Analysing regulatory systems in mixed public-private health systems: A new assessment tool and its application in India

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Health systems in many low- and middle-income countries (LMICs) in the Asia-Pacific region can be characterised as mixed public-private systems, with common features such as blurred boundaries between public and private sectors, low government investment in public services and ineffectual policies and institutions for regulating health care.

As a result, they encounter a range of performance issues, including poor quality and inequitable coverage of health services, health providers who exploit their market position for personal gain and high out-of-pocket expenditure for users, particularly the poor.

Such problems reflect failures in the regulation of health care providers. However, in LMICs there is often little information on the specific nature of these failures or their causes to guide national and sub-national authorities in strengthening the regulation of their health systems.

The Nossal Institute for Global Health and the Public Health Foundation of India collaborated in the development of a structured assessment tool that can be used to describe and assess regulatory systems and organisations and to identify gaps in the design, and failures in the implementation, of regulatory systems. The tool was then tested by assessing the regulatory systems at two sites in India with very different demographics and health care systems: Madhya Pradesh and Delhi.

The assessment tool

The development of the tool was based on a review of literature on frameworks for describing regulatory systems and studies of the regulation of health care systems in LMICs in the Asia-Pacific region. The review demonstrated limited evidence of success—and numerous instances of failure—in the regulation of health systems in LMICs. One of the most pressing issues was the failure of the institutions involved to fulfil their regulatory roles and functions.

The new assessment tool is designed to identify the regulatory roles and responsibilities of institutions in a specific location and their actual performance of these roles. It consisted of structured steps to collect information and a template to document and analyse that information (Figure 1).

**KEY MESSAGES**

- The complex challenges of mixed public-private health systems are often exacerbated by weak or inadequate regulatory policies and their inconsistent enforcement across different sectors.

- In low- and middle-income countries, there tends to be little information on the nature and causes of regulatory failures to guide authorities in strengthening their policies and systems.

- The Nossal Institute and the Public Health Foundation of India have developed a simple tool to assess regulatory systems, in order to identify gaps in design and failures in implementation.

- Field testing in two different contexts revealed the value of such a structured tool in identifying specific constraints and beginning the critical process of strengthening regulatory systems.
The tool first examines the system design and identifies the designated roles of the institutions involved in the regulation of health system activities, such as affordable health care, quality services and ethical conduct of providers. It then examines the actual functions of the identified institutions and the extent to which each fulfils its expected regulatory roles.

**FIGURE 1. THE ASSESSMENT TOOL: 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  
**Sources:** Steps 2 and 3 synthesis

**STEP 5** Identifying gaps in policy design and implementation

**Testing the tool in India**

We tested the assessment tool on an examination of the regulatory systems in two very different sites in India: Madhya Pradesh and Delhi. We collected data on the roles and functions of regulatory institutions in each site through a review of key policy documents (including provincial health laws and organisational constitutions) and interviews with regulatory councils and other health systems actors. We then used the assessment tool to identify gaps in system design and failures in implementation.

Madhya Pradesh is a predominantly rural and generally poor state in central India, while Delhi, to the north, is predominantly urban, with a relatively higher per capita income. In both states, the private sector provides about half of in-patient care and the majority of out-patient and primary health care.

In Madhya Pradesh, the assessment identified a lack of regulatory policies for the control of health care costs; no forum to deal with community complaints; and few policies or schemes supporting rural health care practice. The assessment of institutional functions revealed the repeated modification of laws on quality in health care facilities; poor disciplining of medical misconduct by professional regulatory councils; and poor implementation of rural medical bonds (committing medical graduates to rural placements).

In Delhi, policies on cost containment targeted the designated poor but provided little protection for the middle class or the non-designated poor. Policies on quality did little to limit the practice of unqualified providers. Delhi also lacked a community forum to address complaints and policies to promote equity in access to care. Significant failures in implementation of the laws and regulations governing standards of care were found, while the professional regulatory councils focused more on protecting the rights of health providers than on ensuring their ethical conduct.

**Conclusions**

The assessment tool proved to be reasonably user-friendly and self-explanatory and adaptable to different contexts and policy fields. However, there were challenges in obtaining comprehensive information on all of the relevant institutions involved and in obtaining some data. While the assessment identified clear gaps and weaknesses, more in-depth analysis is needed to understand their underlying causes.

The assessment demonstrated both gaps in the design of regulatory systems and policies and failures in their implementation. While some of these gaps and failures were common to both locations, context-specific issues resulted in individual challenges as well. Regulatory systems were designed around laws for specific areas of practice, and the lack of a holistic approach resulted in gaps being overlooked. Failures in implementation were frequently related to lack of resources, conflicts of interest and regulatory capture and lack of clarity or overlapping of organisational roles and responsibilities.

The application of the tool revealed that the governance of the regulatory system as a whole and the internal governance within the institutions involved were both generally ineffective. Improving regulatory performance
will require not just additional resources and building of capacity, but improvements in governance, coherence and accountability of the system and the involved institutions at all levels.

**Additional reading:**
