

APPROACHES TO HEALTHCARE QUALITY REGULATION IN LATIN AMERICA AND THE CARIBBEAN: REGIONAL EXPERIENCES AND CHALLENGES

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EXECUTIVE SUMMARY

Health sector reform efforts in the Latin America and Caribbean (LAC) region have, in recent years, focused on strengthening the stewardship role of the public sector in regulating healthcare and assuring the quality of health services. Through regulatory approaches, governments establish expectations for the competence of healthcare providers and institutions and for the quality of services these provide. This paper was commissioned to examine experiences in the region with the regulation of the quality of care of healthcare providers and facilities, to derive lessons and implications for future policy development, programming, and research. The research was carried out through literature review and interviews with key informants. While this research is certainly not exhaustive of this extensive subject area, it aims to provide insights into the challenges facing current initiatives in healthcare quality regulation and provide direction for the future.

Three main approaches to quality regulation have been used by governments and professional bodies to ensure, maintain, and improve the quality of healthcare: *licensing*, *certification*, and *accreditation*. The three approaches are not mutually exclusive—each has a distinct purpose and can contribute to a country’s overall strategy for ensuring quality of healthcare services—and indeed are complementary. All three approaches are based on evaluation of adherence to explicitly defined standards and strive to create uniformity of practice by service providers and delivery systems. The three approaches also differ in important ways: whether they are mandatory or voluntary; in the nature of the issuing or enforcing organization; with respect to what entity is the object of evaluation; in the level of detail of requirements and the scope of the standards; in the frequency with which evaluation is carried out; and in the assessment methodology used.

Licensing is a statutory mechanism by which a governmental authority grants permission to an individual practitioner to engage in an occupation or to a healthcare organization to operate and deliver services. Licensing allows governments to ensure basic public health and safety by controlling the entry of healthcare providers and facilities into the healthcare market and by establishing standards of conduct for maintaining that status.

Certification and accreditation, in contrast, are voluntary processes undertaken by a provider or a facility to demonstrate special competence or capability beyond the minimum required for licensure. Certification is a process by which a recognized authority—either a governmental agency or nongovernmental organization—evaluates and recognizes an individual provider or an organization as having met pre-determined requirements, usually to demonstrate competence in a specialty area. Accreditation is the formal process by which a recognized accrediting body assesses and recognizes that a healthcare organization meets pre-established performance standards. Certification generally implies a specialization in a single technical area, while accreditation reflects overall facility performance and competence.

Accreditation standards are usually regarded as optimal yet achievable and are designed to encourage continuous improvement efforts within accredited organizations. The standards used to assess performance for accreditation are commonly developed by expert committees working with the accrediting body and revised periodically to reflect advances in technology or policy changes. By focusing on optimal rather than minimum standards of care, accreditation instills a strong performance improvement orientation, stimulating healthcare organizations to pursue increasingly higher levels of quality. A recent adaptation of the traditional accreditation model has been to focus on specific services or areas of care, in a process often referred to as *focused accreditation*. Focused accreditation has drawn interest in the region as a tool for improving the quality of selected health services and of primary care facilities.

A strong legal foundation and support for the regulation of healthcare facilities and personnel exists throughout the region, and many regulatory initiatives that affect quality are in the process of development. All countries in the LAC region have licensing programs for healthcare personnel and facilities as well as explicit requirements for the legal practice of healthcare professions. Certification programs for health professionals are less prevalent, and few countries have explicit continuing education requirements for health professionals. While only four countries in the region have well established hospital accreditation programs (Argentina, Brazil, Chile, and Costa Rica), several others are considering or are in the process of developing accreditation programs, including focused accreditation. Annex 3 of the report provides more detailed descriptions of experiences with quality regulation in Argentina, Brazil, the Caribbean Community, Colombia, the Dominican Republic, and Honduras.

Regional efforts to effectively regulate the quality of care of health facilities and practitioners face a number of challenges. A major weakness in most countries is the lack of enforcement of sanctions or consequences for loss or reversal of quality evaluation status. This includes procedures for disciplinary action against licensees who fail to maintain the conditions of licensing as well as procedures for reporting and handling impaired or incompetent providers and facilities. A related problem is lack of ongoing inspection of facilities or periodic review of provider competence to ensure that desired performance is sustained over time. Licensing and certification only at the point of entry into the healthcare market are insufficient to provide assurance to the public and to health sector institutions that providers maintain competency throughout the span of their careers. Time-limited licenses and certificates and clear requirements for renewal are essential to create an impetus for providers to remain current through continuing education and for organizations to maintain physical infrastructure and capacity.

Monitoring and evaluation continues to be a weak link in healthcare regulation in the region. Ongoing evaluation of quality regulation programs is important to ensure that regulatory agencies are accountable to the public and to demonstrate that the investment in quality regulation is cost-effective. Providing sufficient resources to effectively implement any quality regulation approach is also critical. Decision makers must address funding sources and sustainability at each phase of development of a quality regulation program. To have impact, regulatory bodies must have the resources and mechanisms to exert their authority and must regularly collect and act on monitoring data to verify compliance. Facilities also need resources to enable the achievement of standards.

While the number of countries implementing hospital accreditation is growing, to date there is little conclusive evidence that accreditation actually improves the quality of hospital care. Since accreditation programs entail substantial costs, determining whether accreditation is likely to be effective and sustainable is crucial prior to embarking on this approach to quality regulation.

Another opportunity to strengthen healthcare regulation in the LAC region that consistently arises throughout country examples is the need for stronger incentives to improve and maintain quality of care. Providing incentives to motivate providers and organizations to participate in and maintain quality performance is as important as sanctions, particularly in voluntary programs like accreditation. Another challenge for all programs is keeping standards up to date with changes in technology, scientific evidence, and medical practice.

As the demand for private sector services continues to grow throughout the LAC region, addressing the private sector is a major regulatory challenge. Governments need to engage private sector stakeholders in the development of healthcare regulation while also exercising their steering role of regulating and controlling the facilities, services, and personnel of both private and public health institutions. Though many Ministries of Health have the legal authority to regulate private

providers, many do not exercise this power, resulting in largely unknown quality in the private sector.

Finally, it is important to remember quality regulation is only one of many quality assurance strategies that impact quality of care. Quality regulation will have its maximum effect when coordinated with other quality assurance activities at various levels. To truly ensure the quality of health services, governments must not only examine their role as stewards and regulators, but also take steps to inculcate a culture of quality and support quality improvement at all levels of the healthcare system, from individual community clinics to specialized referral hospitals.

ACRONYMS

ANS	National Supplemental Health Agency (Brazil)
CAMC	Caribbean Association of Medical Councils
CARICOM	Caribbean Community and Common Market
CBA	Brazilian Consortium for Accreditation of Health Care Systems and Services
CCP	Center for Communication Programs
COHSASA	Council for Health Service Accreditation of Southern Africa
COMACH	Comisión Mixta de Acreditación (Dominican Republic)
CQH	Hospital Quality Control (Brazil)
CQI	Continuous Quality Improvement
EPS	Health Promotion Organization (Colombia)
FONASA	Fondo Nacional de Salud (Chile)
IPS	Service Delivery Institution (Colombia)
ISO	International Organization for Standardization
ISQua	International Society for Quality in Health Care
ITAES	Technical Institute for Accreditation in Health Care Services (Argentina)
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JCI	Joint Commission International
JCR	Joint Commission Resources
JHPIEGO	Johns Hopkins Program in International Education and Training in Reproductive Health
LAC	Latin America and Caribbean
LAFH	Latin American Federation of Hospitals
LACHSR	Latin America and Caribbean Regional Health Sector Reform Initiative
MERCOSUR	Common Market of the Southern Cone
MOH	Ministry of Health
NAFTA	North Atlantic Free Trade Area
NGO	Nongovernmental Organization
ONA	National Accreditation Organization (Brazil)
PAHO	Pan American Health Organization
QAP	Quality Assurance Project
SESPAS	Secretaría de Estado de Salud Pública y Asistencia Social (Dominican Republic)
SUS	Unified Health System (Brazil)
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

I. INTRODUCTION

In the past two decades, countries in the Latin American and Caribbean (LAC) region have engaged in efforts to improve health sector performance by making fundamental changes in the way healthcare is organized, financed, and delivered. While early initiatives to reform the health sector focused heavily on cost containment, by the mid-1990s, there was widespread recognition among governments in the region that health sector reform initiatives must address the lack of equitable access to basic health services and improve the quality of those services (Ross et al. 2000).

At a Special Meeting on Health Sector Reform in 1995, LAC government and donor agency representatives acknowledged that five overarching goals should be pursued as part of health sector reforms in the region: equity, quality, efficiency, sustainability, and social participation (Lopez-Acuña 2000). Meeting participants agreed that an ideal health sector reform initiative would improve all five aspects of health system performance.

More recent efforts toward health sector reform have highlighted the stewardship role that the public sector has in regulating healthcare and assuring the implementation of essential public health functions, including healthcare regulation and enforcement and assuring the quality of health services (Rivas-Loria and Shelton 2004). Persistent challenges facing healthcare delivery systems in the region, including inadequate funding and failure to assure basic health services to large segments of the population, have also reinforced the importance on the role of the government and regulatory agencies as “stewards” of the healthcare system, setting priorities, establishing and changing laws and regulations, and monitoring the quality of care in the public and private sectors (Dmytraczenko et al. 2003).

To provide analytical and capacity-building support for country programs and to help them fulfill the broader goals of health sector reform, the United States Agency for International Development (USAID) and the Pan American Health Organization (PAHO) established the Latin America and Caribbean Health Sector Reform (LACHSR) Initiative. Since 1998, the LACHSR Initiative has promoted more equitable and effective delivery of basic health services through regional activities to inform and support country level decision-making and activities in health policy and management, health financing, decentralization, health services improvement, and institutional development.

USAID’s Quality Assurance and Workforce Development Project (QAP) was asked to join the LACHSR Initiative in 2002, with the explicit role of enhancing the impact of health sector reform activities on healthcare quality and strengthening the focus on quality within health sector reform activities. The Quality Assurance Project’s activities under LACHSR build upon work that QAP started with PAHO in 2000 to develop a framework for analyzing the interrelationships between health sector reform and quality assurance¹.

As part of its LACHSR work program, QAP commissioned a desk review of current efforts in Latin America and the Caribbean to influence the quality of healthcare through regulatory actions

¹ For further discussion on this topic, see “Maximizing Quality of Care through Health Sector Reform: The Role of Quality Assurance Strategies. Final Draft,” a joint paper of the Quality Assurance Project and the Pan American Health Organization that analyzes the impact of health sector reforms on quality of care and describes ways in which quality assurance and health sector reforms can reinforce each other. Available at: <http://qaproject.org/products.html>.

that control entry into the healthcare market and that standardize, prescribe, or otherwise direct healthcare provider behavior to ensure patient safety.² This paper is the product of that activity and one of several QAP reports developed under the LACHSR Initiative.³

The rationale for the paper's focus on healthcare quality regulation was that experiences in the LAC Region with the direct regulation of healthcare providers and facilities were felt to be less known than other activities to assure health service quality, such as standards development and quality improvement programs. The scope of the paper was thus defined as examining experiences in LAC countries with registration, licensing, accreditation, or certification of healthcare providers or facilities to assure service quality and protect public safety, for the purpose of deriving lessons and implications for future policy development, programming, and research.

This document first describes the key features of licensing, certification, and accreditation as the most common approaches to the regulation of the performance of healthcare providers and facilities. Regional trends in quality regulation are then described, based on specific country experiences that are described in Annex 3. The final section of the paper analyzes the achievements and limitations of these experiences and concludes with lessons for countries interested in applying these regulatory strategies. The paper also highlights areas where further evidence and research are needed to aid country decision makers in using these instruments to improve healthcare quality.

This research was carried out through a combination of literature review and interviews with key informants in the LAC region (see Annex 1 for the list of key informants interviewed and Annex 2 for a list of relevant web links). While this research is certainly not exhaustive of this extensive subject area, it aims to provide insight into current initiatives taking place in healthcare regulation and provide direction for future research efforts in this subject.

Finally, it is important to note that quality regulation is only one of many quality assurance strategies that can impact quality of care. Quality regulation will have its maximum effect only when coordinated with other quality assurance activities at various levels. To truly ensure the quality of health services, governments must not only examine their role as stewards and regulators, but also take steps to inculcate a culture of quality and support quality improvement at all levels of the healthcare system, from individual community clinics to specialized referral hospitals (Ross et al. 2000).

² It is important to keep in mind that governments influence the quality of healthcare services in several ways apart from regulation of entry into the health sector and of health provider behavior: through the regulation of medical and nursing education; through the development of evidence-based standards; through financing mechanisms that link resource transfer to evidence of compliance with standards of care or that channel resources toward investments expected to improve healthcare quality (e.g., upgrading of equipment, assuring adequate supplies of essential drugs, etc.); through defining guaranteed health benefits and minimum service packages for private and social insurance; and through direct quality improvement activities. This paper addresses only quality-oriented regulation of healthcare providers and facilities.

³ See also: Quality Assurance Project. 2005. Maximizing Quality of Care in Health Sector Reform: The Role of Quality Assurance Strategies. LACHSR Report No. 64. Quality Assurance Project: Bethesda, MD and Hermida, J., Robalino, M.E., Vaca, L., Ayabaca, P., Romero, P., Vieira, L., and Abarca, X. 2005. Scaling up and Institutionalizing Continuous Quality Improvement in the Free Maternity and Child Care Program in Ecuador. LACHSR Report No. 65. Quality Assurance Project: Bethesda, MD. Both reports available at: www.lachsr.org.

II. APPROACHES TO THE REGULATION OF HEALTHCARE QUALITY

OVERVIEW

There is increased interest around the world in evaluation of healthcare, coming not only from governments, but also providers and consumers. Because all countries face the problem of scarce resources for health, increasing attention is being focused worldwide on the health impacts and results that are achieved with those healthcare resources. Health sector reform processes have given further impetus to ensuring accountability in the health sector and to developing the steering role of Ministries of Health, particularly with respect to the government's role as steward and protector of the public's health.

Through regulatory approaches, governments establish expectations for the competence of healthcare providers and institutions and for the quality of services these provide. Regulators of quality may define specific standards and require that health providers comply, but they can also allow healthcare or professional organizations to prescribe their own rules. Regulators can simply specify that standards are to be used and that those standards be formulated and applied through an acceptable process. How prescriptive is the quality regulation depends in large part on the perceived competence of provider institutions and on regulators' confidence that the desired ends of regulation will be achieved.

Three main approaches to quality regulation have been used by governments and professional bodies to ensure, maintain, and improve the quality of healthcare: *licensing*, *certification*, and *accreditation*. The three approaches are not mutually exclusive—each has a distinct purpose and can contribute to a country's overall strategy for ensuring quality of healthcare services. While each approach has a different focus, they have certain features in common. First, all three are based on external assessment or evaluation against explicitly defined standards; for this reason, quality regulation is sometimes referred to as external quality evaluation. Second, all three approaches share a common goal of ensuring public safety and promoting the quality of healthcare by striving to create uniformity of practice by service providers and health care delivery institutions.

The three approaches also differ in important ways: whether they are mandatory or voluntary; in the nature of the issuing or enforcing organization; with respect to who is the object of evaluation; in the level of detail of requirements and the scope of the standards; in the frequency with which evaluation is carried out; and in the assessment methodology used.

Approaches targeting the regulation of healthcare facilities differ from those directed at individual practitioners. The quality evaluation of healthcare facilities, for example, may assess the level of compliance with established standards for structure (e.g., presence of policies, facilities, equipment), work processes of staff as a whole (e.g., overall adherence to clinical guidelines, staff supervision), or outcomes (e.g., infection rates, case fatality rates) for the facility as a whole or for individual departments, though not for individual providers within the facility.

The quality evaluation of individual providers allows the government to develop educational and practical frameworks for the professional development of healthcare workers. Certification and licensure programs for healthcare providers define professional requirements and also facilitate the development of technical standards with which professionals are expected to comply (Quintana 2000). The evaluation of individual providers might assess knowledge, skill at performing specific procedures, completion of continuing education requirements, or clinical practices.

It should also be pointed out that there are variations in how the terms licensing, certification, and accreditation are used and interpreted from country to country. In the United States, where healthcare accreditation originated in 1951 under the auspices of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), accreditation is focused on the performance of healthcare facilities and not on that of individual providers. In many European countries, however, physicians are individually “accredited” upon completion of specialty training; in the United States, this recognition of individual provider specialization is known as certification. The International Organization for Standardization (ISO) has in recent years moved into the healthcare arena by “certifying” laboratories, radiology departments, and diagnostic centers as compliant with related ISO production and quality control standards, often as a substitute for accreditation (Shaw 2004).

Table 1 summarizes and compares the main characteristics of licensing, certification, and accreditation. The remainder of this chapter will be used to discuss each approach in more detail and review implementation issues that have emerged from international experience.

TABLE 1: DEFINITIONS OF LICENSING, CERTIFICATION, AND ACCREDITATION⁴

APPROACH	ISSUING ORGANIZATION	OBJECT OF EVALUATION	COMPONENTS/ REQUIREMENTS	STANDARDS
Licensing (mandatory)	Governmental authority	Individual	Regulations to ensure minimum standards, exam, or proof of education/competence	Set at a minimum level to ensure an environment with minimum risk to health and safety
		Organization	Regulations to ensure minimum standards, on-site inspection	
Certification (voluntary)	Authorized body, either government or NGO	Individual	Evaluation of predetermined requirements, additional education/training, demonstrated competence in specialty area	Set by national professional or specialty boards
		Organization	Demonstration that the organization has additional services, technology, or capacity	Industry standards (e.g., ISO 9000 standards) evaluate conformance to design specifications
Accreditation (voluntary)	Recognized body, usually an NGO	Organization	Compliance with published standards, on-site evaluation; compliance not required by law and/or regulations	Set at a maximum achievable level to stimulate improvement over time

LICENSING

Licensing is a statutory mechanism by which a governmental authority grants permission to an individual practitioner to engage in an occupation or to a healthcare organization to operate and deliver services. Licensing allows governments to ensure basic public health and safety by

⁴ Adapted from Roa and Rooney 1999, p.5.

controlling the entry of healthcare providers and facilities into the country's healthcare market and by establishing standards of conduct for maintaining that status (Quintana 2000; Roa and Rooney 1999).

Licensing differs from other approaches to quality regulation in that it is mandatory and is performed uniquely by a government agency. Licensing regulations also specify the time period for which the license is valid and the required procedure for maintaining or renewing the license. Assuming that problems with the provider or facility have not been identified or reported, licenses may often be often renewed with the payment of a specific fee or submission of documentation.

Licensing standards are typically set at a minimum level, defined by the government as that needed to ensure health and safety in that country. For individual providers, licensing standards are usually defined in terms of training (e.g., completion of degree from an acceptable training institution) and demonstrated technical competence (e.g., passing of a licensing examination).

Although licensure exams are the most common example of regulation through licensing, other regulatory programs related to licensing include the reciprocal granting of licenses to professionals of other countries, establishing standards for professional practice, and developing systems to investigate and punish professionals that violate professional license standards (Quintana 2000).

Similar to licensing is *registration*, by which a provider may be admitted into a registry of providers recognized by the government as providers of healthcare services in the country. If registration requirements are based not only upon completion of educational requirements but also demonstrated technical competence, such as passing of a qualifying examination, the registration process may be a more effective mechanism for quality regulation. Registration has the added advantage of facilitating the creation a database of information about healthcare professionals that are practicing or intending to practice their profession in a given country.

Organizational licensing or registration is used in some countries to enable organizations to legally deliver healthcare services; granting of the license is often based on on-site inspection to determine if minimum health and safety standards have been met. The licensing of healthcare facilities differs from accreditation and certification in that it is mandatory, thus providing the government control over the entry and operation of healthcare facilities in the health sector. However, in some countries, a new registration or licensing process has been proposed for existing healthcare facilities that more closely resembles accreditation in the sense that detailed standards covering various functional areas have been proposed, with initial and subsequent evaluation of compliance, and the possibility of assistance being provided to facilities to help them achieve the standards.

CERTIFICATION

Certification is a process by which a recognized authority, such as a governmental agency, professional association, or specialty board, evaluates and recognizes either an individual or an organization as having met pre-determined requirements or criteria, usually demonstrated competence in a specialty area, beyond the minimum requirements set for licensing. Certification is a voluntary process undertaken by a provider or a facility to demonstrate special competence or capability in a particular area.

The certification of healthcare providers recognizes that an individual has demonstrated special skill or knowledge in a specific field. The intent of such certification is to provide evidence that the

provider has successfully completed an approved educational program and evaluation process and possesses the knowledge, skills, and educational experience required to provide quality patient care in their specialty. Certification may also be tied to scopes of practice, which are legally sanctioned definitions of what types of services a particular health professional may deliver.

Healthcare provider certification through specialty boards often requires a re-certification after a defined period of time. Such assessment typically evaluates an individual provider on a number of levels, including experience, skills, professional standing, clinical performance, and even outcomes. Although certification is voluntary, an individual who does not meet re-certification requirements may encounter negative consequences such as withdrawal of certification, which could have implications for the individual's ability to legally deliver certain services if licensure for a specialty area is tied to certification (Roa and Rooney 1999).

When applied to an organization, such as a laboratory, certification usually implies that the organization has additional services, technology, or capacity beyond those found in similar organizations (Rooney and vanOstenberg 1999). A specialized certification may grant an organization the legal authorization and funding to perform specialized activities. For example, a laboratory may pursue specialized certification that allows specialized staff to conduct procedures and permits the use of specific equipment and materials (Rooney and vanOstenberg 1999). In many countries, the ISO provides certification for hospital radiology and laboratory departments and more recently to quality assurance systems in hospitals and clinical departments (Shaw 2004).

When used to refer to healthcare facilities, the terms certification and accreditation are often used interchangeably, but in reality, they are different approaches (Rooney and vanOstenberg 1999). Certification generally implies a specialization in a single technical area, while accreditation reflects overall facility performance and competence. Certification means that an organization has demonstrated that it has additional services and is therefore able to meet special requirements or industry standards (Roa and Rooney 1999). The emergence of "focused accreditation" programs has also contributed to confusion, since, as will be discussed below, focused accreditation programs resemble certification in their concern with a single technical area.

ACCREDITATION

Accreditation is a formal process by which a recognized body—either governmental or nongovernmental—assesses and recognizes that a healthcare organization meets pre-established performance standards. Accreditation standards are usually regarded as optimal yet achievable and are designed to encourage continuous improvement efforts within accredited organizations. The standards used to assess performance for accreditation are commonly developed by expert committees working with the accrediting body and revised periodically to reflect advances in technology, treatment regimes or policy changes (Rooney and vanOstenberg 1999).

Accreditation has attracted great interest in recent years as a comprehensive approach for improving and maintaining healthcare quality. The key difference between accreditation and other forms of quality regulation is that by focusing on optimal or desirable, rather than minimum standards of care, accreditation has a strong performance improvement orientation, stimulating healthcare organizations to pursue increasingly higher levels of quality beyond the minimum needed for licensing. Another difference is that accreditation has traditionally been a voluntary process in which organizations choose to participate, rather than one required by government regulations; more recently, however, some countries have made participation of healthcare organizations in accreditation programs compulsory (Shaw 2004).

Accreditation tends to be a participatory approach rather than a “top-down” process from the government, as it requires agreement upon standards, criteria, and policies among participating parties (Arce 1999). Standards and criteria for accreditation are generally developed through consensus among healthcare providers and other stakeholders such as medical associations, Ministries of Health, and nongovernmental organizations (NGOs). Accreditation programs are generally funded through survey fees, member fees, publications, educational programs, grants, consulting fees, and government support (Roa and Rooney 1999).

Evaluation for accreditation is performed by a group of surveyors that carry out a variety of assessment techniques, such as a review of documents and records, interviews, observation, inspections of the facility, and evaluation of achievements. Based on the results of this thorough evaluation, the survey team recommends whether or not the facility should be accredited or should implement further improvements and be re-evaluated in the future. Renewal of accreditation status is usually required every two to three years.

Participation in accreditation programs is voluntary, though some countries have tied accreditation systems to financing mechanisms, thereby creating a strong incentive to achieve and maintain accredited status. Another incentive to participate in accreditation programs is public demand for accredited services as a result of the dissemination of accreditation results (Silimperi 1999). Sharing accreditation results helps a facility or department to gain recognition for its accomplishments and be recognized by the community as a quality institution.

While healthcare accreditation programs originated in the United States and Canada in the 1950s, their spread to other developed and developing countries has occurred mainly in the past 15 years. South Africa was the first developing country to create an accreditation program (1995), followed by Indonesia (1995), Argentina (1996), Brazil (1998), Thailand (1999), Zambia (1999), and the Philippines (2000) (Shaw 2004). The introduction of accreditation programs into developing country public sector health systems has resulted in recognition of the need to adapt traditional accreditation methodologies to the realities of the severe resource constraints and weak underlying performance of many countries’ health sectors.

A particular adaptation of healthcare accreditation in developing countries has been the use of *facilitated accreditation*, whereby the accrediting organization or another healthcare body assumes responsibility for helping the facility undertake the quality improvement activities needed to achieve satisfactory levels of compliance with accreditation standards. Under such a scheme, a facility that fails to achieve the threshold for accreditation or meets only some criteria may be granted provisional accreditation status during which time it receives assistance to help it improve its performance. Another strategy for facilitated accreditation is work with the facility for an extended period prior to the initial accreditation survey to provide in-service training and assistance in quality improvement.

The Council for Health Service Accreditation of Southern Africa (COHSASA) is a pioneer in the use of the facilitated accreditation approach in developing countries. COHSASA uses an approach based on facility empowerment and continuous quality improvement (CQI). COHSASA facilitators initially assist each participating facility to understand the accreditation standards and to perform a self-assessment (baseline survey) against the standards. Detailed written reports on the level of compliance to the standards and reasons for non-conformance are generated and sent to the hospital for use in its quality improvement program. Next, the facilitators assist the hospital in implementing a CQI program to enable the facilities to improve on standards identified as sub-optimal in the baseline survey. This preparatory phase usually takes hospitals from 18 months to two years to complete (Whittaker and Rooney 1999).

Another recent adaptation of the traditional accreditation model has been to focus on specific services or areas of care, in a process often referred to as *focused accreditation*. Focused accreditation is defined as the “process by which a recognized body performs a selective (or focused) review of one or more functions of a healthcare organization and assesses its ability to meet a set of standards and criteria specifically related to the selected function or service area” (Silimperi 1999, p.25).

In focused accreditation programs, healthcare organizations which meet certain pre-established standards receive recognition from the assessing body and may be awarded a symbol (e.g., gold star, special plaque) to exemplify their achievement. The symbolic quality award and ensuing public recognition make focused accreditation a powerful vehicle to improve individual provider and organizational performance. The process also fosters increased public expectations of quality service.

Internationally, the most prominent example of focused accreditation is the United Nations Children’s Fund-World Health Organization (UNICEF-WHO) Baby Friendly Hospital Initiative, a focused accreditation program to recognize hospitals and birthing centers for establishing optimal environments for the promotion of successful breastfeeding. Hospitals or birthing centers seek accreditation by submitting an application, which includes a letter of intent, a fee, and self-appraisal in regard to adherence to the “10 steps to successful breastfeeding” established by UNICEF and WHO. When a participating hospital has implemented all 10 steps, an on-site assessment is conducted by a UNICEF-WHO-appointed “baby friendly” survey team, along with a review by the Baby Friendly External Review Board. Those hospitals found by the survey team and the Review Board to have successfully implemented all steps are deemed “baby friendly” and may display the logo of the Initiative.

An example of focused accreditation in the LAC region is the PROQUALI program in Brazil, which targets primary healthcare facilities and is directed at improving the quality and accessibility of reproductive health services. The PROQUALI model is also a facilitated accreditation approach in that it includes support to improve facility infrastructure and clinical and management improvement interventions to help clinics reach accreditation standards. (For more discussion of PROQUALI, see Annex 3 and Blake et al. 1999.)

Focused accreditation is a relatively new concept and one that is likely to evolve over time. As differing from traditional accreditation, focused accreditation has more commonly been applied in primary healthcare facilities and is usually carried out by a body established specifically to perform the focused assessment. The performance standards used in focused accreditation may be pre-existing, but often they are developed expressly for the purpose of focused accreditation. Hence, although pre-agreed upon by the participating organizations and the accrediting body, they may only be published with the start of the focused accreditation program. The accrediting local body for focused accreditation is more likely to be part of or directly associated with the Ministry of Health.

CHALLENGES RELATED TO QUALITY REGULATION

Worldwide experience with quality regulation points to a number of challenges that countries face in implementing these three approaches.

First, a critical requirement for achieving the intended impact of quality regulation is that the approach must build in mechanisms to ensure that the desired performance or competence is sustained over time. Licensing and certification only at the point of entry into the healthcare market

are insufficient to provide assurance to the public and to health sector institutions that providers maintain competency throughout the span of their careers. Time-limited licenses and certificates and clear requirements for renewal are thus essential to create an impetus for providers to remain current through continuing education and for organizations to maintain physical infrastructure and capacity (Miller 2000).

A related issue is the need for enforcement of sanctions or consequences for loss or reversal of quality evaluation status. This includes procedures for disciplinary action against licensees who fail to maintain the conditions of licensing as well as procedures for reporting and handling impaired or incompetent providers and facilities. Regulation is only as effective as the power and mechanisms that governments and other regulatory bodies have to enforce it. Regulations that are not enforced, or that are enforced with mild sanctions, do little but contribute to a general disregard of the regulatory authority of the government (World Health Organization 2000).

Providing incentives to motivate providers and organizations to participate in and maintain quality performance is as important as sanctions, particularly in voluntary programs like accreditation. Financial incentives, such as linkages to payment systems, market advantage, reduction of liability insurance premiums, preferential reimbursement from private insurers, and quality bonuses can be powerful motivators to maintain quality programs, reward organizations' superior performance, and stimulate professional commitment (Shaw 2004). Symbolic rewards, including professional and public recognition through publicity or special awards, can also be highly motivating, particularly if these are perceived to endow the provider or organization with a competitive advantage.

Another challenge for all quality regulation programs is keeping standards current with changes in technology, scientific evidence, and medical practice. Any changes in standards need to be communicated to organizations and individual providers as well as to the public, to ensure transparency of quality evaluation criteria.

Providing sufficient resources to effectively implement any quality regulation approach is also critical. Decision makers need to address the funding sources and financial sustainability for each phase of a program as part of its design. For quality regulation to be effective, regulatory bodies must have the resources and mechanisms needed to exert regulatory authority and must regularly collect and act on monitoring data to verify compliance.

Finally, ongoing evaluation of quality regulation programs is important to ensure that regulatory agencies are accountable to the public and to demonstrate that the investment in quality regulation is cost-effective. While the number of countries implementing hospital accreditation is growing, to date there is little conclusive evidence that accreditation actually improves the quality of hospital care in less developed countries (Salmon et al. 2003; Shaw 2004; Quality Assurance Project 2005b). Since accreditation usually entails a significant cost, determining whether it is worthwhile is crucial, especially in countries where resources are constrained.

III. REGIONAL EXPERIENCE WITH REGULATION ACTIVITIES

REGULATION WITHIN THE CONTEXT OF HEALTH SECTOR REFORMS IN THE LAC REGION

Health sector reform and therefore, healthcare regulation, has evolved in a variety of ways in the different countries of the LAC region (Infante et al. 2000). For example, while constitutional reforms catalyzed healthcare reform in Argentina, Colombia, and Ecuador, efforts to “modernize” the state led to health sector reforms in countries such as Chile, El Salvador, Jamaica, Dominican Republic, and Trinidad and Tobago. Other countries (Bolivia, Colombia, Paraguay, Puerto Rico, and the Dominican Republic) have focused efforts on to modify the relationship between public and private sectors in the healthcare system.

Variation exists not only in the reasons for and approaches to health sector reform, but also in the institution that is given the power of enforcing the reforms (Infante et al. 2000). While most countries grant enforcement responsibilities to their Ministries of Health, other countries leave enforcement to the Ministry of Finances (Guatemala) or Ministry of Work and Education (Colombia). Some countries have established special commissions to oversee reforms. Examples of these commissions include the Commission for Reform and Modernization in the Dominican Republic, the Executive Committee for the Reform of Public Administration in Nicaragua, and the Inter-ministerial Committee for Administrative Reform in Jamaica. Countries such as Costa Rica, Guatemala, Guyana, and Peru have also included a strong component of social participation throughout the development and enforcement of reforms (Infante et al. 2000). Regardless of which organization is given enforcement responsibilities, most governments have tried to orchestrate the objectives, strategies, and pace of implementation of reforms among the various stakeholders (Infante et al. 2000).

While healthcare quality regulation activities have been in the process of development in conjunction with health sector reforms for a number of years throughout the LAC region, few of these regulatory initiatives have been documented or monitored in great detail. Therefore it is difficult to assess the impact and lessons learned from these initiatives. For example, while regulatory requirements for the practice and continuing education of healthcare professionals exist in almost every country in the LAC region, little documentation exists that describes the functioning of these programs or modifications to make them more successful. In contrast, a greater level of documentation exists for accreditation programs. Therefore, while many regulatory activities are occurring throughout the LAC region, this research has been skewed towards accreditation simply due to the greater number of resources and information that document this topic.

The remaining discussion in this section will summarize the status of the main approaches to quality regulation the LAC region as well as provide some insights into the overall crosscutting themes, challenges, and successes of their implementation. More detailed descriptions of selected examples of quality regulation in the LAC region are found in Annex 3.

LICENSING, REGISTRATION, AND CERTIFICATION OF HEALTHCARE PROVIDERS

Regional Background

All countries in the LAC region have licensing programs for healthcare personnel in place as well as explicit requirements for the legal practice of healthcare professions (see Table 2, based on Bolis 2001). In addition to a diploma in the professional area, applicants must also register with the regulatory authority and take any licensure exams. Many countries also require a professional practicum for a defined period of time as well as a period of community or social service. In addition to these procedures, many countries also require on-going registration before a regulatory authority or a professional board.

An interesting example of a registration program is the collaboration between the English-speaking countries of the Caribbean to establish a uniform set of requirements for physicians practicing within the region (PAHO 2002e). This program aims to address the issue of the fluid borders between the Caribbean countries. Before the program, physicians who could not obtain professional licenses to practice in one country would relocate to another neighboring country (Mullings 2000; Mullings 2003). This resulted in varied abilities and skills of physicians and presented a public health risk to the general population. Therefore, a common licensure exam and registration process was established to standardize the knowledge and skills necessary to practice medicine in the participating countries. (See further discussion in Annex 3.)

Although licensing programs are widespread in the LAC region, a weakness exists in continuing education and re-certification of healthcare providers (Infante et al. 2000; Bolis 2001). Few countries have continuing education requirements for healthcare providers (only Uruguay, Argentina, and the Bahamas as of 2001—Bolis 2001). Jamaica is currently in the process of targeting requirements for continuing education in order to maintain professional licenses and is expected to implement reforms in this area (Mullings 2003). This weakness in continuing education and re-certification presents a challenge to maintaining the quality of the healthcare system as evidence-based standards, technology, and knowledge change rapidly.

TABLE 2: EXISTENCE OF LICENSING REQUIREMENTS FOR HEALTHCARE PROVIDERS

COUNTRY	REGULATORY ORGANIZATION	SPECIFIC REQUIREMENTS FOR PROFESSIONAL PRACTICE?⁵	REQUIRES CONTINUING EDUCATION PROGRAMS?⁶
Argentina	Superintendencia de Servicios de Salud	Yes	Yes
Belize	Ministerio de Salud	Yes	
Bolivia	Ministerio de Salud	Yes	
Brazil	National Supplemental Health Agency (part of the MOH)	Yes	

⁵ Bolis 2001

⁶ It is important to note that while many countries have programs for the continuing education of healthcare providers, this table refers only to those countries where continuing education is required to maintain the legal right to practice (Bolis 2001).

Chile	Secretarías Regionales Ministeriales	Yes; also studying certification program according to professional profile ⁷	Project established in 1998 for Permanent Education in Health ⁷
Colombia	Superintendencia Nacional de Salud	Yes	
Costa Rica	Ministry of Health/ Consejo Secretarial de Salud	Yes	
Dominican Republic	Secretaría de Salud (SESPAS)	Yes	
Ecuador	Ministerio de Salud	Yes	
El Salvador	Consejo Superior de Salud Pública/ Ministerio de Salud Pública y Asistencia Social	Yes	
Guatemala	Ministerio de Salud/ Dirección General de Regulación, Vigilancia y Control de la Salud	Yes	
Guyana	Ministry of Health ⁸	Yes	
Honduras	Ministerio de Salud/ Subsecretaría de Política Sectorial/ Dirección General de Regulación	Yes	
Jamaica	Regional Health Authority	Yes	In process of implementation ⁹
Mexico	Secretaría de Salud National Academy of Medicine and Surgery ¹⁰ National Board of General Medicine	Yes General Physicians Specialists	
Nicaragua	Ministerio de Salud	Yes	
Panama	Ministerio de Salud	Yes	
Paraguay	Superintendencia de Salud	Yes	
Peru	Ministerio de Salud	Yes	
Suriname		Certification of general practitioners proposed under health sector reforms ¹¹	
Trinidad and Tobago	Ministry of Health	Yes	
Uruguay	Ministerio de Salud	Yes	Yes ¹²

⁷ PAHO 2002b

⁸ PAHO 2001h

⁹ Mullings 2003

¹⁰ PAHO 2001h

¹¹ PAHO 2002g

¹² Bolis 2001

Cross-cutting Themes, Successes, and Challenges

Several cross-cutting themes and challenges are shared throughout the LAC region with regards to the licensing, registration, and certification of healthcare providers. These include continuing education, the nature of the workforce market, and an overall shortage of qualified personnel.

Needs for Continuing Education

Health sector reforms have also increased the need for continuing education among active healthcare workers. Reforms, especially those targeted towards new organizational and management structures, require new skills that existing healthcare workers must fulfill. Therefore, these reforms have resulted in the need to re-certify or re-license healthcare personnel, or at the very least, provide workforce training. This demand for professional development creates challenges for regulation of education programs, as countries experiment with new ways to increase access to continuing education through requesting international assistance, networking academic institutions, instituting new subject matter, and utilizing methods of distance education (Quintana 2000).

Flexibility of the Workforce Market

One of the largest challenges facing the regulation of the healthcare work force in the LAC region today is the apparent trend moving towards “flexibility” of the labor market (Quintana 2000). Labor laws in the healthcare sector of LAC countries tend to favor flexibility as a way to reduce costs by allowing the labor force to fluctuate with market conditions. Another outcome of flexibility of the labor market is increased competition within the labor force. Examples of countries with flexible labor laws in the public sector include Brazil with temporary contracts through the decentralized municipal governments, Costa Rica with flexible subcontracting of some services such as security, laundry, and cleaning, and Peru with flexible contracts in order to increase coverage of target services and promote community governance of healthcare (Quintana 2000).

While these characteristics signify a positive change to improve the efficiency and quality of the labor market, this flexibility must be balanced with protection for healthcare workers. When flexibility is combined with an unstable job market, “flexibility without protection” may result (Quintana 2000). For instance, Panama and El Salvador have reported high numbers of temporary contracts, under which many contracted employees were faced with conditions of unemployment, under employment, or holding multiple jobs. The unstable conditions created under these flexible contracts—such as high turnover, absenteeism from work, and low worker motivation—present new challenges for the regulation of human resources in the health sector (Quintana 2000).

Shortage of Personnel

In many cases, tension exists between the need for regulation of human resources through licensing and certification and the shortage of qualified individuals to work in the healthcare system (Mullings 2000; Quintana 2000). For instance, when Brazil experienced a shortage of general practitioners that were needed to extend basic coverage throughout the population as a part of health sector reforms, the government paid over \$106 million for scholarships to medical schools (Quintana 2000). This apparent need for personnel places a strain on the education system to graduate large numbers of healthcare professionals and not necessarily focus on the quality of the education. Critics of this program stated that resources could have been more efficiently used to

evaluate and improve the quality of medical education, reinforce continuing education programs in organizations, re-certify and license existing personnel, and improve the performance of auxiliary personnel (Quintana 2000).

Some countries have experienced shortages in specialized areas of medicine. This gap or conflict has been addressed in some countries in the LAC region through interventions by NGOs. For example, NGOs have intervened in Chile and Mexico to assist in the professional development of medical specialists (Quintana 2000). While this helps to address an issue of shortage of qualified personnel, it also introduces regulatory tension as Ministries of Health observe a weakening in their power to regulate and coordinate the various licensing and certification programs in the country (Quintana 2000).

LICENSING, REGISTRATION, AND CERTIFICATION OF HEALTHCARE FACILITIES

Regional Background

Most countries have policies in place to regulate the operation of healthcare facilities. In the LAC region, the operation of healthcare facilities generally requires a government (national, state, and/or municipal) license (Novaes 2003). Licensing inspection, however, tends to focus on structural requirements and safety standards (e.g., inspection of fire hazards by the fire department) and not on technical standards of care or daily operations (vanOstenberg 2003). Certification regulations, if used, verify only if a healthcare facility has the necessary infrastructure, capacity, and personnel needed to handle specialized areas of care.

Unfortunately, there is little documentation of the effectiveness of quality regulation of healthcare facilities in the region. Although the policies are in place, their enforcement is not well documented, nor are the consequences for facilities that fail or cease to meet requirements.

Table 3 notes progress by country in developing quality regulation programs covering healthcare facilities. Some countries are implementing efforts to establish new requirements for healthcare facilities of different levels of care and to implement systems to periodically reassess those facilities. Examples of such efforts in Colombia, the Dominican Republic, and Honduras are discussed in Annex 3.

Cross-cutting Themes and Challenges

The major challenge for the regulation of healthcare facilities in the LAC region is the enforcement of minimum requirements. Under many facility licensing laws, facilities are only inspected once (generally, when they are new) without a mechanism for ongoing inspection of facilities or for updating requirements (Novaes 2003; vanOstenberg 2003). Furthermore, many countries pass policies with a vision of what health facilities should look like in the future. While vision and direction are important in shaping policy, regulations also need to be grounded in the reality of what is feasible at the moment. “Futuristic” policies that are unrealistic lead to a lack of enforcement, which promotes a general disregard for health regulation (vanOstenberg 2003).

Even though facilities are required by law to comply with regulations, many facility operators do not know which regulations apply to them. Without enforcement or support mechanisms established to help facilities meet minimum requirements, many facilities do not comply, either out of lack of knowledge of the system or disregard for the regulation (Novaes 2003).

TABLE 3: COUNTRIES CONSIDERING THE IMPLEMENTATION OF AN ACCREDITATION PROGRAM OR UTILIZING OTHER APPROACHES TO REGULATING HEALTHCARE FACILITIES

COUNTRY	STATUS OF PROGRAM
Belize	Accreditation program recommended in Health Policy Reform Project ¹³
Bolivia	Preparing accreditation for first level of care through the National Hospital Accreditation Commission; ¹⁴
Colombia	In process of implementing accreditation by Centro de Gestión Hospitalaria with assistance from the Canadian Council of Health Services Accreditation ¹⁵
Ecuador	Instruments have been designed for accreditation of public and private facilities ¹⁶
El Salvador	Reviewing standards and requirements for accreditation of educational facilities ¹⁷
Guatemala	Health facility registration department within MOH ¹⁸
Guyana	No accreditation process; Draft of Health Facilities Accreditation Act (2001); MOH licensing of private hospitals through Private Hospitals Act ¹⁹
Honduras	Hospital Accreditation started in 1990 but ceased in 1996 Program for licensing of health facilities in process of implementation ²⁰
Jamaica	Accreditation process being created/ reformulated ²¹
Mexico	Certification of healthcare facilities through the National Arbitration Commission ²²
Nicaragua	Accreditation standards and tools, not yet developed, are envisioned for a second phase of quality assurance programming ²³
Panama	Guidelines for clinical practice have been developed but not implemented for registration of health facilities ²⁴
Paraguay	Health Authority (under law 1,032) has power to accredit health facilities. Clinical guidelines and treatment protocols are being made universal. ²⁵
Suriname	Accreditation of health centers and hospitals proposed in health sector reforms ²⁶
Trinidad and Tobago	Hospital and primary care accreditation system being developed; National accreditation standards drafted ²⁷
Uruguay	MPH authorizes facilities to operate, but not under accreditation program; Baby-Friendly focused accreditation for public and private maternity hospitals began in 1996. ²⁸

¹³ PAHO 2002e

¹⁴ PAHO 2001a

¹⁵ Centro de Gestión Hospitalaria 2003

¹⁶ PAHO 2001b

¹⁷ PAHO 2002i

¹⁸ PAHO 2001c

¹⁹ PAHO 2001h

²⁰ PAHO 2001d

²¹ Mullings 2003

²² PAHO 2001i

²³ PAHO 2002f

²⁴ PAHO 2002a

²⁵ PAHO 2002i

²⁶ PAHO 2002g

²⁷ PAHO, 2002c

²⁸ PAHO 1999b

The growth of and demand for private sector services continues to prevail throughout the LAC region as a major regulatory theme and challenge. Governments need to strike a balance between including private sector stakeholders in the development of healthcare regulation while also exhibiting the ability to regulate and control the facilities, services, and personnel of both private and public health services. Though many Ministries of Health and regulatory bodies have the legal power to regulate the private sector, many do not exercise this power, resulting in largely unknown quality of health services in the private sector.

An emerging issue in the regulation of the private health sector in the LAC region is the influx of private international health service companies. As regulations in North America become increasingly restrictive, private health services look to expand to new geographic regions where fewer regulations control health service delivery (vanOstenberg 2003). This privatized care is particularly growing in new areas that have been traditionally underdeveloped in the LAC region, such as services for home care, non-acute and long-term care, and psychiatry. Since many of these services are offered in the homes and communities of clients, these newly developing services present a challenge to the regulatory control of governments in the LAC region (vanOstenberg 2003). While globalization and the private health sector provide access to new areas of care, this will be an important area of growth and development for future regulatory initiatives.

ACCREDITATION OF HEALTHCARE FACILITIES

Regional Background

An agreement for technical cooperation between PAHO and the Latin American Federation of Hospitals (LAFH) in 1990 sparked initial conversations for a regional accreditation process (Arce 1999). In addition to this agreement, three other main influences are credited with catalyzing accreditation programs in Latin America (Arce 1999):

- PAHO promoted the idea of preparing an assessment tool specifically designed for the LAC region. The development of this tool ultimately led to the recommendation to start accreditation programs in LAC countries.
- The international expansion of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in USA resulted in the creation of the Joint Commission International (JCI). JCI has been very influential in the development of many accreditation programs in the LAC region.
- Regional commercial agreements such as North Atlantic Free Trade Area (NAFTA) and the Common Market of the Southern Cone (MERCOSUR) emphasized the need for common standards of care and regulatory processes throughout the LAC region.

The first regional accreditation manual was drafted by a group of medical audit experts in Argentina with the technical input of various professional societies. The standards published in this manual were intended to be flexible and adapted as appropriate for each country. The manual provides standards for 37 services encompassing hospital services, ambulatory care, and laboratory services (Novaes and Neuhauser 2000). Throughout the manual, standards are organized according to three levels of complexity:

- Level one: credentials of human resources, basic structure for quality of care
- Level two: documented and applied standards, processes and procedures; proof of efforts to improve the quality of care; patient-centered care

- Level three: evidence of improvement and compliance in level 1 and 2 standards, system to monitor satisfaction, and a hospital quality and productivity program.

This categorization of standards requires that in order for an organization to continue to the next level of complexity, it must first pass the first level of standards.

Upon publication of the accreditation manual, PAHO recommended that the accreditation process be implemented throughout the region (Arce 1999). The process recommended to countries was to establish a national accreditation commission. This commission would ideally include representatives from hospitals, healthcare providers, and hospital associations, private health insurance companies and health maintenance organizations, and public sector organizations such as the Ministry of Health and Social Security Institute. The commission would then appoint a survey team—composed of individuals with professional prestige as well as clinical and administrative experience—consisting of at least one nurse, physician, and hospital administrator (Novaes and Neuhauser 2000).

The final version of the accreditation manual was reviewed and adopted by 22 nations in May of 1991. Four sub-regional meetings were held to discuss the adoption of the accreditation process. By 1995, however, it was evident that not all countries were adopting the program. This was due, in part, to the resistance of other key local stakeholders who wanted to have input into the accreditation process (Arce 1999). As a result, countries implemented many variations of the accreditation program, including:

- Peru, Cuba, Guatemala, and Dominican Republic adopted a modified version of PAHO manual. Bolivia also modified the manual and adopted the program only in public hospitals.
- The MOH of Chile developed a continuous improvement program for public hospitals based on a model developed by JCAHO.
- Brazil adopted a variety of programs. While some states adopted the PAHO version, the State of Rio de Janeiro later signed an agreement directly with JCI to adopt their model of accreditation.
- Mexico developed accreditation standards through the National Institute of Public Health. These standards focused on compatibility with North American neighbors for NAFTA.
- Argentina implemented the accreditation manual strictly.

An assessment of country profiles of healthcare systems conducted by PAHO in 1999 revealed that of eleven countries in the region that provided information on accreditation activities, only four had established accreditation systems. At that time, the majority of the countries were still in the initial planning stages for developing and implementing accreditation programs (Ross et al. 2000). Very few of the countries have followed through on the implementation of these accreditation programs due to a general lack of support among Ministries of Health and financial restraints. Due to these considerable limitations, many countries have opted not to “open Pandora’s box” by addressing quality issues that exist in many of the hospitals (Novaes 2003).

Table 4 provides an overview of accreditation programs currently functioning in the LAC Region.

TABLE 4: OVERVIEW OF ACCREDITATION PROGRAMS IN THE LAC REGION

COUNTRY	ACCREDITING ORGANIZATION	GEOGRAPHIC COVERAGE OF ACCREDITATION PROGRAM	NUMBER OF FACILITIES ACCREDITED
Argentina	Technical Institute for Accreditation in Health Care Services (ITAES)	Cities of Mar de Plata, Santa Fe, Buenos Aires, Corduba, and Rosario ²⁹	Accreditation of 22 private hospitals
Brazil	Brazilian Consortium for Accreditation of Health Care Systems and Services (CBA)	Hospital Israelita Albert Einstein (São Paulo); Instituto Estadual de Hematologia – Hemorio (Rio de Janeiro); Instituto de Olhos Freitas (Salvador-Bahia); Hospital Moinhos de Vento (Porto Alegre)	Four private hospitals accredited by CBA with assistance from JCI ³⁰
	National Accreditation Organization (ONA)	Rio Grande do Sul, Paraná, São Paulo, Rio de Janeiro (4 of 26 states) ³¹	Accreditation of 20 public hospitals through ONA ¹⁴
	PROQUALI	Bahia and Ceará, Northern Brazil	Focused accreditation of reproductive health services
Chile	Ministry of Health	Nationwide voluntary program	Voluntary accreditation to protect against intra-hospital infection ³²
	Fondo Nacional de Salud (FONASA)	Nationwide “voluntary” program; accreditation is voluntary, but FONASA only gives certain resources to accredited facilities ¹⁵	Accreditation of 60% of hospitals (100% of complex hospitals), emergency services, intensive care units, and facilities with complex diagnostic procedures ³³
Costa Rica	Ministry of Health; Dirección de Servicios de Salud ³⁴	Voluntary national accreditation program for public and private facilities. The establishment receives accreditation if it complies with 100% of maximum risk standards (Level 0), 90% of Level 1 standards, 80% of Level 2 standards, and 70% of Level 3 standards ¹⁷	Accreditation and certification of health establishments and hospitals since 1998 ^{35 36} Accreditation of specialty services such as orthodontics, elderly care, and palliative care ¹⁷

²⁹ Arce 2003

³⁰ Joint Commission Resources 2003

³¹ Novaes 2003

³² PAHO 2002b

³³ PAHO 1999a

³⁴ Ministerio de Salud de Costa Rica 2002

³⁵ PAHO 2002k

³⁶ PAHO 2002l

Dominican Republic	SESPAS and the National Hospital and Clinic Accreditation Commission	Nationwide implementation of facility registration (" <i>habilitación</i> ") program planned.	Manual for " <i>habilitación</i> " and evaluation instrument developed ³⁷ –Registration of services mandated through the General Health Law (Law 42-01). ³⁸
Peru	MOH; Accreditation Unit for Health Facilities ³⁹	Nationwide. Peru has invited JCI to come to Peru to evaluate the possible development of an accreditation model through the medical education community ⁴⁰	Approximately 30 public hospitals of different levels (with a focus on infrastructure standards) ⁴¹

Cross-cutting Themes, Successes, and Challenges

Since accreditation is voluntary, incentives are needed to encourage hospitals to participate in accreditation and sustain the results (Arce 2003; Novaes and Neuhauser 2000; Novaes 2003). Legal and financial formalization of accreditation by governments greatly strengthens the incentive for hospitals to participate in accreditation programs (Novaes 2003). For example, in the United States, in order for hospitals to receive funding from Medicare and Medicaid, they must be accredited by a recognized organization (Novaes and Neuhauser 2000). Such a link provides a strong incentive for hospitals to achieve and maintain accreditation status.

Another way to strengthen accreditation programs is to create community demand for quality services (Novaes 2003). The dissemination of accreditation results within the community can increase community demand for services from that facility as well as empower healthcare workers with the pride of contributing to an establishment known for its quality of care. Community advocacy for improved quality of care linked with the dissemination of accreditation results may be effective tools for strengthening accreditation programs.

Another cross-cutting theme among countries of the LAC region is the need for "buy in" of key stakeholders in order to develop, implement, and sustain regulations (Arce 1999). Regulation is a highly political process that includes a wide variety of stakeholders—such as departments of the Ministry of Health, hospital administrators, healthcare providers, teaching institutions, and community members. Local implementation of regional initiatives may face resistance from those who did not have input into their development. This is evident in the regional accreditation process that was initiated in 1991. Though ultimately many countries adopted modified versions of the accreditation process, Argentina was the only country that implemented the original process. One explanation for this variation is that Argentina had more ownership over the process because a local team developed the regional manual.

One of the key results of the accreditation programs that are functioning in the LAC region has been the creation of a strong sense of social responsibility for offering quality services among

³⁷ PAHO 2001g

³⁸ Flores de Parra 2003

³⁹ PAHO 2001f

⁴⁰ vanOstenberg 2003

⁴¹ PAHO 2002d

hospital directors (Novaes 2003). Accreditation empowers healthcare providers and administrators to see how their efforts can contribute towards the enormous responsibility of providing their communities with quality care.

Accreditation programs throughout the LAC region have encountered similar challenges (Novaes 2003). These include:

- Some accreditation programs have targeted only specific services or facilities. Accreditation programs should be extended to all services to guarantee that quality standards are met for all aspects of care.
- Accreditation should only be implemented where a strong licensure program exists. These initiatives are complementary and ensure the quality of the healthcare facility as well as personnel.
- The technical skills of surveyors present a challenge to accreditation programs. Surveyors need to be respected in their professions and have the technical background upon which to base assessments.
- The impact and role of strong leadership for accreditation cannot be overemphasized. This is particularly critical during the implementation of a national accreditation program.

IV. FUTURE OPPORTUNITIES FOR STRENGTHENING QUALITY REGULATION IN THE LAC REGION

As described in this document, significant advances have occurred in the LAC region in regulating healthcare quality. A strong legal foundation and support for the regulation of healthcare facilities and personnel exists, and many initiatives are in the process of development throughout the region. Although most of these reforms are still in the early stages of development, they provide a basis for understanding where future development and opportunities lie in healthcare regulation in the LAC region.

One major opportunity to better understand regulatory initiatives is to improve the documentation of initiatives (Ross et al. 2000; Infante et al. 2000). Improved documentation would not only serve as an institutional memory of the development of healthcare regulation, but also allow for improved benchmarking within the LAC region. Although some documentation about the accreditation of healthcare facilities exists, this tends to provide very general information as opposed to an in-depth view of qualitative and quantitative results. A significant deficit in information available about registration, certification, and licensure prevails throughout the region. The extensive researching and documentation of these initiatives would greatly enrich knowledge of regulation experience in the LAC region.

In addition to documentation, monitoring and evaluation continues to be a weak link in healthcare regulation (Ross et al. 2000; Infante et al. 2000). Although many initiatives are in the stage of implementation, few have established ongoing monitoring systems to assess whether the reforms are meeting the established quality objectives, and if not, how to re-direct efforts to achieve improved results. An excellent opportunity exists to establish these systems now, while many regulation initiatives are still in the early stages of implementation. It is important to keep in mind, however, that monitoring and evaluation systems will need to take into account that many confounding factors that can co-exist along with the implementation of reforms. Since reforms often require long periods of time for implementation due to their complexity, these monitoring systems will need to take into account the confounding factors introduced over time (PAHO 2002d).

Another opportunity to strengthen healthcare regulation in the LAC region that consistently arises throughout country examples is the need for the development of incentives to improve the quality of care. Examples of such incentives include increased government support for and commitment to regulation, the inclusion of quality criteria into financing systems (Ross et al. 2000), and the stimulation of community demand for quality services. Such incentives are needed system-wide, for healthcare delivery networks, hospitals and clinics, and individual healthcare providers.

In order to improve the work of healthcare professionals and therefore the quality of care provided, improved management of human resources must be viewed as a key component of health sector reform (Quintana 2000). A need exists to develop a framework and mechanisms for human resource regulation and educational development. This framework particularly needs to examine how to balance adequate human resource management within a job market that tends to be flexible and fluid (Quintana 2000). The development of continuous education and re-certification programs for healthcare providers of entire healthcare delivery systems also presents a significant opportunity for future development (Ross et al. 2000; Bolis 2001). Human resource

management and new programs should not only target technical healthcare providers, but also other key personnel in the healthcare delivery system, such as administrators and support staff.

Achieving the goals already established in healthcare quality regulation as well as exploring ideas for future directions will require coordination and cooperation between multiple stakeholders. The formation of independent, inter-institutional commissions would greatly improve the ability to collaborate in achieving common objectives (Novaes 2003). As discussed throughout this document, much of the momentum for healthcare quality regulation has occurred through regional initiatives. Therefore, these regional and national links must be fostered and strengthened in order to continue to drive ongoing progress in healthcare quality regulation in Latin America and the Caribbean.

V. REFERENCES

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VI. ANNEXES

ANNEX 1: CONTACT INFORMATION FOR KEY INFORMANTS OF RESEARCH

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ANNEX 2: WEB RESOURCES

These country web resources were compiled from research completed to prepare this document as well as from references cited in Bolis 2001. Where available, web links to download documents used for this research are provided in the References section.

COUNTRY	WEB LINK
Argentina	www.msal.gov.ar
Bolivia	www.sns.gov
Brazil	www.saude.gov.br
Chile	www.minsal.cl
Colombia	www.cgh.org.co
Costa Rica	www.netsalud.sa.cr/index.htm
Ecuador	www.msp.gov.ec
El Salvador	www.mspas.gob.sv
Guatemala	www.mspas.gob.gt
Guyana	www.guyana.org/Ministry_Health.htm
Jamaica	www.moh.gov.jm
Mexico	www.ssa.gob.mx
Paraguay	www.mspbs.gov.py
Peru	www.minsa.gob.pe
Uruguay	www.msp.gub.uy

ANNEX 3: PROFILES OF REGULATORY INITIATIVES IN SELECTED COUNTRIES

The research for this paper looked in-depth at specific country examples to provide insights into the variety of regulatory initiatives occurring in the LAC region. This annex presents the information gathered for specific countries and/or programs.

ARGENTINA—ITAES ACCREDITATION PROGRAM

Background

Argentina's health system is comprised of three main service providers: the private and public sectors and the social security system. Argentina has demonstrated steady improvements in important health indicators among its population; for example, infant mortality declined from 26.9 per 1,000 in 1986 to 17.6 in 1999 (PAHO 2002h). Unfortunately these improvements in the health status are not necessarily uniform throughout the Argentine population, as economic barriers still block access to quality care among a significant portion of the population (PAHO 2002h).

These economic barriers have been exacerbated by the economic recession affecting the country in recent years. In 2002, the government declared a national state of emergency in a variety of health, social, and economic areas (PAHO 2002h). While Argentina has been a leader in healthcare regulation within the LAC region in the past, its programs have experienced delays and challenges due to the current economic situation.

Accreditation in Argentina

Accreditation has evolved in Argentina over the past 30 years and has experienced a lot of changes and adaptations along the way. Accreditation was in its preliminary stage from 1970-1990 during which time several versions of quality standards were developed and published. Formal tests and pilot programs were implemented, targeting specific hospitals or services (Arce 1999).

As discussed in previous sections, PAHO signed an agreement of technical cooperation with the Latin American Federation of Hospitals (LAFH) in 1990 that promoted the development of a regional accreditation methodology (Arce 1999). The accreditation manual for the LAC region was drafted in Argentina by a group of medical audit experts with technical input from different Argentine technical societies.

Although other countries opted to adopt modified or different accreditation programs, Argentina sought to implement an accreditation program according to the published manual. Almost simultaneously in 1990, however, another agreement was signed between the Joint Commission on Accreditation of Healthcare Organizations, financing associations, and healthcare providers, resulting in an initiative called COMCAM (Arce 1999).

A collapse in government leadership 1991 for the accreditation program was detrimental to its implementation. The desire to implement the initiative still existed, however, among a number of private health care facilities. In 1993, a group of hospitals, health providers, financial entities, and scientific societies formed the Technical Institute for Accreditation of Healthcare Organizations (ITAES) as a not-for-profit NGO (Arce 1999).

The first initiative of ITAES was to compile existing tools from the PAHO/LAFH manual and COMCAM to develop accreditation standards (Arce 1999). The team also consulted with local

experts and scientific societies. The standards were developed to be simple and practical yet representative of the quality of care of some 40 services or activities. The initial standards developed addressed only services at general acute care hospitals.

ITAES differentiates the accreditation process from the evaluation by health financing institutions. ITAES defines the accreditation process as “a voluntary, periodic and confidential method based on known standards and on objective accreditation bodies” (Arce 1999). Service assessments conducted by financial institutions may be biased since they are linked to healthcare providers by work contracts. Accreditation, however, is conducted by a neutral, recognized authority.

The accreditation process was designed in the following manner (Arce 1999). First of all, the weight of each standard is equivalent. The standards are divided, however, into two categories: mandatory standards and suggestions for improvement. The suggestions for improvement are only assessed once the mandatory standards are met. Once a hospital verifies that it meets preliminary requirements, surveyors assess the hospital in one day using an operative form to record results and observations for 40 standards and 675 corresponding closed, binary questions (yes/no).

This information is entered into a computer system, which ultimately provides the final score for accreditation. Possibilities for results include: not accredited, temporary accreditation for one year, full accreditation for two years the first time and three years thereafter, or accreditation with merit (Arce 1999). A new addition to the accreditation program is “coaching” assistance for healthcare facilities. Facilities that do not achieve accreditation have the option of requesting “coaching” from ITAES to improve the quality of care to prepare itself for another assessment (Arce 2003). Alternatively, if a healthcare facility feels uncertain of its ability to pass accreditation before the assessment, it can request coaching before the initial survey. Three healthcare facilities are currently receiving coaching assistance.

Another important aspect of this accreditation program is the team of surveyors. Prerequisites for survey candidates include a university degree in healthcare or related discipline and that surveyors come from a different city or state than the hospital location. Surveyors receive a 16-hour intensive training course in the accreditation methodology and form practical work groups of up to 20 people. As of 1999, 200 surveyors had been trained. After training, surveyors are still required to uphold a code of ethics. This code emphasizes the importance of confidentiality of results and states the hospital’s right to reject a surveyor for a just cause (Arce 1999).

ITAES is funded through survey and consultant fees. Survey fees vary based on the size of a healthcare facility, the number of beds, staff, and annual budget. For example, the smallest hospitals are charged approximately USD\$1,000 while the largest hospitals pay approximately USD\$2,000 (Arce 2003). Because most hospitals in Argentina are small, it is important to keep survey fees to a minimum so that it will not be too costly for smaller hospitals to participate.

ITAES began the accreditation program in acute care hospitals. Since then, ITAES has also developed accreditation programs for ambulatory care services (diagnostics and laboratory), dental care, mental health, and dialysis (Arce 2003). Currently the accreditation program is operating in five cities (Mar de Plata, Santa Fe, Buenos Aires, Cordoba, and Rosario) in a mix of public and private healthcare institutions with the following results (Arce 2003):

- Accreditation of 22 private hospitals
- Three hospitals received accreditation with merit
- Accreditation of 3 laboratories

- Coaching of 3 healthcare facilities
- Ten facilities did not meet accreditation standards (3 public, 7 private). One of these facilities is currently receiving coaching.

Evident from the results to date, the accreditation program has been strongest in private healthcare institutions. This is primarily due to an overall lack of government support for the initiative. Public healthcare institutions have not had an incentive to participate in accreditation programs and only do so on their own initiative (Arce 2003).

Although the number of hospitals currently accredited is encouraging, it is important to remember that this is a small percentage of the country's healthcare delivery system, which has approximately 3,200 public and private hospitals (Arce 2003). Most of these hospitals are small—with an average of about 70 beds for public hospitals and 35 beds for private hospitals. The expansion of the coverage of the accreditation program will largely depend on its ability to provide accreditation within the constraints that exist among smaller healthcare facilities (Arce 2003).

ITAES has also developed an evaluation system for healthcare facilities for health insurance providers. Under this system, ITAES has developed the capacity to evaluate entire networks of facilities with a condensed set of standards and criteria. If the facility does not achieve favorable assessment results, ITAES notifies the insurance company who then decides a course of action for future contracts (Arce 2003).

Successes, Challenges, and Future Directions

A significant success and validation of the ITAES accreditation program recently occurred when two main Health Maintenance Organizations of Argentina provided clients with a special list of accredited facilities (Arce 2003). This list also included physicians with specialized certifications. This is a significant milestone for ITAES as it shows the development of a culture of esteem for accreditation and quality.

Challenges for the ITAES accreditation program include (Arce 2003):

- Lack of incentives for healthcare facilities to participate in the accreditation process, which is not tied to financing.
- Overall, there is limited appreciation of accreditation among healthcare facilities and communities. Since clients do not demand accredited facilities, this does not provide any incentive for healthcare institutions to undergo accreditation.
- A lack of government support and commitment by national and regional authorities has made it difficult to cultivate the accreditation program. This support is growing, however, and there is hope that more regions and facilities will take the initiative to become accredited.
- The economic crisis in Argentina has severely impacted the program. The situation improved in 2003, and the program is now advancing again.

Certainly a big advance for the recognition of quality and regulation occurred with the International Society for Quality in Health Care (ISQua) meeting in Buenos Aires, Argentina in 2001 (Arce 2003; vanOstenberg 2003). A lack of continuous support and commitment on the part of the Argentine Ministry of Health has presented an ongoing stumbling block to the expansion and development of nationwide accreditation in Argentina. The ISQua conference, however, provided

an opportunity to highlight the experiences to date in Argentina and promote its future development among key stakeholders.

Several opportunities for future growth of the accreditation program have been identified (Arce 2003). First, ITAES is collaborating with the Argentine Society for Quality of Care to develop and implement monitoring through a set of 12 basic indicators and 48 optional indicators. These indicators are currently in the stage of pilot testing in twelve hospitals (two public, ten private). This initiative has been well received by government officials and shows promise for data with regards to the impact of accreditation on the quality of care. Secondly, ITAES previously published a magazine that highlighted international articles and research on the quality of care. Unfortunately, this publication was suspended during the economic crisis. Currently there are hopes of re-starting this publication to ignite interest in quality issues throughout the country.

BRAZIL—HOSPITAL ACCREDITATION

Background

Brazil, with a total population of 176,029,560 comprised of over 230 different ethnic groups (CIA 2002), is a country with vast differences in geography, ethnicity, and socio-economic status. Brazil's epidemiological profile is just as diverse as its population. Although chronic and degenerative disease presents the leading cause of mortality, communicable disease also places a major demand on the health system, particularly in the northern regions of the country (Odegbile 2001). Therefore, the health system in Brazil faces the challenge of meeting all of the diverse needs of this varied population.

The Unified Health System (Sistema Unico de Saúde, SUS) is comprised of an enormous healthcare delivery system with 63,650 ambulatory healthcare facilities throughout the nation providing approximately 153 million procedures and 251 million laboratory exams per year (PAHO 2003). Initially, the public SUS was intended to act as the principal health care delivery system for Brazil, using the private sector only as a government contractor for services (Odegbile 2001). This dynamic changed, however, as the public health sector could not meet all of the needs of the population, and clients with resources to pay began to look to the private sector. By 1996, private insurance covered 20% of the Brazilian population with a total expenditure of approximately US\$9 billion (Noronha and Rosa 1999).

The Brazilian MOH recognized the need to regulate the large private sector of the healthcare market and passed Law Number 9656 in 1998. In 2000, the National Supplemental Health Agency (ANS) was formed as an arm of the Ministry of Health (Odegbile 2001; Agencia Nacional de Saúde Suplementar 2000). ANS' role is to:

- Improve the capacity and participation of the private sector
- Unify the information provided to key stakeholders in the private sector
- Standardize and maintain the continuity of the private sector
- Protect the access and rights of users

The diverse population and vast size of Brazil necessitate improving the quality of healthcare through a variety of strategies to best meet local needs, rather than a single-tracked approach to regulation. In this content, improvements in the quality of care cannot be achieved without being integrated with efforts to mobilize communities, healthcare providers, insurers, and other

stakeholders (Noronha and Rosa 1999). Brazil's efforts to improve the quality of care have been broad in addressing the structure of care, inputs, processes, and outcomes. For the maximum improvement in the quality of care, however, these efforts need to be implemented synergistically (De Geyndt 2001).

Hospital Accreditation

Brazil's experience includes an interesting combination of hospital accreditation through collaboration with both PAHO and JCI/JCR as well as the accreditation of primary health clinics through PROQUALI (discussed in the subsequent section). Two main hospital accreditation programs currently operate in Brazil that have stemmed from the following earlier initiatives:

- The "Controle da Qualidade Hospitalar" (CQH or Control of Quality of Hospitals) was formed in 1990 by the São Paulo Medical Association and the Regional Council of Medicine in São Paulo. By 1997, 120 hospitals participated in CQH, 20 of which earned a "Seal of Quality" (Noronha and Rosa 1999).
- PAHO, in collaboration with LAFH, published the regional accreditation manual. A modified version of this manual was applied to 40 hospitals. The State Secretariat of Paraná developed an accreditation program using this manual (Noronha and Rosa 1999).
- In 1997, the Brazilian MOH created a national agency for accreditation and established a technical group to review the manual of standards for hospitals. A final version was published in 1998 (Noronha and Rosa 1999; Novaes et al. 2000).

In 1998, however, the accreditation initiative followed two separate paths with the formation of two major accreditation organizations, the Brazilian Consortium for Accreditation of Health Care Systems and Services (CBA) and the National Accreditation Organization (ONA). The CBA⁴², using the JCI model of accreditation, has offered accreditation to private hospitals in Brazil. The ONA⁴³, however, is a national level organization that focuses on assuring quality in public facilities (Novaes 2003).

CBA

The CBA received assistance from JCI to publish a set of standards in 1999 and initiate hospital accreditation (Noronha and Rosa 1999). Its hospital standards address:

- Patient-focused functions, including: patient rights, organizational ethics and education, access and continuity of care, assessment and care of patients.

⁴² The CBA consists of organizations such as the Program for the Evaluation and Quality Certification of Health Services, Permanent Commission for the Accreditation of Hospitals, and the Cesgranrio Foundation as well as members from the National Academy of Medicine, Brazilian College of Surgeons, and the universities of the state of Rio de Janeiro. (Noronha and Rosa 1999).

⁴³ It was proposed that the ONA consist of three main parties: Health Service Delivery Institutions (Novaes 2003) (The Brazilian Teaching Hospital Association, Brazilian Hospital Federation, Brazilian Confederation of Charitable Hospitals, National Health Confederation of Hospitals, Establishments and Services); Health Service Buyers (The Brazilian Association of Group Medicine, National Federation of Private Insurance and Capitalization, National Union of Self-Management Institutions in Health, National Confederation of Medical Cooperatives); and Public Sector Entities (MOH, National Council of State Secretaries of Health, National Council of Municipal Health Secretaries).

- Organizationally focused functions, including: quality improvement, leadership, environment of care, human resource management, management of information, surveillance, and prevention and control of infection.

The accreditation process was designed so that facilities either passed or did not pass accreditation, without options of partial or temporary accreditation (vanOstenberg 2003). The reason for this “cut and dried” approach was that in a country where accreditation is a relatively unknown approach, clients do not understand differentiations of “partial” or “temporary”. Therefore, it was determined that the categories of “accredited” or “not accredited” were more appropriate. The eventual goal of this accreditation program, however, was to establish three levels of accreditation in Brazil: accredited, fully accredited, and accredited with excellence (Novaes and Neuhauser 2000).

There are currently four hospitals in Brazil that have received a three-year accreditation through JCI (JCR, 2003). These include:

- Hospital Israelita Albert Einstein (São Paulo): First accreditation achieved 1999; Reaccredited in 2002
- Instituto Estadual de Hematologia – Hemorio (Rio de Janeiro): Accreditation achieved in 2002
- Instituto de Olhos Freitas (Salvador-Bahia): Accreditation achieved in 2002
- Hospital Moinhos de Vento (Porto Alegre): Accreditation achieved in 2002

ONA

When the ONA was formed by the MOH in 1998, several accreditation initiatives already existed in the states of Rio Grande do Sul, Paraná, São Paulo, and Rio de Janeiro. ONA granted these existing mechanisms the power to carry out accreditation using a modified version of the PAHO standards. The ONA does not conduct accreditation surveys itself, but supervises and coordinates the various organizations that do (Novaes 2003). These organizations are required to follow ONA standards and regulations.

The ONA approach to accreditation is “step-wise”, in which facilities must pass level one accreditation (mostly dealing with structural aspects) before passing to level two, and must pass level two accreditation (focusing on processes) before passing to the third level of accreditation (targeting outcomes) (Novaes 2003).

Since 1998, ONA has accredited twenty public hospitals throughout Brazil. This accreditation status is valid for two years. As in Argentina, a main frustration and obstacle to the growth of the national accreditation program is a lack of incentive for healthcare facilities to participate. Without financial incentives for organizations to become accredited, this program has lacked the legal support and backing that it requires to grow.

Successes, Challenges, and Future Directions

The two major accreditation initiatives in Brazil are interesting to track as one has largely focused on public facilities while the other focused on private facilities. CBA, with technical support from JCI, has accredited four private healthcare facilities in Porto Alegre, Salvador-Bahia, São Paulo, and Rio de Janeiro. ONA, with 20 accredited hospitals, has targeted facilities primarily in the regions of Rio Grande do Sul, Paraná, São Paulo, and Rio de Janeiro.

Although these two initiatives show significant progress for the development of accreditation in Brazil, the number of facilities that have been accredited is very small. Brazil has a total of 6,124 hospitals throughout the country—47% are private, 32% are public and provide free services, and 20% are not-for-profit facilities (Novaes 2003). Thus, although advances have been made, much work remains to develop the impact and coverage of these programs.

Incentives to participate in and achieve accreditation remain one of the largest obstacles facing this program. Like programs in many other countries, the accreditation program is voluntary and not linked with the financing system (Novaes 2003).

There are a number of directions for the growth of accreditation in Brazil (vanOstenberg 2003). There is growing interest in the implementation of standards and accreditation for homecare, which is a new and rapidly growing industry. Another area of growing expertise and interest in Brazil is measuring the impact of accreditation on the quality of care (vanOstenberg 2003). Hospitals accredited through JCI/CBA have worked to improve information sources and their collection of monitoring data. As capability and interest in this issue grows, there may be more information about the potential quality impacts in the future.

BRAZIL—PROQUALI (FOCUSED ACCREDITATION)

Background

The PROQUALI initiative, funded through USAID, presents a model of accreditation focused on improving the quality of reproductive health services. This focused accreditation model was developed in 1996 by a variety of organizations, including USAID, the Secretariats of Health of Bahia and Ceará States in Brazil, JHPIEGO, JHU/CCP, and Management Sciences for Health.

The PROQUALI model differs from most accreditation models in that it targets primary healthcare organizations rather than hospitals. Despite widespread efforts in Brazil to increase access to services through community centers, demand remained greatest for hospital-based care due to the widespread perception that quality was better in hospitals (Blake et al. 1999). Therefore, it was determined that the most appropriate intervention to increase utilization of reproductive health services was to improve the quality and public image of private and public primary health clinics and community health centers, particularly in rural and smaller municipalities. PROQUALI was implemented in the states of Bahia and Ceará—both of which were targeted due to their poor economic status and limited resources (Blake et al. 1999).

With the same objective of increasing access to reproductive health services, the PROQUALI model targeted non-physician reproductive health providers, such as nurses, community educators, and auxiliary staff for the introduction of the PROQUALI performance improvement interventions, seeking to improve clinical skills as well as other important facets of healthcare delivery, such as interpersonal communication, management systems, facilities, and logistics (Blake et al. 1999). With the areas targeted for improvements, the PROQUALI model applies the continuous quality improvement approach—identifying gaps in performance through self and external assessments and improving performance through quality improvement activities.

It is also important to mention that PROQUALI was implemented in the context of decentralization reforms throughout Brazil. These reforms gave increased responsibility to local municipalities and held local authorities accountable for identifying “quality gaps” and improvement strategies (Silimperi 1999). Another important input was the prior development and approval of reproductive health services guidelines for the states of Bahia and Ceará, which served

as performance improvement standards for PROQUALI. These guidelines, developed with the assistance of JHPIEGO, aimed to provide a mechanism for standardizing education and training as well as service delivery. These guidelines also provided explicit expectations for service delivery in order to evaluate the quality of care and provide a benchmark for improvement (Blake et al. 1999).

Although the remainder of this section will focus on PROQUALI's clinic-based accreditation component, it is important to keep in mind that the PROQUALI model goes beyond traditional accreditation, addressing three main areas (Blake et al. 1999):

- Infrastructure support: Involvement of important stakeholders such as the municipal, state, and regional health agencies, accreditation commissions, service delivery organizations, and collaborating agencies.
- Clinic-based accreditation process: Focused on compliance with reproductive health guidelines, the development of job roles and descriptions, self and external assessment, accreditation, and rewards and recognition.
- Performance and quality improvement: Clinical interventions (competency-based training and on-the-job assistance), management interventions (team-building, management training, logistics strengthening, on-the-job assistance), and information, education, communication interventions (training in counseling and education, client education materials, campaigns, and on-the-job technical assistance).

Clinic-based Accreditation Process

Selection Criteria

Clinics and health centers were selected as candidates for PROQUALI accreditation based on several criteria. These include that the clinic (Blake et al. 1999):

- Provides services to low-income clients
- Serves a specific community
- Employs at least one staff person trained by JHPIEGO in reproductive health

Another important factor in the pre-selection process was the level of commitment to and involvement in the accreditation process on the part of the municipal level Secretariats of Health.

Job Descriptions and Incentives

The PROQUALI accreditation process began by providing healthcare workers a better sense of the roles and responsibilities of their jobs by expanding job descriptions with the direct assistance of state and regional staff (Blake et al. 1999). Separate job descriptions were developed for all of the different positions in clinics, such as doctors, nurses, auxiliary nurses, and community health workers. These job descriptions not only aimed to clarify roles and responsibilities, but also allocate service delivery responsibilities to non-physician staff and empower them to learn and utilize new clinical skills (Blake et al. 1999).

The incentive to improve performance is another important facet of the PROQUALI model. Non-monetary incentives, such as recognition of high performing clinics by government-supported commissions, provide a powerful motive to improve performance. IEC campaigns in communities also reinforce quality care by raising awareness among community members about the quality achievements of a clinic (Blake et al. 1999). Although financial incentives are not part of the accreditation model, high performing clinics could potentially benefit from increased allocation of

supplies and human resources. While each individual healthcare worker does not directly benefit in a monetary sense, he/she benefits by taking pride in how his/her work contributes to the performance of a well-recognized system.

Self and External Assessment

Self-assessment tools were also developed in order to provide healthcare providers and clinics with the ability to judge their own performance and determine where opportunities for improvement existed. These tools helped staff to prepare themselves for external assessment by the accreditation commission.

Accreditation commissions were established in Ceará and Bahia in 1997 to oversee the accreditation process. These commissions included representatives from the Secretariats of Health, NGOs, healthcare providers, universities, and communities. Members of the Quality of Care Recognition Commission conducted the external assessment. First the clinic had to pass a two-day visit to demonstrate that it had complied with reproductive health guidelines for at least two months (Silimperi 1999). Once this had been established, the facility was assessed over five days on five key areas (Silimperi 1999; Blake et al. 1999):

- Reproductive health service delivery
- Infection prevention and control
- IEC programs
- Physical plant and materials
- Management infrastructure support systems

A score of at least 80% on the first visit was necessary to qualify for a second visit. During the second visit, the criteria changed based on the results of the first visit (Blake et al. 1999). Each criterion was supported with a number of verification items; in order for the criterion to be met (equaling one point), each verification item had to be satisfied. Clinics that met 95% or more of the criteria were accredited during the second visit (Silimperi 1999; Blake et al. 1999). Clinics that did not achieve accreditation the second visit were visited three months later for reassessment.

Results and Future Directions

The PROQUALI pilot program was implemented in three healthcare facilities in the State of Ceará and two in the State of Bahia in the middle of 1997. A baseline measurement of 61 quality criteria determined that the five health clinics on average met 12% of the criteria. After 12 months of participation in the PROQUALI accreditation program, four of the five clinics met an average of 94% of the criteria (CCP, 2000). By the end of 18 months of technical assistance, the four clinics achieved between 94 and 98% of the quality criteria (MAQ Exchange).

In addition to these quantitative figures, qualitative data also revealed improvements in the quality of care. Clients felt that the quality of care greatly improved. In addition, they felt that their needs were better met at an earlier stage of seeking care. This represents a major achievement for the PROQUALI project, as one of the main goals of the initiative was to improve early access to care. Finally, clients were better able to articulate their expectations for quality care—demonstrating that the initiative was effective in creating demand for and recognition of quality (CCP 2000).

Expansion was targeted for 25-30 additional clinics throughout Brazil. The State Secretariat of Ceará has redirected the PROQUALI model to address the primary healthcare needs of adults and children throughout the state. The Secretariat of Bahia created the Reproductive Health Reference Center with the objective of expanding the PROQUALI model throughout the state (CCP 2000).

The PROQUALI model is an excellent example of a focused accreditation initiative that resulted in dramatic improvements in the quality of care. Based on its success in Brazil, this model is currently being considered for replication and adaptation in areas of Central America (Bossemeyer 2003).

CARIBBEAN COMMUNITY AND COMMON MARKET (CARICOM) AND CARIBBEAN ASSOCIATION OF MEDICAL COUNCILS (CAMC)

Background

The Caribbean Association of Medical Councils (CAMC) was established in 1998 by the Caribbean Caucus of Health Ministers with the goal of improving access and quality of healthcare to people of the different nations in the Caribbean. The CAMC, composed of sixteen member nations, aimed to achieve this goal by addressing the lack of standardization in the skills and knowledge among physicians. Many of the region's physicians are foreign trained and come from all over the world. Therefore, it is difficult to ensure the skills and knowledge of physicians. In addition, the close proximity and fluid borders of the sixteen CAMC nations create challenges in tracking where physicians are working.

To address these challenges, specific responsibilities for the CAMC were developed, including (Caribbean Association of Medical Councils 2000):

- Standardizing registration requirements for physicians wishing to practice in CARICOM member nations
- Establishing a regional exam
- Networking the National Medical Councils of each country
- Establishing a database of physicians wishing to practice in the Caribbean region
- Establishing common standards of medical care
- Establishing a regional code of ethics.

The remainder of this section will focus on the regulatory responsibilities of CAMC, especially the effort to establish a regional exam and registry system for physicians.

Physician Registration Exam

One of the major initiatives earmarked for the CAMC was to establish a unified registration system for physicians practicing in any of the sixteen CARICOM countries. A registration system would help to establish a minimum set of requirements for the skills and knowledge of physicians to ensure a basic level of quality (Mullings 2000). This exam would also establish a uniform set of requirements throughout the region, therefore addressing the challenge of physicians moving between fluid borders when they did not meet specific registration requirements of one nation.

A major component of this registration system was to establish a regional exam required for all physicians practicing in the region and any physicians wishing to begin practice. Three main objectives were outlined for the implementation of this exam:

- Measure the competency level of providers, particularly their ability to assess and manage patients as well as monitor and measure outcomes of care
- Develop uniform, objective, and broad-based standards to evaluate medical graduates
- Contribute to the development of clinical standards across Caribbean nations.

The registration exam, required of all physicians working in the public and private sector, was designed and administered by Faculty of Medical Sciences at University of West Indies (Mullings 2000). The exam was originally designed in two parts, including demonstration of both knowledge and clinical skills. As of October of 2003, the two sections of this exam were delivered separately. Part one, more theoretical in nature, is a computer-based multiple-choice test. Part two, the clinical skills section, involves a demonstration of skills (Mullings 2003).

Initially, the tests produced low pass rates—25% in April 1999, 12% in December 1999, and 21% in April 2000 (Mullings 2000). This low pass rate created a difficult situation for member nations. While on one hand it was disconcerting to document how many physicians did not meet the knowledge and skill requirements established by the exam, a shortage of physicians in the region limited the ability to stop these physicians from practicing (Mullings 2003).

In response to this situation, it was determined that physicians that did not pass the exam would operate on a temporary license under supervision until they successfully passed the exam. As of 2004, a formal preparatory system for the exam does not exist. Informal preparation, however, such as the rotation of government employees through different departments, has helped to strengthen and refresh the knowledge of applicants before taking the exam. Once a physician passes the exam, he/she is registered in the system and is not required to be re-examined. As of 2004, however, registered physicians were required to take continuing education courses and pay an annual fee in order to keep their registration status up to date (Mullings 2003).

Limited resources have presented a significant challenge to CAMC (Caribbean Association of Medical Councils 2000). Initially, the program relied on funding from annual dues, approximately USD \$1,000, from all member nations. The program encountered difficulty in collecting the dues from all of the members, and therefore ran into financial instability. The program is currently funded through applicant exam fees, approximately \$250 for the exam and \$50 for an administrative fee. The fee structure was changed as of October 2003, to charge an estimated \$200 for each of two exams (Mullings 2003).

Challenges and Future Directions

Although this program is well established in its structure, unfortunately it has not been uniformly adopted throughout all of the member countries. CAMC is currently assessing the implementation of the program and looking at the barriers to its implementation. Since it is a regional initiative, the registration program will only be as strong if it is uniformly implemented and enforced (Mullings 2003).

Communication between the National Medical Councils of member nations has also been a significant challenge for CAMC. Not all member nations have access to e-mail and technological tools to maintain contact. Fluid communication is required to facilitate the development of

national and regional databases, regional standards, code of ethics, and legal frameworks for the National Medical Councils of each country (Caribbean Association of Medical Councils 2000).

Therefore, future directions for this program will involve strengthening the cooperation, uniformity, and communication between borders. Another area in discussion for future development is the implementation of a monitoring system to assess if the registration process has indeed improved the quality of care extended to the population (Mullings 2003). This has not yet been developed and would provide valuable data as to whether the registration system is meeting its goals and objectives.

It is also interesting to note that this registration system is now being implemented in conjunction with a new mandate to develop an accreditation system for medical schools across the Caribbean region. This system will include representatives from both private and public schools from different nations. These two systems will complement each other as one addresses physicians already practicing in the region and the other develops uniform curriculum and expectations for the education of future healthcare providers.

COLOMBIA

Background

Colombia, a nation of 43 million inhabitants, is divided into 32 departments and 1 federal district. Its epidemiological profile, like that of many other nations in the LAC region, includes both chronic and communicable diseases. Circulatory system diseases, trauma, and homicide constitute the largest causes of mortality in the country (PAHO 2002j).

Colombia has introduced major health sector reforms with the objectives of decentralizing the healthcare delivery system and achieving universal healthcare coverage for the population. Despite widespread reforms and efforts, universal coverage for the population has not yet been achieved, as unemployment and slow economic growth have created obstacles to obtaining this goal (PAHO 2002j).

Law 100 and Other Important Health Sector Reforms

A major piece of health sector reform legislation was enacted in Colombia in 1993 under Law 100 (PAHO 2002j). This law was passed with the objective of extending universal health coverage for public and private health services for the population, independent of ability to pay. Law 100 responded to problems in health coverage that are not uncommon to many countries in the LAC region, including low coverage of vulnerable groups, inequity in access to healthcare, high costs of healthcare for the poor people, and an overall inefficiency in the healthcare delivery system (González-Rossetti and Ramírez 2000).

Law 100 continued the trend of decentralization by shifting many of the responsibilities that previously fell under the domain of the Ministry of Health, to a variety of other institutions (González-Rossetti and Ramírez 2000). The National Council for Social Security in Health was created under Law 100 in order to carry out regulatory roles. Responsibility for the provision of health services was shifted to independent providers and agencies under the supervision of a Superintendency. A National Health Fund was created to separate the finance system from the healthcare delivery system. These changes separated the different functions of the health system

and allowed the Ministry of Health to focus on the management of health services and the delivery of technical assistance.

Another important change introduced by Law 100 was the separation of health service facilities (such as hospitals and clinics) from the health financing entities, known as Entidades Promotoras de Salud (EPS) (González-Rossetti and Ramírez 2000). Under Law 100, all families enroll with the EPS of their choice for a period of one year, after which time families can change EPS. The objective of this aspect of Law 100 was to create a spirit of competition among the health facilities to attract clients and therefore financing. This competition was intended to provide an incentive for facilities to offer quality services that focused on the needs of clients.

Law 100 was not passed in isolation, but rather fit into a history of important reforms that were focused on the decentralization of health expenditures (González-Rossetti and Ramírez 2000). One important reform was the establishment of the Fondo Nacional de Seguros de Accidente de Tránsito. The creation of this fund later paved the way for systems introduced under Law 100. Other important reforms that preceded Law 100 focused on the reorganization of the health system as well as the decentralization of resources and responsibilities. These reforms, as well as Law 100, were passed in response to demand for regulation of the growing private medical sector.

In 1999, the Colombian Ministry of Health established a Quality Assurance Project to oversee strategies and incentives for quality improvement within the Colombian health system. With funding from the World Bank, the project included five separate but complementary components to improve quality (Proyecto Garantía de Calidad 2003):

- Essential Requirements for Registration (*Habilitación*)
- Accreditation of EPS and Instituciones Prestadores de Servicios (IPS or Service Delivery Institutions)
- Incentives
- Information for users/clients
- Audit

Registration of Healthcare Facilities

As part of this reform, it is the responsibility of the Ministry of Health and the Superintendency of Health to supervise, inspect, and monitor that healthcare facilities comply with minimum, essential requirements. Therefore, a registration system for public and private healthcare services was established for facilities to receive approval for operation. This registration process (*habilitación*) assesses facilities on standards in a number of categories, including human resources, physical infrastructure and maintenance, maintenance of medical equipment, resource management, primary care, clinical records and registries, referral and counter-referral of patients between interdependent services, and follow-up of high risk cases (Centro de Gestión Hospitalaria 2002). Requirements for health facilities now also include components such as the design and implementation of quality improvement initiatives, ongoing measurement of client satisfaction, and use of a system to process claims and suggestions (PAHO 2002d).

The registration process contains four main parts (Centro de Gestión Hospitalaria 2002):

- Auto-evaluation and declaration: The healthcare facility conducts a self-assessment of compliance with requirements and standards. The facility then submits its self-assessment to the Departmental or District health office.

- Registration: The Departmental or District health office registers the self-assessment in a database and arranges for verification within six months.
- Verification: The Departmental or District health office conducts field visits to the facility to verify compliance with standards and minimum requirements according to a training manual.
- Follow-up: The Departmental or District health office provides feedback during or after the verification and assists in compliance with standards.

Accreditation

A consortium of organizations was formed to design and implement the accreditation system, including the Centro de Gestión Hospitalaria, the Canadian Council on Health Services Accreditation, and Qualimed of Mexico. The consortium began by researching international experiences in accreditation in a variety of countries, including Canada, the United States, Brazil, Argentina, Chile, France, Spain, Sweden, Norway, New Zealand, Thailand, and Japan (Ministerio de Salud de Colombia 2003). Components of each of these systems were then modified to meet the specific needs of Colombian health system (Proyecto Garantía Calidad 2003).

A market study was then conducted among 183 healthcare facilities to assess interest in participating in an accreditation program. This study revealed that 70.5% of facilities expressed interest in accreditation and that 45% of facilities were willing to pay between USD\$2,000-USD\$10,000 in survey fees. Next, the consortium established key features of the accreditation program, stating that the accreditation system should be voluntary, involve components of self and external assessment, and use realistic standards that have been previously validated. A number of accreditation instruments were developed, including a set of standards, an evaluation manual, a set of indicators to track progress, and a training manual for surveyors (Proyecto Garantía de Calidad 2003). The standards developed cover various aspects of healthcare delivery, including client care, administrative processes, management, information systems, and the physical condition and infrastructure in the facility (Centro de Gestión Hospitalaria 2003).

In November of 2002, the Colombian Ministry of Health passed Resolution 1474, establishing a Unified Accreditation System. This accreditation system was established with three guiding principles: confidentiality, efficiency, and gradual implementation to facilitate continuous quality improvement (Salud Colombia 2002). Under this resolution, the Ministry of Health established an accrediting entity with the following responsibilities (República de Colombia Ministerio de Salud 2002):

- Select and train professionals to carry out the accreditation
- Standardize procedures for accreditation
- Define operative procedure and how organizations can carry out the accreditation process
- Form an integrated group with specialists in the areas of management, evaluation, and quality improvement to make accreditation decisions
- Design, systematize, and maintain a database of information on healthcare institutions that participate in the accreditation process
- Disseminate information about the organizations achieving accreditation

- Promote the accreditation system
- Inform the Ministry of Health periodically about the accreditation system.

Under this accreditation program, the Instituto Colombiano de Normas Técnicas y Certificación was given the responsibility of continuously revising and updating the standards manual every three years. Critics of the accreditation program claim that more qualified organizations exist in Colombia and would be better equipped to respond to this great responsibility (Salud Colombia 2002).

The program is currently in the process of development, which is estimated to take about a year and a half (Centro de Gestión Hospitalaria 2003). A pilot program will be implemented in six IPS and four EPS throughout Colombia. The IPS, both public and private, will range from ambulatory care to the highest level of care. The EPS will include a mix of public and private institutions (Proyecto Garantía de Calidad 2003). This program, still in the stages of design and development, is expected to establish an accreditation system that is strongly supported by the government.

The biggest challenge for the accreditation program will be to market or position the accreditation program as an element of prestige for healthcare institutions (Proyecto Garantía de Calidad 2003). Promoting the prestige of the accreditation program will provide an incentive for healthcare institutions to participate in accreditation and allow consumers to choose institutions that take pride in offering quality care.

Challenges

Skeptics of this major push towards quality regulation state speculate that these reforms are too optimistic, given that the appropriate support systems are not yet in place. With regards to the accreditation program, without nationwide capacity in the healthcare delivery system for the training of personnel, the development of protocols, and the ongoing evaluation of cases, a system-wide accreditation program appears unrealistic (Salud Colombia 2003). With respect to the essential requirements for healthcare facilities, critics fear that corruption and/or a lack of enforcement will undermine this system (Salud Colombia 2003).

DOMINICAN REPUBLIC

Background

The Dominican Republic consists of 30 provinces that are divided into 111 municipalities. The population of 8,400,000 is largely concentrated in urban areas, where 67% of the population resides. Poverty is a major issue affecting the population of the Dominican Republic—40% of urban families and 80% of rural families are under the poverty line. The Secretaría de Estado de Salud Pública y Asistencia Social (SESPAS) provides free health care for impoverished families (PAHO 2001g).

The Dominican Republic has implemented major reforms in the health sector. Pressure for these reforms mounted in the early 1990s, resulting in the development of the current large health sector reform initiative. Approximately \$120 million in funding from the World Bank, the Inter-American Development Bank, and other collaborating agencies is supporting the ambitious reform project that aims to (PAHO 2001g):

- Decentralize the public sector
- Reform the social security system
- Provide universal access to basic health services
- Redefine public-private financing mechanisms
- Initiate a per capita tax to fund universal public-private family insurance
- Increase the regulatory power of the government.

The remainder of this section will focus on the efforts of health sector reforms to strengthen the regulatory role of the government.

Development of Regulation Policy

Like other countries, the regulation of healthcare facilities in the Dominican Republic was instigated through the agreement between PAHO and the Latin American Hospital Federation to cooperate to strengthen the delivery of health services and the quality of care. In 1992, the first workshop on quality assurance was held in the Dominican Republic, focusing on the use of accreditation to improve clinics and hospitals. Later that same year, the Comisión Mixta de Acreditación (COMACH) was formed and drafted an accreditation manual to be utilized in clinics and hospitals. This manual was developed and reviewed over two years through a series of workshops to arrive at consensus about its content. In 1993, regulations for the accreditation program were written in addition to instruments for the accreditation survey (Flores de Parra 2003).

In 1995, COMACH revised these regulations and accreditation tools and presented them to the National Health Commission. This led to a major push in the evaluation of health facilities in the Dominican Republic. In that year alone, surveyors were trained in the accreditation methodology and 20% of health facilities and 50% of laboratories in the Dominican Republic were evaluated (Flores de Parra 2003).

A change in government in 1996 halted the accreditation initiative (Flores de Parra 2003). It was felt that the regulatory framework in place was not sufficient to proceed with accreditation. From 1996-2000, the government shifted its focus from accreditation towards an initiative to modernize and strengthen the health system through decentralization. In this initiative, efforts concentrated on developing leadership at the provincial and municipal levels, strengthening SESPAS supervision, and restructuring hospital management. Within efforts to reorganize services, however, elements of regulation still existed, and the idea of accreditation was revisited in 2000.

In 2001, two important laws were passed to articulate the regulatory authority of SESPAS. Law 42-01, the General Health Law, in Article 99 explicitly accorded SESPAS the power to approve or reject private and public health facilities based on periodic supervision and regulation (Flores de Parra 2003). Article 100 of this same law assigned responsibility to SESPAS and the National Hospital and Clinic Accreditation commission for guaranteeing that health facilities provide clients with adequate care, fulfilling the minimum requirements according to their level of care. The second law, Law 87-01, complements Law 42-01 through Article 163 that created a system for quality assurance and self-regulation.

Registration of Healthcare Facilities

These laws led to the creation of a registration process for clinics and health services as well as for laboratories and blood banks. Under this registration process (referred to in Spanish as “*habilitación*”), public and private healthcare facilities must comply with the standards passed by the Consejo Nacional de Salud in order to receive approval to provide services. These standards encompass a variety of service delivery components, including physical infrastructure, personnel, documentation, information, security and hygiene, management and supervision. Examples of norms for each of these components are discussed below each topic (Secretaría de Estado de Salud Pública y Asistencia Social). It is important to keep in mind, however, that requirements for medical facilities vary based on the level of care provided (e.g., hospital with admitted patients vs. an outpatient clinic).

Physical infrastructure

Physical infrastructure requirements generally refer to the overall maintenance, cleanliness, and hygiene of the clinic. The standards also specify needs for ventilation, lighting, water supply, and insect control. Other specific requirements include:

- Easy access to the facility and parking for emergency vehicles
- Waiting room should have seating capacity for a minimum of 4-6 patients, with enough space for the reception area; the area should be free of noise and disturbances
- Clear access and signs to direct clients
- Restrooms and sinks for hand washing for clients, their companions, and personnel
- Consultation rooms should have a bed, desk, three chairs, and enough space for the patient to sit down, change, and be evaluated
- Basic indispensable medical supplies (e.g., stethoscope, scale, medical supply cabinet) as well as any supplies for any medical specialties offered through the facility.

Personnel

Medical professionals are required to hold a diploma from a university recognized by the Secretary of Higher Education for Science and Technology (SEESCYT) as well as a certification in any specialty areas by a recognized authority. In addition to this diploma, personnel must also have a national identification card, national registration, and proof of payment of taxes. Administrative staff should have adequate training in order to perform and carry out their responsibilities.

Documentation

Requirements for documentation of health services and clinics include:

- Registration of the facility according to the services offered
- Referral/counter-referral system according to the national norms
- Necessary permits and authorization to prescribe drugs
- Written standards and protocols of care
- Patient records and medical histories
- Notification forms for the Department of Epidemiology.

Information

Information requirements include systems to communicate with clients as well as health authorities. Information for clients includes service hours, rights, and responsibilities. A system to communicate information to health authorities as needed also must be in place.

Security and Hygiene

Requirements for security and hygiene aim to protect the security and health of personnel, clients, and the environment from any risk of harm from biological or chemical waste (according to the regulations set by the Secretary of the Environment and Natural Resources).

Management/ Technical and Administrative Procedures

These procedures specify that any medical facility that is currently operating and has not yet been through the registration process, should begin it immediately. In addition, health services and facilities are obligated to communicate with SESPAS within 15 days of the following situations:

- Any change in facility design affecting security related to biohazards
- A change in the Technical Director
- Moving the medical facility to another location
- Opening of new services that increase the complexity of the facility (e.g., new use of radioactive materials).

These standards also specify SESPAS' responsibility for enforcement and verifying that health facilities comply with these standards. These enforcement powers include:

- SESPAS claims the right to verify ongoing compliance with standards and registration requirements at any given moment.
- If a facility does not meet registration requirements or standards during a supervisory visit, registration status will be revoked.
- SESPAS authorizes the opening and functioning of all medical consultation facilities.
- The registration of medical facilities will be determined by SESPAS, in consultation with regional, municipal, and provincial health authorities.

Successes, Challenges, and Future Directions

The registration initiative is targeted towards all public and private healthcare facilities in the Dominican Republic. This encompasses a wide variety of facilities, including blood banks, ambulances, clinics, hospitals, and laboratories. This comprehensive initiative remains in the early stages of implementation. Therefore, data are not yet available on the percentage of facilities that meet established requirements nor regarding improvements in quality that occur as a result of the increased regulation.

Although these reforms are not fully implemented, the development of all the appropriate tools and infrastructure to support a nationwide initiative represents a major mark of success. This initiative represents a significant investment on the part of the Dominican Republic in health sector reform that will hopefully yield the desired results with time. Like reforms in other countries, an ongoing challenge will be maintaining continuity and growing momentum for healthcare regulation, even in the face of government and leadership changes.

As momentum for this facility registration program grows, future directions have already been identified to strengthen the program (Flores de Parra 2003). First, the need to create an inter-institutional commission has been identified in order to strengthen support for the program across different stakeholders. Secondly, an evaluation system needs to be established in order to assess the experiences and successes to date and modify the system accordingly.

HONDURAS—MOH FACILITY LICENSING PROGRAM

Background

Honduras is a country facing significant challenges in the delivery of health services. While a large part of Honduras' population lives in semi-urban areas, a significant rural population remains scattered throughout the country with difficult access to healthcare (PAHO 2001d). In addition, 66% of the population lives in poverty, 49% of which lives in extreme poverty. Of 174 countries, Honduras ranked as 114 on the Human Development Index, with great disparities between the rich and the poor.

The Secretariat of Health system is divided into nine main health regions and 39 health areas. Although the public sector is the primary source of healthcare coverage for the Honduran population (52% by the Secretariat of Health and 11% by the Honduran Social Security Institute), the extent of the existence and coverage by private healthcare providers remains widely unknown (PAHO 2001d). Regulation of the private sector thus presents a significant challenge to any healthcare regulatory initiative.

The Government of Honduras initiated health sector reforms as part of a "modernization" process that began during the 1990s. To focus on these reforms, the MOH appointed an Under Secretary of Health for Sectoral Policy and Institutional Development to oversee the Department of Facilities. This initial step towards modernization also included the enactment of the Health Code of 1991, which states that the Secretariat of Health has the regulatory power to control "the opening, functioning, transfer, and enlargement of health facilities on national territory, in order to ensure that they meet minimum requirements for people's safety" (Carías 2000).

Although the government has taken structural and legal steps towards regulating the healthcare sector, this does not always happen in practice within public or private sector facilities (Carías 2000). Three main gaps in regulation prompted the Secretariat of Health to prioritize health sector reform, institutional development, and decentralization in its health policy agenda for the years 1999-2001. First, the private sector grew considerably, largely unregulated, in response to the increased demand that the public sector could not meet. Secondly, the number, quality, and resources of both private and public sector facilities were largely unknown. Finally, approximately 75% of healthcare facilities—mostly in rural areas—were staffed with auxiliary and student clinicians with relatively little supervision.

Facility Licensing

To address these three challenges, the Department of Facilities initiated the licensing program for healthcare facilities (Carías 2000). Under the licensing program, the government developed a legal framework for licensure, establishing expectations for the safety of healthcare users and providers as well as for the continuous improvement of healthcare delivery. This legal framework was developed by a working group including central level health officials, representatives from

medical and nursing associations, professional groups, and private sector representatives (Carías 2000).

The licensing program began as a pilot project in Health Region 7 of Honduras. Region 7 was selected for the pilot study area based on its interest in the program, leadership to follow through on the activities, and commitment to fulfilling a regulatory role. A baseline assessment, conducted by local health workers, helped to establish an understanding of the needs of public and private facilities (Carías 2003). For public facilities, the baseline study revealed the need to strengthen supervision systems and identified which facilities required greater investment. As a result, supervision tools were approved and resources were redistributed to improve existing maternal and child health clinics in Region 7 and construct a new health center. Other outcomes of the baseline study include a greater awareness among personnel of the changes that they can make that do not require financial investments, a greater involvement of hospital management (one sub-director of a hospital personally delivered hospital beds one by one to be repaired), and the use of the baseline data by nongovernmental and donor organizations to prioritize investments in the public sector in Honduras.

In 2002, this baseline assessment was extended to the entire country, representing quite an accomplishment for the licensing program. Despite changes in national leadership, the baseline study successfully managed to conduct an exhaustive review of healthcare facilities with the participation of healthcare workers and personnel. Other significant milestones achieved to date include:

- Classification of all healthcare facilities in the country according to their level of risk and responsibility.
- Publication of a manual of standards of technical requirements for licensure of facilities according to level of care. The goal of this manual is to explicitly establish minimum requirements for healthcare facilities. These standards were developed with the participation of the public and private healthcare sector and have been approved at a national level.
- Publication of inspection instruments as well as a pocket guide for inspectors.
- Design of administrative documents.
- Development of an auto-instructional guide for technical inspectors.
- Training of inspectors in each health region.
- Development of the Subsistema de Información para la Regulación de Establecimientos de Salud (SIRES, or Information Subsystem for the Regulation of Health Facilities).

Five evaluation instruments were developed to assess if facilities qualify for licensure (Carías 2003). Evaluation instruments differ for facilities at risk level one than for those for facilities at risk levels two and three. These include evaluations for:

- A general evaluation of the facility
- Disaster prevention
- Waste management
- Institutional image

- Specific instruments to evaluate health posts, health centers, maternal and child health facilities, and hospitals (evaluated by service, e.g., management, laboratory, emergency, etc).

Each instrument evaluates the healthcare facility on five main categories of standards: human resources, existence of norms, physical infrastructure, equipment and supplies, and service delivery. Some standards are classified as “indispensable” while others are classified as “convenient”. Facilities will have to comply with 100% of the indispensable standards and 80% of the convenient standards in order to receive licensure. These data will be tracked through the facility regulation information system and will be used to determine compliance with standards in health facilities and to allocate resources (Carías 2003).

The licensing program is still in the process of development, as the government regulations to operationalize the nationwide licensing of facilities are still in the process of review and modification (Carías 2003). The development of this program has been financed by a variety of international organizations, including USAID, Japanese International Cooperation Agency, Inter-American Development Bank, World Bank, and PAHO. The Honduran Secretariat of Health has contributed human resources and logistical support to the development of the program.

The Honduras facility licensing program aims to be self-sustainable in the future by recovering costs through charges to health regions. The program also expects to generate cost savings for the health regions by improving the efficiency of service delivery, thereby reducing expenditures (Carías 2003).

Successes, Challenges, and Future Directions

The scaling up of this licensing initiative from a regional pilot project to a national program represents a significant advancement for securing minimum requirements in healthcare facilities in Honduras. The national study conducted in 2002 will serve as a baseline of information regarding the needs for improvement that exist and where to focus efforts in national implementation.

The implementation of the licensing program has also encountered a number of challenges along the way (Carías 2003). Some of these key challenges include:

- Lack of continuity of the process through changes in the government and technical support.
- Delays due to the process of legal approval.
- Limited human resources, as personnel are not designated exclusively for the licensing program.
- Financing limitations of donor agencies.

The implementation of this licensing program, however, will be interesting to follow over the coming years. Lessons learned from this program will provide perspective on the evolution of a nationwide initiative to license and regulate healthcare facilities as well as data on improvements in the quality of care provided.

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