Approaches to regulating the quality of hospital services in low- and middle-income countries with mixed health systems: A review of their effectiveness, context of operation and feasibility

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SUMMARY

Universal health coverage (UHC), a priority for many low- and middle-income countries (LMIC), encompasses health financing (social protection), access to services (equity) and quality/appropriateness of services. Recent debate on UHC has focused on health financing and access, with little attention paid to quality of services. This paper examines regulating the quality of care in LMIC hospitals.

The regulation of quality of care requires a range of linked strategies, termed ‘responsive regulation’. This provides a hierarchy of mechanisms that encourage voluntary self-regulation while ensuring compliance through financial sanctions and punitive measures.

Hospitals consume a high proportion of health expenditure and also provide a pre-existing institutional framework that can support regulatory reform. We undertook a ‘realist review’ to describe the approaches being used in LMIC hospitals to regulate quality, and to determine whether evidence exists for the effectiveness and feasibility of different approaches in LMIC contexts.

A realist review provides the opportunity to study how contextual and environmental factors affect a particular regulatory approach. Our initial search included both peer-reviewed and ‘grey’ literature to obtain a broad selection of publications. Two hundred and thirty-nine articles were initially identified; 72 met our criteria, and, of these, 18 met our ‘quality criteria’ and formed part of the realist evaluation.

We have categorised approaches into two broad areas: those focusing on provider capacity and behaviour and those focusing on the enabling environment. The former include continuous quality improvement, training and clinical guidelines, and address self-regulatory responsive regulation. Approaches targeting the enabling environment include accreditation, payment and governance reforms, and address third party co-regulation, economic incentives and meta-regulatory responsive regulation.

Accreditation and payment reforms have been effective in improving quality indicators, with several countries moving towards linking discretionary payments to accreditation. Devolving governance to hospitals is associated with improved efficiency, but seems to have little influence on clinical quality. Limitations in data management systems and motivating personnel about quality are seen as barriers to any approach. Continuous quality improvement and human resource training have also been effective, although data are lacking on long-term sustainability. Strategies that concurrently support the provider and the external environment are likely to be more effective than targeted interventions.

Abbreviations

<table>
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<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>COHASASA</td>
<td>Council for Health Service</td>
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<td></td>
<td>Accreditation of Southern Africa</td>
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<td>CQI</td>
<td>Continuous quality improvement</td>
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<td>HIC</td>
<td>High-income countries</td>
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<td>LMIC</td>
<td>Low- and middle-income countries</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>PBI</td>
<td>Performance-based indicators</td>
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<td>PPP</td>
<td>Public-private partnership</td>
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<td>QI</td>
<td>Quality improvement</td>
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<td>UHC</td>
<td>Universal Health Coverage</td>
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INTRODUCTION AND BACKGROUND

Universal health coverage has emerged as a key issue in current global health policy. Many low- and middle-income countries are committing to the introduction of UHC, the aim of which is for all members of a population to receive appropriate, quality services with financial protection from catastrophic spending (Carrin 2008). The World Health Report (WHO 2010) describes three different aspects of UHC: health financing (social protection), access to services (equity) and the quality/appropriateness of services. Much of the recent debate on UHC policy has focused on health financing strategies and the introduction of pre-paid insurance, with relatively little attention paid to quality and access (Kutzin 2012; WHO 2010). When quality of care has been discussed, the tendency has been to describe it from a financing perspective, with efficiency and the elimination of waste at the core of discussion (Kutzin 2012). However, how waste and inefficiency are measured depends on the desired outcome and, in particular, how quality is measured.

The introduction of UHC provides an opportunity to define and address quality through the linking of health service purchasing to performance standards. However, it also introduces a risk that providers will respond to increasing demand for services by reducing quality or providing inappropriate or unnecessary services to increase revenue. There is a need, therefore, to develop a robust regulatory system surrounding quality of care. The regulation of quality of care is complex and requires a range of linked strategies that give voice to stakeholders, build commitment among payers and providers and yet ensure regulatory adherence (Braithwaite 2011). Such an approach entails a broad perspective on regulation that includes legal and policy directives as well as co-regulation with independent agencies, self-regulation and economic instruments such as purchasing. This approach is referred to as ‘responsive regulation’, introduced by Ayres and Braithwaite (1995). Responsive regulation envisages a series of regulatory mechanisms arranged as a hierarchy in the form of a pyramid (Braithwaite 2011). Voluntary self-regulation forms the foundation of the regulatory pyramid, above which are independent regulatory agencies and financial sanctions designed to ensure non-compliers adhere to policy goals. At the top of the pyramid are punitive measures such as licence revocation.

Responsive regulation assumes a basic regulatory environment that can be used for a specific purpose. However, such an environment may not be in place in LMIC, which creates obstacles to achieving quality goals. For example, poor professional knowledge of, and commitment to, ideas surrounding quality present a major challenge for self-regulation and monitoring. This is compounded by poorly developed professional organisations and institutions. Within hospitals, rudimentary health information systems and a lack of data on key quality indicators prevent any meaningful assessment of quality. Many LMIC also have mixed health systems1, and the regulatory process is further complicated by the complex interaction between the private and public markets.

Despite these challenges, significant efforts have been made to address quality in LMIC. These efforts have particularly focused on the regulation of the quality of hospital services. Hospital services consume a high proportion of health expenditure, and may expose patients to high levels of risk (ACSQHC 2010). Hospitals also provide a pre-existing institutional framework that can be used to introduce and support regulatory reform. The objective of this review is to describe the approaches currently being used in LMIC to address the regulation of quality in hospitals and to determine whether any evidence exists of the effectiveness of different approaches. Moreover, the review will consider whether there is evidence to suggest that one approach might be more feasible and effective in particular LMIC contexts.

METHODS

This review uses the realist review framework described by Pawson, Greenhalgh et al (2005) for complex policy interventions. A strength of realist reviews is their capacity to examine how an intervention works, including the contextual and environmental factors that support its effectiveness. It is thus appropriate for this review.

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1 Defined as health systems in which out-of-pocket payments and market provision of services predominate in an environment in which publicly financed government health delivery coexists with privately financed market delivery (Evans et al 2008).
In undertaking the review, we used a four-step process allowing an explanatory and contextual analysis to develop. First, an analytic framework was formulated, based on a theoretical exploration of strategies to address quality of care. The framework initially identified three approaches to quality: focused on quality improvement, quality assurance and outcome. A search of the literature was then undertaken to identify examples of quality improvement and regulatory interventions reported from LMIC, and how they related to the theoretical approaches. The search strategy involved electronic searches of peer-reviewed journals, relevant articles sourced from personal libraries, a grey literature search using Google Scholar and a snowball search for relevant articles not identified by other means. Search terms included: LMIC, low-middle income country, developing country, low income, Africa, Pacific, Asia, hospital, inpatient, regulation, quality, performance-based incentives, quality metrics, quality improvement and quality assurance. The search was limited to papers published between January 1993 and January 2013, in English, with an abstract available. The search was not intended to be a full systematic review, and some relevant articles may not have been identified. The results of the search were then reviewed by the first author, their quality and appropriateness assessed and the selected articles analysed. The analysis used the elements of the realist review to focus on the relationship between the context of the intervention, the mechanism of its action and its outcomes within a specific context.

During the initial literature search, 239 article titles were identified as potentially relevant. From these, 72 articles were identified as potentially relevant based on the following criteria: quality as a clear objective with a focus on hospital services; focus on LMICs; included new information or data. Articles were excluded if they focused exclusively on high-income countries (HIC) and/or had a disease management focus, or if they provided a discussion or commentary without any new information or concrete examples. The 72 articles were read and the quality of publications was assessed and given a ‘rank’ between 1 and 6 using a combination of Hierarchy of Evidence for Assessing Qualitative Research (Daly, Willis et al 2007) and the GRADE Strength of Recommendation framework (GRADE 2013). A rank of 1 equated with articles of very poor quality with limited theoretical foundation and no data provided to support claims. A rank of 6 equated with high-quality articles based on sound theory and supported by either quantitative or qualitative data. Articles achieving a score of 5 or 6 were included in the final analysis. A total of 17 articles met the inclusion and quality criteria and were included in the final analysis (Figure 1).

**FIGURE 1. OUTLINE OF LITERATURE SEARCH PROCESS**

<table>
<thead>
<tr>
<th>Literature Search</th>
<th>239 articles</th>
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<tr>
<td>Abstract Review</td>
<td>72 articles</td>
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<tr>
<td>Quality Assessment</td>
<td>17 articles</td>
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**RESULTS**

**Categories**

Articles identified in the literature review were grouped into the following categories based on broad similarity of approach (Table 1; summaries of each article are included in the appendix).

**Strengthening Human Resources** (3 articles): These approaches follow the logic that improvements in quality of care at an individual provider level can be addressed through strengthening training programs for health professionals. These may take the form of...
on-the-job training and mentorship, external courses or the design of nursing and medical training programs to reflect current best practice and knowledge.

E-technology, IT Systems: The development of e-technology and IT systems has been poorly researched in LMIC. The initial search identified two articles that discussed the development of IT systems; however, neither was deemed to be of sufficient quality to be reviewed as part of this search.

Continuous Quality Improvement (3 articles): CQI principles and methods stem from the belief that quality issues are often caused by poor organisational management, rather than by individual errors. National, district or facility quality improvement teams identify system problems and develop action plans to resolve them. CQI practices differ from quality assurance in that there is an emphasis on continuous improvement, rather than the satisfaction of minimum standards.

Accreditation (5 articles): External quality assessment—accreditation—can be voluntary or compulsory and is usually associated with facilities or providers being issued a formal status by an accreditation body. Clinical quality indicators may be incorporated into accreditation programs, and programs may be also associated with eligibility for performance bonuses or other financial motivations.

Governing Structure (4 articles): Governance of hospitals refers to the structures and functions of the hospital and health system that enforce policies and exercise the ultimate authority for decisions made in and on behalf of the hospital (Umbedstock and Hageman 1991; Holland, Ritvo and Kovner 1997; Pointer and Orlikoff 1999). The governing structure of the hospital therefore refers to how hospitals are managed, including human resources, finances and the composition of the governing board.

Payment Mechanisms (1 article): A payment mechanism can be defined as a contract among two or more players—patients, providers and payers—that creates specific incentives for the provision of health care and minimises the risk of opportunistic behaviour (Maceira 1998). It is designed to correct partially for the information asymmetry that exists between providers and payers by defining rules for costs per treatment.

System-wide Reform (1 article): System-wide changes to improve and regulate quality are not often documented in the literature. They require large financial investment, and assessing the impact of the reform is difficult. However, undertaking an assessment of how different strategies have been used concurrently may provide insight into how linking strategies can potentiate quality effects.

Different Regulatory Approaches

In the articles selected from the research, two sets of mechanisms to regulate quality in hospitals emerged. One set focused directly on health care providers and developing their capacity and engagement in improving quality. These mechanisms tended to be implemented

<table>
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<th>TABLE 1. CATEGORISATION OF ARTICLES SELECTED FOR REVIEW</th>
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<td>Category of Approach</td>
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<tr>
<td>Payment mechanisms</td>
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<td>System-wide Reform</td>
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in local or individual facilities, and addressed the self-regulatory level of the responsive regulatory hierarchy.

A second set focused on the institutional and broad policy enabling environment to encourage changes in provider practice. These tended to be implemented nationally, and addressed co-regulation, financial incentives and meta-regulation in the responsive regulatory hierarchy. Approaches that target the enabling environment have tended to be more authoritative and involve external (positive and negative) motivators, whereas those directed at the individual provider have focused on self-regulation. However, the split between environmental or authoritative compliance and provider self-regulation is not always maintained, some independent health insurance schemes requiring quality checklists before discretionary payments are made (Ergo, Paina and Morgan 2012).

**Approaches focusing on provider capacity and behaviour**

Continuous quality improvement initiatives have been used to regulate and improve quality in several LMIC. The largest scale of implementation documented in the literature was in Kenya, where quality assurance teams (QAT) were used to support staff in local problem solving and quality improvement activities across the whole health system (Gill and Bailey 2010). Local QAT developed action plans and, with support from a national ‘core QAT’, generated solutions that included addressing gaps in policies and procedures (national issues), improving supply chains for pharmaceutical and medical provisions (district issues) or retraining in clinical practice guidelines (facility issues). QAT resulted in noticeable improvements in obstetric care performance indicators. Between 2002 and 2006, the proportion of obstetric patients who prematurely discharged themselves from the hospital dropped by 90 per cent, and in 2007 there was a significant improvement in the clinical response time for both obstetric emergencies and outpatient visits.

A strength of CQI is its ability to improve communication between different levels of the health sector and provide opportunities for individual providers to ‘buy in’ to the reform process. In the USAID-funded ‘Improvement Collaborative’, collaboration between ‘QI teams’ was fundamental to the program’s success (USAID Health Care Improvement Project 2008).

Improvement Collaboratives have been introduced in 16 LMIC countries over the past 15 years, and all programs are reported to have been successful, although no quantitative estimates are available. The Collaboratives run for one to two years, with several QI teams being established in different facilities and/or clinical departments. Individual teams develop solutions to quality issues, reporting back to the Collaborative on successes and failures. Following feedback, successful initiatives may be adopted across the Collaborative, unsuccessful approaches being modified or discarded based on the results of discussion. Improvement Collaboratives are said to produce noticeable change within nine to 18 months; however, no impact evaluations have been published.

CQI in the form of a regular, hospital-wide, morbidity and mortality meeting was used in a small, mission-based hospital in rural Nepal (Schwarz, Schwarz et al 2011). The meeting structure served as a basis for a root-cause analysis of health care delivery at the hospital. Clinical and non-clinical staff were required to attend the meeting and provide feedback on each case. Again, collaboration between hospital departments was seen as a strength of this approach, motivating staff and driving quality change. The program itself required very little investment in infrastructure or financial commitment, although additional resources were required to solve issues identified. Illustrative examples show how the meetings have led to investment in new equipment, such as a portable oxygen tank for hospital transfers, and retraining of nursing staff in resuscitation skills.

Human resource development is often considered a key driver of organisational change and improvements in quality. A recent study in Ghana found that interventions directed at human resource management may encourage organisational commitment among clinicians, leading to ‘good’ hospital performance (Marchal, Dedzo and Kegels 2010). Conversely, poor hospital performance has been linked to inadequate human resource management, particularly during periods of change (Penn-Kekana, Blaauw and Schneider 2004). The strongest evidence for the role of human resource development in fostering provider quality is an article describing two training programs developed specifically for former Soviet Union midwifery and obstetric staff (Glatleider 2006).
During the Soviet regime, UHC focused on coverage and access to services, rather than quality. The legacy of this policy is that these countries are in the unique position of having relatively high numbers of obstetric providers, reflected in high rates of institutional childbirth and antenatal visits, and yet also have high maternal and neonatal mortality and morbidity. Glatleider (2006) describes two successful midwifery training programs that used an adult learning methodology and ‘change theory’ to retrain midwives in patient-centred obstetric care. Following the retraining, the authors report sustained improvements in the quality of obstetric care, with 11 of 11 participating centres in Moldova practicing skin-to-skin contact post-intervention and nine of 11 allowing freely chosen birthing positions. In Uzbekistan, the training programs also prompted national health policy changes to support appropriate maternal and neonatal health.

Creating an enabling environment

Overall, the introduction of hospital accreditation has had mixed results in LMIC, with a trend towards accreditation being associated with improvements in quality benchmarks. An advantage of accreditation programs is their capacity to tailor the process and outcome to country-specific issues. In 2002, the Lebanese Ministry of Public Health introduced a hospital accreditation program based on several HIC examples. Following an initial ‘scorecard’ survey in 2002, assessment was adapted to a single ‘grade’ across the hospital (El-Jardali 2007). In 2004, among the 142 hospitals surveyed, 85 met the accreditation requirements compared to 47 (out of 128) surveyed in 2002, an increase of 23 per cent.

Accreditation programs seem to be most effective when they are voluntary and implemented independently from the government. The South African program, COHASASA, is cited in several publications as a model of success in LMIC (Alkhenizan and Shaw 2011; Montagu 2003). At the tertiary teaching hospital in Bloemfontein, COHASASA was introduced in association with the development of a cardiothoracic training program. COHASASA standards were used to identify hospital-wide quality issues in readiness for the cardiothoracic surgical units development (Linegar, Whittaker and Van Zyl 2012). Senior hospital personnel and clinical staff were motivated to make accreditation improvements because these were seen as beneficial to their work. Over a four-year period, the hospital’s accreditation rating went from a baseline of 64 per cent (entry level grade) to 94 per cent (full accreditation), which was maintained over two years.

Over-reliance on government is a potential issue for fledgling accreditation programs. The viability of programs may be threatened if governmental change brings policy shifts and the accreditation body is unable to function independently. The Brazilian and Zambian programs experienced significant problems due to over-dependence on government (Montagu 2003). Moreover, independence from government may have additional benefits by creating an environment removed from authoritative law enforcement and providing a platform for consensus building toward change (Alkhenizan and Shaw 2011). However, in principle, government support is still necessary. The feasibility of accreditation programs seems to be dependent on a government supportive of, but independent from, the process. For this to occur, most LMIC will require external financial and technical support until accreditation programs can operate with relative financial independence.

One article assessed the impact of physician accreditation on quality of hospital service delivery. The accreditation of individual providers seems to be less effective than facility-based accreditation programs. PhilHealth, the largest insurance program in the Philippines, reimburses both hospitals and individual providers for health services, including services and procedures provided by accredited physicians. A ‘clinical vignette’ survey of 147 public and private doctors working in the central Philippines found that there was a significant difference between the quality of services delivered by accredited and non-accredited doctors, although private doctors, whether or not accredited, seemed to be more influenced by insurance payments than by the accreditation process (Quimbo, Peabody et al. 2008).

There are many hospital governance structures operating in LMIC. However, as a general rule, they can be grouped into the following types (Table 2): (1) budgetary unit of government, (2) autonomous unit of government, (3) corporate unit of private conglomerate or broader private hospital system, (4) non-autonomous sub-unit of larger private organisation and (5) private and autonomous unit (Bogue, Hall et al 2007).
Approaches to regulating the quality of hospital services in low- and middle-income countries with mixed health systems: A review of their effectiveness, context of operation and feasibility

Several South and Central American countries have mixed health systems with public, private and private not-for-profit (NGO) hospitals operating side by side, allowing the impact of governance structures on quality and efficiency of services to be compared. Bogue, Hall et al (2007) surveyed 397 hospitals in Argentina, Brazil, Colombia and Mexico and found that autonomous units, whether state or privately owned, were more efficient overall than hospitals operating as budgetary units of the MoH. Comparisons were made using accountability, quality and efficiency indicators. Performance differences were noted across all areas, particularly in facility and equipment upkeep, availability of medicines and auxiliary services, administrative and labour efficiency. However, only minimal (non-significant) differences were seen across the clinical quality indicators. Similar results were also noted by La Forgia and Harding (2009) and McPake (2003) in their studies assessing hospital governance in Brazil and Colombia, respectively. Exposure to market pressures appears to improve the efficiency and responsiveness of service delivery, reducing ‘waste’ and eliminating competitive disadvantage. However, at least in the short term, changes to hospital governance structures do not directly affect the quality of clinical service delivery.

Providing hospital boards with the autonomy to implement competitive human resource systems is cited as an important factor in the success of autonomous units. In Brazil, the creation of a public-private partnership (PPP) model allowed hospital boards to institute competitive hiring practices. Contracts were limited and were not renewed if employees failed to meet minimum quality performance standards (La Forgia and Harding 2009). Overall, the PPP hospitals were associated with a better bed turnover rate (annual number of discharges per bed), bed substitution rate (average number of days a bed remains unoccupied between patients), bed occupancy and length of stay than similar public hospitals operating along traditional lines.

However, hospital governance reform is not a quick or easy process. In many cases, legislative and policy changes may be required, necessitating broad political support. In addition, sufficient time must be allocated for changes to be communicated to national, district and hospital personnel. Failure to communicate changes can have a negative impact on quality, as illustrated in a qualitative case series from South Africa (Penn-Kekana, Blaauw et al 2004). The Public Financing Management Act devolved financial decision making to facility-based health managers. Changes were introduced relatively quickly; managers were unprepared and, in some cases, did not have the skills necessary to implement the reforms, resulting in high levels of worker stress.
staff losses and negative impact on clinical quality in the two hospitals interviewed.

Significant research has been undertaken on the influence of different payment mechanisms on quality in HIC. There is also a small body of emerging evidence looking at similar reforms in LMIC. Of the variety of payment methods available, those most commonly cited as appropriate for the regulation of quality are performance-based indicators (PBI), case-based payments and global budgets.

Altering payment mechanisms to providers is often considered an effective driver for quality in hospitals in HIC (Christianson, Leatherman and Sutherland 2008). The role of payment in LMIC is still relatively new and poorly studied. Ergo, Paina et al (2012) provide a realist review of current payment mechanisms used in LMIC to influence quality. There is no evidence to suggest that one mechanism works better than others. Indeed, while the review describes the different approaches, there is almost no discussion of the impact of payment mechanisms on quality.

The only PBI scheme to be assessed for effectiveness in LMIC is the linking of achievement and maintenance of accreditation to incentive payments. In this approach, hospitals receive a bonus payment for entering an accreditation process or maintaining their accreditation status. It has been implemented successfully in Africa, Asia and South America; however, effectiveness results are available only from Brazil. In Brazil, one health insurer covering 250 hospitals linked accreditation to incentive payments. Since the program’s introduction (date not provided in paper) 23 hospitals and 23 labs/clinics had achieved accreditation (Ergo, Paina and Morgan 2012). No additional data on the effectiveness of the PBI-accreditation schemes is available; however, both Rwanda and Burundi have integrated similar programs into their national health plans following successful pilot projects.

In Benin and Tanzania, PBI payments have been linked to adherence to clinical guidelines and quality indicators (e.g. financial reward for timely referral of complicated deliveries, number of women receiving malaria prophylaxis at antenatal care). Effectiveness results are not available. A potential limitation of this approach is that global quality improvements and/or other clinical areas are neglected in favour of clinical indicators that are financially more rewarding (Ergo, Paina and Morgan 2012).

Whichever PBI scheme is used, deficiencies in electronic medical records and poor IT infrastructure are consistently seen as barriers to effective implementation. Consequently, countries with the most success with PBI schemes tend to be middle-income countries with existing IT systems. In these circumstances, the introduction of PBI may stimulate renewed efforts to strengthen rudimentary national and facility health management systems. However, where it is unfeasible to scale up electronic health information systems, it may be possible to circumnavigate IT limitations through the introduction of government health vouchers for quality indicators. India, Pakistan and Kenya have introduced vouchers for specific obstetric conditions that can be reimbursed only through accredited hospitals or health clinics (Ergo, Paina and Morgan 2012). Reimbursement is therefore not only linked to quality indicators but also acts as a motivator for obtaining accreditation, which, in turn, drives quality.

There were no articles of sufficient quality available on the development and role of e-technology within hospitals. Despite this omission, e-technology is considered an important requirement for approaches to regulate quality, particularly those that involve payment schemes (Ergo, Paina and Morgan 2012; La Forgia and Harding 2009; Sulku 2012). In many cases, non-existent or ineffective data management systems prevent some regulatory mechanisms being introduced, as paper-based data systems cannot cope with the quantity or quality of data required for these approaches to be effective.

Sulku (2012) provides a summary of Turkey’s Health Transformation Program, a significant health reform that focused on capacity building through health information systems, improved medical diagnostics, outsourcing of services to the private sector, payment reform via PBI (diagnostic related groups) and introducing performance-based payments to individual providers. Underlying the reform was an aim to align the health care system with the European Union and OECD countries prior to joining the European community. Overall, the efficiency and quality of service delivery improved across in-patient, out-patient and surgical performance indicators; however, the equity of the health system was compromised, with a deterioration...
of services in the least developed provinces. Sulku (2012) suggests that ongoing health personnel shortage (an issue not addressed by the reform) in socio-economically disadvantaged districts continued during the reforms and provided one explanation for the deterioration in quality of service delivery in these regions.

**DISCUSSION**

**Limitations**

Overall there is a lack of published material on the regulation of quality in LMIC hospitals. This review relied heavily on non-traditional search methods to identify relevant articles. Finding and accessing the material was initially difficult, and in many cases the scientific quality of the publications was not adequate for inclusion in the review. In addition, many articles were commentaries or case studies written by consultants and/or academics with vested interests in the success of the approach being reviewed. These factors point toward significant publication bias having been introduced.

A glaring omission from the papers identified in the search was articles on the Asia-Pacific region. Despite Thailand’s successful UHC program and the strong inroads into achieving UHC in Indonesia and China, there was only one article (Gani 1996) from this region. Although the theoretical approach underlying every reform is similar, it is not clear how transferable the experience of one country is to another. Health systems vary, and cultural differences may mean that regulatory mechanisms that have been successful in Africa and the Middle East do not easily translate to Asia-Pacific.

The bed size and service capacity of a hospital are rarely mentioned as factors in the success of regulatory approaches to quality. Hospital size is likely to influence not only the logistical capacity to handle regulatory change but also the dissemination of information to hospital staff and a hospital’s ‘change culture’. More research is needed on the influence of hospital size on quality and adherence to regulatory policy.

Despite initial signs that PBI may be an effective regulator of quality in LMIC, there have been almost no attempts to quantify the impact. This may be because effective e-technology systems are needed for successful monitoring and evaluation. Reliable data collection systems are also needed to scale up PBI schemes to maximum capacity. Many LMIC have only rudimentary data management systems, and developing these systems requires significant investment. Given the initial signs that PBI are effective regulators of quality, PBI could potentially be used as a catalyst for investment in e-technology, leading to significant quality gains and, in turn, a better understanding of the effectiveness of this approach.

Finally, most publications provide only short-term effectiveness evaluations. The long-term impact of regulatory strategies in LMIC has not been assessed, and in almost all cases there is the ongoing difficulty of proving that the results are due to the intervention and not to other changes within the health system or broader development space. Given these limitations, there are still some patterns that emerge through the literature, suggesting that some strategies may be more feasible and effective.

**Approaches That Focus on Provider Behaviour**

People will continue to be at the forefront of health care delivery. Hospitals are ultimately reliant on individual providers to practise quality care. A key theme that emerges from this review is an underlying need for human resource management to be included in any regulatory approach. The experiences of Uzbekistan and South Africa provide some indication of what happens when providers are either included or excluded during implementation (Penn-Kekana, Blaauw et al 2004; Glatleider 2006). The Public Financing Management Act in South Africa was designed to make hospital budgets more adaptive and responsive to individual facility needs. However, changes were introduced quickly, with minimal time for communication and training of hospital staff. The result was a poorly understood policy whose implementation had a negative effect on quality. In contrast, the WHO Essential Antenatal, Perinatal and Postpartum Care Training was designed specifically to address provider quality issues. Midwifery-led multidisciplinary teams delivered evidence-based training alongside local and regional capacity building and policy support. In Uzbekistan, the program was not only associated with clinical improvements but also had flow-on effects, with policy and legislative changes to support appropriate maternal and neonatal health.
CQI is a further development of human resource management, with a greater focus on improving quality of care. With minimal infrastructure requirements, CQI encourages providers to analyse quality issues. It fosters teamwork among different health sectors with the development of local solutions. CQI initiatives are also cited as achieving significant improvements within a short time frame. However, almost all of the published literature on CQI in LMIC is about projects implemented by external academics, clinicians and/or donors with previous experience working in quality improvement, often in HIC. These mentors have been key to the success of the programs. Long-term effectiveness data are not available, and the sustainability of the programs is uncertain once the lead academics have left.

**Approaches That Focus on the Enabling Environment**

Performance-based payments, whether linked to accreditation or social insurance, produce a strong external motivation for quality service delivery. Providers have a personal interest in providing quality services; quality services are not dependent only on altruistic sentiments to ‘do good’, but providers receive a financial reward for quality. However, even in HIC, pay for performance is relatively new, and the long-term viability is unclear. There are concerns that pay for performance may be ineffective if patient numbers are small and may increase overall cost within the system and unfairly discriminate against providers who manage complex-care patients (Christianson, Leatherman et al 2008). These issues might be particularly pertinent for small LMIC with large rural populations.

Accreditation also provides an external motivation for quality reform and is consistently seen as an effective driver for quality in LMIC. Accreditation programs can be tailored to a country’s quality issues and, as was the case in Lebanon (El-Jardali 2007), step-wise implementation can allow for changes to be made based on initial results and feedback from early adopters. Moreover, there is some suggestion that accreditation may improve equity. Early data from South Africa’s COHASASA program suggest that national accreditation improves social equity by raising standards of care across the system in incremental stages (Montagu 2003). Although reducing inequity does not necessarily lead to improved quality, as a key feature of UHC, it is no less significant an outcome.

Devolving hospital governance from traditional budgetary units to autonomous units is associated with improved efficiency and responsiveness of services. Exposing hospitals to market forces encourages fiscal responsibility and the elimination of competitive disadvantage. However, it is a poor lever for quality because it does little to address the information asymmetry between purchasers and providers. Although autonomous units have been successfully introduced in many HIC, they appear to be less effective in LMIC, where introduction is earmarked to deliver both efficiency and quality improvements.

What emerges from this review is that no single strategy is sufficient to regulate quality in hospitals. The implementation of top-down policies will have only a limited effect on providers if worker motivation and hospital culture are not addressed. Likewise, it is naive to assume that training and the provision of evidence-based guidelines are sufficient to motivate clinicians to provide appropriate and timely services of maximal quality. A combination of strategies focusing on both enabling environments and individual provider behaviour is required.

National approaches require approval from, at a minimum, the MoH, and potentially other ministries and/or the reigning political power. Policy and legislative changes tend to be slow, and in many LMIC, external donors will be needed to support fledgling programs both technically and financially. Accreditation programs, particularly if linked to PBI, may lift quality in hospitals across indicators provided they are financially and politically independent from government. Investment in electronic data systems is important and will facilitate a better understanding of the role of PBI schemes in the regulation of quality in LMIC.

Strengthening human resources and introducing CQI may build support for national reforms and improve individual provider skills. While such approaches can be undertaken in the absence of a supportive environment, providers are unlikely to be motivated to undertake significant change towards improving quality without some form of responsive regulation.

Improving clinical services is the ultimate goal of any regulatory approach targeting quality in hospitals. Regulation fails if this goal is not met. Ideally, providers should be self-motivated to practise good quality
clinical care, with regulation providing an environment that encourages ongoing education and self-regulation. When self-regulation fails, external motivators should be active, subtly channelling providers towards quality goals. As a final step, non-compliers can be forcefully encouraged to uphold quality directives through punitive measures such as licence revocation and fines. However, such a regulatory pyramid can be effective only if enforced, and guaranteeing compliance is not always simple in LMIC.

CONCLUSIONS

Regulation of quality of care in hospitals is complex and is a challenge even in well-resourced HIC. However, a range of interventions have been implemented in LMIC, providing some guidance on which strategies might best be introduced in a given situation. Strategies that directly address provider behaviour, such as human resource strengthening and CQI, can be implemented at a local or facility level, and require few additional resources. However, ongoing mentoring is important for sustainability.

Strategies that address the enabling environment can be effective in motivating and encouraging provider quality, but require investment in information systems, changes to national policies and governance structures and changes to payment mechanisms. Low capacity in LMIC can be a significant constraint; inadequate information systems are a particular problem.

An effective program requires investment in strategies at both levels and alignment between local and facility initiatives with national policies and programs. For LMIC with limited capacity, developing human resource capacity through selected facility CQI, establishing accreditation programs and providing incentives for accredited facilities could be a good starting point.
APPENDIX: SUMMARY OF ARTICLES

Alkhenizan and Shaw (2011) reviewed the impact of hospital accreditation programs on quality with a focus on LMIC. The search included Medline (1996-2009), Cinahl (1982-2009), Embase (1980-2009) and HealthStar (1980-2009). Key words utilised in different combinations included ‘accreditation’, ‘health services’, ‘quality’, ‘quality indicators’, ‘quality of health care’ and ‘impact’. Twenty-six studies were identified; 10 studies evaluated the impact of a general accreditation program on the overall performance of the hospitals, nine studies evaluated general accreditation on a single aspect of hospital performance and seven studies evaluated the impact of sub-specialty accreditation programs. Overall there were mixed results, with a trend towards accreditation being associated with improved quality. Each country used accreditation in a slightly different manner based on country needs, many countries moving towards linking hospital payments with accreditation to motivate ongoing improvements. The authors conclude that accreditation indicators need to be closely linked to quality indicators in order for accreditation to lead to improved hospital quality.  

Type of publication: Systematic review.

El-Jardali (2007) reviewed the impact of a national accreditation program introduced by the Lebanese Ministry of Public Health in 2002. The review focused on identifying barriers that need to be addressed to make the accreditation policy more effective. Over five years, Lebanon used a phased introduction of general hospital accreditation. The initial survey in 2001-02 found that among the 128 surveyed hospitals, 47 met the accreditation requirements; 32 hospitals were found not meeting basic safety requirements. In 2004-05, 142 hospitals were surveyed and 85 met the accreditation requirements, with 15 hospitals categorised as ‘A grade, 8 as ‘B grade, 36 as ‘C-grade and 26 as ‘D-grade’. Making changes to organisational culture was cited by the author as the key barrier to accreditation programs. The program is also currently government owned and funded; the author suggests that an independent body may distance accreditation from policy/political interference and help with ongoing sustainability of the project.  

Type of publication: Case study.

Bogue, Hall and La Forgia (2007) assessed whether different hospital governance structures are associated with performance in four Latin American countries (Argentina, Colombia, Mexico and Brazil). Hospitals were grouped into four different governance types and assessed for planning and decision making, provider relations, ‘self-rating’ of services, clinical quality and efficiency. Three hundred and ninety-seven hospitals responded to the survey; there was a significantly different response rate across countries, with 13.5 per cent of invited hospitals responding in Argentina compared to 61.3 per cent in Colombia. Overall performance differences were noted for facility and equipment upkeep, availability of medicines and auxiliary services, administrative and labour efficiency and clinical quality, including the level of nurse training. Hospitals operating as autonomous units (private or public) tended to perform better; however, the authors note that public hospitals may have patients with more acute illnesses or have no place to discharge patients due to ineffective relationships with sub-acute care providers, which may confound results.  

Type of publication: Working paper.

English, Nzinga et al (2011) assessed the impact of introducing best-practice guidelines using a multifaceted approach. Eight hospitals in Kenya were selected, four receiving the full intervention and four partial intervention. The full interventions included concrete inputs (training, guidelines, job aides) and a low-intensity, normative, re-educative approach to organisational change, including resetting norms and values and a focus on partnership, local problem solving and empowerment. The partial interventions received the clinical guidelines and training sessions. The study found global improvement in full intervention hospitals in 14 of the indicators used (malaria treatment, documentation of child weight, severity indicators for illness on admission). Indicators that were not the focus of day-to-day contact (for example, severe malnutrition, newborn care) showed no improvement. The authors suggest that ongoing feedback and support were required to enable initial quality gains.  

Type of publication: Randomised clinical trial.
Ergo, Paina and Morgan (2012) reviewed different payment mechanisms that may influence quality in LMIC health systems, providing vignettes from different countries. The mechanisms discussed within the realist review were linking performance-based indicators to accreditation status, discretionary payments linked to clinical guidelines and increasing or decreasing payments based on the ability to complete a ‘quality checklist’. It is not possible to determine the research methodology used for identifying payment mechanisms or country examples. No performance indicators are provided. The PBI schemes described have mostly been used to target maternal and child health services, rather than hospital-wide quality improvement. The authors suggest that the central role of data in PBI schemes may stimulate efforts to improve data management systems. Quality scorecards/checklists have the advantage of targeting locally relevant performance benchmarks, including overall vision (for example, gender balance in service provision in Afghanistan). The illustrated examples provide insight into the contextual application of PBI schemes across a range of LMIC countries.

Type of publication: Working Paper

Gill and Bailey (2010) describe a systemic intervention designed around a national ‘core’ quality assurance team (QAT) and a network of health care professionals to support staff in local (facility) problem solving and quality improvement across different levels of the health system (policy, facility management and individual provider training). The role of the district QAT is to identify system problems and help develop action plans to resolve them. A case study within the article describes the impact of the approach in a regional referral hospital in Garissa, Kenya. Between 2002 and 2006 both overall in-patient and out-patient attendance increased by over a third, while the proportion of patients who prematurely discharged themselves dropped by 90 per cent. Nationally, quarterly core QAT visits have been used for support with ongoing updating and review of clinical guidelines.

Type of publication: Case study.

Glatleider (2006) described the introduction of two midwifery training programs designed for former Soviet Union (FSU) countries and assessed their impact on obstetric practices. The two programs, the Family Centred Maternity Care Training of Trainers (FCMC-TOT) and the World Health Organization Essential Antenatal, Perinatal and Postpartum Care Training, were developed to change the maternal and newborn care practices in the FSU, where there is a paradox of moderate-high coverage for antenatal visits, skilled birth attendants and institutional childbirths with unacceptably high maternal and neonatal mortality. The FCMC-TOT program showed a significant decrease in inappropriate practices (for example, pubic shaving) and increase in skin-to-skin contact and early breastfeeding. The WHO program showed sustained improvements in skin-to-skin contact and breastfeeding in 11 of 11 participating facilities in Moldova. The program had flow-on effects in national policy and legislative changes to support maternal and neonatal health in Uzbekistan. The discussion cites a multifaceted strategies and adult learning methodology, as well as local, regional and national policy support and a willingness of participants to undergo a cultural change, as being important factors in the program’s success.

Type of publication: Case series.

La Forgia and Harding (2009) assessed the impact of a public-private partnership (PPP) model on performance quality in 24 hospitals in Sao Paulo, Brazil. General hospitals, averaging 200 beds and offering basic specialties, were assessed on clinical quality and efficiency indicators. PPP hospitals had better information keeping systems, allowing more accurate performance assessment than traditional public hospitals. PPP performed better on a number of efficiency indicators including bed turnover rate, bed occupancy and length of stay. By 2008, half of the PPP hospitals had achieved accreditation but no control hospitals. There was no difference in clinical performance indicators across groups. The authors suggest that differences in human resource practices were key to the success of the PPP model. Performance-based targets have also been introduced into PPP hospitals and may explain some of the differences.

Type of publication: Case-control study.
Linegar, Whittaker and Van Zyl (2012) undertook a retrospective case study on hospital accreditation in a tertiary hospital in South Africa. The national COHASASA accreditation framework was linked to development of a cardiothoracic surgery training program. Successive improvements across the indicators were seen over five years. At baseline the hospital achieved an overall rating of 64/100 (entry level) and within four years the hospital had achieved, and maintained, a score of 94/100. The authors suggest that significant improvements were possible because senior hospital personnel and clinical staff were motivated to change because accreditation improvements were seen as beneficial to their work (the building of the cardiothoracic unit).

Type of publication: Retrospective case study.

Marchal, Dedzo and Kegels (2010) reviewed the role of human management and hospital culture in hospital performance through a mixed-method realist review of a well-performing hospital in Ghana. The authors took a broad definition of human management encompassing staff induction, training (induction and ongoing), personal development, communication and decentralised decision making. Teamwork, recognition and trust emerged as key features of a well-performing organisational culture, with the mission and values of the hospital reflected in all aspects of work. Based on the discussion provided, it is not possible to comment on the strength of the realist review methodology used by the authors.

Type of publication: Realist review.

McPake (2003) describes the health reform in Colombia, which aimed to provide UHC at the same time as introducing market pressure on hospitals with the objective of improving efficiency and responsiveness. Public hospitals were transformed into ‘autonomous state entities’ run by a board of trustees with control of the budget. The impact of the program was assessed in five hospitals in the Bogotá region. Autonomous state entities were associated with an overall increase in activity (admissions, outpatient visits), increased bed occupancy in obstetrics and gynaecology and improved structural quality, reflected in a larger number of specialties and diagnostic and therapeutic procedures. However, there was no change in clinical quality indicators. The review period was short (one year), and outcome indicators such as clinical quality make take longer to change.

Type of publication: Mixed-methods review.

Montagu (2003) assessed the role of accreditation in engaging with health care providers and organisations in LMIC to improve quality and affordability of health care. The paper takes a theoretical approach, with examples used to illustrate arguments. Based on the discussion provided, it is not possible to determine the search methodology or comment on the strength of the review process. The author suggests that accreditation programs need to be independent of government in order to distance accreditation from policy/financing changes as well as creating a non-threatening environment for quality improvement. Based on a review of accreditation programs in South Africa, Brazil, Zambia, India, Pakistan and Kenya, he suggests that they are more effective when they combine both evaluative and supportive consultation in a voluntary, non-threatening and interactive environment.

Type of publication: Working paper.

Penn-Kekana, Blaauw and Schneider (2004) reviewed the impact of the Public Financing Management Act on two 130-bed hospitals in South Africa. The hospitals were selected to include an upper-income urban environment and a low-income rural setting. The act was designed to devolve financial decision making to health managers, who better understand local realities and priorities. However, the policy had unintended consequences on the quality of maternal health services in hospitals surveyed. The qualitative survey found that nurses did not feel that they could make purchasing decisions and the budget constraints of the act conflicted with other quality initiatives (for example, clinical guidelines). Discussion of the problems identified in the survey suggested that some issues may be associated with initial resistance to change. However, poor management experience and a poorly communicated reform package contributed to a decrease in quality in maternity services.

Type of publication: Qualitative study.
Quimbo, Peabody and Shimkhada (2008) investigated whether accreditation by a national insurance program can support higher quality standards among private and public providers. One hundred and forty-five doctors (89 public, 56 private) from the central Philippines participated in a ‘clinical vignette’ survey for selected high prevalence paediatric conditions (pneumonia, diarrhoea, dermatitis). Results were compared between private and public providers who were either individually accredited, working in accredited clinical units or not accredited. The average aggregate vignette score was 54 per cent. Accreditation seemed to play a role in influencing quality of care for both private and public doctors. However, private doctors were more influenced by insurance payments than by accreditation. Insurance reimbursement on average represents 7-12 per cent of total physician income. The authors conclude that accreditation alone may not be sufficient to influence quality; further improvement may be achieved through properly designed payment schemes.

Type of publication: Cohort study.

Schwartz, Schwartz et al (2011) describe the introduction of a mortality and morbidity meeting involving clinical and non-clinical staff in a rural, mission-based hospital in Nepal. The meetings focused on root-cause analysis of problems in health care delivery at the hospital, with seven domains of causal analysis identified (operations, supply chain, equipment, personnel, outreach, societal and structural). Eighty to 85 per cent of on-duty personnel attended meetings, which are cited as improving collaboration and team-based learning and improving understanding of non-clinical and clinical roles. Only 54 per cent of scheduled meetings eventuated due to senior staff shortages and clinical emergencies; engagement with non-clinicians was also difficult to sustain, and some higher level issues could not be resolved in the hospital (for example, poor road transport). However, case studies in the article describe successes such as purchasing of a mobile oxygen tank for transport and retraining of nurses in resuscitation procedures.

Type of publication: Case study.

Sulku (2011) described the Health Transformation Program that aimed to align the Turkish health care system with the European Union and OECD countries. Approaches included investment in the health information system, medical technology and diagnostics, outsourcing of services to the private sector, devolving hospital budgets from the MoH to facilities and the introduction of discretionary payments for clinical performance indicators (for example, outpatient procedures). Over five years, the mean number of out-patient visits rose approximately 78 per cent, in-patient cases 30.3 per cent, case-mix adjusted in-patient cases 20 per cent and surgeries 122 per cent. The total number of beds rose 18 per cent; the bed occupancy rate stayed almost the same at 55 per cent. Overall there was no improvement in clinical performance indicators. Sub-analysis by socio-economic status of province indicated that productivity in the least developed provinces had not changed and efficiency of services had decreased. The discussion suggested that efficiency gains were achieved by restructuring public hospitals with several hospital mergers. Equity within the health system was also compromised by the reforms, particularly in rural areas, where existing provider shortages are the main quality issue, and this was not addressed by the reform process.

Type of publication: Discussion.

USAID Health Care Improvement Project (2008) describes the USAID-funded initiative, the Improvement Collaborative, an approach that incorporates elements of traditional health programming (guidelines, training, job aides) with modern QI elements (teamwork, process analysis). Different hospital or district sites collaborate to share and rapidly scale up strategies for improving quality and efficiency of the health service in their area. Collaboratives are intended as a time-limited strategy, with results seen in nine to 18 months. The common feature of all Improvement Collaboratives is that an intervention is introduced, and one or more indicators are monitored to see the intervention’s effect. If the intervention yields the desired improvement, it is then instituted as part of the new work process and implemented across the other providers. The article does not provide evidence of the program’s success.

Type of publication: Discussion.
REFERENCES


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