The oversight and regulation of non-state healthcare providers

A rapid review in selected middle- and high-income countries

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January 2009

Oxford Policy Management

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Executive summary

The non-state health sector in low-income countries is both increasing in size and becoming more organised. Yet the ability to regulate the sector has not kept up with its rapid growth. Reviews of regulation of the health sectors in low-income countries invariably conclude that the state's ability to monitor and ensure quality is extremely weak. The objective of this review is to focus on regulation in five countries with stable health systems—Brazil, Canada, New Zealand, Thailand and the United Kingdom—and attempt to draw out lessons this experience has for regulation in low income countries.

The review was based on a series of key informant interviews, by telephone and e-mail, based on a semi-structured list of targeted questions. The interviews were supported by a literature search and material from relevant web sites. The review demonstrated substantial differences in the detailed regulatory architecture from country to country but also a number of core mechanisms. These are:

Professional statutory self-regulation This is the dominant way of controlling practitioner practice undertaken both through maintenance of a register of professionals allowed to practice and investigation of complaints. Regulation is, in effect, devolved to professional bodies by Government by primary legislation.

Licensing of facilities The application of minimum facility standards usually administered by the national or local health ministry/department based on inspections. In practice this is largely a way of attempting to ensure the quality of facilities although it may also be used to limit their number and distribution.

Accreditation of providers Standards designed to improve services through voluntary provider participation in a process of quality improvement which should enhance the market position of participating facilities.

Information and disclosure The provision of information to permit consumers and purchasers to take more informed decisions over the use and funding of facilities can be regarded as a core regulatory mechanism. As with accreditation this may exert a market pressure to improve standards.

Purchasing Strategic purchasing decisions can be used as a regulatory lever to enforce compliance with standards.

The regulatory context in all five countries is changing. Traditional forms of self-regulation and licensing are under scrutiny. Other forms of self-regulation and greater disclosure of information are also becoming important as ways of distinguishing between good and bad quality.

Weaknesses in traditional Ministry of Health minimum standard-based licensing are apparent in all countries as a result of the large size of the private sector, inadequate and inconsistent procedures and a feeling that a health ministry should mainly be responsible for public services or at least publicly financed services. Increasingly countries are changing how the licensing function is managed. One change is to delegate the function both through independent inspectors and by contracting out the entire function. A second change is to replace traditional inspection-based licensing with certification that requires the accumulation of evidence to show standards have been achieved.

Accreditation has become popular often because of the failings of licensing. It is attractive because it is voluntary, places the onus on facilities to raise standards and is financed by

health providers. It may encourage competition in raising standards. Yet accreditation can be complex to establish and costly to administer—placing a burden of cost on providers that is not affordable.

A second issue is how to persuade providers and consumers that the standard introduced is worth having—a sign of quality. The role of a strong purchaser is important here. Health systems in the countries reviewed are only just beginning to insist on accreditation as a qualification for receiving funding. Yet this may be the only way to motivate a significant proportion of private providers to participate in quality-enhancing schemes. Financial assistance may be required to help providers comply with standards.

Professional regulation is also rapidly changing. The assumption of automatic professional self-interest in promoting standards has eroded. At the same time there appears to be no appetite for eliminating the idea of self-regulation entirely. Instead the emphasis is on improving the operation of statutory bodies. A more consistent application of standards across different professional bodies is being emphasised, including the appointment of an agency to monitor and report on their work. Councils are increasingly being opened up to lay participation, and their business made more public. Professional licensing is increasingly seen, not as a one-off deal, but as a process of continuous assessment, with professionals themselves being required to show that they continue to meet the required quality standards.

Information has a vital regulatory role in helping purchasers and providers to take informed decisions. Information is most effective where a genuine choice is available to those taking purchasing decisions. Testing out mechanisms for providing easily assimilated information to consumers, particularly in urban areas, could have substantive benefits.

As the practice and complexity of regulation increases, so the costs increase. It is important to ensure that inputs of regulation are proportionate to the outcome achieved. A Government should focus its effort on areas most likely to yield benefit including the harmonisation of regulatory practices. A coherent response to improving health service regulation does not require Government to take responsibility for all aspects of inspection, information and enforcement activity. Indeed the experience of all countries surveyed is that increasingly other agencies may be called upon to implement regulatory mechanisms. Government action is, however, required in ensuring a consistent approach to regulation and enforcement, monitoring of self-regulatory bodies and actively promoting systems of accreditation to raise industry standards. The creation of umbrella statutory bodies designed to increase the consistent interpretation of statutory self-regulation across professionals is an important example of this approach.

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1 Introduction

The non-state health sector in low-income countries is both increasing in size and becoming more organised. In the past the sector has been dominated by small clinics and drug stores. While these still continue to represent a significant part of the sector, the number of larger facilities such as hospitals and diagnostic centres is rising rapidly. In India, for example, it is estimated that 93% of all hospitals are in the private sector (RTI International 2008). An earlier study suggested that the non-state sector accounted for around 20% of beds in Latin America, 30% in Asia and more than 34% in Africa (Hanson and P.Berman 1994). At the same time the movement to utilise non-state capacity to drive forward national health policy changes continues to grow. In Bangladesh, for example, the current health sector programme, HNPSP, places substantial emphasis on contracting non-state providers, although the implementation of this approach has so far been slow (MOHFW 2005).

The ability to regulate the non-state sector has not kept up with its rapid growth. Reviews of regulation of the health sectors in low-income countries invariably conclude that the state's ability to monitor and ensure quality is extremely weak (Hongoro and Kumaranayake 2000; Kumaranayake, Lake et al. 2000). Regulation is hampered by the large size of the sector, weak health ministries that are ill-prepared to exercise a strong stewardship role and corrupt relationships between state and non-state actors (Soderlund and Tangcharoensathien 2000; Ensor and Weinzierl 2007).

Systems frequently learn from the experience of other countries—in Thailand the development of health technology assessment, modelled on UK experience, and accreditation modelled on the Canadian experience are good examples. This paper focuses on the way in which the sector is regulated in five middle- and high-income countries: Brazil, Canada, New Zealand, Thailand and the United Kingdom. The aim is to focus on recent approaches to regulation in these countries, assess those that work well and those that work less well and attempt to draw lessons for the development of regulation in lower income countries.

2 Methods

The review is based on a series of key informant interviews undertaken by telephone and e-mail (Annex 1). Initial key informants were then asked to recommend other key informants with knowledge of specific aspects of the regulatory landscape. A semi-structured list of questions was developed and the appropriate sections used to obtain information from each informant. Lists of websites of the main regulatory agencies were obtained from key informants. National and provincial/state websites were also searched. A literature search (not systematic) of Pubmed and Ingenta was undertaken using the terms medical/health regulation, licensing, and self-regulation combined with the five countries of interest. Most of the information searched was English language (most of the Thai websites have English language versions). Some machine (Google) translation from Portuguese to English for Brazilian websites and short summary documents was necessary.

The report is written up thematically according to the type of regulation emphasised during interviews with respondents. The main mechanisms are:

- professional self-regulation
- licensing and bureaucratic approaches
- accreditation
- information and disclosure
- purchasing.

There is considerable overlap between these themes reflecting the necessity that regulatory strategies need to be linked within individual agencies often adopting two or more approaches. The final section attempts to draw out key lessons from the experience for low- and middle-income countries.

3 Professional self-regulation

Self-regulation is the dominant form of regulation used to maintain individual practitioner standards. Statutory self-regulation is invariably based on primary legislation that delegates authority over both practitioner licensing and discipline to professional bodies. The extent of decentralisation, particularly federalism, is an important determinant of the structure of regulatory bodies. Both Canada and Brazil operate decentralised systems whilst the other countries have centralised (one council) systems.

Statutory professional self-regulators have two central functions. The first is to maintain a register of individuals licensed to practice, including their scope of practice. Registration must usually be updated on an annual basis and the register is financed by registration fees of members. The second role is to investigate complaints and, if necessary, discipline individual members.

The Canadian system of self-regulation in the 10 provinces is based upon delegation through national legislation (Medical Act) to councils within the provincial Colleges of Physicians and Surgeons. Each council is dominated by elected medical representation— usually area-based, lay members appointed by the provincial Minister of Health or Lieutenant-Governors— and, in some cases, representation of medical colleges.

Table 1: Medical Council membership composition in provinces of Canada (where information is available)

	Name	Medical elected	Lay/public	Medical Schools	Total Council	Open to the public
Alberta	College of Physicians and Surgeons	10	3 appointed	2	12	Not known
Saskatchewan	College of Physicians and Surgeons	12	5 appointed by Lieutenant-Governor-in-Council, the Dean of Medicine (or his/her designate), and the immediate Past Present of the College		12	Yes
Manitoba	College of Physicians and Surgeons	18	4: 2 by Lieutenant-Governor in Council and 2 by the Council	2	20	Not known
Ontario	College of Physicians and Surgeons	16	13–15 by provincial government	3	19	Yes
Quebec	Collège des médecins	20	4: Office of the professions (regulator of professions)	4	24	Not known
New Brunswick	College of Physicians and Surgeons	9–12	5: 1 Minister of Health, 4 Lieutenant-Governor		0	Yes
Nova Scotia	College of Physicians and Surgeons	8	7: 1 by Dean, 1 by society, 5 by Governor General		8	Not known
Prince Edward Island	College of Physicians and Surgeons	6–9	3: 1 by Minister, 2 by Lieutenant-Governor		0	Not known
Newfoundland and Labrador	College of Physicians and Surgeons	7	6: 4 minister (3 lay), 2 minister proposed by council		7	Not known

An important issue in some provinces has been whether the councils act consistently and fairly. In Ontario a Fairness Commissioner1 has been created to scrutinise the way in which professions ensure robust and fair registration practices (health and non-health professions). The office hires public auditors to scrutinise the records of these bodies to ensure they are

[1] http://www.fairnesscommissioner.ca

transparent and an accurate reflection of their work. Fines of up to CA $100,000 can be imposed.

In the UK, the General Medical Council and Nursing and Midwifery Council serve all constituent countries despite the increasingly different health services of Scotland, Wales and England. There has been much concern at the effectiveness of professional self-regulation. High-profile enquiries such as Shipman2 and the Bristol babies scandal3 led to much national newspaper discussion of the effectiveness of self-regulation. Following the cases there were calls for the GMC to be stripped of its regulatory powers (S.Hall 2007).The GMC was long seen as rather cumbersome and over-representing professional self-interest. In 2000, doctors voted to retain GMC self-regulation but also agreed to reduce the size of the Council (from 104 members) aiming for roughly equal medical and lay representation4. In 2002 the Council was reduced in size to 35: 19 elected medical members, 14 nominated lay members appointed by the Privy Council and 2 appointed from the universities (Talbot-Smith and Pollock 2006).

Concern about the work and self-interest of statutory professional bodies (there are nine in the UK) stimulated the creation of the Council for Healthcare Regulatory Excellence (CHRE) in 20035. Its role is to review decisions made by fitness-to-practice committees. CHRE has no power to investigate cases which the respective statutory body has not referred to its own disciplinary committee. The Council also undertakes an annual review of each regulator which focuses on its governance function, highlights examples of good practice and suggests areas needing improvement. In 2008, for example, it was critical of the Nursing and Midwifery Council's recording of fitness-to-practice cases which made it difficult for managers to track the progress of cases (Council for Healthcare Regulatory Excellence 2008). The reports also highlight incidences of conflict of interest by individual members of councils.

In Thailand there has been considerable criticism of the passive role and often extremely slow investigation of cases by the Medical Council (Teerawattananon, Tangcharoensathien et al. 2003). In 1999 only 22% of cases filed were actually followed up. Other bodies, notably the Law Society of Thailand and media organisations, have shown themselves to be rather more active in following up cases of apparent malpractice. Furthermore the lack of lay representation on the Council has led to the perception that it is overly protective of members when considering cases of malpractice.

New Zealand introduced new regulatory primary legislation, the Health Practitioners Competence Assurance Act in 20036. The objective of this act is to bring consistency to procedures for registering and monitoring the various professions across 16 councils and boards. It seeks to ensure that councils not only provide a general licensing function but also monitor practitioners to ensure that what they do conforms to their particular specialty areas. It places a much greater burden of information-gathering on councils. A recent review of the implementation of the act found that the requirements of the act appear to have led to a substantial increase in the annual practice certificate fee charged to those registering (in the case of midwives an increase in the fee of more than 1000% was recorded) (Ineson 2008).

[2] A GP who was found to have systematically murdered a large number of his patients over an extended period of time.

[3] Where perhaps 100 babies were found to have died needlessly at Bristol Royal Infirmary as a direct result of mismanagement and poor care.

[4] http://www.gmcpressoffice.org.uk/apps/news/latest/detail.php?key=285

[5] http://www.chre.org.uk

[6] http://www.moh.govt.nz/hpca

Increasingly, it is recognised that licensing of professionals should not be a one-off event but require regular revalidation with proof that standards are being maintained. In Thailand the nursing council requires relicensing every five years including the need for nurses to accrue continuing education credit. Licensing for doctors remains lifelong although relicensing for new graduates has been required since 2004 (Teerawattananon, Tangcharoensathien et al. 2003). In the UK revalidation for doctors will be required every five years from 2009. This will require doctors to collect evidence on participation in training, patient and colleague feedback on their practice and certification from an independent practitioner of their competence to practice.

4 Licensing of health facilities

Mandated legal minimum standards to enter the health care market are common to most countries throughout the world. In principle the licensing has two objectives. The first is to ensure provider quality: authorities need to ensure that only providers that meet basic standards of hygiene, competency and readiness to deliver specified medical services enter the market. All the countries in the study apply or attempt to apply such standards. A second objective is to limit entry into the market and ensure facilities are evenly spread. It is notable, however, that this second objective is not seen as a primary objective of licensing in the private sector. The exception to this is when the private sector is used substantially to deliver on public service priorities. So, for example, general practitioners in the UK, which are effectively self-employed private partnerships, are the principle outlets for publicly financed primary care. There are, as a result, strong controls on the number of practices that can be established in any particular area. Where providers are financed largely or wholly by out-of-pocket payments or private insurance, regulators appear to place little emphasis on the regulation of facility numbers.

Licensing is often distinguished from facility certification and accreditation (Table 2) although in practice the distinction is increasingly blurred.

Table 2: Licensing, certification and accreditation

Licensing	Compulsory: Administered by government entity, legal permission to practice and based on inspections by regulatory agency
Certification	Onus placed on organisation to prove standards have been reached by gathering evidence, commissioning independent audit.
Accreditation	Voluntary enrolment into a programme that targets quality improvement. Entry stimulated by perceived market advantage. Not a one-off process but introduces a programme that emphasises continued quality improvement.

Basic licensing and standards for independent medical facilities in the UK was, until recently, under the control of local health authorities. The process was unsatisfactory for two reasons: firstly, the primary legislation, the Registered Homes Act 1985, did not include some services (including newer technologies such as MRI) on the list of services to be regulated; secondly, the legislation placed the onus of proof that standards were not being adhered to on the authority; and thirdly enforcement was fragmented with more than 100 authorities interpreting their responsibilities differently (Walshe 2003). It was in order to eliminate this fragmentation that the Commission for Health Improvement was created by primary legislation in 2000, later to be replaced by the Healthcare Commission in 2004. The Commission is a statutory quasi-autonomous body largely financed by fees (set by Government) for undertaking inspections.

The Healthcare Commission has delegated statutory responsibility for standards in both the NHS (public) and independent (private) sector in England7. In the public sector the Commission undertakes an annual health check of NHS hospitals and Primary Care Trusts (PCTs) which is used as a basis for summary reports on NHS performance (see section 3.4). In the independent sector minimum licensing standards set by the health ministry are enforced by the Commission through registration, annual self-assessment and five-yearly inspections. The standards are a combination of traditional minimum input standards—premises, equipment, health and safety, recording and reporting—and some process-based

[7] www.healthcarecommission.org.uk, It took over responsibility for inspections from the National Care Standards Commission.

standards, for example on care for the dying and the monitoring of quality (Department of Health 2002). The Commission has statutory powers to force compliance including fines and facility closure. The Healthcare Commission will be replaced by the Care Quality Commission in 2009 which will also include responsibility for social care and mental health (replacing the Commission for Social Care Inspection and Mental Health Act Commission).

Other bodies in Wales and Scotland mirror the function, although are not identical, of the Healthcare Commission. The Healthcare Inspectorate Wales (HIW)8, established in 2004 by the Welsh Assembly Government, inspects and investigates health care services commissioned and provided by Welsh NHS bodies. Since 2006 it was also established as the regulator of independent health care. HIW inspects NHS trusts, Local Health Boards (LHBs) the Cancer and Coronary Heart Disease Networks, the national Public Health Service (NPHS), the health enquiry line NHS Direct in Wales and the Welsh Blood Service. Other approaches include unannounced cleanliness spot checks of health care facilities, specifically themed reviews such as heart disease and cardiac services and child protection, as well as special reviews of areas or facilities with past problems.

In Scotland the regulation function, referred to as 'external scrutiny', is supported by the NHS Quality Improvement Scotland (QIS)9, established by the Scottish Parliament to focus on improving the quality of health care in Scotland (Crerar 2007). Scrutiny represents a small element of NHS QIS's portfolio which lists its three main responsibilities as: i) providing advice and guidance, including standards; ii) support for implementation and improvement; and iii) assessment, measurement and reporting. There is a clear demarcation between scrutiny and regulation. NHS QIS assesses measures and reports in order to compile and present evidence for NHS Scotland, who in turn take necessary regulation and enforcement action though the performance management system. NHS QIS produces a range of publicly available publications including Best Practice Statements, clinical indicators, Health Technology Assessments (HTA) as well as standards and national and local health overview reports. Lay representatives are recruited and trained to be active members of the review teams.

In New Zealand the Health and Disability Services Act (2001) removed the requirements for licences for hospitals. Instead each facility must now obtain certification. Facilities undergo an annual audit of their services from one of a number of designated auditing organisations10. An advantage is that the onus is placed on the health care organisation and the weight of inspection is carried by designated independent agencies rather than Government. Auditors must themselves demonstrate competence and compliance with requirements of the act. Auditors are not expected to be experts in all fields but have designated competences (e.g. mental health, child health) that are listed.

The ban on private insurance coverage of core physician and hospital services in Canada has had the effect of limiting the size of the private acute and primary care sector, although there is considerable private capacity in other areas such as dentistry, optometry and medicines (Steinbrook 2006). Licensing is the responsibility of state or provincial governments but they may utilise other professional bodies to undertake inspection assessments. In Ontario, for example, the Ministry of Health and Long-Term Care contracts the College of Physicians and Surgeons to undertake assessments where the function of the facility is mainly related to medical-led care11.

[8] www.hiw.org.uk

[9] See lwww.nhshealthquality.org

[10] See http://www.moh.govt.nz/moh.nsf/indexmh/certification-designatedauditingagencies

[11] See www.health.gov.on.ca/english/public/program/ihf/ihf_factsheets/ihf_fact.html#2

Long wait times in the Canadian public sector is raising interest in private care; yet there is increasing concern that licensing of private facilities is not functioning adequately and that many smaller clinics are going unregulated (Anon 2008). It is suggested that one of the problems is that provinces, although responsible, have not seen it as their responsibility to inspect facilities that do not offer insured (publicly financed) services.

Private hospitals and clinics in Thailand must register and relicense each year with the Medical Registration Division of the Ministry of Health. Licensing largely looks at physical adequacy such as beds and staffing. It does not examine the volume of services through facilities even though the volume of particular services is usually seen as a key determinant of quality. As in many countries, there is no requirement for public hospitals to be licensed.

Brazilian licensing is largely a state or municipal responsibility. Federal authorities set basic rules such as prevention and control of hospital infections but enforcement is entirely the responsibility of states and municipalities. Licenses are renewed every year after inspection by officials from the municipality. Inspections tend to focus on basic standards such as building safety, environmental health and minimum beds and staff. Enforcement tends to be extremely variable since wealthier states and municipalities can afford more inspections and better regulation. Reports of licensing failure are commonly illustrated by a recent newspaper report on one large hospital in Brasilia which had to be evacuated because the building was in danger of collapse12. Perceived inadequacies in the licensing system are a major reason why quite complex and multi-layered accreditation systems have been developed in some states (see section 3.3).

The nature of health-facility licensing is beginning to change in a number of countries. A traditional physical input approach based on inspections by the Ministry of Health/Health Department remains the norm in Brazil and Thailand. This traditional model, whilst still the norm in Canada, is beginning to change with specialty agencies being contracted to carry out inspections. The UK has gone further in delegating the licensing function to a quasi-autonomous body that also monitors the standards of public sector agencies. This increases the likelihood that public and private bodies will be judged by similar standards. In New Zealand the emphasis is on abolishing traditional licensing altogether and introducing a certification system with an emphasis on the accumulation of evidence by providers to prove they meet requirements.

[12] http://g1.globo.com/Noticias/Brasil/0,,MUL471641-5598,00.html#-100

5 Voluntary accreditation: Competing in the health care marketplace

Hospital accreditation has immediate appeal in countries struggling to maintain systems of effective licensing of health care providers. The essential differences from licensing are:

- licensing is a legal requirement for all facilities, accreditation is based on voluntary opt-in;
- licensing systems are often financed by governments, accreditation is usually financed from the fees from facilities;
- licensing is based on minimum input-based standards, often little more than health and safety standards, whilst accreditation encourages higher level achievement in inputs, processes and even outcomes.

The key question is: why should facilities voluntarily opt to be scrutinised and pay for the privilege? One reason is that it may offer market advantage. Providers need to distinguish themselves in a crowded marketplace and one way of doing this is to go through the accreditation process and then display this prominently in order to win customers—either individuals paying directly for services or purchasers (insurers or other intermediaries) looking for high-quality service providers to contract. An alternative paradigm is that purchasers actively demand that providers accredit themselves before they are given a contract.

Private medical care in Thailand, particularly Bangkok, is big business. Thais with employment-based insurance can opt to obtain care from private hospitals. The city is also a major medical tourism centre with patients from other parts of Asia and Europe coming to the country as an alternative to more expensive services in Singapore or further afield in the United States. There are at least 100 large private hospitals in Bangkok alone. In a crowded and competitive market it has proven important for hospitals to distinguish their services from those of their competitors. During the 1990s hospitals increasingly sought ISO certification (ISO 9002) although this standard measures consistency in process rather than outcomes. The Tourism Board even published a list of hospitals that had achieved ISO registration on its website[13].

A country-wide hospital accreditation was launched in the late 1990s by the Health System Research Institute and later taken up by the Institute of Hospital Quality Improvement and Accreditation. This is a multifaceted quality improvement programme that focuses on the development of clinical team working. There is some evidence that hospitals, in attempting to achieve accreditation, have improved standards of patient satisfaction and even health outcomes (S.Jiruth and Yuwaree 2004). In addition, some hospitals have begun to obtain JCI (Joint Commission International) accreditation, the international version of the Joint Commission on Accreditation of Hospitals, US (JCAHO). Accreditation has now taken over from ISO certification as a marketing tool. A quick survey of the websites of the 15 private hospitals referred to on the Thai Ministry of Health website suggests that most refer to some type of accreditation (Table 3). Where JSI accreditation is held it appears to be put before other standards such as the QIP or ISO. Such experience mirrors Indian experience. Hospitals seeking JCAHO-based accreditation are largely those that seek to attract international demand (Ensor and Dey 2003). Despite these advances, accreditation in

[13] www.thailandtourismdirectory.com—the listing still exists but the reference to ISO does not.

Thailand remains voluntary and it is thought that less than 100 of the 1,400 hospitals in Thailand are accredited.

Table 3: Publicised accreditation of top private hospitals in Thailand

	JCI	QIP	ISO	Other
Bangkok General Hospital, Bangkok	Yes	Yes		Tempos
Bangkok Nursing Home Hospital, Bangkok		Yes		Various
Bumrungrad Hospital, Bangkok	Yes	Yes		
Nonthavej Hospital, Bangkok	No	Yes	Yes	Bupa Award
Phuket Adventist Hospital, Phuket				
Research and Development Institute	No website found			
Samitivej Hospital, Bangkok	Yes	Yes		WHO, Baby friendly etc
Sikarin Hospital, Bangkok		Yes	Yes	URS
Piyavate Hospital, Bangkok			Yes	
Phyathai Hospital, Bangkok		Yes		Readers Digest Trusted Brand
St. Carlos Hospital, Bangkok				Other award
St. Louis Hospital, Bangkok				
Thai Nakarin Hospital, Bangkok		Yes		
Thonburi Hospital, Bangkok	No website found.	.		
Vichaiyut Hospital, Bangkok				

A number of sophisticated accreditation schemes aimed at hospitals have been developed in Brazil. The three main ones—ONA (Organizacao Nacional de Acreditacao), a national scheme, CBA (Consorcio Brasileiro de Acreditacao), based on Rio State and CQH (Control de Qualidade Hospitalar), based in Sao Paulo—are based partly on the US JCAHO standards (La Forgia and Couttolenc 2008). The ONA scheme is the most sophisticated and is based on a PAHO manual developed for Latin America, based on three levels (Novaes and Neuhauser 2000). Level one accreditation roughly conforms to basic licensing standards while a further two levels (Level two and Level three) require successively higher standards of achievement on process and outcome quality. All three programmes are self-funded from payments made by facilities attempting to achieve accreditation. Accreditation is thought to cost, on average, less than 1% of the annual budget for a 'medium-size public hospital' (La Forgia and Couttolenc 2008).

There are reports that accredited facilities outperform other facilities. It is unclear, however, whether there is a causal link between accreditation and quality. One explanation is that it tends to be the better, more proactive, facilities that are more likely to seek accreditation. These would have improved over time anyway, with or without accreditation.

Although accreditation systems have been in use for 10 years or more (CQH dates back to 1991), a relatively small proportion of hospitals applies and achieves the standards. It is estimated that by 2003 only 55 hospitals (10 public, 44 private and 1 military) had received accreditation out of more than 7,000 hospitals across the country (La Forgia and Couttolenc 2008). A major reason for this appears to be that no one knows which standard to choose as the benchmark. Since accreditation is expensive for the facilities to obtain this means either facilities must trust that the scheme they choose will remain as an acceptable standard or they wait until one standard is chosen by politicians. Unsurprisingly the states developing their own scheme are reluctant to use a scheme developed in another state.

Adoption of accreditation could be made more rapid if the major purchasers—private insurers or the state the ONA accreditation level reached (La Forgia and Couttolenc 2008). health services (SUS)—determined a standard that must be adhered to by providers. This has so far not happened although one purchaser, UNIMED in Belo Horizonte, has introduced higher reimbursement according to

Accreditation in the UK has largely focused on improvement in public hospitals which represent the majority of acute health care services. The oldest such scheme is the Health Quality Service, established by the Kings Fund in the 1980s and now part of CHKS Ltd, and it also accredits services in both the public and independent sector14. CHKS Ltd is itself accredited to award ISO 9001:2000 for quality management systems as part of the overall accreditation process. CHKS presents annual awards to top hospitals across a number of criteria including patient safety and quality of care.

Another system, the Trent Accreditation Scheme, was developed by former NHS practitioners in the late 1990s15. It is based on a process of peer review, self-assessment, and surveys by independent surveyors that lead to accreditation status (valid for two years). In the UK its activity is so far limited to NHS facilities in the Trent area. It is involved in accrediting independent (particularly faith-based) hospitals in Hong Kong. These hospitals use accreditation by Trent and schemes such as JCI to promote the quality of their services in their publicity (such as websites).

The strength of a basic licensing mechanism may to some extent be reflected in the way hospitals publicise information about their regulation. Hospitals overseas that receive CHKS, Trent or other accreditation often advertise this prominently on their website. In England, hospitals such as Nuffield and Spire (formerly Bupa), are more likely to mention their registration with their licensing authority, the Healthcare Commission16.

National accreditation of healthcare in Canada is undertaken by Accreditation Canada (AC)17. AC is itself accredited by the International Society for Quality in Health Care. Accreditation remains voluntary and is financed from fees calculated as a proportion of the organisation's budget (currently 0.013%) plus a flat fee per survey. Accreditation is based on a combination of information generated by the organisation, self-assessment and surveys carried out by independent surveyors (organised into geographic teams to ensure national coverage). Recommendations for improvements by surveyors must be implemented within six months. Sanctions are light, based largely on the reputational effects of getting a bad report that may be made public to staff and the wider community.

Accreditation in Canada remains largely voluntary although there is increasing interest to make it compulsory. Quebec made accreditation compulsory for both public and private sectors in 2006 and Alberta did the same in 2008. The Royal Colleges stipulate that any health care organisation that has medical students must be accredited by AC.

In addition to publishing lists of accredited organisations every six months, AC publishes required organisational practices (ROPs) that document procedures and best practices in areas such as narcotic safety, information transfer and infection control guidelines. Adherence to these guidelines is to be made a requirement for accreditation from 2009. AC also accredits health care organisations in a number of countries including Saudi Arabia, Bermuda and Italy.

[14] www.chks.co.uk

[15] www.trentaccreditationscheme.org

[16] See www.spirehealthcare.com & www.nuffieldhospitals.org.uk

[17] www.accreditation-canada.ca based on interview with Wendy Nicklin

6 Information—disclosure and competition

Information provided in a transparent and accessible way can be seen as an important part of better regulation. The aim is to empower consumers, providers, purchasers and policy makers with relevant technical information that can be used to make informed judgements about what services to obtain and which facilities and practitioners to visit.

In Canada, the Canadian Institute for Health Information publishes information largely aimed at health authorities rather than consumers18. Particular emphasis is given to human resource issues, health spending trends and process and outcome data on particular treatments such as hip joint replacements.

In the UK a wide range of information is provided on different aspects of health and health care. League tables have for some time been published that provide information on hospital process performance such as inpatient waiting times, readmissions and cleanliness. Assessments are now undertaken annually by the Healthcare Commission (England), Healthcare Inspectorate Wales and NHS Quality Improvement Scotland. Reports are made public, typically via websites and public facilities. NHS QIS produces a range of publications and has also made strides in ensuring that reports are widely accessible to the public by publishing patient-focused reports in cartoon format.

Over the years the information has become more sophisticated although summaries of performance are still offered to provide an instant impression of services. Although such information may act to stimulate improvements in quality there are criticisms of this approach. One problem is that it is not always clear how consumers or agents (general practitioners, etc.) should make use of the information. Often consumers have little effective choice of provider unless they wish to travel long distances—which most people do not want to do. Another is that whilst the assessments may be accurate for the facility as a whole, the quality of individual specialties can vary substantially.

Another approach to the provision of better information, also in the UK, is offered by the website Dr Fosters19. Information is tailored to two distinct constituencies, patients and professionals. Patients can obtain information on individual hospitals and also on specialists. In the latter case information is provided on sub-specialty focus, GMC registration date and gender but not whether they are pleasant to patients or numbers of complaints made against them. The birth guide identifies management of care (consultant- or midwife-led), numbers of births and caesarean rates.

There is no comparable information source to Dr Fosters in New Zealand, Brazil or Thailand. Some professional councils (e.g. New Zealand, UK) permit online checks on individual practitioners although this is limited to whether the practitioner holds current registration.

The media also has an important function in providing information. Two distinct roles can be identified. One is as an outlet for systematic information on the performance of health services. Publishing league tables of hospitals (and other public bodies such as schools) in the UK is one such example. This remains an important role although its significance has perhaps been diminished by the growth of independent websites providing similar information. A second role is in disclosing egregious behaviour that otherwise would not reach the public's attention. Such a role for the media is common in countries such as India and Bangladesh. In these countries, published reports of inadequate standards in hospitals

[18] http://secure.cihi.ca

[19] www.drfoster.co.uk

and other health services serve as an important way of raising consumer and public authority awareness of failures that are in large measure due to inadequate system regulation. In the countries covered in the study there are also important cases of media-induced regulation. In Thailand, a free press is credited with a vital role in stimulating debate and awareness of corrupt organ donation practices, including payment of live non-relative donors (Teerawattananon, Tangcharoensathien et al. 2003). Similarly, the press appears to be important in Brazil in raising issues of inadequate standards of health facilities caused, at least in part, by inadequate inspections.

The media role is not of course unbiased and information can easily get distorted. Recent reports in the UK media suggest that most hospitals are failing hygiene tests20. In contrast the same report on the regulator's own homepage praised NHS progress on infection control while pointing out that in most hospitals there were relatively minor lapses which meant they did not receive a perfect score21.

[20] 'Acute hospitals fail hygiene test', November 24th 2008, BBC Health, http://news.bbc.co.uk/1/hi/health/7744984.stm

[21] Watchdog praises NHS progress on infection control and urges trusts to maintain pressure, Healthcare Commission, 24th November 2008, http://www.healthcarecommission.org.uk/newsandevents/mediacentre/pressreleases.cfm?cit_id=1513&FAArea1=customWidgets.content_view_1&usecache=false

7 Regulation through purchasing

Purchasers of services are potentially one of the most powerful instruments of regulation. Purchasers include public funders, social insurance organisations and private insurance companies. There are two main opportunities for regulation through purchasing. One is to dictate the general standards of a provider—physical, staffing, process of care—that a purchaser requires before a contract is given. The second is to set out detailed standards on which, and in what way, specific services should be purchased.

Purchaser-enforced general standards appear to work best where there is an arm's length relationship between the purchaser and provider. Integrated public systems of finance, where funding is automatically budgeted to public providers, are anathema to the idea of requiring providers to accredit before they receive funds. It is also the case that public systems operate in areas where there are few health facilities. In parts of rural Thailand, for example, there is usually only one public hospital so it is not really possible to insist that standards are achieved as a condition for receiving a budget (although managers could still be judged on their ability to raise standards). Even when public providers assume a degree of separation from purchasers, as has occurred in the UK, New Zealand and Canada, the idea of providing funding contingent on reaching standards has not really gained currency. In these systems it is the power of 'naming and shaming' and possibly the replacement of senior managers for not maintaining standards, rather than contracted funding flows, that remains the main enforcement tool.

With the private sector, purchaser–provider relationships perhaps offer more of an opportunity to enforce general standards. Yet even here there is little evidence that this actually occurs. It is true that UNIMED, a large work-based health plan operator in Brazil, is providing higher reimbursement tariffs to hospitals that accredit their services; but other examples are hard to find.

It is usually the case that stronger regulation of public facilities only becomes possible when providers are given some autonomy from purchasers through a contract mechanism. The Universal Scheme (30 Baht) in Thailand does not apply any standards to facilities since all are part of the integrated public provider network with little, if any, choice in many areas. Both the schemes for employees (SSO) and civil servants (CSMBS) permit the use of private facilities and it might be expected that they specify minimum standards before facilities are contracted. Although SSO does not specify accreditation as such, it does have its own quite stringent quality standards applying mainly to the infrastructure and minimum staffing rather than process of care. Contracts are let with any providers exceeding these minimum standards. CSMBS is not considered well managed and specifies no standards—rather it is seen as a passive conduit for reimbursements.

A second way in which purchasers can influence standards is by mandating the types of treatment and the way they are provided. Thus purchasers could agree only to refund medicines that are on an approved cost-effective list or reimburse surgery where there is evidence that correct protocols have been followed. For this to function adequately purchasers need intelligence on the best quality or cost-effective services. Since most will not have the ability to generate their own information they must rely on an outside body. The National Institute for Health and Clinical Excellence (NICE)22 in the UK is one such body that produces recommendations to the Ministry of Health on which health technologies it should finance. The calculation of cost-effectiveness offers a way for purchasers to direct funding to services producing most health gain. Health technology assessment is also well

[22] www.nice.org.uk

established in Canada where assessments are routinely used to influence purchasing decisions of public health care providers23. In Thailand, the model of NICE has been harnessed to develop the Health Interventions and Technology Assessment Program24. Established in 2006, the programme seeks to increase knowledge of appropriate health interventions and technologies using internationally recognised methodologies. It appears to have influenced the items on the medicines reimbursement list, and health authorities are increasingly asking for health technology assessment advice before taking resource allocation decisions.

[23] Main agency is the Canadian Agency for Drugs and Technologies in Health, www.cadth.ca

[24] www.hitap.net

8 Discussion: What lessons for low-income countries?

The regulatory context in all five countries reviewed in this study is changing. Traditional regulation based on self-regulation of professionals and licensing requirements for facilities is under scrutiny in all countries. Other forms of self-regulation or greater disclosure of information are also becoming important as ways of distinguishing between good and bad quality. In this section we focus on those aspects of the changing regulatory landscape of relevance to health systems in low-income countries.

One of the problems of transferring lessons from one context to another is that the reasons why mechanisms work (or do not work) are usually highly dependent on the institutions that operate in the originating country. This is particularly the case when examining the transfer of mechanisms from contexts where resources and governance are very different. Any conclusions or lessons must, therefore, be extremely tentative.

8.1 Delegating the licensing function

It is notable from the review that problems with licensing of non-state providers are not confined to low-income countries. In general, ministries and local health authorities do not appear to be well suited to the task of ensuring that non-state providers are properly licensed and inspected. In Canada and the United Kingdom implementation of the legal obligation to regulate has, in the past, often been fragmentary and inconsistent. New Zealand has given up the requirement to license altogether, whilst in Canada there are concerns that many non-state providers go unregulated. The Brazilian system of licensing is so disregarded that the accreditation agencies incorporate a basic standards requirement into their accreditation programme before proper quality improvement can begin. The reasons for inadequate public sector licensing are various but are at least partly explained by the public sector's lack of experience and a general feeling that non-state providers, particularly those not receiving public funding, are not their responsibility. A further issue, which is dominant also in low-income countries, is that the task is just too enormous. The fact that systems often require public organisations to prove that standards are breached, based on these irregular inspections, further hampers enforcement.

Several innovations in the countries surveyed could have potential for improving the way in which licensing is implemented. Contracting out or delegating the inspection and auditing function can help to free public organisations from a task that they are often ill suited to fulfil. An alternative approach is to retain the regulatory role in-house but contract outside specialist agencies to undertake audits, as happens in New Zealand and Canada. This is similar to the approach of most accreditation systems and demonstrates the blurring of the distinction between licensing and accreditation.

Delegation can be complex to implement. In England, for example, the body that regulates private facilities has undergone three incarnations in the space of eight years as functions have been merged. The end result in 2009 should be one agency that regulates public and private health and social care organisations across England.

Delegation does not of itself reduce workload. Rather it transfers the work to an organisation that is more competent to carry out the tasks. The introduction of certification in New Zealand has the potential to alter the way in which proof of competence is provided. Rather than the regulator taking an adversarial role, making inspections in an attempt to catch wrongdoers, and the facilities trying to avoid being caught, the burden of proof is placed on facilities to deliver evidence that they have achieved standards across different areas of

activity. Evidence is built up during a period specified by the regulator with audit inspections being used to verify particular aspects of concern rather than as the only tool to monitor activity.

8.2 Can accreditation be used to fill gaps in licensing?

Accreditation is attractive for a number of reasons. It is voluntary, generally financed by health facilities and is designed to induce continued improvements in quality rather than simple achievement of minimum (even minimal) standards. The apparent failure of licensing in many low- and middle-income countries, often also the cases in richer established systems, lends further weight to the case for encouraging accreditation.

Yet there are problems with accreditation. The first issue is that accreditation processes are costly and complex to establish. Although much of the cost may be passed on to providers, there is an initial investment cost involved in establishing systems of standards, training inspectors and publicising and selling the process to providers. It means that, in practice, such systems are mainly limited to larger hospitals with a strong revenue base, leaving out clinics and smaller hospitals. Mature accreditation processes can take many years to develop and become accepted. Accreditation Canada has been developing its processes for 50 years, yet it is only in the last couple of years that provinces have begun to mandate provider enrolment. The home-grown Thai system QIP started more than eight years ago and it is beginning to build some acceptability amongst Thai hospitals, yet many providers still prefer to opt for other systems to gain market advantage.

One way to short cut some of the research and development is to link domestic accreditation to already existing international standards, either by importing a proprietary standard or adapting a standard already in the public domain. The most successful and well-known proprietary standard is the US JCI scheme which is used by larger private hospitals in many countries including India and Thailand. This standard remains expensive to use. The JCI website estimates the average cost of a survey is around $41,000, not including the reimbursable costs of the survey team (which could easily increase this amount by 50%)25. This is not a large sum for a large private international hospital in Calcutta or Delhi serving an international market. It remains a large amount for a small- to medium-sized hospital in a low-income country. In one study of maternity care the cost of accreditation for medium-sized hospitals in Andhra Pradesh was considered a prohibitive barrier (Ensor and Dey 2003). In Nepal, for example, the 2003 National Health Accounts found that the average total expenditure for a private hospital was less than $100,000 (Prasai, Karki et al. 2006).

A second way to extend accreditation more rapidly is by adapting a generic standard. This approach was adopted in Brazil where PAHO standards were adapted to develop the ONA standard. This can certainly short cut some of the work involved in developing guidelines; yet there is still a need for a well-respected national agency to administer the procedures. The process may also often not be cheap to operate. The ONA accreditation system is estimated to cost hospitals around $100,000—more than the cost of JSI accreditation.

A second issue is how to interpret the results of accreditation. Although there is a supposed market incentive for facilities to gain accreditation in order to distinguish their product, it is far from clear whether consumers are really able to utilise this information properly, particularly where multiple standards are available. How, for instance, is a consumer supposed to distinguish between one Bangkok hospital that possesses the Thai QIP standard from

[25] http://www.jointcommissioninternational.org/Cost-of-accreditation

another that holds ISO registration and a Readers Digest award26? Multiple accreditation standards can be a problem in establishing a national standard, particularly given that facilities need to pay substantial sums to achieve the standard. This is a substantial issue in Brazil where a number of extremely well thought out standards compete but where, in practice, very few facilities sign up to any of them.

8.3 The need for a strong purchaser

In countries where health tourism is important, including Thailand and India, accreditation may act as an important selling point but it is not the case that any old accreditation will do. In both countries achievement of an international gold standard, particularly the US JSI, is most coveted. It is also likely that these standards are as important, perhaps more important, as ways of marketing services to insurers or public purchasers rather than individual clients. This seems to bear out a conclusion from a previous WHO review that accreditation 'may be more effective when initiated in conjunction with a powerful purchaser' (S.Bennett, Hanson et al. 2005). Only a small fraction of hospitals in both Thailand and Brazil currently undergo any kind of accreditation even though reasonably well-established systems have existed for some time. Accreditation perhaps will only begin to have impact when the major purchasers—SUS in Brazil, the civil servants, social security or universal coverage scheme in Thailand—begin to require accreditation as a condition of contract. The cost of many schemes means that it may not be feasible to insist that providers both participate in and fully fund accreditation. Some assistance may also be required from purchasers or the Government, particularly for small providers, to promote compliance.

8.4 Improving professional self-regulation

Ideally self-regulators should have a market interest to ensure high standards; if one member misbehaves this can have a detrimental impact on the credibility of the entire profession. This market mechanism is rather undermined by the monopolistic nature of the collective medical profession27. If the profession falls into disrepute patients still have little choice but to consult with practitioners if sick. There continues to be much distrust of self-regulation of medical professions but at the same time no great desire to abandon the principle altogether or a feasible alternative structure. Yet the way of self-regulation is changing and a number of trends are apparent.

8.5 More consistent and transparent application of standards

The idea of professional councils as entirely autonomous bodies, policing themselves largely according to their own rules and practices, is no longer tenable. Instead countries increasingly wish to ensure that councils implement their statutory duties in a consistent way. Most of the countries have at least three councils (nursing/midwifery, medical and pharmacy) controlling professional standards and some have many more28. Public sector stewards increasingly wish to ensure that standards and procedures are applied equally. The UK's Council for Healthcare Regulatory Excellence reports annually on the way in which each

[26] Interestingly one hospital website reviewed the award of a Readers Digest trusted brand award on its front page whilst consigning other awards, including the Thai QIP, to the inner pages.

[27] It might be argued that the argument holds less well where there is choice, even if informal. So, for example, in countries where there is a flourishing unofficial sector (village doctors, quacks etc.) consumers have an alternative if the regulated professions turn out to misbehave through overcharging or prescribing.

[28] New Zealand includes dieticians, medical auxiliaries, occupational therapists, optometrists, physiotherapists and psychologists.

council interprets and implements its regulatory function, as well as reviewing all cases of malpractice referred to constituent councils' disciplinary committees. The Medical Practitioners Act in New Zealand places a much greater onus on councils to report fully on their members' registration and disciplinary concerns.

8.6 Non-medical representation

Lay representation on professional councils is not a new concept. Many, although not all, councils have some proportion reserved for lay members. Yet this representation is often nominal and not properly representative of lay concerns. Increasingly, lay representation is seen as an important counter to professional vested interests but this can only function properly if such representation is seen as more than token. In the UK, for example, a number of newsworthy cases have led to calls for a majority of members to be appointed from outside the relevant professional community.

8.7 Scrutinising the disciplinary function of councils

It is acknowledged that the two main functions of medical councils—registration and discipline—should be seen as distinct roles and separated within the structure of the council. The registration fees that support most councils financially should never be seen to conflict with the need to discipline members. Consistent and regular scrutiny of the decisions and working of professional councils is one way of improving transparency and bringing these decisions to account. In most countries, this is probably not a role for a ministry to take on itself. Instead non-government organisations might be given a contract to carry out ongoing audits of the functions and decisions of professional bodies.

8.8 Certifying standards

Historically professional registration has tended to be primarily a one-off procedure. Although periodic renewal of certification has usually been required this has generally been automatic, largely as a way to collect registration fees. Increasingly, this situation is changing with practitioners being required to produce evidence that shows they have maintained and extended their competence in their particular specialty areas.

8.9 Regulating through disclosure of information

Given the importance of delivering quality services for the public, efforts are expected to be focused upon meeting the needs of the public. However it appears that engagement of service users and the public within the regulatory system is inconsistent across the countries. The use of lay representatives on assessment panels is the most prevalent public engagement approach, yet there is far less evidence of how the public perspective is captured and considered in setting standards. With regard to complaints there is a strong suggestion that professional councils can play an even greater role in regulation and that the practice of involving lay representatives on councils will improve transparency and objectivity in this area.

Information is an important aspect of any system of regulation. Without good data and sound analysis it is impossible to make any meaningful judgements about the quality of service. Independent information can be seen in its own right as a type of regulation since it empowers purchasers—individual consumers or third-party agents—to take market decisions on the services to be funded. It can be seen as a way of encouraging the principle of what Walshe calls tri-partism, where the beneficiaries of regulation are encouraged to participate with the regulator in overseeing the behaviour of the regulated (Walshe 2003).

It is increasingly recognised that providing information on the quality of services is important. A plethora of information sources are available that purport to offer independent advice on health care providers. Some of these, such as the Canadian Institute for Health Information, largely target health care purchasers. Others, such as the UK's Dr Fosters, focus on providing information to patients.

There is very little experience of systematically providing information to consumers in low-income contexts. Report cards in various countries have been shown to have some impact on quality as well as increasing consumer interest in services (Ensor and Weinzierl 2007). Whether information can be utilised effectively depends both on the way information is made available and on whether genuine choice exists. Yet there is also evidence that, given a little information, consumers in even relatively unsophisticated health systems do make complex and correct choices about where they obtain care (Leonard 2002). Testing out mechanisms for providing easily assimilated information to consumers, particularly in urban areas, could have substantive benefits.

8.10 Encouraging consolidated regulation

There is not always a clear demarcation of regulatory role and corresponding responsibilities between agencies. This is typically compounded by the evolving role of regulatory agencies and the burgeoning breadth of their responsibilities as a reaction to the ongoing changes in services, policy or regulatory intention. As a result, organisational configuration can often be complex and efforts duplicated, suggesting the need for a coherent strategic overview of the purpose, aim and roles of all parties involved. As an example, NHS QIS Scotland is the first health service in the world to introduce a systematic approach that involves NHS Scotland, Scottish Parliament, patients and professional bodies in their Patient Safety Programme. The regulation landscape can quickly become crowded and so coordination of agencies is paramount.

Regulatory systems are not always managed consistently, despite good intentions and known best practice. The administration of the regulatory system, effective joint working and the use of an agreed regulatory standard or benchmark have all been noted as important factors that improve the coordination and effectiveness of regulatory agencies. A consistent approach to managing regulatory bodies within a cohesive system is required so that effort is directed and coordinated across agencies. Clear leadership is indicated, focusing upon the outcomes of regulation rather than the processes to deliver improvement.

One of the problems with health care regulation is that regulatory actors often only control one aspect of the care process. So, for example, medical or nursing councils control one profession; licensing authorities control particular facilities, medicine agencies control the quality and availability of one input. If done well such regulation can raise the standard of these particular elements of health care but may not ensure the overall provision of good-quality services that are made up from a number of different elements. In some cases the overall cohesion of service delivery is so important it is necessary to establish an agency that focuses on the service as a whole. One such example is organ donation in Thailand. This had been the responsibility of the Thai Medical Council. Laws were fragmented since they related to different aspects of service inputs (e.g. practitioner standards, health and safety) rather than the service as a whole (Tungsiripat and Tangcharoensathien 2005). Altogether seven organisations were found to have a medium or high interest in the issue. As a consequence of the review, responsibility for the programme was given to the organ donation centre because it was seen as a body that would focus on the service in its entirety.

8.11 Lack of active enforcement

One of the most striking aspects of the review was the limited examples available of active enforcement. These were largely restricted to the use of practitioner reviews (and rare examples of withdrawal of licence), further investigations and repeat assessments. Rather, assessment has been used to clarify, encourage and plan incremental improvements and the use of sanctions has been limited. This is in contrast to advice given that, when establishing a regulatory culture, it needs to be clear, directive and decisive. This difference between practice and opinion could be explained by the progressive culture of regulation within the developed countries that reflects common organisational life cycles. Effort, focus and direction are required at ‘start up’, to be replaced by a supportive and delegated managerial approach once the establishment of structure and systems is achieved. Indeed we have noted that, in established regulatory systems, the responsibility for regulation and self-assessment is clearly expected at the front line of services and the onus of demonstrating compliance is on service providers.

In contrast, evidence of rewards for meeting standards was far more readily available with the use of accreditation, league tables, best-practice statements, learning points and beacon sites being typical examples. As noted earlier, the use of enforcement was far less evident and there is scope for strengthening the application of sanctions. The revocation of licences is rare and there are suggestions that professional councils can protect members rather than reprimand them in cases of malpractice.

9 Conclusion

The paper has not sought to identify a single system of regulation as an exemplar but rather has highlighted successful aspects and difficulties experienced within established systems, to inform the design and delivery of regulation in low-income countries. Regulation covers a broad spectrum of health system activity and models vary significantly across mid-higher income countries although common themes are apparent.

Government responsibility for regulation is changing dramatically. Increasingly Government sees its function as one which ensures consistent and transparent standards across the sector. Where responsibilities are devolved, there is a need to ensure that this does not lead to uneven application of rules and perpetuation of vested interests. The increasing use of outside agencies as inspectorates to ensure evidence is collected in compliance with standards could help to relieve over-burdened ministries. Yet it is important that such practice does not lead to rent-seeking (corrupt) behaviour by public officials eager to extract benefit from contracts with potential inspectors.

The greater involvement of civil society in the regulation of health services, as seen in the increasing lay representation on medical councils, is an important trend. In low- and middle-income countries the participation of civil society is often seen as confrontational as newspapers, for example, bring to public attention incidences of poor public (or private) sector practice. Greater civil society involvement in the health systems of care could help to generate a more positive participation and introduce Walshe's 'tri-partism' in regulation.

Accreditation is becoming a popular regulatory model. To be effective, accreditation requires both objective assessment and dissemination of results. The limited use of enforcement revealed by the study implies that the use of accreditation could become a particularly strong regulatory lever that engages and informs consumers. Government's role in accreditation requires careful thought since it is clear that simply allowing the market to choose and apply standards does not guarantee consistent or even any application of standards.

As the practice and complexity of regulation increases, so the costs increase. The benefit of services that are safe, effectively managed and appropriate to the needs of users cannot only be measured in financial terms; however, the diversion of resources from delivering services to regulating them should be avoided. The inputs of regulation need to be proportionate to the outcome achieved and the harmonisation of regulatory practices and partners, working within a clear and transparent system, should go some way to achieve this. It is hoped that achieving a balance of costs and benefits can be influenced by the adoption of the best practices and advice offered by the participating countries in this study. Establishing regulatory systems requires a phased approach that takes account of the culture and stage of regulatory development, understanding where the most impact can be made, and also creates a culture of expectation and vigilance of both the consumer and service provider.

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