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What explains regulatory failure? Analysing the architecture of health care regulation in two Indian states

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Regulating health care is a pre-eminent policy challenge in many low- and middle-income countries (LMIC), particularly those with a strong private health sector. Yet, the regulatory approaches instituted in these countries have often been reported to be ineffective—India being exemplary. There is limited empirical research on the architecture and processes of health care regulation in LMIC that would explain these regulatory failures. We undertook a research study in two Indian states, with the aims of (1) mapping the organizations engaged with, and the written policies focused on health care regulation, (2) identifying gaps in the design and implementation of policies for health care regulation and (3) investigating underlying reasons for the identified gaps. We adopted a stepped research approach and applied a framework of basic regulatory functions for health care, to assess prevailing gaps in policy design and implementation. Qualitative research methods were employed including in-depth interviews with 32 representatives of regulatory organizations and document review. Several gaps in policy design were observed across both states, with a number of basic regulatory functions not underwritten in law, nor assigned to a regulatory organization to enact. In some instances the contents of regulatory policies had been weakened or diluted, rendering them less effective. Implementation gaps were also extensively reported in both states. Regulatory gaps were underpinned by human resource constraints, ambivalence in the roles of regulatory organizations, ineffective co-ordination between regulatory groups and extensive contestation of regulatory policies by private stakeholders. The findings are instructive that prevailing arrangements for health care regulation are ill equipped to enact several basic functions, and further that the performance of regulatory organizations is subject to pressures and distortions similar to those characterizing the wider health system. This suggests that attempts to strengthen health care regulation will be ineffectual unless underlying governance failures are addressed.

Keywords Health care regulation, mixed health systems, policymaking, implementation, policy analysis, policy mapping, qualitative research, India

KEY MESSAGES

- The ineffectiveness of health care regulation in low and middle income countries (LMIC) is widely observed, but there is little empirical research exploring the reasons for these failures
- We adopted a stepped research methodology to map health care regulatory institutions and investigate gaps in the design and implementation of regulatory policy, in two Indian states
- Extensive gaps in policy design and implementation were identified and found to be underpinned by human resource constraints, problematic organizational relationships and the 'capture' of regulatory processes by private interests.
- Attempts to strengthen regulatory institutions may be ineffectual unless the underlying governance failures are addressed.

Introduction

The challenge of health care regulation in LMIC

Populations in many low- and middle-income countries (LMIC) suffer, not just from the lack of access to health care, but from widespread poor quality, and affordability barriers, whenever it is available. Strong regulation of health care is essential to correct these negative aspects of health services and mitigate their ill effects. LMIC governments have adopted a range of approaches to health care regulation, yet the evidence for their effectiveness is scarce (Roberts *et al*. 2004; Ranson *et al*. 2010). Conversely, evidence of the failures of health care regulation in numerous LMIC abound. These include problems in assuring quality of care and upholding ethical provider conduct (Maestad and Mwisongo 2011; Peabody 2006), the inability of governments to stem spiralling health care costs and contain informal health markets (Barber *et al*. 2004; Matsebula *et al*. 2005; Mujinja *et al*. 2003; Peabody 2006; Ranson *et al*. 2010) and the enduring crisis of skewed workforce distribution affecting basic access to health care (Dussault 2008; Serneels *et al*. 2007). Health care regulation is a major challenge for health policy in many LMIC.

In spite of the importance of LMIC health care regulation for global health, the foundation for understanding the failures and challenges it presents is limited. Individual case studies make up the bulk of research investigating health regulatory failure in LMIC, and the institutional contexts for failures of health care regulation remain poorly explored. Given the importance of the subject, the rarity of empirical enquiry into how health care regulation operates in real-world settings of LMIC is remarkable—yet it is also typical of the broader neglect of research on health policy processes in LMIC contexts (Gilson and Raphaely 2008). We attempt to address this gap in the knowledge through an empirical study of the architecture and implementation of health care regulation in two states of India—Madhya Pradesh (MP) and Delhi. The aims of the study were to (1) map the different organizations engaged with, and written policies focused on health care regulation, (2) identify gaps in the design and implementation of policies for health care regulation and (3) investigate underlying reasons for the identified gaps.

Our understanding of regulation follows a definition by Roberts and colleagues—i.e. the power of governments to impose constraints on organizations and individuals (Roberts *et al*. 2004). This understanding acknowledges that regulatory operations are not undertaken exclusively by government departments, and that designated parastatal or privately managed organizations can also play an important role in regulation. The scope of the study is limited to regulation of the activities of organizations and individuals engaged in clinical-care provision (clinics, hospitals, doctors), and not of related spheres of activity such as professional education, drug production and sale or production of medical technology. As such, we concentrate on regulatory actions targeted at modifying the costs, quality and accessibility of health care, and the conduct of health care providers. Table 1 presents a framework of basic regulatory functions for health care, clustered under the four aforementioned outcome areas (adapted from Roberts *et al*. 2004).

The context of mixed health systems 'syndrome'

While undertaking any study on health care regulation, it is first important to understand the character of the health care system that is the object of regulation. While most countries combine private and public health care delivery in different degrees, a number of LMIC, including India, are additionally marked out by a distinctive mix in which 'out-of-pocket payments and market provision of services dominate as a means of financing and providing services' (Nishtar 2010). Nishtar theorizes that when such a public–private mix in health care shows signs of compromised quality and equity, it can be characterized as having 'mixed health systems syndrome' (ibid.). The adverse impacts of this syndrome for users of care are severe, and include high, frequently catastrophic out-of-pocket expenditures on health care contributing to impoverishment of households (Killingsworth *et al*. 1999; van Doorslaer *et al*. 2006); poor quality of care affecting the health of individuals as well as communities; frequent discrimination, denial of care and exploitation and outright unavailability of health care from qualified providers in villages as a result of their preferences for urban areas.

It is noteworthy that the syndrome is, in large part, underpinned by a complex of undesirable behaviours of health care providers. Overspending on health care partly results from providers advising unnecessary medicines, investigations and procedures and from informal payments sought and made in public-sector facilities (Bloom and Standing 2001; Maestad and Mwisongo 2011). Health care quality declines as a result of acts of commission or omission in both the public and private sectors, as well as knowledge gaps—particularly in the informal

Table 1 Framework of basic regulatory functions for health care (adapted from Roberts *et al.* 2004)

Target of Regulatory Activity	Regulatory functions	Existing health law or state-level health policy		Organization assigned to enact in health administration		Extent of implementation (as reported by officials)	
		MP	Del	MP	Del	MP	Del
Costs of care	Enact anti-trust laws and restrict predatory market conduct	No	No	No	No	NA	NA
	Establish price schedules	No	No	No	No	NA	NA
	Establish reference prices for treatment and procedures	No	No	No	No	NA	NA
Quality of care	License health care professionals	Yes	Yes	Yes	Yes	High	High
	License health care facilities	Yes	Yes	Yes	Yes	Low	Low
	Establish practice guidelines	Partial	Partial	Yes	Yes	Partial	Partial
	Establish patient reporting / feedback procedure	No	No	No	No	NA	NA
	Establish standard reporting procedures	Public sector	Public sector	Yes	Yes	Partial	Partial
	Establish clinical audit	No	No	No	No	NA	NA
Conduct of providers	Ensure patients' rights to redress	No	No	No	No	NA	NA
	Establish malpractice norms for health care professionals	Yes	Yes	Yes	Yes	Low	Low
	Ensure functioning disciplinary boards for health care professionals	Partial	Partial	Yes	Yes	Low	Low
	Establish liability norms for health care professionals	Contested	Contested	Yes	Yes	Low	Low
Accessibility of care	Ensure equitable rural-urban distribution of health care professionals	Yes	No	Yes	Yes	Low	Low

private sector. Provider misconduct passes widely unchecked in the poorly regulated environments that prevail in many LMIC (Bloom *et al*. 2008). And finally, as private health care providers gravitate towards cities, and rural government facilities suffer, due to the reluctance of health workers to locate in villages, and associated behaviours such as health worker absenteeism and dual job-holding in rural areas (Chaudhury *et al*. 2006; Dussault 2008; Radwan 2005). The Indian health system is widely afflicted by this complex of behaviours and as such, typifies mixed health systems syndrome.

What explains regulatory failure? Review of the literature

Laws mandating provider behaviour and client rights are considered to be the most stringent of direct regulatory strategies, yet there is limited evidence of their effectiveness. Explanations for the limited success of conventional legal mechanisms for health-care regulation vary. Inefficiencies in legal mechanisms have been widely attributed to lack of specificity and detail in the framing of relevant legislations (Peters and Muraleedharan 2008; Kumaranayake 1998). Additionally, in the event that legal controls are well established on paper, their actual implementation is often questionable (Peters & Muraleedharan 2008). Logistical issues and severe delays within the court system have been reported to reduce the effectiveness of these mechanisms (Bearak 2000).

In response to the concerns around conventional legal approaches, several countries have incorporated consumer-based legislation holding medical providers liable for adverse client experiences and outcomes, which purport to address many of the concerns of bureaucratic inefficiency and delay associated with the judiciary. The mechanism was shown to be popular in India, with over 75 000 medical cases filed all over India in a 15-year period (Muraleedharan and Prasad 2003). Yet, the same study, however, showed that medical cases were subject to extreme delays. The vast majority of cases involving medical complaints in Consumer Forums have ruled in favour of medically qualified defendants (Bhat 1996; Muraleedharan and Prasad 2003; Ensor and Weinzierl 2007), and their value as an effective instrument for regulating health care has been challenged.

Licensing and registration of health care professionals and/or facilities are legally supported regulatory strategies commonly used in LMICs, with the aim of assuring a standard quality of health care (Afifi *et al*. 2003). Typically, the responsibility of implementation and enforcement is delegated to non-state autonomous bodies such as professional medical councils. Failure in the efficient monitoring and enforcement of the licensing of practitioners is widely prevalent—ascribed to lack of funding support in a study of several African countries (Bennett and Ngalande-Banda 1994). This model of professional self-regulation has also been criticized on grounds that medical bodies are reluctant to take action against their own members—a phenomenon referred to as regulatory capture, observed in several different country contexts (Bennett and Ngalande-Banda 1994; Muraleedharan and Nandraj 2003; Tangcharoensathien *et al*. 2008; Teerawattananon *et al*. 2003).

Given the limited successes of legal and bureaucratic interventions in health-service regulation, there has been growing interest in the use of incentives and other less costly, market-harnessing mechanisms to influence behaviour in health-service delivery and utilization. Accreditation is one such mechanism that increases benefits to providers for complying with quality regulations. There is very limited data available on the effectiveness of accreditation in the improvement of performance, and of this much is limited to high-income countries (HICs) (Ranson *et al*. 2010). Questions frequently arise around how the voluntary nature of accreditation affects financial sustainability and inspection capacity. In addition, concerns have been expressed about whether the agencies in charge of enforcement have the legal standing to conduct their activities (Ensor and Weinzierl 2007).

In an effort to promote an equitable urban–rural distribution of health providers, many countries introduced medical educational bonds and mandatory rural service as regulatory instruments. Several LMICs have opted to place medical graduates in rural, remote and underserved areas for a set period of time, linked to the completion of their education and/or granting of a licence to practice (Roberts *et al*. 2004). Very limited evaluation has been conducted on the effectiveness of rural bonds, either with or without incentives attached (Ranson *et al*. 2010). It has been observed that incentives are often effective only as short-term measures (Reid 2002; Serneels *et al*. 2007). The ineffectiveness of rural bonds and compulsory service has been attributed to the lack of administrative capacity or the political will for enforcement in many countries (Dovlo 1999; Reid 2002), and in other instances to rampant corruption and favouritism (Wibulpolprasert and Pengpaibon 2003).

In summary, explanations for the failures of health care regulation in LMICs are varied and include the following:

- Lack of capacity and financial resources, and inadequacy of legal and organizational frameworks for regulation (Balabanova *et al*. 2008; Bennett and Ngalande-Banda 1994; Peters and Muraleedharan 2008)
- Corruption and lack of transparency and accountability of regulatory organizations (Wibulpolprasert and Pengpaibon 2003)
- Discrepancies between putative functions of regulatory organizations and the roles they actually perform (Bloom *et al*. 2008; Hongoro and Kumaranayake 2000; Sheikh 2008)
- Low political will for regulation, and 'capture' of regulatory institutions by vested interests (Tangcharoensathien *et al*. 2008; Verma *et al*. 2002)
- Information asymmetries and unequal power relationships between providers and users in LMIC (Ensor and Weinzierl 2006; Muraleedharan and Prasad 2003)

We attempted to build on this limited body of research evidence explaining the causes of failures of health care regulation in our study, using a combination of policy mapping and in-depth qualitative research methodology. The following section details the research methods used in the study.

Methods

Study setting

Since states are granted jurisdiction of health in India's federal political system, the studies were undertaken with states as the

focus of enquiry. Delhi and MP were identified purposefully as two states with disparate health systems and regulatory capacity. Delhi, as the national capital region (NCR), is a relatively prosperous region with a largely urban character and a preponderance of private health facilities, whereas MP is one of the Government of India's Empowered Action Groups states (distinguished by poor development indicators) with a rural predominance, and a relatively low concentration of private care. These states were selected on the basis that their differing contexts—Delhi having the attendant privileges of being the NCR, and MP being a less developed state—were likely to be reflected in variations in the regulatory architecture and performance, thus providing an appropriate breadth of scope.

MP (population 72 million) is a vast state in Central India with a predominantly rural population and health status indicators poorer than the national average (Registrar General India 2009). The majority of hospitals in rural areas are government-run; however, the private sector dominates in urban areas and in the primary and outpatient sectors in general. Government institutions, including health regulatory institutions are concentrated in the state capital, Bhopal.

Delhi (population 16 million) is an urban agglomeration in northern India, part of which, New Delhi, is the national capital of India. Delhi NCR has better health indicators than many other states, and is home to some of the most advanced health-care facilities in the country. Delhi's numerous government health facilities are managed variously by the Directorate of Health Services (DHS), Delhi's two municipal corporations and by other public agencies such as the railways, armed forces and employee insurance organizations. There is also a dense concentration of private clinics and networks of corporate hospitals providing health care services.

Research process

We adopted a stepped research approach to map the regulatory architecture and investigate regulatory processes in each state. The approach facilitates the systematic identification of gaps in the design and implementation of regulatory policy, and of the underlying reasons for the gaps. The steps are summarized in Figure 1. Fieldwork for the study was undertaken in the year 2010.

In Step 1, the broader context was outlined—i.e. details of the political and administrative system and characteristics of the health system in the state being studied. Step 2 of the framework involved collating laws and policies related to different aspects of regulation of health care provision, and extracting the clauses that relate to specific regulatory activities. Relevant policy documents were obtained from Internet sources, and physically from various government departments. These documents consisting of laws, government orders, constitutions of organizations, organizational rules, circulars and official correspondence were scrutinized in depth for mention of the specific regulatory functions assigned to different groups. Relevant text from these documents was extracted and used to populate the map of regulatory architecture (Figure 2) for the state in question.

Step 3 involved listing all regulatory groups identified by reading the materials collected in Step 2, and conducting interviews with senior officials or representatives of the identified regulatory groups. A list of senior and experienced officials of each of the groups was prepared, who would be expected to be aware of the goals and objectives of their respective organization, and of its internal functioning. Appointments were sought by telephone, email or personal visits, and all participants were interviewed in their usual places of work. A total of 47 respondents were approached of whom, 15 declined to participate, or indicated that they did not have the time to meet. In such instances an alternative official representative of the group was approached.

Details identifying the study participants and linking them to the group they represented are withheld for reasons of anonymity. In addition to government regulators ($n=29$), representatives of voluntary medical and nursing home owners' associations ($n=3$) were also interviewed. A total of 32 interviews (14 in Delhi and 18 in MP) were conducted by teams of two investigators. Topic guides included questions on the 'expected' regulatory functions of the represented groups, actual experiences of executing these functions and probes to elicit explanations of these experiences.

Text from the transcripts of interviews was thematically organized using the 'framework' approach of qualitative analysis for applied policy research (Ritchie and Spencer 1994), and written up. Quantitative data on the performance of many of the regulatory organizations (e.g. numbers of establishments empanelled or number of doctors struck off) were unreliable, and hence do not form part of the analysis except, in some instances, to corroborate or support the qualitative findings.

Step 4: the data from Steps 2 and 3 was synthesized into maps of the regulatory architecture in the state (see Figure 2). In the final step, the maps were examined to identify regulatory functions, from the framework of basic regulatory functions for health care (Table 1), which were not underwritten in policy nor assigned to any group or organization to enact. A comparison of the expected roles of different organizations with their actual roles enabled identification of implementation gaps. In-depth analysis of interviews yielded underlying explanations for these gaps. Outputs of the research included (for each state) a map of the regulatory architecture (Tables 2 and 3), and an accompanying narrative report elaborating the policy gaps and the reasons for the gaps.

All interviews were conducted following verbal consent and presentation of a standardized information sheet. Consent was recorded by way of a signed and witnessed undertaking by the interviewers, stating that free and fully informed consent was taken from the participant. Care was taken while writing up to exclude particulars of individuals that may have led to their identification.

Results

Organizations and government departments with functions relating to health care regulation, as well as the laws and rules defining these respective functions, were identified in the two states. The regulatory architecture maps for the states are presented in Tables 2 and 3.

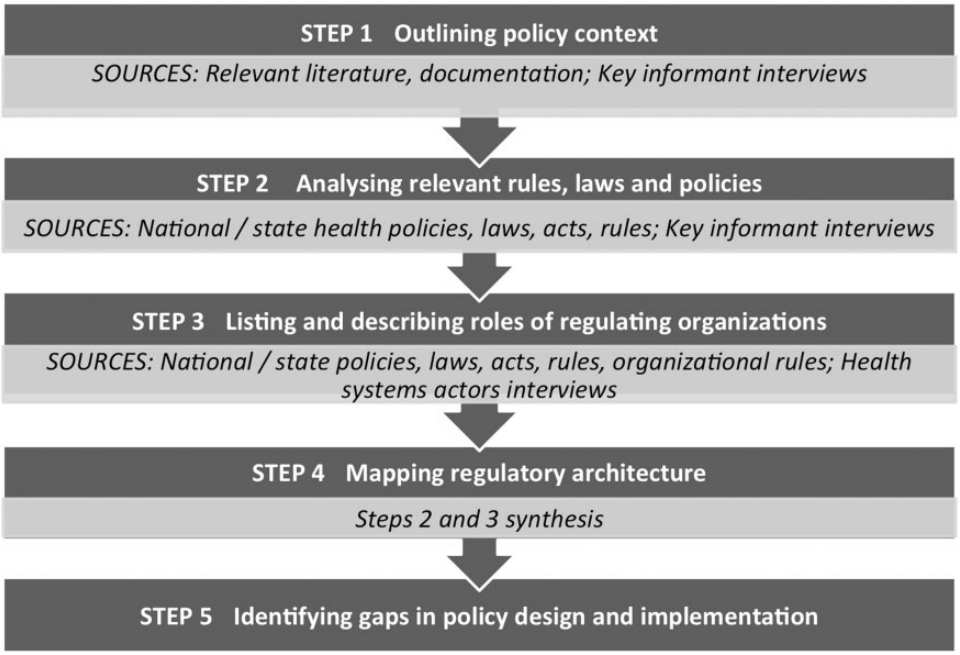

Figure 1 Outline of research process: steps, sources of data and outputs

Primary target of regulatory policy	Groups tasked with relevant functions	Relevant laws, rules and policies	Type of law / rule / policy	Relevant activities expected of groups	Relevant activities performed by groups
Cost of health care					
Quality of health care					
Conduct of health providers					
Accessibility of health care					

Policy design

Implementation gaps

Figure 2 Template for regulatory architecture map

Policy design

An overview of the existing health care regulatory architecture for these two states revealed notable issues with policy design. When compared with the list of basic regulatory functions in Table 1—several key regulatory functions are either entirely absent or are not well developed. In other instances, states have undertaken regulatory measures that are not listed under the basic functions.

Costs of care

Within the health administration, MP had no known regulatory approach for alleviating high costs for users of health care,

Table 2 Map of the regulatory architecture for health care: MP state

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
Costs of care	DHS: Office of the Chief Medical and Health Officer (CMHO) of the District	Official (government scheme)	Janani Sahayogi Yojana (JSY)	Assessment of applications of interested private sector providers, physical verification by a committee headed by the CMHO and granting of accreditation	
			Source: Government of MP, Department of Public Health and Family Welfare, DHS, Government Order	Receipt of weekly report of from accredited providers, forwarding report to State Directorate	(Not enough data, since scheme recently initiated)
				Physical inspection of a minimum number of accredited providers, periodically.	
			RCH/MH/09/160 dated 01.07.2009 and RCH/MH/10/638 dated 16.06.2010, Bhopal	Cancellation of accreditation in case of private provider's non-compliance to minimum standards	
Quality of care	DHS: Office of the Chief Medical and Health Officer (CMHO) of the District	Statutory	MP Upcharyagriha Tatha Rajopchar Sambandi Sthapanaye (Rajistrikaran tatha Anugyapan) Adhiniyam, [Clinical Establishments Act] 1973; § 4(1) & (2), § 7, § 8 ff, § 5, § 6, § 19	Registration of private clinical establishments in accordance with infrastructure and personnel standards	Registration not universally implemented, many establishments function unregistered
				Periodic inspections of facilities to assess adherence to norms	Inspection routine severely impeded by manpower shortages/unavailability, and by requirement of coordination with magistrate and police
				Imposition of penalties for non-compliance to norms, issuance of notifications for rectifying faults	Conducted, frequently contested by establishments
				Cancellation of registrations due to non-compliance and conviction	Possibly infrequent or delayed, as a result of contestations. Further action leading to physical closure of establishment is often delayed
				Receipt and processing of applications for renewal of clinical establishments, every 3 years	Recently introduced. Qualified cooperation from nursing homes
				Maintenance and receipt of records of births, deaths and infectious diseases	Partial compliance by establishments
			Medical Termination of Pregnancy Rules, 2003. § 6 ff., § 7 ff., § 4 (5).	Inspection, verification, and approval of private establishment for conducting MTP	Not undertaken fully, due to low prioritization of issue. Cancellation predicated on prior registration under CEA, which is not always the case
				Cancellation of approval of facility to conduct MTPs in case of non-compliance	
				Soliciting weekly statements from approved facilities about MTPs conducted	Likelihood of frequent under-reporting, non-adherence to norms

(continued)

Table 2 Continued

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
	DHS District Quality Assurance Group Department of Maternal and Child Health	Official (government policy)	Government of MP, Department of Public Health and Family Welfare, 2006. '*Quality Assurance procedures for Reproductive and Child Health Services in Public Health System*', Bhopal, 2006	Plan visits of Quality Assurance Group to public facilities, undertake inspections, compile findings, prepare reports Feedback to the facilities with guidance for corrective action, forward minutes to CMHO and Deputy Secretary, Maternal Health Training and monitoring the implementation of Standard Treatment Protocols for maternal health	QAG visits, training and dissemination of STPs conducted. Some deficits in providing feedback and undertaking corrective action
	MP Medical Council	Statutory	MP Ayurvigyan Parishad Adhiniyam, 1987. § 10 (1), § 11 (3), § 13 ff, §22, Indian Medical Council Act, 1956	Registration of graduates for practice of allopathic medicine, registration of additional qualifications, submission of updated list to the National Medical Register	Registration activities ongoing as mandated
					Issuing certificates of good standing for emigrating doctors
	MP Ayurvedic, Unani and Naturopathy Board	Statutory	MP Ayurvedic Unani Tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970. § 21 ff, § 27, § 24 Indian Medicine Central Council Act, 1970	Registration of the practitioners of Ayurveda, Unani and Naturopathy, registration of additional qualifications, submission of updated list to central Register of Indian Medicine	Registration activities ongoing as mandated
	MP Homeopathic Council	Statutory	MP Homeopathy Parishad Adhiniyam Central Council of Homeopathy Act, 2002	Registration of the practitioners of Homeopathy, registration of additional qualifications, submission of updated list to central Register	Registration activities ongoing as mandated
Conduct of providers	MP Medical Council	Statutory	The MP Ayurvigyan Parishad Adhiniyam, 1987. § 15 ff, § 16 (1) & (2), § 16 (3) ff.	Receipt of complaint against practitioner or taking cognizance if the practitioner has been convicted in the court. In-camera hearing and adjudication by disciplinary committee Suspension or cancellation of practitioner from the State medical register, if guilty Restoration of the suspended name on expiry of the term of suspension	Minimal emphasis on disciplinary role and procedures
					Receipt of, and forwarding complaints about non-qualified providers

(continued)

Table 2 Continued

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
	MP Ayurvedic, Unani and Naturopathy Board	Statutory	MP Ayurvedic Unani Tatha Prakritik Chikitsa Vyavasayi Adhiniyam, 1970. § 29 (1) ff, § 35	Removal of the name from the Register either for a fixed term or permanently for proven misconduct.	Minimal emphasis on disciplinary role and procedures
	MP Homeopathic Council	Statutory	Homeopathy Central Council Act 1973	Removal of the name from the Register either for a fixed term or permanently for proven misconduct.	Minimal emphasis on disciplinary role and procedures
	State Consumer Disputes Redressal Commission, District Forums	Statutory	Consumer Protection Act, 1986. § 11 (2) ff, § 17 (a) (ii) Consumer Protection (Amendment) Act, 2002, § 7, § 13	Adjudicating cases of medical negligence under consumer law, and consequent redress Entertain appeals against adjudications of the District Forum (State Commission)	Numerous cases adjudicated. Outcomes in favour of defendents predominate
	DHS Office of the Chief Medical and Health Officer (CMHO) of the District	Statutory	Pre-conception and Pre-natal Diagnostic Techniques Act 1994 §17 (4) (a), §23 (1), §17 (4) (i), §19 (3) Pre-conception and Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002. §14 ff.	Registration and licensing of Genetic counselling centres, clinics and laboratories Investigation of complaints of breach of the provisions of the Act and suspension/cancellation of registration of genetic counselling centre, laboratory or clinic for non-compliance to standards Renewal of existing licenses	Registration activities conducted as mandated Very few or no cancellations—no data made available. Cancellation predicated on prior registration under CEA, which is not always the case Renewal activities conducted as mandated
	Directorate of Medical Education	Statutory	Transplantation of Human Organs Act, 1994 § 13 (3) i), § 13 (3) ii), § 13 (3) iii) , § 13 (3) iv)	Registration of hospitals to perform organ transplantation (cornea, kidney and liver transplants) Enforce standards, investigate the breach of conditions of Act, cancel registration of hospitals found to breach conditions	(Data on actual activities inconclusive)
Accessibility of care	Directorate of Medical Education	Statutory	MP Medical and Dental Undergraduate Entrance Examination Amendment Rules, 2009. §11. Pre-Post Graduate Test Rules (Amendment) 2009. §9 ff, §12 ff	Compilation of list of eligible graduates for mandatory rural service (rural bond), delivery of list to DHS for postings	Limited implementation due to inability to make appropriate placements, and due to extensive legal contestation of Bond provisions by doctors' associations.

Table 3 Map of the regulatory architecture for health care: Delhi NCR

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
Costs of care	Rashtriya Swasthya Bima Yojana (RSBY)Nodal Agency	Official (government scheme)	Government of India, Ministry of labour and Employment, *'Rashtriya Swasthya Bima Yojana'*, http://www.rsby.gov.in/about_rsby.aspx accessed on 10 November 2010	Empanelment of private facilities based on minimum standards, ensuring adherence to norms and standards, de-registration in case of breach	90 private establishments enrolled Post-facto monitoring of the records maintained by private establishments. Identification of fraud in some instances and three hospitals de-empanelled. No direct oversight to prevent fraud and unnecessary procedures
				Enrolment and allocation of smart cards to RSBY eligible members, dissemination of information to RSBY members about eligible facilities for health services	Enrolment lower than targeted, possibly due to low awareness of programme among beneficiaries
	Directorate of Health Services: Nursing Home Cell	Official (State government policy)	Guidelines for provision of free treatment facilities to patients of EWS category in private, 2007 http://www.delhi.gov.in/wps/wcm/connect/3cd0a5004d9238eeaa5eaf09e0ee946a/guidelines.pdf?MOD=AJPERES accessed on 24.05.2010. § A 5, § A 10,§ A 5, § A 16 & 17	Monitoring of the free treatment for 10% in-patient beds and 25% of Out-patient to the Economically Weaker Sections (EWS) by the Private Hospitals that have been allotted land on concessional rates by the inspection committee. Inspection of the records, solicitation from private facilities of twice-daily report on the availability of free beds, and three-monthly report on utilization of free beds	Inadequate regulation of subsidy conditions widely recognized, attributed to lack of role clarity between departments, and resource limitations
Quality of care	DHS: Nursing Home Cell, and district CDMOs	Statutory	Delhi Nursing Home Registrations Act, 1953. § 4 (1),§ 9 ff, § 7 ff, § 6, § 8	Registration and renewal of private clinical establishments in accordance with infrastructure and personnel standards	Registration not universally implemented many establishments function unregistered
			http://www.delhi.gov.in/wps/wcm/connect/doit_health/Health/Home/DHS/Nursing+Home+-Cell accessed on 24.05.2010	Inspections of facilities to assess adherence to norms, periodically, and in response to complaints	Inspections inadequately performed, typically only in response to complaints, attributed to lack of capacity, motivation, political influence of facility owners
				Cancellation of the registration, imposition of penalties in case operating without registration	Cancellations of a small number of establishments. Action in case of non-registration rare, attributed to lack of capacity, motivation, political influence of facility owners
	DHS: CME Cell	Department policy	-	Organization of CME for government practitioners, dissemination of information regarding training programmes	CME undertaken in various technical domains, however overall execution of CME reported to be inadequate. Attributed to lack of official mandate, coupled with inadequate follow up by DMC

(continued)

Table 3 Continued

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
	Delhi Medical Council	Statutory	Delhi Medical Council Act, 1996. §15(3),§ 22 ff, § 15 (2), Indian Medical Council Act, 1956. §22	Registration of graduates for practice of allopathic medicine, maintenance of State Medical Register, periodic reporting of the registry to the National Register	Registration activities ongoing as mandated. Several forged certificates identified in previous months, leading to arrest of culpable parties
				Notifying registered practitioners for renewal of registrations every 5 years contingent on CME credits, receipt and processing of renewals from practitioners	Enforcement of renewals of registration inadequate, CME credits rule not implemented
					Receipt of complaints of non-qualified providers, forwarding to authorities, and anti-quackery advocacy *Guidance to, and protective measures for practitioners at risk of violence from patients and families*
	Delhi Bharatiya Chikitsa Parishad	Statutory	Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998. § 10(a), § 25 ff, § 33 ff, § 10(h). Indian Medicine Central Council Act, 1970. § 24	Registration of the graduates for practice of Indian medicine, maintenance of State register of Indian Medicine, reporting to Central Council	Registration activities ongoing as mandated
					Active identification of, and receipt of complaints of non-qualified providers, forwarding to authorities, and anti-quackery advocacy
Conduct of providers	Delhi Medical Council	Statutory	Delhi Medical Council Act, 1996. § 21 (2) ff. § 21 (3) & (4).	Receipt of complaint against practitioners In-camera hearing and adjudication by disciplinary committee Suspension or cancellation of practitioner from the State medical register, if guilty Restoration of the suspended name on expiry of the term of suspension	Complaints from aggrieved patients received and processed. Some instances of rulings against doctors, typically followed by minimum punitive action, i.e. suspension for 1–3 months. Precise data of de-registrations not made available
	Delhi Bharatiya Chikitsa Parishad	Statutory	Delhi Bharatiya Chikitsa Parishad Adhiniyam, 1998, § 23 (2) ff. § 23 (4) ff. § 24 (2)	Receipt of complaints on ethical misconduct, conduct of enquiry by disciplinary Committee. Suspension of practitioner or removal from Register on establishment of the misconduct Reinstatement of the name in the register if found that the implicated charges are found to be false, or expiry of suspension period	No evidence of disciplinary action forthcoming. Minimal emphasis on disciplinary role and procedures

(continued)

Table 3 Continued

Target of Regulatory Activity	Group(s) tasked with relevant activities	Type of authority invested with group	Relevant policies and clauses	Relevant activities expected of the organization	Relevant activities actually performed by the organization (and additional activities in *italics*)
	State, District Consumer Disputes Redressal Forums	Statutory	Consumer Protection Act, 1986. §11(2)ff, § 17(a) (ii) Consumer Protection (Amendment) Act, 2002. §7, §13	Adjudicating cases of medical negligence under consumer law, and consequent redress	Numerous cases adjudicated. Subjective nature of the cases related to medical negligence makes it difficult to determine the ruling. 'Benefit of doubt' is often given to doctors
Accessibility of care	DHS: Hospital Cell	Official (State government policy)		Planning and establishment of hospitals, under supervision of DoHFW, following assessment of need and due inspections	Limited control over location of hospitals due to greater controlling influence of Urban development authority

other than (at the time of the study) a recently introduced scheme for contracting private providers to provide free obstetric services (Table 2). In Delhi, a national social insurance scheme and government subsidies to private hospitals on condition that they provide free treatment to a minimum number of poor patients, are both aimed at reducing costs of accessing private health care, specifically for the poor (Table 3). It is likely that national laws and a national-level agency exists to regulate anti-trust practices in industry generically. However, there was no known policy, nor any group or department designated with functions in this area specifically for the health care sector, in either of the two states. There are also no policies, nor any regulatory groups focused on benchmarking prices of medical treatment and procedures in the private health care sector, in either state.

Quality of care

Both states had a number of policies aimed at improving the quality of care in health services, and had mandated specific organizations to enact these policies (see Tables 2 and 3). These included laws covering the licensing of health care professionals by professional councils, as well as health establishments laws for health care facilities to be licenced and to follow standard infrastructure and staffing norms. Notably, numerous amendments had been made in the health establishments law in both states, following contestation by doctors' groups. Several original conditions for facility registration were reported to be weakened or absent in the current iterations of the laws.

Paradoxically, while there were policies requiring qualified professionals to obtain licences, there was no specific mechanism to limit the practice of medicine by unqualified providers in either state. There was no standard procedure in place for receiving or processing patient feedback and reports on the quality of health care, or for clinical audit, in either state. In MP, centralized clinical practice norms and standard reporting procedures were adopted to a limited extent (for reproductive and child health services and medical termination of pregnancy only) and were only applicable in government-run health care facilities. In Delhi no such policies were in operation.

Conduct of providers

Professional regulation by quasi-autonomous councils, and consumer legislation through fast-track courts or 'forums' were, in both states, the *de facto* regulatory approaches to address the issue of conduct of health providers (see Tables 2 and 3). Professional medical councils had disciplinary boards, and some council laws included clear definitions of provider malpractice. Neither state had a policy guiding the processing of patient grievances and providing redress against provider misconduct.

Offices of the health directorate and department of medical education were, respectively, tasked with implementing two special laws focused on preventing the misuse of health technology in health care settings. These laws were focused, respectively, on preventing the common practice of foetal sex-determination associated with sex-selective abortions, and with controlling human organ transplantation to ensure technical standards and to obviate exploitative practices and trade in organs. Specifically, the government departments were tasked

with licensing health care facilities to perform diagnostic tests and undertake human organ transplantation, with ensuring standards in the licensed facilities, and with investigating instances of breach of the laws.

Accessibility of care

Neither state had policies to incentivize or support health practice in rural or outlying areas, or to improve working conditions in these areas. MP had a policy requiring mandatory rural service for recent medical graduates, as a means to improve the distribution of qualified health care professionals to rural areas (Table 2). This policy and its contents had been the subject of contestation by medical groups and associations, leading to several concessions and modifications in content. In Delhi, the issue of improving accessibility of care through more equitable workforce and facility distribution was not addressed by any policy (Table 3). However all new hospitals in Delhi were expected to be established under supervision of the health directorate.

Policy implementation

Where regulatory policies did exist and particular groups were mandated to implement them, data from interviews with regulators and from the review of policy documents revealed widespread differences between the expected and actual activities of different regulatory organizations (See Tables 2 and 3). In some instances regulatory groups undertook additional duties that were not part of their official mandate.

Costs of care

The social insurance scheme had very low coverage in Delhi. At the time of the study, a small fraction of the actual numbers of eligible hospitals and beneficiaries, respectively, had been enrolled in the scheme. The policy of free provision of services to poor patients by government-subsidized private hospitals was widely reported to be inadequately implemented in Delhi, with few hospitals complying with the requirement. The scheme to contract private providers for obstetric services in MP had just commenced at the time of the study, and no data were available on its implementation.

Quality of care

Registration of qualified health professionals was widely reported to be undertaken as mandated by professional councils in both states. However newer initiatives for continuing medical education (CME) and for linking CME to retention of licences in Delhi were not being widely implemented. Professional councils also undertook specific tasks that were not part of their official mandate such as campaigns against the practice of medicine by unqualified practitioners, fact-finding and referral of complaints about unqualified practitioners to government health departments, and advocacy for better security of doctors at risk of violence from patients and their families.

Inspections of registered establishments by government health departments in both states were reported to be infrequent, and cancellation of hospital licenses was extremely rare. If a nursing home does not follow norms, it is liable to be de-registered. However, in MP, it was reported that this seldom occurred, partly due to long-drawn and frequent contestations by the establishments, and partly because de-registration was sometimes regarded as a low-priority concern by higher authorities. Unregistered hospitals and clinics flourished in both states, and were reported to outnumber those with formal licences.

Within the government health care sector, there was an effort to improve treatment practices through the imposition of standard treatment protocols for reproductive and child care in MP. Training of trainers had taken place, materials had been developed for display and case sheets monitored for prescribing details. However, there was no procedure for corrective action, if it was found that the treatment protocols were not being followed.

Conduct of providers

In both states, the engagement of different professional councils with their disciplinary roles and procedures was minimal, and in some instances there was no evidence of any disciplinary activity. When negligence was ruled, punishments were often of the lowest order. Some representatives of councils questioned the necessity of their playing a disciplinary role, given the emerging role of the consumer forums in adjudicating medical negligence.

The consumer forums in both states reported having processed numerous complaints against medical professionals. Medical cases typically took very long to adjudicate, and outcomes were heavily weighted in favour of defendants, they reported. It was suggested that the 'subjective' nature of medical cases, and requirements of expert medical testimony often made it difficult to rule against doctors. Forum officials frankly admitted that doctors often received 'the benefit of the doubt' in judgements, since they are seen as doing fundamentally noble work.

Registration and renewal of facilities under the two special laws (against foetal sex-determination and on organ transplantation, respectively) were reported to be conducted as mandated. However, there were difficulties reported in establishing infringements of the law on technical grounds, in some cases. Paradoxically, many well-established facilities offering ultrasound diagnostics operated unofficially and did not have basic licences to practice (under the basic establishments law—see above). Since the special laws were only applicable for licensed establishments, the unlicensed facilities were not listed for inspection in the first place, and continued to operate entirely outside regulatory scrutiny.

Accessibility of care

The implementation of mandatory rural service was widely admitted to be partial and piecemeal. Despite the compilation of lists of eligible candidates for rural postings in MP, the postings had not been assigned over the preceding 2 years. In Delhi, while the health directorate is mandated to oversee the locations of new hospitals, in actuality, informants said that agreements to provide land for establishing new private hospitals were implemented by the urban development authority. The health directorate was reported to have merely an advisory, not authoritative, role in this respect.

Reasons for policy gaps

Human resource shortages

Inadequacies of the human resource capacities of regulatory organizations, notably shortages of inspectors, was one of the main emerging explanations for regulators' inability to fulfil mandated roles. Efforts of government departments to scale up facility registration and conduct regular inspections were reported to be constrained by a disproportionately small number of inspectors compared to facilities. In Delhi, lack of enforcement of the policy for free provision of services to the poor in government-subsidized private hospitals, was also ascribed to shortages of inspectors. Respondents suggested that recent shifts in policy had led to reduced investment in the regulatory capacity of government health departments.

Ambivalent organizational role and identity

Ambivalence in organizational role and identity was another apparent impediment to the successful implementation of existing regulatory policies. Typifying this were the statutory professional councils in both states, which were observed to be less engaged with their primary, disciplinary function, and more with voluntarily added roles of providing leadership and protection to the medical community. The councils were not only widely ineffective in enforcing the codes of ethics but, further, they also participated in a range of non-mandated activities including facilitating action against unqualified medical practitioners and advocating personal security for doctors. Some members of professional councils questioned whether councils should have a disciplinary function at all.

For officials in government departments, it was sometimes difficult to combine their regulatory roles with other functions necessitating good relationships with the politically influential community of local health care providers. In one instance, health department officials highlighted how they could not de-register many private establishments that were not adhering to standards, since they needed their co-operation to collect epidemiological data on an outbreak. Government health departments tasked with both regulatory and community functions tended to neglect the former.

Inter-organizational factors

Problems of co-ordination and communication, including conflicts, between various departments and organizations engaged in regulation played a role in impeding effective implementation of regulatory policies. A significant example of this is the difficulties posed by the requirement for health departments to co-ordinate with the police department and a magistrate, while undertaking inspections and closures of private health facilities. This was cited as one reason for the ineffectiveness of inspections as a regulatory mechanism, and the rarity of closure of non-complying health facilities.

The implementation of mandatory rural medical service in MP was similarly reported to be hampered by problems in co-ordination between government departments—essential for placing graduating students in appropriate rural centres. Another example of inter-organizational constraints highlights that health-sector organizations frequently do not have the power to implement key decisions. In Delhi, the role of determining the location of new private hospitals is reportedly mandated to the urban development authority, with the health department playing only an advisory, non-decisive role.

Stakeholder contestation of regulatory activities

Private groups in both states were reportedly active in lobbying to influence both the contents of regulatory policies and their implementation. In particular, medical professional associations appeared to have exercised their voice actively in regard to the contents of regulatory policies. Typical of this voice and influence were the repeated amendment of laws for minimum standards in health facilities in both states, following contestation by medical professional groups. Several original conditions for clinic registration were reportedly weakened or absent in the present iterations, including minimum standards for space, infrastructure for invasive procedures and personnel. Similarly, in MP the contents of mandatory rural practice policies for graduating doctors were the subject of repeated contestation by doctors' groups.

The implementation of rural practice policies was also reported to be weakened by widespread non-compliance by the graduates, supported by influential medical associations.

Health facility inspections by government regulators were frequently contested by the owners of the facilities, who in some instances reportedly wielded social pressure and political influence. In another instance of power of organized professions, negligence rulings against doctors in consumer courts were reported to be rare, partly explained by difficulties in obtaining negative testimonies from other medical professionals. Voluntary medical associations were also reported to lend their active support, by way of legal and financial assistance, to doctors accused of medical negligence.

Discussion

Contrary to some perceptions of a highly bureaucratized regulatory environment in India, our findings suggest that the health regulatory architecture in these two states is inadequately developed. Deficiencies in policy design are compounded by numerous shortfalls and obstacles in the way that existing policies are implemented. The marked similarity of findings in these two states with otherwise varying characteristics suggests that these may not be atypical of other settings in India.

Health being a subject of jurisdiction by states in India, enquiries were undertaken only at state level, and we only investigated regulatory policies and groups that explicitly dealt with health care. A richer analysis of policy gaps could be expected through in-depth study at both higher (national) and lower levels, and by investigation of policies and regulatory organizations that were not explicitly focused on regulating health care. However, this was felt to be beyond the scope of this study.

Gaps in policy design included omissions in the existing legal and policy framework for health care regulation, with many basic regulatory functions being either not underwritten in policy or not assigned to an implementing organization, or both. This was particularly marked in the context of regulating the costs of care (see Table 1). These findings support Peters and Muraleedharan (2008), who highlighted gaps in the legal framework for regulation in India. Another

type of gap in policy design was the weakening of the content of existing policies, rendering them less effective—something observed in a variety of LMIC settings (Kumaranayake 1997; Peters and Muraleedharan 2008). This was observed particularly in instances where doctors' groups felt that their interests were at risk of being compromised such as in the case of laws regulating standards for health care establishments, and rural service policies.

Gaps in implementation were more diverse, and were observed across the four outcome areas, as reported from other different LMIC contexts (Bennett and Ngalande-Banda 1994; Tangcharoensathien *et al*. 2008). Implementation gaps were most pronounced around ensuring the conduct of health care providers (Table 1). Disciplinary actions by professional councils were rare, and rulings on medical liability cases in consumer courts were heavily weighted towards defendants. Apart from the one-time task of licensing qualified health care professionals, most policies regulating health care quality, accessibility and costs were reported to be poorly or partially implemented.

Cardinal among reasons for regulatory gaps was the incapacity of regulatory agencies to perform their roles as a result of inadequacy of human and financial resources. Additionally, many officials of regulatory organizations expressed ambivalence or conflicting views about the roles and goals of their own organizations, and the division of functions with other regulatory organizations. The problem of health officials experiencing ambivalence between their regulatory and community roles, leading to neglect of the regulatory functions, echoes findings from another Indian study (Sheikh and Porter 2011). The widespread infiltration and expression of private interests within regulatory agencies, reflected in conflicts of interest and distortions in both the design and implementation of regulations, echoes reports of regulatory 'capture' from other Asian contexts (Tangcharoensathien *et al*. 2008).

The emerging complex of poor capabilities of public-sector organizations and the infiltration and dominance of private interests in how regulatory policies are made and implemented, parallels the broader pathology of the mixed health systems syndrome in the Indian health sector. Plausibly, as regulatory institutions are embedded in societies and markets, they are subjected, in the performance of their roles, to a similar set of pressures and distortions to those characterizing the broader health system.

The unpreparedness of existing institutions for the formidable challenges of regulating health care raises discomfiting questions around their societal relevance. Paradoxically, even as they occupy publicly mandated spaces, some regulatory organizations may be responsible for perpetuating rather than alleviating the distortions of mixed health systems syndrome. A state of regulatory inefficiencies and private capture persists and evades correction, highlighting broad-based failures of governance and accountability in the health administration. The inattention to regulatory failure also indicts civil society and political institutions for their ineffectiveness in, respectively, enabling citizen action on the ills of mixed health systems, and aggregating political capital on the need for stronger regulatory institutions. As important as it is, regulation has few influential champions and is seldom a popular aspect of health reforms, borne out by the prevailing emphasis on distributive innovations and reforms in India (Kumar *et al*. 2011). More populist programmes such as reforms to achieve financial coverage receive much more attention (Dror and Vellakkal 2012; Shukla *et al*. 2011).

Institutional strengthening for better health regulation in Indian and comparable LMIC mixed health systems may necessitate reforms that combine greater resources with statesmanship and vision, and the will to address inequalities of power. In the first place is the issue of capacity. Clearly the regulatory agenda will remain unmet if governments do not commit to raising the profile of health care regulation, and building the physical and financial resources of regulatory institutions, to the level that they are able to exert an equivalent influence on the problems at hand. Building capacity also involves ensuring clarity of roles for different regulatory organizations and ensuring that their actions are mutually complementary and synergistic. Divorcing the regulatory and public health functions of government departments may be an important part of such role clarity, since the two functions call for radically different types of relationships with the community of health providers. Second is the question of oversight. The findings highlight the need for a renewed approach to the architecture and design of regulatory policy, one which ensures that all basic regulatory functions are written into the law, and enacted. Finally, efforts to strengthen regulation will not progress, and may even regress, if governments do not explicitly recognize and confront the power of vested interests entrenched within regulatory institutions.

Authors' contributions

All three authors were involved in conceptualizing and designing the research study, and drafting and critically revising successive drafts of the manuscript. K.S. and P.S. were instrumental in collecting, analyzing and interpreting the data.

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