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Regulating the quality of health care: Lessons from hospital accreditation in Australia and Indonesia

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SUMMARY

Regulation of the quality of care is a key challenge for governments, particularly because of the complexities of defining and measuring quality. However, with the introduction of national health insurance schemes and the move towards universal health coverage, there is increasing recognition of the need to address quality of care as part of these reforms.

Hospital accreditation has been established in many high-income countries, and some low and middle-income countries (LMICs), as an approach to improving the quality of care that combines the two elements of quality assurance and quality improvement.

While hospital accreditation was originally introduced and managed as a professional and industry voluntary self-improvement initiative, recent reforms, such as mandatory requirements, have tended to increase government control of accreditation schemes, and to shift towards a more explicit regulatory role.

This paper builds on the analysis and review of hospital accreditation systems and recent reforms in Australia and Indonesia, to examine the questions: To what extent have these reforms shifted accreditation towards a more regulatory role? What issues have arisen in using accreditation as a regulatory approach in the context of low and middle income countries (LMICs) ?

In analysing accreditation programs from a regulatory perspective, we use the responsive regulatory framework developed by Ayres and Braithwaite in 1995. This framework views regulation as a series of regulatory actions or tools of varying degrees of intervention and cost, arranged in the shape of a pyramid. At the base of the pyramid are the least interventional and costly activities, such as self-regulation and persuasion, while progressively more intensive and costly interventions occupy successive levels of the pyramid. At the apex are the sanctions and ruinous powers available to government. This approach proposes that regulation should focus on low cost and low intervention activities at the base of the pyramid, and only progressively escalate if these activities fail to have the desired effect.

Hospital accreditation programs in Australia have a long history, with a range of programs provided by independent organisations, such as the Australian Council for Healthcare Standards (ACHS) since 1974. However, despite high levels of voluntary participation, studies in the 1990's identified high rates of medical errors and adverse events, resulting in significant costs. Review of the accreditation system identified problems such as the increasing complexity and cost of compliance with standards, the resultant significant implications for government expenditure, and the lack of accountability to government or to the public.

The Council of Australian Governments (COAG) introduced reforms progressively from 2000, in particular, the establishment of a new independent agency, the Australian Commission on Safety and Quality in Health Care (ACSQHC). This agency took responsibility for the determination of service standards, thus separating this function from the measurement and assessment of performance, which was still undertaken by independent accrediting organisations. In addition, reforms increased the level of reporting on accreditation assessments to government and the public, and introduced mandatory accreditation to be regulated at state government level. From the perspective of responsive regulation, the reforms created a meta-regulatory level, and strengthened accountability to government and the public.

In Indonesia, hospital accreditation had only been relatively recently introduced, through the establishment of a government agency, the Commission for Accreditation of Hospitals (KARS - Komisi Akreditas Rumah Sakit) in 1995. However, the accreditation program tended to focus on management processes rather than clinical care, and had only achieved low levels of voluntary participation, and little clinician engagement. The Hospital Law of 2009 introduced mandatory accreditation, strengthened the role of KARS in setting standards and assessing hospitals, and established new hospital performance oversight bodies at provincial and national level (Supervisory Board for Hospitals - BPRS - Badan Pengawas Rumah Sakit). These reforms also demonstrated a shift towards a more explicit government regulatory approach, but with a greater role for government in actual provision than in Australia.

The greater role for government reflects some of the implementation challenges in LMICs, particularly the low levels of clinician engagement and understanding of accreditation, and the absence of non-government accrediting bodies such as in Australia. In the

absence of professional or non-government capacity, government has had to take more of an implementing and capacity building role.

The examination of issues and reforms in the two countries demonstrates the usefulness of the responsive regulatory pyramid in analysing complex regulatory strategies such as accreditation, where there are multiple inter-connected levels. The regulatory perspective demonstrates how governments in both countries have strengthened the regulatory and accountability aspects of the accreditation program, confirming a shift noted in the literature.

As an approach to regulate quality of care, accreditation programs offer a number of potential benefits to policy makers in LMICs. These include:

- Engaging the medical profession and industry in self regulation, thus reducing costs to government
- Combining incentives and rewards with sanctions for non compliers, reducing the need for regulatory action by government
- Supporting increased accountability by the non-state sector to government

However, accreditation programs are complex and involve a range of institutions and processes which need to be aligned. This presents a number of challenges in a LMIC context, including:

- Difficulty of engaging clinicians and building capacity for self motivated quality improvement
- Building capacity for management and delivery of accreditation activities in professional or industry bodies
- Governance to address potential conflicts of interest for professional and industry bodies undertaking self-regulatory roles
- Aligning financial payment mechanisms to provide reinforcing positive incentives for participating hospitals
- Clarifying roles and building capacity of decentralized levels of government to oversight and ensure compliance with the regulatory pyramid.

Accreditation is a good example of a responsive regulatory pyramid, but application in LMICs requires greater initial government involvement, which may undermine effectiveness of the self-regulatory elements. While accreditation provides a framework to engage clinicians and health care facilities in quality assurance, and thus supports the regulation of quality of care, more evidence is needed of the effectiveness of accreditation on improving the quality of care through motivating quality improvement efforts, particularly in the LMIC context.

INTRODUCTION

Regulation is an often neglected aspect of health systems that has been identified as particularly important for mixed public-private health systems in low- and middle-income countries (LMICs), where market failures need to be addressed (Harding and Preker 2003; Lagomarsino, Nachuk and Kundra 2009). But many commentators have noted weak regulatory capacity, weak institutions and lack of priority given to regulation in LMICs (Harding and Preker 2003; Teerawattananon, Tangcharoensathien et al 2003; Kumaranayake, Lake et al 2000; Ahmer 2011) as well as in high income countries (Grabosky and Braithwaite 1986).

One aspect of health care that requires regulation is quality (Harding and Preker 2003). Quality of care in hospitals has been identified as a key focus in high-income countries, such as Australia, because of evidence of a high rate of inappropriate care, variations in the incidence of procedures unrelated to differences in patterns of disease, and high expenditure on treatment of adverse events and medical errors (Fletcher 2000; ACSQHC 2010).

Quality of care has also been highlighted for attention in LMICs, as one of the key elements of the approach to universal health coverage. The World Health Report of 2010 identified control of inefficiencies and wastage through better quality care as the third element, alongside financial protection and access to health services, in achieving universal health coverage (WHO 2010).

However, quality of care is difficult to define, has multiple dimensions and is difficult to measure (Woodward 2000). These dimensions include equity, accessibility, acceptability, appropriateness, comprehensiveness, effectiveness and efficiency (Woodward 2000; Fletcher 2000). As a result, quality might be said to be in the eye of the beholder. While some have defined quality as 'the degree of excellence, the extent to which an organisation meets clients' needs and exceeds their expectations' (Shaw 2004), others have suggested a simpler and more direct statement such as 'Doing the right thing, to the right person, at the right time, at the lowest cost' (Woodward 2000).

Two main approaches have developed towards addressing quality of care: quality assurance and quality improvement. While quality assurance is about meeting agreed standards, quality improvement is a continuous process of raising the standard of care. Quality assurance focuses on defining minimum standards for the provision of care and assessing the extent to which the standards are fulfilled. Where standards are achieved, no further action is required (Woodward 2000). Licensing, which requires organisations to meet minimum standards of facilities and availability of staff, uses a quality assurance approach.

Quality improvement is based on a continuous process of measuring performance, identifying strategies to improve performance, implementing the strategies and evaluating the results. This approach suggests that quality cannot be 'inspected into' a health care organisation, but involves changes in the attitudes and practices of managers and staff, towards what has been termed a 'quality culture'. This is a change in the organisation culture and development of a culture of transparency and acceptance of personal and corporate responsibility among management and clinical staff (Shaw 2004).

Accreditation has been commonly used as an approach to monitor and improve quality of care in hospitals (Ovretveit 2003). Initially introduced in the US as an approach by the medical profession to demonstrate providers with higher quality and provide them with a marketing advantage (Scrivens 2002; Shaw 2003), it has been adopted and adapted in many countries. The key characteristic of accreditation is the 'public recognition of the achievement of a ... standard', through 'independent external peer assessment' (Shaw 2004).

An accreditation program usually consists of the following components (Shaw 2004):

- Establishment of agreed standards expected of health service organisations.
- Development of a process for measurement of the provision of services by health service organisations wishing to be accredited. This is usually undertaken through a survey by peer surveyors.
- Conduct of the survey. This usually involves initial preparatory activities by the health service

organisation, such as documentation of current quality improvement, followed by an assessment by the surveyors of the organisation's compliance with the standards.
- Award of accreditation by the accrediting organisation, which may be for variable periods of time, depending on the level of compliance with standards, and reporting of the results to relevant authorities and to the general public.
- Evaluation and monitoring of the accrediting organisations, to ensure that they maintain credibility and legitimacy in the conduct of accreditation.

Accreditation recognises that quality must be both assured and improved (Woodward 2000), and combines elements of both quality assurance (in terms of assessment against standards) and quality improvement (in terms of changing of culture towards more focus on quality).

While all accreditation programs contain these basic steps, the design and operation of accreditation varies in different countries, adapting to the different regulatory, institutional and cultural contexts (Shaw 2003).

Scrivens (2002) identified a range of attributes of the accreditation system that could be varied in different contexts. These include:
- extent of government intervention and the independence of the regulatory agency;
- voluntary or mandatory participation;
- confidentiality or the extent to which results are made public;
- mechanisms for action on findings;
- extent of rules-based (process and procedure focus) or outcomes-based standards;
- extent of regional autonomy and decentralisation or central control;
- extent to which standards encourage continuous quality improvement and focus on appropriate level of performance, not just on inspection and satisfying minimum standards.

Changes in these parameters can shift an accreditation program from one largely outside of government and controlled and managed by the medical profession, to one controlled and managed by government, using standards it sets.

With increasing awareness of the frequency of medical errors, adverse events and their high cost, particularly in hospital services, governments are no longer willing to leave the management of the quality of care in the hands of the medical profession (Healy and Braithwaite 2006). Parallel with this has come an increased focus on measurement of the outcomes of health care in terms of patient satisfaction and health status, rather than the measurable aspects of facilities, staffing and processes (Woodward 2000).

As a result, a number of governments have instituted reforms to hospital accreditation that have tended to increase the extent of government control and accountability. This raises the question: To what extent have these reforms shifted accreditation towards a more regulatory role? What issues have arisen in using accreditation as a regulatory approach in low and middle income countries?

Recent reforms to the hospital accreditation system in Indonesia and Australia provide an opportunity to explore these questions by examining and comparing the problems that were identified with the existing systems, and how these were addressed through reforms.

This paper builds on the analysis and review of hospital accreditation systems in Australia and Indonesia undertaken by a group of Indonesian policy makers during a study visit to Australia in 2012, and their discussions with Australian hospital accreditation policy makers. The paper aims to address the following questions:

(1) What were the problems identified in Indonesia and Australia, in the hospital accreditation system, and what reforms were introduced to address them?

(2) Examining these problems and reforms from a regulatory perspective, do these changes suggest a more regulatory function for the hospital accreditation system?

(3) What issues have arisen in the implementation of these reforms in Indonesia, and what lessons can we draw about the use of hospital accreditation as a regulatory approach in a LMIC?

METHODOLOGY

In examining hospital accreditation from a regulatory respective, this paper adopts the framework of responsive regulation introduced by Ayres and Braithwaite (1995). Their approach seeks to link a range of regulatory strategies and mechanisms into an effective and efficient regulatory regime. It has been applied in a variety of policy areas, including in the health sector, and has been recommended for addressing patient safety and quality of care (Healy and Braithwaite 2006).

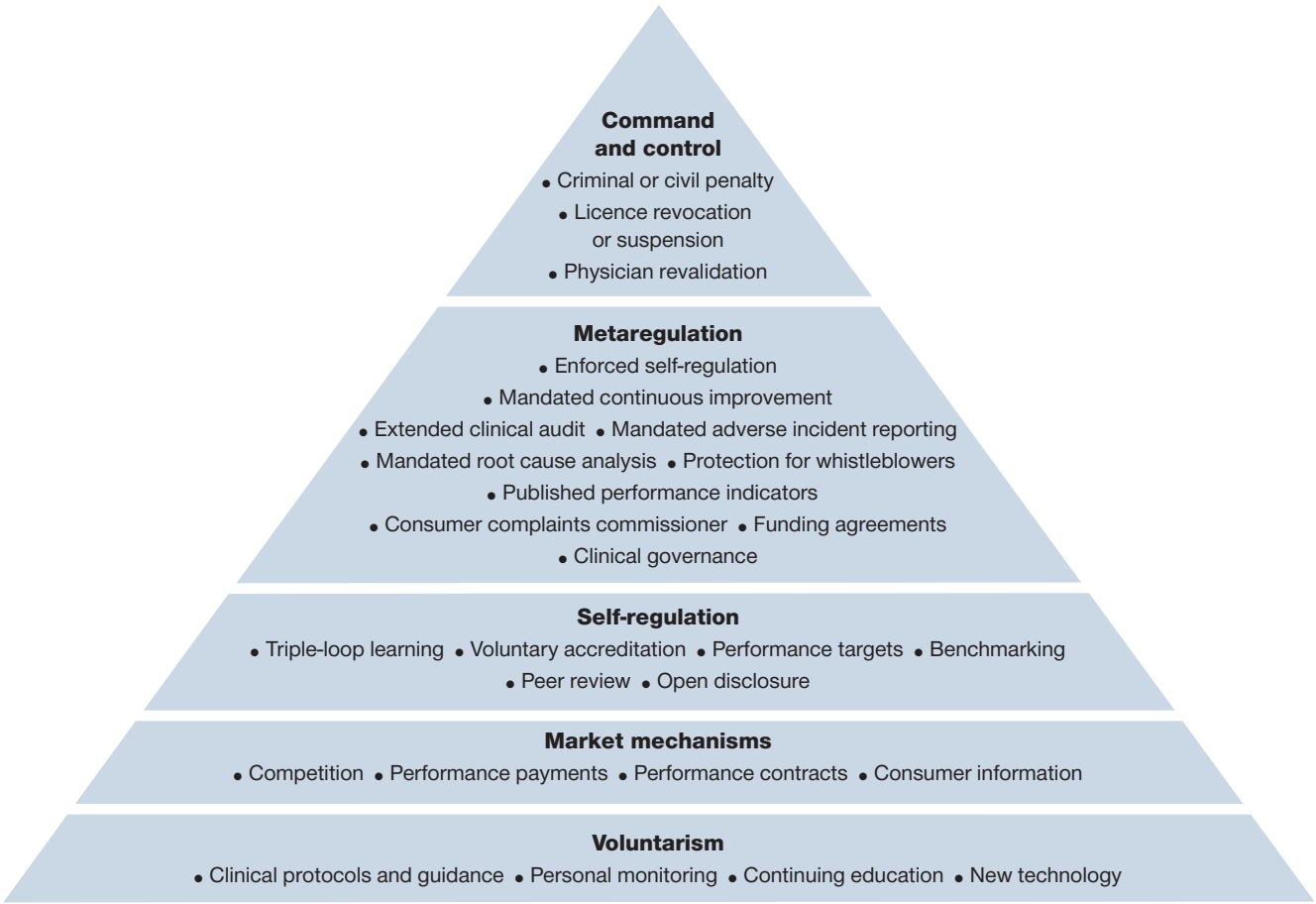
Responsive regulation argues that regulators are more likely to succeed if their strategies are responsive to the culture of those being regulated. Regulation begins with persuasive efforts and then applies more punitive deterrence in accordance with the response and behaviour of those regulated.

The key elements of the responsive regulatory approach are a series of regulatory actions or tools of varying degrees of intervention and cost. These are arranged in a pyramid, beginning with those of least intervention and cost—relying more on self-regulation and persuasion—and progressively increasing in extent of intervention and deterrence.

Empirical research in a number of sectors has established that the occasional exercise of ruinous powers at the apex of the pyramid drives self-regulatory activity at the base, with successive layers supporting and complementing those below. Multiple layers are needed: 'a single regulatory mechanism is seldom sufficient as the weaknesses of one mechanism must be complemented by the strengths of another' (Healy and Braithwaite 2006).

The regulator maintains the capacity for escalation to the level above if persuasion fails, up to the apex of

FIGURE 1: REGULATORY PYRAMID AND EXAMPLES OF SAFETY AND QUALITY MECHANISMS



Source: Braithwaite et al, 2005

the pyramid where the ultimate sanction is removal of licence or restriction on service provision.

See Figure 1 for a generic example of the pyramid applied to safety and quality mechanisms in health care (Healy and Braithwaite 2006).

Accreditation demonstrates many of the features of responsive regulation, such that the components of accreditation described above can be mapped against the levels of the regulatory pyramid, as illustrated in Table 1.

The table follows quite closely the application of the regulatory pyramid to patient safety mechanisms in Healy and Braithwaite (2006), with one notable difference. We found it useful to separate public information as a specific regulatory strategy and to place it just above voluntary regulation, rather than include it as just an economic instrument, as was done by Healy and Braithwaite. This approach follows the advice of Ensor and Wienzierl (2007) on the importance of using consumer voice through the provision of information as a low cost and empowering regulatory intervention.

TABLE 1. LEVELS OF REGULATORY PYRAMID COMPARED TO COMPONENTS OF ACCREDITATION

Level of pyramid	Regulatory role	Accreditation role
Base	Voluntary or self-regulation	Professional engagement in quality improvement programs
Level 2	Public information	Informed public chooses accredited facilities
Level 3	Professional self-regulation	Accrediting agencies assess and accredit facilities
Level 4	Financial/ economic	Insurance agencies make payments only to accredited facilities
Level 5	Meta-regulation	Independent agency sets standards and oversees accreditation
Apex	Government sanctions	Government mandates regulation for permission to operate

Based on Healy and Dugdale (2009)

Using this framework, the institutions and their roles at the different levels of the pyramid were identified in Australia and Indonesia, based on reports and descriptions of the accreditation systems, and policy and regulatory documents describing the systems, institutions and roles.

Following this, the problems and issues identified in reviews of hospital accreditation and as targets for reform, were aligned with the appropriate level of the accreditation regulatory pyramid. Problems and issues were identified through reports and review papers from both countries, and by the issues raised by Indonesian and Australian policy makers in discussions during the study visit.

Finally, the reforms, including creation of new institutions, changes in institutional roles and new processes or procedures introduced in either country, were also aligned with the accreditation regulatory pyramid and, where possible, to the problems they were purported to address. This was, again, based on the review documents and also on the descriptions of new policies and institutions in legal and regulatory documents.

FINDINGS

Accreditation in Australia

Australia has a mixed public-private health system, health being a shared responsibility between the national (Commonwealth) and state or territory governments. The Commonwealth Government has responsibility for the national health insurance scheme (Medicare) and the Pharmaceutical Benefits Scheme, while the state and territory governments have responsibility for public hospitals and population health programs (with joint funding from the Commonwealth). Primary health care is delivered through a mix of private providers (general practitioners), financed through Medicare and user fees, and state government-funded community health centres. Of the $5479 health care expenditure per capita in 2009-10 (equivalent to 9.4 per cent of GDP), government provided 70 per cent and private sources 30 per cent, with 17.5 per cent as out-of-pocket expenditure (AIHW 2011a).

In 2010-11, there were 1340 hospitals in Australia, 752 public and the remainder private, including private day

clinics. These hospitals provided about 3.8 beds per 1000 population and consumed about 50 per cent of total health expenditure (AIHW 2011a, 2011b).

Prior to reforms introduced in 2005, hospital accreditation was largely managed outside government. A number of non-government accrediting agencies provided competing programs, notably the Australian Council on Healthcare Standards (ACHS) in the hospital sector and the Quality Improvement Council (QIC) for community facilities. Under these programs, 98 per cent of hospitals were accredited (AIHW 2011b).

The ACHS is an independent not-for-profit company established in 1974 by a group of industry organisations, including professional colleges, consumers, peak industry bodies and government. It provides an accreditation program which combines the Evaluation and Quality Improvement Program (EQuIP), consisting of standards and a review process, with the Performance Outcome Service program of clinical indicators. Organisations using the ACHS accreditation program undergo self-assessment, followed by an organisation-wide survey undertaken by peer surveyors and administered by ACHS.

QIC accreditation provides a flexible approach, which can be applied across a variety of health and community organisations. Its standards are available in modular form, including a generic core set, and complementary service delivery modules for specific service types, such as primary health care, home-based care or alcohol, tobacco and drug services. QIC accreditation begins with an internal assessment, followed by a review carried out by a team of external peer reviewers (Swerissen, Macmillan and Skok 2000).

Despite this system, increasing government and public concern was expressed for the safety and quality of health care in Australia particularly following the 1995 Quality in Australian Health Care Study, which found a higher than expected number of hospital admissions associated with adverse events. These studies identified the risks of harm from health care range from 1:2 (ICU care) to 1:300 (being harmed while in hospital) and 1:854 (dying from medication error in hospital), and estimated that adverse events contributed an additional 15-20 per cent to costs of health care (ACSQHC 2010). At the same time, there was concern in health management circles that hospital doctors were only engaging in a very limited way with the ACHS accreditation processes

In response, a number of reviews of the system of health care quality were undertaken in early 2000 (Fletcher 2000; Swerissen, Macmillan and Skok 2000; ACSQHC 2010). These reviews identified issues including a proliferation of accreditation standards, a variety of accreditation programs with different requirements and a lack of accountability or transparency to the public or government.

In 2005, reforms to hospital accreditation were introduced through a high level agreement between state and Commonwealth governments at the Council of Australian Governments (COAG). The reforms established new independent government-funded agencies with responsibility for national oversight of hospital performance. These included the Australian Commission on Safety and Quality in Health Care (ACSQHC), with a role of developing and overseeing a national framework for safety and quality, and national safety and quality standards; and the National Health Performance Authority (NHPA) with responsibility for developing national performance standards and compiling and reporting on hospital performance against these standards.

Using the responsive regulatory pyramid, the issues and reforms can be considered at each level (summarised in Table 2):

(a) Voluntary initiatives. The long history of work of the ACHS has progressively built the level of engagement of the health professions in quality improvement initiatives, and encouraged high levels of participation in accreditation programs on a voluntary basis.

(b) Public information. Because accreditation was largely an arrangement between individual hospitals and the accreditation provider, information on accreditation status or any issues identified was not readily available, either to the general public or to the state authorities responsible for hospital oversight. The reforms required public disclosure of accreditation status and reporting of accreditation outcomes to the ACSQHC and the state regulatory authorities.

TABLE 2: ISSUES AND REGULATORY RESPONSES IN AUSTRALIAN HOSPITAL ACCREDITATION

Level	Institutions	Issues	Responses/reforms
Base Voluntary	Hospital quality improvement programs; clinical governance	Strong professional & organisational engagement	
Level 2 Public information	Consumer organisations; public media	Information on accreditation status not readily available	Increased public availability of accreditation & hospital performance information
Level 3 Self-regulation	Accrediting agencies (ACHS, QIC)	Multiple agencies & standards; compliance costly; complex standards	Establish meta-regulator & single national standards
Level 4 Financial	Insurance agencies; state health departments	Payments/state government funding require accreditation	State given more control over standards and expenditure
Level 5 Meta-regulation		No national meta-regulation institution	ACSQHC established; new national standards with a focus on patient safety
Level 6 Sanctions	State & commonwealth governments	No reporting to health ministers; no control or oversight of costs; varying accreditation requirements	Increased accountability for accreditation & hospital performance to commonwealth and state governments; mandatory accreditation

(c) Self-regulation. Issues identified in the reviews included the proliferation of different standards and accrediting programs, the lack of a consumer focus in the standards and the lack of accountability to regulatory authorities for action if standards were not met. The reforms established new national standards, which had a much stronger focus on patient safety and which were mandatory for all accreditation programs. However, accreditation continues to be provided by a range of independent providers.

(d) Financial incentives. Prior to the reforms, most private insurance agencies required hospitals to be accredited in order to receive payment for services to insured patients. A key issue for state health authorities had been that previous accreditation programs introduced requirements for state hospitals that required state funding, but over which the state authorities had no control. The reforms reinforced state regulatory control over hospital expenditure and gave government greater control in determining the standards and requirements for accreditation.

(e) Meta-regulation. This was the level at which the reforms introduced new agencies, the ACSQHC and the NHPA, and a national framework and standards, where previously there had been no national institutional allocation of responsibility or standards.

(f) Sanctions. The reforms also introduced clearer accountability and authority for government agencies in the regulation of hospital accreditation. The governments agreed to require mandatory accreditation of all hospitals from 2012, with the authority for regulation of this requirement the responsibility of state government. Both the NHPA and the ACSQHC report to the Australian Health Ministers' Advisory Council as part of the COAG.

Applying the issues identified and reforms undertaken to the regulatory pyramid demonstrates that the reforms have particularly strengthened the higher levels, by establishing a meta-regulatory level and strengthening the role and capacity of government to apply sanctions at the apex of the pyramid.

Accreditation in Indonesia

Indonesia also has a mixed public-private health system and collective government responsibility for health across national and regional jurisdictions. However, with a population of 240 million (more than 10 times that of Australia's 23 million) and a GDP per capita of $2946, expenditure on health is much lower, at $77 per

capita (2010), equivalent to 2.6 per cent of GDP. The proportion of contribution from government is also lower (48 per cent) than in Australia, while the proportion of private out-of-pocket expenditure, 38 per cent, is nearly double the proportion in Australia (WHO 2012).

The Indonesian system of government is a devolved rather than federal system, with all three levels of government having significant responsibilities for health care and regulation of hospitals. The national government is responsible for regulation of central hospitals, provincial government for provincial hospitals (both government and private) and district and municipality governments for their level of hospitals (government and private).

In 2012, of the 2081 hospitals registered in Indonesia, 1200 or 58 per cent were in the private sector, while the remainder were in the government sector (Direktorat Jeneral BUK 2012). The ratio of hospital beds to population, 0.9: 1000, is much lower than Australia's 4: 1000.

Primary health care is delivered through a network of 9321 community health centres (*puskesmas)*, as well as through the part-time private practice of doctors and midwives employed in state facilities (Kementerian Kesehatan 2012).

Various forms of health insurance covered approximately 63 per cent of the population in 2011. These included the national social health insurance (*jamkesmas*) covering 32 per cent, local government health insurance (*jamkesda)* (13.5 per cent), other state insurance schemes (9.5 per cent) and private insurance (7.7 per cent) (Coordinating Ministry of Social Welfare, 2012).

A program for accreditation of hospitals began in 1995. The national hospital accreditation committee (KARS) was established in 1998 to manage the program. Standards were developed based on the EQuIP program from ACHS, modified with elements of programs delivered in Indonesia. The program was voluntary and had a very low coverage.

The Association of All Hospitals in Indonesia (PERSI - Perhimpunaw Rumah Sakit Seluruh Indonesia) provided some support to the accreditation program by providing information, education and promotion to its members. Government oversight was through the regulation sub-directorate in the Ministry of Health (MoH), and through provincial and district government health offices. However, the main role of government health departments was to register and provide licences for the construction and operation of hospitals. Few provincial government health offices were actively engaged in or promoting hospital accreditation, although some had established health regulation units (for example the city of Yogyakarta).

Research by Soepojo, Koentjoro and Utarini (2002) identified several issues in hospital accreditation system at that time, including:

1. KARS had limited credibility as an accrediting agency.
2. Hospitals complained of inconsistencies in the assessments and advice provided by different surveyors, and questioned surveyor qualifications and quality.
3. Accreditation standards were focused mainly on input and administration, with little attention to patient satisfaction or clinical outcomes.
4. The program focused the hospital's efforts on gaining accreditation status, rather than on ongoing quality improvement.
5. Hospital directors reported little impact of the accreditation program on hospital performance and little incentive to participate in accreditation.

Indonesia commenced a process of reforming and strengthening regulation of the health system from 2000. An initial aspect was to strengthen the registration and licensing of doctors through a new law on medical practice (UU 29/2004). This was followed by new laws on health (UU 36/2009) and on hospitals (UU 44/2009). The new hospital law introduced reforms to the hospital accreditation program, by requiring all hospitals to be accredited (clause 40) by an independent accrediting agency.

These new legal provisions increased the role and responsibilities of KARS. KARS is nominally an independent agency, but operates as a semi-autonomous unit of the Ministry of Health, with the following responsibilities:

- development of national standards for accreditation (in conjunction with the regulatory unit of the MoH);
- development and provision of accreditation educational materials and technical support;

- recruitment, training and management of accreditation surveyors;
- determination of accreditation status and reporting it to the MoH;
- provision of recommendations to hospitals to address any deficiencies identified during the accreditation process.

The Hospital Law of 2009 also provided for the establishment of independent national and provincial hospital oversight boards (BPRS), which report directly to the president and provincial governors respectively. The role of these oversight boards is to receive reports from hospitals on their performance and provide advice to the president and governors on measures to improve hospital performance.

During 2010, the Ministry of Health and KARS reviewed the existing accreditation standards, and introduced a new set, based on the US Joint Commission International (JCI) framework rather than the ACHS framework. The new standards are divided into 22 sections, grouped under four headings: patient-focused services, hospital management, patient safety and the Millennium Development Goals.

The institutions of the Indonesian hospital accreditation system, and the issues and policy responses identified by this study, were mapped against the responsive regulatory pyramid as in Table 3:

(1) Voluntary regulation. Medical professionals in hospitals, through various internal hospital structures, are involved in voluntary quality improvement activities, such as the Professional Quality, Patient Safety Team (KKPRS - Komite

TABLE 3. ISSUES AND REGULATORY RESPONSES/RECOMMENDATIONS FOR INDONESIAN HOSPITAL ACCREDITATION

Level	Institutions	Issues	Responses/reforms
Base Voluntary	Medical and health professionals working in public and private hospitals	Limited engagement and support for quality improvement; professional associations' limited focus on this issue	Recognition that accreditation needs to link to quality improvement; KARS to develop materials & training; PERSI to encourage medical and health professionals to participate
Level 2 Public information	Consumer organisations; public media	Little public information available on hospital quality or standards; public not accustomed to expect or demand high quality	No specific policy or recommendations
Level 3 Self-regulation	KARS; international providers (JCI, International Standards Organisation (ISO)	KARS has low credibility and capacity, has not been accredited as an accrediting agency; complaints about lack of consistency in accrediting	KARS required to obtain accreditation as an accrediting agency; KARS has additional resources to improve accrediting
Level 4 Financial	*Jamkesmas*/ *jamkesda*/ other insurers; provincial & district governments	Insurers have not required accreditation; provincial & district governments have not required accreditation	New health insurance agency has opportunity to require accreditation; role of provincial & district governments to be clarified
Level 5 Meta-regulation	KARS; Regulatory sub-directorate; MoH	Appropriateness of standards adopted from ACHS; lack of policy attention to accreditation as a system	KARS and regulatory sub-directorate revise standards; regulatory unit to develop national framework and guidelines for roles of province and district
Level 6 Sanctions	National government; provincial and district governments	No requirement for accreditation; low participation levels; provincial & district government low involvement; poor compliance with licensing requirements	National, provincial and district governments have responsibility to license establishment & operation of hospitals; new national and provincial oversight boards to advise on hospital performance.

Keselamatan Pasien Rumah Sakit), Team of Prevention and Control of Antibiotic Resistance (PPRA - Program Pengendalian Resistensi Antimikroba), and Infection Prevention and Control (PPI) Team. However, hospital directors in the pre-visit study reported that, in general, doctors working in hospitals, even those in charge of departments, were not very supportive of accreditation.

(2) Public information. While some information, such as the number of hospitals accredited, is available publicly, information on which hospitals are accredited or individual hospital performance is not publicly available, and there are currently no policy plans or recommendations to address this.

(3) Self-regulation. KARS is the main provider of hospital accreditation services, but functions more as a semi-autonomous government unit than as a peer organisation. However, there are close connections with PERSI, the chair of PERSI also being the chair of KARS. The new hospital law has strengthened and increased the role of KARS, and required it to obtain international accreditation.

(4) Financial. Currently there do not appear to be many financial incentives that support hospital accreditation. Hospital directors in the pre-visit study reported that accreditation status did not appear to effect insurance payments or to improve public confidence and demand, although only accredited hospitals can participate in the government health insurance scheme (Jamkesmas). The proposed move towards universal coverage and the establishment of a national health insurance agency (BPJS - Badan Pelaksanaan Jaminan Sosial) will provide further opportunities to use financial incentives to encourage accreditation.

(5) Meta-regulator. This role is shared between the regulatory unit of the Ministry of Health and KARS itself. The two agencies have worked together to develop the revised national hospital quality and safety standards and to strengthen the implementation of hospital accreditation. However, the MoH regulatory unit has responsibility for overall monitoring of quality and patient safety, including developing the recommended national framework strategy.

(6) Sanctions. While the national government and Ministry of Health set out the national regulations, national, provincial and district governments have separate responsibilities for the licensing of hospitals at different levels. There appears to be reluctance to sanction non-compliers. New national and provincial oversight boards will be established to monitor hospital performance and advise national and provincial governments.

Implementation issues

Following these reforms, KARS increased its provision of accreditation services and, by December 2012, was able to report that 969 (47 per cent) of hospitals had been accredited. KARS has also begun the process of obtaining accreditation as an accreditation provider through the International Society for Quality in Health Care (ISQua). The Ministry of Health recently issued further guidance for the roles and functions of KARS and other institutions involved in the process of hospital accreditation (*Permenkes* 12/2012) and set a target of 90 per cent of all hospitals to be accredited by January 2014.

In order to examine constraints on implementation, a group of national and provincial hospital regulators and those involved in managing the Indonesian hospital accreditation system visited Australia in September 2012 and consulted with Australian hospital regulators and providers of hospital accreditation. Prior to the visit, researchers at the Universitas Gadjah Mada undertook a brief survey of regulators and hospital directors in four provinces (city of Yogyakarta, provinces of Central Java, East Java and East Kalimantan) to obtain their opinions on the current state of hospital accreditation. This study confirmed the earlier findings of Soepojo, Koentjoro and Utarini (2002), but also identified a number of issues hampering implementation (Utarini, Djasri, and Irfianti 2011; Djasri, Utarini and Hort, 2012):

(1) Fragmentation. A number of existing patient safety and quality activities, such as the National Committee on Patient Safety in the Hospital (KNKPRS - Komisi Nasional Keselamatan Pasien Rumah Sakit) and the national and provincial hospital oversight bodies (BPRS) have yet to be integrated into the accreditation structure.

(2) Lack of clarity on the role of provincial and district health offices in accreditation and quality programs. While several provinces have established quality

assurance teams, their role in relation to the management of hospital accreditation by KARS is not clear. At the same time, KARS as a national body, does not have any direct provincial or district representation.

(3) Lack of readily accessible materials and guidelines to guide the accreditation process and subsequent recommendations, particularly for clinicians. While KARS and PERSI have developed materials, these have not been updated or standardised, and are not readily available through the internet.

(4) The new more clinical indicators require greater involvement from hospital clinicians, yet accreditation tends to be seen as a management responsibility, and there is little clinician engagement or support

(5) Provision of licences to operate to hospitals that do not satisfy the minimum licensing requirements. Provincial and district health authorities responsible for licensing have, in some cases, issued licences to hospitals that have not fully satisfied minimum facility and staffing standards, often under local political pressure. Once licensed, the hospitals have little incentive to make the necessary investments. These, often small, hospitals will face challenges in achieving accreditation by the mandatory date.

DISCUSSION

Application of the Responsive Regulatory Pyramid to Hospital Accreditation

The responsive regulatory pyramid was useful in clarifying how the different elements of an accreditation program can contribute to an overall regulatory strategy.

It also demonstrated how the problems and issues identified, and the reforms undertaken in Australia and Indonesia, could be viewed as applying a regulatory approach to accreditation, and how other regulatory activities, such as financing and payment incentives, link to accreditation activities.

It suggests that reforms are likely to shift the hospital accreditation program towards a more regulatory approach and towards greater accountability to government. In particular, both governments introduced a mandatory requirement for accreditation, which entails an element of compulsion and potential sanctions, not previously included.

In Australia, the key problems identified in the existing professional hospital accreditation program related to concerns that the program was outside the control and oversight of government. The reforms strengthened the meta-regulatory function by creating a new meta-regulatory agency, the ACSQHC, and separating the meta-regulatory functions from delivery of accreditation services. The reforms also strengthened the role of government at the apex of the pyramid, and, especially in setting the standards for accreditation.

On the other hand, the problems identified in Indonesia related more to a lack of engagement or support from the medical profession, and a lack of capacity to manage and administer the accreditation program. The response has been to strengthen the role of government and its accreditation agency in establishing and operating the process. Reforms in Indonesia have also increased accountability to government through the establishment of national and provincial hospital oversight boards.

As government is the main funder of hospital services, these reforms are likely to increase the availability of the resources needed by hospitals to improve standards of care and achieve accreditation requirements. However, there is a risk that the greater emphasis on quality assurance and compliance with standards could lead to neglect of the links with engaging clinicians in quality improvement.

Implementation of Hospital Accreditation in a LMIC context

Accreditation is a complex process involving multiple institutions. Programs need to adapt to different institutional, political and economic environments. Implementation issues identified in Indonesia demonstrate how the different institutional and political context of a LMIC impact on the implementation and design of the program.

Institutional capacity and engagement of clinicians

A key institutional difference between the two countries was the level of engagement and capacity of health care providers, particularly the medical profession, in voluntary quality improvement. In Australia, the long-

running professionally managed accreditation program had built strong engagement and capacity among health care professionals to develop and apply quality improvement in their service delivery.

However, in Indonesia, quality improvement is a relatively recent program, and clinician engagement and understanding are much less than in Australia. As a result, the Indonesian program lacked non-government independent accrediting organisations such as exist in Australia, and the government had to take a more active role in the provision of accreditation and building clinician capacity and understanding of quality improvement.

This is likely to be a common situation in LMICs, where professional institutions are in general less well developed than in high income countries. It needs to be recognised that building clinician engagement in accreditation programs takes many years.

Roles of different levels of government

The other key implementation problem identified in Indonesia was the lack of active engagement of provincial and district governments, despite their having responsibility for funding and management of state hospitals in their areas, and for regulation of both state and non-state hospitals. This reflects the centrally driven nature of the program, and the lack of provincial and district institutional and regulatory capacity, as demonstrated by the licensing of non-compliant hospitals. It creates a challenge for the central agency, KARS, which does not have regional branches, in managing implementation across 33 provinces and 530 districts and cities.

While the Australian system also has health as a responsibility of state governments, the reforms clarified and strengthened the role of state governments as regulators of hospital performance, thus engaging state governments firmly in the accreditation program. However, in Australia, the central level could rely on the capacity and quality of regulatory functions at state level, which is much more variable across provinces and districts in Indonesia.

Governance of the accreditation program

These implementation problems can be seen as relating to the broader issue of the governance of the accreditation program. Governance here refers to the allocation of roles and responsibilities, authority and accountability among the institutions involved.

The regulatory pyramid perspective demonstrates that the function of each level is dependent on the oversight, authority and accountability of the levels above. For example, as Healy and Braithwaite (2006) explain, the meta-regulator needs power to enforce self-regulation, to ensure the 'problem solving creativity of self regulation' and the assurance of minimum standards. This power is provided by government authority at the apex of the pyramid.

However, as critics have noted, the main problem that arises in poorly functioning responsive regulatory regimes is the failure to escalate to higher level sanctions when lower levels are not effective—due to lack of capacity, power or political support for the regulator (Baldwin and Black 2007). An important contributory factor is regulatory capture, where the interests of those regulated improperly influence the action of the regulator. This is recognised as a risk in collaborative regulatory regimes (Baldwin and Black 2007), especially where there is institutional weakness (Braithwaite 2006).

This may be particularly a problem in LMICs, where weak regulatory institutions, low capacity to enforce and regulatory capture have been frequently described (Kumaranayake, Lake et al 2000; Harding and Preker 2003; Teerawattananon, Tangcharoensathien et al 2003; Ahmer 2011).

Implications

Accreditation as a regulatory mechanism

There are clearly attractions for government in using accreditation as a regulatory mechanism, particularly in adapting it as a responsive regulatory approach. The responsive regulatory approach enables the combination of a range of mechanisms into a regulatory framework, which defines the roles of different players and how these roles complement and support each other.

This clarifies the need to align different mechanisms, such as financial incentives, with regulatory aims. This alignment and coordination among the regulatory mechanisms requires collaboration among the involved institutions and an overall governance mechanism to oversee and monitor institutional roles. However, the

layered structure of the pyramid provides some built-in accountability, as the roles of higher levels include oversight of lower levels; for example, the meta-regulator oversees and ensures accountability of self-regulators.

An important advantage is that this approach makes efficient use of low capacity in regulatory institutions by combining stakeholders and focusing limited state regulatory capacity where it is most needed (on those who do not respond) (Braithwaite 2006). It can also be seen as supporting the larger government role of developing democratic accountability and the shift in the role of government from 'command and control' to steward (Braithwaite 2006).

Problems in LMICs with low institutional/ regulatory capacity

This study also draws attention to challenges and risks with using a responsive regulatory approach in a LMIC. Some of these challenges relate to the low institutional capacity of professional organisations that could take a role in self-regulation, and the weak regulatory capacity of government, particularly sub-national (provincial and district) levels.

In particular, there is a risk of regulatory capture and failure of some institutions in the regulatory pyramid to undertake their regulatory role, due to inadequately managed conflicts of interest. Such failure could undermine the effectiveness of the system and emphasises the need for governance oversight of the whole system. Braithwaite (2006) speaks of networked governance involving non-state actors or civil society in oversight of regulatory performance.

However, challenges also arise from the overall political and regulatory context of LMICs. A responsive regulatory approach works best when the overall political and regulatory environment is supportive of compliance with the rule of law, recognition of public responsibilities and accountability of public and private institutions (Baldwin and Black 2007). This may not always be the case in LMICs.

Other challenges in the LMIC context include the difficulties of gaining clinician engagement and support for self improvement. Improvement in the quality of services requires the active engagement of the health care provider, and in the hospital context, of the clinicians as the head of the health care team. Developing this engagement and motivation has taken several decades in high income countries.

Finally, there is the challenge of aligning and managing incentives, particularly payment mechanisms that encourage hospitals to participate in accreditation programs and to improve quality of care. Reliance on mandating accreditation alone may not be effective, as can be seen in the Indonesian context in the failure of licensing to ensure compliance with minimum facility standards.

Need to strengthen governance

Given these potential risks and challenges, a key issue for multi-institutional regulatory frameworks is to ensure adequate governance of the regulatory system.

The reforms in Indonesia and Australia could be seen as attempts to strengthen governance by clarifying accountabilities, and separating roles of institutions at different levels to avoid conflict of interest (at least in the Australian reforms).

In Australia, the reforms also strengthened accountability to the general public through public reporting of hospital performance and accreditation status. However, in Indonesia, public capacity to demand accountability is weaker, and the medical profession is generally subject to less public scrutiny. The lack of a culture of public scrutiny, and potentially the need to maintain support from the medical profession, have resulted in less attention to requirements for public reporting in the Indonesian reforms.

The Australian reforms also separated the institutional responsibility for the development of standards (a responsibility of the ACSQHC) and the measurement and reporting of performance against standards (a responsibility of accrediting agencies). This separation of responsibilities reduces the risk of conflict of interest. However, in Indonesia, the same institution (KARS) is responsible for both functions and could face a conflict of interest.

The final guarantor of the integrity of the regulatory regime is the government's authority at the apex of the regulatory pyramid. However, the different responsibilities of different levels of government

introduce an element of complexity in both country regimes.

In Australia, the role of state governments as regulators of mandatory compliance with accreditation is clear, but there remains some lack of clarity of accountability for hospital performance overall, which is reported at both state and Commonwealth level. There remains the potential for conflict between the Commonwealth and state governments on responsibility for poorly performing hospitals.

A similar difficulty exists in Indonesia, complicated by the presence of three levels of government responsible for regulation of hospitals at their level. One of the results is the granting of licences by provincial and district governments to hospitals that do not satisfy national minimum standards, in an effort to address local demands for more hospital services. Indonesia lacks the mechanism of the COAG, and the current largely centrally driven reforms do not appear to have engaged or clarified the role of lower governments. There is clear scope to improve the connections between and integration of the various regulatory efforts to achieve a more effective network of governance. The relation between each level of government's regulatory activities and the hospital accreditation system could be a focus for such integration.

It is interesting that both countries have introduced a parallel system of monitoring, oversight and reporting of hospital performance (the NHPA in Australia and the provincial hospital oversight bodies (BPRS) in Indonesia). While the rationale for a separate hospital performance mechanism has not been explicitly stated, it further strengthens oversight of hospital performance and addresses some potential conflicts between different levels of government.

Effectiveness and impact on quality improvement

A final issue yet to be resolved is the effectiveness of accreditation in improving the standards of services and quality of care. While this paper has focused on the use of accreditation for regulation of quality, with a focus on a quality assurance perspective, there is also an expectation that accreditation can drive a shift towards a quality improvement approach.

Evidence on the effectiveness of accreditation in improving outcomes of health care is weak, particularly in LMICs. Recent systematic reviews suggest that accreditation is a complex process and outcomes are quite variable.

Greenfield and Braithwaite (2008) reviewed the literature and identified 66 papers. Studies identified evidence of professional support for accreditation programs; some evidence of changes in structures and processes in accredited institutions, but variable results in organisational performance; and variable results in clinical performance indicators, particularly comparing accredited and non-accredited hospitals.

A more recent review (Alkhenizan and Shaw 2011) focused on the impact of accreditation on the quality of health care services. It identified 26 studies. They concluded there was consistent evidence that accreditation improved the process of care and some evidence of improvement in specific clinical outcomes, notably acute myocardial infarction, trauma, ambulatory surgical care, infection control and pain management. Most of the studies were undertaken in the US and other high-income countries, but there were three studies in LMICs (Zambia, South Africa and the Philippines), of which improved outcomes were noted in Zambia and the Philippines.

CONCLUSIONS

Improvement in the measurement, monitoring and regulation of the quality of hospital care is an important policy priority for governments in LMICs, particularly with the introduction of national publicly financed health insurance schemes to achieve universal health coverage. Hospital accreditation provides a potential mechanism for governments to address this issue. Recent reforms to hospital accreditation in both Australia and Indonesia demonstrate a shift towards a more regulatory approach and greater accountability to government.

However, hospital accreditation is complex, with multiple actors and potentially conflicting interests. In using hospital accreditation more as a regulatory mechanism, the responsive regulatory pyramid provides a useful framework to guide design and analysis. The pyramid clarifies the relationships between the roles of institutions at different levels and can identify institutional gaps. It demonstrates how reforms to accreditation in Australia and Indonesia attempted to strengthen meta-regulation and government authority

at the apex of the pyramid, in order to support better self-regulation and voluntary activities.

The pyramid also provides guidance on the governance arrangements needed to ensure proper functioning of each level and highlights potential conflicts of interest when institutions undertake functions across different levels. It illustrates how the reforms in Australia and Indonesia sought to strengthen government engagement in setting of standards, and lines of accountability to government.

Use of hospital accreditation as a regulatory mechanism in LMICs encounters particular challenges, where governments may need to take a more active role in the management of surveying and assessment, and in capacity building for health care providers, than in countries with a longer institutional history of accreditation and greater capacity outside government. This increases the risk of conflicts of interest and may reduce the impact on motivating self-improvement.

The proposed parallel systems for monitoring and reporting of hospital performance in both countries may provide a safeguard against potential governance failures. As capacity in non-government actors grows in the LMIC context, it may be possible for government to hand over more of this role to non-government actors and to focus more on governance issues.

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