will be required to demonstrate efficient use of limited public funds while providing safe quality healthcare. External evaluation provides assurances that healthcare facilities have quality systems in place and the data to demonstrate the required level of service provision. Depending on the comprehensiveness of the standards against which health service performance is being measured, external evaluation programmes such as accreditation and certification can contribute to quality improvement, risk mitigation, patient safety, improved efficiency and accountability, and can contribute to the sustainability of the healthcare system. They can provide information on how well health services are being delivered, identify issues, and assist the decision-making of funders, regulators, healthcare professionals and the public. External evaluation supports transparency, benchmarking and accountability, so that government funding is allocated in a fair and equitable way and supports a culture of change and quality and an increased focus on risk.

Patients expect to receive safe care and are demanding quality services that meet their needs. They expect to be treated with respect, to receive services of an appropriate and consistent standard that are delivered with care and skill, that minimise risk and harm, comply with legal, professional and ethical standards, and that facilitate continuity of care. Patients need to receive information about their condition and treatment in a way they can understand, to be able to make informed choices about their treatment and to be communicated with openly and honestly. They want the right to complain if services do not meet their needs and expect action to be taken to address the problem.

They have a right to trust that their health provider or hospital has systems and processes in place to provide such patient-centred, reliable, efficient, effective and responsive care. An external evaluation programme based on best practice standards will make a significant contribution to achieving this.

With preventable error rates estimated to be 83% in developing and transitional countries and a 30% rate of adverse events associated with deaths, these countries require not only more resources to improve the safety and quality of care, but a political environment, policies and mechanisms that support quality initiatives. The contribution of external evaluation organisations centred on promoting improvements, applying standards and providing feedback is being increasingly recognised in these countries. Preventable error rates of over 10% in developed countries are also unacceptable. A flourishing accreditation programme is one element of the institutional basis for high quality healthcare[7].

1.2 Models of external evaluation

External evaluation

Is a process by which an objective independent assessor gathers reliable and valid information in a systematic manner by making comparisons to standards, guidelines or pathways for the purpose of enabling more informed decisions and for assessing if pre-determined and published requirements such as goals, objectives or standards have been met. An organisation, object, process or individual may be assessed and evaluation may be undertaken by peers, including organisations and professionals, private professional auditors or consultants, purchasers / funders / insurers, consumers / patients or governments.

The distinguishing features of external evaluation are as follows:

- It is a formal process
- The object being assessed is an organisation, object, process or individual person
- Assessment is undertaken by an objective, independent assessor
- Assessment is against pre-determined and published requirements / criteria
- It is designed so that decisions are not influenced by those being assessed
- The assessment results in a defined output

There are a number of models of external evaluation and it should be acknowledged that there can be confusion regarding terminology due to the diverse applications of the external evaluation models. Examples of external evaluation models include the following:

Accreditation

Accreditation may be defined as a self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system. Although primarily applied in relation to organisations, processes may also be accredited. Accreditation standards assess the organisation's or process's ability to fulfil its core mission and may address more than legal requirements. They are usually recognised as optimal, evidence-based and achievable and are designed to encourage continuous improvement[8]. The output of accreditation is a report summarising the findings of the assessment and a recognition decision regarding the accreditation status.

Accreditation is one of the longest established models of external evaluation. It is a self-assessment and external peer review process that assesses the entire organisation including both clinical and management processes and activities. Traditionally, health and social care organisations engaged in accreditation on a voluntary basis and accreditation schemes were provided by non-governmental agencies. However, there has been a shift over time towards greater governmental involvement in accreditation with the development of national government funded accreditation programmes and a shift from voluntary to mandatory participation in such schemes. For example, in 2011 the Australian Health Ministers endorsed the National Safety and Quality Health Service (NSQHS) Standards and a national accreditation scheme. As a result, all hospitals and day procedure services and the majority of public dental services across Australia now need to be accredited to the NSQHS Standards. Private health service organisations are required to confirm their requirements for accreditation to any standards in addition to the NSQHS Standards with the relevant
health department. Prior to 2011, participation in accreditation was voluntary for Australian hospitals[9].

Certification

Certification is a process by which an authorised body, either a governmental or non-governmental organisation, evaluates and recognises either an individual, organisation, object or process as meeting pre-determined requirements or criteria. The pre-determined requirements are set out in standards which are developed specifically for the purpose of assessment. The standards assess the performance of the organisation, object, process or person, may focus on specific aspects of performance and may address more than legal requirements. The output of certification is a report summarising the findings of the assessment and a recognition decision regarding the certification status.

Certification may be used by governments or other authorised agencies to assess the compliance of healthcare facilities or specific departments / services within those facilities with a set of standards. The focus is usually on essential elements being in place rather than on continuous quality improvement. The standards and certification may not be organisation-wide, but may apply to a particular service, e.g. physiotherapy. Governments may authorise independent assessment organisations to assess health and social care providers' compliance with government-mandated standards.

An example of a certification scheme is ISO: the International Organization for Standardization. ISO provides standards, e.g. ISO 9000 Quality Management, against which organisations or functions may be certified by ISO accredited certification bodies or organisations[10]. Although originally designed for the manufacturing industry, e.g. medical devices, these have been primarily applied to radiology and laboratory systems in healthcare, and more generally to quality systems in hospitals and clinical departments. Conformance with ISO standards is assessed by professional quality auditors and any non-conformance is followed up with a subsequent audit.

When applied to individuals, certification usually implies that the individual has received additional education and training, and demonstrated competence in a specialty area beyond the minimum requirements set for registration or licensing. For example, a doctor may be certified by a professional specialty board in the practice of obstetrics[8].

There can be confusion between the terms accreditation and certification and they are often used interchangeably. However, accreditation usually applies only to organisations, while certification may apply to individuals, as well as organisations.

Regulation

Regulation is a form of external evaluation by which a body, authorised by law, assesses an organisation or a person against pre-determined requirements. The pre-determined requirements are derived from legislation and therefore, the regulator may take a number of actions in the event of non-compliance.

Licensing

Licensing is a process by which a governmental authority grants permission to an individual practitioner or health or social care organisation to operate or engage in an occupation or profession. Licensing regulations are generally established to ensure that an organisation or individual meets minimum standards to protect public health and safety.

The output of licensing is the awarding of a document or licence allowing an organisation or person to provide a service within a specified scope.

Organisational licensing or registration is granted following an on-site inspection to determine if minimum health and safety standards have been met. Maintenance of registration or licensure is an ongoing requirement for the health or social care organisation to continue to operate and care for patients or clients.

Individual or professional licensing or registration is usually granted after some form of examination or proof of education and may be renewed periodically through payment of a fee and / or proof of continuing education or professional competence[8].

Countries may have more than one model of external evaluation in operation in specific sectors. For example, hospitals may be required to be licensed and meet specific government-mandated standards in order to be able to provide health services in a particular country, but may still engage voluntarily in organisational accreditation or certification programmes for specific departments in the facility e.g. laboratory certification programmes. Individual healthcare practitioners may need to be registered with their professional body in order to be employed in a hospital but they may also voluntarily undergo additional education in order to be certified in a respective field by a professional specialty board.

The key characteristics of accreditation, licensing and certification are set out in Table 1.

Table 1: Definitions of accreditation, certification and licensing

Process	Participation	Issuing organisation	Object of evaluation	Components / Requirements	Standards
Accreditation	Voluntary or mandatory	Non-governmental organisation (NGO) or government authority	Organisation	Compliance with published standards, on-site evaluation; compliance may not be required by law and / or requlations	Set at a maximum level to stimulate improvement over time
Certification	Voluntary or mandatory	Authorised body, either government or NGO	Individual	Evaluation of pre-determined requirements, additional education / training, demonstrated competence in speciality area	Set by national professional or speciality boards
			Organisation or component	Demonstration that the organisation has additional services, technology or capacity	Industry standards (e.g. ISO 9000 standards) evaluate conformance to design specifications
Licensing	Mandatory	Governmental authority	Individual	Regulations to ensure minimum standards, exam, or proof of education / competence	Set at a minimum level to ensure an environment with minimum risk to health and safety
			Organisation	Regulations to ensure minimum standards, on-site inspection	

1.3 Benefits of external evaluation

External evaluation has contributed to improving the quality and safety of healthcare for nearly 100 years and the majority of the published literature relates to accreditation. Research on the benefits of certification, regulation and licensing is sparse. It must be acknowledged that historically there has been limited evidence of the impact of accreditation but in recent years more empirical research has been undertaken to identify and quantify the benefits.

Some of the specific benefits of accreditation identified in the literature include impacts on structural elements of quality improvement in healthcare organisations such as leadership, governance and management, and process elements such as organisational performance[11].

From a leadership, governance and management perspective, accreditation is perceived as: providing a framework for helping to create and implement systems and processes that improve operational effectiveness and advance positive health outcomes; providing organisations with a well-defined vision for sustainable quality improvement initiatives; and as a means of demonstrating credibility and a commitment to quality and accountability.

From an organisational performance perspective, some of the identified benefits include:

- Increases healthcare organisations' compliance with quality and safety standards
- Stimulates sustainable quality improvement efforts and continuously raises the bar with regard to quality improvement initiatives, policies and processes
- Decreases variances in practice among healthcare providers and decision-makers
- Highlights practices that are working well. Promotes the sharing of policies, procedures and best practices among healthcare organisations[11].

Accreditation has also been perceived as having an impact on team working by strengthening interdisciplinary team effectiveness and promoting capacity building, professional development and organisational learning[11].

Similarly, a recent synthesis of 122 empirical studies that examined either the processes or impacts of accreditation programmes concluded that research evidence generally presents health service accreditation as a useful tool to stimulate improvement in health service organisations and to promote high quality organisation processes. Some of the cited studies found that accreditation promotes standardisation of care processes; increased compliance with external programmes or guidelines; development of organisational cultures conducive to quality and safety; implementation of continuous quality improvement (CQI) activities; and superior leadership. There was limited evidence showing positive associations between accreditation and patient outcome measures. However, this was attributed to poor research design[12].

A comparison of accreditation in low- and middle-income countries versus higher-income countries showed all programmes promote improvements, apply standards and provide feedback. Accreditation programmes are contributing to incremental improvements in quality systems and clinical processes in health systems around the world and are one element of the institutional basis for high-quality healthcare[7].

A recent review examining the use of economic evaluation techniques in health services accreditation research identified that no formal economic evaluation of health services accreditation has been carried out to date. It also highlighted that the impact or effectiveness of accreditation has been researched with a variety of foci and to differing degrees. The research design of some studies, particularly those that are observational or qualitative in nature, makes it difficult to provide statistically robust evidence for the efficacy of accreditation or causality. The lack of a clear relationship between accreditation and the outcomes measured in benefit studies makes it difficult to design and conduct economic appraisal studies where a more robust understanding of the costs and benefits involved is required. In turn, the absence of formal economic appraisal means it is challenging to appraise accreditation in comparison to other methods to improve patient safety and quality of care[13].

While the evidence for the direct impact of accreditation on patient / client outcomes is inconclusive, the available research suggests that accreditation may contribute to improving health outcomes by strengthening interdisciplinary team effectiveness and communication and by enhancing the use of indicators for evidence-based decision making[14]. The challenge for mature external evaluation systems is to become more outcome driven. This reduces the burden of audit but also helps to highlight its benefits.

1.4 Challenges for external evaluation programmes

The principal threats to new external evaluation programmes include: inconsistency of government policy; unstable politics; unrealistic expectations; and lack of professional / stakeholder support, continuing finance and / or incentives. To be sustainable, external evaluation programmes need a number of elements to be in place, including some of the following: ongoing government and / or private support; a sufficiently large health or social care market size; stable programme funding; diverse incentives to encourage participation; and continual refinement and improvement in the external evaluation organisation's operations and service delivery[15] (refer Chapter 2).

To be sustainable and credible, new programmes need sufficient numbers of trained and skilled personnel and a realistic timeframe for the development of the programme. They need to demonstrate objectivity and independence with transparent procedures for the assessment of healthcare services and for decisions on accreditation or certification awards. The expectations of governments and stakeholders about what the external evaluation programme can achieve need to be realistic, in line with the purpose and scope for which it has been designed and resourced, and in line with the government's broader strategy or policy for healthcare quality and safety. Within that strategy or policy there needs to be a balance between the objectives of external control or regulation and internal organisational development or improvement. Attempts to prescribe and control every process of a complex system like a healthcare organisation or service, which cannot be understood as simply a sum of a number of discrete and predictable processes, will evoke resistance from staff, and can be counterproductive in terms of quality and safety. Health and social care staff need to be motivated and committed to improving quality rather than directed and sanctioned.

Expectations of accredited or certified health or social care services can be unrealistically high. The external assessment of organisations for the purposes of accreditation or certification is based on an on-site survey or assessment of compliance with, or achievement of, standards. This is a snapshot in time and does not guarantee, nor is it meant to guarantee, ongoing performance at the same level. However, external evaluation organisations who themselves engage in an external evaluation process, such as ISQua's International Accreditation Programme (IAP) are expected, as part of this process to monitor the continued maintenance of standards and quality improvements by the organisations they have accredited or certified, e.g. submission of action plans and reports of their implementation, periodic self-assessment or external reviews, random reviews, follow-up of significant complaints or sentinel events.

Given the amount of effort and money invested worldwide in external evaluation and regulation of healthcare delivery, and the common pursuit of valid standards and reliable measurement, there are economic and technical reasons to share research and experience more actively in the international community.

A study comparing European hospitals in terms of quality and safety was found to be challenging because of the different hospital accreditation and licensing systems in each country; the different indicators collected; different definitions of the same indicators; different mandatory versus voluntary data collection requirements; different types of organisations overseeing data collection; different levels of aggregation of data (country, region, hospital); and different levels of public access to such data.

This means that patients are unable to make informed choices about where they receive their healthcare in different countries and some governments will remain in the dark about the quality and safety of care available to their citizens as compared to that available in neighbouring countries[16].

Ongoing research is needed into the benefits and limitations of external evaluation in healthcare. To measure the impact of any new programme, before and after measurements are needed of the indicators that the programme is intended to address.

This chapter has introduced different external evaluation models and has outlined the benefits of external evaluation and the challenges associated with establishing a new programme. The following chapters will present the factors that need to be considered when deciding which external evaluation model to adopt in a country and the steps to be undertaken when setting up an external evaluation organisation and programme.

Chapter 2: Establishing the Fundamentals

This chapter outlines the initial decisions that need to be made when a new external evaluation programme is being established: the purpose of the programme; its scope; the role of government; and the incentives that may be needed to ensure health and social care organisations participate. It also highlights the importance of identifying who the main stakeholders may be and what external influences for the programme will look like.

2.1 Defining the purpose of the external evaluation programme

One of the first steps in the development of a new external evaluation programme is to determine its purpose.

Factors to consider in determining the purpose of an external evaluation programme or organisation include the following:

Developmental or regulatory

According to the World Bank[17], governments regulate health services in order to guide private activity and achieve national health objectives. Regulation can be used for control, with instruments that use the force of law to ensure that services provided adhere to legal requirements. Instruments that aim to control include: licensing, restrictions on dangerous clinical practice and registration. Examples include: basic legislation on health personnel such as registration and licensing requirements, which can also be used to set minimum requirements for health services or facilities to operate. Regulation can also use financial or non-financial incentives that change the behaviour of private healthcare providers. The advantages of using incentive-based regulation is that it avoids the informational, administrative and political constraints that control-based interventions entail. Accreditation, certification and contracts are examples of incentive-based regulation. However, in developing countries, regulation is often ineffective because of the low level of enforcement and insufficient resources.

Standards-based external evaluation

Standards-based accreditation is a programme that contributes to developing an organisation, and is designed to improve the quality as well as the safety of health services.

Accreditation programmes monitor and promote, via self and external assessment, healthcare organisation performance against pre-determined optimal standards[18]. They also aim to contribute to the provision of high quality and safe healthcare services and to improve patient health outcomes.

Certification may be similarly standards-based and use a rating system that encourages improvement over time but its focus is usually more on continuing compliance with criteria and the standards may be more limited. Licensing may be used when the priority is ensuring basic health and safety requirements are met in order for a healthcare organisation to operate and will usually be facility focused.

Values and objectives underpinning a new programme

A survey of healthcare accreditation organisations revealed that quality improvement was the reason healthcare organisations participated in accreditation. On the other hand, the government agenda commonly focused more on the protection of public money and public health as a priority, meaning reducing variation in practice to increase efficiency and improve patient safety, consistent with WHO global initiatives[15].

Values or principles may relate to features such as leadership, a system and process approach, multidisciplinary teamwork, capacity building and training, patient centredness, devolved decision-making and accountability, evidence-based decisions for continuous improvement and performance-based incentives.

Objectives of external evaluation programmes identified in some developing countries have included: improving leadership of a quality health system; improving resources and capacity of the system and staff; improving performance by clearly defining the roles and responsibilities of staff at all levels; developing the structures, systems and capacity to support quality improvement; strengthening the focus and role of health service consumers and other stakeholders; and improving health services through systematic implementation of standards.

The following table compares capacity building and regulatory external evaluation approaches[15].

Table 2: Comparison of capacity building and regulatory external evaluation

	Capacity building	Regulatory
Purpose	Dynamic, organisational improvement	Static, control
Terminology	Accreditation, certification	Licensing, regulation
Governance	Non-governmental organisation, stakeholders	National / regional government agency
Primary Customers	Healthcare providers	Government
Secondary customers	Patients, professions, healthcare insurers	Population, politicians, public finance
Incentives for healthcare organisations to participate	Ethical, commercial	Legal, mandatory
Uptake	Voluntary self-selection to available programs	All institutions in all sectors
Standards	Defined by non-governmental organisation, optimal, achievable, encourage quality improvement	Defined by regulation, minimal acceptable
Funding	Self-financing	State
Cross-border mobility	Limited by language, culture	Limited by political borders

Possible purposes or objectives of an external evaluation programme might be to:

- Improve the performance of health services by setting and measuring the achievement of standards
- Increase public safety and reduce risks associated with injury and infections for patients / clients and staff
- Increase public confidence in the quality of healthcare services
- Promote accountability of health services to funders and the public.

How do these values and objectives relate to plans for health reform in general, and to the national quality strategy in particular?

The next important step is to identify if there are plans for health and / or social care reform in the country or region and if there are any national or regional quality strategies or plans in place. Reform plans outline the changes that a government intends to make to a particular sector and outlines the specific actions that it will take to achieve those reforms. For example, a government may outline in a reform plan that it intends to establish an external evaluation organisation and what the role or purpose of this organisation will be. A quality strategy provides an agreed direction and identifies the most important activities for improving quality in the health and social care sector in the country or region. It helps to identify the strengths of the system and also the constraints that prevent the provision of a quality service. A quality strategy may outline the role or will help to identify or clarify the role that external evaluation is expected to play in achieving the country or region's quality vision.

These factors will guide all further decisions - the role of the government, relationships with stakeholders, the governance and management framework, the standards or criteria to be used for assessment, the assessment process, and the outcome of licensing, certification or accreditation.

The case study examples below provide further insight into the factors that influenced the establishment of external evaluation agencies in different jurisdictions.

Case Studies – Foundation of the programme

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
The Danish accreditation programme (DDKM) was established as part of the "National Strategy for Quality Development in the Healthcare System – Joint Goals and Action Plan 2002-2006". The strategy was developed by the national, regional and local political authorities in cooperation with stakeholder organisations, representing professionals and consumers.

At that time, a number of hospitals already had positive experiences with accreditation provided by international accreditors – one of the intentions of the strategy was to spread this to the entire healthcare system, based on a Danish model.

Health Care Accreditation Council (HCAC)
Country: Jordan
The HCAC is the national healthcare accreditation agency of Jordan. Several reasons were stated for why the programme was developed including to improve the quality of hospitals and to enhance medical tourism. In addition, it was a response to public complaints of poor quality of care and a need to improve the entire healthcare system in the country.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand
The commencement of the Health and Disability Services (Safety) Act on 1 July 2002 represented a significant change in the regulatory environment in the New Zealand health and disability sector. This Act replaced several previous pieces of legislation and changed the way in which residential and hospital services were licensed or registered. In addition, the Act introduced health and disability standards for hospitals, rest homes and residential disability services aimed at improving safety levels and quality of care that became mandatory from 1 October 2004. The Act required that designated audit agencies (DAAs) are approved by the Director General of Health for the purpose of auditing these services to those standards.

2.2 Defining the scope of the external evaluation programme

Once the purpose is established it is important to define the initial scope of the programme. The purpose of a new external evaluation programme may depend on the government's priorities, the national health reform or quality strategies, available funding, the commitment of stakeholders and the problems or issues that need to be addressed.

Factors to consider in defining the scope of the external evaluation programme include the following:

Primary or hospital care?

Traditionally, accreditation has been developed for hospitals or aged care facilities and then moved outwards towards home support, hospice and other community services and then to regional networks or networks of preventive and curative services.

However, in developing countries the most urgent need may be for improved primary and community care and the programme will initially be developed to cover primary care clinics and outreach services, although there may be some resource advantages in developing primary care and hospital programmes at the same time.

Often it is easier to develop facilities based programmes first, starting with core standards and external evaluation for single institutions, e.g. acute hospitals, polyclinics or health centres. Standards can then be developed for more specialised services, e.g. rest homes or hospice care or mental health, followed by the linkages between them, preventive health or health networks, and they can then be covered by the programme. Assessment of single units, services or departments could offer large organisations a gradual entry to a full programme but it does not carry the benefits of integration and organisation consistency. It may hide the opportunities for improvement which frequently lie in communication between services rather than within them. However, there are many service specific external evaluation programmes which are operated either by a larger generic programme, or by a provider or association which works only in that area, e.g. palliative care, laboratory medicine, speech therapy, autism, general practice, aged care, and community services.

Some programmes have started with tertiary hospitals and services, with the intention of expanding to secondary care services later. Some programmes in North America (e.g. Accreditation Canada) accredit entire health networks and regions and are applying accreditation across the continuum of care. Some governmental programmes in Europe address public health priorities (such as cardiac health, cancer services) by assessing local performance of preventive to tertiary services against national service frameworks. In such programmes, measures may include the application of evidence-based medicine (process) and the measurement of population health gain (outcome) but many health determinants, e.g. housing, education and poverty, remain outside the scope of healthcare external evaluation programmes.

However, current best practice is to provide a programme that focuses on the patient or client and their journey through the service, hospital, network or care programme and the continuity of service or care for that individual or family across the entire continuum of care.

Historically, external evaluation programmes have set their scope in a way which compartmentalises care and service rather than optimising quality outcomes for the patient or client.

Public or Private coverage?

Most external evaluation programmes offer services to both public and private sector services, although some are restricted to either the public or private sector. Evaluating across sectors has advantages to healthcare organisations in facilitating the focus on the patient or client journey, providing a level playing field for comparing and benchmarking potential competitors, to surveyors in learning from another sector and to self-financing programmes in having a larger potential market. Sometimes either the private or public sector has the size, resources and incentives such as funding incentives, medical insurance and competitive advantage to adopt an external evaluation programme earlier. Medical tourism is another large incentive. To attract patients who are crossing national borders in search of affordable and timely healthcare, private and public health services need accreditation or certification to demonstrate their competence and safety.

Many medical tourism companies are now involved in organising cross-border health services and it has been recommended that the care they arrange should only be at accredited international health facilities. Other recommendations include the medical tourism companies themselves having to undergo an accreditation review; standards to ensure patients make informed choices; and continuity of care as an integral feature of cross-border care[19].

The case studies provide some further insights into how the scope of external evaluation agencies in different jurisdictions was determined.

Case Studies – Scope of the programme

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
Public and private hospitals, pharmacies, municipalities (primary care services, including long-term care), ambulance providers and General Practitioners (GPs) all participate in DDKM.

Health Care Accreditation Council (HCAC)
Country: Jordan
The HCAC is the national healthcare accreditation agency of Jordan. The organisation sets standards for hospitals, primary healthcare centres, family planning and reproductive health, transport services (ambulances), cardiac care, and diabetes mellitus. HCAC surveys against the standards and awards accreditation. HCAC also provides consultation and education to prepare healthcare facilities for accreditation and offers certification courses.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand
The commencement of the Health and Disability Services (Safety) Act on 1 July 2002 represented a significant change in the regulatory environment in the New Zealand health and disability sector. This Act replaced several previous pieces of legislation and changed the way in which residential and hospital services were licensed or registered. HDANZ's scope was determined by the Safety Act – the assessment of standards is a legal requirement for public and private hospitals, rest homes and residential disability services. Standards New Zealand (SNZ) is responsible for the New Zealand standards and this includes others such as for home support, allied health, and day surgery procedures.

Critical mass: economy, consistency, equity, objectivity

Larger countries can achieve economies of scale; smaller countries (perhaps with a population of less than 5 million), or large ones which choose to devolve the process to regional government, e.g. Italy, or ethnic groups, e.g. Aboriginal, have to share the considerable costs of infrastructure and development among a smaller number of healthcare organisations (giving higher unit costs). If the surveyor workforce is voluntary, this may also mean having a smaller choice of surveyors (giving more potential for conflict of interest). However, there are options such as contracting or employing a smaller paid surveyor workforce or contracting surveyors from other countries for surveys.

Other options for enhancing the opportunities for smaller programmes include:

- Sharing a programme with a neighbouring region or state which has similar culture and language
- Designing one national programme, rather than several regional ones
- Providing national standards, guidelines or tools for regional agencies or designated assessment organisations
- Using a single organisation to provide multiple accreditation programmes
- Using the same organisation or agency as a centre for research and development of other quality methods, e.g. performance indicators, clinical guidelines, patient surveys, technological assessment
- Obtaining accreditation services from another region or state.

2.3 Establishing the role of government

The development of an external evaluation programme may be part of broader health reforms, or part of an overall governmental strategy for quality improvement and a transition from a centralised system to one which is more open and independent. It may be necessary for the health ministry to re-define its own duties and responsibilities in the context of a reformed organisational structure of the health system.

The relationships between departments of government which have a major impact on quality may be unclear. The roles of agencies responsible for such areas as public health, blood products, pharmaceuticals or medical devices and inspectorates responsible for such aspects as control of the environment, safety, radiation at national or local level need to be clarified as part of the overall quality plan. Dissemination of this structure and plan would also provide an opportunity to develop a strategy for active communication of the aims and operation of an integrated quality system.

Government controlled or not?

Specific to external evaluation is the question of whether the programme should be organised and administered directly and solely within the ministry of health, like licensing, or by an independent body totally unconnected to government, or by something between these two extremes – which has become more common. The legitimate and necessary role of government is the licensing of healthcare facilities, using basic safety standards or criteria. Licensing of individual medical practitioners may be a government function but is usually carried out by a medical council. However, there are challenges for governmental external evaluation programmes which include:

- Inconsistent policy and management with changes in government
- Reviewing and updating standards consistently and in a timely way
- Public perception of government that is too low to make them credible assessors of healthcare
- Conflict of interest between government roles as purchaser, regulator and insurer, and lack of independence and continuity
- Delegation of powers to local areas, which may result in multiple government programmes duplicating development and ongoing costs of running the programmes.

Some countries, such as France and Saudi Arabia, have made participation in accreditation by healthcare organisations legally compulsory, but most countries merely authorise the functions of the external evaluation organisation. Two-thirds of accreditation organisations surveyed in 2010 were supported by enabling legislation. However, many independent programmes thrive without it. Five accreditation organisations were struggling or inactive, despite being supported by a published government strategy. If enabling legislation is not essential and national strategies often change with ministers and governments, external evaluation organisations must choose reliable partners for survival[15].

Need for government support

To be successful, external evaluation programmes often need government support and collaboration and to be recognised as an important part of the national health quality strategy. The support may be through funding, providing incentives for participants such as limiting other forms of inspection or audit, or recognising the programmes as a legitimate and essential part of the overall health quality strategy.

Some functions, such as the definition of standards, the assessment of compliance and the grading of awards may be totally independent or may be shared between government and independent external evaluation organisations. Some governments, for example, New Zealand, have developed or approved standards that they require healthcare organisations to meet. However, the government have devolved the process of assessment of compliance with the standards and follow-up to ensure the standards are being maintained to independent designated auditing, accreditation or certification organisations. These organisations in turn need to be internationally recognised by a 3rd party accreditor such as ISQua. In Australia, a similar system operates through the Australian Commission on Safety and Quality in Health Care which has developed national quality and safety standards. The accreditation of healthcare organisations who meet the national quality and safety standards has been devolved.

The mandatory requirement for external evaluation, as in the above examples, is an increasing trend as governments seek to improve the quality and safety of health services.

Key roles which governments might play in supporting external evaluation include:

- Enabling the external evaluation process, e.g. through policy decisions such as by reciprocal recognition of assessments; joint development of standards; avoiding conflict such as perverse incentives and competing mechanisms for assessment
- Providing leverage, e.g. by according preference to accredited or certified facilities, services or networks such as reimbursement tariffs and payment procedures
- Using accreditation or certification as a criterion in its own purchasing decisions, e.g. in defining preferred providers and contract monitoring
- Regulating individuals and institutions, e.g. by ensuring consistency and distinction between licensing and accreditation
- Acknowledging or endorsing accreditation or certification programmes against defined criteria to maintain standards, avoid duplication and potential exploitation
- Providing financial support in establishing programmes and / or contributing to the funding of programmes' continuing development.

The extent of government support and involvement in the external evaluation programme may also depend on the country's overall stage of development. In developing countries, where there may be a more limited health industry or where professional organisations may not have the resources or financial capacity to initiate an external evaluation programme, government organisations may be needed to establish such programmes. For example, in Kenya, the National Health Insurance Fund (the insurer) manages accreditation; their standards, known as the Kenya Quality Model, were developed by a broad coalition of professionals outside of the Insurance Fund and are supported by the Ministry of Health. In Ghana in West Africa, the National Health Insurance Scheme originally placed responsibility for accreditation within government; that task is now being transferred to an independent body[20].

The case studies highlight the nature of the relationships between external evaluation agencies and governments in different jurisdictions.

Case Studies – Role of the government

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
IKAS and the Danish accreditation programme (DDKM) were established by an agreement between the regional and local political authorities, who are responsible for delivering healthcare, and the national government that sets the overarching political priorities, including the economic frame, and is the healthcare legislator and regulator. The first step in the development of DDKM was the development of a cooperation agreement between the government and the regions of a joint model for quality assessment which included provisions for the funding for DDKM. IKAS is a formal independent organisation but the government provides part of the funding for IKAS.

Health Care Accreditation Council (HCAC)
Country: Jordan
The HCAC is a private, not-for-profit shareholding company registered under the Ministry of Trade and Industry.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand
The Safety Act required that designated audit agencies (DAAs) who monitor compliance with health and disability standards for hospitals, rest homes and residential disability services are approved by the Director General of Health for the purpose of auditing these services to those standards. HDANZ is a private, independently owned company. It is linked to government as a Ministry of Health (MOH) approved designated auditing agency and for these services HDANZ submits the audit report to the MoH who issues the certificate. HDANZ was designated as an approved designated auditing agency in October 2002.

2.4 Determining incentives

If the external evaluation programme is not mandatory, evidence suggests that incentives are useful to promote and sustain it. Possible incentives for healthcare organisations to participate in an external evaluation programme include:

- Organisational development: self-assessment, team-building, benchmarking, guided pathways
- Increased public funding such as health insurance fund payments moderated by accreditation or certification status, additional government subsidy, e.g. per accredited or certified bed, or some other linkage to core funding or reimbursement
- Effective exchange of data between external evaluation programmes and insurance programmes to inform their purchasing decisions and payments
- Preference from private insurers: insurers prefer to deal with facilities or services whose clinical and management processes have been independently verified; they also make reimbursement simpler and faster for such organisations
- Market advantage: public recognition brings status and advantage in a competitive market which can attract patients / clients, staff and income
- Reduction of liability insurance costs: premiums reflect reduced risk rating
- Exemptions from regulatory inspection: e.g. the state issues a licence to an accredited or certified facility on the basis that accreditation or certification standards include and exceed licensing standards ("deemed status"); this may be a condition of receiving public funding
- Linkage to training posts: status conditional on accreditation or certification
- National quality competitions: for example, making accreditation or certification status one of the judging criteria.

Healthcare organisations may be discouraged from participating in an external evaluation programme by:

- The cost in terms of time, management, and money
- Fears about the outcome - sanctions for shortcomings, loss of staff morale if denied the award of accreditation or certification, misuse of performance data, and of gaining the award and then losing it when standards get more demanding
- Lack of recognition for the resources invested
- Lack of information about the benefits
- Resistance from healthcare professionals and other staff and the failure to recruit clinical and other staff champions
- The difficulties of effecting culture change without external support and
- Failure to recognise and celebrate the achievements of participating organisations.

Consideration also needs to be given at this time to the issue of consequences when organisations do not achieve or meet the accreditation or certification standards to the acceptable level. What are the consequences, if any, for these organisations? For example, do the consequences include financial sanctions?

The case studies provide examples of some of the incentives put in place for external evaluation programmes.

Case Studies – Incentives for external evaluation programmes

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
DDKM (Danish accreditation programme) is not required by any legislation, but is based on agreements as follows:

- Public hospitals: all hospitals participate by agreement between National and Regional governments
- Private hospitals: voluntary, but participation is a prerequisite to obtain a contract to treat patients for the regions (also required by some insurance companies)
- Pharmacies: voluntary, financial incentive in place
- Municipalities (primary care services, including long-term care): voluntary, no incentives in place
- Ambulance operators: prerequisite to obtain contract with Regions
- General practitioners: mandatory (with some minor exceptions) by agreement between the Regions and the Organisation of General Practitioners in Denmark; financial compensation as part of the agreement.

Health Care Accreditation Council (HCAC)
Country: Jordan
Accreditation is voluntary. There are no incentives (laws, regulation, insurance requirements) in the country for accreditation.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand
The Safety Act 2002 introduced health and disability standards for hospitals, rest homes and residential disability services aimed at improving safety levels and quality of care that became mandatory from 01 October 2004. Under the Safety Act 2002, service providers such as hospitals, rest homes and residential disability service providers must be certified. From September 2005, physiotherapy services were required to be certified if they wished to provide services under the New Zealand Accident Compensation Scheme (ACC) physiotherapy services contract. From September 2012, health funders made certification mandatory for home support providers and from March 2013, a health insurance provider Southern Cross Health Society made certification mandatory for their affiliated providers.

Practice Incentive Program (PIP)
Country: Australia

The Australian Government introduced the Practice Incentive Program (PIP) in 1998. The PIP is aimed at supporting general practice activities that encourage continuing improvements and quality care, enhance capacity and improve access and health outcomes for patients[21].

In the 2015-16 Australian Government Budget, in excess of $1.5bn over four years[22] was allocated to the PIP to support the continuation of incentive payments to general practices.

The PIP is used as a lever by government to influence behavioural change within the general practice environment. To access payments under the PIP, practices must meet the eligibility requirements, including that a practice must be accredited or registered for accreditation against the Royal Australian College of General Practitioners (RACGP) Standards for general practices and must maintain full accreditation.

Approximately 80% of all practices that meet the RACGP definition of a general practice participate in accreditation and, therefore, may access PIP payments.

There are three types of payments available under the PIP[21]:

1. **Practice Payments**

The majority of payments through the PIP are made to practices and focus on those aspects of general practice that contribute to quality care. These payments are intended to support the practice to purchase new equipment, upgrade facilities or increase remuneration for GPs working at the practice.

2. **Service Incentive Payments**

Service Incentive Payments (SIPs) are generally made to GPs to recognise and encourage the provision of specified services to individual patients. The Cervical Screening, Asthma and Diabetes incentives have service incentive payment components, and the Aged Care Access Incentive is a service incentive payment only.

3. **Rural Loading Payments**

Practices participating in the PIP, with a main practice location situated outside capital cities and other major metropolitan centres, are automatically paid a rural loading.

There are ten individual incentives available to general practices and GPs under the PIP[23]: (See Appendix 1d for further information)

Since the inception of the PIP in 1998, successive Australian Governments have committed to ongoing funding for the program; and during this time, have retained the requirement that a practice must be accredited, or registered for accreditation, and must maintain full accreditation in order to access such payments.

Given the level of participation in accreditation by Australian general practices, it can be assumed that the highly incentivised PIP has been instrumental in encouraging practices to engage in the process, and in turn has had a positive impact by supporting practices to focus on improvements and quality outcomes.

2.5 Developing relationships with stakeholders

Another key exercise at this stage is to identify or map out the other main stakeholders in the quality and safety arena in the country or region; their role; and their link to the external evaluation programme. This may be different for each country or region and this exercise will help to establish what external influences for the programme will look like and what the nature of the relationship with the other stakeholders should be. For instance, if the external evaluation organisation does not itself manage related functions at a national or regional level, then it needs to define communications and relationships with other departments and agencies to harmonise the setting and assessment of healthcare standards, to avoid waste and conflict between systems, and to minimise the "burden of audit" on healthcare organisations. A new organisation should seek where possible to integrate and build upon existing systems of standards and inspections. For example, by establishing a process to recognise existing ISO or mandated audits. In addition, there are a number of organisations internationally who define and assess standards, and with whom they could usefully collaborate, ISQua being one.

Key stakeholders with whom the external evaluation organisation may consider developing relationships with include the following:

Consumer groups

Representatives of a recognised consumers' council or association should be involved in the creation and support of the proposed external evaluation organisation as a means of making health services more transparent and accessible to the public. They should help define what standards and services the public should expect from healthcare providers, and develop and promote reliable and consistent methods for measuring them. They may assist with developing a consumer code of rights. Consumer and patient representatives may also be part of the advisory committee of the external evaluation organisation and later sit on the governance board.

Regulatory inspectorates and other external agencies

These might include statutory bodies with responsibility for areas such as fire safety, radiation, medical device safety, hygiene and health data collection agencies. The relationship between the country's or region's ISO accreditation organisation and the health service accreditation or certification organisation needs to be explored and defined. Relationships also need to be built with the assessment organisation that certifies laboratories, x-ray departments or other technical services and organisations to relevant ISO standards, to understand each other's needs and requirements and possibly coordinate activities and assessments.

Key relevant legislative requirements such as for buildings, health and safety in employment, equal opportunities, consumer rights or waste management can be more specifically referenced in the external evaluation organisation's standards in consultation with the relevant agencies responsible. Specific technical standards or regulatory requirements relating to safety such as infection control, fire safety, equipment safety and emergency preparedness can be integrated into the standards as criteria and assessed as part of the survey or assessment visit.

Most accreditation or certification organisations assume that statutory inspections are carried out as intended, and expect to examine safety certificates, such as for radiation protection as part of their own surveys, but in some countries the statutory radiation protection agency does not have the resources to carry out its own inspections and may turn to the accreditation or certification organisation to provide its own expertise.

A process needs to be developed to determine which alternative evaluations are robust enough to be accepted as proof of compliance.

Public and community health bodies

Links between these bodies and the external evaluation organisation would give an opportunity to share data to describe the impact on population and community health and on the performance of providers and the healthcare delivery system. Where countries currently employ inspectors to regulate healthcare facilities, the inspectors' role could be modified to include assisting local facilities to prepare for external evaluation surveys by the organisation when it is established, and to monitor the implementation of the ensuing recommendations for improvement. This would require initial and continuing education programmes.

Technical agencies

Relationships with agencies for aspects such as health technology assessment, clinical guidelines, clinical pathways and patient / consumer safety are useful, especially to enable consultation and advice on the development of appropriate evidence-based standards and for keeping information and communications current.

Professional bodies

Independent bodies such as medical academies or councils will offer wisdom and advice to the organisation and be recognised for that purpose. Other bodies responsible for such duties as supervising training or licensing or registering clinicians (doctors, nurses, dentists, pharmacists, allied health professionals) will contribute to the setting of standards and to their local assessment.

In particular, the role of professional chambers, associations and colleges needs to be defined with respect to:

- Professional regulation
- Setting and monitoring of clinical performance standards
- Monitoring of clinical practice according to these standards
- Development and dissemination of quality improvement methods.

The functions of statutory bodies should be defined in relation to voluntary associations and to the external evaluation organisation. The organisation should work with local government ministries, insurance funds and professional associations and chambers to develop consistent incentives for measurable achievement of agreed national standards of process and outcome in primary, ambulatory and hospital care.

Health insurance funds

Using contracted service providers offers an alternative to the traditional centralised model in healthcare management. In several countries, laws on healthcare insurance specify that only accredited organisations, from either the public or private sector, have the right to sign contracts to provide services under compulsory insurance. The external evaluation organisation can work with health insurance funds to help them obtain and protect best value from available funding by recognising accreditation or certification for its impact on quality improvement.

External assistance

A further group of stakeholders with whom an external evaluation organisation may interact would be individuals, organisations or groups providing external assistance. External assistance is available from a number of sources including:

- International external evaluation businesses or initiatives
- International aid organisations and technical corporations
- International experts
- Neighbouring external evaluation organisations
- ISQua.

Assistance may be for any part or all of the components of an external evaluation programme. Before engaging formal external assistance, it is important that:

- The project specifications have been scoped out and are appropriate
- Competency criteria for selection of external assistance include relevant experience with health or social care standards based external evaluation
- References and advice are sought from experienced accreditation or similar organisations and ISQua.

Most accreditation organisations have based their standards on existing research, clinical practice guidelines, input from experts and other accreditation and technical standards. New organisations can, in consultation with the owners of these standards, choose a model that best reflects their purpose, scope and cultural context, and then adapt those standards or build on them to make them appropriate to the local context. It is important that the standards adhere to the ISQua Guidelines and Principles for the Development of Health and Social Care Standards[4] as these are accepted as best practice by organisations and so that they can become internationally accredited (See Chapter 4 for more information).

ISQua's Guidelines and Standards for External Evaluation Organisations[3] and for Surveyor Training Standards Programme[5] provide guidance on what structures, systems, processes and evaluation methods need to be in place to be a best practice organisation. When organisations seek ISQua accreditation, they get assistance with their self-assessment and they can have a mock survey prior to an international accreditation survey.

Information specific to healthcare external evaluation is widely available - see web links in the bibliography section.

The next chapter will focus on the initial steps involved in setting up an external evaluation organisation including how to involve and engage with other stakeholders as part of this process.

Chapter 3: Setting up the External Evaluation Organisation

This chapter focuses on the process of establishing an external evaluation organisation and the different stages in this process. This process may be different for each country or region depending on government policy, the stakeholders involved and the size of the health or social care sector. The case study examples outline the approaches adopted in different countries.

3.1 Establishing a preliminary board or advisory committee

The impetus for setting up an accreditation or certification organisation may come from a number of possible stakeholders: Ministry of Health, health professional associations, consumer organisations, private insurers, university departments, voluntary membership societies, health service charities or aid organisations. The initiative may come from a company or group of individuals who see a market opportunity, e.g. as assessors of government standards. If the purpose of the programme is clear, it is not difficult to identify whom it will serve and whom it will affect. Traditional, profession-driven programmes have tended to build links with regulators and consumers, thus becoming more accountable and transparent. More recent programmes have been more influenced by commercial providers and insurers or actively supported by government.

One way of involving relevant stakeholders who have or will have an interest in the success of the new organisation is through setting up a preliminary board or an advisory committee to establish the organisation. This enables them to feel they have a stake in the organisation and its work and to provide advice and expertise.

The preliminary board or advisory committee will provide guidance and direction on the practical aspects of establishing the external evaluation programme including:

- Clarifying the role of the external evaluation programme in the context of other departments and agencies working in the quality and safety arena in the country or jurisdiction e.g. other external evaluation programmes
- Funding of the external evaluation programme
- Governance framework for the external evaluation organisation
- The use of external assistance for development and delivery of the external evaluation programme.

The composition of the interim board or advisory committee will be unique for each country depending on government policy and the range of stakeholders working in the quality and safety arena. Some members from this board or committee may form the basis for the governance board in the established organisation. Table 3 outlines suggested members of a preliminary board or advisory committee.

Table 3: Potential composition of a preliminary board or advisory committee

Stakeholder Group	Examples of representatives
Government	Ministry of Health and / or other related departments e.g. Finance. Local government e.g. municipality, canton, oblast level
Consumer groups	Recognised national consumer council / association or advocacy organisation
External evaluation organisations	Regulatory and other external evaluation agencies working in the quality and safety arena in the country or jurisdiction e.g. statutory bodies with responsibility for areas such as health and safety, radiation, medical devices, medicines, regulatory inspectorates, certification agencies
Service providers	Public and private providers in country or region e.g. national representative bodies such as national hospital association or national disability service providers association / forum
Professional bodies	Independent bodies with responsibility for the licensing or registration of health and social care professionals or the supervision of training such as medical academies or councils
Academia	Universities or colleges who deliver education and training programmes for health and social care professionals
Technical agencies	National agencies with a specific role e.g. health technology assessments, clinical guidelines and pathways, patient / consumer safety
Independent	Independent experts, neighbouring external evaluation organisations, international external evaluation initiatives

3.2 Proposing a governance board and framework

One of the first tasks for the interim board will be to develop a draft governance framework for the external evaluation organisation or programme, with a formal constitution, governance board and draft policies and procedures. For credibility and in line with best practice, a commitment should be made that the organisation will be established in line with the ISQua Guidelines and Standards for External Evaluation Organisations[3] (currently 4th edition, 2014, but note that these are updated on a regular basis and the latest ones should always be obtained).

3.2.1 Governance body

If it is to be a non-governmental organisation, it is preferable for the organisation to have a board comprising and accountable to the various stakeholder organisations rather than the government. The board should represent professional, public and governmental interests and bring personal qualities to the governance of the organisation, such as finance, legal and public relations, but be dominated by none of them. For example, in Malaysia accreditation programmes are delivered by the Malaysian Society for Quality in Health (MSQH), which was established by the Malaysian Ministry of Health in association with the Private Hospital Association and the Malaysian Medical Association. All three organisations are represented on the board of MSQH[24].

Typically, independent boards include consumers; representatives of professional associations such as nurses, managers and doctors; industry associations such as hospitals or rest homes; funding agencies; and statutory bodies. Some boards are now appointed according to skillsets, expertise and experience rather than chosen by representative stakeholder organisations because of the perceived conflicts of interest the representative members may have, being the provider, consumer and sometimes also purchaser of the external evaluation. Government representatives in particular may have a perceived conflict of interest.

Public involvement goes beyond the sharing of information; it also demands the sharing of authority. Many external evaluation organisations have representatives of patients and the public in their governance structure to ensure their involvement in the development of policy and standards and in ensuring that agreed procedures are followed throughout the external evaluation process.

As per good governance practice, members of the governing body must be oriented to their roles and have ongoing information and education to assist them in their role. They should be guided by a set of governance policies.

Case Studies – Composition of governing board

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
IKAS and DDKM were established by an agreement between the regional and local political authorities, who are responsible for delivering healthcare, and the national government that sets the overarching political priorities, including the economic frame, and is the healthcare legislator and regulator. The government is represented on the board of IKAS; the Chair of the Board is a government representative, a Director of the Danish Health and Medicines agency.

Health Care Accreditation Council (HCAC)
Country: Jordan
The board of directors is made up of representatives for all healthcare sectors in Jordan, medical and nursing professions, and education.

3.2.2 Governance framework

The external evaluation organisation needs to be set up as a legal entity, or a part of one, with clear legal responsibilities for all its external evaluation activities. If it is part of a Ministry or government agency, this independence is particularly important.

The organisation's governance arrangements need to be clearly described in a deed, constitution or similar document that defines powers, accountability and responsibility including:

- The composition of the governing body
- The process for appointing its members
- Lines of accountability including lines of accountability out of the legal entity
- The terms of reference of the governing body and any of its committees
- Responsibility and rules for making decisions such as on accreditation or certification awards.

The organisation requires a clear vision and mission or purpose and strategic direction to provide the basis for the organisation's planning and direction and must be guided by a defined set of values which are reflected in all services and activities. It is also important that the organisation has an explicit set of ethical principles to inform all decision-making and a code of conduct outlining the expected behaviours of those working in and / or on behalf of the organisation. Other responsibilities for overseeing, monitoring and approval also need to be defined[3].

3.2.3 Committing to fairness and transparency

External evaluation organisations which have succeeded in making improvements in client healthcare organisations have generally done so by stimulating internal motivation and commitment to self-assessment and change. This requires a culture of transparency and acceptance of personal and organisational responsibility among management, clinicians and other staff. However such a culture is not universal, especially in hierarchical systems. External evaluation organisations cannot rely on health professionals' ethics and self-regulation to ensure an open and fair culture that promotes quality improvement. The commitment to fairness and transparency must be built into the governance framework and the ways of leading the organisation.

In setting up the new external evaluation organisation, a commitment must be made that it will:

- Use transparent and objective systems, decision-making and reporting
- Be free from undue influence by any party
- Avoid conflicts of interest
- Establish a fair complaints and appeals system
- Design and publish procedures for contracting, facilitation, assessment, reporting and accreditation or certification decisions to promote confidence and
- Put arrangements in place that ensure that external evaluation activities are strictly separated from consultancy.

This commitment should be defined in policies, including one requiring accreditation or certification decisions to be made solely based on the relevant standards, the findings of the surveyors / assessors and other objective evidence related to the standards. A growing trend is for decisions on accreditation status to be made based on a formulaic, mathematically oriented approach, which avoids any perception of bias[3].

3.3 Funding of the programme

Most new external evaluation organisations require at least two years to establish their organisation and / or programme, longer before they are sustainable, and longer still before they are self-financing. In short, political and financial support generally needs to be consistent beyond the term in office of most health ministers and many governments. External funding from government, health insurers, aid organisations or other partners will be required for:

- Establishment of the external evaluation organisation
- Initial development and testing of the standards
- Marketing
- Possibly subsidising the running of the organisation for the first few years or a year after break-even.

However, the initial set-up costs may be much less for external evaluation organisations whose role is to accredit or certify health or social care organisations against government-mandated standards or similar. In this situation, there is an identified potential client pool, there will be guaranteed payment of costs of the assessment by either the clients or the government and there may be a shorter time period in which clients are required to be assessed (See the example from HDANZ in the Case Studies section).

For most other organisations the number of potential client health or social care organisations will be a key determinant of programme costs, as will other factors such as whether the programme:

- Is a single national programme, regional or sector specific
- Is limited initially to a priority focus, e.g. nursing homes, or to the entire health system
- Is supplementing or replacing existing external assessments
- Is development focused, requiring training and education of clients
- Develops its own standards
- Employs specialist expertise.

One of the major potential costs for an external evaluation organisation will be the surveyor workforce and in particular whether they are paid or voluntary. Traditionally, accreditation organisations have relied upon participating accredited institutions to provide or loan staff to work as surveyors and to promote the concept of peer review. Certification agencies usually employ or contract their assessment personnel on a paid basis, sometimes supplemented by technical experts. However, accreditation organisations are now also increasingly paying surveyors as employed or contracted personnel, or using a mix of both paid and voluntary. The organisation would need to consider factors such as the availability of suitable personnel in the country to act as surveyors; the feasibility of suitable personnel being released by their organisations to work as surveyors; and the number of and costs of employing full or part-time surveyors when deciding on which approach to take.

Thorough system design and testing will be another cost, as will the investment in communications, information management and marketing.

Although a sustainable external evaluation organisation and its programme are constantly under development, the start-up costs may last 3-5 years before a tested and valued product is sufficiently marketable to begin to recover operational costs from client organisations. Whether they choose to participate, or whether they can afford to, depends on the incentives and sanctions provided and existing operating budgets.

During the first year, the organisation may manage with a small core staff, several working groups and low overheads; however costs increase rapidly with the addition of, surveyor training, document production and the direct costs of field testing. In some countries external expertise is required and must be factored in to the start-up costs. At the next stage, when the initial development is completed and the organisation is ready to offer accreditation or certification, it may face another challenge; the faster the rate of uptake, the faster it must invest to build capacity. Funding should be profiled to reflect this growth.

At the same time as obtaining funding, incentives need to be negotiated if possible.

The case studies outline the experiences of external evaluation agencies in different countries in terms of funding arrangements.

Case Studies – Funding

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark

Set-up costs

When IKAS was being established, a decision was made to seek external assistance to help with the establishment of the organisation and the development of the accreditation programme. A request for tender was issued to international accrediting organisations to provide consultancy services for the establishment of IKAS and the development of DDKM. The United Kingdom based international accreditation organisation CHKS was awarded the contract to assist with the establishment of IKAS as an accreditation organisation; the development of standards; and the training of surveyors.

Funding of the accreditation scheme

IKAS is an independent organisation but receives an index-linked annual grant from the central government, regions and local government. Public clients such as public hospitals or pharmacies do not have to pay any fees to participate in DDKM. Other private clients pay a fee that covers direct expenses plus an overhead.

Health Care Accreditation Council (HCAC)
Country: Jordan

Initial funding

The original funding to develop the HCAC came through the Jordan Healthcare Accreditation project funded by the United States Agency for International Development (USAID) and grants. The HCAC is a private, not-for-profit shareholding company registered under the Ministry of Trade and Industry. Since March 2013, HCAC has been financially sustainable through charging fees for services offered including surveys, education and consultation.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand

HDANZ is a private, independently owned company. It is linked to government as a Ministry of Health (MOH) approved designated auditing agency. HDANZ audits these services on behalf of the MOH and submits audit reports to the MOH who then issues the certificates to the services.

Service providers pay fees to HDANZ for survey and monitoring visits. Certification has been mandatory for the MOH Safety Act since October 2002. From September 2005, it became mandatory for physiotherapy services if they wanted to provide services under the New Zealand Accident Compensation Scheme (ACC) physiotherapy services contract. From September 2012, health funders made certification mandatory for home support providers and from March 2013, a health insurance provider Southern Cross Health Society made certification mandatory for their affiliated providers.

3.4 Setting up strategic, operational and financial management systems

Once the governance board has been established and the governance framework has been developed, the next step is to staff the external evaluation organisation and to develop the management systems.

3.4.1 Staffing the organisation

The most important task of any board is to appoint the chief executive, with the appropriate skills and experience for the role. The governing board may delegate accountability, authority and responsibility for managing the external evaluation organisation to a chief executive. The responsibilities for managing the organisation, the level of authority and the chief executive's relationship and accountability to the board need to be defined in a job description or similar document. It is also the board's role to confirm strategic and operational plans, to receive regular reports on achievement of goals and targets and to review the chief executive's performance annually against set performance targets[3].

After the chief executive has been employed, personnel need to be selected, trained and paid, including employed staff, seconded staff, e.g. surveyors, and sub-contractors e.g. legal, statistical, marketing, communications. Sometimes financial and information technology staff are contracted.

In larger organisations, staff may be structured into functional units such as:

- Survey planning and management
- Surveyor recruitment and development
- Standards research, development and revision
- User education and development
- Technical support staff – financial, human resources, information management
- Administration.

Smaller organisations can be sustained on very few core staff if they have significant support from unpaid experts and staff seconded from employment in health and social care services. Staffing numbers and skill levels need to be planned and transparent policies developed for recruitment, selection and appointment; orientation; health and safety; ongoing training; and regular performance assessment. Personnel records with defined content need to be established for all staff.

It is important that the lines of responsibility within the external evaluation organisation are clearly defined; made known to all staff; and that there are processes in place to ensure that staff and surveyors are free from influence by those who have a direct interest in the services and accreditation / certification decisions. The lines of authority, responsibility and allocation of functions in the external evaluation organisation may be outlined in an organisational chart or organogram. The lines of responsibility may be outlined to staff as part of their orientation and updates provided whenever there is a change of responsibilities.

A financial system needs to be set up to develop budgets and record and track income and expenditure and past, current and projected financial positions. It needs to be able to produce timely reports to assist staff to manage their budgets. Control and audit systems will be needed to protect assets and ensure the transparency of financial transactions.

3.4.2 Developing the system for financial sustainability

Initial budgeting is challenging and depends on how much funding is received for development or how much of the set-up costs need to be included in the budget. Provision usually needs to be made for external assistance and expertise. Some organisations consider guided facilitation and / or training on the survey standards and process as an integral part of the development process. Others provide separate consultancy (including general education and development) for which they charge a fee which can be budgeted for.

If client healthcare organisations are required to pay on an event basis, ongoing costs will depend on the length and depth of surveys (which are influenced by the standards), length of the survey cycle, mid-term monitoring system, the efficiency of scheduling, survey logistics, report handling and award adjudication. Budgets have to predict when events such as training, on-site surveys, and mid-term surveillance visits will occur and how much they will cost. Any postponement or cancellation can negatively affect anticipated cash flow. Some organisations include all documentation and direct survey costs, e.g. surveyor travel and accommodation, into a single-price package per survey but costs and revenues are still dependent on the event occurring. A number of accreditation organisations have moved to a membership or subscription based financial system, whereby clients become members of the accreditation programme and are charged a regular annual fee based on anticipated costs over the whole accreditation cycle, including overheads, education, guidance, standards, tools, survey and mid-term progress visits. While it still requires budget forecasting of the number and type of clients, it limits the uncertainty of whether and when events will happen and has contributed to the ongoing sustainability of a number of accreditation organisations.

A marketing programme and budget will be needed by most new external evaluation organisations to publicise itself, the services it offers and the benefits of its programme to attract healthcare providers. Getting a sustainable market share of client organisations will be fundamental to its success. Wider marketing and publicity will be needed for potential insurers, funders and the general public.

3.4.3 Establishing information systems

Information management covers both technological and paper based information, including educational and marketing resources. Internal information systems are essential for planning, operations and finance, but they also need to have the capacity to collect, aggregate and compare data over time within and between participating organisations, standards and surveyors, such as:

- Data of compliance with achievement of individual criteria or standards
- Profiles of participating organisations
- Calculation of standard scores, function scores, and overall score for each organisation
- Aggregated results for comparison over time, function and place
- Profiles of individual surveyors and their participation
- Survey scheduling and management
- Overall impact of programme.

Data which show that participating organisations have made improvements associated with the programme since the first (baseline) contact are essential to demonstrate the value of the programme to the healthcare system[3].

3.4.4 Addressing risk management and performance improvement

The external evaluation organisation must model the safety and quality approach it expects from its client organisations. A robust risk management framework that identifies and manages risks and promotes safety must be implemented. While most of these organisations demonstrate a safety culture, it needs to be demonstrated by establishing a quality improvement policy and framework. Essential to this will be the documentation of policies and procedures for all functions, the development and use of key quality indicators which can be monitored and benchmarked over time or with similar organisations, the use of audits and reviews to ensure compliance with policies and procedures, documented quality improvement projects and a transparent complaints system that is available to staff, surveyors, clients and other stakeholders[3].

3.4.5 Providing education services

Most external evaluation programmes provide a variety of education and training as an essential component of their services. Education services need to be systematically designed and implemented to meet quality standards and client needs. These include:

- Induction and development of staff
- Orientation and ongoing education of members of the governing board
- Initial and continuing training of surveyors
- General preparation of participating organisations and their staff as a basic component of their participation
- Specific methods of internal quality improvement required to meet external evaluation standards, such as infection control, risk management, performance measurement, patient / client surveys – these are usually additional to services covered by fees and are charged separately
- Quality improvement programmes for the health or social care sectors in general.

These training and education programmes and courses and their resources need to be planned, scheduled and costed. Information provided needs to be kept up-to-date and based on current research and evidence. Trainers and educators, whether internal or external, need to have the competence and expertise to deliver the programmes.

3.5 Timeframes

The most commonly underestimated resource is the time needed to plan, design, build and deliver a sustainable new external evaluation organisation. The pace at which this can be done is limited largely by factors outside the control of the organisation, notably by the prevailing culture and attitudes towards leadership, innovation, improvement, team-working and transparency.

In practice the development stages, which may overlap, are:

- Policy decision to develop an external evaluation organisation / programme and defining its scope
- Option appraisal on existing models and their adaptation
- Setting up the organisation structure and obtaining of funding
- Development and testing of standards
- Development and testing of assessment methodologies
- Surveyor selection and training

- Pilot testing, education and marketing campaigns
- Revision of standards and methods based on feedback from piloting
- First "live" surveys
- First accreditation / certification recognition status decisions.

This process is likely to take at least two years but can take much longer (The case studies outline the order of development and the timescales involved for the three different agencies. Please refer to Appendices 1 a, b and c for further information.).

Taking time to establish communication with all stakeholders and the public and continual updating of information as the organisation develops, is essential for success.

The following chapters focus on and provide more detail in relation to the development and testing of standards; the development of assessment methodologies and mechanisms for evaluating systems and performance.

Chapter 4: Developing the standards

This chapter focuses on the different elements required when developing standards. It includes the use of quality dimensions and the importance of a reliable and valid measurement scale.

The standards used or developed by external evaluation organisations are the most fundamental element of their programme. While not always realistic, it is advisable to consider what evaluation methodology will be used while the standards are still in the development phase. The standards will help to inform the public what to expect from health and social care providers and will act as a benchmark against which providers and the government can measure quality. The standards will form the framework for self-assessment and internal audits.

Standards development can often commence prior to the setting up of governance and management systems in the external evaluation organisation and can take two or more years to complete. Funders may want to know the shape and content of the standards before they commit to funding the organisation. Separate funding is often available for the standards development process.

4.1 The role of standards

An external evaluation organisation's standards have to reflect its purpose and cover the key functions and processes of the healthcare or social care sectors that are being evaluated. Similarly, if standards are owned or mandated by government, they need to reflect the purpose for which government intends them. They have to reflect legislative requirements, safety and good practice. They should be relevant, understandable, measurable, beneficial and achievable (RUMBA)[25].

Standards also need to be realistic and reflect the availability of resources, especially in developing countries where resource limitations can significantly impact a healthcare organisation's ability to achieve optimal performance. For example, Malaysia and Thailand began with relatively achievable accreditation standards but committed to continue updating and improving these over time. In this context, Malaysia has published the 4th edition of their hospital standards since the accreditation programme began in 1999. Thailand has also made progressive changes, introducing a stepwise recognition programme in 2004 and patient safety goals in 2006[20]. Standards can also be prioritised and incremental improvements made in achieving them can be recognised and rewarded. In India, the National Accreditation Board for Hospitals & Healthcare Providers (NABH) has developed Pre-Accreditation Entry Level certification standards, in consultation with various stakeholders in the country, whose aim is to introduce quality and accreditation to healthcare organisations as their first step towards awareness and capacity building. Once organisations have met the Pre-Accreditation Entry Level certification standards, they can then prepare and move on to the next stage –Progressive Level and can then work towards Full Accreditation status. This methodology provides a step by step phased approach for healthcare organisations[26].

The long-established accreditation organisations generally began with standards and surveys which reflected management units, e.g. departments. They also tended to focus on structures, e.g. staffing arrangements, funding, equipment or committees. Most programmes now focus their standards and assessments on a client focused continuum of care or patient's journey rather than management units and on processes and outcomes rather than structures.

However, for developing countries, basic structural standards may still be an important starting point. External evaluation may be primarily a vehicle for taking stock and developing greater equality of structure and access where the healthcare system has wide regional and social divisions. In this case, the health system must be able to mobilise resources in order to respond appropriately to the priorities which are objectively demonstrated through the external evaluation process. For example, participants from external evaluation organisations in low and middle-income countries attending a 2013 workshop in Bangkok, Thailand highlighted that standards are important in their countries to improve the overall quality of care and not just to differentiate between hospitals that pass an accreditation visit and those that do not. In many low and middle-income countries, institutions that fail to meet standards may still be the only available source of care for parts of the population and therefore, it is important that there is a focus on improving the care they do provide[20].

4.2 Principles for standards

Standards are developed and written in many different ways and are designed to meet the purpose and scope of the particular external evaluation programme, as discussed in Chapter 2. However, they must be user-friendly, able to meet the purposes for which they have been designed, and be able to measure achievement in a consistent way. Evidence-based mechanisms by which standards are developed, promulgated, reinforced, audited and evaluated are needed. Linking the writing of standards, including the wording, structure, design, focus and content, to demonstrating improved outcomes requires further investigation[27].

ISQua has focused on addressing this gap by developing principles to guide the development of health and social care standards and enable their assessment and accreditation. These were originally developed in 2000, and revised on numerous occasions. The most recent 4th edition was published in 2014[4]. The principles are based on the Institute for Medicine (IOM) quality dimensions[28], of effective quality performance, efficient organisational performance, safety and patient focus. The ISQua Principles (2014)[4] also give guidance on how to develop and measure standards. ISQua recommends that the development and content of all standards should meet its internationally accepted best practice principles.

The purpose of some external evaluation organisations is to assess, and sometimes certify, health and social care organisations against government standards or the standards of another external evaluation organisation, perhaps adapted to local circumstances. For the credibility of its own assessments, these organisations should encourage the owners of the standards to get them ISQua accredited.

The ISQua Principles cover all the functions of a healthcare or social care organisation, from governance, to management, to client care, to quality. They are:

1. Standards Development: Standards are planned, formulated and evaluated through a defined and rigorous process.
2. Standards Measurement: Standards enable consistent and transparent rating and measurement of achievement.
3. Organisational Role, Planning and Performance: Standards assess the capacity and efficiency of health and social care organisations.
4. Safety and Risk: Standards include measures to manage risk and to protect the safety of patients / service users, staff and visitors.

5. Patient / Service User Focus: The standards focus on patients / service users and reflect the continuum of care.
6. Quality Performance: Standards require service providers to regularly monitor, evaluate and improve the quality of services[4].

Steps for developing standards in line with the ISQua Principles for Standards[4] include:

- Reviewing other external evaluation organisation standards, current research and evidence, recognised guidelines, recommendations from WHO and other professional organisations and experts
- Incorporating legislative, technical and safety requirements
- Incorporating best practice where evidence is available
- Ensuring the standards are client focused, cover the functions or systems of a whole organisation or service, address the dimensions of quality, and support quality improvement
- Consulting stakeholder groups, including consumer groups
- Involving stakeholders in standards development committees and working groups
- Developing the rating system for measuring compliance with / against the standards
- Testing the standards and the way they are rated through self-assessment and pilot surveys
- Using feedback from testing to improve the standards and rating system
- Developing guidelines to assist users to interpret and apply the standards
- Ensuring the standards are approved by the external evaluation organisation governing body
- Applying for ISQua standards accreditation.

This development process may take two years or more if the standards are being fully developed. With the rapidly changing healthcare environment, 12 months would be an appropriate timeframe for organisations adapting other organisations' standards.

4.3 Referencing to quality dimensions

Standards can be grouped around quality dimensions to demonstrate their relationship to quality. The six quality dimensions as defined within the Institute of Medicine (IOM) report Crossing the Quality Chasm, are the most commonly referenced[28].

- Safe S
- Timely T
- Efficient E
- Equitable E
- Effective E
- Patient-centered P

By defining the dimensions of quality, organisations are able to ensure that their inclusion can be justified but can also measure achievement in relation to those dimensions, demonstrating that quality is not an optional extra but the essence of a good and acceptable service. When standards are developed the criteria should address all of the quality dimensions.

Codes of patient / consumer rights have now been developed or adopted in many countries. These are designed to protect an individual's rights when they access health or social care services and describe what their rights are when accessing such services. In some jurisdictions, the codes of patient / consumer rights are specified in or underpinned by legislation and service providers are required to have processes in place to meet them. In such cases the codes of patient / consumer rights may be referenced in the standards as this will provide a means of assessing how service providers are meeting patient / consumer rights. In other countries, codes of patient / consumer rights have been developed by organisations such as national consumer or advocacy organisations and service providers may adopt them on a voluntary basis. Referencing the codes of patient / consumer rights in standards is one way of helping to ensure that standards are focused on the patient / consumer. This in turn will help service providers to focus on delivering patient / consumer focused care that meets their needs and protects their rights.

Mature accreditation organisations have now moved to designing their standards to reflect the patient / consumer journey or pathway and then surveyors may, as part of the survey process, trace or follow selected patients' / consumers' journeys to check at each stage if the standards were met for that individual and their family.

Many sets of standards label some criteria as core or compulsory, usually based on safety and risk. The core criteria are usually then required to be met or a defined ratio of them met, e.g. 80%. These core criteria may be used for licensing or regulation purposes.

4.4 Developing the measurement system

The rating scale should reflect the purpose of the standards, be transparent and enable users to rate and measure standards, criteria or elements consistently. A yes / no scale is good for determining compliance or non-compliance with a criterion or standard, especially for measuring structural elements, so its use should reflect the nature of the standards. It leaves less scope for recommendations for improvement where a criterion is mainly met, but some elements are missing.

Likert-type rating scales are particularly suited for standards with a strong quality improvement approach, e.g. 3, 5 or 7 point scales, often with descriptions for each point or some of the points. These descriptions may relate to principles such as compliance, consistency, evidence and implementation.

There is a tendency for assessors to favour a middle or neutral point, so an even point scale such as a four point scale can give a clear cut-off point as to whether the criterion is met or not but still provide a graduated measure of how well it is met or how badly it is not met. The clearer the descriptors, the more consistent the assessments are likely to be.

As well as a measurement system for rating each measureable criterion, element or standard, a system is needed to determine if the standards are met overall which will be the basis for awarding accreditation or certification where that is applicable. In a study comparing the organisational attributes of accreditation programmes in low- and middle-income countries with those in higher-income countries, it was found that the low- and middle-income countries' programmes were more likely to use a formulaic mathematically oriented approach to make accreditation decisions[7]. Traditionally, accreditation organisations relied on accreditation panels to make decisions but this was not always a transparent process, the basis of the decision was not always clear, it could be more prone to bias or external influence and was also likely to result in appeals against the decision.

Therefore, best practice is to determine overall achievement of standards based on a formula which includes the level of achievement of or compliance with the measureable elements of the standards, risk and other elements of the standards such as core criteria or high priority criteria.

Some organisations measure only at the criterion level, so their overall decision will be based on achievement of criteria while others use the overall ratings of the criteria within each standard to rate achievement of the standard, so their overall decision will be based on achievement of the standards. For example, the methodology could be that all core or compulsory criteria must be met, or all criteria or standards must be met at a defined level such as 3 or 4 on a 4 point scale, or no standards must be rated at below a certain level.

Like the rest of the standards, the rating scale needs to be developed in consultation with stakeholders and the satisfaction of users regularly assessed. As with the standards themselves, the rating scale needs to be tested and piloted before use to ensure it is reliable and can produce consistent and fair results.

The case study examples highlight the approaches to standards development adopted in different countries.

Case Studies – Development of standards

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark

Range of standards
IKAS has developed all standards used in its programmes. They were first developed for hospitals and community pharmacies. Standards have since been developed for primary care services, delivered by municipalities, and for ambulance services. Currently standards are being developed for general practitioners and specialist physicians. Over the coming years, all healthcare professions who operate outside of hospitals in their own office or premises will be covered.

Development process
Standards were developed by theme groups (for related groups of standards) of standard developers, consisting of senior professionals, appointed by the Regions and the Association of Danish Pharmacies. IKAS and HQS / CHKS served as advisors and secretariat for the groups.

Rating scale
Compliance with standards is assessed by scoring a number of elements (for the hospital standards roughly 450) according to a four point scale (Fully / Largely / Partially / Not Met), where the two upper levels indicate a satisfactory performance (except for certain safety critical standards, where only Fully Met is considered satisfactory). Any element not met to satisfaction will require follow up, and if not corrected, results in accreditation with comments. An Accreditation Award Panel decides, guided by certain rules, whether the nature and / or amount of the comments preclude accreditation – if so, status as "not accredited" is awarded and published.

Health Care Accreditation Council (HCAC)
Country: Jordan

Range of standards
As the national accreditation agency of Jordan, HCAC sets standards for hospitals, primary healthcare centres, family planning and reproductive health, transport services (ambulances), cardiac care, and diabetes mellitus. HCAC surveys against the standards and awards accreditation.

Development process
All the standards are developed in Jordan. No standards developed by other organisations are used. Hospital standards were developed first, then standards for primary care centres, family planning and reproductive health, transport services (ambulances), cardiac care, and diabetes mellitus.

Rating scale
Standards are classified as critical, core and stretch.100% of critical standards must be met; and a specified percentage of both core and stretch standards must be met in order for a service to be accredited.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand

HDANZ is a private, independently owned company. It is linked to government as a Ministry of Health (MOH) approved designated auditing agency. HDANZ audits these services on behalf of the MOH and submits audit reports to the MOH who then issues the certificates to the services.

Service providers pay fees to HDANZ for survey and monitoring visits. Certification has been mandatory for the MOH Safety Act since October 2002. From September 2005, it became mandatory for physiotherapy services if they wanted to provide services under the New Zealand Accident Compensation Scheme (ACC) physiotherapy services contract. From September 2012, health funders made certification mandatory for home support providers and from March 2013, a health insurance provider Southern Cross Health Society made certification mandatory for their affiliated providers.

The rating scale for compliance against the health and disability sector standards is:

CI = Continuous improvement

FA = Fully attained

PA = Partially attained

UA = Unattained

The Ministry of Health uses the assessment ratings to determine certification. The length of certification can vary from one to four years depending on the level of achievement of the standards.

The next chapter outlines the factors to be considered in developing assessment methodologies.

Chapter 5: Developing assessment methodologies

This chapter explores factors to be considered in the development of the assessment methodology such as the selection, training and evaluation of surveyors; the development of the survey management process; and the establishment of processes for determining the accreditation or certification status.

A survey against standards can be achieved by either a desk top review or an on-site survey. Desk top reviews may be suitable for some specialities such as diagnostic imaging or clinical pathways such as stroke care. For organisations an on-site survey is recommended, which can be planned or unannounced.

Surveyors are the main interface of the external evaluation organisation with its clients, and the survey is the key event on which the clients will judge the organisation. It is essential that surveyors and the survey and award processes are managed consistently, transparently and well.

5.1 Selection, training and evaluation of surveyors

Accreditation organisations generally use the term "surveyors" while certification organisations usually use the terms "assessors" or "auditors" to describe the personnel who visit, assess and draft reports. Regulatory bodies may use the term "inspectors". They are central to the credibility, objectivity and sustainability of the organisation. Accreditation surveyors are generally regarded as peer reviewers – doctors, nurses, managers and allied health professionals – who understand the work their peers do but their role is to assess processes and systems rather than their peers' performance. Auditors are professional quality auditors, usually certified as such, who can audit or assess across industries and do not need to be a healthcare professional peer. In this guide the term "surveyor" is used to cover all assessment personnel and the term "survey" to cover all external assessments.

Paid or voluntary?

As previously highlighted in Chapter 3 (See Section 3.3 Funding of the programme), accreditation organisations have traditionally relied upon participating accredited institutions to provide or loan staff to work as surveyors and to promote the concept of peer review. This has the advantage of reducing survey costs, maintaining the acceptability and independence of peer review, and sharing the experience and knowledge of accreditation widely throughout the health system. However, it assumes that there are personnel with enough experience who are able and willing to be seconded by their employers to be trained as surveyors without creating a conflict of interest. To maintain skill levels and currency with standards and systems, surveyors should be expected to undertake a minimum number of working days (usually ten) a year. It can be a challenge for them to get released from their full-time job for this amount of time.

Certification organisations usually employ or contract their assessment personnel on a paid basis, supplemented by technical experts. However, as highlighted in Chapter 3 (See Section 3.3 Funding of the programme), accreditation organisations are now also increasingly paying surveyors as employed or contracted personnel, or using a mix of both paid and voluntary. Surveyors mostly come from a health background and have previously been involved in accreditation programmes.

The advantages of having a more stable workforce of paid surveyors is their greater availability, the reduced number of surveyors needed, reduced demand for recruitment campaigns and new training programmes and more reliable and consistent performance of the role because of the increased frequency of undertaking surveys and writing reports.

Selecting and appointing

The first steps in developing a surveyor workforce are to:

- Determine the number, skill mix and mix of paid / employed or voluntary surveyors needed for the planned programme of work (the numbers will need to be increased as more organisations join the programme)
- Define the required competencies, including personal attributes, professional qualifications and experience, knowledge and skill sets relevant to the programme.

The number of surveyors to be recruited should be estimated from the volume of surveys planned, their duration (in terms of surveyor days), the number of days each surveyor would provide per year, the number of surveyors withdrawing each year and the paid / voluntary mix of surveyors. Their professional background, culture and skills should reflect the function and scope of the programme. Recruitment may be done by advertising in relevant publications, sending notices to all potential client organisations and professional associations, and directly approaching likely candidates.

Surveyors should be appointed through a clearly stated and fairly applied process in accordance with the defined competencies and the numbers determined. Competencies could include:

- Personal attributes, including the ability to communicate effectively and to work as a team member
- Professional qualifications and experience, usually at a senior level
- Current healthcare or social care sector knowledge
- Skills in the areas covered by the programme.

Whether surveyors are seconded (on their usual salary), or employed directly by the external evaluation organisation, they must be committed to comply with the rules of that organisation, particularly with respect to confidentiality and independence. If the external evaluation organisation employs them directly, it may have to accept additional legal responsibility and have to provide additional liability insurance.

Training to be a surveyor and undertaking the role is a form of professional development and is recognised as such by many professional colleges and associations. Surveyors become familiar with the standards and survey processes and are able to learn for their own practice from what they observe in the organisations in which they survey. They in turn become educators of the staff they survey, able to identify areas where they can improve and best practice methods or tools they could use.

Training

After selection, surveyors will then need to be either employed or contracted, and trained and oriented to the role. Training cannot begin until at least draft standards and procedures are available. In established organisations, training is provided by existing surveyors and staff; new organisations generally use expertise from other programmes, at least for initial training.

The initial training programme can be of one to five days duration and should cover topics such as:

- Standards' interpretation
- Survey process
- Interviewing and observation skills
- Documentation review
- Specific areas, e.g. safety, infection control
- Report writing techniques

Trainees then need to be evaluated to determine their suitability for the role. Mock assessments are often included so that trainees can demonstrate their aptitude. They then usually go on one or more survey visits as observers or trainees with a mentor to accustom them to the role and further test their suitability. They need manuals and other resources to assist them. Programmes are increasingly using technology on-site for the recording of the assessment and use of this also needs to be part of the training.

The surveyor training programme of accreditation organisations in low- and middle-income countries tend to be surveyor certification programmes and organisations in developed countries are also moving in this direction. Such certification provides a recognised status for the surveyor but may also provide the opportunity for more rigorous evaluation of performance and ongoing training and development. Certification programmes generally expect their auditors or assessors to be certified.

Ongoing development and evaluation

Surveyors must be provided with ongoing training and development opportunities, and be evaluated regularly to ensure their ongoing competence. External evaluation organisations need to define criteria for selecting, training, retraining and deselecting surveyors. Some organisations have an independent committee to monitor inter-rater reliability of the survey and rating performance of surveyors and / or satisfaction surveys by an independent third party, as well as in-house survey team assessments. It is common to ask client organisations to evaluate the standards, the survey, and the performance of the surveyors after the external survey. These evaluations are most useful if they relate to the individuals rather than just the team. All these reports, and participation in continuing training, contribute to the systematic appraisal of each surveyor.

Where there is a surveyor certification programme, surveyors must meet the annual requirements to maintain their certification.

The ISQua Surveyor Training Programme Standards (2009)[5] provide guidance on setting up these training programmes which can then be ISQua accredited. The ISQua Guidelines and Standards for External Evaluation Organisations also contain a standard (Standard 6) on surveyor management[3].

5.2 Developing the survey management process

Contracting with the client organisation

There should be a defined process to ensure that participating organisations are aware of their rights and responsibilities in relation to the external evaluation programme, and that they understand the procedures and responsibilities of the programme. This usually involves a standard contract or service agreement between the applicant healthcare or social care organisation and the external evaluation programme.

Training and educational support are often provided by the programme for the staff of the client organisation as an integral part of the preparatory process. This may include for example: project manager training, standards interpretation, and internal assessment and self-assessment training. Where self-assessment is a component of its programme, the external evaluation organisation's staff can guide the client as to how to undertake and complete this. Self-assessment against the published standards develops insight and commitment, and reduces the burden of external assessment because it helps organisations to identify, understand and resolve their own problems. Many programmes consider this internalisation to be a key factor in the rapidly increasing compliance with standards which can be demonstrated in participating organisations in the months prior to external survey. It is important to determine what is included within the programme fees and what training / educational support is provided at an additional fee.

Many programmes provide facilitators, such as programme staff or trained surveyors, to support client organisations to prepare on first entering the programme, and to feed back to the programme any problems with systems or processes. This acknowledges that the early external surveys are as much a test of the standards, surveyors and procedures as they are of the organisation being visited. The facilitators should not be permitted to take part in or influence the external survey. They can arrange training, participate as a trainer, advise clients on interpretation of the standards or what needs to be in place to meet the standards but they can only provide generic advice that is freely available in the public domain. They must not give any advice on how things should be done or provide any technical assistance such as preparing or producing documentation or procedures, or giving client-specific advice, instructions or solutions. This would be regarded as consultancy which must be strictly separated from external evaluation activities.

A pre-survey review or mock survey can also be a valuable part of preparation. It identifies whether the client organisation is interpreting the standards correctly and has appropriate documentation as evidence of how it meets different criteria as well as indicating the client's progress towards survey readiness. It also provides a good practice run for staff so they know what to expect from the actual survey.

Planning and conducting the survey

Planning the scope of the survey, duration and the size of the survey team should be transparent, based on the needs of the organisation and the policies of the external evaluation body. The surveyor team for the external survey should include an appropriate mix of skills and experience and avoid conflict(s) of interest. A more experienced team leader is generally chosen to guide the process. Dates for the external survey are usually set 6-12 months in advance to allow for self-assessment and preparation and possibly a mock survey.

The standards must be incorporated into a tool in which surveyors can make findings, ratings and recommendations for improvement. The self-assessment can be included in the tool if this is part of the process. The tool may be on paper or loaded into a tablet or similar technological device.

Site visits may extend from half a day for one surveyor for a small rural primary care clinic to two weeks for large teams for a healthcare network. Small hospitals or rest homes often use two people for two days (four surveyor days); larger ones commonly use three people for five days. Time for surveyor preparation, travel, team briefing and report completion must be added to these "on-site" estimates. At the end of the visit, most organisations provide time for the team to prepare a report back of findings which they present at a meeting to the leadership of the client organisation and preferably also to staff. This enables the client to correct any errors at the time and means there should be no surprises when they receive the final report.

The efficiency of the survey visit and the transparency and consistency of the process can be improved through the provision of tools and guidelines to assist the surveyors; thorough preparation by the organisation being surveyed and the surveyors; the timely submission of complete and accurate self-assessments and other pre-visit documents; a realistic survey timetable; explicit sampling procedures; specified documents being made readily available for review on site; and time management. Increasing the number of surveyor days may not help, but will certainly increase the complexity and cost of the visit.

Writing the report

The surveyors write a report of their findings and rating of achievement against the standards either while still on-site at the end of the visit or afterwards. Doing this electronically contributes to the speed with which the report can be submitted. New external evaluation organisations should include the e-generation of the report as part of their programme if possible. It is important that strict timelines are put on this process, otherwise the surveyors can get back to their usual workplace and try to catch up on that work before finishing the report. A delay at this stage leads to a delay in making the award decision which is frustrating for the client. The report is submitted to the external evaluation organisation which must have processes for editing and reviewing the reports to ensure they are complete, accurate, balanced, constructive and consistent with the intent of the standards.

Performance indicators

The external evaluation organisation should determine what indicators it requires its client organisations to monitor. These should cover the different management, safety and clinical functions of the healthcare organisation and may include things such as complaints, patient / client satisfaction, staff satisfaction, staff turnover, financial ratios, adverse events, accidents, clinical indicators such as falls and infections, and medication errors. These demonstrate that the client organisation has the capacity to generate and analyse performance data as part of an internal quality improvement programme and is using the results to make improvements.

Sometimes the collection, analysis and publication of the results of indicator data is part of the scope of the external evaluation organisation. In these cases, there must be processes to ensure the indicators have standardised definitions and numerators and denominators, that the data collected is clean, complete, accurate and timely. The data can then provide comparable measures of achievement over time for a healthcare organisation or between similar organisations in terms of processes and outcomes in clinical, safety, financial or other areas[3].

5.3 Establishing the accreditation / certification process

Responsibilities for accreditation / certification

The external evaluation organisation is responsible for setting the criteria for determining accreditation or certification status, and the decision on whether or not to grant accreditation status is made in accordance with the criteria on the basis of the findings in the survey report. These criteria should ensure:

- Transparency for organisations being accredited or certified, for surveyors and for the public
- Consideration for the clients of the service and their safety
- Decisions based on the achievement of the standards
- Consideration of how accreditation or certification status will facilitate further quality improvement
- Consistency between award decisions
- A non-adversarial process for appeals.

Basis for recognition decisions

Earlier programmes based the recognition decision or accreditation status primarily on the capacity for good clinical care, demonstrated by compliance with accreditation standards, but the emphasis has now shifted towards overall performance. Newer accreditation programmes, especially in developing and under-resourced countries, may need, at least initially, to focus on and to reward the existence of basic infrastructure and demonstrated progress towards, rather than absolute compliance with, the published standards. Different programmes may have different priority concerns, e.g. critical functional areas such as patient care, infection control, quality improvement or management of the environment; patient safety goals such as patient identification, high alert medications, wrong-site surgery or communication among caregivers; or areas of difficulty such as information flow, patient records or medical equipment surveillance.

In case there is any dispute about the recognition decision, a transparent, independent and clearly described appeals process is necessary.

Timeframe for recognition decisions

Having worked hard to prepare for the external survey, staff and management of client organisations are eager to receive a timely decision from the external evaluation organisation. Many programmes still aim to provide the majority of decisions within two months of the survey, although those using electronic technology for reports and formulaic criteria for decision making are able to make the decisions much quicker. As the delay increases, the report and decision become increasingly irrelevant, staff become demotivated and improvement is not sustained. The adjudication process must therefore be transparent and thorough, but also timely.

Duration and maintenance of accreditation

Accreditation status is normally awarded for a period of between one and four years. Sometimes there are different grades of achievement, e.g. conditional, or with commendations, or exemplary. ISQua criteria now require monitoring by the external evaluation organisation of the continued maintenance of standards and quality improvements by accredited or certified organisations.

Monitoring could include submission of an action plan following the award with timeframes for making improvements recommended in the report and regular updates on progress with implementation. In most programmes, the majority of report recommendations after the external survey are about improving systems in the organisation rather than about increasing resources and, as with the preparation, the organisation should be incurring much of that cost anyway so it should not be a barrier to improvement. Other monitoring may require a review of specified documents that were deemed incomplete, inadequate or missing; annual or mid-term visits and random reviews. Longer intervals between external surveys tend to instil a false sense of security and remove the momentum for internal improvement.

Publication of results

The extent and methods of public disclosure of survey findings and accreditation or certification awards must be agreed in advance by the external evaluation organisation and the various stakeholders. The public should have access to information about which organisations are accredited or certified. Some organisations are now publishing the survey reports or a summary of them. Regulatory bodies are usually mandated to publish full reports.

Example: Public disclosure of accreditation reports: Japan

The Japan Council for Quality Health Care (JCQHC) was founded in 1995 and has developed standards and criteria for accreditation and began carrying out on-site assessments in 1997. Japan has a universal health insurance system and so Japanese people have a right to receive medical care at any healthcare organisation and hospitals cannot refuse any patients. Hospital accreditation is voluntary and requires an application fee. Hospitals receive scores for each item in all areas with comments from JCQHC in the standard accreditation process. There are two forms of disclosure of hospital accreditation reports in Japan:

1. Self-disclosure to the public directly by hospitals;
2. Disclosure by the JCQHC with agreement from the hospital concerned.

Hospitals are not permitted to disclose only selected parts of their accreditation report as the purpose of disclosure of accreditation reports is to give consumers access not only to favourable aspects of the report but also to information about those aspects of the service that require improvement. The data disclosed by the JCQHC to the public include summary comments and accreditation scores for all the items assessed.

A study was performed in Japan to examine the association between accreditation scores and the disclosure of accreditation reports. This included a questionnaire to hospitals who disclosed their accreditation reports to gather data about hospital characteristics along with perceptions about the public disclosure of accreditation reports. A total of 547 of the 817 hospitals accredited by JCQHC participated in the study. Comments about the disclosure of accreditation reports were categorised into five general subject areas: (1) impact of disclosure on the public, (2) advantages to the hospital, (3) risks to the hospital, (4) JCQHC disclosure, and (5) hospital self-disclosure of information—that is, voluntary disclosure by the hospital by, for example, a pamphlet or a notice on all billboards in the hospital. Feedback from participating hospitals, highlighted that most hospitals (60%) perceive disclosure as good for consumers and hospitals; with most hospitals who disclosed their reports to the JCQHC (80.5%) agreeing that "disclosure provides incentives for improving the quality of care because consumers in the community read accreditation reports".

A total of 508 (93%) of the participating hospitals disclosed their accreditation reports on the JCQHC website. Public hospitals were significantly more committed to public disclosure than private hospitals, and larger hospitals were significantly more likely to participate in public disclosure than smaller hospitals. Accreditation scores were positively related to the public disclosure of hospital accreditation reports. Scores for patient focused care and efforts to meet community needs were significantly higher in actively disclosing hospitals than in non-disclosing hospitals. Among the large hospitals, scores for safety management were significantly higher in hospitals advocating disclosure than in non-disclosing hospitals.

Most hospitals who agreed to disclosure by the JCQHC (410/508 – 80.7%) reported that their public disclosure was helpful. A total of 489 of the 547 respondents (89.4%) indicated that they also disclosed their accreditation reports themselves: 366 disclosed only their accreditation status and 123 disclosed more than this. The study found that significantly more of the hospitals who agreed to disclosure of their report by the JCQHC also released information than those who were not in favour of disclosure by the JCQHC.

The study findings suggest that public disclosure of accreditation reports should be encouraged to improve public accountability and the quality of care. The authors highlighted that there is a need for further research to explore the interaction between public disclosure, processes and outcomes[29].

5.4 Quality Assurance

External evaluation organisations need to be able to demonstrate their integrity, objectivity and reliability. Mechanisms include:

- The programme's standards, survey processes and criteria for accreditation or certification awards are made publicly available
- Surveyors are selected, trained and evaluated against explicit published criteria
- Survey teams are tailored to each individual client organisation, according to published criteria, to avoid any conflict of interest
- The survey team reports initial findings back to the client organisation before leaving the site, especially in relation to those likely to generate recommendations, in order to check the observation and to ensure there are no surprises later
- Team reports are prepared and agreed jointly and in compliance with procedures which are often defined in a surveyors' handbook
- Team reports are independently checked within the external evaluation organisation for content, consistency and compliance with procedures
- Final draft reports are referred to the client organisation for verification before the accreditation or certification decision
- Accreditation or certification awards are made by a panel or staff independent of the process, based on the team's report and in line with defined decision-making criteria or formulae, not by the team itself[3].

The final chapter will look at evaluation systems that need to be established.

Chapter 6: Evaluating systems and achievements

External evaluation organisations need to set an example of quality improvement within their own organisation. This includes defining, monitoring and improving their own performance. This chapter outlines some of the mechanisms which external evaluation organisations can employ to do this.

6.1 Measuring performance internally

Internal audits, indicators and quality improvement projects will form part of the overall quality framework of the organisation.

Indicator data routinely collected by external evaluation organisations and reported to governing boards include:

- Recruitment, drop-out of participating organisations
- Denial rate (proportion of organisations refused accreditation or certification)
- Report turnaround times (from survey date to final report or to award decision)
- Financial performance, such as actual against budget and various financial ratios
- Website hits
- Surveyor recruitment, training and evaluation
- Client satisfaction with surveyors, education services, the survey process, the survey visit and other products provided by the programme
- Staff satisfaction
- Surveyor satisfaction
- Satisfaction of other stakeholders.

The ISQua organisation standards require the external evaluation organisation to evaluate the performance of various functions (such as governance, human resources management, surveyor and survey management and accreditation or certification processes and outcomes), by collecting data on defined indicators and other measures of performance, analysing it, making improvements and evaluating achievements[3].

External evaluation organisations typically undertake many development and improvement initiatives. These need to be treated as quality projects and the objectives, actions, timeframes, responsibilities, progress and results documented. These project documents will form an important part of the evidence needed when the organisation undergoes its own external evaluation survey through ISQua.

Audits need to be scheduled, results documented and actions taken as a result recorded and evaluated. Audits can address a number of areas; for example, audits can be conducted of staff, surveyor and client records; award decisions; health and safety; and the complaints register.

6.2 Evaluating independently

Independent evaluations of new accreditation organisations have been commissioned, often by governments or as conditions of receiving initial development funding. Examples from Australia, South Africa, Zambia and the UK document benefits perceived by organisations and their users, but include little data on individual or population health improvements[1].

A WHO study of external quality assessment programmes for maternal and child health concluded in 2002 that these bring benefits to clients, the community, staff and the service, summarised as[30]:

- The linkages, networks and structures which have been developed and / or improved to influence the political, legislative, economic, socio-cultural and public health environment within which services operate (enabling mechanisms)
- The reorganisation and / or development of the healthcare delivery systems at the service level
- The change in attitude and / or development of skills and knowledge of health service staff
- Improvements to health facilities and equipment
- A client-centred and clients' rights approach to healthcare whereby services consult with and support clients, are needs based and able to deliver better care to clients and the community.

6.3 Monitoring by regulatory agencies

Some regulatory bodies, e.g. in USA and Canada, monitor independent accreditation programmes, primarily by representation on the governing board or by checks on selected surveys. The federal government follow The Joint Commission into 5% of surveys in "deemed status" hospitals within a few weeks of the visit to validate reports; the National Committee for Quality Assurance (NCQA) in USA has a proportion of co-visits; and the Accreditation Association for Ambulatory Health Care (AAAHC) has a similar proportion of post-accreditation validation surveys of ambulatory care centres. In South Africa, the provincial government, which is also the contractor, provides monitoring by co-visiting. In New Zealand, the Ministry of Health arranges monitoring audits of 5% of all certification audits undertaken by independent designated audit agencies[1].

6.4 Accrediting the external evaluation bodies

The International Society for Quality in Health Care's (ISQua's) International Accreditation Programme has been in existence since 1999 and "accredits the accreditors". The scope of the programme has been extended from the evaluation of national healthcare accreditation organisations, their standards and surveyor training, to include other standards based certification and audit organisations.

The International Accreditation Programme (IAP) provides three products for health and social care external evaluation bodies:

- Survey and accreditation to international standards for external evaluation organisations
- Standards assessment and accreditation to international principles for healthcare and social care standards
- Assessment and accreditation of surveyor training programmes.

The international standards for external evaluation organisations are the outcome of several years of development, testing, peer review and consultation with the international accreditation community. They were designed to address the quality of all aspects and functions of an accreditation body, broadly incorporating the International Standards Organisation (ISO) requirements for certification bodies, the Baldrige criteria for performance excellence, and criteria for organisational excellence from the accreditation standards of a number of national accreditation bodies. These standards assess the key business functions as well as best practice in assessment methodologies, surveyor management and award recognition.

The standards and principles and their criteria are intended to guide external evaluation organisations in their development by identifying best practice processes and systems and providing an assessment process and recognition system for achievement of these.

Many smaller and developing programmes cannot justify the resources required for full international recognition but they could embark on a defined progression of development and standardisation starting from self-assessment, to peer review, and aiming eventually for international accreditation.

ISQua provides technical and advisory services such as self-assessment review and mock surveys to assist external evaluation organisations develop their programmes and prepare for international accreditation.

ISQua requires at least one set of the organisation's standards to be ISQua accredited before the organisation can enter the organisation accreditation programme.

Conclusions

This document has aimed to highlight some of the questions, issues and challenges which need to be addressed before deciding on and implementing an external evaluation programme. The decisions made must be specific to the values, health policies or strategies and organisations of individual countries, regions and care sectors. Steps have been identified that need to be taken to ensure that the foundation is set for a sustainable organisation. The order may be different, but the fundamentals must be established first. Some steps may be done in parallel, for example obtaining funding, negotiating incentives and developing standards, or establishing the governance framework and management systems.

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Useful web resources

The International Society for Quality in Health Care (ISQua) is not responsible for external website content. Please note that many organisations have English language content on their websites and where possible the direct link to such material is provided. However, in some instances the website content is only available in the native language.

Accreditation Canada	http://accreditation.ca/
Agency for Quality and Accreditation in Health and Social Welfare, Croatia	http://aaz.hr/
American Accreditation Council	http://www.americanaccreditationcouncil.com/
American Association for Accreditation of Ambulatory Surgery Facilities International	http://www.aaaasfi.org/
American Association of Blood Banks	http://www.aabb.org/
Australian Aged Care Quality Agency	http://www.aacqa.gov.au/
Australian Commission on Safety and Quality in Health Care	http://www.safetyandquality.gov.au/
Australian General Practice Accreditation Ltd (AGPAL)	http://www.agpal.com.au/
Canadian Accreditation Council	http://www.cacohs.com/
CHKS, United Kingdom	http://www.chks.co.uk/
Consortium for Brazilian Accreditation (CBA)	http://www.cbacred.org.br/
DAA Group Ltd	http://www.daagroup.co.nz/
DNV GL Business Assurance	http://www.dnvba.com/
Global-Mark Pty Ltd	http://www.global-mark.com.au/
Haute Authorité de Santé, France	http://www.has-sante.fr/portail/jcms/r_1455134/fr/about-has
Health Accreditation Service, Columbia	http://www.icontec.org/
Health and Disability Auditing New Zealand Ltd (HDANZ)	http://www.healthaudit.co.nz/
Health and Disability Auditing Australia Pty Ltd	http://www.hdaau.com.au/
Health Care Accreditation Council, Jordan	http://www.hcac.jo/
IKAS, The Danish Institute for Quality and Accreditation in Healthcare	http://www.ikas.dk/IKAS/English.aspx
Japan Council for Quality Health Care	http://jcqhc.or.jp/pdf/top/english.pdf
Joint Commission International	http://www.jointcommissioninternational.org/
Joint Commission of Taiwan	http://www.tjcha.org.tw/FrontStage/aboutus_en.html

Malaysian Society for Quality in Health	http://www.msqh.com.my/
Ministry of Health New Zealand – Health and Disability Services Standards	http://www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/health-and-disability-services-standards
National Accreditation Board for Hospitals and Healthcare Providers, India	http://www.nabh.co/
Quality Innovation Performance, Australia	http://www.qip.com.au/
Joint Commission of Taiwan	http://www.tjcha.org.tw/FrontStage/aboutus_en.html
The Australian Council on Healthcare Standards	http://www.achs.org.au/
The Healthcare Accreditation Institute (Public Organisation), Thailand	http://www.ha.or.th/
The Council for Health Service Accreditation of Southern Africa	http://www.cohsasa.co.za/
The Diagnostic Accreditation Program, British Columbia, Canada	http://www.dap.org/
The Netherlands Institute for Accreditation in Healthcare (NIAZ)	http://en.niaz.nl/

Appendix 1 - Case Studies

Appendix 1a.

IKAS – Danish Institute for Quality and Accreditation in Healthcare
Country: Denmark
Contributed by: Carsten Engel

Foundation of the programme

The Danish accreditation programme (DDKM) was established as part of the "National Strategy for Quality Development in the Healthcare System – Joint Goals and Action Plan 2002-2006". The strategy was developed by the national, regional and local political authorities in cooperation with stakeholder organisations, representing professionals and consumers.

At that time, a number of hospitals already had positive experiences with accreditation provided by international accreditors – one of the intentions of the strategy was to spread this to the entire healthcare system, based on a Danish model.

IKAS is formally an independent organisation, but IKAS and DDKM were established by an agreement between the regional and local political authorities, who are responsible for delivering healthcare, and the national government that sets the overarching political priorities, including the economic frame, and is the healthcare legislator and regulator.

The government provides part of the funding for IKAS. The government is represented on the Board of IKAS; the Chair of the Board is a government representative (a director of the Danish Health and Medicines Authority).

Development steps

The following steps describe the initial development of DDKM. The programme has since been extensively developed, based on the experiences obtained.

1. Cooperation agreement between the government and the regions on the establishment of a joint model for quality assessment, including provisions for the funding for DDKM (2004)
2. Appointment of a Board by the parties to the cooperation agreement and endorsement of bylaws for IKAS
3. Establishment of IKAS as an organisation (2005)
4. Tender for consultancy by an established international accreditor, resulting in a contract with HQS / CHKS for support to develop standards, establish IKAS as an accreditation organisation, and train surveyors
5. Development of first two sets of standards (hospitals and pharmacies) by theme groups (for related groups of standards) of standard developers, consisting of senior professionals, appointed by the Regions and the Association of Danish Pharmacies. IKAS and HQS / CHKS served as advisors and secretariat for the groups.
6. Public hearing, which for the hospital standards resulted in an extended revision by an editorial group with members from IKAS and the Regions, followed by a second hearing.
7. Pilot testing of standards for usability (for clients) and understandability
8. Submission of standards for ISQua accreditation

9. Development of an IT system to support implementation and external assessment
10. Development of a rating system
11. Development of information for hospitals and pharmacies and holding a series of courses for key persons in client organisations
12. Development of a survey methodology, described in a handbook
13. Selection and training of surveyors
14. Appointment and training of an Accreditation Awards Panel
15. Development and implementation of processes to process survey reports
16. Preparation for ISQua accreditation as an external evaluation organisation and of the surveyor training programme (obtained early 2011).

The standards actually led the development process; steps 9 – 15 overlapped each other and the later phases of standard development, but continued up to the commencement of surveys, 1½ years after finalising the standards.

The first survey was conducted 4½ years after the establishment of IKAS.

Funding & incentives

In terms of funding, IKAS has an index-linked annual grant from the central government, regions and local government. There are no fees for public clients or pharmacies. Other private clients pay a fee that covers direct expenses plus an overhead.

The programme is not required by any legislation, but is based on agreements as follows:

- Public hospitals: all hospitals participate by agreement between National and Regional governments
- Private hospitals: voluntary, but participation is a prerequisite to obtain a contract to treat patients for the regions (also required by some insurance companies)
- Pharmacies: voluntary, financial incentive in place
- Municipalities (primary care services, including long-term care): voluntary, no incentives in place
- Ambulance operators: prerequisite to obtain contract with Regions
- General practitioners: mandatory (with some minor exceptions) by agreement between the Regions and the Organisation of General Practitioners in Denmark; financial compensation as part of the agreement.

Standards and measurement

IKAS has developed all standards used in its programmes. They were first developed for hospitals and for community pharmacies. Standards have since been developed for primary care services, delivered by municipalities, and for ambulance services. Currently standards are being developed for general practitioners and specialist physicians. Over the coming years, all health care professions providing office-based services, outside of hospitals, will be covered.

Compliance with standards is assessed by scoring a number of elements (for the hospital standards roughly 450) according to a four point scale (Fully / Largely / Partially / Not Met), where the two upper levels indicate a satisfactory performance (except for certain safety critical standards, where only Fully Met is considered satisfactory). Any element not met to satisfaction will require follow up, and if not corrected, results in accreditation with comments. An Accreditation Award Panel decides, guided by certain rules, whether the nature and / or amount of the comments preclude accreditation – if so, status as "not accredited" is awarded and published.

Assessment methodology and focus

The assessment methodology used is external survey with extensive use of tracer methodology. The focus is on exploring the implementation of safe processes and investigating the use of quality data for improvement activities.

Quality improvement is fundamental. There is an extensive set of national quality registers in Denmark, and one of the purposes of DDKM is to support and assess that data is not just collected, but also used for quality improvement. Demonstration of completed and evaluated improvement activities is required from the second accreditation cycle.

Surveyors are active senior health care professionals who are contracted for 15 survey days per year. In addition, they are obligated to participate in continuous training activities.

Barriers

Development of an accreditation programme from scratch is much like building a bridge while you are crossing it. Even with the best support from consultants, there are a lot of lessons to be learned when the programme is applied in practice. A full pilot test, including complete implementation and external assessment, would be ideal, but would add a considerable delay.

Lessons learned

One lesson learned is that while it adds to the legitimacy of the programme that standards are developed involving a large number of healthcare professionals as standard developers, a strong editorial process is needed if this is to result in a uniform and balanced standard set. Furthermore, these types of standard developers will almost exclusively focus on the standards as implementation guides; it may be a challenge to assess performance in a reliable and uniform way. To support reliable assessment, the standards must include a lot of guidance for surveyors, both as to methodology and to rating, while avoiding surveys becoming exercises of "ticking check boxes".

We have underestimated the need to communicate that the standards are different from regulatory rules. The latter contain specific directions that must be strictly adhered to, whereas many (albeit not all) standards express a goal to strive for or require the client to define the specifics, according to local needs and priorities. You will meet clients asking to be told exactly what to do, and you will meet examples of "over implementation", where clients demand their staff to rigidly apply the same standardised procedures to all patients; an example could be hospitals believing that the standards require them to screen all patients for malnutrition, regardless of the likelihood for a certain patient or type of patient to be malnourished. This is, in our experience, an important source of resistance to accreditation among staff.

Our surveys are announced and are preceded by a lot of preparation by the clients. Many of their staff perceive this as building a nice picture to show the surveyors, but not necessarily giving a fair picture of the real performance; the risk is that preparing for accreditation is seen by staff as a show, designed to obtain a certificate, more than as a value adding activity. Doing unannounced or partially unannounced surveys would no doubt add to the face validity of accreditation. We are currently preparing a controlled study to investigate the merits of unannounced surveys.

One typical way to articulate resistance is to ask for the evidence for accreditation. While you must argue that accreditation is a complex intervention that cannot be backed by evidence of the same type as a drug treatment, design of a formal evaluation as part of the programme should be considered.

More information, including accreditation standards, can be found at http://www.ikas.dk/IKAS/English.aspx

Appendix 1b.

Health Care Accreditation Council (HCAC)
Country: Jordan
Contributed by: Ed Chappy

Foundation of the programme

Several reasons were stated for why the programme was developed including to improve the quality of hospitals and to enhance medical tourism. In addition, it was a response to public complaints of poor quality of care and a need to improve the entire healthcare system in the country.

The HCAC is the national healthcare accreditation agency of Jordan. The organisation sets standards for hospitals, primary healthcare centres, family planning and reproductive health, transport services (ambulances), cardiac care, and diabetes mellitus. HCAC surveys against the standards and awards accreditation. HCAC also provides consultation and education to prepare healthcare facilities for accreditation and offers certification courses.

The HCAC is a private, not-for-profit shareholding company registered under the Ministry of Trade and Industry. The board of directors is made up of representatives for all healthcare sectors in Jordan, medical and nursing professions, and education.

Development steps

1. Decision on funding and incentives
2. Standards or criteria development if applicable
3. Survey / Assessment management processes
4. Development of manuals, tools, education programmes for clients or others
5. Selection and training of surveyors / assessors
6. Type of proposed governance board and framework, constitution
7. Setting up of governance board, governance policies and procedures
8. Development of management systems, strategic and operational plans
9. Accreditation / Certification processes
10. Monitoring, review and evaluation systems
11. Development and use of website, portal or other electronic aids

A decision was taken to develop standards, prepare 17 pilot hospitals from the public, private, university, and military sectors for accreditation and then create the agency based on demand for accreditation.

The first set of hospital standards were developed in 2005, surveyors trained in 2006 and the agency (HCAC) established in December 2007. The first hospital accredited using HCAC standards was in March 2008.

The first services developed were consultation and education services to prepare hospitals for accreditation and mock and accreditation surveys. Then preparation of primary healthcare centres to meet standards and mock and accreditation surreys for them were added. Later, local and regional consultation and education surveys and certification courses for infection prevention staff, risk managers, and quality improvement coordinators were added.

Funding and incentives

The original funding to develop the HCAC came through the Jordan Healthcare Accreditation project funded by the United States Agency for International Development (USAID) and grants. Since March 2013, HCAC has been financially sustainable through charging fees for services offered including surveys, education and consultation.

Accreditation is voluntary. There are no incentives (laws, regulation, insurance requirements) in the country for accreditation.

Standards and measurement

All the standards are developed in Jordan. No standards developed by other organisations are used. Hospital standards were developed first, then standards for primary care centres, family planning and reproductive health, transport services (ambulances), cardiac care, and diabetes mellitus.

Standards are classified as critical, core and stretch.100% of critical standards must be met; and a specified percentage of both core and stretch standards must be met in order for a service to be accredited.

Assessment methodology & focus

Mock and accreditation surveys are used. The focus is on quality improvement.

Surveyors are certified for two years and are paid per survey. Staff are trained as surveyors but are only used in emergencies when a surveyor is ill or for other reasons cannot do a survey.

Challenges

The main challenge was deciding where the organisation was going to be placed in the country – Ministry of Health, other government agency, professional association, or as an independent company. The second challenge was to determine how it would be funded.

Lessons learned

- Every country must develop their system based on their needs and goals.
- See what other countries are doing but create your own system.
- Many activities can be done in parallel and you do not need to wait until one task is done before proceeding to the next (do not have to wait for the agency to be developed before standards are developed).
- Recognise that accreditation is a business and look at the agency as any other business with strategic, business, and operational plans and business processes.
- Do not neglect the need to market accreditation to the population as well as healthcare facilities and professionals.
- Partner with clients and maintain a relationship after and between accreditations.
- Look at accreditation as a means of improving the entire healthcare system, not just hospitals.
- See accreditation as one means to quality, not the only means.
- Always seek ways to do things better, which may be different from what everyone else is doing.

Appendix 1c.

Health and Disability Auditing New Zealand Ltd (HDANZ)
Country: New Zealand
Contributed by: Jim duRose

Foundation of the programme

The commencement of the Health and Disability Services (Safety) Act on 1 July 2002 represented a significant change in the regulatory environment in the New Zealand health and disability sector. This Act replaced several previous pieces of legislation and changed the way in which residential and hospital services were licensed or registered. In addition, the Act introduced health and disability standards for hospitals, rest homes and residential disability services aimed at improving safety levels and quality of care that became mandatory from 1 October 2004. The Act required that designated audit agencies (DAAs) are approved by the Director General of Health for the purpose of auditing these services to those standards.

HDANZ became designated in October 2002. In 2004 3rd party accreditation was with International Accreditation New Zealand (IANZ). Due to a change in IANZ's legislation they could no longer accredit HDANZ and in December 2008 HDANZ decided to proceed with ISQua accreditation. The objective was to have a seamless transition from IANZ and this was achieved by August 2009. Also, as of December 2008, the Ministry of Health did not require 3rd party accreditation but a few months later this became a requirement to maintain designation.

HDANZ's scope was determined by the Safety Act – the assessment of standards is a legal requirement for public and private hospitals, rest homes and residential disability services. Standards New Zealand (SNZ) is responsible for the New Zealand standards and this includes others such as for Home Support, Allied Health, and Day surgery procedures.

HDANZ is also 3rd party accredited with ISQua in order to audit and certify services to these standards.

HDANZ is a private, independently owned company. It is linked to the government as a MoH approved designated auditing agency and for these services, HDANZ submits the audit report to the MoH who issues the certificate

Development steps

1. Type of proposed governance board and framework, constitution
2. Decision on funding and incentives
3. Development of management systems, strategic and operational plans
4. Setting up of governance board, governance policies and procedures
5. Survey / Assessment management processes
6. Accreditation / Certification processes
7. Selection and training of surveyors / assessors
8. Monitoring, review and evaluation systems
9. Development of manuals, tools, education programmes for clients or others
10. Development and use of website, portal or other electronic aids – HDANZ had a website early on but web based assessment tools were introduced in 2008.

The first assessment was undertaken approximately 6-8 months after HDANZ was established.

There was no trial period but pre-audit "gap analysis" work was commonplace for most services before they completed their first assessment in 2003 / 04.

At first, HDANZ provided assessment services for all services under the Safety Act: rest homes, geriatric hospitals, maternity, surgical, hospice, mental health, disability services and addiction services. These continue but also HDANZ certifies home care, allied health / physiotherapy services, day surgery / office-based services and community services. HDANZ also completes funder contract auditing with NGO providers for a wide range of personal health and mental health and addiction services. General practice reviews are completed on behalf of Primary Care Organisations (PHO). HDANZ also assists the Royal College of General Practitioners (RNZCGP) with their Cornerstone general practice accreditation programme by independently reviewing reports and issuing a recommendation for accreditation.

Funding & incentives

Service providers pay fees to HDANZ for survey and monitoring visits. Certification has been mandatory for the MoH Safety Act since October 2002. From September 2005, it became mandatory for physiotherapy services if they wanted a special contract from the Accident Compensation Corporation (ACC). From September 2012, health funders made it mandatory for Home Support providers. From March 2013, Southern Cross Health Society insurance made certification mandatory for their affiliated providers.

Standards and measurement

Standards New Zealand is responsible for the standards. In 2003, the main standards were Health and Disability Sector Standards and this includes Infection Control and Restraint Minimisation. These were updated in 2008. In 2003, Home and Community Support Standards were issued by SNZ and these were updated in 2012. In 2005, Allied Health Standards and Day stay surgery standards were issued by SNZ.

The rating scale is:

CI = Continuous improvement
FA = Fully Attained
PA = Partially attained
UA = Unattained

The Ministry of Health uses the assessment ratings to determine certification. The length of certification can vary from one to four years depending on the level of achievement of the standards.

Assessment methodology & focus

Audit teams are formed for on-site visits and reporting to the relevant standards. This includes documentation, observation, client records sampling, tracer methodology, and interviewing of staff, management, clients and family.

Quality improvement is the focus and at the same time the provider has to have achieved the standards being assessed, noting that areas identified for further work (PA / UA ratings) have to have progress reported and are reviewed at the surveillance audit.

Assessors are paid per event and in addition to the two operational company Directors who audit there is one employee auditor. HDANZ maintains two separate auditor networks; one is for DAA / other services which includes about 20 assessors and is a mix of lead, clinical, consumers, technical experts, cultural and financial auditors and the other is for Physiotherapy services with an auditor network of 8 auditors.

Challenges

- In October 2002 there were 10 DAAs and all but HDANZ had a formal status in either ISQua health accreditation at the time or non-health ISO certification.
- Development of HDANZ's services and the infrastructure to deliver a range of audits.
- Setting up the quality management system.

Lessons learned

- Early investment in a customer relationship database was very important and then later improved at identifying sub-groups for marketing and other information.
- The two key drivers for this business are a) operational efficiency with competent administration staff and b) assessor competency.
- Added value for governance and robust organisational management from maintaining a 3rd party accreditation status.
- Sound decision as growth occurred to structure into programmes.
- Costs need to be closely monitored and managed as they can easily escalate otherwise.
- Outsourcing the financials in 2009 was a positive decision.
- Maintaining NZQA auditor training course approval for credibility and HDANZ purpose despite not being a revenue generator.
- 2008 investment into a marketing course reaped substantial dividends.
- To be perceived as the expert.
- Board / governance development in hindsight could have been more of a priority earlier on.

Appendix 1d.

Practice Incentive Program (PIP)
Country: Australia
Contributed by: Steve Clark

The Australian Government introduced the Practice Incentive Program (PIP) in 1998. The PIP is aimed at supporting general practice activities that encourage continuing improvements and quality care, enhance capacity and improve access and health outcomes for patients[21].

In the 2015-16 Australian Government Budget, in excess of $1.5bn over four years[22] was allocated to the PIP to support the continuation of incentive payments to general practices.

The PIP is used as a lever by government to influence behavioural change within the general practice environment. To access payments under the PIP, practices must meet the eligibility requirements, including that a practice must be accredited or registered for accreditation against the Royal Australian College of General Practitioners (RACGP) *Standards for general practices* and must maintain full accreditation.

Approximately 80% of all practices that meet the RACGP definition of a general practice participate in accreditation and, therefore, may access PIP payments.

There are three types of payments available under the PIP[21]:

1. **Practice Payments**

   The majority of payments through the PIP are made to practices and focus on those aspects of general practice that contribute to quality care. These payments are intended to support the practice to purchase new equipment, upgrade facilities or increase remuneration for GPs working at the practice.

2. **Service Incentive Payments**

   Service Incentive Payments (SIPs) are generally made to GPs to recognise and encourage the provision of specified services to individual patients. The Cervical Screening, Asthma and Diabetes incentives have service incentive payment components, and the Aged Care Access Incentive is a service incentive payment only.

3. **Rural Loading Payments**

   Practices participating in the PIP, with a main practice location situated outside capital cities and other major metropolitan centres, are automatically paid a rural loading.

There are ten individual incentives available to general practices and GPs under the PIP[23]:

- **After-hours Incentive,** supporting general practices to have appropriate arrangements in place that ensure their patients have access to quality after-hours care.
- **Asthma Incentive,** which aims to encourage GPs to better manage the clinical care of people with moderate to severe asthma.
- **Cervical Screening Incentive,** which aims to encourage GPs to screen under-screened women for cervical cancer, and to increase overall screening rates.
- **Diabetes Incentive,** which aims to encourage GPs to provide earlier diagnosis and effective management of people with established diabetes mellitus.
- **eHealth Incentive,** which aims to encourage general practices to keep up-to-date with the latest developments in eHealth and adopt new eHealth technology as it becomes available.
- **GP Aged Care Access Incentive,** which aims to encourage GPs to provide increased and continuing services in Residential Aged Care Facilities.
- **Indigenous Health Incentive,** which aims to support general practices and Indigenous health services to provide better healthcare for Aboriginal and / or Torres Strait Islander patients, including best practice management of chronic disease.
- **Procedural GP payment,** which aims to encourage GPs in rural and remote areas to maintain local access to surgical, anaesthetic and obstetric services.
- **Quality Prescribing Incentive,** which aims to encourage practices to keep up-to-date with information on the quality use of medicines.
- **Teaching payments,** which aim to encourage general practices to provide teaching sessions to undergraduate and graduate medical students who are preparing for entry into the Australian medical profession.

Since the inception of the PIP in 1998, successive Australian Governments have committed to ongoing funding for the programme; and during this time, have retained the requirement that a practice must be accredited, or registered for accreditation, and must maintain full accreditation in order to access such payments.

Given the level of participation in accreditation by Australian general practices, it can be assumed that the highly incentivised PIP has been instrumental in encouraging practices to engage in the process, and in turn has had a positive impact by supporting practices to focus on improvements and quality outcomes.

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