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Mapping the regulatory architecture for health care delivery in mixed health systems in low- and middle-income countries

Kabir Sheikh

Public Health Foundation of India

Prasanna Saligram

Public Health Foundation of India

Lakshmi E. Prasad

Public Health Foundation of India

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Corresponding author:

Kabir Sheikh

Kabir.sheikh@phfi.org

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SUMMARY

Many low- and middle-income countries (LMIC) in Asia share an emerging climate of health care provision that is increasingly recognised as 'mixed health systems syndrome'. Regulation of health care remains a pre-eminent challenge for future health policy in these LMIC. The failure of regulation can be most proximally located in the failure of regulatory institutions. Yet, the specific institutional and systemic contexts for failures of regulatory policies remain poorly explored and represent a significant gap in the knowledge.

Policy Research Tool

The research tool proposed in this paper is designed to map empirically and characterise the prevailing regulatory architecture for health care provision in a sub-national geopolitical unit (province or state). The tool combines the use of desk and field-based methods and is founded on actor-centred frameworks of policy research, including 'empirical constitutionalism' (Hjern and Hull 1982) and 'backward mapping' (Elmore 1982). The analysis we propose is both on policy and for policy, and is exploratory and diagnostic. It is not evaluation research, since it does not purport to assess the performance of organisations or systems against a standard.

Actual roles of state and non-state groups and organisations in enacting different aspects of health care regulation are elicited and compared with the putative or expected architecture of regulation. Consequently, gaps can be identified in the design and implementation of regulatory policies. The outputs of the research can be utilised to effect modifications in the design of regulatory policies and institutions, to strengthen particular aspects of implementation and as a baseline against which to assess the success of regulatory reforms.

Pilot Studies

The research tool was applied to conduct pilot studies in two states in India, Madhya Pradesh and Delhi. The regulatory architecture for health care provision was mapped and key design and implementation gaps identified in both states. In Madhya Pradesh, policy design gaps were most apparent in the cost of care. Also key was the absence of a formal system for the control of quackery, of a community-based platform to address grievances with care quality and conduct of providers and of supportive or incentive-based approaches to improve provider distribution in rural areas. Major gaps in implementation included low coverage of policies for registering clinical establishments and inefficiencies in corrective procedures for erring establishments and medical professionals and for enforcing mandatory rural placements. In Delhi state, design gaps identified included the absence of systematic approaches to regulate accessibility of care, costs of care for non-economically weaker sections (EWS) and the absence of a formal mechanism to limit quackery and of a community-based platform to address grievances with care quality and conduct of providers. Key implementation gaps included low coverage of schemes for social insurance and policies for registering clinical establishments and inefficiencies in implementing disciplinary procedures for medical professionals and determining the locations of new hospitals.

Assessment of Methodology

Strengths of the tool are its self-explanatory nature, coverage of regulatory domains and adaptability to different policy areas, while limitations include problems in achieving comprehensiveness, lack of analytic depth below state level, the related issue of accounting for a complicated federal structure and unresolved gaps in data collected. The tool has utility as a basis on which policy planners can redesign and re-delegate policy functions and plug unrecognised implementation gaps, for benchmarking institutional development and for comparative research, but needs further testing in varied settings.

INTRODUCTION

LMIC Mixed Health Systems

In this paper we are concerned particularly with mixed health systems in LMIC. Mixed health systems have been defined by Oxfam (2009) as entailing 'centrally planned government health services that operate side-by-side with private markets for similar or complementary products and services'. While most countries combine private and public health care provision in different degrees, a number of LMIC in South and South-East Asia, South and Central America, Central Asia and parts of Africa (constituting a significant proportion of the population of the world) are additionally marked out by the following distinct set of attributes and peculiarities.

Diversity in health care provision: this manifests as varied types of health establishments—from solo formal and informal providers and clinics to large mutli-speciality hospitals in the state and non-state sectors (Bloom and Lucas 2000; Berman 2001; Standing and Chowdhury 2008; Oxfam 2009), and also in the plurality of health practices encompassing informal local health traditions, more formalised indigenous or alternative systems of medicine and allopathic or Western medicine (Leslie 1980; Pedersen and Baruffati 1989; Sheikh and George 2010).

Dominant, poorly organised private markets: numerous reports from LMIC indicate that non-state providers are frequently more numerous, more accessible and more utilised than public sector services (Yazbeck et al 2001;; Standing and Chowdhury 2008; Mahal,; Limwattananon 2008 Lagomarsino, Nachuk and Kindra 2009), and that out-of-pocket payments dominate (Normand 1999; Lagomarsino, Nachuk and Kindra 2009; Nishtar 2010).

Compromised public services: public spending on health care constitutes a minority of health expenditures in LMIC (Nandakumar, Bhawalkar et al 2004; Nishtar 2010) of which, typically, disproportionately high amounts are put towards large capital investments, leaving recurrent costs underfunded (CMH 2001. It is also widely observed that there are significant deficits in the management and oversight of government health care services in LMIC (CMH 2001; Peters, Yazbeck et al 2002), resulting in a poor standard of essential services and lack of procedural transparency and accountability (Peters and Muraleedharan 2008); Nishtar 2010

Blurred public-private distinction: another critical characteristic is that overlapping financing mechanisms and employment arrangements make it difficult to differentiate public and private domains (Standing and Chowdhury 2008; Lagomarsino, Nachuk and Kindra 2009; Nishtar 2010). Private practice by government practitioners is common in LMIC (Macq, Ferrinho et al 2001), and many government health systems partner with private providers to deliver services (Mills, Brugha et al 2002; Peters, Yazbeck et al 2002; Harding, Stewart et al 2003; Dewan, Lal et al 2006).

Weaknesses in the health system: This characteristic configuration, of underfunded state health systems overlapped or overrun by anarchical and heterogeneous private markets, is the backdrop for a proliferation of documented phenomena and behaviours with severe implications for health equity, users' rights and public health and development goals (Nishtar 2010). A scan of the literature yields widespread evidence of the failures of health care provisioning in LMIC mixed health systems, which can be summarised under four core themes.

Unnecessarily high costs of health care

The cost of health care has been cited as a major problem and a key obstacle to access for users, especially poor users (Mamdani and Bangser 2004). Out-of-pocket spending on health in LMIC mixed systems accounts for the bulk of health expenditures in these economies, contributing directly to catastrophic spending and impoverishment (Killingsworth, Hossain et al 1999; Van Doorslaer, O'Donnell et al 2006). Frequently high spending compromises families' ability to pay for future care needs, creating vicious cycles of impoverishment and deterioration in health (Whitehead, Dahlgren et al 2001).

Variable, often poor quality of care

There are extensive documented instances of substandard quality of care in both private and government facilities in LMIC worldwide (Nolan, Angos et al 2001; Das and Hammer 2004; Peabody 2006). Infringements of standard treatment guidelines for diseases of public health concern are widely reported; these have significance beyond the individual patient since they can lead to the spread of drug-resistant micro-organisms (Aznar, Mejía et al 2005; Ng, Lum et

al 2007; Mannan, Malik et al 2009). Informal providers and alternative systems of medicine, even when legitimated by national governments, are also beset by significant concerns about quality, even as poorly defined standards often make these deficiencies difficult to estimate (Unnikrishnan, Kumar et al 2010)

Irregular ethical conduct by health care providers

Overspending on health care often has exploitative underpinnings, providers utilising information asymmetries to encourage or coerce patients into paying for unnecessary investigations and treatment (Radwan 2005; Mæstad and Mwisongo 2010; Anand 2008). Medical negligence in LMIC is widespread and unchecked, particularly affecting poorer and less literate people (Jesani, Singhi et al 1997). Discrimination and lack of respect towards the poor by health workers is another theme that emerges from a number of studies (Tibandebage and Mackintosh 1999; Mamdani and Bangser 2004).

Widespread unavailability of health care providers

According to the WHO's global health report 2000, all countries report a disproportionate presence of qualified health personnel in urban and wealthier areas. Private health providers naturally favour areas where their clients are likely to be able to pay more (Lagomarsino, Nachuk and Kindra 2009). However, public sector providers too are loath to remain in rural areas (Zaidi 1986; Dussault and Franceschini 2006; Serneels, Lindelow et al 2007). This is often compounded by absenteeism—health workers failing to attend their clinics for varying lengths of time, even while drawing a salary (Chaudhury, Hammer et al 2003; World Bank and PHFI 2008).

Collectively, these varied failures of health care provision represent major challenges for LMIC governments seeking to improve equity and quality in health care. It is critical to note that these 'symptoms' of mixed health systems 'syndrome' (Nishtar 2010) are underpinned as much (or more) by aspects of behaviour—of individuals, organisations and professions—as by limitations of human, financial and material resources. Regulatory mechanisms are commonly used by governments to constrain and modify provider behaviours (Bennett, Russel and Mills 1996; Roberts, Hsiao et al 2004). Examination of the regulatory policies and systems in LMIC may shed light on their effectiveness in addressing the failures of health care provision noted above.

Purpose

This paper arose from consideration of how governments and policy makers in LMIC could address regulation in mixed public-private health systems. It forms part of a program of studies into the function and performance of mixed health systems undertaken by the Nossal Institute for Global Health in collaboration with researchers in countries of Asia, as part of the work of the Health Policy and Health Finance Knowledge Hub.

This work has focused on the current and potential role of regulation and regulatory policy as a strategy to address provider behaviour in mixed health systems in LMIC. It describes work undertaken by the Public Health Foundation of India, in collaboration with the Nossal Institute, to develop and test an analytic approach and methodology to describe and analyse regulatory frameworks in relation to the problems identified in mixed health systems in LMIC.

We begin by reviewing the literature to identify how regulatory policy is understood and the issues arising from its application in LMIC. We then describe the rationale and approach to developing a tool to assist analysis of regulatory frameworks, and the components of the tool.

In the results section, we describe the application of this tool to analysis of regulatory frameworks in two states of India, Madhya Pradesh and Delhi, and finally offer some comments on the findings and lessons in the discussion section.

Review of Regulatory Policy and its Application in LMIC

According to Roemer (1993), regulation is said to occur when a government exercises control over the activities of individuals and firms. More specifically, regulation has been defined as the government's 'action to manipulate prices, quantities, and quality of products' (Maynard 1982). In reference to health services, regulation has been most commonly associated with the distribution of drugs and pharmaceuticals (Stenson, Tomson and Syhakhang 1997; Vogel 1998; Danzon and Chao 2000; Abraham and Reed 2001; Wright 2004). Starting in the 1990s, the discussion on regulation expanded to include various facets of health services such as the monitoring of provider entry into the health sector and

the registration and establishment of health facilities (Bennett and Ngalande-Banda 1994; Yesudian 1994; Hongoro and Kumaranayake 2000; Muraleedharan and Nandraj 2003), quality of care (Bennett and Mills 1998; Bhat 2000; Loevinsohn and Harding 2005) and cost of health care (Bhat 1996a; Ensor and Weinzierl 2006). The growing recognition of regulation as an intervention in health systems was catalysed at a time when many LMIC began to experience the growth of formal private health markets (Zwi and Mills 1995; Kumaranayake, 1997; Mackintosh and Koivusalo 2005; Bloom, Champion, et al 2009). This expansion gave way to questioning about the presence of quality and efficiency in the process of health service provision and delivery (Kumaranayake 1997; Mackintosh 2007; Bloom, Champion et al 2009). Consequently, the debate on regulation has gained a steady momentum.

The rationale for regulating health care has been argued by different authors based broadly on two complementary perspectives: the neoclassical economist's view of regulation as a means to correct market failures; and more broadly based perspectives of regulatory policies as a means to promote equity and health rights. The market-oriented perspective stipulates that problems associated with quality and cost of care and inappropriate provider behaviour are fuelled in a health market by economic uncertainty, externalities and information asymmetry, which are considered to be market failures (Broomberg 1994; Bloom, Champion et al 2009). While others have argued that this essentialist view of health markets as implicitly good is ideological (Hindess 1987), there is no doubt that it has been an influential policy perspective, and, as a result, regulation is seen as having the ability to restore balance, competition and efficiency in the health market (McPake and Mills 2000). Regulation can alleviate market failures through the establishment of a basic set of rules that define the legal obligations of various actors in market transactions and delineate their responsibility and accountability to lower health costs and promote openness and honesty (Williamson 1985; North 1990; Kumaranayake 1998; Roberts, Hsiao et al 2004).

In recent years, a number of commentators have emphasised the significance of regulation in promoting inclusion and equity in order to allow individuals and communities access to affordable, quality and comprehensive health services (Cornwall, Lucas and Pasteur 2000; Whitehead, Dahlgren et al 2001; Mackintosh and Koivusalo 2005; McIntyre, Whitehead et al 2007). This is envisioned through the installation of appropriate rules and incentives to ensure fair distribution of health resources, appropriate provider behaviour and adequacy in health staff, supplies and infrastructure. Regulation seen through this lens should minimise the likelihood of individuals experiencing adverse financial and health outcomes related to health services.

These different views of regulation suggest a broader definition of regulatory policy that denotes all aspects of policy associated with controlling the actions of individuals and organisations—not merely an instrument in the governance of health markets, as it has been characterised by health economists (McPake and Mills 2000). In order to denote this broader concept of regulation, we use the term 'regulatory policy' in this paper. 'Regulatory policy' avoids the presumption that this wide-ranging sphere of policy activity is solely the domain of government, with a variety of non-state and societal actors also involved in regulatory processes even though they would not be classified as 'regulators' or agents of 'regulation' in the orthodox understanding of the term. Here we draw on the emerging 'new' institutionalism in the policy sciences (distinct from new institutional economics [Williamson 2000]), which integrates societal and state-oriented models to achieve an understanding of how policy is made (Scott 1995; John 1998).

Regulatory policy is undertaken through a range of mechanisms and instruments, which have been classified in various ways. These include direct 'command and control' through rules and sanctions imposed by government, including licensing and registration; financing and purchasing arrangements; engaging independent third party and non-state institutions such as professional bodies; and self-regulation and voluntary arrangements. (Kumaranayake 1998; Baldwin and Cave 1999;; Peters and Muraleedharan 2008).

Regulation of Health Systems in LMIC and in India

The experiences of health service-related regulations in many LMIC reveal that the existence of basic regulations does not automatically imply their adequate enforcement and performance (Yesudian 1994;

Bennett and Ngalande-Banda 1994; Kumaranayake 1997; Mujinja 2003; Matsebula, Goudge and Gilson 2005). Evidence is scarce for the effectiveness of various approaches, including provider re-licensing, regulations on dual practice, different models for regulation of the private sector and how professional bodies can be made more effective in regulation (Ranson, Chopra et al 2010). Different mechanisms have had limited success at scale, and regulation of health care provision remains one of the pre-eminent challenges for future health policy in LMIC and for progress toward the Millennium Development Goals.

In LMIC, the majority of current regulatory mechanisms are legislated requirements focusing on registration/ licensing of health personnel and establishments and curbs on the behaviour of health care providers. Indian civilian courts have had limited effectiveness in dealing with medical negligence (Peters and Muraleedharan 2008) and have tended to rule in favour of providers (Verma, Srivastava and Jilani 2002). Explanations vary for the limited success of conventional legal mechanisms in health care regulation. Inefficiencies in legal mechanisms have been widely attributed to lack of specificity and detail in the framing of relevant legislations (Kumaranayake 1998; Peters and Muraleedharan 2008). Additionally, in the event that legal controls are found to be well established on paper, their implementation is often questionable (Bearak 2000; Peters and Muraleedharan 2008). Knowledge about relevant laws and regulations among those concerned can be low (Hongoro and Kumaranayake 2000).

Consumer law is now widely applicable for medical care in LMIC, but is underutilised (Muraleedharan, Jan and Prasad 2006; Tangcharoensathien, Limwattananon et al 2008). Further, consumer cases involving medical complaints have tended to rule in favour of defendants, and have been hamstrung by lengthy delays (Bhat 1996b; Muraleedharan and Prasad 2003; Ensor and Weinzierl 2007).

Licensing and registration are legally supported strategies most often used in LMIC (Afifi, Busse and Harding 2003), intended to influence quantity and quality of health services (Bennett and Ngalande-Banda 1994; Ensor and Weinzierl 2007). India, Egypt and Nigeria offer typical examples of physician licensing practices. For the most part, however, the roles of statutory councils are limited to the inspection of colleges and assurance of graduate standards, and do not sufficiently address standards of practice and care (Peters and Muraleedharan 2008). Funding was found to be a severe constraint in the operation of African country medical councils (Bennett and Ngalande-Banda 1994).

Registration of establishments has been another regulatory approach in LMIC. However, Muraleedharan and Nandraj (2003) observed a consistent lack of detail in laws and regulations governing health facilities in India, as did Kumaranayake, Lake et al (2000) in Zimbabwe. Nandraj and Duggal (1997) and Kumaranayake, Lake et al (2000) have also noted poor implementation, where laws do exist.

Given the limited successes of legal and bureaucratic interventions in health service regulation, there has been a growing interest in the use of incentives and other less costly, market-harnessing incentives to affect behaviour in health service delivery and utilisation (Cassels 1995; Kumaranayake 1997; Saltman 2002; Tangcharoensathien, Limwattananon et al 2008). Incentive schemes are used in various LMIC; however, there has been little study of the role of incentives in regulating health service provision. The use of accreditation is increasing in popularity in LMIC, but data on the effectiveness of accreditation are limited and inconclusive. Questions have been raised around financial sustainability and inspection capacity, legal support and standing of accreditors and administrative and infrastructural failures (Bukonda, Tawrov et al 2002; Ensor and Weinzierl 2007; Tangcharoensathien, Limwattananon et al 2008).

Very limited evaluation has been conducted on the effectiveness of rural placement bonds and incentives that promote an equitable urban-rural distribution of health providers (Ranson, Chopra et al 2010). In South Africa, where financial incentives appear to have convinced some health workers to change their short-term career plans, understaffing in most rural hospitals remained unchanged (Reid 2002; Serneels, Lindelow et al 2007). The low effectiveness of enforcement of rural bonds is also attributed to the lack of administrative capacity or the political will for enforcement in many countries (Dovlo 1999; Reid 2002). Additionally, rampant corruption and favouritism have been reported to compound ineffective enforcement (Wibulpolprasert and Pengpaibon 2003).

The impact of pay-for-performance incentives on health provider performance and retention, particularly in the long term, is poorly understood in LMIC (Oxman and Atle 2008). Financial incentives of this nature have been reported variably to have partial or positive effects on short-term behaviour (Petersen, Woodard et al 2006).

Self-regulation by professional peer councils has been criticised on the grounds that medical bodies tend to remain loyal and self-interested and are reluctant to operate against their own members (Baldwin and Cave 1999; Ensor and Weinzierl 2007). Evidence to support regulatory capture has emerged from Zimbabwe (Bennett and Ngalande-Banda 1994), India (Bhat 1996b; Muraleedharan and Nandraj 2003) and Thailand (Teerawattananon, Tangcharoensathien et al 2003; Tangcharoensathien, Limwattananon et al 2008). In some countries, such as India, the functioning of self-regulatory councils has been defined by inflexible legal statutes and subjected to government intervention, making it barely distinguishable from direct regulation (Muraleedharan and Nandraj 2003).

Despite the increase in the use of social insurance, private contracting and co-production of health services in LMIC as a means to enhance health care access (Palmer 2000), little is known about utility of these approaches in regulatory terms. Evidence from India (Bhatia and Mills 1997; Peters and Muraleedharan 2008), Thailand (Tangcharoensathien, Limwattananon et al 1997) and Zimbabwe (McPake and Hongoro 1995) suggests that mechanisms to influence health provider behaviour or work with government regulators are not well developed, and that there is inadequate monitoring of quality of care in many such schemes.

METHODOLOGY

Rationale for Approach

We attempt an alternative understanding of regulatory policy in health care that stems from a policy science perspective. Drawing from the 'backward-mapping' approach to policy analysis (Elmore 1982), we orient our enquiry from the bottom up, with an understanding of field level phenomena and behaviours that generate the need for policy. We start by asking: What are the aspects of health care delivery in LMIC mixed health systems that necessitate better policies? The major failings of health care delivery identified earlier can consequently be interpreted as core putative concerns of regulatory policy, as follows:

- costs of health care;
- quality of health care;
- conduct of health care providers;
- availability of health care providers.

This bottom-up approach oriented on the front-line problems of health care provision in mixed health systems implicitly aligns to a normative understanding of the rationale of regulatory policy as a means for achieving health equity and quality, actualising health rights and promoting public health. We limit our scope to delivery of health care in the most immediate sense (i.e. pertaining to health care providers and establishments), and not the associated, but distinct in terms of regulation, domains of pharmaceuticals or education.

Our review of the application of regulatory policy in LMIC mixed health systems finds limited success and many areas of failure. What are the explanations for this widespread inadequacy? A key issue across the board is the performance of the institutions and groups expected to take a role in regulation and their inability to fulfil these expected roles. Existing diagnoses of deficiencies in the regulatory response in LMIC include:

- lack of institutional capacity, legal and organisational frameworks and resources in the public sector for governance of mixed health services (Peters and Muraleedharan 2008, Balabanova, Oliveira-Cruz and Hanson 2008);
- misalignment of institutional roles and actions, and of formal and informal relationships in institutions, problems of inter-organisational coordination (Sheikh 2008; Bloom, Champion et al 2009);
- regulatory capture of public institutions by vested interests (Gonsalves 1997; Tangcharoensathien, Limwattananon et al 2008).

While these are credible diagnoses, they are generic, are supported by only a limited empirical research base, and tend to be drawn only from particular country contexts. The specific institutional and systemic contexts for failures of regulatory policies remain poorly explored and represent a significant gap in knowledge. The characteristics of regulatory institutions in different LMIC and provinces are unique and necessitate independent understanding. A particularly poorly explored aspect is the complementarity of different

regulatory approaches and the institutions that implement them. The rarity of empirical enquiry into how regulatory interventions are implemented in LMIC is remarkable and typical of the neglect of health policy research in LMIC (Gilson and Raphaely 2008).

In their landmark WHO publication, *Systems Thinking*, de Savigny and Adam reflect that planned interventions in developing countries often fail to achieve their goals, not due to inherent flaws in the intervention so much as to the lack of knowledge about the system through which they are implemented—its configuration, strengths and weaknesses. Systems that remain thus 'unmapped and misunderstood' are likely to cause interventions to fail (de Savigny and Adam 2009). Regulatory systems for health care in LMIC are exemplary of this. The literature has tended to lump regulation in LMIC mixed health systems under broad negative descriptors of inefficiency and lack of capacity. These tell us little about the actual character of regulation in different polities and societies; the nature of institutional arrangements and activities, cultures and values and inter-organisational relationships remain largely undescribed and poorly understood, even when they are key determinants of policy success in a particular context.

How then can we better map and understand regulatory systems so that this knowledge may be used in their improvement? The policy research approach provides a framework on which such meaningful enquiry can be conducted.

Proposed Policy Research Approach

Public policy analysis per se is not a new activity. As long as there have been governments and governance, policies have been scrutinised informally and formally. However, as a distinct entity, the field has attracted increased interest in the second half of the 20th century (Hogwood and Gunn 1984). Policy approaches accommodate different disciplinary contributions in order to achieve a more complete understanding of actors and policy processes. These include concepts from the political and management sciences, psychology, sociology and economics (Walt 1994; Sabatier 1998) and, in its more recent applications, from philosophy and critical theory (Fischer 2003).

Analytical approaches vary based on the purpose of enquiry. The function of public policy analysis in its original conception was to generate specific knowledge to evaluate, support or contribute to government programs or interventions. Such analyses 'for' policy typically use targeted methods such as operational research and economic analysis to inform policy decisions (Parsons 1995). Subsequently, however, research 'on' policy, an approach with a more reflective orientation concerned with formation and implementation of policy, has received increased attention.

The analysis we propose is both on policy and for policy, and is exploratory and diagnostic. It is not evaluation research, since it does not purport to assess the performance of organisations or systems against a standard.

Development of Research Tool

Implementation theorists Hjern and Hull recognised that the roles organisations actually play in the implementation of policies frequently do not conform to formally expected norms. They suggested that this divergence between norms and behaviour is underpinned by the difference between the 'living constitution' of policy—how policy problems are defined and addressed—and the 'written constitution'—policy problems as defined by the political system. They advocated that organisational activities and interrelationships be investigated through empirical research to understand what 'actually happens or gets done, how and why', rather than simply in terms of divergence from the norm (Hjern and Hull 1982).

We developed a policy research tool: to map the regulatory architecture for health care delivery at the level of a province or state; and, consequently, to identify gaps in the design and implementation of regulatory policy.

The proposed research tool, a stepwise process presented in the subsequent section, draws from these theoretical foundations, and also Elmore's (1982) backward mapping approach. The architecture of a particular policy domain may be seen to be constituted by:

- variously interlinked state and non-state groups and organisations that participate in the continuum of decision-making and implementation; and
- the laws, policies and rules that guide their actions (Buse, Mays and Walt 2005).

In the case of regulation of provincial or state health care provision, the policy architecture may be constituted by a range of organisations, bureaus and departments involved in making and implementing regulatory policies, and by the contents of policies, laws and guidelines.

The tool primarily serves as a first level of analysis: mapping, consolidating knowledge about the configuration of the domain and diagnosing policy gaps. It involves the use of field research methods to understand the actual roles of various state and non-state groups and organisations. The roles of these groups are then compared with the expected roles based on the architecture of regulation—as outlined in written policies—to identify policy gaps (Hjern and Hull 1982). The tool is designed for the state or provincial level, but it may be adapted to focus on the national arena. While organisations with regulatory functions may also operate at sub-provincial level, including in districts, municipalities and even health facilities, this level of detail is outside the scope of this exercise. In addition, empirical analysis of the impact of regulations on health outcomes is beyond the scope of the tool.

The Research Tool—A Stepwise Approach

We propose a stepwise research process for mapping the regulatory architecture, involving a mix of methods and primary and secondary sources of data. The main steps in the Tool are illustrated in Figure 1. The research may be undertaken by trained researchers (preferably policy analysts) independently or on commission from ministries or departments of health. The framework is inherently flexible and may (in other instances) be used to characterise other aspects such as regulation of pharmaceuticals or other policy domains.

Step 1: Outlining policy contexts

Regulatory processes must be understood in the broader context of the status and organisation of health services in the respective province or country. An overview of health services in the province encompasses details such as the prevailing public-private mix of services and the human resources scenario, and may be prefaced by any remarkable particulars of the political system, the economy, demography or epidemiology, or of any situational, cultural or exogenous factors that bear on regulation

FIGURE 1. TOOL OVERVIEW: STEPS, SOURCES OF DATA AND OUTPUTS

STEP 1	**Outlining policy context**
SOURCES:	Policy elite, key informant interviews Review of literature, documentation
STEP 2	**Analysing relevant laws and policies**
SOURCES:	Policy elite, key informant interviews National/provincial health policies, laws, acts, rules
STEP 3	**Analysing roles of regulatory organisations**
SOURCES:	National/provincial policies, laws, acts, rules, organisational rules and constitutions Health systems actors interviews
STEP 4	**Mapping regulatory architecture**
	Steps 2 and 3 synthesis
STEP 5	**Identifying gaps in policy design and implementation**

(Leichter 1979). A combination of literature and document review, complemented by discussions with key informants and policy elites, can be used to elicit the necessary information.

Step 2: Analysing laws and policies

Varied formal policies represent the *de jure* context, or the 'written constitution' of policy, based on which regulatory groups are expected to act. Step 2 involves collating policy documentation related to different aspects of regulation of health care provision, and extracting sections and clauses that direct regulatory activities. These include national and provincial policies and laws of the land that contain details of the mandated responsibilities of different regulatory groups.

The scope of this step is all those laws and policies targeting the four key problems identified:

- costs of care—all regulatory activities aimed at reducing the expenses of health care;
- quality of care—all regulatory activities aimed at improving the quality of health care, including monitoring of management practices and reduction

in irrational treatments, basic and continuing provider education, control of entry into health care professions, reducing practice by unqualified providers, improvement of supporting infrastructure or process standards related to health care;

- conduct of providers—all regulatory activities aimed at reducing deliberately unethical practices of providers, including enforcement of codes of conduct, discipline and redress for medical negligence, and reduction in rent-seeking practices and unnecessary diagnostic/therapeutic procedures;
- accessibility of care—all regulatory activities aimed at increasing the presence and active service of quality and qualified medical providers in hitherto underserved areas.

Step 3: Analysing roles of organisations with regulatory functions

The third step is to analyse the roles of all organisations with regulatory functions. In the first place, it is necessary to prepare a list of all institutions with regulatory roles: state and non-state organisations, departments and bureaus tasked with regulation of health care delivery. An attempt should be made to make this list comprehensive; however, the list can be supplemented as the research progresses. It is useful to begin with a standard taxonomy of regulatory strategies, in order to identify the groups associated with each of these strategies. All the organisations that are mandated with developing and implementing each of these regulatory strategies are to be enlisted.

Additionally, various mechanisms for engagement with health care providers are identified which are not instituted primarily to regulate, but have inbuilt regulatory provisions. Examples of such arrangements include:

- health program partnerships with independent hospitals and practitioners;
- mechanisms to contract 'in' and contract 'out' or to franchise private health facilities with public health goals of increasing access or expanding the scope of rational care;
- social insurance schemes for the poor that empanel private providers.

The organisations associated with implementing the regulatory components of these schemes and strategies may be enlisted and merged with the list of regulators, to prepare a provisional list of groups with regulatory functions (Box 1. Groups and Organisations Associated with Different Regulatory Approaches).

BOX 1. GROUPS AND ORGANISATIONS ASSOCIATED WITH DIFFERENT REGULATORY APPROACHES

Direct regulation

Statutory licensing and registration agencies for providers

Statutory registration agencies for establishments

Medical and consumer law boards

Market based

Accreditation and certification boards

Departments implementing incentive schemes and bonds

Other approaches

Departments handling service purchasing and contracting

Social insurance boards

Professional associations

Third party accrediting organisations

The most important step in the research then entails describing relevant organisational activities in real-world settings, using field research methods including interviews and document review. Core areas of enquiry for this step are presented in Box 2. A detailed topic guide for interviews with health systems actors, and format for obtaining informed consent prior to interview, is annexed.

BOX 2. AREAS OF ENQUIRY

Organisational activities corresponding to each regulatory 'target' (cost, quality, conduct, access)

Regulators' experiences of performance of each activity

Relationships and affiliations with other groups

Organisational goals and priorities

Discussions with policy elites and key informants may be used liberally to develop the groups list. In addition,

a review of relevant national and provincial health policies, laws, acts and rules can assist in identifying departments and bureaus officially mandated to enact regulatory functions. The organisational arrangements and activities of each group as they pertain to a particular regulatory function are investigated primarily through in-depth interviews with organisational representatives. This may be supplemented by review of organisational documentation (constitutions, rules and standard operating procedures, as well as internal circulars and communiqués, if available). Transcripts of interviews and policy documents for each set of organisations are thematically organised and written up.

Step 4: Mapping the regulatory architecture

No new data are required to be collected in this step. The documentation collected is synthesised into a map or chart of the regulatory architecture in the country or province. The chart is made up of six columns:

- Column 1, the targets of regulatory policy for health care provision identified above are listed (reiterated in Box 3).
- Column 2 lists groups with various regulatory functions against each target.
- Column 3 indicates what type of authority is vested with that particularly group. Is it legally enshrined or statutory? In other instances, the authority may not be statutory, yet may be officially underwritten or bound by legal contract or agreement. Alternatively, the organisation may have a voluntary interest in performing a regulatory function.
- Column 4 annotates the relevant policy document and clause that directs each regulatory activity.
- Column 5 details the regulatory activities expected to be undertaken by that organisation in relation to each target policy issue listed in step 2.
- Column 6 presents activities actually performed by the respective organisations.

BOX 3. TARGETS OF REGULATORY POLICY FOR HEALTH CARE PROVISION

High costs of health care for users

Variable quality of care

Ethical conduct of health care providers

Variable accessibility of health care

Step 5: Identifying gaps in regulatory policy or implementation

Analysis of the regulatory architecture charts will reveal that particular aspects of regulatory policy may be inadequately assigned, or not assigned to any group or organisation. These are designated as gaps in design of regulatory policies. Implementation gaps are identified by comparing putative roles of different organisations with their actual roles as described in respondents' accounts.

FIGURE 1. TEMPLATE FOR MAPPING REGULATORY ARCHITECTURE

COL 1. Target of regulatory policy	COL 2. Group(s) tasked with activities	COL 3. Type of authority vested with group	COL 4. Policies and clauses	COL 5. Activities expected of organisation	COL 6. Activities actually performed
COSTS OF CARE	1.				
	2.				
QUALITY OF CARE	1.				
	2.				
CONDUCT OF PROVIDERS	1.				
	2.				
ACCESSIBILITY OF CARE	1.				
	2.				

Gaps in policy implementation

Gaps in policy design

RESULTS OF PILOT STUDIES

The tool was piloted in two states of India: Madhya Pradesh and Delhi. The two were chosen because they are at different ends of the development spectrum. Delhi is the national capital, predominantly urban, relatively wealthy and with better health indicators than the national average. Madhya Pradesh is predominantly rural and tribal, with large areas of forest coverage. Its per capita income is below the national average, and its health indicators are also considerably behind national indicators.

The national regulatory arena provides a broad context for the state pilot studies. Under the Indian federal system, health is devolved to the states. It is the prerogative of the states to regulate and enact the laws pertaining to health care. However, there are certain laws, policies, regulatory institutions and schemes that are either operational at national level (and hence can be applied in all states) or are not specific to either of the states in this study. National policies and organisational structures are either directly applicable in the states or guide actions and operations of corresponding state regulatory organisations.

Key national level laws are listed below. Some of these laws provide for the establishment of state institutions.

- The Clinical Establishments Act (2010) is applicable to some states for the registration of health facilities, but some of the other states have their own acts pre-dating this one.
- The Medical Council of India Act (1956) covers requirements for licensing and registration of providers of Western medicine.
- The Indian Medicine Central Council Act (1970) covers the requirements of licensing and registration of providers of Indian systems of medicine.
- The Consumer Protection Act (1986) provides for the protection of consumer interests against deficiencies in quality of service and unfair trade practices. The act brings within its purview all the services hired or accessed by the consumer for a payment.
- The Medical Termination of Pregnancy Act (1971) provides guidelines for legal termination of pregnancy.
- The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act (1994) bans sex determination of the foetus and makes it a punishable offence.

Madhya Pradesh

Madhya Pradesh is a predominantly rural state, with a large land area, nearly 50 per cent of which is forest, and a significant proportion of tribal people. It is also one of the poorest states, with an annual per capita income of Rs 8000 in 2004-05 compared to the national rate of Rs 12000 (Govt MP 2007). Its health indicators are below the national average, with life expectancy at birth of 59 years for males and 58 years for females compared to national figures of 63 years and 66 years respectively (WHO 2010).

Ninety-two percent of the hospitals in rural areas are government-run (657 of 714), whereas private facilities are dominant in urban areas with 69.8 per cent (1080 of 1546) of listed hospitals. The private sector, however, is completely dominant in the primary and outpatient sectors, with 133,412 clinics compared to the 10,160 government primary and secondary health centres, urban health posts and civil dispensaries. Practitioners of all the systems of medicine (allopathy, ayurveda, unani, siddha and homeopathy) also work in the state. Of the 24,807 qualified doctors in the state, 77.3 per cent serve in urban areas. In contrast, qualified non-clinical professionals (paramedics, pharmacists laboratory technicians) are 71.5 per cent (67,153 out of 94,019) of service providers in rural areas (De Costa and Diwan 2007).

Design of regulatory policies: Madhya Pradesh has no known laws or regulatory policies for the curtailment of costs for users of health care, other than the recently introduced Janani Sahayogi Yojana, in which private providers are franchised to provide free obstetric services. There are, however, numerous policies and schemes aimed at improving the quality of care in existing health services. These include the MP Clinical Establishments Act (CEA), which mandates minimum infrastructure and personnel standards for hospitals; rules and procedures for ensuring the quality of reproductive health services or of specific interventions such as medical terminations of pregnancy; professional self-regulatory councils' control over qualification requirements to practice

medicine; and voluntary medical associations' efforts to boost continuing medical education.

Conduct of health care providers is putatively regulated through the quasi-judicial processes of the professional self-regulatory councils and increasingly through consumer courts. There are also specific laws for ethically contentious areas such as prenatal sex determination and transplantation of human organs. For both quality of care and conduct of providers, the absence of a credible community-based forum for grievance redress emerges as an apparent gap in design. Inequalities in health workforce distribution are putatively regulated by means of a mandatory rural service policy for graduates of government medical colleges. There are no alternative policies or schemes based on incentives or support for rural health practice or improving working conditions in rural areas.

Implementation of regulatory policies: Costs of care: The Janani Sahayogi Yojana is a recently introduced scheme in MP, and representatives of implementing organisations were unable to provide informed views on their experience.

Quality of care: The MP CEA has been subjected to repeated modifications since its original implementation, and even in its present diluted form, its implementation is partial. Unregistered establishments flourish and may outnumber registered establishments. Regulation of registered facilities is impeded by personnel constraints, and further difficulties are posed by the need to coordinate inspections with the police and a magistrate. Reports of inspections are frequently contested, and physical closure of establishments is rare, since this again requires interdepartmental coordination and can compromise the health department's relationships with hospital owners, whose cooperation is required for other functions. The implementation of special laws such as the Medical Termination of Pregnancy Act and Pre-Natal Diagnostic Techniques Act is also partial, predicated as it is on establishments being previously registered under the CEA.

The registration of medical practitioners is broadly implemented as mandated, by the professional self-regulatory councils. The role of voluntary medical associations, however, is complicated by their history of taking an active stance against strengthening regulations, including opposing the CEA and other regulatory laws, and their active support to doctors accused of medical negligence, even though they are active in promoting and conducting continuing medical education programs.

Conduct of providers: Medical self-regulatory councils' commitment to their disciplinary functions is ambivalent and made problematic by their close relationships with medical associations that have an avowed interest in opposing regulation. Their engagement with voluntarily adopted additional tasks such as reducing quackery is greater than the minimal performance of their disciplinary roles. Consumer forums were apparently more active in adjudicating cases of medical negligence and misconduct.

Accessibility of care: The implementation of rural medical bonds was hampered in the first place by extensive contestation of the conditions by doctors' groups and by problems in coordination between government departments, essential for placing graduating students in appropriate rural centres.

Delhi State

Delhi state is an urban agglomeration in northern India, part of which, New Delhi, is the national capital. Delhi has an area of 1483 square kilometres, making it one of the smaller states in the country. The population is predominantly urban, the rural population comprising only 6.99 per cent in 2001. The per capita income in 2007 was Rs 60,189 (Govt NCT Delhi 2009: 1-10), significantly higher than the national average.

Delhi has better health indicators than many other states. Life expectancy at birth, 69.6 years, is higher than the national average (Govt NCT Delhi 2006). The birth rate, death rate and infant mortality rate are better than national averages at 18.4 (national: 22.8) per 1000 population, 4.8 (7.4) per 1000 population and 35 (53) per 1000 live births (Registrar General 2009). The maternal mortality ratio for Delhi is 172 per 100,000 live births, again better than the national ratio of 254 (Delhi State Health Mission 2009) .

Delhi is home to some of the best health care facilities in the country. The profile of public sector establishments ranges from primary dispensaries and urban health centres to multi-speciality medical colleges and hospitals. Government agencies such as the Directorate of Health Services, Municipal Corporation

of Delhi, New Delhi Municipal Corporation, Railways, Cantonment Board, Employees State Insurance and Central Government Health Services provide services to the people of Delhi. Spending on the health sector is one of the highest in the country at nearly 9.45 per cent of the total Delhi government outlay in 2008-09 and approximately 1.19 per cent of the state gross domestic product. There is also a dense concentration of private clinics and networks of corporate hospitals providing health care services. In 2009, 42 per cent of 36,352 hospital beds in Delhi were in the private sector (Govt NCT Delhi, 2009: 92-108). In spite of the favourable numbers compared to other states, primary health care infrastructure in Delhi is significantly deficient. In March 2008, there were only 41 sub-health centres in the state, against the population norm of 188. Similarly there were only eight primary health centres as against the mandated 31, and there were no community health centres when there were expected to be seven.

Design of regulatory policies: Policies for reducing the costs of care in Delhi have been based on the recognition that the majority of care is sought in the private sector. The national social insurance scheme (RSBY) and government subsidies for free care both aim at reducing the costs of private care for the economically weaker sections of society. They do not address the attendant issue of high incident costs of care in public facilities, or the financial protection of the middle class and those in poverty but who are not officially designated as economically weaker.

There is no direct control of costs of care for packages of interventions, nor is there any agency apparently tasked with regulation of competition in health markets. The mandate of regulating quality of care is divided between the state health department's oversight of standards of establishments, self-regulatory councils' control over qualification requirements to practise medicine and voluntary medical associations' undertaking to boost continuing medical education. There is no credible regulatory mechanism to limit the practice of medicine by unqualified providers.

Conduct of health care providers is putatively regulated through the quasi-judicial processes of the professional self-regulatory councils, and increasingly through consumer courts. For both quality of care and conduct of providers, the absence of a credible community-based forum for grievance redress emerges as an apparent gap in design. The concern of equal accessibility of care is not addressed through a distinct act or policy of the state.

Implementation of regulatory policies: Costs of care: The implementation of the RSBY is as yet very partial, significant information asymmetries resulting in slow uptake by target communities. The scheme is run mainly through contracting of insurance companies and by way of an elaborate electronic system to maintain and audit records. Instances of fraud and abuse of the system have been reported. The absence of a stringent regulatory component to monitor real-world health care processes and relationships may diminish the success of the program in reducing costs for users.

Government policies to subsidise private hospitals on the condition that they provide some services free to economically weaker individuals are largely unimplemented, a phenomenon underpinned by inter-departmental dynamics within the state health sector and reduced investment in regulatory capacity of relevant departments.

Quality of care: The Delhi Nursing Homes Registration Act may be characterised as widely ineffective. This can be attributed in part to multiple contestations of its contents by the medical fraternity, leading to a dilution of the standards it proposes. Secondly, very few establishments are actually registered, and inspections of those which are registered are infrequent; these failures of implementation result from personnel constraints and organisational inertia of the state health department. Medical politics may underpin both of these phenomena, the doctors' fraternity exerting its influence to reduce regulatory interference, which is seen to adversely affect commercial interests.

Professional self-regulatory councils are expected to play a largely instrumental role in this domain, by maintaining registers of practising professionals. However, they also participate in additional unmandated activities including action against unqualified medical practitioners and protection for doctors who are under threat of violence. Councils appear to have undergone a transformation in organisational identity to be focused less on their putative role of a highly neutral regulatory body and more on protecting the rights of individual practitioners and the sanctity of the medical profession. This divergence of identity is further complicated by

the close relationship between the councils and the largest voluntary medical association, which has a principal interest in advancing the interests of its doctor members. The medical association undertakes continuing medical education (CME) and is also active in efforts to eradicate quackery, protect doctors from physical harm and provide advice and support to doctors accused of negligence.

Conduct of providers: Professional councils are mandated to uphold standards of conduct among medical practitioners through enforcement of a code of ethics and the disincentive of disciplinary action. However, councils were observed to be less engaged with this function and more with their voluntarily added functions of providing leadership and protection to the medical community. This may have been a factor in determining that instances of disciplinary action were infrequent, and punishments of doctors found culpable of negligence or misconduct were often of the lowest order. Consumer forums were apparently more active in adjudicating cases of medical negligence and misconduct, but may frequently have been influenced by the subjective and specialised nature of medical knowledge not to indict doctors.

Accessibility of care: Determining the location of new hospitals is mandated to the urban development authority, with the health department playing only an advisory role. New hospitals are primarily being constructed through public-private partnerships, which further reduces the influence of the state department in determining location.

DISCUSSION AND CONCLUSION

The study set out to map the regulatory architecture as applied to costs, quality, conduct of providers and their distribution in both design and implementation. There were some gaps in data, due to some of the regulatory policies being relatively new or the concerned actor's non-availability. The findings of the pilot studies in the two states bring out the inadequacies of regulation in both design and implementation. Some of the findings, such as poor human and material resources, lack of priority accorded to the regulatory processes by policy makers and implementers and regulatory capture by private interests, were on expected lines. But the bottom-up nature of the study also brought out the subjective nature of the implementation of the same regulatory policy in two different contexts. This demonstrates the utility of the approach adopted by this study, of moving away from a generic to a context-specific policy diagnosis. Such an approach enables policy makers to make context-specific course corrections for their regulatory policies.

The research outputs consist of a report for the province or country being investigated, supported by detailed charts of the prevailing regulatory architecture in that province or country, and diagnoses of gaps in design and implementation of regulatory policy. These outputs may be utilised by provincial, national and international policy makers and by researchers:

- to redesign and/or modify institutional arrangements for regulation (design gaps);
- to strengthen aspects of institutional implementation (implementation gaps);
- as a baseline against which to assess the success of future reforms in regulatory policy;
- to compare the architecture of regulatory systems across different countries or provinces;
- as the preliminary stage of an in-depth exploration of implementation of regulatory policies.

Key strengths of the research tool include:

Its self-explanatory nature: the steps in the tool, and also the map matrix—the key outcome of implementing the tool—are simple and self-explanatory. The matrix follows an intuitive hierarchy of actors, their putative roles, level of implementation and the contribution to outcomes, similar to the log-frame arrangement of inputs, outputs and outcomes. This demonstrates both the mapping function and the diagnostic function of the tool (gap identification) with good effect.

Domain coverage: within the limited purview of health care provision, the backward mapping approach effectively covers the majority of regulatory activities and policies, which can be attributed to focusing on field phenomena requiring policy intervention.

Adaptability: the tool is inherently flexible, and members of the research team have adapted part of it to address other policy domains including (1) mainstreaming of

indigenous health providers (Sheikh, Nambiar et al 2011) and (2) community participation for health (Public Health Foundation of India 2011), as part of other institutional activities at the Public Health Foundation of India. The tool awaits field testing in other country settings and in other states of India.

Sensitivity: the two case studies in a relatively poor and a relatively wealthy state illustrate the sensitivity of the tool through the variation in regulatory density apparent in the outcome maps (Annex 2) generated by the tool in the two contrasting situations.

Key limitations or weaknesses of the tool include:

Comprehensiveness: while the researchers attempted to list all the relevant organisations and policies, the pilots threw up lists that were not comprehensive; representatives of some organisations were unavailable, and in other instances policies relating to the activities of some regulatory organisations are not in the public domain and could not be accessed.

Surface analysis: the tool maps province or state regulatory activities, but not those at lower levels. Far richer analyses of implementation gaps can be expected through more in-depth study of lower echelons or regulatory institutions. India's complicated federal structure, which frequently features sharing or splitting of roles between national and state organisations, is also a source of ambiguity.

Data gaps: In a few instances, no information about organisational activities was forthcoming from the participants. While these are technically unresolved gaps in the data, triangulation revealed that these refusals frequently reflected organisational deficits.

Further testing in varied LMIC settings is required to establish the utility and applicability of the research tool.

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ANNEXES

ANNEX 1: TOPIC GUIDE FOR IN-DEPTH INTERVIEWS WITH REPRESENTATIVES OF REGULATORY GROUPS

<Name of Research Organization>

<Year>

Characterising the Regulatory Environments of Mixed Health Care Systems in Low and Middle-Income Countries (LMIC)

Case Study: *<Name of Country / Province>*

TOPIC GUIDE – POLICY ACTORS

- Introduce self and engage respondent
- Provide information on the study and objectives, confidentiality and further information as detailed in the consent form
- Take informed consent for interview

Commence the interview

1. Personal designation and role within the organisation/department
2. Administrative structure, oversight and financing of the organisation/department
3. Legal status of the organisation/department
4. Affiliations and interlinkages with other bodies/organisations, if any
5. Goal and philosophy of organisation/department
6. Designated functions of the organisation/department
7. Designated functions of the organisation/department in regulating health care (corroborate with putative roles)
8. Experiences of executing each of these functions
9. Shortfalls and obstacles in executing each function
10. Interactions with other organisations and departments for each of these functions
11. Additional tasks and activities undertaken in sphere of health care regulation
12. Position or stance of organisation/department vis-à-vis regulation of health care
13. Opportunities to strengthen/modify role of organisation/department in regulating health care
14. Avenues for strengthening/modifying regulation of health care in the State

Obtain / reconfirm the following details

Full name of respondent _____

Designation of respondent_____

Close the interview with thanks

Leave contact details with respondent

ANNEX 2: OUTCOME FRAMEWORKS

PART A: MAPPING THE REGULATORY ARCHITECTURE: MADHYA PRADESH STATE

Target of regulatory activity	Group(s) tasked with activities	Type of authority vested with group	Policies and clauses	Activities expected of the organisation	Activities actually performed by the organisation (and additional activities in *italics*)
COSTS OF CARE	Directorate of Health Services: Office of the Chief Medical and Health Officer (CMHO) of the district	Official (government scheme)	Janani Sahayogi Yojana Source: Government of Madhya Pradesh, Department of Public Health and Family Welfare, Directorate of Health Services, Government Order RCH/MH/09/160 dated 01.07.2009 and RCH/MH/10/638 dated 16.06.2010, Bhopal	Assessment of applications of interested private sector providers, physical verification by a committee headed by the CMHO, and granting of accreditation	(Not enough data, since scheme recently initiated)
				Receipt of weekly report from accredited providers, forwarding report to State Directorate	
				Physical inspection of a minimum number of accredited providers, periodically.	
				Cancellation of accreditation in case of private provider's non-compliance with minimum standards	
QUALITY OF CARE	Directorate of Health Services: Office of the CMHO of the district	Statutory	Madhya Pradesh 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	Numerous amendments to act, following contestation. Several original conditions for registration diluted or absent in present iteration. 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

Target of regulatory activity	Group(s) tasked with activities	Type of authority vested with group	Policies and clauses	Activities expected of the organisation	Activities actually performed by the organisation (and additional activities in *italics*)
QUALITY OF CARE (continued)				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 prioritisation 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
	Directorate of Health Services District Quality Assurance Group Department of Maternal and Child Health	Official (government policy)	Government of Madhya Pradesh, 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	QAG visits, training and dissemination of STPs conducted. Some deficits in providing feedback and undertaking corrective action.
				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	
	MP Medical Council	Statutory	Madhya Pradesh 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
	Madhya Pradesh Ayurvedic, Unani and Naturopathy Board	Statutory	Madhya Pradesh 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

Target of regulatory activity	Group(s) tasked with activities	Type of authority vested with group	Policies and clauses	Activities expected of the organisation	Activities actually performed by the organisation (and additional activities in *italics*)
QUALITY OF CARE (continued)	Madhya Pradesh 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
	MP Medical Association	None (Voluntary body)	Indian Medical Association Charter http://www.imampstate.com/ accessed on 25 July 2010	Provides continuing medical and health education to doctors through privately organised events	CME activity through private events
					Providing support to doctors accused of misconduct
					Opposing the institution of regulatory legislations (CPA and CEA) (historical)
	Nursing Home Association	None (Voluntary body)	-	Educating nursing home owners on legal requirements and procedures	Educating nursing home owners on legal requirements and procedures
					Opposing the institution of regulatory legislations (CEA) (historical)
	MP Medical Council	Statutory	Madhya Pradesh 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 court	Members ambivalent about value of disciplinary role, given other mechanisms such as CPA. No data on disciplinary procedures undertaken
				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	
					Receipt of and forwarding complaints about non-qualified providers
	Madhya Pradesh Ayurvedic, Unani and Naturopathy Board	Statutory	Madhya Pradesh 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

Target of regulatory activity	Group(s) tasked with activities	Type of authority vested with group	Policies and clauses	Activities expected of the organisation	Activities actually performed by the organisation (and additional activities in *italics*)
	Madhya Pradesh 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	Numerous cases adjudicated. Some concerns around application of Bolam test, which has since been deemed unnecessary
				Entertain appeals against adjudications of the district forum (State Commission)	
	Directorate of Health Services Office of the 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	Registration activities conducted as mandated
				Investigation of complaints of breach of the provisions of the act and suspension or cancellation of registration of genetic counselling centre, laboratory or clinic for non-compliance to standards	Concerns over methodology for investigation, since infringements difficult to establish. Cancellation predicated on prior registration under CEA, which is not always the case
				Renewal of existing licences	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)	(Data on actual activities inconclusive)
				Enforce standards, investigate the breach of conditions of act, cancel registration of hospitals found to breach conditions	
ACCESSIBILITY OF CARE	Directorate of Medical Education	Statutory	Madhya Pradesh 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 Directorate of Health Services for postings	Limited implementation due to inability to make appropriate placements and extensive legal contestation of bond provisions by medical fraternity

PART B: MAPPING THE REGULATORY ARCHITECTURE: DELHI STATE[1]

Target of regulatory activity	Group(s) tasked with activities	Type of authority invested with group	Policies and clauses	Activities expected of the organization	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 10th Nov. 2010	Empanelment of private facilities based on minimum standards, ensuring adherence to norms and standards, deregistration in case of breach	90 private establishments enrolled, indirect regulatory mechanism: contracted insurance company as intermediary has financial interest in minimising gross expenditure, but not directly in reducing costs to users. Does post-facto monitoring of the records maintained by private establishments. Identification of fraud in some instances and 3 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 program among beneficiaries
	Directorate of Health Services: Nursing Home Cell	Official (state government policy)	Guidelines for provision of free treatment facilities to patients of economically weaker 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 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 utilisation of free beds	Inadequate regulation of subsidy conditions widely recognised, attributed to lack of role clarity between departments and resource limitations. Litigation against private establishments reneging on subsidy conditions was followed by creation of new body: Social Jurist, to oversee subsidy conditions.

1 Caveat: may not be comprehensive. Contents of table are derived from analysis of subjective accounts of policy actors and review of documents.

Target of regulatory activity	Group(s) tasked with activities	Type of authority invested with group	Policies and clauses	Activities expected of the organization	Activities actually performed by the organization (and additional activities in *italics*)
QUALITY OF CARE	Directorate of Health Services: Nursing Home Cell, and district CDMOs	Statutory	Delhi Nursing Home Registrations Act, 1953. § 4 (1),§ 9 ff, § 7 ff, § 6, § 8 http://www.delhi.gov.in/wps/wcm/connect/doit_health/Health/Home/DHS/Nursing+Home+Cell accessed on 24.05.2010	Registration and renewal of private clinical establishments in accordance with infrastructure and personnel standards	Multiple contestations and subsequent dilutions of standards, current focus mainly on infrastructure standards. Registration not universally implemented; many establishments function unregistered
				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 factors within medical fraternity
				Cancellation of registration, imposition of penalties in case of operating without registration	Cancellations of a small number of establishments. Action in case of non-registration rare, attributed to lack of capacity, motivation, political factors within medical fraternity
	Directorate of Health Services: Continuing Medical Education Cell	Department policy	-	Organisation of CME for government practitioners, dissemination of information regarding training programmes	CME undertaken in various technical domains, but overall execution of CME reported to be inadequate. Attributed to lack of official mandate, coupled with inadequate follow up by DMC
	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 in discharging their professional duties

Target of regulatory activity	Group(s) tasked with activities	Type of authority invested with group	Policies and clauses	Activities expected of the organization	Activities actually performed by the organization (and additional activities in *italics*)
	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 and receipt of complaints of non-qualified providers, forwarding to authorities, and anti-quackery advocacy
	Delhi Medical Association	None (voluntary body)	Indian Medical Association Charter	Continuing medical and health education to doctors through privately organised events to promote and advance medical and allied sciences	CME in a number of topic areas, efforts to involve more practitioners in public health efforts, such as vaccination and health camps
					Active reporting of cases of quackery to the government, anti-quackery advocacy
					Protection of doctors against physical threats and violence
					Advice and support to doctors accused of medical negligence
CONDUCT OF PROVIDERS	Delhi Medical Council	Statutory	Delhi Medical Council Act, 1996. § 21 (2) ff. § 21 (3) & (4).	Receipt of complaints against practitioners	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 deregistrations not made available.
				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	

Target of regulatory activity	Group(s) tasked with activities	Type of authority invested with group	Policies and clauses	Activities expected of the organization	Activities actually performed by the organization (and additional activities in *italics*)
	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	No evidence of disciplinary action forthcoming. Minimal emphasis on disciplinary role and procedures
				Reinstatement of the name in the register if found that the implicated charges are found to be false, or expiry of suspension period	
	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. Reportedly the 'benefit of doubt' is often given to doctors
ACCESSIBILITY OF CARE	Directorate of Health Services: Hospital Cell	Official (state government policy)		Planning and establishment of hospitals, under supervision of DoHFW, following assessment of need and due inspections	Reduced control over location of hospitals due to emerging PPP policies and greater controlling influence of urban development authority

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