

essentially remained on paper owing to lack of political will, increased liberalization of economy, outdated standards and practical difficulties in securing adherence to the regulatory standards from private providers.

Sri Lanka, Pakistan, India, Nepal have tried to introduce some kind of new frameworks for regulation with varying degrees of participation of non-state actors at different levels. However, these frameworks mostly ended up with representation from private healthcare providers. It is to be highlighted that in these frameworks the representation of civil society organizations working on patient's rights issues, health activists, women's organizations, and prominent citizens remains very nominal (some exception of Punjab Healthcare Commission). This creates a contradiction within these apparently participatory structures where private healthcare sector got overwhelming representation that is supposedly to be regulated and civil society organizations working for patients got very less representation. There is an urgent need of strong intervention by people's health movement and to force appropriate authorities to change the composition and processes of these regulatory bodies in order to make it more patients centric.

Double Danger of Expert Capture and Capture of Regulation by Private Interests

Given the context of large and often dominant private sectors within the health systems of many LMICs like Bangladesh, India, Nepal, Pakistan, Sri Lanka the mechanisms for regulation are often weak, under-resourced, bureaucratic and inadequately effective^{1, 2}. There are major gaps in policy design and implementation, human resource constraints, problematic organizational relationships, and major risk of 'capture' of the 'participatory' regulatory bodies by private interests and experts³. As a result, regulation may be minimal, limited to addressing certain physical infrastructure issues, and standards may be influenced by either academic experts or the corporate healthcare industry. Private Health Sector Regulatory Council (PHSRC) in Sri Lanka is an example of this capture. It is only country in South Asia with explicit Directorate of Private Healthcare Sector Development in Health

Ministry. If not timely and vigorously intervened by people's movements then Indian story of regulation of private healthcare sector may go in same direction considering deeply entrenched nature of global healthcare capital in India. These situations call for an urgent need to remain alert to safeguard the emerging regulatory frameworks in Bangladesh, India, Nepal, Pakistan, Sri Lanka from these twin dangers of expert capture and elite capture.

Need to View Private Healthcare Sector as a Socio-Political Process

There is an emerging view that the problems with regulation of the private sector are not just narrow technical issues of poor design, but healthcare services in the private sector have certain unique features requiring special regulatory strategies compared to other services or products. In fact regulation is a socio-political process which must address issues of quality, safety, affordability, access, transparency, accountability, equity and justice^{4, 5}. It is a triangular contract between citizens, the state and healthcare providers. The participation of citizens and civil society organisations in most of the regulatory structures in key South

1 Peters, D., and Muraleedharan, V.R. (2008) Regulating India's health services: To what end? What future? *Social Science and Medicine* 66:2133-44.
2 Bloom, G., et al (2014)
3 Sheikh, K., Saligram, P., and Hort, K. (2013) What explains regulatory failure? Analysing the architecture of health care regulation in two Indian states; *Health Policy and Planning* 2013: 1-17
4 Same as footnote 16
5 Santos, F.P. and Merhy, E.E. (2006) Public Regulation of the Healthcare system in Brazil

Asian countries is missing to a large extent. There is a need for broader campaign for to bring citizens/patients at the centre of the regulation by creating more effective avenues for their voices within these regulatory structures and procedures. The goal of universal health care provides a basis for taking a Health Systems perspective to manage the private sector, and in the ambit of it the main aim of government policies must be to develop a healthcare system that ensures widespread availability of good quality, free or highly affordable care, so that this system meets the needs of the population as a whole, especially working people and marginalized populations⁶.

Need of Bottom up Governance, Social Accountability of Regulators and Social Regulation of Private Healthcare Sector

Linked with such a broader socio-political context, people-oriented approach to regulation is the need to explore 'bottom-up governance', and related concepts of social accountability of regulators, and social regulation, related to the health care system including the private medical sector. Social accountability refers to formal or informal mechanisms through which

citizens and/or civil society organizations bring officials or service providers to account. 'Social regulation' refers to action-oriented approaches designed to reinvent and democratize regulation, with greater participation and accountability of the regulatory process to users and the public. This includes developing participatory oversight mechanisms for regulatory bodies, such as patient and citizen involvement in monitoring of enforcement of rules and regulations related to health care providers, from a patient-oriented and rights-based perspective.

Using Patient's Rights as a Fulcrum for Social Mobilisation Related to Regulation

The regulation of the private medical sector has often been looked upon as a bureaucratic function of the state, largely divorced from issues of patient's rights, and accountability of private hospitals to patients and citizens who use health services. The idea of patient's rights charter and grievance redressal mechanism for patients is finding its place in emerging regulatory frameworks like Punjab Healthcare Commission in Pakistan, few state acts in India that of Karnataka, Chhattisgarh, a

proposed bill in Maharashtra; new guidelines in Nepal, and PHSRC guidelines in Sri Lanka. Thus, social mobilisation around demands like protection of Patients' rights, and regulation of private hospitals to ensure affordability and quality of care, could be a central strategy of the health movement and civil society organisations. This also calls for working within the medical profession and developing a voice for social responsiveness from sections of doctors interested in ethical, rational care, who may be concerned about the negative impacts of gross commercialization on their profession.

Regulating Dominant Private Healthcare Sector a Mammoth Task

Regulation of widespread private healthcare sector in key South Asian countries is a challenging task in itself. It requires dedicated human resources to carry out different tasks like registration, inspection, data maintenance, developing physical and quality standards of care, developing standard treatment guidelines in consultative manner, monitoring compliance of regulatory guidelines/standards, effectively executing grievance redressal mechanism on continuous basis etc. In addition, regulatory authority requires dedicated budgetary support from the government. In the absence

6 Santos, F.P. and Merhy, E.E. (2006) Public Regulation of the Healthcare system in Brazil

of these two inputs, it becomes difficult for regulatory authorities to carry out its assigned functions. Poor performance of understaffed, underfunded Private Health Sector Regulatory Council in Sri Lanka exemplifies this situation.

Conclusion

A well-defined regulatory framework is quite essential. A pro-people framework to regulate the private healthcare sector needs to include different aspects such as:

- Include and protect patients' rights with effective and people-friendly redressal mechanisms
- Function to assure that patients' receive good quality, rationalised, evidence based treatment in the private healthcare sector at reasonable rates along with transparency in rates. Mere registration of private hospitals is not enough. Regulation of quality and affordability of care is more important.
- Take care of the concerns of rational and ethical private providers, small nursing homes, and genuinely not-for-profit hospitals, and health care facilities working in rural, tribal areas
- To not allow corporate hospitals to enforce their vested interests through technical sub-committees for defining standards and treatment guidelines to weed out small providers
- Prevent corruption and make the executive regulatory authority accountable to genuinely

participatory bodies comprising of prominent citizens, civil society organisations working on health rights issues and rational health care professionals. Ensure watchfulness in composition of multi-stakeholder forums so that vested private interests cannot dominate the forums and citizen's voices can be effective enough. A strong political will is required for a pro-people framework which can be generated from below by mobilizing people around the issue of patient's rights, affordability of care and regulation of private healthcare providers on a massive scale to make it an important public issue. This requires dedicated efforts from people's organisations. Increasing number of urban middle class in South Asian countries can be effectively reached out to build such kind of campaign and overcome resistance from vested interests.

Sri Lanka is the first country to come up with new kind of regulatory framework in the form of PHSRC in South Asia (in 2006) but there is no concrete evidence to show any progress made beyond registration of hospitals. Process seems to be

captured by private interests and understaffing, underfunding of PHSRC crippled it further.

In the absence of a strong political will, the implementation of Clinical Establishment Act (CEA) in India has faced significant hurdles. Even after seven years of the passing of the legislation, standards have not been notified. Though increasing numbers of state governments are coming up with state specific legislations to regulate private clinical establishments with some variations in CEA, 2010 but the overall pace of regulation remains very slow. The state CEAs are largely focusing on provisional registration aspect of regulation. Other aspects of regulation like quality of care, affordability of care, clinical governance are still not in discourse in India. Though Patient's Rights discourse has begun but it has a long way to go to make an impact.

Similarly the regulatory process in Nepal is facing difficulties in going beyond registration. In Bangladesh, the discourse on private sector regulation is yet to be begun. Initial attempts to bring in new legislation have met many obstacles.

Comparatively, Punjab Healthcare Commission in Pakistan has made significant progress as far as registration, anti-quackery drives, dengue prevention and trainings of healthcare establishments towards observance of minimum standards.

It has a robust legal framework which specifies many details including types of complaints to be made by patients/healthcare providers to PHC.

There is need to include healthcare experts from civil society organisations in technical

committees. The overall focus is correctly placed on quality of healthcare with clinical governance as its vision. Patient's rights, consumer aspects of hospital-patient relationship, issues related to violence in health care premises, responsibility of private hospitals

in preventing spread of communicable diseases are all brought under single authority. Overall, it appears promising model but, it is difficult to claim about its effectiveness in achieving its objectives in the absence of any independent evaluation report.

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