Troubling realities of private hospitals in Key South Asian countries: Need for regulatory checks and balances to safeguard patient’s interests

Section 1: Introduction

South Asia is the most populous and the most densely populated geographical region in the world and one fourth populations of the entire world lives here. But healthcare situation in this sub-continent is abysmal. With notable exception of Sri Lanka, it is well known fact that most of the South Asian Countries scores low on Universal Health Care. Health care in a key South Asian countries, like other Low-Middle Income Countries (LMICs), is delivered by a Mixed Health System – defined as a health system in which out-of-pocket payments and market provision of services predominate as a means of financing and providing services in an environment where publicly-financed government health delivery coexists with privately-financed market delivery. Mixed health syndrome compromises the quality of public services and defeats the equity objective in several ways. Poor performance of such systems is due to interplay between three factors in the mixed health system\(^1\):

(i) insufficient state funding for health;
(ii) a regulatory environment that enables the private sector to deliver social services without an appropriate regulatory framework; and
(iii) Lack of transparency in governance.

Today despite massive growth of the private medical sector, and widespread evidence of negative consequences of market failure, regulation of private medical sector remains very weak in most LMICs including South Asia. Despite large scale dissatisfaction related to malpractices, unethical practices, overcharging, and violation of patient’s rights, movements around these issues have remained weak until now. Hence there is an urgent need to promote the discourse on patient’s rights and accountability of the private medical sector especially in South Asian countries, through involvement of civil society organisations, rational healthcare practitioners and policymakers.

This policy brief brings attention towards urgent necessity of patient centred approach for regulation of private hospitals in key South Asian countries with important provisions including charter of patient’s rights and responsibilities, grievance redressal mechanism for patients, standard treatment guidelines, transparency in rates, rate regulation while emphasising on participation of civil society organisations, citizens representatives in the

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ongoing regulatory process to reflect citizens concerns primarily. There is an urgent need to save emerging regulatory structures to save from twin danger of elite capture and expert capture by promoting social regulation; as against existing private interests dominated models of regulation and previous models of command and control kind of regulations which were plagued by bureaucratization and corruption etc.

Section 2- Highly privatized, commercialized healthcare terrain of South Asia with weak public health infrastructure and its disastrous repercussion for ordinary patients

A) Most of the Governments in South Asian countries spend poorly on public health than the world average of Low Income Countries. High out of pocket expenditure on healthcare is dominant reality in South Asia! Sri Lanka is the only notable exception.

*Chart 1*- Low government expenditure percentage (in blue colour) VS high private, out- of pocket expenditure percentage (in red colour) in key South Asian countries (Source-World Bank Open Data, 2014)

B) 97 Million People were pushed below the $1.90 ($ 2011 PPP) poverty line by out-of-pocket health expenditure in 2010. More than 58% such people belongs to South Asia!

*Chart 2*- Number of people (in millions) pushed below the $1.90 ($ 2011 PPP) poverty line by out-of-pocket health expenditure

C) Private Doctors, hospitals are dominant healthcare providers in key south Asian countries with notable exception of Sri Lanka.

The private health care sector in South Asia is tremendously heterogeneous, ranging from informal and formal practitioners to small, medium and large hospitals, charitable hospitals and corporate hospital chains and diagnostic centres. While there are similarities among all the five countries as far as presence of a private sector goes, there are also significant differences among them with respect to the size, nature, and importance of the private sector, and the relationship between the private and public healthcare segments. Private healthcare providers are dominant providers of healthcare in South Asia.

| Chart 3-Private healthcare facilities in selected countries in South Asia for inpatient care² |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Hospitals                       | Private 54004                   | Private 350                     | Private 2983                    | Private 692                      | Private 155                     |
|                                 | Public 20306                    | Public 97                       | Public 559                      | Public 1142                      | Public 592                      |
| Hospital beds                   | 978000                          | 19580                          | 45485                           | Around 20000                     | 5205                           |
|                                 | 675779                          | 6944                           | 45853                           | 128998                          | 70000                          |

A bird’s eye view indicates that Sri Lanka has a much better resourced public sector, with a smaller private sector, and overall lower levels of commercialisation of healthcare. However, the private sector is reported to be a growing force even in Sri Lanka, due both to greater investment from private players.³ India has a very large and dominant private sector ranging from large corporate hospital and diagnostics, not-for-profit hospitals, smaller doctor owned nursing homes, individual practitioners (qualified and unqualified), chemists, and traditional healers. Bangladesh, Nepal and Pakistan have weak public health infrastructure and a diverse, rapidly growing private sector including for-profit and not-for-profit hospitals, general practitioners (qualified and unqualified) and diagnostic laboratories⁴. However, this private sector is mostly located in large towns, cities as the paying clientele are concentrated in these areas. In Nepal three quarters of hospital beds are located in the Central Region where access is relatively good, compared with virtually no private hospitals in the Far Western Region. Similarly, In Sri Lanka, half of all private hospitals have been consistently located in the Western Province. An interesting trend is emerging in India where private facilities are expanding to smaller town and cities. Currently 48% of all private hospitals and two thirds of corporate hospitals are in smaller cities⁵.

The BMJ article⁶ notes that in India about 80% of outpatient services and 60% of inpatient services are provided by the private sector. In Nepal, 55% of patients access private facilities for acute illnesses and 57% for chronic illnesses. In Bangladesh 13% of patients use government services, 27% access qualified practitioners in the private or non-governmental organisation (NGO) sectors, and 60% access unqualified private practitioners. In a survey conducted in Pakistan in 2010-11, 71% of people who had consulted a health provider in the

⁴ Same as 2
⁵ Same as 2
⁶ Same as 2
past two weeks reported going to a private facility. Only exception is Sri Lanka where 90% in-patient cares and 40% out-patient care is provided by the public health system\textsuperscript{7}.

\textbf{Chart 4- Concentration of private hospitals in relatively prosperous Central Region of Nepal and Western Province in Sri Lanka respectively\textsuperscript{8}}

\textbf{Chart 5- Tale of two healthcare systems- Where patient seek OPD and IPD care (in %)? - Private Sector dominated system in India Vs Public Sector anchored system in Sri Lanka}

\textbf{D) Growing corporatization of healthcare in South Asia with India as an epicenter}

India has one of the largest private healthcare sectors in the world, and it is much more developed compared to other South Asian countries, where it is in an emerging phase. The private healthcare sector in India is more established as well as diversified, and more influential in policy making. The most significant development is that there has been organized promotion of healthcare provision as a big business opportunity and the rise of the healthcare industry\textsuperscript{9}, projecting healthcare provision as a highly profitable economic venture. The healthcare sector in India has become an attractive area for private capital investment by global investment firms, private equity funds, and high-net-worth-individuals, and also by global financial institutions such as International Finance Corporation (IFC).

\textsuperscript{7} https://www.rvo.nl/sites/default/files/2016/01/Health%20sector%20in%20Sri%20Lanka.pdf
\textsuperscript{8} (Source- Overview of Public–Private Mix in Health Care Service Delivery in Nepal, Ministry of Health and Population, Govt of Nepal, June 2010 and Private Health Sector Review, Revised edition, August 2015, Institute for Health Policy, Sri Lanka)
\textsuperscript{9} The term “healthcare industry” is used as an umbrella term while referring to hospitals, diagnostic centers, drugs and pharmaceutical- medical equipment and devices and the insurance industries. The hospitals sector is reported to be the major segment, and hence the term healthcare industry is often used while talking about corporate and other big private hospitals.
Further there are several Indian multinational healthcare companies that have growing presence in neighbouring South Asian countries, as well as in the Gulf and in some African countries, and have listed on stock exchanges to access more capital to finance their expansion\textsuperscript{10}.

Bangladesh has a liberal FDI regime, with no limit for equity participation and repatriation of profits and income. In the late 2000s, Goldman Sachs identified Bangladesh and Pakistan among the eleven next big emerging markets (N-11), which was expected to have implications in healthcare arena, for healthcare financing and potential for private investment in infrastructure\textsuperscript{11}. Nepal broadly follows a free markets approach to healthcare and allowed 100% FDI in private healthcare companies. 81% of FDI is channelled into private hospitals that too into tertiary hospitals mainly. FDI in healthcare sector has been growing at a CAGR of 45%, and top contributors have been India, Turkey and China\textsuperscript{12}. In Sri Lanka, medical tourism is reported to be a key growth driver, which is concentrated in the Western Province, while rising per capita income was also seen as increasing demand for private healthcare\textsuperscript{13}. This was accompanied by increase in the technologies available at private hospitals, and a shift in the private sector from smaller to larger facilities having over 100 beds\textsuperscript{14}. An important, noteworthy development in the region is the active role of the International Finance Corporation (IFC - a World Bank institution) in not only promoting but also actively financing its growth and expansion of private big hospitals through measures such as lending and directly investing in hospitals for expansion, and also investing in private equity funds and companies that in turn invest in healthcare companies in ‘emerging economies’. In fact several large global private equity companies have created specific funds for investing in hospitals in South Asia and the MENA (Middle East North Africa) region\textsuperscript{15}.

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\textsuperscript{12} Dolma Development Fund report on Market Data for Private Sector Investments in Nepal Healthcare Sector, 2014 


\textsuperscript{15}
E) **Performance of the private healthcare sector – Blind optimism belied by troubling reality**

It was claimed that private services are better in terms of efficiency and quality etc. However increasing number of studies and accounts point to the myriad problems with the private medical sector. In this context, the South Asia Learning Exchange Workshop on Patient’s Rights, organised by Thematic Hub on Patient’s Rights and Private Medical Sector Accountability associated with COPASAH, in Mumbai on 23rd, 24th January 2018 was a step in right direction. Delegates from Bangladesh, Nepal, Sri Lanka and India in the workshop shared their country wise experiences about gross medical malpractices, violation of patient’s rights, over charging, unnecessary surgeries and poor state of regulatory frameworks. Tragic death of 7 year old girl Adya Singh due to dengue in one of the top most corporate hospital in India, in September 2017, attracted a lot of media attention over medical negligence, unjustified profiteering in big corporate hospitals. Hospital prescribed expensive medicines, billed them for 660 syringes and 2,700 gloves during her 15-day hospital stay. The 20-page itemised bill from the hospital added up to Rs 18 lakh. Her father Jayant Singh shared their tragic story in the workshop. Another speaker Adv Birendra Sangwan shared details about whopping 1000 to 2000% profiteering in cardiac stents in India before his successful legal battle through Public Interest Litigation in Delhi High Court, for capping prices of cardiac stents at Rs 29,000 only with massive 85% reduction in costs!

The path breaking book ‘Dissenting Diagnosis’ published in India based on testimonies of 78 ‘whistleblower’ doctors has ripped the lid on the myriad malpractices in the commercialised private medical sector, including unnecessary treatments and interventions, and irrational care driven by profit seeking by large hospitals, pharma industry–doctor nexus, institutionalised system of kickbacks, and inflated, arbitrary costs of care.

Subsequently, in February 2018, an analysis of bills from four reputed private hospitals in National Capital Region by the National Pharmaceutical Pricing Authority (NPPA)-

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16 http://www.privatehospitalswatch.in
19 Dissenting Diagnosis - by Arun Gadre and Abhay Shukla, Penguin Random House India, 2016
Government of India, has revealed that big private hospitals are making profits of up to 1,737% on drugs, consumables and diagnostics and that these three accounts for about 46% of a patient’s bill\textsuperscript{20}.

In Bangladesh, percentage of caesarean section deliveries in private hospitals was found to be whopping 68%!!! It indicates grossly irrational medical practices and profiteering! According to one study, injections were used in 77.7% of the studied illness cases in the health facilities in Bangladesh\textsuperscript{21}.

<table>
<thead>
<tr>
<th>Chart 6- Whopping 68% caesarean section deliveries in private hospitals in Bangladesh!!!</th>
<th>Government Hospitals</th>
<th>Non-Government Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Normal Deliveries</td>
<td>549,836</td>
<td>99,645</td>
</tr>
<tr>
<td>%</td>
<td>75%</td>
<td>82%</td>
</tr>
<tr>
<td>Number of Cesarean Section</td>
<td>175,888</td>
<td>21,081</td>
</tr>
<tr>
<td>%</td>
<td>24%</td>
<td>17%</td>
</tr>
<tr>
<td>Other Assisted deliveries</td>
<td>6,330</td>
<td>293</td>
</tr>
<tr>
<td>%</td>
<td>1%</td>
<td>0</td>
</tr>
<tr>
<td>Total number of deliveries in corresponding category of hospitals</td>
<td>732,054</td>
<td>121,019</td>
</tr>
</tbody>
</table>

All this constitutes only a tip of the iceberg. There is an urgent need for documentation of instances of patient’s rights violation, medical malpractices in key South Asian countries considering scarcity of such documents in the public domain.

Section 3- Country wise analysis of current regulatory frameworks for private clinical establishments

A) India-
As per Constitution of India, health is a state subject. Hence, state government have prerogative to make legislations to regulate private hospitals. However, the Clinical Establishments Act, 2010 was enacted by the Government of India for registering and regulating all types of public and private clinical establishments in the country, including single-doctor clinics. This is a kind of model act and it is adopted by 14 state governments and union territories (UTs) administration namely- Andaman & Nicobar Islands, Chandigarh, Dadra & Nagar Haveli, Daman & Diu, Puducherry, Arunachal Pradesh, Assam, Himachal Pradesh, Jharkhand, Rajasthan, Uttar Pradesh, Uttarakhand, Mizoram and Sikkim. The Act provides for the creation of a regulatory authority at the national and state levels with minimal representation to civil society groups and overwhelming representation to medical

\textsuperscript{20} The office memorandum File N. 27(2)/2017-Div III/NPPA issued by National Pharmaceutical Pricing Authority Government of India dated 20\textsuperscript{th} February 2018; http://www.nppaindia.nic.in/order/overcharging_details(20022018).pdf

community in multi-stakeholder Clinical Establishment Councils. Standards to be followed by the clinical establishments are to be defined in consultative manner by these multi-stakeholder councils with the help of expert committees of medical personnel. Thus, legislation tries to avoid inspector raj as far as possible. Act provides registering authority at district level which will have a representative from medical association. Other key elements include the grading of clinical establishments, adoption of standard treatment guidelines, minimum physical standards, and rate display and rate standardisation. However, there is no provision for patient’s rights, grievance redressal mechanism for patients. There is no specification of dedicated structure, additional staff (and related dedicated budget) for implementation of clinical establishment act. The process of standards formulation is highly centralised at national level which may not augur well for local conditions in the huge country like India. Now, display of patient’s rights charter has been incorporated into minimum standards. There are some problematic provisions from medical community point of view like mandatory stabilization of emergency patients within available resources and representation to police in the registration body. Despite of its participatory nature and overwhelming representation to medical community in councils, this act met severe resistance from medical community. Hence, even after 7 years of passing the legislation, its implementation has largely remained on paper. Standards are not notified yet. As of now, only 11 states and UTs have started reporting initial provisional registration stage of implementation.

Considering above drawbacks in the central legislation, with virtually no scope for state governments to influence the process and resistance of medical associations, many state governments like Chhattisgarh, Karnataka, Manipur, Nagaland, Telangana, MP, Orissa, West Bengal, Haryana and Kerala have enacted their state specific CEA act with some variations from central act. Maharashtra, Delhi, Punjab state governments are actively considering about legislating state specific acts. Provisions like charter of patient’s rights and responsibilities, rate display, rate regulation and grievance redressal mechanism for patients are included in some state legislations. E.g. West Bengal state legislation has provisions for rate regulation, grievance redressal, patient’s rights, separate regulatory commission; Karnataka state legislation includes provisions for rate display and mandatory self regulation of displayed rates by hospitals, patient’s rights and responsibilities charter, grievance redressal mechanism; Chhattisgarh state legislation has charter of patient’s rights and responsibilities and grievance redressal mechanism for patients.

However, despite of many good provisions, implementation of these legislations in fair, non-corrupt manner without harassing doctor community but at the same time offering justice to aggrieved patients and preventing elite capture of the process will be challenging.

B) Bangladesh

The Medical Practice and Private Clinics and Laboratories (Regulation) Ordinance of 1982 provides regulatory framework for private medical sector in Bangladesh. The 1982 Ordinance specifies that no person shall establish a private clinic without a license (from the Ministry of Health and Family Welfare). The MOHFW will grant a clinic a License after fulfillment of certain physical standards. Like AC operation theatre, 36 essential equipments,
adequate supply of life saving and essential medicines, round the clock presence of one registered medical practitioner along with two nurses and one sweeper per ten beds, 80 sq.ft per patient space etc.

Clause 3 of the Ordinance spells out that DGHS office shall fix the maximum charges and fees that may be demanded in a private clinic or private laboratory for surgical operations, conduction of labour, electrocardiogram, pathological or radiological examinations and other medical examinations or services, as the case may be. Initially Ordinance had provision for fixing maximum fees for consultations also but it was subsequently deleted by 1984 amendment after doctors protested against it. Clause 4 prohibits private practice during office hours by registered medical practitioner in the service of the Government. Ordinance makes it mandatory to maintain register of patients with their names and addresses; maintain receipts in printed form for the charges and fees realized from the patients; prominently display a list of charges and fees.

If an owner or registered private medical practitioner wants to register clinic/hospital then he/she shall apply in the prescribed form to the Director-General with prescribed fee. The ordinance does not specify any time period during which a licensing decision will be made. DGHS (Directorate General of Health Services) or authorized persons by DGHS have inspection powers. DGHS can reject the application for license if conditions of registrations are not fulfilled after issuing show cause notice to the applicant and giving opportunity to hear the applicant. Aggrieved applicant can appeal to MOHFW against the decision of DGHS within 30 days. Decision of the MOHFW on the appeal or review order would be final and it cannot be challenged in the court of law. Violation of the Ordinance is punishable with the fine up to 5000 Taka or imprisonment up to 6 months. This ordinance is legally still in force but its implementation has remained largely on paper. Even after 35 years of this ordinance, DGHS is struggling to keep updated database of private hospitals, clinics and laboratories. The department has only a seven-member inspection team for around 14,000 private hospitals, clinics and diagnostic centres. Shortage of manpower, lack of capacity and absence of proper regulatory measures made it difficult for DGHS to carry out proper supervision on such private healthcare facilities. Private hospitals and diagnostic centres are charging patients exorbitant fees at whim for lax government monitoring\(^\text{22}\). Following chart shows that there is huge disparity between maximum rates fixed by 1982 ordinance and prevailing market charges.

\[\text{Chart 7- Comparison- maximum charges as per Ordinance and actual market charges}\]

<table>
<thead>
<tr>
<th>Heads</th>
<th>Details</th>
<th>Maximum charges as per ordinance in TK</th>
<th>Market rates(^\text{23}) in TK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal delivery</strong></td>
<td>Delivery Charges including labour room charges</td>
<td>400</td>
<td>Normal Delivery – 10,000 Tk</td>
</tr>
<tr>
<td><strong>Major Operations</strong></td>
<td>Operating room charge</td>
<td>600</td>
<td>Caesarean Section – 50,000 Tk</td>
</tr>
<tr>
<td></td>
<td>Anaesthesia charge with cost of drugs and gas</td>
<td>800</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operating charge</td>
<td>2000</td>
<td></td>
</tr>
</tbody>
</table>

\(^{22}\) http://www.thefinancialexpress-bd.com/2017/07/08/76255/Pvt-hospitals,-diagnostic-labs-fleece-patients/print

\(^{23}\) http://www.daily-sun.com/post/56772/Caesarean-births-in-Bangladesh-up-mostly-on-greed
This act is typical example of bureaucratic, over centralized piece of legislation with design flaws that failed in bringing about effective regulation. Above table makes it more clear. It focused on regulating physical infrastructure and there is no mention or scope for monitoring the actual quality of clinical care provided. There is no scope for participation of key stakeholders like doctors, hospital owners, consumer rights groups, patient’s rights groups and civil society groups to make this regulation pragmatic and more acceptable. There is no provision for standard treatment guidelines, clinical audit, patient’s rights and grievance redressal mechanism for patients. Any regulatory system must be supported by dedicated human and financial resources. Regulation of private healthcare sector is in itself huge task considering size, diversity of the private sector in South Asian countries. Hence, it cannot be left with already over burdened public healthcare top officials as an add-on task. Apart from design flaws, Bangladesh MOHFW failed in providing much needed dedicated human and financial resources for regulatory task. Besides that, the regulatory framework in Bangladesh has not kept pace with rapid changes in the structure, nature of private medical sector in Bangladesh over last three decades and as a result, it has failed in safeguarding interests of the patients.

C) Sri Lanka-
The 13th amendment to the Sri Lanka Constitution in 1987 shifted responsibility for regulation of private sector medical institutions from Ministry of Health and assigned it via the concurrent list to the joint responsibility of the central government and the provincial councils. The Private Health Services Regulatory Council (PHSRC) is a statutory body, independent of Ministry of Health, established under the Private Medical Institutions Registration Act, No.21 of 2006 (PMIRA,2006). The Act controls the registration, regulation, monitoring and inspection of all kinds of private medical institutions. Regulatory Council is composed of 12 Ex-officio Members and 16 appointed Members as follows:

- **Government sector**- Director General of Health Services as a Chairperson, Director of Private Health Sector Development as a Secretary and 9 Provincial Directors of Health Services- total 11
- **Representative of Sri Lanka Medical Council** -1
- **Various associations of private healthcare providers** - 12
- **Non-doctor members, one each from Law, Nursing, Finance and Management** - 4

Main functions of the council includes registration of private healthcare institutions, collection of health statistics for national programmes, grading of private healthcare institutions, maintaining minimum standards of recruited staff in private healthcare institutions, formulation of quality assurance programmes for patient care in Private Medical Institutions and monitoring the same. Besides that, council can carry out scheme of accreditation of private medical institutions. Application for registration has to be made through Provincial Director of Health Services. Then PHSRC will check fulfilment of registration criteria, send NOC to Provincial Director to issue certificate of registration.

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24 Private Medical Institutions (Registration) Act, No. 21 of 2006(Government of Sri Lanka 2006)
While some non-doctor representatives are included in the council but representation to patient’s rights groups and civil society groups is not given. Functions of the council do not include prescribing standard treatment guidelines which is essential pre-requisite for quality control. Charter of patient’s rights and responsibilities is not included in the act. Council meetings are held once a month on a fixed date. Attendance by the government sector representatives has been poor, reflecting the difficulty of Provincial Director of Health services attending meetings in Colombo, given their other commitments in their home provinces. In addition, although the DGHS/MoH is supposed to chair the meetings, the DGHS has often not attended, partly owing to his other heavy responsibilities. Government representatives complain that the legislation does not allow them to appoint proxy representatives to represent senior officials who cannot attend in person, e.g., a Deputy DGHS cannot attend in place of the DGHS. As per the law, DGHS shall preside over Council meetings and in the absence of the Chairman, the members present shall elect one from amongst them to preside over. As a consequence, the private sector representatives have been in the majority at most meetings, and frequently ended up chairing meetings.

| Chart 8- Attendance by government representatives at PHSRC meetings |
|------------------|--|--|--|--|--|--|
| Year             | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
| Total meetings   | 12   | 12   | 12   | 7    | 10   | 11   |
| DGHS attendance  | 8    | 5    | 8    | 2    | 4    | 1    |
| Meetings with public majority(%) | 17 | 25 | 67 | 14 | 50 | 55 |
| Meetings chaired by a public sector representative (%) | 67 | 42 | 67 | 43 | 60 | 18 |

Source- PHSRC Minutes of meeting; Ref- Private Health Sector Review, revised edition 2015, Institute for Health Policy, Sri Lanka

argely, council is self funded with money raised through share of registration fees, fines, grants, donations with practically no budgetary support from the government. After an initial inflow of funds when it started licensing of providers in 2007–08, its annual revenues have fallen substantially. This has affected its functioning. Assessment of the PHSRC shows that it is completely ineffective, failing to discharge its functions. The one function it does attempt is the annual licensing of private medical providers, but analysis shows that it does this badly, with most private hospitals failing to obtain their annual license, and an even greater proportion of other providers also not doing so. PHSRC licensing performance is actually deteriorating over time (see chart- 7). PHSRC lacks adequate staff to carry out its statutory functions. At the PHSRC itself, staffing is inadequate even to handle the registrations of private medical institutions. In 2012, only two people were employed on a fulltime basis, and additionally one person had been assigned temporarily from the MoH to ease out the workload. Act gets implemented through existing provincial health bureaucracy. None of the Provincial Directors of Health Services have dedicated units or


26 Private Health Sector Review 2012, revised edition 2015: Sarasi Amarasinghe, Sanil De Alwis, Shanaz Saleem, Ravi P. Rannan-Eliya and Shanti Dalpatadu, Institute for Health Policy, Sri Lanka
staff for managing the licensing process. Institute for Health Policy, Sri Lanka observes that PHSRC is tolerating non-renewals of licensing.²⁷

<table>
<thead>
<tr>
<th>Year</th>
<th>Share of private hospital complying with annual licensing requirement of PHSRC (%)</th>
</tr>
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<tbody>
<tr>
<td>2007</td>
<td>85</td>
</tr>
<tr>
<td>2008</td>
<td>86</td>
</tr>
<tr>
<td>2009</td>
<td>61</td>
</tr>
<tr>
<td>2010</td>
<td>60</td>
</tr>
<tr>
<td>2011</td>
<td>48</td>
</tr>
</tbody>
</table>

Besides the registration of private healthcare institutions, PHSRC has prescribed physical standards for different medical institutions, issued only few treatment related guidelines, guidelines for display of rates, requested private institutions to follow prescribed range for consultation charges and range of charges for 33 common tests. It has set up a grievance redressal mechanism for patients through complaint sub-committee. Whosoever violated the provisions of the act is charged with fine up to 10, 20 and 50 thousand rupees; and imprisonment for 6 months for continued violations. However, data about punitive action taken so far is not available on its website.

On the whole, experience of PHSRC, Sri Lanka provides many insights into the danger of elite capture and expert capture of such regulatory mechanisms by vested interests. Composition of the council is an important factor and there is a need for adequate representation to health rights activists on such forums. Regulation of private providers in healthcare sector is mammoth task and cannot be dumped over the already overloaded public health bureaucracy. Regulation is an important task and it requires financial support from the government. Fate of self financed regulatory mechanism remains uncertain. Dedicated staffs, resources are very much needed to implement regulatory framework optimally.

D) Pakistan

Regulation of healthcare establishments, public or private, is responsibility of provincial governments in Pakistan. Punjab province stands out brightly as far as laying down regulatory frameworks for hospitals are concerned. The Punjab Healthcare Commission (PHC) came into existence under PHC Act 2010 with aim to improve the quality of healthcare services delivery across Punjab by fostering a culture of Clinical Governance and offer greater protection against medical abuse and denial of quality healthcare in both the Public and Private sector Healthcare Establishments at the Primary, Secondary and Tertiary levels.

²⁷ Private Health Sector Review 2012, revised edition 2015: Sarasi Amarasinghe, Sanil De Alwis, Shanaz Saleem, Ravi P. Rannan-Eliya and Shanti Dalpatadu, Institute for Health Policy, Sri Lanka
The PHC has been set up as an autonomous body governed by a Board of Commissioners, responsible for providing oversight in vision-setting and maintaining a strategic direction. The Board also monitors performance and achievements of the Commission at regular intervals. The Board takes all the decisions regarding penalties, suspension and revocation of licenses. Currently, a retired judge is holding the post of chairperson and 9 eminent persons are acting as board members. Currently, it has only 2 members belonging to medical profession.

The Technical Advisory Committee (TAC) is an advisory body which acts as an advocacy arm for the Commission, engaging with stakeholders. The TAC consists of experts from diverse professional backgrounds within the health sector including academia, medical professionals, medical associations, and representation from health regulatory bodies in Pakistan, representatives from District governments, international health experts, and members from the Provincial Assembly. There is no representation to health sector civil society organisations in TAC.

The mandate of PHC to regulate hospitals and safeguard patient’s rights of 110 Million people is executed through executive team of 123 staff when this policy brief was being written. The Chief Operating Officer is senior doctor and operational head of the Commission. The Senior Management consists of Directors heading the core directorates:

1. Directorate of Licensing and Accreditation
2. Directorate of Clinical Governance and Organizational Standards
3. Directorate of Patient Rights and Complaints
4. Directorate of Business Support
5. Department of Communications

It is supported by other cells like procurement cell, monitoring and evaluation cell, legal cell, anti-quackery cell, finance cell etc.

Within 14 days of receiving any application from a hospital or an individual doctor or homeopath or any healthcare establishment, the PHC issues conditional registration after physical verification and evaluation of the health facility. PHC arranges training and capacity building of the persons on minimum service delivery standards, and after that, the final registration and license is issued. The PHC is mandated to enforce and regulate Minimum Service Delivery Standards (MSDS) through licensing of Healthcare Establishments, encompassing Allopathic, Homeopathic and Tibbi disciplines of treatments, which comply with the Standards. MSDS have been developed by the PHC through a consultative approach, bringing together healthcare experts, managers and healthcare practitioners from public and private sectors. These standards need to be fulfilled by healthcare establishments whether public or private for their continued registration. The Commission has the authority to conduct inspection surveys to ascertain implementation of MSDS, before granting a Regular License to the Healthcare Establishment. Inspections are conducted at the time of issuance and renewal of License or on a receipt of complaint or as a surprise visit for quality assurance and regular monitoring. MSDS have been prescribed in following areas – Access, Assessment and Continuity of Care (ACC), Care of Patients (COP),
Management of Medication (MOM), Patient Rights and Education (PRE), Hospital Infection Control (HIC), Continuous Quality Improvement (CQI), Responsibilities of Management (ROM), Facility Management and Safety (FMS), Human Resource Management (HRM) and Information Management Systems (IMS). However, there is no provision for rate display and rate standardization in the PHC Act.

The Directorate of Patients Rights and Complaints is responsible for the development of Charters of Rights and Responsibilities for Patients and for Healthcare Establishments. It also started Complaints Management System in 2014 in line with the MSDS to meet the key objectives of the Commission. The Directorate is entrusted with the responsibility of effectively managing complaints dealing with maladministration, malpractice, medical negligence, non compliance of charter of patient’s rights, non compliance of MSDS etc The Commission may investigate into a wide variety of matters some examples are enlisted below:

1. Inordinate delay in provision of medical care
2. Failure to take informed consent
3. Failure to maintain adequate services for clinical management including but not limited to, assessment, diagnosis, treatment and follow up
4. Undertaking the management of a patient without the availability of requisite competence, human resource, equipment or other facilities related thereto,
5. Inadequate clinical assessment and/or diagnosis
6. Failure to keep, maintain or secure record including medical record, in accordance with the Standards (MSDS) prescribed by the Commission
7. Failure to foresee and take comprehensive precautionary measures against system failures and/or possible mishaps
8. Inappropriate and unjustifiable costs of services or procedures
9. Violation of rights provided in the Charters
10. Inadequate recordkeeping
11. Failure to prevent unnecessary diagnosis and or treatment
12. Failure to install systems to prevent cases of sexual harassment, and or improper conduct, such as unbecoming at the healthcare establishment
13. Failure to release patient records
14. Failure to install systems to prevent substance abuse
15. Billing or documentary fraud
16. Flawed medical condition(s) or qualification(s) of the staff including contractual staff
17. Failure to implement or comply with the Standards
18. Harassment of Healthcare Service Provider or member of the staff of the Healthcare Establishment including but not limited to, verbal, psychological or physical harassment
19. Damage to the reputation of the Healthcare Establishment; Damage to the property of the Healthcare Establishment
20. Quackery; or Sale of drugs without prescription

Thus, it is a single window system for patient’s and healthcare provider’s grievances. Complaint is registered, assessed, acknowledged, and investigated by PHC based on
available documents. If required, both parties are invited for hearing. Expert opinion taken if required. Final decision is made by Board of Commissioners.

There is no empirical study available in the public domain about effectiveness of PHC in regulation and standardization functions. In one of the newspaper story, PHC Chief Operating Officer claimed following achievements on 28th March 201828-

- PHC has registered and licensed more than 41,000 healthcare establishments (HCEs)
- PHC had carried out over 10,000 inspections, which included 5,747 pre-assessment and 4,560 regular inspections.
- For the capacity-building of the health professionals and implementation of the MSDS, the commission has arranged about 400 training sessions for 16,300 health professionals of more than 12,000 HCEs.
- PHC has sealed about 8,200 businesses of quacks, and imposed a fine of more than Rs 63.50 million on them so far.
- Seeing its success in the implementation of its mandate, other provinces are in the process of replicating the PHC Act and model.

Taking cue from PHC, other provinces like Khyber-Pakhtunkhwa and Sindh have also started their own Healthcare Commissions with some variations.

In short, the concept, structure and scope of the Punjab Healthcare Commission looks more promising. However, there are no sufficient empirical studies available in public domain about its different aspects of the functioning of the Punjab Healthcare Commission but it’s worth studying further.

E) Nepal
In the early 1990s, after political reform and the introduction of a parliamentary monarchy, Nepal adopted an economic liberalization policy that resulted in the massive growth of private sector industries, including in the field of healthcare. The irony is that Nepal has a progressive constitution, which guarantees health as a fundamental right, and health policies aimed at achieving universal health coverage, yet there was a lack of corresponding enforcement of regulatory mechanisms for the private sector. The private sector has over two thirds of the hospital beds in Nepal and 60% of Nepal’s doctor’s work in this sector. However, there is little information on the quality of care provided by this sector. There is limited empirical information available on the size, composition, and characteristics of the private health sector. There is a lack of routine monitoring by regulatory bodies, and insufficient institutional structure or resources to monitor the sector and guide it towards achieving government policy. Hence, the private health sector has grown without robust standards and protocols in last two decades29.


However, in year 2013, Nepal Government had issued the Guidelines for Health Institutions Established Upgrade Standard (Nepali Calendar Year 2070) which makes registration mandatory for all public and private health institutions covering all recognized streams of medicines in Nepal\(^\text{30}\). As per the guidelines, different authorities are responsible to issue licenses to hospitals, clinics etc and to renew those licenses.

<table>
<thead>
<tr>
<th>Licensing authority</th>
<th>Healthcare establishments with number of beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>District Public Health Office</td>
<td>25</td>
</tr>
<tr>
<td>Regional Health Directorate</td>
<td>26-50</td>
</tr>
<tr>
<td>Health Department</td>
<td>51-200</td>
</tr>
<tr>
<td>Ministry of Health</td>
<td>201 plus</td>
</tr>
</tbody>
</table>

Guidelines lay down following provisions to be fulfilled-

- Quality standards which includes physical and human resource standards along with list of essential medicines for health institutions and standards for infection prevention and hygiene in hospital
- The hospital structures built must also be quake-resistant and in line with the building code
- Standard operating manual
- Display of patient’s charter
- Display of rates,
- Round the clock emergency service provision,
- implementation of protocols developed in Nepal’s national health programmes
- Reservation of 10% free beds for poor and destitute patients
- Special provisions for senior citizen in big hospitals etc.
- Provision for rate regulation and rates would be decided by a multi-stakeholder high profile committee.
- A geographical restriction on setting any new hospital which is obvious considering the terrain of the country. The new hospital must be set up at least a kilometer away from another hospital and registration would be given after considering number of health institutions in given area’s population density.

Every hospital has to submit self assessment report regarding observance of the guidelines to the public health authorities. Besides that, there are hospital waste management guidelines and guidelines for blood banks. The guideline further states that a 25-bed capacity hospital must have a land leasing agreement for 15 years before developing infrastructures, and coming into operation. The guideline further states that 25-bed capacity hospitals seeking to upgrade and 50-plus bed capacity hospitals must own their own buildings. There are many other criteria that most of the hospitals operating from poorly equipped rented facilities built for residential purpose cannot fulfill.

Besides these guidelines, the National Health Policy and the National Health Laboratory Policy identify the National Public Health Laboratory (NPHL) as the central specialized national referral public health laboratory for the country and the regulatory body to license public and private labs. NPHL monitors these laboratories through its external quality assurance of lab services and the quality control testing of samples.

There is no information available about implementation of these guidelines and standards. But, the Department of Health Services (DoHS) of Nepal claims that 80% of private health facilities are reporting to HMIS in the year 2015-16. In the absence of any public data regarding this new regulatory mechanism, it is difficult to comment about its effectiveness and robustness. However, one can comment upon the structure laid down in the guidelines. To ensure implementation of the guidelines, there is provision of Monitoring Committees at the levels of District, Region, Health Department and Health Ministry whose membership includes health bureaucrats and selected doctor representatives. But Monitoring Committees do not include civil society organizations at any level.

Though guidelines mention that hospital should display patient’s charter but what content of the charter is not explained anywhere in the guidelines. This guideline has a provision for nine member multi-stakeholder Fee Assessment Committee to prescribe the rates, fees related standards in hospitals/health institutions. Its membership includes secretaries from health and commerce ministries, senior top level officials from health, ayurved and pharmacy department, Chief of medical service, President of Association of Private Health Institution of Nepal (APHIN), representative of Consumer Confederation, representative of Industry and Commerce Confederation. It is learned that Fees Assessment Committee has given its suggestions to the Government of Nepal in 2016-17 and Chief of Medical Service has been instructed to speedup up the process of regulation of private health institutions. However, no other details are available about suggestions given by Fee Assessment Committee and its status of implementation.

Section 4- Insights and key learning about regulation of private healthcare sector in South Asian countries

1. Strengthening and massively expanding public health system with provision of increased resources will have huge regulatory effect on private medical sector

We have seen that private health sector in key South Asian countries have expanded within the vacuum of shrinking public health system. Low investment by governments of these countries in public health system coupled with privatization oriented policies, growing number of public-private-partnerships in healthcare sector and transfer of big proportion of

31 The annual report of the Department of Health Services (DoHS), Nepal for fiscal year 2072/73 (2015/2016)
32 http://nepaliheadlines.com/%E0%A4%BB%E0%A5%8D%E0%A4%85%E0%A4%BE%E0%A4%B8%E0%A5%8D%E0%A4%A5%E0%A5%8D%E0%A4%AF-%E0%A4%AE%E0%A4%A8%E0%A5%8D%E0%A4%85%E0%A4%B0%E0%A5%8D%E0%A4%B2%E0%A5%87-%E0%A4%85%E0%A4%B8%E0%A5%8D%E0%A4%A5/
funds towards private sector through publicly financed healthcare schemes in these countries has fuelled growth of private healthcare sector. This has led to massive commercialization of healthcare in this sub-continent. To reassert public good nature of healthcare, there is urgent need to paradigm shift in policy making with emphasis on strengthening, expanding, qualitatively improving public health system in South Asia. Massive poverty in India, Nepal, Bangladesh, Pakistan and Sri Lanka owing to large scale out-of-pocket expenditure on healthcare necessitates the urgency of this policy shift. Such an expanded and improved public health system would have huge regulatory effect on private medical sector in checking its gross commercialization.

2. **Reality of dominant private healthcare sector in South Asia cannot be wished away and there is an urgent need to engage with ongoing process of regulation of this sector to make it more patient centric**

We have seen that except Sri Lanka, rest key South Asian countries (India, Pakistan, Nepal, Bangladesh) have huge proportion of private healthcare sector which cannot be simply wished away. We simply cannot afford to turn blind eye to regulation of private healthcare sector. In the early 21st century, ‘zero regulation’ or ‘just registration’ of the large and dominant Private medical sector is not an option. In fact, all of these above mentioned countries have started their journey towards some kind of regulation of private healthcare sector. The old command and control model of regulation has mostly given up its position to new kind of regulation reflecting dominant marketisation of healthcare. Private healthcare sector is no longer under the shadows. It has become a dominant system in South Asia and asserting its might in the arena of policy making in regulation of private healthcare sector. Except Bangladesh, all other South Asian countries have witnessed new kinds of regulatory legislative frameworks for both public and private hospitals in last one and half decade. Regulatory mechanism in Bangladesh is typical example of command and control kind of regulatory framework which 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 to 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. This is alarming. 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.
3. 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. 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 experts. 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. So, there is 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!

4. Need to look regulation of private healthcare sector as a socio-political process involving triangular contest between the state, private healthcare sector and citizens

There is an emerging view that the problems with regulation of the private sector are not just narrow, technical issues of poor design, rather healthcare services 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. It is a triangular contract between citizens, the state and healthcare providers. Now, participation of citizens and civil society organisations in most of the regulatory structures in key South Asian countries is missing to 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. Further the goal of universal health care provides a basis for taking a Health systems perspective to manage the private sector, and 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 populations.

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36 Same as footnote 16
38 Same as in footnote 5.
5. Need of bottom up governance, social accountability of regulators, and social regulation of private healthcare sector

Linked with such a broader socio-political and 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.

6. Using Patient’s Rights as a fulcrum for social mobilisation related to regulation and demanding substantial representation of civil society, citizens in regulatory framework

Until now, 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. However if we agree that regulation is a form of social accountability writ large, then regulators must be accountable to citizens, and citizens concerns must be strongly reflected in the regulatory framework. Otherwise regulatory bodies may be captured by elites, or regulation may remain minimal, or may become an additional channel for corruption. Given this context, we propose that demand for protection of Patients rights could be an important fulcrum for social mobilisation related to regulation and social accountability of the private medical sector. 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 (Karnataka, Chhattisgarh, proposed bill in Maharashtra), new guidelines in Nepal, and PHSRC guidelines in Sri Lanka. So, 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. Along with this there is also need 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.
7. Regulating dominant private healthcare sector is a mammoth task which requires dedicated human resources, budgetary support, well designed legal framework, strong political will and ‘pressure from below’!

Regulation of widespread private healthcare sector in key South Asian Countries is a very 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 It cannot be just another additional task for already overloaded existing public health officers especially when public health system is plagued with vacant posts. Besides that, regulatory authority requires dedicated budgetary support from the government. In the absence of these two inputs, it becomes difficult to regulatory authorities to carry out its assigned functions. Poor performance of understaffed, underfunded Private Health Sector Regulatory Council in Sri Lanka testifies this point.

Besides that, a well defined regulatory framework is very essential. The weaknesses in regulatory frameworks of each mentioned country are provided in earlier section. We have come to conclusion that any pro-people framework to regulate the private healthcare sector needs to cover following aspects –

1) Include and protect patients’ rights with effective and people-friendly redressal mechanism
2) Function to assure that every patient receives good quality, rational, evidence based treatment at the hands of private healthcare sector within 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.
3) 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
4) Not allow corporate hospitals to enforce their vested interests through technical sub-committees for defining standards and treatment guidelines to weed out small providers
5) Avoid bringing in Inspector raj, 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. Composition of such multi-stakeholder forums should be carefully drafted to ensure that vested private interests would not dominate the forum and citizen’s voices would be effective enough to defeat sinister proposals with the help of public health official representatives in this forum.

To bring in or alter existing frameworks towards this goal requires a strong political will which can be generated from below through mobilizing people around the issue of patient’s rights, affordability of care and regulation of private healthcare providers on such a 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 needs to effectively reach 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 solid 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 strong political will, implementation of Clinical Establishment Act (CEA) in India is facing lot of hurdles. Even after 7 years of the passing the legislation, standards have not been notified which has created a huge roadblock in the implementation of CEA. Increasing numbers of state governments are coming up their state specific legislations to regulate private clinical establishments with some variations than CEA 2010 but the overall pace of regulation remains very slow. Mostly they are still focused on provisional registration aspects of regulation. Other aspects of regulation like quality of care, affordability of care, clinical governance are still not in discourse in India. Patient’s Rights discourse has begun and still 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 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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