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Quality Assurance Methodology Refinement Series

# **Licensure, Accreditation, and Certification: Approaches to Health Services Quality**

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## I. Introduction

### The Growth of the Quality Movement

In the past decade, the quality movement that has been embraced by the service and manufacturing sectors has spilled into the health care sector. The fundamental quality assurance and improvement theories of Joseph Juran and W. Edwards Deming, as well as the comprehensive quality management approaches of Total Quality Management (TQM) and Continuous Quality Improvement (CQI), are finding their way into the daily operations of health care organizations around the world. Most health care managers and policy makers now view as imperatives the evaluation and control of quality and improvements in quality. Less agreement exists, however, as to a quality evaluation approach that will meet the needs of a particular health care organization, regulatory agencies, those who pay for health care services, or those who purchase services. In addition, there is an increasing expectation that the community and patients should have access to quality information to assist with choices between health care facilities and health care providers.

### Health Care Reform and the Quality Movement

At the same time, many countries are attempting to efficiently manage excess capacity in their health system and rein in total cost. The hope is that this can be done without deterioration in the availability and quality of health care services. New methods of payment for services are being designed to introduce efficiencies into the provision of health care services and thus reduce cost. For instance, centralized systems that previously paid all costs for facilities' operation and services delivery to the population are implementing payment controls through the introduction of payment linked to diagnosis, employer-supported insurance, and private insurance. Centralized systems are also finding that the efficiencies found in networks and integrated delivery systems hold promise. Privatization efforts in the industrial sector of some economies have been introduced into the health sector in terms of private professional practices and private ownership of health facilities. In other economies, the private sector is being consolidated into large, publicly-traded corporations.

Also evident around the world is the movement to provide services to patients in less costly ambulatory care and community-based settings. The introduction of home care, long-term care, and even hospice care is most frequently in response to the need to use acute care facilities more efficiently, reduce the length of stay, and thus increase the utilization of beds and services.

In both developed and developing countries, the significant cost of the health care, thrusts health issues onto legislative and regulatory agendas with great frequency. Legislative and regulatory approaches are typically fragmented and result in change that may or may not be an improvement. Rarely is a country afforded the opportunity to significantly redesign its health sector.

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Thus, incremental change, frequently through the micro-management of individual elements of the system, is commonly encountered. Such incremental change is accompanied by the high expectation that improvements in access to health care, greater efficiency in the delivery of services, and ultimately improvement in the health and well-being of the population will result.

Patients commonly do not have sufficient information to effectively navigate through repeated changes. As information of all kinds becomes more accessible in a society, the expectation is that this will also be true for health care information. Information is needed that will help identify sources of care that meet certain “quality” expectations. These expectations can relate to structures (“Where is a clinic with an X-ray machine?”), processes of care (“How long is the wait at the clinic or emergency department?”), and outcomes of care (“Will my child get well?”). Objective information that can answer these questions is most frequently not available to the public, and frequently not even available to the health care facility, health care professionals, and responsible regulatory agencies.

## Growing Interest in a Quality Evaluation of Health Services

These and other factors have created a climate in which decision makers at all levels are seeking objective quality evaluation data on health care organizations. Licensure, accreditation, and certification are systems available to meet the need for quality and performance information. These systems have different purposes and different capabilities. Selecting the right system or combination of systems requires careful analysis of user needs and expectations. This is as true for a single hospital seeking accreditation as it is for a national health ministry wishing to set minimum quality standards for the licensure of rural family planning facilities.

## Purpose of the Monograph

The purpose of this monograph is to provide assistance to decision makers in analyzing various approaches to health services quality evaluation and management. Chapter II guides the reader through the steps in assessing the needs for quality evaluation. Chapters III and IV provide a description of the various approaches appropriate for meeting these needs, including the strengths and weaknesses of a standards approach and an outcome measurement approach. Finally, the factors that decision makers should consider in the design and implementation of the quality evaluation approach that they select are reviewed in Chapter V. Appendix A includes a case study illustration describing the development and implementation of a hospital accreditation program in Zambia—one innovative approach to health services evaluation in a developing country. Appendix B includes a comparison of health sector accreditation programs around the world.

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Figure 1-1

## **Definitions of Licensure, Accreditation, and Certification**

**Licensure** is a process by which a governmental authority grants permission to an individual practitioner or health care organization to operate or to engage in an occupation or profession. Licensure regulations are generally established to ensure that an organization or individual meets minimum standards to protect public health and safety. Licensure to individuals 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. Organizational licensure is granted following an on-site inspection to determine if minimum health and safety standards have been met. Maintenance of licensure is an ongoing requirement for the health care organization to continue to operate and care for patients.<sup>1,2</sup>

**Accreditation** is a formal process by which a recognized body, usually a non-governmental organization (NGO), assesses and recognizes that a health care organization meets applicable pre-determined and published standards. Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. An accreditation decision about a specific health care organization is made following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years. Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation.

**Certification** is a process by which an authorized body, either a governmental or non-governmental organization, evaluates and recognizes either an individual or an organization as meeting pre-determined requirements or criteria. Although the terms accreditation and certification are often used interchangeably, accreditation usually applies only to organizations, while certification may apply to individuals, as well as to organizations. When applied to individual practitioners, 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 licensure. An example of such a certification process is a physician who receives certification by a professional specialty board in the practice of obstetrics. When applied to an organization, or part of an organization, such as the laboratory, certification usually implies that the organization has additional services, technology, or capacity beyond those found in similar organizations.

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## II. Assessment of the Need for Quality Evaluation

One of the first steps in establishing a quality evaluation system is determining those needs it is intended to address so that the most effective system can be designed or selected. As quality evaluation is not designed to address all the diverse needs found in most health care delivery systems, it is essential that the system's limitations be as clearly identified as its capabilities. For example, licensure requirements do not provide insight into a hospital's capacity to initiate and sustain a quality management program; however, accreditation requirements do typically identify this capacity. Similarly, although ISO 9000 standards address an organization's quality management system, the focus is more on process control and product design specifications and less on evaluation of patient outcomes, whereby the latter is inherent in an accreditation system. ISO stands for the International Organization of Standardization, a non-governmental federation based in Geneva of national standards bodies from more than 90 countries. Although there may be divergence in approach, in fact, licensure, certification, and accreditation systems of evaluation may have many common elements. Each approach will be explored in greater detail in Chapter III.

Decision makers selecting a health services quality evaluation strategy most frequently identify the following needs and purposes:

### Maintain quality

During times of the most rapid and dynamic change in the health care sector, it becomes critically important to ensure that quality is at least maintained at its current level and does not deteriorate. New insurance mechanisms, restructuring and health reform initiatives, privatization within the health sector, redistribution of human and other resources, reduced public funding, new technology, and many other factors may raise concern for the quality of health care. Those accountable for change management in the health sector are seeking to implement quality monitors to preclude unexpected or undesirable change in quality.

### Improve Quality

A fundamental tenet of all approaches to health services quality evaluation and management is that every system and process in an organization produces information which, when collected and analyzed, can lead to improvement in the system or process. That process becomes a continuous cycle of improvement as organizations implement a quality management framework. Patients, regulators, health care professionals, employers, and legislators may all have different perceptions of quality and different priorities as to what needs to be improved. For example, waiting times in the outpatient department may be the most pressing concern to a patient who has been waiting for 2 hours to be assessed by a physician. On the other hand, implementing processes to reduce the rate of post-operative infections may be a surgeon's highest priority. For the most part, these stakeholders also recognize that today's quality may not be acceptable in the future, thus creating the need to "manage" for continuous improvement in the dynamic health care sector.

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## Ensure public safety

Public agencies have a fundamental responsibility to ensure that citizens will not be harmed, be exposed to hazards such as infectious wastes, or be at risk for injury when they enter a health care facility. Most individuals presume that they will not be exposed to high levels of radiation, that they will be evacuated quickly and safely if a fire occurs, and that medical equipment failure will not result in personal injury. Individual health care organizations have a responsibility to comply with laws and regulations related to public safety and to reduce the risks of patient or staff injury within their organizations.

## Establish entry level requirements and legal recognition

Prior to commencing operations, a governmental agency usually grants most health care organizations a permit to operate based on an evaluation of the organization's capacity to meet certain minimal requirements. Such requirements frequently address basic structural issues, such as patient and staff safety, staff qualifications, availability of water and electricity, basic equipment needed, types of services provided, etc. The granting of such a permit is not based on any judgement about the actual quality of the services provided by the organization. Thus a facility is classified as a hospital or ambulatory care clinic based upon the set of operating requirements that are met. These requirements may be set by one or more statutes, laws or regulations, which may or may not be current. Requirements for a specific governance structure, financial capacity, reports, or commitment to abide by relevant laws and ethical codes may also be present. For example, payment for services may be tied to status as a recognized pharmaceutical distributor.

Health care professionals are frequently required to meet certain criteria or regulations that convey status as legally authorized individuals to do business or practice within the scope of a given health care profession such as medicine or pharmacy.

## Verify that design or maintenance specifications are met

Health care facilities and health care equipment can pose risks to patients and staff when they are not designed correctly or are not maintained according to design specifications. Examples of the type of design specifications which health care facilities are often required to meet include:

- ◆ Availability of a required number and well-located emergency exits
- ◆ Availability of fire alarm and suppression equipment
- ◆ Availability of potable water and electricity
- ◆ Adequate radiation shielding
- ◆ Safe mechanisms for hazardous and infectious waste disposal



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- ◆ Protection from injurious electrical shock related to improperly maintained equipment, and
  - ◆ Properly calibrated laboratory and radiology equipment.

Design specifications can originate from many sources in a country, including public, private, professional, and manufacturing organizations or agencies.

## Document special capability as an organization or health care professional

As organizations gain the resources to provide special services, they must meet certain criteria to be designated as an approved provider of those services. Such special designation may be associated with the provision of services, such as organ and tissue transplantation, trauma care, blood banking, critical care, or renal dialysis. Similarly, as health professionals gain the knowledge and skills to provide new services, use new technology, or practice in different settings, they must meet certain criteria in order to be deemed as competent in these areas. Such designations may convey that the organization or professional is the sole or preferred source of the service, or convey that payment for the service is authorized to the organization or professional. Such designations are frequently used to direct or limit access to certain services or to concentrate scarce resources into a limited number of designated settings.

## Risk management

A number of clinical and administrative activities can be undertaken by a health care organization to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors, and the risk of loss to the organization itself. The effectiveness of these activities can be evaluated independently or within the context of a quality management program. Such programs can be of value in providing documentation to the public as to the nature of risks in an organization and the actual frequency of occurrence of various types of injuries. This type of information is also of value to public officials, agencies that finance the loss from incidents, and sources of payment for care.

## Private sector monitoring

In countries undergoing a privatization of health care services, there is a need for governmental oversight of the emerging private sector. The most effective oversight includes the use of performance standards and quality monitoring either provided directly or through independent non-governmental agencies. A uniform set of quality monitors or indicators, such as rates of surgical complications or patient satisfaction measures, will provide a valuable comparison of performance between the public and private health sectors. Such monitoring will preclude over-regulation of the private sector and limitation of the privatization strategies.

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## Implementation of new delivery settings

A common element of most health care cost reduction strategies is to provide needed services in the most effective and lowest cost setting. Therefore, health care services have increasingly moved from an acute care setting to ambulatory care and even into the patient's home or a congregate setting for long-term care. These strategies require quality monitoring to ensure that the desired reductions in the cost of care do not limit access to care, reduce the quality of care, or increase the risks to the patient or staff. For example, moving surgical services to the ambulatory setting should not increase the risk of anesthesia-related deaths. Likewise, providing medications in the home to a chronically ill person should not increase the risk of a medication error related to improper technique in the administration of the drug, simply because of a change in setting. Similar standards and quality monitors between all settings providing similar services will shape and support these strategies.

## Address national public health issues

Quality management targeted to critical public health issues such as HIV/AIDS, maternal and child care, malnutrition, tuberculosis, and management of childhood illnesses is an appropriate strategy in many countries. Accreditation of primary health care centers, networks, or managed care organizations may require that a predetermined rate of beneficiary coverage for preventive services be achieved. An example might be a requirement that 80 percent of the children covered in an accredited managed care organization or health plan are fully immunized by one year of age. Quality management can improve the effectiveness of the organization and management of services, bring efficiency to the care processes, reduce rework and the inappropriate use of scarce resources, improve staff performance and oversight, and enhance patient and staff education. Frequently such "demonstration" experiences lay the foundation for a lasting national public health and quality program.

## Allocation of limited resources

Efficient use of limited health care resources is a concern to health care organizations and public officials in all countries. Appropriate allocation or redirection of limited resources is not an easy task. Such decisions are frequently based on political factors, evidence of the greatest patient need, the strongest voice of the involved health professionals, and evidence of the presence of the needed medical expertise and technology. Allocation decisions based on objective quality data have increased acceptance and sustainability. For example, if the length of stay, complication rates, and mortality rates for a certain type of surgery are lower in one hospital compared to other hospitals providing this service, it would seem logical to direct patients and resources to this facility under circumstances of limited resources.

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## Create centers of excellence

As noted above in the discussion of the need to allocate limited resources on the basis of objective quality determinations, such data can also be used to identify those hospitals and other facilities where the outcomes of care for certain services are superior. Such identification of superior outcomes will serve to direct physicians, clinicians, patients, students, research funding, and advanced technology to these centers. As these centers often provide a greater volume of services in a given area, they typically achieve greater efficiency and thus reduce the cost per case. The center of excellence concept also provides “benchmarks” or “best practices” for use in quality improvement efforts in other facilities.

## Formation of new systems or networks of services

The integration of organizational structures and clinical services among several hospitals or among a diverse group of health care organizations, such as a group of district health centers and a centralized referral hospital, has great potential for improving the coordination and efficiency of care, and reducing administrative costs. A common concern in the formation of such systems or networks is the variation in performance and in quality among the components. The “whole is as strong as its weakest part” may be a relevant expression here. The development of a unified quality management framework is an important first step in addressing this concern. Also, the implementation of uniform standards for information management, human resource management, infection control, leadership, and many more processes and functions is also essential for the long-term success of the network.

In summary, consensus on the nature of the need for a system of quality evaluation and management is the essential first step in selecting an approach. Some broad categories of need are presented above. Other needs may be identified and should be included. The process for the assessment of need should include all relevant stakeholders, from patients to senior public health officials. This is true when conducted by one hospital or by the Ministry of Health. The process should conclude with a prioritization of the needs to be addressed in the shorter term and in the longer term. The next chapter in this monograph will identify and discuss the different approaches found most effective to meet these and other identified needs, with particular emphasis on licensure, accreditation, and certification strategies.

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### III. A Standards-Based Approach to Quality Evaluation

#### Standards as the Basis for Evaluation

In the context of approaches to quality evaluation, a standard is defined as an explicit, predetermined expectation set by a competent authority that describes an organization's acceptable performance level.

When applied to licensure of an individual practitioner or organization, the standard is usually set at a level designed to protect public health and safety. Accreditation or certification standards, on the other hand, are designed as optimal and achievable which, when met, would lead to the highest possible quality in a system.

Standards are generally classified as addressing a system's inputs (or structures), the processes the organization carries out, or the outcomes it expects from its care or services. Figure 3-1 provides a brief summary and examples of these types of standards. Standards can develop from a variety of sources, from professional societies to panels of experts to research studies to regulations. Standards might also be organization-specific, such as those reflected in a hospital's clinical policies and procedures or clinical practice guidelines for the management of emergencies. Standards might evolve from a consensus of what are "best practices," given the current state of knowledge and technology.

Figure 3-1

#### **Types and Examples of Standards**

**Structure standards** look at the system's *inputs*, such as human resources, the design of a building, the availability of personal protective equipment for health workers, such as soap, gloves, and masks, and the availability of equipment and supplies, such as microscopes and laboratory reagents.

**Process standards** address the *activities or interventions* carried out within the organization in the care of patients or in the management of the organization or its staff. Process standards for a hospital or health center might address areas, such as patient assessment, patient education, medication administration, equipment maintenance, or staff supervision. Recently, professional bodies have developed explicit process standards called "clinical guidelines." Such guidelines are based on scientific medical evidence (Evidence Based Medicine). Governmental agencies, insurers and professional bodies are promoting their use in the management of common or high-risk clinical conditions.

**Outcome standards** look at the *effect* of the interventions used on a specific health problem and whether the expected purpose of the activity was achieved. Examples of outcomes, both positive and negative, are patient mortality, wound healing without complications (e.g., infection), delivery of a healthy infant without complications, and a resolution of an infection through the appropriate use of antibiotic therapy.

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## Characteristics of a “Good” Standard

There are many components to the litmus test as to whether a standard accomplishes its intended purpose of improving quality. Some questions that are useful to consider in developing, revising, or implementing a standard are addressed in Figure 3-2.

Figure 3–2

### **Checklist for Evaluating a Standard**

- ✓ Does it focus on the patients or clients receiving the care or services?
- ✓ Does it have face validity and demonstrated reliability?
- ✓ Does it address the performance of common or important functions of a health care organization, such as patient management, leadership, infection control, and management of human resources?
- ✓ Do experts believe it to be important to practice or in improving health outcomes?
- ✓ Is it amenable to assessment and quantification through an internal or external evaluation process?
- ✓ Can it be uniformly applied to all organizations of a particular type, such as a hospital or clinic?
- ✓ Is it consistent with existing laws and regulations?
- ✓ Does it complement any existing international standards, such as those published by the World Health Organization?
- ✓ Is it culturally sensitive and appropriate?
- ✓ Does it reflect what experts consider "best practices"?
- ✓ Does it provide a framework for the inclusion of advances in clinical practice or technology?
- ✓ Is it flexible enough to be revised as needed?

## Components of a Standard

In writing a standard, it is useful to consider both its intent and purpose, as well as an expectation of how it will be met. A standard needs to be clear so that any reader will understand how it will be carried out. For example, a standard that states only, “Patients are assessed,” gives very little information about such essential elements as the assessment’s components or timeliness, or the qualifications of the individual who is completing the assessment. It would be

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difficult to ensure any degree of consistency in carrying out this standard in a health care organization unless more details are provided. A better standard might state: “Patients receive a complete physical examination by a physician or clinical officer within two hours of arrival to the clinic.” Within the standard itself or some associated measurable criteria, guidelines, or tools, the components of a “complete physical examination” might be further delineated.

Another important component to the standard is the description of how the performance will be measured or scored; for example, is this standard expected to be met 100 percent of the time? Are there any valid exceptions that need to be considered? If a standard is to be used in conducting an external quality evaluation such as an accreditation survey, what type of scoring methodology will be used? Are there ranges of performance that need to be considered, such as what might be seen in a 5-point Likert-type scale (e.g., always met, usually met, sometimes met, rarely met, and not met)? The standard should also consider what type of evidence of performance is required, such as documentation in the patient’s medical record or in aggregate quality assurance data. The standard described above addressing the patient assessment process might be evaluated through a combination of techniques, including a record audit, as well as patient interviews and direct observations of the clinician conducting the assessment. It is helpful to consider this evidence of performance in building a monitoring system for standards performance; otherwise, the standard might sound good in the abstract, but the organization will have little way of determining if it is actually implemented in daily practice. In developing countries particularly, reliance on abstracting data from the patient’s medical record to determine whether a standard has been met may be too narrow or shortsighted. The records system may not yet be sufficiently complete or consistent to serve this purpose. However, a variety of sources of evidence, including patient and staff interviews and direct observation of the organization’s processes will provide a fuller picture of its level of standards performance.

## Overview of Models of Quality Evaluation

Three primary approaches to the standards-based evaluation of health care quality have had broad health sector acceptance for many years: licensure, accreditation, and certification. These approaches have been refined with experience to serve different purposes and to provide different perspectives on the level of quality achieved. For example, accreditation standards most typically are set at a maximum achievable level to stimulate improvement over time. Criteria or standards used for licensure, on the other hand, are most typically set at a minimum level consistent with ensuring that the organization has the essential components required to provide care to patients in an environment with minimum risk to health and safety. Certification is an approach that may address individual practitioners as well as organizations or components of an organization (e.g., laboratory or radiology services), such as the ISO 9000 standards which evaluate conformance to design specifications. Certification can also include an evaluation of an organization’s ability to meet certain standards in order to qualify for government funding. Individual health professional certification may demonstrate a practitioner’s advanced knowledge and skill in a certain specialty area such as or emergency medicine or midwifery. The next section examines each approach and definition in more detail.

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## Licensure

As described above, licensure is always conferred by a governmental entity or its designated agent, such as a licensing or regulatory board (e.g., a state, provincial, or national medical or nursing board), and addresses the minimal legal requirements for a health care organization or practitioner to operate, care for patients, or function. Unlike accreditation or certification approaches that are based on optimal and achievable standards or a demonstration of special knowledge or capability, the purpose of licensure requirements is to protect basic public health and safety.

### Licensure of Practitioners

By defining legal requirements for a physician or other health professional, licensure standards restrict entry to practice to qualified personnel meeting minimum qualifications, such as graduation from an approved educational program and passing an examination intended to evaluate expected knowledge for a practitioner. The components of a licensure program for health care practitioners include:

- ◆ Examination of an individual's credentials to determine whether their education and experience meet legal requirements
- ◆ Inspection of educational programs to determine whether training programs meet required standards
- ◆ Administration of examinations to test professional qualifications
- ◆ Granting of licenses on the basis of a predetermined reciprocity to applicants of other jurisdictions (e.g., states or provinces) or countries
- ◆ Issuance of regulations establishing professional standards of practice, and
- ◆ Investigations of charges of violations of standards, which may lead to revocation or suspension of an individual's license to practice.<sup>3</sup>

The uniform development and use of consistent standards language and definitions can be a problem for large and culturally diverse countries. Also, such uniformity should extend to the licensure of all types of health professionals. Professional and governmental agencies frequently participate in setting requirements for such uniform policies and practices. In the United States, the Federation of State Medical Boards and its member boards use the long-established document, *A Guide to the Essentials of a Modern Medical Practice Act*, in guiding the adoption of new medical practice acts or the amendments to existing ones. Eighteen key elements addressed in the *Guide* are useful to consider for any country or jurisdiction interested in establishing or improving its system of physician regulation and medical practice act. Indeed, the *Guide's* concepts and general policy statements could easily be applicable to other types of health professional licensure. Among the topic areas covered include examinations, requirements for full licensure, granting of temporary and special licensure, disciplinary action against licensees, procedures for handling impaired or incompetent practitioners, unlawful practice of medicine, and periodic re-registration.<sup>4</sup>

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## Licensure of Health Care Organizations

Licensure standards are intended to define the quality level that is necessary in order for patient care or health services (e.g., drug dispensing by a pharmacy) to be safely delivered. These standards also define the capabilities that are needed in order for a health care organization to advertise to the public that it is a hospital or health center. For example, licensure standards in a particular jurisdiction might require that a health care facility provide certain services (e.g., surgery, radiology testing, round-the-clock nursing care for patients, pharmacy services, and laboratory services) in order to be classified as a hospital. Unlike accreditation or certification, which are usually voluntary forms of external evaluation, licensure is always mandatory. The government's granting of a license to an organization signifies its permission to the organization to be open and provide care or services to patients. In the United States, the licensure process for a new hospital, hospital component, or health center might also require some demonstration of the need for this service in the local community, so that health care resources are allocated appropriately. This demonstration is typically referred to as a "certificate of need," in which a health care organization submits extensive written justifications to a regulatory authority (e.g., state health department or planning commission).

Depending on the scope of the license (organization or individual) and the individual laws of the country or jurisdiction, licensure is granted initially based on some form of external evaluation or examination using minimum standards or capabilities. The standards by nature are country- or jurisdiction-specific. For example, in developing countries, licensure standards for a hospital might address basic services, such as the availability of potable water 24 hours a day, linen and other bed supplies, and laboratory services capable of performing the most common diagnostic testing done in country (e.g., malaria smears, complete blood counts). Issues of building and fire safety, including hazardous waste handling, are frequently considered in health facility licensing standards. Continued licensure may be either automatically renewed with a payment of a specified fee, assuming no problems have been identified or reported, or the renewal may require periodic inspections or submission of documentation.

Many countries currently have some system of licensure in place for health care organizations and practitioners, although due to funding restrictions or poor oversight, these systems may not always be as effective as intended in protecting public health and welfare. Facility licensing inspectors generally focus strictly on the organization's compliance with the minimum regulation required, and unlike accreditation surveyors, do not see their role as one of consultation and education. Sharing of "best practices" from other health care organizations or innovative ways to meet standards and improve organizational processes is typically not encouraged in the course of a licensing inspection. Whereas accreditation and certification standards are periodically revised in order to stay current with changes in health care practices and technology, licensure requirements usually change little from year to year and require legislative or regulatory initiatives, a much more difficult political process in many cases.

## Evaluating the Effectiveness of a Licensure Mechanism

In assessing its quality evaluation mechanisms for health care, countries may want to investigate in more detail the scope and effectiveness of its licensing of health professionals and how it is actually used in the provision of health care services. The licensing body may accomplish



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its work within its defined legal framework, yet the intended purpose of the licensure—to protect public health and safety—is not fully met. Figure 3-3 outlines elements and questions that a country or jurisdiction may find useful to consider in evaluating the effectiveness of its licensing mechanisms for health care professionals.

Figure 3–3

### **Issues for Consideration in Evaluating Licensure Mechanisms for Health Care Professionals**

- ◆ What systems are in place for licensing all categories of health professionals, including physicians, nurses, pharmacists, physical therapists, etc.?
- ◆ Does the system provide for primary source verification for each practitioner’s credentials, including graduation from an approved educational program?
- ◆ Does the health care organization, such as a hospital or health center that employs these professionals, routinely require and maintain written documentation of their current licensure?
- ◆ Are the professionals allowed to practice only within the defined scope of their licenses, and is this consistently addressed in some organized manner, such as by a credentialing mechanism or through written job descriptions? For example, if the hospital does not employ a licensed pharmacist to manage its pharmacy and dispense medications, can a pharmacy technician, nurse, or physician legally do these tasks?
- ◆ What mechanisms are in place, such as thorough staff supervision and quality assurance monitoring, to ensure that health care professional staff are practicing within their legal scope, level of demonstrated competence, and defined job description?
- ◆ How are complaints against specific licensed individuals investigated?
- ◆ What is the system for licensure revocation and renewal?

## Credentials Collection and Verification

The collection, verification, and use of a practitioner’s professional credentials is often a quality mechanism defined by an individual health care organization, but in some countries, may also be addressed in licensing requirements. Professional credentials usually include training, education, experience, and licensure. The process of obtaining, verifying, and assessing the qualifications of the health care practitioner to provide specific patient services is frequently referred to as “credentialing.” For example, a physician may be licensed to practice medicine in a particular jurisdiction such as country, state, or province, but a specific hospital may limit

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the scope of that practice based on education and demonstrated ability to perform a specific patient care procedure. The hospital may determine that only physicians who have demonstrated a level of skill and ability—by having conducted a defined number of endoscopy procedures—have sufficient credentials to perform these procedures at the hospital. Credentials review is an ongoing process for rechecking the individual’s qualifications and competence. Advantages to the credentials review approach are that it is typically based on self-regulation within the profession and health care organization, and can promote continuous improvement, education, and professional accountability.

## Accreditation

Accreditation is usually a voluntary program, sponsored by a non-governmental agency, in which trained external peer reviewers evaluate a health care organization’s compliance with pre-established performance standards. Accreditation addresses organizational rather than individual practitioner capability or performance. Unlike licensure, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards rather than adherence to minimal standards intended to assure public safety.

Accreditation standards are typically developed by a consensus of health care experts, published, and reviewed and revised periodically in order to stay current with the state-of-the-art thinking about health care quality, advances in technology and treatments, and changes in health policy. Depending on the scope and philosophy of the individual accreditation program, accreditation standards may take a “systems” approach that is organized around key patient and organizational functions and processes, such as patient assessment, infection control, quality assurance, and information management. Alternatively, standards may be grouped by departments or services within a health care organization, such as nursing, pharmacy, and radiology services. The major purposes of accreditation include the following:

- ◆ Improve the quality of health care by establishing optimal achievement goals in meeting standards for health care organizations
- ◆ Stimulate and improve the integration and management of health services
- ◆ Establish a comparative database of health care organizations able to meet selected structure, process, and outcome standards or criteria
- ◆ Reduce health care costs by focusing on increased efficiency and effectiveness of services
- ◆ Provide education and consultation to health care organizations, managers, and health professionals on quality improvement strategies and “best practices” in health care
- ◆ Strengthen the public’s confidence in the quality of health care, and
- ◆ Reduce risks associated with injury and infections for patients and staff.

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In order to make an accreditation decision concerning a health care organization's ability to meet published performance standards, a team of trained peer reviewers or surveyors conducts an on-site evaluation of the organization at pre-determined intervals, typically every two to three years. Depending on the accreditation program's design and policies, these on-site evaluations or surveys may be conducted with advance notice to the organization, or may be unannounced. There are advantages and disadvantages to both approaches. When the health care organization is advised of the survey dates, it can ensure that its key managers and staff are present and available to participate in the process, thus promoting optimal opportunities for consultation and education with the survey team. On the other hand, when the organization knows the exact dates that the team is scheduled, there may be a tendency for the organization to invest in a last-minute effort to "look good" for the survey, such as an extra cleaning of the facility, thus making it more difficult for the survey team to determine the usual practices and operations. Regardless of the approach used in scheduling the on-site evaluation, a well-trained and thorough survey team will look beyond surface appearances to determine if the health care organization meets a wide range of patient care and organizational standards.

Surveyors typically employ a variety of evaluation strategies to determine if the health care organization meets standards related to key systems and functions, such as patient care, infection control, management of the environment, human resource management, and quality assurance. For example, the survey team may review written documents (e.g., operational plans and budgets, clinical policies and procedures, or standard operating procedures for conducting certain laboratory tests). In addition to a review of documents, surveyors will frequently interview organizational leaders, clinicians, employees, and patients in order to determine the organization's performance and compliance with standards. For example, a surveyor might choose to interview a patient about his or her level of satisfaction with the care provided by the organization, as well as ask the patient for feedback on how the organization could improve its care or services. Leaders, including the members of the governing body and administration of the organization, may be interviewed regarding the organization's processes and how they are designed to meet standards related to planning, budgeting, quality assurance activities, and human resource management. Clinicians may be interviewed about patient care processes (e.g., patient assessment, medication usage, or diagnostic testing).

Accreditation surveyors usually tour the health care organization's buildings and patient care areas in order to evaluate standards related to overall building safety, waste management, overall upkeep and cleanliness, equipment and supply management, infection control, fire safety, and emergency preparedness. Diagnostic services such as the radiology department and the laboratory are also assessed with respect to safety, effectiveness, quality control, and equipment management. Support services such as dietary, pharmacy, and rehabilitation therapy are also areas included in the accreditation survey of a hospital or health center. Typical activities or components of an accreditation survey of a health care organization are highlighted in Figure 3-4.

The surveyors' evaluation findings are then analyzed to determine whether the hospital or health center meets an acceptable threshold of compliance in order to be awarded accreditation. One advantage of the accreditation approach is that it combines the evaluation and findings of multiple surveyors into a single impression about the organization's compliance with standards and overall quality of care. Since the focus is on continuous improvement of organizational

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Figure 3–4

### **Typical Evaluation Approaches Used in Conducting an Accreditation Survey**

Most health care accrediting bodies use a variety of evaluation approaches during the on-site survey in order to determine the health care organization's compliance or performance with applicable structure, process, and outcome standards. These methods might include any combination of the following:

- ◆ Leadership interviews
- ◆ Clinical and support staff interviews
- ◆ Patient and family interviews
- ◆ Observation of patient care and services provided
- ◆ Building tour and observation of patient care areas, building facilities, equipment management, and diagnostic testing services
- ◆ Review of written documents such as policies and procedures, orientation and training plans and documents, budgets, and quality assurance plans
- ◆ Evaluation of the organization's achievement of specific outcome measures (e.g., immunization rates, hospital-acquired infection rates, patient satisfaction) through a review and discussion of monitoring and improvement activities, and
- ◆ Review of patients' medical records.

systems and processes, the on-site survey is often consultative and educational, as well as evaluative in nature. Surveyors are often able to offer recommendations regarding “best practices” at other similar organizations or make suggestions on quality approaches that the organization might want to adopt in the future. For example, a surveyor might suggest an improvement strategy to decrease the waiting times for women being seen at the family planning clinic.

The threshold for determining whether or not the health care organization is accredited must be based on pre-determined rules that are consistently applied in order for an accreditation program to maintain its credibility and enjoy the public's and health care professionals' confidence. Processes to protect the accreditation decision from political and professional influences are essential to establish. One mechanism to accomplish this is the publication and distribution of the explanation of the standards' intent, as well as the decision rules, so that any interested individual or organization knows exactly what level of compliance to the standards is needed to achieve accreditation.

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Depending on its specific rules, an individual accreditation program may use various types of accreditation decisions or awards to indicate the health care organization's level of performance with standards. For example, the Joint Commission on Accreditation of Healthcare Organizations, the largest health care accrediting body in the United States, designates an organization as accredited with commendation, accredited with or without Type I recommendations (a form of recommendation requiring corrective action), conditionally accredited, or not accredited.<sup>5</sup> Other health care accrediting bodies may use the length of time that accreditation is awarded, for example, from one to three years, as a way of differentiating among various accredited organizations' performance with standards. Frequently some type of follow-up action or improvement is required when problem areas or opportunities for improvement are noted during the course of the accreditation survey. The health care organization receives a detailed written report, which depending on the policies of the accrediting body, may or may not also be disclosed to the public. In addition, some form of special designation, award, or certificate is typically given to the organization as well.

A number of vital elements need to be considered, developed, and implemented in order to ensure the effectiveness and sustainability of an accreditation program.<sup>6</sup> These elements are highlighted in Figure 3-5. Each of these elements is intrinsic to the accreditation program's success, which in the final analysis should not be measured by the number of organizations it accredits, but rather on the impact it makes in stimulating improvements in the care that patients and communities receive.

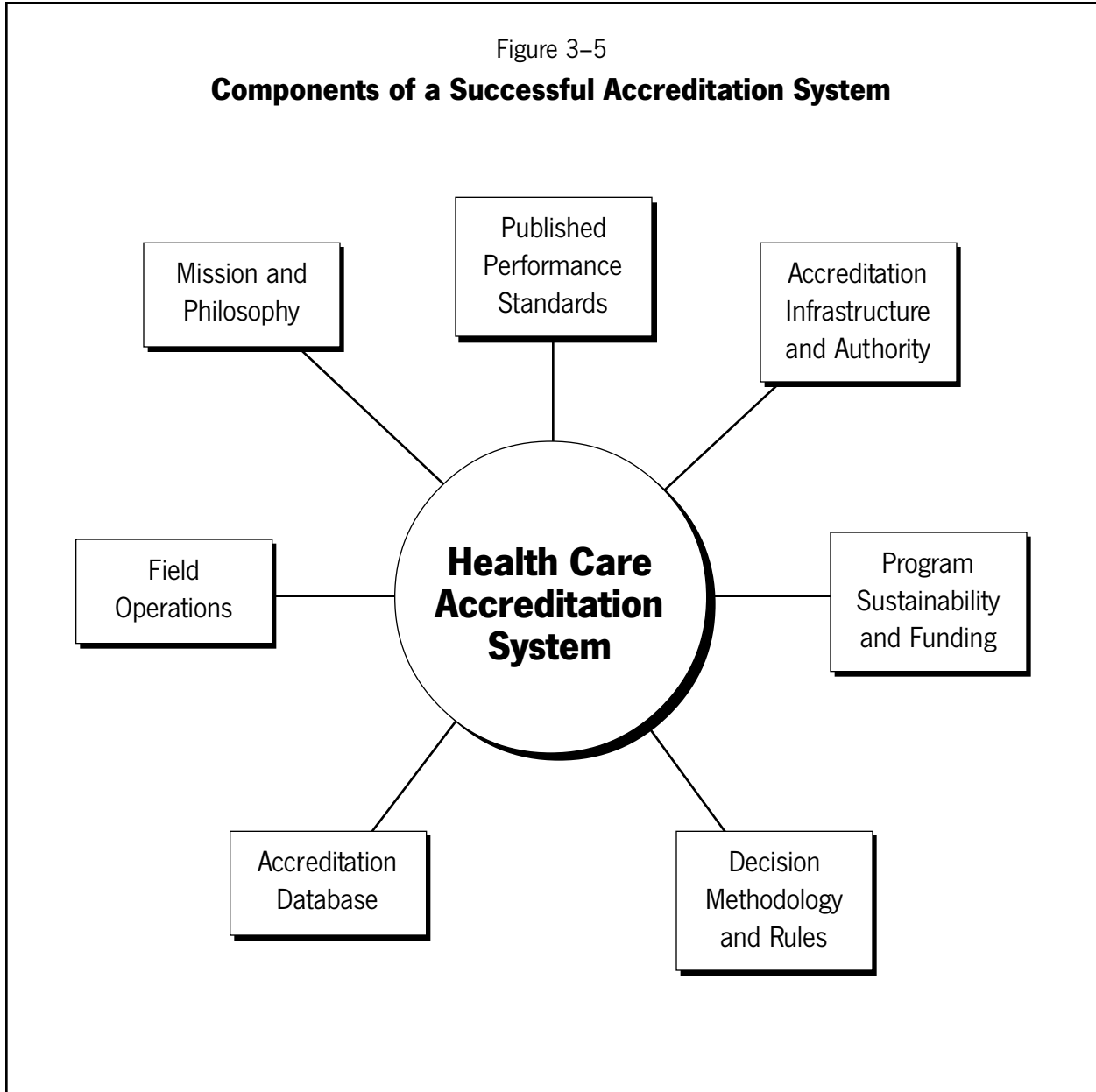
## Components of an Accreditation System

First, the *mission and philosophy*, as well as *infrastructure and authority for the program* must be determined; for example, will the accrediting body be a governmental or non-governmental entity? Who will serve as the key decision makers? Will there be a special committee that is charged with promulgating standards and rendering the accreditation decision? Most accrediting bodies seek to have health care professionals play an active role in standards development and interpretation, in order to ensure professional commitment to the goals and objectives of the accreditation program. It is important to consider whether accreditation will be voluntary or required by law and regulation, and whether funding or reimbursement will be linked to accreditation.

Relevant, objective, and measurable *standards* are essential if the expected improvement in health care quality is to be achieved. Accreditation standards, unlike minimum licensure standards designed to protect public safety, must encourage health care organizations to continuously seek to improve quality while recognizing what is possible to achieve given potential resource limitations. This philosophy—"doing the best, given available resources"—is especially important to consider in developing countries where resource limitations can significantly impact an organization's ability to achieve optimal performance. If the standards are set unrealistically high, organizations will feel demoralized and unmotivated to work towards meeting them; however, incremental improvements may be possible and should be rewarded. Chapter 4 addresses in more detail the considerations of standards development, distribution, review, and revision.

Figure 3-5

**Components of a Successful Accreditation System**



A third essential ingredient to building an effective accreditation program is the *management of field operations*. This includes surveyor supervision and training, consultation with the health care organization in advance of the survey, for example through educational seminars, and the processes associated with conducting on-site surveys. Specific components to consider with respect to the management of field operations include the following:

- ◆ Selection and training of peer reviewers or surveyors
- ◆ Supervision and ongoing education of surveyors

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- ◆ Education and consultation about the standards to health care organizations
  - ◆ Pre-survey processes: application, scheduling, notification, and logistical arrangements (e.g., survey or travel) for on-site surveys
  - ◆ Development of a standardized evaluation methodology to assess standards performance,
  - ◆ On-site surveys conducted at pre-determined intervals
  - ◆ Processes by which surveyors document and score their findings, and
  - ◆ Post-survey analysis of surveyor findings.

*A framework for accreditation decision-making* is necessary in order to ensure that the process is fair, valid, and credible. This framework should consider the following:

- ◆ Published thresholds of performance in order to achieve accreditation
- ◆ Levels or types of accreditation awards (e.g., basic, intermediate, or advanced accreditation, "gold star" accreditation)
- ◆ Rules regarding whether follow-up evaluations or corrective actions will be required
- ◆ Format and distribution of the accreditation report, and
- ◆ Policies regarding public disclosure of accreditation findings.

As the accreditation program conducts its evaluations, analyzes its findings, awards accreditation decisions, and stores information, an *accreditation database* will emerge. This database can provide useful aggregate data that will highlight where many organizations are meeting the expected standards, as well as pinpoint problematic areas or opportunities for improvement. For example, the aggregate data might reveal that the function of pharmacy management and drug distribution is the most common deficiency in 60 percent of hospitals surveyed. This data can provide powerful testimony to public policy makers. Such information can be useful in identifying both resource priorities, as well as needs for further education and technical assistance. In addition, health care organizations also have an opportunity to "benchmark" their results against other similar organizations, providing an incentive for improved performance. This benchmark data can also help to inform the public, assist in consumer choice, and encourage local pressure to be put on health services to improve.<sup>7</sup>

Finally, for an accreditation program to flourish, the question of *program sustainability*, including financial viability, must be addressed. The initial program development may be funded by foundations, government agencies, and donor agencies; however, most successful programs eventually require the health care organizations seeking accreditation to pay for the services associated with achieving this recognition, such as the on-site survey costs, education, and publications. Beyond the intrinsic value that the organization and its leaders find in meeting standards and continuously improving health care services, it is often market forces that add the financial incentive to maintain accreditation once it is achieved. For example, in the United States, accreditation is often linked to governmental, insurance, and other third party reimburse-

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ment through formal or informal means, such as the Health Care Financing Administration's recognition of accredited hospitals that meet the requirements for participation in the Medicare program. In countries where many of the health care organizations are owned and managed by the government, policy makers may want to consider some form of financial incentives or optional bonuses that reward organizations achieving a high level of performance with standards.

One of the major strengths of the accreditation approach is its support of continuous improvement efforts through consultation and education, in addition to evaluation, rather than reliance on a punitive inspection methodology. In preparing for an accreditation survey, a health care organization assesses itself in order to determine its compliance with standards, as well as to identify opportunities for improvement. This self-assessment can provide managers and clinicians with important information about the organization. Since health care experts generally develop standards through a consensus process, a sense of commitment to their intended purposes is more likely. Because accreditation standards are intended to be optimal and achievable rather than minimal, they can be revised and updated based on the introduction of new delivery models (e.g., community-based care), public policies, quality assurance and improvement concepts, and health care technology.

Can health care accreditation work successfully in developing countries where often little or no external quality evaluation has existed? The answer is a definite yes! Appendix A describes the emergence of one such hospital accreditation program in Zambia, a developing country in south central Africa, where most of the country's hospitals are government-owned and prior to accreditation, underwent no structured external quality evaluation. Appendix B includes a table comparing various accreditation models in both developed, as well as developing countries. Readers interested in obtaining additional information on a specific accreditation program are encouraged to write or call these accrediting bodies, and/or to review the program information published on the Internet web sites.

Finally, reference should be made to a variety of voluntary programs that review one or more aspect of an organization against a set of standards or criteria and give the organization an "accreditation" certificate. An example of such an "informal accreditation" process is that of the "Baby Friendly Hospital" certificate under the UNICEF program to encourage breastfeeding. Other examples of organizational accreditation programs that address a particular service or specialty are highlighted in Figure 3-6.

## Certification

Although certification is often used interchangeably with accreditation, one important distinction exists. While accreditation applies only to health care organizations, certification can also apply to an individual practitioner, such as a physician, nurse, or other health care professional or worker. Certification is the process by which an authorized agency, usually either a governmental agency or a certification board of a professional society, grants recognition to those practitioners or workers who have met certain pre-determined qualifications. These qualifications often include graduation from an approved program, acceptable performance on a qualifying examination or series of examinations, and/or completion of a given amount of work.<sup>8</sup>



Figure 3-6

## **Examples of Focused Types of Accreditation Programs**

### **BABY FRIENDLY HOSPITALS**

The Baby Friendly Hospital Initiative is a worldwide project of the World Health Organization (WHO) and UNICEF. The initiative's goal is to recognize hospitals and birthing centers that take special steps to provide an optimal environment for breastfeeding. Approximately 14,000 hospitals worldwide have received this prestigious award. To earn the "Baby Friendly" award, organizations must demonstrate that they have implemented the "Ten Steps to Successful Breastfeeding." There are three major steps to the process. First, a birthing center decides to work on becoming Baby Friendly and commits to the process by submitting an application (including a letter of intent, an annual fee, and a completed self-appraisal tool) to the Baby Friendly Initiative. Next, after receipt of a Certificate of Intent, the facility works toward the full implementation of all ten steps. Last, there is an on-site assessment by the Baby Friendly survey team and a review by the External Review Board.

### **GOLD STAR PROGRAM IN EGYPT**

The Egyptian Ministry of Health and Population (MOHP) operates a network of 3,800 clinical facilities. In 1987, the Ministry began a comprehensive upgrading of its family planning services and facilities. In 1993 it instituted a Quality Improvement Program in selected clinics. This program emphasizes training to standardize the quality of care and a consumer-oriented approach aimed at improving client services and raising client satisfaction. An MOHP clinic that earns a *gold star* is among the "best of the best" of the MOHP units.

Clinics are supervised and rated according to a comprehensive checklist of 101 quality indicators. Clinics are rated each quarter according to the quality indicators. A clinic earns a gold star by attaining a 100% quality standards certification score for two consecutive quarters and retains its gold star by maintaining that score at successive quarterly evaluations.

### **PROQUALI**

The PROQUALI Project is a comprehensive system that accredits the reproductive health units of community health centers in Northeast Brazil. This project is a collaborative initiative of the Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO), Johns Hopkins University/Center for Communications (JHU/CCP), and the Secretariats of Health of the states of Bahia, Ceara, and Brazil.

The project integrates technical assistance and training at the health center level in the areas of clinical skills, information, education, communication, and management. A total of 61 criteria and internal and external checklists cover service delivery, infection prevention, interpersonal communication and counseling, information, education, and communication. State accreditation teams visit the reproductive health units of participating clinics every 6 to 12 months. Clinics that score 100 percent are accredited and can display a quality seal and will be promoted in community campaigns.

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Figure 3-6 continued

### **MOTHER FRIENDLY HOSPITALS AND CLINICS**

The Coalition for Improving Maternity Services is a coalition of individuals and national organizations with concern for the care and well being of mothers, babies, and families. The evidence-based model focuses on prevention and wellness as the alternatives to high-cost screening, diagnosis, and treatment programs. One of the ten steps is to incorporate the WHO/UNICEF “Ten Steps of the Baby Friendly Hospital Initiative” to promote successful breastfeeding. To receive CIMS designation as “mother-friendly,” a hospital, birthing center, or home birth service must carry out the philosophical principles by fulfilling the Ten Steps of Mother-Friendly Care.

## Certification of Physicians and Other Health Care Practitioners

In many medical specialties, such as surgery, internal medicine, or neurology, certification is conferred by a professional specialty board to those individuals who meet rigorous requirements as far as advanced training in accordance with established educational standards and demonstrated specialized knowledge and skill verified through comprehensive examinations. This mechanism provides a means by which to assure the public that a physician who claims to be a specialist is indeed so qualified through a professionally-accepted evaluation. In collaboration with other concerned agencies or organizations, the specialty boards can also assist in improving the quality of medical education by elevating standards of graduate medical education and approving facilities for specialty training. Typically the governing bodies of specialty boards are comprised of specialists qualified in the particular field represented by that board, such that there is a system of self-regulation among expert practitioners. In some countries, this designation may also be acknowledged through a regulation or licensure as well; for example, a license to practice surgery may be conferred through a regulatory authority, instead of or in addition to that given by a professional society’s certification board.

Similar to the licensure of individuals, the certification process benefits from clear standards, precise definitions, and standardized processes. This is especially true when certification is new in a country, or when a new area of medicine or clinical practice wishes to establish a certification program. In the United States, all medical specialty boards have been officially approved by action of the American Board of Medical Specialties (ABMS) and the American Medical Association Council on Medical Education (AMA/CME) in a collaborative effort of the two bodies to standardize the approaches of specialty boards. In evaluating the standards and procedures of a new or existing medical specialty board, a Liaison Committee from both organizations uses the current edition of *Essentials for Approval of Examining Boards in Medical Specialties*, a document that has been revised numerous times since it was first published in 1934. New specialty boards must undergo a rigorous process of application and review, and demonstrate that the establishment of a specialty board represents a distinct and well-defined field of medical practice, such as that defined by the American Board of Medical Genetics, the newest member board of the ABMS. In order to practice in this new field, practitioners must

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receive additional training that is beyond that which is included in established training programs. A specialty board must also detail how it proposes to assess the qualifications of the individual practitioners it will certify. The new board must also demonstrate that there is broad professional acceptance within the medical specialty, and that the establishment of a certification program will promote and enhance recognition of a single standard in preparation for practice

The issue of re-certification is an important one to consider in establishing this form of quality mechanism, since ongoing knowledge and skill cannot necessarily be assured without some system of verification at periodic intervals. Most medical specialty boards in the U.S. thus require re-certifications at intervals of 7 to 10 years. Re-certification may be contingent on meeting certain requirements such as the following:

- ◆ Continuing professional experience, such as by documenting a certain number of hours of professional practice each year
- ◆ Assessment of skill and proficiency, such as through periodic tests of clinical knowledge or judgment or a specific procedural skill
- ◆ Assessment of performance, such as through an evaluation of a physician's authenticated medical records of cases over a period of time, and/or
- ◆ Assessment of clinical outcomes.

Most certifying bodies have the authority to withdraw or withhold re-certification if an individual fails to meet re-certification examinations or demonstrates major deficiencies in professional performance. One limitation of this system of ongoing evaluation for medical specialty certification is that it does not include a review of the actual care processes provided by a physician to his or her patients, nor are patient outcomes specifically considered.

In addition to long-established forms of medical specialty certification by specialty boards, in recent years professional organizations are beginning to evaluate qualifications of individuals in the context of the individual's actual practice conditions and environment. For example, the American Medical Association has introduced a standards-based system for individual physician uation for called the American Medical Accreditation Program (AMAP). Although this initiative uses the term "accreditation" because it evaluates single practitioners rather than health care organizations, this mechanism most closely follows the definition of certification used in this monograph and therefore is considered in this section. AMAP is a voluntary uation for mechanism that measures and evaluates individual physicians against national standards, criteria, and peer performance in five areas:

- ◆ Credentials, including primary source verified informa for
- ◆ Personal qualifications, including ethical behavior and documented participation in continuing medical education, peer reviews, and self-assessment of performance
- ◆ Environment of care, including practice site review of office operations and medical records

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- ◆ Clinical process, including standardized measures of key patient processes, such as appropriate diagnostic testing and treatment, and
  - ◆ Patient outcomes.<sup>9</sup>

AMAP is intended to be complementary rather than duplicative of medical specialty certification. Once a physician is accredited through AMAP, he or she is eligible to be re-evaluated every two years. A portfolio of verified credential data and site review data are made available to health plans and hospitals with which the physician participates.<sup>10</sup>

In addition to the certification for physicians described above, another common example of this mechanism is the recognition given to nurses or other health professionals who, on the basis of additional specialized education, training, and demonstrated skill, are certified to practice in a specialty area. In some cases, such as that of the nurse midwife or certified nurse practitioner, this recognition might grant the certified practitioner the authorization to expand his or her scope of practice as defined by law and regulation. Other forms of certification, such as recognition as a certified critical care nurse, may be sought primarily as a matter of professional pride and development. For employers, hiring certified staff in a particular specialty area such as pediatrics often ensures a demonstrated knowledge base and skills. Many hospitals require all clinical staff to maintain ongoing certification in a specific skill or technique, such as cardiopulmonary resuscitation, because such knowledge is seen as important in assuring that clinicians are able to appropriately respond in the event of a life-threatening emergency.

## Certification of Health Care Organizations

Like accreditation, both governmental or non-governmental bodies grant certification status to health care organizations. While often voluntary, certification may award a certain distinction that promotes the ability of the organization or practitioner to practice in a particular area. For example, a laboratory may be *certified* to conduct certain types of diagnostic testing that require specially trained staff, equipment, reagents, and procedures. Without this certification, the laboratory may not be recognized as having the necessary capabilities and thus not funded or legally recognized. Governmental authorities and private organizations, such as insurance providers, employer groups, or health plans, may require a health care organization to meet some form of certification standards in order to receive reimbursement for health services.

## ISO Certification Standards and Quality Evaluation

In recent years, the health sectors of some European countries have expressed an interest in incorporating ISO 9000 certification standards into their external quality evaluation programs. The ISO mission is to promote the development of standardization and related activities in the world, with a view to facilitating the international exchange of goods and services. ISO itself is not an auditor or certification body of quality systems, nor does it specifically endorse any such activities performed by other entities. ISO at present develops international standards for manufacturing and service industries, but operates no system for evaluating conformance to them.<sup>11</sup>

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However, accrediting and registration bodies or other external evaluation entities are increasingly considering the relationship of the ISO 9000 standards series to other forms of quality standards in health care. The ISO 9000 standards focus on the maintenance of a quality management system for each product or service such that each product will meet defined performance expectations. However, these standards do not address what the specifications should be in order to produce a service or product of high quality. The ISO 9000 standards are classified into 20 categories, addressing areas such as management responsibility, quality system, internal quality audits, and process control. Figure 3-7 addresses a few key points in understanding the ISO standards and their applicability to certification or accreditation of health care organizations.

ISO standards are general to service industries and focus on *capability* rather than results, and more on the quality and conformity of the process than on the outcome. As highlighted in a formal position paper endorsed by the Executive Board of the International Society for Quality in Health Care, Inc. (ISQua) at its 1996 meeting, some ISO standards, such as those related to “product identification and traceability,” can be readily applied to hospital areas, such as laboratory and radiology services. While these standards may have narrow applicability in a defined area (e.g., laboratory), it requires some creative interpretation to demonstrate their applicability to patient care or patient outcomes. However, the ISQua position paper identified opportunities for a convergence of existing or emerging accreditation programs and ISO standards. ISQua also highlighted the need for core international frameworks that encourage the development of health care standards that are sensitive to patient expectations, evidence-based practice, and clinical outcomes that uses common language (e.g., to differentiate accreditation from certification).<sup>12</sup>

## Summary

Depending on the specific needs of a country or jurisdiction (e.g., state or province), systems of accreditation, certification, and licensure can provide valuable information about the capability, quality, and safety of health care organizations and practitioners. Using these objective external evaluations in comparison to pre-established standards, either independently or in combination, can greatly strengthen the delivery of quality health care or services.

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Figure 3–7

**Key Concepts in Understanding ISO 9000 Standards and Health Care<sup>13</sup>**

- ◆ ISO stands for the International Organization for Standardization, a worldwide federation of national standards bodies from over 90 countries.
- ◆ ISO 9000 series of standards are general to service industries and focus on the evaluation of processes against design specifications. ISO originally developed industrial standards to facilitate international coordination and unification of standards.
- ◆ Unlike accreditation standards, ISO standards do not incorporate concepts of continuous improvement or evaluation of patient outcomes.
- ◆ The primary ISO standards deal with manufactured products and set basic rules for quality systems whatever the product (electronics) or service (banking).
- ◆ ISO as an organization does not accredit, certify, or register an organization as meeting its standards; however, other external auditors or evaluators may use ISO standards in their independent certification reviews.
- ◆ The ISO 9000 standards approach may be useful to consider in designing quality control systems for certain health care “production” services, such as laboratory, radiology, and food services.

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## IV. An Indicator Monitoring System of Quality Evaluation

### Indicator-Based Quality Evaluation

An indicator may be defined as a measure used over time to determine the performance of functions or processes. It can be used to assess the adherence to a standard or the achievement of quality goals. It is a quantifiable value that can be used to evaluate performance over time, such as through quarterly analysis of aggregate data, rather than just a “snapshot” evaluation on a periodic basis, (e.g., a standard-based evaluation in a bi-annual accreditation survey). Rather than a general statement such as “patients are satisfied,” an indicator gives a specific and quantifiable measurement to this expectation, such as “75 percent of patients surveyed in the last quarter expressed satisfaction with the services they received.” Indicator monitoring often provides a valuable adjunct to standards-based evaluation, since indicators often focus on a few key structures, processes, or outcomes that represent an overall picture of quality of the organization. For example, monitoring of a health center’s immunization rates for children at one year of age could provide useful information about how well children are assessed and clinically managed by the health center staff.

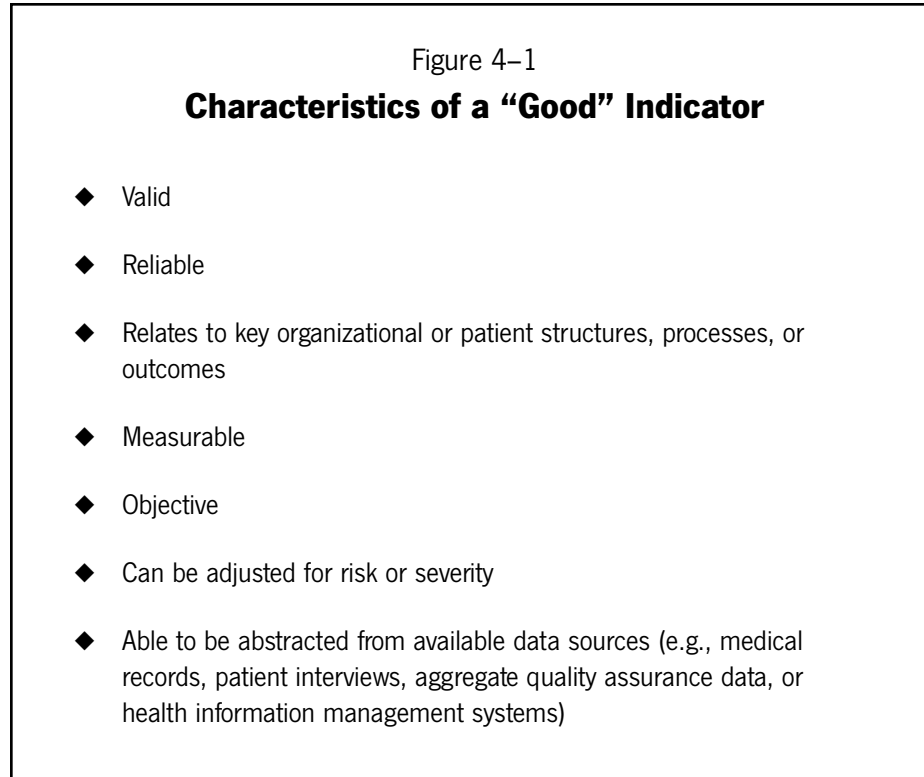
Indicators are often expressed as a rate or a ratio, which adds to their usefulness both in measuring trends over time, as well as providing comparative data among similar types of organizations. Common examples of indicators used in health care settings are maternal mortality rates, hospital-acquired infection rates, immunization rates, patient satisfaction measures, and surgical complication rates. In establishing these types of indicators, it is important to begin with a clear definition of terms and the numerator and denominator that will be used. An example of this can be seen in establishing an indicator to monitor post-operative wound infections. The numerator can be defined as the number of surgical patients with clean surgical wounds who develop a wound infection during their hospital stay, with the denominator defined as the number of patients undergoing a clean surgical procedure within a pre-determined data collection period (e.g., monthly or quarterly). Less straightforward is the definition of infection. For example, will a positive culture be required as evidence of a wound infection? If the physician prescribes antibiotic therapy on the basis of purulent drainage and redness at the wound site but no culture is obtained, can this be assumed as an infection for the purposes of reporting? Who will make that judgement, and where will the data be obtained?

Another type of indicator is one that is based on sentinel events or adverse outcomes. Although the indicator can sometimes be formulated as a rate as well (e.g., number of medication errors over the number of medications administered). If the adverse outcome is expected to occur infrequently, it usually is evaluated on a simple tracking of occurrences within a pre-determined reporting period. Examples of sentinel events or adverse outcomes might include the following:

- ◆ Adverse drug reactions
- ◆ Medication prescribing, dispensing, or administration errors
- ◆ Patient management errors, such as performance of a treatment or procedure incorrectly such that results in patient harm

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- ◆ Patient falls
  - ◆ Needle punctures and other staff injuries
  - ◆ Lapses in security, resulting in the kidnapping of an infant, and
  - ◆ Unexpected death of a patient.

Characteristics of a good indicator are highlighted in Figure 4-1.



## Application of an Indicator Monitoring System

An indicator system can be useful in monitoring structures, processes, and outcomes at an individual organizational level, as well as at a community, regional or national level. If the indicators selected meet the test what constitutes a “good” indicator as described in Figure 4-2, they will be seen as providing useful information about a health system’s inputs or structures, as well as its processes and outcomes. Because the collection of indicator information and maintenance of a database can be time-consuming and labor-intensive, it is essential that the indicators selected truly reflect what is most important to monitor. Too many indicators in the data set will be overwhelming to practitioners and the quality of data collection will likely be compromised. For example, instead of developing an indicator to measure every organizational function or standard, it might be helpful to initially select four to six indicators that have a consensus



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as to their importance and validity. It is more helpful in the long run to have complete and accurate data on a few key aspects—the “vital signs” of the organization—than to have dozens of indicators for which the burden of data collection and analysis simply outweighs the benefits.

## Indicator Monitoring with Outcomes

Performance measurement or outcomes evaluation is an emerging form of quality evaluation that has found increasing support in the past decade. As quality of care concerns garner public interest and scrutiny, a resulting demand for objective and comparative outcome information has developed. There are at least two major limitations to the external quality evaluation approaches already described through accreditation, certification, licensure, and credentialing. One is that they generally focus more on the evaluation of structures (e.g., adequate clinical staffing, building safety, policies, and procedures) and processes (e.g., infection control, patient assessment) rather than on actual patient or health *outcomes*. While well-designed structures and processes are essential building blocks in any quality system, in the end, what is most important is the effect of these on improving the health care of the patients served or the community as a whole. Secondly, the on-site evaluation during an accreditation or licensure survey might also be seen as only an organizational “snapshot” on the given day of the survey.

A good and thorough accreditation, certification, or licensure survey should lend credible data in helping to make conclusions about the overall quality and capability of an organization, yet this every two or three year snapshot is no substitute for ongoing monitoring of key quality indicators and outcomes. For example, accreditation standards might address whether the organization has a mechanism or process for evaluating the satisfaction of the patients it serves, yet evaluation of the existence of this process does not in itself answer the following questions. Are patients satisfied? How does the level of satisfaction of the sample of patients interviewed during the accreditation survey compare to the organization’s own outcomes monitoring of this measure from the past year’s number of patients?

Outcomes evaluation, through centralized databases that store information on key performance measures or indicators, can be a valuable source of quality information for an individual health care organization or for an entire country’s health sector. This aggregate data can be beneficial for planning purposes as well as ongoing monitoring for continuous improvement. For example, at an individual organization level, the outcomes data might reveal that there are an unacceptable number of serious medication errors that can be traced back to root causes such as inadequate training of nurses, incorrect administration of the medications, or incorrect dispensing from the pharmacy because of poorly written prescriptions. This information can help the organization to investigate more fully the reasons for the root causes so that the necessary improvements can be instituted.

At a national level, outcomes evaluation can provide an overall “report card” on at least some key aspects of the country’s health, such as hospital maternal mortality, patient satisfaction, or the numbers of errors in health service delivery (e.g., medication errors or significant errors in clinical judgment resulting in harm to the patient). The benefits of such a system are fairly straightforward, yet serious challenges exist. A few of the questions a health system or Minis-

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try of Health might want to consider in establishing a national database of health sector outcomes are highlighted in Figure 4-2. In addition to these potential concerns, a standardized outcomes evaluation is usually limited in the number of outcome indicators that it is reasonable to address due to the unavailability of data and the potential burden of data abstraction and monitoring. Additionally, while data on the rate of infected C-section wounds might be an excellent performance measure of the infection control processes in the hospital's obstetrical area, it says nothing about whether the hospital has a safe and effective process for handling and disposing of hazardous wastes, a process where quality standards may be necessary.

Figure 4-2

**Questions to Consider in Establishing an Evaluation System  
Using Outcome Indicators**

- ◆ What quality or health outcomes will be measured?
- ◆ What is the relationship of the chosen outcome measures to established standards?
- ◆ How will the validity and reliability of the data be assured?
- ◆ How will the data be collected (e.g., abstraction from the medical record, observation)?
- ◆ Who will collect the data in each health care organization? At what time intervals?
- ◆ How will individual data be transferred to the aggregate database?
- ◆ What are the special technology needs to be considered in establishing an outcomes database?
- ◆ Should there be a risk or severity adjustment made for certain outcomes (e.g., based on patient demographics, severity of illness, comorbidities)?
- ◆ What potential confounders to the data will need to be considered?
- ◆ How will the data be used for benchmarking and for identifying "best practices"?
- ◆ Will the outcomes data be accessible to the public?
- ◆ Will the public need further education and information in order to interpret the data correctly?

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## Combined Standards and Indicator Evaluation Systems

The use of standards and indicators in quality evaluation are not mutually exclusive approaches. In fact, combining them maximizes the advantages and benefits of each in order to provide a fuller picture of the overall performance of an organization or an entire national system. Since indicators are often based on standards, it is a natural evolution to integrate the two.

One example might be seen in the manner that a health care organization handles obstetrical emergencies. The *standards* addressing this aspect of patient care might be broad organizational standards related to patient assessment and qualified staff or include actual clinical policies and procedures or practice guidelines for the management of specific conditions, such as abruptio placenta or pre-eclampsia. A related *indicator* might address the overall maternal mortality rate or the number of preventable obstetrical deaths to all cases of maternal mortality. Both the standards and the indicators in this example help to guide practice, promote safe and effective patient care, and provide valuable information that can be used to improve the organization's performance and the clinical outcomes of the patients it serves.

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## V. Deciding on an Approach to External Quality Evaluation

### Introduction

The various approaches to quality evaluation and improvement in the health sector—licensure, accreditation, certification (including credential review processes), and indicator measurement—offer ministries of health and key policy makers a number of choices to consider. These choices may lead to a country-specific approach or even a regional approach.

There are numerous and challenging factors that must be considered in assessing the environment and choosing a particular approach to quality evaluation. A growing health services quality imperative worldwide offers many opportunities for sharing information and approaches between countries. In this chapter, several possible sequential approaches to analysis and decision-making are discussed, including the following:

- ◆ Needs assessment
- ◆ Situational analysis
- ◆ Gap analysis
- ◆ Decision analysis, and
- ◆ Design and pilot testing of a new or improved system of quality evaluation.

### Needs Assessment

One of the first steps in deciding on an approach to external quality evaluation is to conduct a countrywide or regional needs assessment, depending heavily on input from key stakeholders in the health care delivery system. The needs assessment might include consideration of the major objectives of a quality evaluation system, such as protection of the public's health and safety, fostering an environment for continuous improvement, or building a system to monitor the competence of health care practitioners. Once a comprehensive listing of the needs related to quality evaluation is developed, needs should be prioritized in order to inform the decision-making process.

The needs assessment should start by identifying the major stakeholders in the health care delivery system and then soliciting their perspectives on what is most needed in the system. Stakeholders might include the Minister of Health, senior governmental and health officials, regulatory bodies such as a licensing board for health professionals, professional societies such as a national hospital directors' association, medical association or regional nurses association, consumer advocacy groups, payers such as insurance companies, employee benefit managers, or health plans, and the community at large. Each stakeholder will have needs unique to his or her perspective. An insurance company or managed care provider might be particularly interested in having a quality evaluation system that stresses improvements and comparative databases with respect to health outcomes as well as overall cost-effectiveness, whereas the needs of the

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consumer or community at large might focus more on basic assurances of public safety and access. Conducting focus groups, workshops, or some form of survey with as many types of stakeholder groups as possible will help to identify these needs and objectives, which can then be grouped and prioritized for further analysis.

## Situational Analysis

This step in the decision-making process takes into account what is happening currently in the country or region with respect to external quality evaluation. For example: Is there a licensing system in place for health care organizations and various practitioners, and if so, what is its scope and structure? One might begin by listing the types of health care organizations or providers currently operating within a country, such as hospitals, primary health centers, pharmacies, physician group practices or clinics, and laboratories, and then determining if there are laws and regulations that govern their operations. One component of the situational analysis might also be an “appreciative inquiry” that determines what is currently working well and how additional capacity in these areas could be established.

If such laws and regulations exist for a particular category of provider, are they current and being followed? What is the system for assuring that a provider must meet certain requirements and how effective is the system? For example, one might discover that there are regulations for radiation protection that govern the provision of radiology services in a hospital or primary health center, but there is no regular evaluation system to assess their proper implementation. In a related example, the situational analysis might reveal that most diagnostic radiology is provided by unlicensed individuals who received no formal or standardized training, a finding that should be considered a “gap” in the next step of the decision making process.

In some cases, it may be appropriate to conduct the situational analysis before the needs assessment. This might be done when the stakeholders are not clearly known or identified. It may also be appropriate when a meeting of stakeholders to ascertain needs would be more productive after the results of the situational analysis are known. In such a case, the needs assessment, gap analysis, and decision analysis could be done in one workshop to save time.

Figure 5-1 provides examples of the types of questions that key decision makers will want to consider in conducting a situational analysis of a country’s or region’s current quality monitoring and evaluation. Doing such a comprehensive analysis will help to ensure that no major areas are left out and avoid duplication or rework in redesigning the current system.

## Gap Analysis

This step in the decision making process compares the major stakeholder needs identified in the first step with the situational analysis to determine where there are system-wide gaps that are not being adequately addressed. In other words, it examines the remaining priority needs based on what we understand about our existing system of quality evaluation. Some criteria for assessing the importance or risk of the identified gaps might be useful to develop in conducting this analysis. Sample criteria might include the following:

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Figure 5–1

### **Questions to Consider in Conducting a Situational Analysis**

The following questions can provide a useful self-assessment framework for a health system or an individual health care organization in conducting a situational analysis of its quality monitoring and evaluation mechanisms:

- ◆ What is the historical approach to health sector regulation and evaluation in the system for both organizations and health care practitioners?
- ◆ What are current societal factors (e.g., financing, health reform initiatives) impacting the overall quality of the health sector and influencing the needs for an evaluation system?
- ◆ What infrastructures (e.g., regulatory agencies, accrediting bodies, professional societies) exist to implement an external quality evaluation system? What is working well?
- ◆ What is the scope of the current quality evaluation activities (e.g., hospitals, clinics, community-based care systems, physicians, nurses, pharmacists, traditional birth attendants)?
- ◆ What laws, regulation, or standards of performance exist? Are these current and relevant? Are they widely disseminated? Are they consistently implemented?
- ◆ How effective is the current system in meeting its established objectives? What are its outcomes?
- ◆ What are the costs of implementing the current quality evaluation system?
- ◆ Is there an existing database of performance measures in the health sector? If so, how valid and reliable are the measures that it includes?

- ◆ Potential risk or harm to patients and the community
- ◆ Impact as far as size and number of organizations or individuals where the gap exists
- ◆ Resource implications in addressing the identified gap, and
- ◆ Expected overall impact in improving quality.

In conducting a gap analysis, one stakeholder group might identify a need for a quality evaluation mechanism that would be useful to consider at a later time, but is not seen as an immediate priority by the majority. Physicians in a small and emerging specialty area of practice, such as human genetics might identify as a gap the lack of defined certification program for this specialty. However, other stakeholders might see such a gap as relatively low priority given other

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pressing national considerations, such as the inadequacies of the current system for re-licensing nurses who are the country's largest group of health practitioners. The gap analysis should help decision makers prioritize the needs in order to develop possible solutions.

## Decision Analysis

The next step in the systematic problem-solving process is to analyze potential solutions in response to identified gaps and needs. In this step, brainstorming all possible solutions and approaches is a useful strategy to redesign the current system or develop a new system. Key decision makers will also find it helpful to “benchmark” or compare current systems of quality evaluation that are being used effectively in other regions or countries and adapt these approaches to local needs when possible. Some regions that have similar concerns and needs might choose to work collaboratively in developing a quality evaluation mechanism, such as a reciprocal licensure system that allows practitioners in nearby states, provinces, or countries to practice when moving between these jurisdictions.

Information sources for benchmarking might include large national or international bodies such as the WHO, the International Society for Quality Assurance (ISQua), national or international professional societies such as the International Society of Chest Surgeons, or federations, such as the International Organization for Standardization (ISO) and the U.S.-based Federation of State Medical Boards. Appendix B provides a comparison of existing and emerging national health care accreditation programs by identifying major characteristics of the various systems. In 1999, Joint Commission International Accreditation, a subsidiary of the Joint Commission on Accreditation of Healthcare Organizations in the USA, developed and published a core set of international accreditation standards that can be adapted for use in an individual country.

In brainstorming possible approaches to design or redesign a system for quality evaluation, resource implications and long-term sustainability should be carefully considered. For example, those involved should decide if the licensure system will be supported by fees from organizations or individuals under its jurisdiction or if supplemental government funds will be required to achieve intended objectives. A clear pitfall to avoid is designing a system that exists only on paper, such as radiation protection regulations that are never evaluated in an actual radiology practice. Many questions regarding long-term management and sustainability have been addressed elsewhere in this monograph, but are useful to reconsider here. For example, in designing a system for certification of nurse midwives, what will it take to ensure that certified midwives are re-evaluated for current competence at periodic intervals? If a new system for licensing primary health centers is designed, how many reviewers or inspectors will be required to conduct the licensing inspections for all involved centers? Who will train and manage these inspectors? What type of infrastructure will be required?

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## Design or redesign of a system for quality evaluation

Once the possible solutions are identified and prioritized in the decision analysis process, the final step involves planning and testing for implementation. In the first step, changes to the current system or entirely new strategies are carefully thought through, so that their implementation will achieve maximum effectiveness. Using the example of designing a certification program for primary health workers in basic emergency care such as handling snake bites or head trauma, one might begin by thinking through all of the new system's components. Components may include: pre-testing to understand the worker's baseline knowledge and skills, collecting data about the most common types of emergencies received in a primary health center, designing a training program for health workers in basic emergency care, and developing an examination mechanism for determining the competence of workers in order for certification to be granted. Each of these steps will have a number of more detailed steps and processes that will need to be developed. A written plan or strategy, including timelines and assigned responsibilities, can be extremely beneficial in keeping the design or redesign on track.

In the next step, the plans may be pilot-tested on a small group or for a limited time period. For example, the emergency care certification program might be tested on a group of 20 staff from the primary health care centers in one district or province. This stage allows further refinement before a new certification system is implemented on a national or regional basis. Another example of pilot-testing might include dissemination of newly-developed standards or regulations for a period of public comment, followed by a testing of the standards through an external evaluation of a sample of health care organizations. After a careful analysis of findings, the new or revised system will have a greater chance of success when it is implemented for a larger group.

The findings of the pilot-testing can then be carefully analyzed based on some pre-determined criteria, and refinements made to the existing plans. A study of the new emergency care certification program might include analyzing and comparing pre-training scores testing workers' skills and knowledge with their post-training scores. Such a comparison might identify training gaps that need to be addressed before the certification program can be implemented on a wide scale, such as a need for additional content on handling obstetrical emergencies. Other study criteria might include the participants' satisfaction with the training program and recommendations for improvements, or an assessment of the cost-effectiveness of launching such a certification program. A careful analysis of the findings from pilot-testing in this stage usually identifies further opportunities for refinement or design.

When the new or redesigned system is launched, it will have incorporated, tested, and analyzed recommendations gathered from the pilot-testing stage. The emergency care certification program for primary health workers is now ready to be fully implemented on a larger sustained scale. An important component to build into this phase is some mechanism for monitoring and evaluating the effectiveness and cost of the new system on an ongoing basis, so that necessary refinements can be made. The implementation of the new system, such as a national hospital accreditation program, might include a built-in mechanism for periodic standards review and revision at two-to three-year intervals. A planned review and evaluation mechanism will help the new accreditation program reflect the state-of-the-art standards and remain responsive to the needs of stakeholders.



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## Summary

Implementing one or more external quality evaluation mechanisms on a national or regional basis requires significant planning, stakeholder support, resource allocation, infrastructure and legal support, and ongoing measurement of its effectiveness. Careful analysis of existing quality evaluation models and systems, both internally in a country and in comparison with “best practices” elsewhere, along with a planned and thoughtful implementation strategy, can help to ensure that the final product meets its stated objectives for improving quality throughout the health care system.

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Appendix A

**Quality Evaluation in a Developing Country**

The Development and Implementation of Hospital  
Accreditation System in Zambia

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## Introduction

Zambia, a developing country of 9 million people located in southern central Africa, initiated a major health reform effort in the mid-1990's, resulting in a restructuring of the health sector planning, financing, and monitoring and evaluation structures and functions. Initial reform efforts focused primarily on improving access and clinical care delivery in primary health centers in health districts throughout the country, with special emphasis on management of childhood illnesses, preventive care such as immunizations, improved maternal and infant care, HIV/AIDS prevention, and treatment of endemic diseases such as tuberculosis and malaria. In support of this reform effort, and under the sponsorship of the USAID Quality Assurance Project, Zambia instituted a country-wide initiative for introducing quality improvement concepts into the provision of primary health services in order to improve efficiency, effectiveness, and access to care. The training and ongoing field support provided by the project helped to lay an important conceptual framework for applying quality principles and standardization to health services that could be expanded on a broader scale.

## Application of Quality Assurance Principles to Hospital Standards and Performance

While primary health care improvements remain a priority, the scope of the quality assurance activities in Zambia expanded to also include an evaluation and standardization of the hospital system. Since no standards or regulations existed for the performance or evaluation of Zambia's approximately 80 hospitals, other than a licensure inspection for three private hospitals, Zambian health leaders identified as a priority the development of a mechanism for evaluating hospitals and encouraging continuous improvement of hospital systems and processes. The development of hospital standards and a hospital accreditation program was initiated in 1997, one of the first of its kind to be attempted in a developing country.

In order to facilitate the standards development and the design of the accreditation program, an advisory group named the Zambia Health Accreditation Council (ZHAC) was formed as a first step. This group represented multidisciplinary professional associations and expertise in Zambia, and included physicians, clinical officers, and nursing, dental, pharmacy, laboratory, radiology, and community representatives. The vision statement formulated by the ZHAC at its initiation is highlighted in Figure A-1. The council served an advisory role to the Zambian Central Board of Health and the Ministry of Health in the development of accreditation standards, a hospital survey process, and accreditation policies and procedures.

Figure A-1

### **Vision Statement for Zambia Health Accreditation Council**

The vision of the Zambia Health Accreditation Council is to steadily improve the quality of health services delivered by health facilities in both the public and private sectors in order to improve the health status of Zambians.

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## Development and Testing of Hospital Standards and Survey Process

The ZHAC was actively involved in developing and field testing a first draft of standards that identified 13 key functional areas for every hospital (Figure A-2) and 49 performance standards and associated measurable criteria. These draft standards were distributed to hospitals and health professional associations throughout Zambia for comment in the “field review” phase of the program development. The reviewers’ responses were overwhelmingly positive and urged that the standards, with some modifications, should be adopted. Reviewers also prioritized those standards that they felt could have the greatest impact on improving hospitals care in Zambia and therefore should be prioritized for adoption.

Following the field review, the standards were revised and a draft survey process developed for field testing at 8 hospitals of various sizes and types. The hospitals ranged from a 100-bed mission hospital in a rural village to a large teaching hospital in the capital city of Lusaka. The survey methodology included a combination of leader, patient, and staff interviews, building and equipment tours, observation of patient care provided, document review, and clinical record review. All areas of the hospital, from patient care areas to the operating theater, laboratory, pharmacy, radiology, kitchen, laundry, and central sterile supply, were included in the scope of the hospital accreditation survey process. Because of limited resources and the relative absence of formalized structures, such as written policies and procedures, much of the emphasis in the survey process was placed on evaluating the processes and outcomes of care through direct observations and interviews. A sample survey agenda is included in Figure A-3.

Figure A-2

### **Key Functional Areas Addressed in the Zambian Hospital Accreditation Program**

- ◆ Admission and Assessment
- ◆ Laboratory Services
- ◆ Radiology Services
- ◆ Pharmaceutical Services
- ◆ Patient Care
- ◆ Patient Rights
- ◆ Continuity of Care
- ◆ Environment of Care
- ◆ Infection Control
- ◆ Leadership
- ◆ Quality Assurance
- ◆ Human Resource Management
- ◆ Management of Information

Figure A-3

## Zambia Health Accreditation Council

### Sample Survey Agenda for a Hospital

Time	Activity	Hospital Participants
<b>Day #1</b> 0900 – 0930 hours	<b>Opening Conference with Hospital Leaders</b> <ul style="list-style-type: none"> <li>• Review agenda and scheduled interview times</li> <li>• Review objectives</li> <li>• Introductions of participants</li> <li>• Designation of a hospital liaison to the survey team</li> </ul>	<ul style="list-style-type: none"> <li>• Executive director or hospital administrator</li> <li>• Board member, if available</li> <li>• Nursing managers</li> <li>• Department heads</li> <li>• Other leaders, as designated by the hospital</li> </ul>
0930 – 1030	<b>Leadership and Quality Assurance Interview</b>	<ul style="list-style-type: none"> <li>• Board member, if available</li> <li>• Executive director or hospital administrator</li> <li>• Other leaders as designated by the hospital (e.g., senior nursing manager)</li> <li>• Quality assurance committee member</li> </ul>
1030 – 1300	<b>Document Review</b> <i>(Please have these documents available in an office or conference room)</i> <ul style="list-style-type: none"> <li>• Written policies and procedures</li> <li>• Committee meeting minutes</li> <li>• Planning and budget documents</li> <li>• Quality assurance materials: data collection and analysis documents, QA committee meeting minutes, patient satisfaction data</li> <li>• Environment of care documents: fire drill reports, disaster plan, equipment maintenance records</li> <li>• Infection surveillance documents</li> <li>• Patient rights and responsibilities document (e.g., brochure or poster)</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital designee available as a resource</li> </ul>
1300 – 1400	Lunch (surveyors on their own)	
1400 - 1700 hours	<b>Building, Facilities, and Department Tour and Staff Interviews</b> <ul style="list-style-type: none"> <li>• Admitting area</li> <li>• Catering/Kitchen</li> <li>• Pharmacy</li> <li>• Central sterile supply</li> <li>• Laundry</li> <li>• Laboratory, including blood storage areas</li> <li>• Radiology</li> <li>• Overall building structure</li> <li>• Mortuary</li> <li>• Incinerator/Disposal area</li> <li>• Emergency generator</li> </ul>	<ul style="list-style-type: none"> <li>• Building engineer</li> <li>• Maintenance staff</li> <li>• Hospital directors and staff from specific departments/areas</li> </ul>

Figure A-3 continued

## Zambia Health Accreditation Council Sample Survey Agenda for a Hospital

Time	Activity	Hospital Participants
<b>Day #2</b> 0830 – 0900 hours	<b>Daily Briefing</b> <ul style="list-style-type: none"> <li>• Review findings from day #1</li> <li>• Review day two agenda</li> </ul>	<ul style="list-style-type: none"> <li>• Executive director or hospital administrator</li> <li>• Senior nursing manager</li> <li>• Administrative director</li> <li>• Others leaders as designated by hospital</li> </ul>
0900 – 1300	<b>Patient Care Area Review and Clinical Observation</b> <ul style="list-style-type: none"> <li>• Tour areas where patient care is provided</li> <li>• Staff interviews</li> <li>• Patient record review</li> <li>• Patient and family interviews</li> </ul> <p><i>If provided, the following areas should be included:</i></p> <ul style="list-style-type: none"> <li>• Operating theatre and recovery</li> <li>• Isolation ward (if applicable)</li> <li>• Obstetrics ward</li> <li>• Nursery</li> <li>• Pediatrics ward</li> <li>• Emergency/Casualty/Outpatient unit</li> <li>• General medical ward</li> <li>• Surgical ward</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical staff in each patient area visited</li> <li>• Physicians</li> <li>• Clinical officers</li> <li>• Nurses</li> </ul>
1400 – 1530	<b>Human Resources Interview and Document Review</b> <p><i>(Please have available samples of personnel records, job descriptions, licenses, orientation and training documents)</i></p>	Individuals responsible for human resources function
1530 – 1700	Surveyor debriefing to discuss findings/Additional survey time if needed	None
<b>Day #3</b> 0900 – 1300 hours	<b>Surveyor Team Scoring and Documentation Completion</b>	None
1300 – 1400	Lunch	
1400 – 1600	<b>Leadership Exit Conference and Summary of Findings</b>	Hospital leaders <i>(see opening conference participant list)</i>
1600 hours	<b>Surveyors Depart from Hospital</b>	

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## Surveyor Training and Competence Assessment

A surveyor training and competence assessment program was developed and implemented with the first cadre of hospital surveyors, representing many of the health professional disciplines in Zambia, including physicians, clinical officers, nurses, dentists, pharmacists, and laboratory specialists. The three-day initial surveyor training included the following topics:

- ◆ An introduction to the accreditation program
- ◆ Overview of functional area, standards, and associated measurable characteristics
- ◆ Case studies and group exercises using the standards
- ◆ Overview of the survey process and introduction to survey process checklists and tools
- ◆ Interviewing, consultation, and critical thinking skills
- ◆ Scoring and documentation
- ◆ Conducting an exit conference and sharing survey findings, and
- ◆ Surveyor professional demeanor and ethics.

New surveyors then had an opportunity for “hands-on” mentoring during actual surveys with a trainer or experienced surveyor before they were determined to be sufficiently knowledgeable in interpreting the standards, as well as competent in evaluating their application in practice.

## Pilot Testing and Consultative Surveys

The eight pilot test surveys conducted in early 1998 demonstrated that the draft standards and evaluation methodology could be surveyed and measured, although several refinements were recommended and subsequently adopted. Although the primary purpose of the pilot-test surveys was to evaluate the appropriateness of the standards and survey process, the surveyors were also able to identify common areas where improvements were needed in order for most hospitals to meet the intent of the standards. The standards and survey process was designed to assist hospital leaders and staff in prioritizing their resources, needed improvements, and funding. Despite the significant resource limitations in Zambia, both hospital leaders and key stakeholders within the country believe that many improvements in care processes are still achievable, and that the standards will help to prioritize resource allocation and planning.

Throughout the last half of 1998 and into 1999 and 2000, consultative surveys will be conducted in all hospitals in Zambia as part of a major field educational and consultation effort. Each hospital will undergo a consultative survey approximately one year prior to its actual accreditation survey, so that the hospital leaders and employees learn about the standards and survey process, as well as receive consultation on ways that the hospital can meet them. Although the standards are scored, there is no formal report or decision rendered. Figure A-4 presents an example from the Surveyor Scoring Form, for a standard in the functional area of Admission and Assessment. The final rollout of the actual accreditation program is planned for



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1999, whereby actual accreditation decisions and written findings will be formulated and distributed, using a standardized decision methodology and published decision rules. An accreditation database was established so that aggregate data can be stored and trended over time.

## Summary

Zambia represents an innovative attempt to improve the quality of its system of hospitals through the development and consensus on a national set of key patient care and organizational functions and standards. The Zambia approach to applying quality assurance and quality design to its hospital system is unique for a developing country facing significant health, social, and economic problems. If successful in standardizing hospital care processes and improving health outcomes, the Zambian model of hospital accreditation could serve as a model for other developing countries around the world.

Figure A-4

**Zambia Health Accreditation Council  
Sample Hospital Accreditation Standard**

**Functional Area: Admission and Assessment**

AA.1: There is an established process for admitting patients to the hospital that prioritizes care based on the assessed needs of the patient.\*

**Intent Statement**

The order in which patients are seen for admission is determined by their degree of need. Patients with immediate needs are prioritized for assessment and intervention. The hospital designs and implements an effective and efficient process for admitting patients that considers the following elements:

**Scoring**

	<b>Met</b>	<b>Partially Met</b>	<b>Not Met</b>	<b>Not Applicable</b>
a) Registration process is completed				
b) Patients with immediate needs are prioritized for assessment and intervention				
c) There is a standard for checking waiting times of patients in OPD and Admission				
d) Communication of information between departments and staff involved in the care				
e) Timely completion of requested diagnostic testing, and				
f) All of these processes are documented in policies and procedures and standardized within the hospital.				

**Sources of Information**

1. Interview clinical and non-clinical staff and address the registration process
2. Observation of the admitting area
3. Interviews with patient/families
4. Patient records

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\*Standards that were identified as high priority during the field review.



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Appendix B

**Comparison of Existing Hospital  
Accreditation Organizations**

## Comparison of Existing Hospital Accreditation Organizations

Country	Accrediting Body	Standards Manual Format	Types of Standards	Intent Statement	Scoring Scale	Number of Accredited Hospitals	Developed Indicators	Voluntary	Funding Source	Limited Scope
United States	Joint Commission on the Accreditation of Health Care Organizations	Functional	Structure, Process, and Outcomes	Yes	Yes, 5 Point Scale	5155	Yes	Yes	Survey Fees, Publications, Education Programs, and Consulting	No
United States	American Osteopathic Association	Departmental	Structure, Process, and Outcomes	No	Yes, 4 Point Scale	400	No	Yes	Survey Fees	Yes, Hospitals
United States	Commission of Accreditation of Rehabilitation Facilities	Functional	Structure, Process, and Outcomes	No	Yes, 4 Point Scale	700-800	Proposed	Yes	Survey Fees, Publications, and Education	Yes, Rehabilitation Services
Canada	Canadian Council on Health Services Accreditation	Functional	Structure, Process, and Outcomes	Yes	Yes, 4 Point Scale	502 (1996)	Proposed for 2000	Yes	Member Fees and Survey Fees	No
United Kingdom	Health Services Accreditation	Functional	Structure, Process, and Outcomes	Yes	No	Unknown	Yes	Yes	Survey Fees or Grants	Yes, Hospital Departments
United Kingdom	Kings Fund Organizational Audit	Departmental (1996)	Structure and Process	Yes (Criteria)	Yes, 2 Point Scale	79 (1994)	No	Yes	Survey Fees, and Publications	Yes, Hospitals
United Kingdom	Southwestern Hospital Accreditation Program		Structure and Process			67 (1994)	No	Yes	Grants, Survey Fees, Consulting, and Publications	Yes, Community Hospitals
Netherlands	National Organization for Quality Assurance in Hospitals		Structure and Process					Yes		Yes, Medical Specialist

### Comparison of Existing Hospital Accreditation Organizations continued

Country	Accrediting Body	Standards Manual Format	Types of Standards	Intent Statement	Scoring Scale	Number of Accredited Hospitals	Developed Indicators	Voluntary	Funding Source	Limited Scope
Netherlands	Institute voor Accreditation van Ziekenhuizen	Departmental	Structure and Process	Unknown	Yes, 4 Point Scale	18	No	Yes	Survey Fees	Yes, Hospitals
Australia	Australian Council on Healthcare Standards	Departmental (1995)	Structure and Process	Yes, Most Standards	Yes, 4 Point Scale	201 (1994)	Yes	Yes	Survey Fees, Publications, and Education	No
New Zealand	Ministry of Health	Functional	Structure and Process	Yes		115 (1997, all services)	Proposed	Yes	Member Fee (1998)	No
Taiwan	Ministry of Health	Functional and Departmental	Structure, Process, and Outcomes	Yes	Yes, 6 Point Scale	525	Yes	Yes	Government	Yes, Hospitals
Japan	Council for Quality Health Care					79		Yes		Yes, Community Hospitals
Korea	Joint Commission on Accreditation of Hospitals	Departmental	Structure and Process	Yes	Yes, 3 Point Scale	131	Yes	Yes	Survey Fees	Yes, Teaching Hospitals
Korea	Hospital Performance Evaluation Program		Process and Outcome			96				Yes, Hospitals
China	Hospital Grade Appraisal Committee, HB	Departmental				1086 (1991)				Yes, Hospitals and Teaching Hospitals
South Africa	Council for Health Service Accreditation of South Africa	Departmental and Functional	Structure, Process, and Outcomes	Yes	Yes, 4 Point Scale	40	Proposed	Yes	Survey Fees	No

**Comparison of Existing Hospital Accreditation Organizations** continued

<b>Country</b>	<b>Accrediting Body</b>	<b>Standards Manual Format</b>	<b>Types of Standards</b>	<b>Intent Statement</b>	<b>Scoring Scale</b>	<b>Number of Accredited Hospitals</b>	<b>Developed Indicators</b>	<b>Voluntary</b>	<b>Funding Source</b>	<b>Limited Scope</b>
Czech Republic	Joint Committee on Accreditation	Functional	Structure, Process, and Outcomes	Yes	Yes, 5 Point Scale	13	Yes	Yes	Survey Fees	Yes, Hospitals
Kyrgyzstan	Ministry of Health	Departmental	Structure, Process, and Outcomes	No	Yes, 3 Point Scale		No	Yes	Survey Fees, Board Member Organization Support, Other	Yes, Hospitals
Lithuania	State Accreditation Services by Ministry of Health	Departmental	Structure and Process	Yes	No	53	No	No, Planned to change	Ministry of Health and Survey Fees	Yes, Nursing, Rehabilitation and Medical Care Hospitals

## Comparison of Emerging Hospital Accreditation Organizations

Country	Accrediting Body	Standards Developed	Survey Process Developed	Pilot Testing	Project Implementation Date	Indicators Developed	Voluntary	Funding Source	Limited Scope
Spain	Avedis Donabedian Foundation/JCI	Yes	Yes	Yes	1998	Proposed	Yes		Yes, Hospitals
France	National Agency for Accreditation and Evaluation of Health	Partially	Partially	Planned	1999	Proposed	No		Yes, Hospitals
Philippines	Philippine Council for Accreditation of Health Care Organizations	Partially	Partially	No	Third Quarter of 1999	No	Yes	Department of Health, Grants, and Survey Fees	Yes, Hospitals
Malaysia									Yes, Hospitals
Zambia	Zambia Health Accreditation Council	Yes	Partially	Partially	January, 1999	Proposed	Undecided	Undecided	Yes, Hospitals
Brazil	Consortium for Brazilian Accreditation	No	No	No	1999		Undecided	Undecided	Yes, Rio Region Hospitals and University Hospitals
Poland	Accreditation Council	Yes	Yes	Yes	1999	Yes, currently being tested	Yes	Government Accreditation Council, and Survey Fees	Yes, Hospitals
Romania	National Agency for Accreditation and Evaluation of Health Services	Yes	Yes	Yes	1999	No	Yes	Undecided	Yes, Hospitals
Hungary	Ministry of Welfare	Yes	Yes	Yes		No			Yes, Hospitals

**Comparison of Emerging Hospital Accreditation Organizations** continued

<b>Country</b>	<b>Accrediting Body</b>	<b>Standards Developed</b>	<b>Survey Process Developed</b>	<b>Pilot Testing</b>	<b>Project Implementation Date</b>	<b>Indicators Developed</b>	<b>Voluntary</b>	<b>Funding Source</b>	<b>Limited Scope</b>
Ukraine (JA)	Ministry of Health	Yes	Yes	Partially					Yes, Hospitals
Saudi Arabia (IR)	Independent Organization	Yes	Partially	Partially	3-5 Years	Proposed			Yes, Hospitals
Egypt		Yes							Yes, Hospitals