Policy Paper

Best Practices and Models for Private Sector Regulation

Learnings for Private Sector Regulation:

From a cross country analysis of best practice

and

different models

School of Health Systems Studies

Tata Institute of Social Sciences, Mumbai

World Health Organisation, India Country Office

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Disclaimer

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opinions expressed in this publication are of the authors, and do not necessarily reflect the views of WHO India or of any of the organisations whom we have studied.

This publication is still in draft stage and is open to corrections and modi cations. Even when finally published, responsibilities for any shortcomings and errors are of the authors.

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The report has a series of 11 country case studies from across world. In this series of case studies, we tried to reflect on the existing regulatory mechanisms and institutional regulatory bodies in each of these country, their strategy, their norms, the rationale behind the paths they have chosen in their political and health systems context and their functionality and learnings And with the help of the cross country analysis, we have summarized the learnings and provided the recommendations for the regulation of private health sector in particular context to India.

In our annexure we list a number of key informants from both India and abroad, who have spent time with us in interviews and sent us a number of important reference material. Without their assistance, this work would not have been possible.

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EXECUTIVE SUMMARY

Why this Policy Paper?

India has seen the adoption of the Clinical Establishments Act in 2010. This was done under a provision which requires states to pass a state assembly resolution to make it applicable for their state. As of now other than all union territories, 9 states have come under the CEA 2010. Spurred by this development, 8 states which chose not to come under the central act have passed acts of their own and many are considering the same. Not all these states who framed the necessary rules and regulations, have notified the same. Only 6 states and 4 UTs have done so. Even in these states implementation lags seriously behind and the gains of such regulation are not clear. In this background of a very limited progress, this policy paper was commissioned to review the scope and performance of health sector regulation across nations. Learnings from such a cross-country study can be used to reflect on India's experience on regulation of private healthcare services.

The Study Approach:

This policy paper is based on a study which was designed to identify the various forms of regulation in health sector across nations and based on this theorize how in the contexts of different political and health systems, what is regulated and how, and with what level of success varies. Though we reviewed regulations across many nations, we finally selected five industrialized High Income Countries (HICs) and five Low and Middle Income countries (LMICs) for presenting as case studies. The selection was mainly on the ground that for these nations we had more information and there were distinct paths and experiences that were instructive. The five LMICs studied were Brazil, Thailand, Sri Lanka, Iran and Indonesia. The five HIC studied were Japan, United Kingdom, France, Australia and United States. These case studies were based on published material and interviews with resource persons. A thematic content analysis, supplemented by discussions with peers who had worked in this area was used to formulate this policy paper.

The Meanings and Rationale of Regulation:

The traditional and narrow view that sees regulation control of private healthcare through legislation and bureaucratic methods by the government has given way to modern definition

of regulation where it refers to "the legitimate institutional frameworks that set permissible activities for participating stakeholders and that includes informal constraints or practices that guide or encourage or restrict their activities. If regulation is defined as "imposition of external constraints upon the behavior of an organization or an individual" it implies that the organization to be regulated is capable of at least some degree of autonomous or independent decision-making. This would mean public organizations directly under the government are not the object, since the government administratively controls these organizations.

In no nation that was a part of this study did licensing as a concept apply to public hospitals. When it comes to public hospitals, the discourse shifts to accountability as different from regulation. The scope of this paper is on regulation of private health care providers.

The main rationale for regulation lies in the market failure in healthcare services. In this context we are not talking of public health as a public good, where of course markets fail to act. Rather, we are discussing market failure in healthcare services even where it appears as an individualized priced commodity. The causes of such market failure have been identified to lie in a) high degrees of information asymmetry between provider and patient b) high degrees of uncertainty on outcomes and even on process c) nature of professional practice and professional power and d) different and conflicting principal- agent relationships, implying that providers have motivations other than patient interest and self-interest.

Key Findings:

1. **Scope:** The scope of regulation of health care services across nations covers four broad areas- market regulation, quality assurance systems, professional certification, and access to information. However, the content and emphasis between these four areas differs across nations. In addition in most nations the judicial process contributes to regulation. (We are not considering regulation of drugs and devices or of public health laws as applicable to non-health sectors).
2. **Registration & Licensing**: A sole dependence upon regulations that emphasize only registration and licensing for entry into the market with threat of sanctions or de-licensing as the main form of regulation works in almost no nation. Some nations have requirements for periodic re-licensing, and others have it only at entry. There is a role for licensing and approvals in most countries, but this is effective only in contexts when public health ex-

penditure forms the major part of total health expenditure (like in England or Australia) and there are a large number of successful public providers also and therefore there is a felt need by private hospitals to be on board with the government. In these nations licensing is based on holistic assessments of quality, and seldom based only on input criteria of infrastructure and HR stipulations.

3. **Limiting Competition**: Where private players dominate in the provision of care, there are efforts to shape how markets behave beyond. These efforts are broadly to limit the forms of competition that are deemed harmful or to promote forms of competition that are considered desirable. Nations like Japan prevent entry of any for-profit entity by declaring that no profits can be distributed as stocks or dividends and must necessarily be reinvested in healthcare. Similarly some nations have mandated that insurance agencies have to be not-for-profit. In most nations where permission is required to set up a hospital, a "certificate of need" issued by the local government would be necessary. In Iran medical universities play this role. There is little information on how effectively the local governments exercise this power and how it contributes.

4. **Promoting Competition**: One important pro-competition device is laws and strict regulations against conflicts of interests and kick-backs in any referral or prescriptions. This is a norm in most developed nations including USA which is the most privatized of these. The contrast with India is stark. In India, many successful business models are based on commissions paid for referrals and prescriptions of diagnostics and drugs. Yet another pro-competition device, reported only from England is monitoring to see that contracting agencies do not exclude private parties from bidding for primary care contracts. The other constituents of United Kingdom: Northern Ireland, Scotland and Wales however do not have this policy direction of encouraging competition amongst providers, much less competition between public and private providers.

5. **Strategic Purchasing**: Large scale contracting in of private services is successful in influencing provider behavior. But strategic purchasing is not an alternative to private sector regulation. It is dependent on it. In every instance studied, such purchasing was associated with much better regulation of standards and ethics of care as well as setting of prices. These are also the same nations where licensing, quality accreditation and other

forms of regulation are robust. Clearly public purchasing plays a major role only where private sector regulation is robust.

6. **Quality Accreditation:** QA systems are present in all nations but its links to regulation and even effectiveness in improving quality varies widely. In USA, Japan and Thailand, QA is completely voluntary and not linked to licensing. In England we find in operation the concept of quality as : setting a level for competition in purchasing, so that providers cannot price lower by compromising quality. But the other three states of UK have not adopted it and we do not have any evidence that it is working. In Australia, failure to attain QA norms can meet with sanctions, and instructions on corrective measures, but seldom (if ever) to closure. Public hospitals are included in quality improvement programmes, but not linked to licensing. Extensive private sector participation in quality accreditation also seems to occur best where public sector provisioning is robust and can effectively participate in purchasing. Brazil has an interesting innovation of scoring and ranking the private facilities as a mandatory measure and putting these scores in public domain to stimulate patient choice and incentivize better provider behavior.

7. **Institutions for QA:** Quality accreditation requires multiple institutions with a separation between them- institutions to set the standards, to measure achievement, and to decide on licensing. A quality inspection by the accrediting agency is followed by instructions to the facility for improvements that they must necessarily comply with and failing which there could be sanctions. But the actual revoking of the license takes affordability and feasibility within that context into account.

8. **Information and Patient Rights:** There are four main areas where nations have acted on rights to information:

   a. Rights for patient's access to information on the care they are receiving.

   b. Laws that guarantee privacy and confidentiality. These are clearly laid down in all industrialized nations, being particularly strong in the USA and in Scandinavian and Baltic nations.

   c. Arrangements, preferably backed by law, related to grievance redressal. The Thailand no-fault liability system is an outstanding example in this area.

d. Public Information on performance of the facility. This relates largely to their achievement of quality standards but is also important to indicate prices.

9. **Healthcare IT**: A corollary of these above needs is good IT governance and IT systems so that the required information is generated, accessed and kept confidential. There are many other reasons also for good IT governance

10. **Professional Certification and Licensing:** All nations have adopted mechanisms of certification and licensing of individual professionals with different mode of operating it. In some nations, it is only required at the entry level with no subsequent process and timely updation. However, in some nations it is periodic with flexibility so that acquiring a prescribed minimum credit points on continuing education is adequate for re-certification. And in some nations it is periodic with some process of examination and skill testing. This is very rare and if present relates to only a sub-set of skills.

11. **Professional Councils**: In all nations, professional councils are involved but in many the control of the certification process is with a government nominated body. Councils themselves could be supervised by an overall council for all human resources in health. All professional councils are charged with having to address malpractice and ethical violations but in most instances it is ineffective in this regard. It is the judiciary that plays this role. In many nations councils play a major role in defining professional practice by establishing and implementing standard treatment guidelines and protocols, but even this has now moved on to autonomous agencies like the example of NIHCE in the United Kingdom. The trend is that whereas participation of professional councils is always ensured, none of these functions (certification, malpractice and ethics, standards treatment guidelines) are left exclusively to the councils and government retains an arms-length influence.

12. **The Judicial Process**: In many areas of healthcare and especially in patient rights, on action against malpractice and ethical violations by individuals or by organizations, and even on scope and effectiveness of regulations, the presence of a pro-active judiciary and a necessary legal framework for seeking redress makes a large difference. Where judicial intervention becomes the main or even an important form of intervention there are both desirable and undesirable consequences. Undesirable consequences take the form of ris-

ing costs of care due to both indemnity insurance and defensive medicine. They could also take the form of stringent forms of quality control that link care to higher degrees of professional qualification that compromise access or equity. The main desirable consequence is the strengthening of regulatory frameworks and quality assurance systems.

Options for way forward in the Indian Context:

1. **Licensing of Facilities**: Public expectations of regulation are reasonable prices and protection from exploitative or irrational care, from negligence and lack of competence. But most licensing systems are limited to defining adherence to minimum levels of infrastructure and human resources which is not sufficient to meet the objectives and when mechanically applied makes healthcare less affordable without addressing key issues. Adherence to standard treatment guidelines are difficult to monitor in any situation unless it is part of a purchasing contract.

2. **Registration**: The focus in the Indian context should be on registration linked to providing adequate information of public health value to government and information of value to patients. This requires as a corollary, systems to collect and place relevant information on public domain. This would include median prices on key procedures. But unless legal provisions are breached through criminal action, or patient safety is seriously compromised, the option of shutting down facilities should not to be put on the table. There are concerns that many standards proposed discriminate against affordable care for marginalized sections and there is already enough examples of misusing law for political purposes and anti-competition reasons against small providers and not for profit agencies. (A number of mission hospitals and not -for-profits have reported high degrees of intervention and closure of their establishments on political grounds or to favor local competitors). Administration should be empowered to collect the minimum information required from each clinical establishment. Registration would involve an undertaking for ensuring a code of conduct related to informations, prevention of kick-backs and similar illegal practices and putting in place quality assurance systems with accreditation.

3. Use of Strategic Purchasing as instrument of altering provider behavior:

a. In contrast to weakening a command-and-control licensing approach to regulation of private facilities, when it comes to purchasing care from private facilities, the efforts must be to strengthen regulatory provisions much further. The conditions of empanelment should include strict adherence to standards including standard treatment protocols and to a code of conduct.

b. Regulation of prices in an empanelled provider should possibly apply to all patients seen by the facility and not only to those whom government reimburses (excluding hospitality components). Where such price control for all clients is not possible, at least information on average price for each service should be available. Co-payments charged or incurred by insurance covered patients should be routinely reported and kick-backs (cut practices) should be prohibited.

c. The list of empanelled (contracted) hospitals and reasons for non-empanelment could be displayed. The list of possible reasons could include non-application for empanelment, lack of minimum quality scores, not fulfilling empanelment criteria.

d. Expanded purchasing and expanding scope of regulation moves together. Not-for-profit ethical providers would find these provisions helpful. Those seeking higher profit margins or having more kickbacks may choose to stay out of purchasing arrangements. Over time, as the number of ethical, affordable providers and their bargaining power increases it would become easier to use strategic purchasing in a much more extensive way and to improve provider behavior and practices across the entire private sector.

e. Competition with public hospitals should be discouraged and the need for having a core of public hospitals available as an important, preferably the dominant provider, should be recognized as an important requirement for ensuring regulation in private health sector.

4. Legislating Health Information and Patient Rights:

f. Legal and administrative measures must be fast forwarded to achieve patients right to information especially with respect to their own case records, while simultaneously ensuring the right to privacy and confidentiality.

g. Information on median and mean average prices for different services and performances and quality scores of private and public hospitals must be collected and put on the public domain.

h. It is important to put in a place a grievance redressal mechanism managed by a public authority with civil society participation for complaints from care seekers in the private sector, irrespective of whether the private providers are empanelled, along with legal aid where necessary to protect the interests of the poor.

i. For all public hospitals and for empanelled private hospitals some measure of redressal for denial of care or medical faults on the lines of Thailand's no fault liability compensation should be considered. These could be part of the mandatory code of conduct of empanelled private hospitals and of all public hospitals.

5. Quality Standards and Accreditation:

a. Pro-active promotion of quality accreditation by both public and private sector is one of the most feasible ways for altering provider behavior. Its effectiveness is not beyond doubt but state intervention helps improve its effectiveness in many ways.

b. One form of state intervention is to provide a differential in repayments to those which are quality accredited private sector. Another is public information on scores and ranks.

c. We do not recommend de-licensing on the basis of quality scores. Failure to adhere the quality standards could attract a range of actions- from time given to make improvements, to penalties, to public dissemination of scores and of gaps but not as a rule to de-licensing. However, where purchasing contracts are concerned there could be monetary penalties or even de-empanelment.

d. There is a need to define quality standards with flexibility, allowing district administrations to ask for relaxation where it intervenes with access or affordability of care. A national standards organization and state level council for setting down standards and for allowing flexibility where required must be constituted with legal backing for the same. The council should have representatives of the profession and government but at least half of those representing the profession should be professionals practicing in rural areas and/or familiar with their concerns. These bodies would also have the powers to relax them for specific administrative blocks where the density of providers (both public and private included) is sub-critical and enforcing standards comes in the way of access to care and affordability of care. District administrations would be authorized to move the national/state body for such relaxation of standards.

e. Quality accreditation requires separate institutions for laying down standards, for measuring quality and giving accreditation, for taking regulatory action based on such measures and for providing technical support to achieving quality. These institutions should be separated from each other to avoid conflicts of interests and should be under the government but autonomous and at arm's length from it.

6. Strengthening legal accountability:

a. There is a need for separate legal frameworks for public and private sectors. The focus in public sector is on accountability mechanisms, and this could be built into essential services maintenance act. The quality standards are already defined by the National Quality Accreditation Scheme (NQAS) and the direction of movement would be to make government officers accountable for achievement of the NQAS minimum standards. There is also scope for a separate law – which includes the transparency act from Tamilnadu (which addresses transparency and fairness in procurement), the transfers act from Karnataka (which ensures transparency and fairness in transfers and posting), some elements of the consumer protection act and essential services maintenance act.

b. The focus in private sector act is both on the clinical establishments act and the consumer protection forum. Whereas the first would address issues of information asymmetry, qual-

ity assurance and specify entry criteria, the second would be strengthened to address malpractice and ethical violations.

c. Contracting under purchasing arrangements too would need legal support for enabling a more regulated provider behavior as well as to safeguard the contracted provider especially the small provider from undue harassment and ensure the sanctity of the contract.

d. Kickbacks and commissions for referrals, diagnostics or prescription of drugs should be banned by specific laws as is followed by most nations studied, especially the USA.

7. Human Resources for Health :

a. All professional councils should be supervised by a common "human resources for health regulation" council which is constituted as a body with more direct public accountability.

b. All regulatory functions that councils perform should be done through empowered committees or organizations, where council representatives have the major presence, where government is represented and where the presence of civil society including those representing services users is also ensured. As a rule, industry is not represented in these committees. This particularly applies to professional regulation of ethics in practice and certification as license to practice.

c. Continuing professional education must be mandatory with renewal of accreditation/ license to practice once in five years- but in a non-threatening manner, where the acquisition of a number of credit points through CME programme, attendance in conferences, and online courses are taken as adequate.

In Conclusion:

Regulation in health care is to be understood as institutional approaches to influencing private provider behavior and practices towards ensuring ethical, safe, affordable, patient centered care in the private sectors. If the government is convinced about the need for active regulation, then it can choose from a mix of options available to it. The process would necessarily be incremental and proceed on a number of fronts- with a combination of carrots, sticks, and capacity building. An undue reliance on licensing against a centralized set of standards with a threat of sanctions or closure is counter-productive. The central challenge is to device an ap-

proach that is appropriate to context, which addresses the genuine concerns of the profession while preventing exploitative and irrational care, and while ensuring that the ethical small and not for profit provider who delivers more accessible and affordable care is not pushed out.

SECTION I

BACKGROUND

The private sector exists and it provides a major part of curative health care services in most developing nations including and especially in India. Since unlike most other goods and services, there is a high degree of information asymmetry making it difficult for consumer choice to exercise itself- some forms of regulation have always been considered desirable.

Most nations have a mix of systems. Very few have completely state run systems for healthcare, while none have a totally private-run system. But the dominance of sector varies across nations. Also even if there is a dominant private sector the mode of payment makes a huge difference. Some nations have a large private sector where most payments are made out of pocket- like India. Others have a large private sector where most payments are pre-paid through insurance schemes and health plans, but there are multiple insurance providers, mostly private. USA is an example of this. There is third category of nations where though there are multiple types of providers, it is a single payer- the government – that through an appropriate institutional arrangement makes all the payments.

One form of categorization of private sector is into for-profit, and not-for-profit sector. However, the difference on the ground may wear thin. This is because of the fact that for survival, even the not-for-profit hospitals have to generate a certain margin of surplus and if there is an investment in infrastructure, high end equipment and in highly qualified human resources, the differences in the charges and operational principles between the two sector i.e. for-profit and not-for-profit may not be very different.

The private sector usually claims much higher efficiency in operation, but there is scarce evidence to support this. Rather there is significantly available evidence that is against this. What is clearly a strength of the private sector is their ability to innovate. Private sector is also known for its quick adaptation to latest technology, and strategic response to changes in business ecosystem. On efficiency of use of resources, on quality of the end results and commitment towards R&D, there is a perception that private sector is better. Though this is a

contested perception, private initiatives and business organizations have been promoted by many nations across the world. But egalitarian and pro-poor approaches are far from the scope of private sector except for not-for-profit organizations.

This leads to an important difference between public and not -for-profit on one side and the commercial private sector on the other. With the former one, the meaning of efficiency is related with the number of services delivered (out-patients seen, in-patients treated, cure rates etc., without any compromise to its sustainability. Whereas for the commercial sector, the efficiency is the return on investment without compromising its long term brand image; which has a relationship with outcomes- especially those that are part of public perception of it. This difference is important since many nations have built their regulations around this understanding , and some nations allow only not for profit agencies to act as purchasers or providers.

'Regulation', as meaning the use of coercive power of state to change the behavior of individuals and organizations, is therefore more relevant to situations where the definition of outcome and efficiency of the provider is at variance with goals of population health. The inclusion of public clinical establishments within a regulatory framework was therefore not part of the earlier discourse. In the earlier discourse what was required in public hospitals was the setting of standards and accountability towards achieving those standards. Closing down a public facility due to lack of achievement of those set standards was not an option. On the other hand private clinical establishments were licensed to start functioning and this license was to be renewed periodically.

However, in the last two decades the meaning of regulation is changing. This is due to the re-conceptualization of the state as a purchaser of health care from a large number of providers, where public and private providers compete on equal terms. This leads to another discourse, that of level playing fields i.e. if there are constraints applied on the private systems, the same have to be applied on the public system too. Paradoxically, the more a nation believes in markets and a limited role of the state in the provision of services, the more sweeping becomes it requirement to regulate. As the text on health sector reforms puts it : "In

any fair market situation, exchanges must be open and honest. The provider and customer are usually at unequal levels of knowledge and capacity to make decision in choice of healthcare services. This knowledge gap often results in exploitation of the weaker party by the other, viz the providers, particularly in a private sector dominating market and in monopolistic situations. Quality, safety and transparency can help in bringing fair exchange. Markets do not function by themselves on grounds of equity and fairness. Ethics and norms stand as the normative guards of market, but may not find their place in free market regimes. Communitarians and objective utilitarians find regulation as an acceptable philosophical position." (Robert, Hsiao, Berman and Reich, 2004).

In this understanding of markets, one of the prime functions of regulation is to break this information asymmetry. Therefore regulation has to ensure access to information in areas as categorized below: :

(a) On Clinical practice: information on diagnosis, therapy, adverse reactions and safety,
(b) On Service providers: information on professional training and development, licensing of professionals, informal providers, the infrastructure, Information systems, accreditation of service facilities and,
(c) On Financial aspects**:** the investors, their interests, sources of funding and financial protection .

There is also rise in the need to standardize clinical processes, which could be different for different diseases and even at different levels of service. The standard treatment guidelines are evidence based guidelines that define and therefore could limit clinical decision making, but ensure ethical and legal compliances as well as help in cost containment and elimination of unnecessary or irrational care. Information is also required by purchasers on treatment outcomes which relate to performance standards, and measures of complication rates

Regulation is therefore no longer used to denote only the coercive power of the state. It is redefined as all actions by the state and other non-state actors like professional bodies to influence the behavior of the individual provider and the organization. Much recent interest has

gone onto the question of what is called "strategic purchasing." Here the state uses *modes of payments to providers* in synergy with *contracting* to influence what services are provided and the terms at which they are provided. One context where theoretically strategic purchasing could work, without the use of regulatory means in parallel, is when there is considerable unutilized capacity in the private sector and it is therefore looking for ways to mobilize more clientiele. State role in purchasing care in such a context is often essential for private hospitals to recover the investments made. But this condition is not always available. Even if available the needs of profit maximization lead to considerable supply side moral hazards- with providers doing excessive interventions and charging fee for services in addition to reimbursement claims, or cherry picking cases based on profitability, while denying care to others. Purchasing then, would need to be supplemented by regulation. We need to know more about how strategic purchasing as it exists today and whether it is influencing provider performance and the interface it has with regulation. How does purchasing change the scope and effectiveness of regulation. These questions are particularly relevant in India today as government funded insurance programmes have reached out to over 300 million people many of whom would not otherwise have been able to access or afford private health care.

In summary therefore the key questions that any review of regulation must ask is:

1. The purposes and programme theories of regulation: what are the reasons for introducing regulation and how exactly does regulation act to achieve these desired objectives of regulation. What are the external factors: in structure of health care system and its political economy that facilitate or act as a barrier to regulation?
2. Who and what is regulated: the scope of regulation in terms of which clinical establishments are to be regulated and what aspects of clinical practice need to be regulated. A short list of the important dimensions of regulation could include: price of care, quality of care including both effectiveness of care and its patient centredness, limiting irrational care and malpractice and conflict of interests, ensuring patient rights to information and to privacy and grievance redressal.
3. Who would regulate: the regulatory institutions, their structure, their relationship with government, voluntary regulation, regulation by professional associations and ethical committees.

4. The effectiveness of regulation : (with reference to its broader objective of influencing provider behavior that ensure better patient outcomes and patient centerdness and lesser financial hardships). We would need to study not only the expected results, but also the unintended ones of different strategies. These different strategies are categorized and enumerated below:
    a. Licensing of facilities that allows or disallows them from entry and from providing services
    b. Strategic purchasing in influencing provider behavior and practice?
    c. Leveraging quality accreditation systems for the purpose of regulation?
    d. Leverage the judicial process and the role that legislation performs and the needs for further laws?
    e. Ensuring a greater access to information for patients with respect to their health care as well as the right to privacy and confidentiality.
    f. Grievance redressal systems.
    g. Licensing of providers- especially health care professionals.

In practice most countries have a mix of the above strategies. Our intentions was to study each country as case study, to understand the choices they made and relate it to their context and their own perception of its effectiveness in meeting the objectives that these nations set themselves.

In addition there are regulations on pharmaceuticals and medical devices, marketing of medical products and services, clinical research, that we are not examining in this study. We are not also examining the implementation of specific laws like the laws against sex determination or with respect to abortion services. Nor do we examine public health laws that curtail actions by other departments- like with respect to tobacco control, air pollution safe drinking water and sanitation etc. The focus of this report is on the regulation of curative healthcare providers whether or not they also have other roles.

We also note that we are using the term accreditation to denote a voluntary process where failure to achieve it would not involve penalties On the other hand we use licensing to

denote a circumstance when the failure to achieve a certain standard or certificate would lead to penalties including suspension of the right to provide services.

In our understanding every model has their own strengths and weaknesses and there is relevant learning in each of these. No model can be a 360 degee best practice, but there are some aspects that they get right, and in that sense every model is best practice to be learnt from. In the specific context of India, the study would aim to draw lessons on each of the above elements and propose how one can make incremental progress towards achieving a better framework for private sector regulation.

SECTION 2

OBJECTIVES AND METHODOLOGY

Objectives:

1. To study, in context, the various forms of regulation in health sector adopted in different countries and regions.
2. To identify the best practices and learnings with respect to regulation of private healthcare from the experience of different governments
3. Based on an understanding of the gaps in policy and implementation of regulation of private healthcare in India and learning from other nations, provide the recommendations for the way forward in India.

Methodology:

I. We began with the data collection. There were three data sources:

- One was a review of publications, which were then written up as an annotated bibliography on the subject.
- Second was descriptive material drawn from websites, especially official websites of departments of health and regulatory agencies.
- And third was in-depth interviews done with a number of key informants either face to face, or over skype. The list of persons interviewed were in two categories- those working in the countries and experts within India who have extensively worked on global health issues- eithe as academicians or activists. In most instances the interviews were recorded, but some interviewees preferred not to be recorded and one requested to remain anonymous. (see annexure for the list of those interviewed) .

II. Once a round of information was gathered, the information was triangulated, analysed and written up as country case studies. Country Case Studies were constructed for the following nations:

From Low and Middle Income Nations:

- Brazil
- Thailand
- Sri Lanka
- Iran
- Indonesia

From OECD- High Income Nations:

- Japan
- United Kingdom
- France
- Australia
- United States

The basis of choice from LMICs where those nations that were best practices in terms of progress towards UHC (Thailand, Brazil, Sri Lanka, Iran) as well as one populous nations whose level of development and health systems had considerable similarities with India. We would have liked to study Cuba, Costa Rica and Mexico also as LMIC case studies of good progress – but our access was limited. Amongst nations in a similar context- we did not choose China because governance and path of development has been very distinct and not very comparable. We have added a small note on South Africa and other African states like Kenya and Ghana which we studied, but since there were few new points to make- we have limited ourselves to a small note on South Africa.

In the high income nations, we identified by discussion with key respondents with experience in this area, those nations which were larger economies and which had distinct differences in delivery of health care. United States was chosen since it is the archetype of private provider and private purchasers, United Kingdom which remains mainly dominated by public providers, Japan since it is a context of largely public purchasing but private provisioning, and France and Australia where there is universal insurance with a mix of providers.

Between comparable nations like France and Germany, or Australia and Canada, we chose based upon our access to key informants. Again our data collection is much wider, but to keep the narrative readable we have restricted it to only 5 nations.

I. After the construct of these country case studies, a cross-cutting analysis was conducted on the following framework:

1. The programme theory of regulation- how the choice and mix of regulation measures related to the political economy and path dependence of health systems

2. The intensity and effectiveness of different regulatory measures- where regulation is understood broadly as measures by the state to influence the behaviour of private provider

3. The nature of regulatory institutions.

4. The context and choice of strategies for regulation, which are broadly categorized into 6 groups:

    i. Licensing of facilities for service provision,

    ii. Shaping Market Behavior: through restrictions on market entry, price , promoting or limiting competition,

    iii. Use of public purchasing,

    iv. Quality Accreditation Systems

    v. Information and patient rights including grievance redressal

    vi. Certification, Licensing and influencing professional practices of health care professionals.

IV. Based on this cross country analysis and discussing it in the context of India we present our conclusions and recommendations.

SECTION III

COUNTRY CASE STUDIES

1. COUNTRY: BRAZIL

Brazil is a federative republic spread over 47% of South America and the fifth most populous country with 200 million inhabitants (2010). It is an enormously diverse nation having one of the "most pronounced socioeconomic inequalities in the world". (Victoria et.al. 2011). The percentage of elderly and their life expectancy is increasing, while the birth rate is declining (Blay et.al.2008). Family size among the poor is larger than among the rich (Alver and Timmins 2001). The GDP spending on healthcare is 8.3% of total expenses (World Bank data 2014). The public-private mix of Brazilian healthcare is characterized by certain experts as "primarily private", where the very large public sector is intended to act as a 'safety net' reaching out to meet the demands of those parts of the population that do not have private insurance to cover medical expenses (Alvas and Timmin 2001). This is not however either the official view or even the main assessment. About 50% of health care expenditure is public expenditure and this pays for close to 80 % of all healthcare. Brazil has one of the most extensive and effective primary health care programmes in the world.

Legal context of health regulation

The revised Federal Constitution of Brazil (1988) in its article 196, recognizes that: "*Health is a right of all and a duty of the State, calling for social and economic policies that involve reduction of the risk of disease and of other aggravations and universal and egalitarian access to actions and services for its promotion, protection and recovery*". The context of the adoption of this law is a major political upheaval with the overthrow of a tradition of dictatorships and the establishment of a democratic state- a process that many would almost equate with de-colonization and liberation. Though Brazil had broken its colonial links with Portugal whose colony it had been as far back as 1822, this had meant a transfer of rule to white colonists who had enforced their power through either a monarchy (till 1889) and then military rule or dictatorships for most of Brazilian history, interspersed with some democratic spells (1945 to 1964). The decisive break with this pattern was in 1985 when civilian rule

was established and by 1989 a popularly elected president took office. But whereas there was a liberation and socialist driver behind the new government, it was happening at a time of collapse of socialism worldwide. The health rights bill- and advanced statement for any third world government at this time, must be viewed in this context.

For taking forward this health rights approach, the "Single Health System (Systema Unico de Saude-SUS)" was established in 1988 to ensure universal, free, and equal access to health care. Universality, Completeness and Equality form the principles of SUS and the same is established in the Organic Health Law (1990). According to Boccolini et.al (2016), the principles of Unified Health System (SUS) were driven by civil society soon after the adoption of 1998 constitution. A progressive government came to power in this period, and with the constitutional alignment, resource allocation practices change from 2001 leading to the nation-wide expansion of SUS. A constitutional amendment reverted the system of financing in the health sector to general revenues (Elias and Cohen.2003).

Organization Of Services

In Brazil, the goals of the health care system fall within a very forward-looking and ambitiously conceived system of integrated social rights. Preventive care is emphasised and care should be provided at the most basic level at a reasonable cost, and integrated across levels of care by the primary care provider (Blay et.al.2008).

The resources, administration and responsibilities of SUS are at the federal, state and municipal levels. Paim et.al (2011) say: "*SUS is tasked with undertaking health promotion, health surveillance, vector control, and health education and with ensuring continuity of care to all Brazilians at the primary, specialist outpatient, and hospital levels"*. SUS is financed by taxes on payrolls, business profits, professional earnings, and banking transactions. From the federal and state levels, money is channelized to municipalities. The state control the regional network and provide resources to municipalities who provide and manage health services (Blay et.al.2008).

***Participatory administration*:** The municipal secretary has jurisdiction over SUS health centres, hospitals, labs and services, and administers funds provided by the federal, state and municipal governments. Municipalities need to have a Municipal Health Council consisting of organization members, citizens and school personnel and it should approve health programmes. Such a council is necessary to receive federal funds. Districts and municipalities can share funds, if needed to enhance healthcare efficiency (Alver and Timmins 2001). Health councils at the three levels of government with members from government and society including both the users and producers of health services help in assuring community participation. (Elias and Cohen.2003).

Policy formulation, providing technical and financial assistance to states and municipalities, regulating public-private relations and private sector activity are done by the federal government. Federal organizations monitor the administration of health insurance system, including prices, inflationary increases, and increase by age group (Blay et.al.2008).

Programme content: The public system focus on primary and secondary care, while the private sector focus on secondary and tertiary care. Approximately 70% of the population is covered only by the public healthcare system; the rest high-income class are covered by the private system (Blay et.al.2008).

The core of SUS is the Family Health Strategy (FHS) which was established in 1994 to move from a hospital-centric approach to a more comprehensive primary care approach. It gained wider acceptance and funding support since 2001 and since then, it rapidly expanded to cover 96 percent of municipalities which account for 57 percent of population through 35,000 Family Health Teams. Each family health team has about 5 to 6 CHWs working under a doctor and a nurse along with nutritionists and physiotherapists. Each family health team caters to a population of about 4000. They come under the Department of Basic Care (DAB). Though largely managed by public provisioning some municipalities went for contracting with private providers so as to expand the coverage more rapidly.(Gragnolati, Lindelow and Couttolenc.2013).

The primary care provider is expected to integrate basic services and more complex services to maximize efficient and effective functioning and continuity of care. In the public

system, medications are free to in-patients whereas in out-patient care, only high-cost medicines are free – like for Hepatitis, HIV, Cancer, TB, Psychosis etc. The public system contracts with the private system for use of hospital beds (Blay et.al.2008). About 20% of the available hospital beds in Brazil used by SUS in 1998 belonged to private sector (Alver and Timmins 2001). This may have increased since then.

***Programme Financing*:** The National Health Fund provides resources to the sub-national units based on two different formulae: (1) direct payment for services provided to the SUS and (2) fixed per capita transfers for basic health and epidemiological activities. All the entities are accredited by the ministry of health on the basis of its capacity and level of competence. (Elias and Cohen.2003)

According to Paim et.al (2011), the Brazilian health system at present is made up of three subsystems: (1) the public subsector financed by government (SUS), (2) the private subsector (for-profit and not-for-profit) – services financed by various ways with public or private funds, and (3) private health insurance sector with multiple plans, premiums and tax subsidies. People can choose from among these depending on their ease of access and ability to pay (Paim et.al. 2011).

***Private Sector services*:** HMOs do not exist in Brazil. But most of the private health plans are connected to employment. Small and medium size health plans operate on contractual arrangement with private doctors, mostly through their offices and hospitals. The operators of private plans used to standardize the payments for each particular procedures, leaving less autonomy for doctors and less choice for users. (Elias and Cohen.2003).

Other than the SUS, Brazil also has a SSAM (complementary medical care system). The SSAM provides coverage to Brazilians who are younger, present lower risks, and who have higher purchasing power. On the other hand SUS provides direct service to those with hardly any purchasing power (Elias and Cohen.2003).

***In conclusion*:** There is universal coverage for all health care services and thanks to the improvements in primary healthcare, healthcare utilization have become more equitable from 1998 to 2008. But unequal access persists, with the rich having higher utilization than the poor. There exists a clear dichotomy in accessing healthcare.

Human Resources:

In 2007, 1·7 doctors, 0·9 nurses, and 1·2 dentists were available per 1000 population, and these people were mostly located in the southeast and south of the country where the rich are located. Rapid growth has taken place in terms of university enrolments for these professions. In 2008, 90 000 medical, 220 000 nursing, and 50 000 dentistry students were in training. Uneven regional distribution of qualified personnel, high turnover, scarcity of structured careers, and major differences in salaries between regions, states, and municipalities are still hurdles in this line (Victora et.al.2011). Problems are many and have been described thus: "Legislation that regulates hiring of civil servants in Brazil is rigid. Workers can only be selected through an open competitive process that takes several months, salary overheads are substantial, and to dismiss under-performers is very difficult. For these reasons, doctors, nurses, and community health workers are employed by the Family Health Strategy through special contracts, which makes them much easier to hire and to dismiss and allows payment in some categories (such as doctors or nurses) of competitive salaries that are well above those received by other similarly qualified health workers. This plan also allows remote municipalities to offer high salaries to attract professionals who would not otherwise be willing to live in such areas. The downside is that family health workers have neither a career structure nor job security or fringe benefits that other civil servants are entitled to. As a result, job satisfaction is typically below par and staff turnover is high, leading to discontinuities in patients care".

Private Sector and its Regulation:

There are broadly four routes to regulation of private sector in Brazil.

- Firstly, a high proportion of beds of private sector are contracted into the SUS and therefore have obligations related to cost and quality. Since over 70 % of health care provisioning is based on public financing, this is a very powerful means of regulation in the Brazilian context. In contracted hospitals, the terms of contracting and the mode of payment are both used as strategies of regulation.
- Secondly, for beds and healthcare which is not contracted into SUS there is a regulatory mechanisms that applies to private insurance plans and agencies. This has focused a lot on performance assessment where quality plays a major component. Li-

censing is not the focus, but public information on quality and performance measurements of both health plans and individual providers outside the SUS is used as the main strategy.

- Thirdly, there are laws that ensure restrictions on practice by different groups
- Fourthly, there has been a strengthening of the judicial process of grievance redressal .And introduction of a code of medical ethics and other such legal provisions strengthens judicial action.

Agencia Nacional de Saúde Suplementar (ANS) (National Supplementary Health Agency) was created in 2000 to provide legal and administrative regulation of the private health insurance market. Law 9656/98 made it illegal for insurance companies to deny coverage to patients with pre-existing disorders or to set limits on the use of specific health care services or procedures. (Paim et al.2011)

Since 2003, this private health insurance sector regulatory agency, ANS (Agencia Nacional de Saúde Suplementar) has developed and applied an interesting Program for the Assessment of Health Plans Providers (Programa de Qualificação da Saúde Suplementar), with the objective of evaluating and monitoring the performance of health insurance providers. Indirectly, the initiative aims at promoting performance improvements in the private insurance sector. The program is mandatory for the 1200 health plan providers, and was gradually implemented in three phases between 2003 and 2008. It covers two components, the assessment of the quality of health plans providers, and the assessment of institutional quality. The first component includes 72 indicators in four dimensions with weightage as indicated in brackets- quality of care(40%), financial (15 to 30%), structure and operations (10 to 15%) and users satisfaction (10%). The final composite indicator of performance – IDSS (Indice de Desempenho da Saúde Suplementar) – is constructed from the weighted combination of the four dimensions, varying from 0 to 1. The second component focuses on the internal performance assessment of the agency itself.

Many initiatives in Brazil, both private and public, produce hospital indicators. These cover a small number of hospitals and are not holistic measure and ranking of hospital performance, but a few specific indicators for reference. It usually relates to quality, and largely

designed for use by hospital members with few of the indicators are published (the main exception here is from the PROAHSA program).

Another important approach is that the Ministry of Health has given 'National Humanization Policy' and the 'Code of Medical Ethics' to reinforce patients rights and reduce instances of discrimination. In 2010 new legislation was passed to prohibit sales of antibiotics without a medical prescription (Victoria, 2011). Nurses, Physiotherapists and even audiologists used to prescribe antibiotics when it was available for sale over the counters.. There is also a need for further revision of policies required to guarantee better quality care, the safety of patients and patient rights in Brazil (Paim, 2011).

Judiciary had to intervene in healthcare of Brazil, especially when patients who have been prescribed expensive or experimental medicines which are not part of the essential drug list ask the judges to issue court orders obliging municipal health managers to purchase these drugs or to provide elective medical procedures. There has been concern that such interventions by the judiciary violates the key equity principle of the SUS, by privileging individuals with high purchasing power and more access to information, boycotting rational prescribing practices, and taking resources away from priority areas (Victoria et.al.2011).

2. COUNTRY : THAILAND

Health Sector Regulation in Thailand:

Thailand has a population of 67 million, which is distributed across 6 regions, 77 provinces (including Bangkok) and 867 districts (excluding Bangkok city) and 74,963 villages.

A pyramid of health care facilities under the Ministry of Public Health provides health care for this population. At the apex, there are 96 general hospital or regional hospitals, with the hospital beds ranging between 150 - 500 beds. At the next level, there are 787 Community Hospitals (referred to as District Hospitals), catering to districts with populations ranging from 10,000 to 100,000. Some districts have general hospitals in lieu of the smaller district hospital. A district hospital would typically have 30 to 60 beds. At the next tier, it includes 10973 primary health centers, each covering a population of about 5000. At the bottom of the pyramid, closest to the community are over 80,000 community managed health centers each catering to about 800 population.There are also some other tertiary hospitals under the Ministry of Public health such as the Chest Hospital, the Children's Hospital and the Mother and Child Hospital, which serves as referral hospitals.

There is also a robust private sector, which accounts for about 38% of all providers, but it is located mainly in the cities, and caters to about 23% of outpatients and 19% of inpatients- most of whom can afford it, and pay out of pocket or through private insurance.

The main form of health care financing in Thailand is through tax-based general government revenue. About 65% of total health funding comes from the central government. Local government contributes 4 percent, and the rest is a direct contribution from households or private firms. (Hanvoravongchai, 2013).

Of the total public health expenditure by the center, about 38 % goes to the Universal Care Scheme (UCS) which pays for health care of about 75% of the population, about 26% goes to the Ministry of Public Health (MOPH) for public health activities and administrative functions, another 25% goes to the Civil Servants Medical Benefits Scheme (CSMBS) which provides coverage for 9% of the population, and perhaps about 5 to 7 % goes to Social Secu-

rity Scheme (SSS) which provides coverage for 16% of the population. ((Hanvoravongchai, 2013).

The relative costs to the government of the three schemes are 79$ per capita for UCS, 367 $ per capita for the CSMBS scheme and 71$ per capita for the SSS scheme.

Thailand has implemented initiatives to strengthen its health system with focus on primary health care since the 1960s (Wanitkun et.al. 2011). This has contributed to not only better health outcomes, but also to reducing the proportion of population falling below poverty line, and is a significant contributor for the political and social development of the nation. (Camfield et. al.2013).

The Private Healthcare sector in Thailand:

Private clinical establishments exist in Thailand as hospitals, diagnostic centres, laboratories, imaging centres, and disease -specific service facilities such as for cardiology, ophthalmic or dental services. The Chinese and Thai medical systems as well as traditional massage services are also in practice. In 2008, some 77% of hospitals were public, the vast majority owned by the MOPH, a few by other ministries, while 22% were private, and 1% state enterprises and local governments. There were 17, 671 private clinics, mostly single-practice, and 17,187 private pharmacies in 2009 (Wibulprolprasert et al., 2011b), almost all located in urban municipalities.

Private hospitals hold a share of about 20% of total hospitals and beds in Thailand. They are mostly located in the national capital Bangkok or at district capitals in the provinces. Almost all private hospitals in Thailand are private for-profit and few of them are also on the stock market and they target high-income populations and foreign patients. The number of private hospitals has been found to be declining since 2003. Some private hospitals are registered as main contractors of public health insurance schemes. In 2010, they were 20% and 37% respectively. (Jongudomsuk et al. 2015). Healthcare delivery is done mainly through public sector facilities which hold 75% of hospitals and total 79% of hospital beds.

The historical context of the evolution of private sector healthcare in Thailand was through the Christian missionaries, mostly in the North and Central regions. Many of these are still in existence. Government allowed doctors to open private for-profit hospitals. In the

1990s the numbers of private hospitals increases. This is due to the ASEAN economic crisis which resulted in the squeezed of the public funds, and this had its impact on the Thai public health expenditure. Thus we have an initial phase which is largely private, but with low coverage, and then a major expansion of public sector till it becomes the major player and then some expansion of private sector with the public sector purchasing services from the private sector also.

Private hospitals under the public schemes are usually those of medium size, with 100 beds or more and their target population is low to middle income class (Jongudomsuk et al. 2015). The minimum requirement of hospitals for licensing is at least 30 beds, with no upper limit. By the Law of Monopoly, the ministry of commerce regulates them. Majority of private hospitals are small, with 69% of them having fewer than 100 beds. Larger private hospitals are run by corporate chains which are registered under stock market and targeting international patients. Private not-for-profit hospitals run by charitable organizations have only a negligible share of beds. (Jongudomsuk et al. 2015).

Private hospital services continue to put emphasis on acute care, while there are greater demands for chronic, intermediate and long-term care. Any patient covered by any public insurance scheme can get free hospital emergency service from any public or private hospital, as per the order of Thai government from April, 2012 (Jongudomsuk et al. 2015). There are no specific restrictions for referrals between the private and public hospitals. But in the case of emergency patients, the private hospitals, if they are non-contracted, they first stabilize the patient and then shift to public or contracted facilities. The Emergency Service Act has made it mandatory for all hospitals to treat any emergency irrespective of payment (Somsak 2017).

One stated reasons for purchasing health care is that by purchase of private services, the operational time is saved. There are also incentivized private services by the public servants. Solitary private clinics are no more promoted by the government. A large number, approximately 1.5 million, people have private health insurance to supplement the public programmes covering them. (Hirunrassamee and Ratanawijitrasin, 2009).

Governance and Regulation:

Governance functions for the health sector are distributed across a number of institutions. The Ministry Of Public Health (MOPH) is the national health authority responsible for formulating, implementing, monitoring, and evaluation of health policy. Different autonomous health agencies were established through legislation for different purposes. These include: Health System Research Institute (1992), Thai Health Promotion Foundation (2001), National Health Security Office (2002), National Health Commission Office (2007) and the Healthcare Accreditation Institute (2009). (Jongudomsuk et al. 2015)

Regulation is a function of the Ministry of Public Health, Division of Health Services Support handle the regulation affairs in Thailand. The regulations are same for rural and urban private healthcare. Each ministry and local government has its own regulation mechanisms for its own hospitals. Private health medical institutions are licensed and relicensed annually under the Sanatorium Act 1998 (Medical Premises License Act) in line with stipulated quality and standards. The Bureau of Sanatorium and Art of Healing, Department of Health Service Support, MOPH is responsible for overseeing all private health-care providers. Historically, the Medical Premises Act only applies to the private sector, all public providers are exempt from licensing.

Price of services are not regulated. Although, the ministry has necessitated that all the providers to publish their rates, as the price control has not been implemented. As the prices of the drugs were rapidly increasing, government played an important role in controlling the prices. This was done through the enactment of the 'Commodity Price Control Act', by the Ministry of Commerce and this is by including drugs as essential commodity.

Quality Accreditation:

Regulation and quality accreditation has a close relationship. Quality accreditation gained prominence 15 years ago when there was a move for accreditation by the self-organized group of private hospitals. Accreditation existed then onwards as a voluntary practice. The accrediting agency gained a semi-governmental nature over a period of time and tries to bring every facility under its umbrella by promoting accreditation. But accreditation remains a voluntary practice under Hospital Quality Development-Accreditation Agency. (The King-

dom of Thailand health system review, Health Systems in Transition, WHO Vol. 5 No. 5 2015)

In 2013, the proportion of fully accredited hospitals was about 40% of all hospitals. This has to be renewed annually and is therefore susceptible to fluctuations. Private hospitals providing medical tourism services opt for JCI, but for public hospitals it is expensive and excessive, and therefore HAI standards are more than adequate for quality improvement.

Medico-Legal Interventions:

Subsequent to a case of medical negligence in 2008, the Medical Council forbade district hospitals to perform surgical interventions unless an anaesthesiologist is present. This led to a major reduction in services provided by district hospitals. Since then, all surgical cases that were previously carried out successfully by district hospitals, such as hernia repair, appendectomy, caesarean section, vasectomy, tubal ligation and removal of bladder stones etc. have been referred to general/regional hospitals, resulting in increased burdens faced by these tertiary hospitals. The court rulings also led to district hospital doctors resignations for private practice and this had a tremendous negative impact on the district hospital system.

Strategic Purchase as Regulation:

The Thai health care system is best known for its financing system. This is organized as what is called as the National Health Security office. This NHSO administers the 30 Baht scheme – now known as the Universal Coverage Scheme as well. As stated by Towse, Mills and Tangcharoensathien (2004), the country took a "big bang approach" to introduce universal access to subsidized healthcare in 2001. The coverage for treatment was extended to 18.5 million people, after years of debate and slow process. Under this 30 Baht scheme/UCS, people pay only 30 baht for each visit or admission. Gruber (2014) says that in 2001, Thailand had the 30 Baht programme, one of the largest and most ambitious health reforms ever undertaken in a developing country. The 30 Baht scheme along with Social Security Scheme (SSS) and Civil Service Medical Benefit Scheme (CSMBS) offers financial protection to the majority of Thai population. The SSS covers private business employees, about 8 million, while the CSMBS covers about 6 million people. The latter is financed by taxes, while the former is financed by equal contributions from employees, employers and government. Payment to

contracted hospitals was made on a capitation basis and covers out-patient and in-patient services. Additional utilisation related payments, with ceilings, are made for a limited number of diseases. In 2007, the DRG method was instituted for paying IP services. OP services and drugs are paid per service/per item basis.

This office contracts with district hospitals to provide primary and secondary health care for the entire district population. Over 95% of the primary care providers are public providers, except in Bangkok city where close to 50% of providers are private.

When it comes to tertiary care, private sector is more active and willing. Strong institutional capacity in purchasing from private tertiary sector has resulted in improved equitable access to certain high cost interventions such as cardio-thoracic surgeries, renal replacement and ART. (Jongudomsuk et al. 2015). Services may be purchased only from private providers who are willing to provide services at the DRG rates and who meet basic norms of regulation and quality.

The terms of contracting are strict, with respect to prices and standard treatment guidelines and services to be delivered. This is not attractive to most private providers. There is a small and decreasing private sector participation in primary care. In tertiary care private sector participation is higher, but more in high cost procedures. The private sector outside contracting depends of a small affluent local population or on medical tourism to survive. Thailand therefore has used purchasing as a means to strengthen and extend public provisioning and limit private sector growth to only essential and supplementary areas- where also it is well regulated.

To the question about the resistance from the side of the private players, Dr.Samsak said, “The private sector has raised resistance to regulations. But now they abide by the regulations and have a different segment of clientele”.

Grievance Redressal: One interesting innovation is in accountability and the seriousness given to assured services. Article 41 of the National Health Security Act mandates compensation for injury or damage due to any services provided.

“As mandated by Section 41 of the National Health Security Act 2002, adverse outcomes from medical errors, such as mortality, morbidity or permanent disability, are financially

compensated. This no-fault compensation, offered without proof of which party was at fault, covers all UCS beneficiaries and was fully implemented in 2002. The NHSO earmarks annually not more than 1% of the annual service budget for this compensation. Thus, the NHSO minimizes litigation against doctors and hospital personnel, since patients and their dependants feel that their pain and suffering have been taken into account. Financial compensation is neither large nor small, at a maximum of 200,000 baht (equivalent to approximately US$ 6700) for mortality and permanent disability, 12,000 baht (US$ 400) for disability, and 48,000 baht (US$ 1600) for injury or illness. There is a budget allocation to every district to pay for compensation. In a single year over 704 beneficiaries and 686 providers received compensation in 2010.

A grievance redressal and helpline call center operates from NHSO office with a commitment to complete the process of redressal or other adequate response within 30 days.

Healthcare Workforce Regulation:

Thailand is self-reliant in terms of healthcare workforce. It has more than 2.8 healthcare workforce per 1000 population. Medical colleges are under separate regulation by the ministry of education. Private medical universities are also functioning. But the students from the private universities should get through a national test for the license to practice medicine. Private hospitals can give residency practice if the medical council gives sanction. But for nurses, there are many regional and provincial nursing schools affiliated to local public hospitals. Local students supported by grants and scholarships from local governments serve further in local hospitals. Ongoing attempts are made through educational and financial means to improve the distribution of health professionals in rural areas. (Wanitkun, 2011)

National level licensing examination for all cadres of professionals since 2001 ensures quality of professionals. Licensing by professional councils also is in place. Relicensing of professional nurses is done every five years with continued medical education. After 2002, public sector reform, to downsize the public sector, Thai government terminated all retirement posts. Thus the nurses and pharmacists became contract workers paid by hospital revenue, not civil servants, while the doctors and dentists remained on role as civil servants. (Jongudomsuk et al. 2015)

The policy of 3-year compulsory public service for new medical graduates helped in getting doctors for rural Thailand. But the attrition rate to the private sector remained high once the 3 years of service is completed. Increase in number of regional medical schools helped to attract local students into medical courses and found them remain working longer in rural areas (Wanitkun, 2011).

3. COUNTRY : IRAN

Healthcare In Iran:

The Islamic Republic of Iran (IRI) is a middle income country located in Southwest Asia, in the Middle East region, 17th country in the world in terms of population and 18th in terms of land area. In the national census report of 2011, about 28.5% of its 75.1 million people were rural residents (Moradi-Lakeh,). Life expectancy at birth (2005) of 69 for male and 73 for female, 9.0 physicians per 10,000 inhabitants, 17.2 hospital beds per 10,000 population (2005) and 7.8 % of GDP (2005) spent on healthcare. (WHO. 2009).

Article 29 of the Iranian Constitution guarantees all citizens of the right of access to healthcare. Based on this right, the accessibility and affordability of health services for the entire population is a policy focus of Iranian Government. A strong focus is given to primary health care which is financed from the public budget. It is delivered by the Ministry Of Health and Medical Education (MOHME) through a PHC delivery system (Hajizadeh and Nghiem. 2011).

Public services were established during the Pahlavi kingdom and have expanded since then across different regimes. At the national level, the Ministry Of Health and Medical Education (MOHME) is responsible for policy making, planning, financing and supervision.

On the provincial level, medical universities have some of the responsibility for financing and planning. At the provincial level, the University of Medical Science and Health Services (UMSHS) supervises the operations of health sector. Supporting and implementation of national health policies, delivery and evaluation of health services are the task of UMSHS. The Deputies of Health in universities are responsible for the administration of District Health Network (DHN) in all 336 districts of Iran.

At the district level, urban and rural health centres and district hospitals are executive units. The importance of primary healthcare is emphasized and financed by the MOH and it has an important role in providing hospital care. Secondary and tertiary healthcare is financed through insurance schemes (Palesh.2010). The provider network of PHC is called Health House in rural areas and Health Posts in urban areas. They function as a gate-keeper and

makes referral to the higher facility, if required. (Hajizadeh and Nghiem.2011.)Each Health Center has a standard list of resources and services and covers at least one main village and sometimes some satellite villages (Moradi-Lakeh, interview).

.The chancellor of the medical university is the steward of the health system in its catchment areas (Moradi-Lakeh, interview). The university hospitals are dominant in terms of number of the hospitals, number of beds, variety of specialties and services they provide. Patients are usually admitted through the hospital's clinics or are referred from other health centres and/or private sector physicians (Pourasghar et al.2008).

Medical education is offered by the government and it is free. There is only one private university is available in Iran, where students have to pay.

Private Sector presence:

Healthcare in Iran is provided by both public sector and private sector. In Iran, 60 percent of the total health expenditure is from the private sector, but this accounts for only a lessor share of total services delivered. The services offered by private care are mostly in specialty care, other than pharmaceuticals and medical devices. Out-patient care is more private than public. However; when it comes to in-patient services hardly 15 percent of the population use private in-patient services, and this is mostly in larger cities like capitals of provinces. People of the lower socio-economic status do not go to private hospitals. The services of private providers are not primary. They are specialty clinics, pharmacies, labs and imaging centres.

During the recent decade, the number of private healthcare centres in Iran is on increase. The statistics of the Ministry of Health of Iran (2009) says that 54 (40%) of the 134 hospitals in the health sector of Iran possess 48% of the hospitals beds of this sector are in private sector and most of them have been operating in Tehran, the capital of Iran. (Zarei 2012).

Insurance: The role of purchasing care:

Public Medical Service Insurance Coverage Act (PMSICA – 1995) established the Medical Service Insurance Organization (MSIO) to provide formal health insurance coverage to people from a range of social sections including rural dwellers, nomads and students. The Iranian government subsidizes, 90% of cost associated with hospitalization of rural dwellers and no-

mads. But it does not provide for pharmaceutical expenses of hospitalization and ambulatory care. For the urban population without any health insurance- Urban In-patient Insurance Scheme (UIIS) was established in 2000. Ambulatory care and pharmaceutical expenses of in-patients are not covered here also. Similarly RHIS (Rural Health Insurance Scheme) was introduced in 2005 for Iranians who live in rural areas without insurance. UIIS and RHIS cover 10 % and 30% of Iranians under them respectively (Hajizadeh and Nghiem.2011). Moradi-Lakeh said, "All social financing system are under the regulation of the ministry of wealth".

The health insurers in Iran (Hajizadeh and Nghiem.2011) are:

1. Social Security Organization: It covers formal sector employees (excluding government employees) and their dependents. SSO owns clinics and hospitals in all provinces of Iran. The individuals covered are given services either free of charge or at greatly reduced price.

2. Medical Service Insurance Organization (MSIO): Government employees, rural dwellers, the self-employed and students are covered under this. This system works on a co-payment mode for both ambulatory and in-patient services.

3.Armed Force Medical Service Organization (AFMSO): Defense personnel and their dependents are covered under this scheme.

4.Imam Khomeini Relief Foundation (IKRF): It provides coverage for the uninsured poor.

5.Special organizations : such as Ministry of Welfare and Social Security, oil companies, banks and NGOs provide their employees and dependents with health insurance.

According to Haghparsat-Bidgoli et.al (2013), the MSIO covers about 40%, the SSO covers about 30%, the AFMSO covers about 5% and IKRF covers about 8% of the population. In addition, there are small semi-public companies which provide mainly complementary insurance policies, covering almost 5% of the middle class population.

Insurance companies buy services from private and public providers. Some of the private providers do not accept the insurance rates and they collect cash from the patients. In public facilities the government pays for the expenses over and above the insurance coverage. In private sector, the patient has to pay out-of-pocket if the expenses exceed the insurance

coverage. Complementary insurance is also available. And some people go for it to get a higher coverage. Although the government encourages public services, about 10 percent of the expenses have to be paid by everyone getting in-patient services from the public sector and a higher percentage on out-patient services, depending on the nature of services.

The current employer sponsored health insurance system does not offer equal protection against hospital expenditure in Iran. Length of stay, admission to private hospitals, teaching hospitals owned by MOH, and living in remote areas are associated with higher OOPE in Iran. (Hajizadeh and Nghiem.2011).

An attempt was made in 1994 by the Iranian parliament by introducing Medical Service Insurance (MSI) Act to separate the purchaser from the provider. The MSIO, is regulated by the Insurance High Council tried to set tariffs and leave the hospitals with 'autonomy' to generate revenue by user charges. The system proved to be failure by dropping the bed occupancy in public hospitals by 50 % (Doshmangir.2016).

Regulatory Agencies:

Regulation is done through the central and provincial governments, but enforced through medical universities. This seems a relatively unique feature for any country. Applications for establishment of medical facilities have to be approved by chancellors of medical universities in provinces. They make periodic inspections and issue or renew licenses. Certificate and accreditation from the university in the area are mandatory to start a healthcare facility.

This regulation works as licensing as well as quality accreditation. Regulations are almost the same for private and public sector facilities and in rural and urban as well. The fees for healthcare services are decided by the medical council.

Earlier doctors used to work in public and private facilities simultaneously. But now they cannot do that; they have to make a choice between the two.

Since a major part of primary care is by the public provider and over 80% of hospital care is provided by government hospitals and much of the rest is covered by government funded insurance- the emphasis is on accountability not regulation. Regulation is more ori-

ented to the smaller private sector and is equally by the terms of purchase as well as licensing and quality controls implemented by universities. Insurance agencies are largely government managed- though private complementary is an emerging feature in the cities.

In public hospitals quality controls are an important avenue for improving provider behaviour and making care more effective and efficient

Professional Practice: Ethical aspects & Grievance Redressal

The Medical council in Iran is an independent non-governmental agency with elected president. They are also involved in framing legal requirements for healthcare facilities. *'Code of Ethics'* are in practice and they are within the scope of the professional associations. The patients are free to approach the medical council if they have complaints of unethical practices and to the court in case of negligence. The government has also provided direct line and contact number for all patients to seek assistance if they have grievances.

Traditional medical practitioners work like shops in Iran. They are not much regulated. But if they work against the public interest, the ministry has powers to intervene and even ask them to close down.

Professional Practice:

Iran has a law on use of generic drugs. All doctors are allowed to practice only generic prescriptions. However branded medicines are also available in Iran but are sold out as generic only. About 80 percent of expenses on drugs are on about 20 percent of imported drugs. Despite this there are problems of rational use of drugs and diagnostics. Unplanned diffusion of both MRI and interferon beta have spread rapidly in Iran. Interferon beta has found to be used at levels higher than those in some high-income countries. (Palesh.2010)

Iranian Drug Selection Committee (IDSC) under the Food and Drug Department of MOH prepares drug list for the country. Only those drugs registered in the National Drug List (NDL) are produced in or imported to Iran. The need for Medical devices and equipment are determined and ordered by the Director General of Medical Equipment, under the Deputy Minister for Health Affairs. (Palesh.2010).

4. COUNTRY : SRI LANKA

Introduction :

Sri Lanka is experiencing strong economic growth, driven by large-scale reconstruction and development projects following the end of the 26-year conflict with the LTTE. Sri Lanka is pursuing a combination of government directed policies, private investment, both foreign and domestic, to spur growth in disadvantaged areas, develop small and medium enterprises, and increase agricultural productivity. It has a GDP of 59.1 billion dollars and a growth rate of 8.2%.

Much of Sri Lanka's achievements in health have been possible due to impressive achievements in social sector. Proportion of population living below $1.25 a day -7% (2007). It has a favourable sex ratio at 100, an adult literacy rate of over 90% and youth literacy in women close to 99% and women's share of enrollment in primary and secondary education is nearly 50%. More than 90% of the population has access to improved water and sanitation. Easy physical access to health services close to households was ensured in Sri Lanka as far back as 1971/73.

Sri Lanka healthcare services:

The total expenditure on health is about 3% of GDP and of this government expenditure is about 50%. Government expenditure on health is about 5.8% of its total budgetary expenditure.(WHO report on Sri Lanka National Health Expenditure). Sri Lanka has 31 beds per 10,000 population and a physician density of 5 per 10,000 and a nursing density of 19.3 per 10,000 population- all of this is close to or higher than desired norms. Its infant mortality, under 5 mortality rate are all much better than global averages and the general South Asian performance. Performance in disease control is also much better in recent times and it may be the first country in decades to have successfully eliminated malaria.

Both Public and Private sectors provide healthcare in Sri Lanka with Public sector providing healthcare to more than 60% of the population. The entire range of preventive, curative and rehabilitative services is provided by the Department of Health Services and the Provincial Health Sector. Private sector is largely restricted to Urban and sub-urban areas and caters to nearly 50% of the out patient load of the country.

When it comes to in-patient care, the public sector almost monopolizes inpatient care with 95% of the inpatients being treated in public health facilities has meant that people do not generally fall prey to catastrophic medical expenditure. Health services for the armed forces, police personnel and on the rubber, tea and coffee estates are separately organized.

Regulation of the private sector:

After a 14-year-old struggle, the Private Medical Institutions Act was adopted. A Private Health Services Regulatory Council was formed under this Act, and there are provisions in the Act to regulate the private health services sector. When this became an act, there were over 200 private hospitals in the country, but only 80 such institutions function with licenses. The private sector health care institutions were given a period of three months to register with the newly formed Council. Under the new regulation, it is illegal to run an institution, which provides health care services, without registering with the council. The regulatory council is has representation of the professional bodies such as Sri Lanka Medical Council, Independent Medical Practitioners Association and Dental Association and is headed by the Director General Health Services.

The Act has four main objectives:

* Ensure efficiency and effectiveness of the private sector health care services,

* Improve the health of the population,

* Ensure equity and

* Ensure the quality of the services provided by the private sector health providers.

According to Dr. de Silva, a fine and an imprisonment or both would be given to the service providers who violate the regulation and the fine would vary according to the offence they commit. Apart from 200 hospitals, there are over 450 medical labs, 12,000 part time General Practitioners (GPs), 850 full time GPs, 750 dental practitioners, home nursing care and ambulance service providers in the private health sector, where over 10,000 people are employed.

Other forms of regulation:

Sri Lanka has no major strategy with respect to purchase of services. It's health care system is built around government provisioning of services in secondary and tertiary care levels. Human Resources for Health: Medical and Nursing institutions are also largely in the public sphere and regulated by the professional councils. Sri Lanka is in the process of digitizing its information flows on public health. It has no specific regulatory initiatives with regards to health information.

5. COUNTRY : INDONESIA

Introduction:

Indonesia is the fourth most populous nation and now a lower middle income nation. It has reasonable political stability and is in the process of strengthening its health care system.

The fertility rate was reported at 2.5 births per woman in 2010. The Global Burden of Disease Study 2010 (GBD, 2010) states stroke as the leading cause of death among Indonesians, about 19.5% of all deaths in 2010. Common risk factors include hypertension, smoking and hypercholesterolemia (Kusuma et al., 2009). Cancer ranked second as cause of death in Indonesia. The most common causes of cancer deaths were lung cancer, liver cancer and colorectal cancer (Kimman et al., 2012). Tuberculosis is the third main cause of mortality, claiming 69 000 lives in 2012 (WHO, 2013). Indonesia has one of the highest TB disease burdens in the world, due to a combination of a large population and a high prevalence rate (Collins et al., 2013).

Role of Private Sector:

Indonesia's health system is a mix of Public and private providers and financing. Private providers include for-profit and not-for-profit hospitals, clinics, doctors and midwives who engage in dual practice. The government share of total health expenditure also remains low, at only 39%, whereas private, primarily out-of-pocket (OOP) expenditure is 60%?? source. Indonesia has supported for long the development of the private health sector, beginning with encouraging private sector participation in the delivery of family planning services unlike other countries.

Since 2004, after the implementation of Social Health Insurance scheme, utilization of private sector reduced as the insurance scheme only allows use of public facilities for primary care. Out-of-pocket spending accounts for more than a third of all health spending. Women are increasingly giving birth in a facility – and more than two-thirds of institutional deliveries take place in private facilities across income groups. For in-patient care about one-quarter of government contracted providers are private hospitals.

However, the distinction between public and private provision of health care services and products in Indonesia is not clear. The vast majority of publicly employed health personnel have second jobs in their own private practices or other private facilities. Some public facilities deliver private services and some state-owned enterprises are incorporated as private firms even though the sole or majority shareholder is the government. This lack of clarity may make defining the scope of the private sector more difficult, but it also points to a policy environment that acknowledges the private sector's contribution to health in Indonesia and is conducive to private sector participation in health care delivery.

Scope of Regulation :

Licensing : It includes requirements for individual providers to be registered and gain a licence to practise, while hospitals require a licence to operate and must participate in the hospital accreditation scheme. Quality of Care: This is important for accreditation and licensing- and described below.

Pharmaceuticals: There is also a variety of regulations relating to the production of pharmaceutical products, their advertising, distribution and sale. However, there remains a high rate of illegal sale of pharmaceuticals by unlicensed drug vendors, and self-medication is common.

Patient Information: Patient rights guaranteed by several laws, including the right to confidentiality, to information about treatment and costs, to give consent to any procedures, and not to be treated negligently.

Regulation Governance:

The system for creating laws is complex and distributed across three levels of government. Law No. 12/2011 established the current framework for formulating laws and regulations in Indonesia, in accordance with the 1945 Constitution. It provides for a number of different legislative and regulatory instruments set out in a formal hierarchy order. All of these regulatory instruments play a role in regulating the health sector.

The function of regulation is divided between central, provincial and district governments. Regulations are viewed in a hierarchy from laws to different levels of regulation at

different levels of government. The federal Ministry of Health is responsible for management of some tertiary and specialist hospitals, provision of strategic direction, setting of standards, regulation, and ensuring availability of financial and human resources. Provincial governments are responsible for management of provincial-level hospitals, provide technical oversight and monitoring of district health services, and coordinate cross-district health issues within the province.

District/municipal governments are responsible for management of district/city hospitals and the district public health network of community health centres and associated sub-district facilities. Their function includes licensing individual providers.

Health service activities are conducted by local governments through the local health offices. The PHO has the responsibility for technical guidelines for the DHO, as the representative of the MoH in provinces, and also for direct intervention on cross-district health problems.

Professional associations also exercise some self-regulation functions at the local level. However, the relationship between MoH, PHO and DHO is not a hierarchical one. The district/municipality government is not 'under' the provincial government. Each level has its own mandates and areas of authority. Within the decentralized health system, the hospital is not subordinate to the health office, and the DHO does not answer to the PHO. Likewise, the PHO is not responsible to the MoH, but to the provincial governor. MoH has a few "vertical" programs that directly function at Provincial and District level, e.g. immunization.

Regulation and governance of third party payers:

With the commencement of the JKN, the social security managing agency has taken on the function of a third party payer. The BPJS-K is monitored closely by the National Social Security Council (DJSN). Both these institutions are responsible to the President.

BPJS-K makes payment to health facilities, based on the standard tariffs set by the government (MoH, 2013a), and contracts with health facilities. In case there is no agreement on the amount of payment between the BPJS-K and the health facility providers, the MoH is mandated to make the final decision. In cases where emergency services are provided by

health facility providers that have not entered a cooperation agreement with the BPJS-K, the provider can still claim the cost to BPJS-K and be reimbursed according to the local tariff.

Private insurance is under the supervision of the Ministry of Finance (House of Representatives, 1992) and the payment mechanism is arranged through contract with health facility providers. BPJS-K has established coordination of benefits (President of Indonesia, 2013c) with some of the leading private health insurance providers to provide a top-up option for middle- and high-income members of the JKN.

Regulation of hospital service:

The governance of health-care facilities, particularly hospitals, is set out in the Hospital Act, which provides for the application of good governance and clinical governance principles. In the public sector, public hospital governance is also regulated through public administration regulations should the hospital obtain the status of a Public Service Agency. Both public and private hospitals are subject to supervision by the Monitoring and Supervision Bureau for Hospitals (BPRSI). At the local level, there are supposedly provincial bodies for supervision of hospitals (BPRSP) but not present in all provinces.

Hospitals in Indonesia must be accredited every three years. The Hospital Accreditation Committee (KARS) has conducted hospital accreditation since 1995 (KARS, 2012). Currently, the committee for medical competency testing (PUKDI) and the local committee for dentistry competency testing are the bodies responsible for conducting competence-based test for medical doctors and dentists, respectively, while for pharmacists there is the Sertifikasi Kompetensi Profesi Apoteker (SKPA).The new standard is adopted from 2012 based on the standards of the Joint Commission International (JCI), the International Principles of Health-care Standards from the International Society for Quality in Health-care (ISQUA), and the previous KARS standard (2007 version), together with relevant standards issued by the MoH, as well as local content from national priority programmes, e.g. PONEK, HIV/AIDS and TB-DOTS. The MoH issues the accredited status for a hospital following a recommendation from the KARS, after a hospital is deemed to meet the accreditation standards.

Medical negligence: Medical negligence and litigation related to medical practice conducted by a doctor or a dentist are assessed by the Indonesian Medical Disciplinary Board

(Majelis Kehormatan Disiplin Kedokteran Indonesia/MKDKI). The MKDKI is a competent authority under the Indonesian Medical Council (KKI), which determines the presence or absence of negligence or mistakes or ethical issues in medical practice and ensures that the sanctions imposed are appropriate and proportional. However, mediation and negotiation should be the first choice in resolving conflicts related to medical practice (House of Representatives, 2009c).

Professional Regulation:

Health-care providers are required to be registered. Doctors and dentists are registered by the Indonesian Medical Council. Pharmacists are registered with the National Pharmacist Committee, while other health professions are registered with the Indonesian Health Personnel Assembly

Prior to practising, doctors and dentists must meet several requirements by obtaining: (1) a competence certificate by passing the competence-based test conducted by their collegium; (2) a registration letter issued by the KKI; (3) a license to practise issued by the district/municipality/PHO; and (4) in the public sector, to assist better planning of human resource, an instruction letter issued by the health office to practise at certain health-care facilities (House of Representatives, 2004b; Minister of Health, 2007). The registration letter (STR) is valid for five years and subject to renewal (House of Representatives, 2004b).

The Indonesian Health Personnel Assembly (Majelis Tenaga Kesehatan Indonesia/ MTKI) develops standards of competence for human resources in health, to conducts competence tests for health personnel, and issue certificates of competence and registration letters. (Pustanserdik, 2012).

A licence to practise is issued by the local health office and is valid as long as the registration letter is valid and the practice location is the same as in the licence. The regulation on the licence to practise is quite detailed. Doctors or dentists are only allowed to practise in three locations at most, either in government health facilities or private institutions located in one district/municipality or in another district/municipality either in the same or a different province. The regulation further explains that the licence to practise for a doctor or a dentist who conducts medical practice in a government health service facility, including health-care

facilities for the army and police, can also be used in another government health facility in the same region. The regulation also describes the mechanism used to obtain a licence to practise.

According to the regulation, the head of health office of the district/municipality has to consider the balance of the number of doctors and dentists with the health service demands. The head of health office of the district/municipality is obliged to keep a record of every licence to practise that has been issued. The record should be sent at least once every three months to the MoH and the Indonesian Medical Council, with a copy to the Head of the PHO and professional organization. The head of the health service facility is obliged to make a list of the doctors and dentists who practise in their facility in an easily visible location. A doctor or dentist who owns a licence to practise and conducts an individual practice is also required to install a name plate at the location of the medical practice that states the registration number found on the licence to practise.

Similarly, nurses and midwives are required to obtain their licence to practise from the local health office. Although nurses and midwives are not required to register themselves with their professional associations (PPNI and IBI, respectively), they need to do so to get a recommendation letter as part of the requirements to get their licence to practise.

To be able to extend a licence to practise, a health worker must collect a minimum amount of professional credit units from various scientific and continuing medical education activities, such as attending seminars, training, or research publications (IDI, 2010).

The doctor or dentist that is unable to conduct medical practice or has appointed a substitute doctor is obliged to publicly notify this change at an easily visible location and to inform this change to patients.

Enforcement of regulations:

Enforcement in regard to professional practice of medical doctors and dentists is undertaken by the MoH through the Indonesian Medical Disciplinary Board, local health offices and the professional organizations contribute in accordance with their respective functions, tasks and authorities (House of Representatives, 2004b). The MKDKI is authorized to recommend an administrative sanction and/or disciplinary act for any violation of the regulation.

In practice, monitoring and enforcement are extremely difficult in a decentralized Indonesia without an integrated information system. For example, licensing occurs at the local health office but this information is not shared across districts/municipalities or with central level. Thus, it is difficult to enforce the law that limits physicians to operating in no more than three practices (including private practice), as doctors are able to set up additional practices in neighboring districts/municipalities without being detected.

Regulation of capital investment:

All investment, either domestic or foreign, is supervised by the Indonesian Investment Coordinating Board (Badan Koordinasi Penanaman Modal/BKPM), a government institution that coordinates all necessary steps related to investment in all sectors. The BKPM has the right to approve any investment plan. In the case of some types of hospitals, the MoH also has the authority to issue the licence for hospital operation. Health services and the health-care industry are open for domestic investment. There are two kinds of domestic investment: State investment and private investment. The health insurance implementing agency (BPJS) is allowed to manage its fund of contributions in the form of various types of investment, provided that they comply with the regulations (Government of Indonesia, 2013).

State investment is also allowed in the form of equity investments and establishment of a State-owned enterprise. State-owned enterprises (Badan Usaha Milik Negara/BUMN) are regulated by a different Act (House of Representatives, 2003a) and supervised by the Ministry of State-Owned Enterprises. The BUMN may own health facilities. In terms of private investment, any domestic investment is allowed for health services and the health-care industry.

Hospital investments are available to foreign investors. The investment plan requires formal approval from the MoH and BKPM. The approval usually involves consideration of the geographical setting of the facility. Foreign investment is only allowed in big hospitals (at least 200 beds) including specialty or subspecialty hospitals, thus, prohibiting foreign investment in small- to medium-scale health facilities (Minister of Health, 2010e).

Other LMIC Countries - A note:

Healthcare and its Regulation in South Africa

Gross inequities exist in health expenditure in South Africa. 55–60% of total health expenditure is spent in the private sector on less than 15% of the country's population. South Africa spent one of the highest proportions (43%) of health financing on private health insurance in the world (McIntyre, Doherty et al 2014). Yet private health insurance covered only 17% of the population in 2012 (Doherty 2015).

The scale of the private sector is such that the capacity of the public sector to respond fully to the health crisis is restricted because private medicine absorbs disproportionate numbers of skilled nurses and doctors. Furthermore, the public–private balance in health care has changed greatly in the past decade. Government expenditure on health care for individuals who are not members of a private medical scheme has been stagnant until the past 6 years despite the massive additional burden on such services because of the HIV epidemic. By contrast, an uncontrolled cost spiral has occurred in private medical schemes. For many years a national health insurance scheme has been mooted as a way to raise substantial resources to improve health systems in the public sector, mainly by salary improvement for health workers. But this possible solution has not moved beyond the discussion documents. Sobering experience in South Africa suggests that the public sector has restricted capacity to develop, implement, and monitor health contracts with the private sector.

Very few regulations directly influence the quantity and distribution of health care providers in South Africa. In terms of the National Health Act (2004), the Director General of national DoH is responsible for issuing licenses or a 'Certificate of Need' for all private hospitals, 'private practices' and 'prescribed health technology' or 'high-end equipment', both for existing services and for proposed future services. DG ensures the quality, equity in distribution and rational use of healthcare resources, but the informants tell us that much of this is poorly implemented. Similarly there has been little implementation on prices though National Health Act envisages it.

A comprehensive regulatory framework was introduced with the promulgation of the Medical Schemes Act of 1998 and associated regulations which came into effect on 1 January 2000. The Act ensured that every scheme has to provide 'prescribed minimum benefit package' which includes health services that could impose catastrophic costs on members.(Chopra. Lawn, 2009).

A similar situation exists in many African nations. Almost all of them insist of registration and licensing of facilities. Certain regulations on infrastructure requirements and human resources are found, but quality regulations have not yet gained attention of regulators. No price ceiling is found in the African nations (Doherty 2015). The study done on regulations in African countries made Doherty (2015) conclude that the (a) existence of private provider lead to brain drain from public sector and aggravates fragmentation of health system, (b) Powerful private sector alliance compromise government's ability to regulate the sector in the interests of national health objectives. The study suggested that a perception that people have preference for some form of private provision reinforce the notion that private provision should remain an option for governments seeking to provide UHC. But in the absence of the capacity to regulate, or mobilize funds on the scale needed to make purchase the dominant mode, there is limited forward movement.

6. COUNTRY : JAPAN

Introduction:

At the Eastern edge of Asia, a constitutional monarchy with a parliamentary government is located- Japan, one of the nations in the world with the best population health, with the longest life expectancy and the smallest infant mortality. More than one-fifth of the population is above 65 years and the nation is aging and this poses new challenges. (Tatara and Okamoto.2009).

Presence of private sector:

The island nation of Japan with 127 million population (2015), has a mixture of both public and private healthcare providers. In the post-war era, the government of Japan encouraged the involvement of private sector in many industrial sectors in the country and in the healthcare sector too. This continues even now, but with more regulations from the government. The private sector which includes individuals and medical corporations owns over half of the total number of healthcare institutions. Private hospitals also provide services included under the Public Health Care Plans (HSDP.2012). Over the years, Japanese hospitals have grown up to become large facilities. Dr.Ono observed, "Health care system in Japan is very capital intensive and labour-saving. For example, many hospitals own MRI machines while the nurse per bed ratio is very low. However, the private hospital has discretion to use the technology efficiently".

The healthcare market is open for investment, but is not attractive, especially for the foreign investors, because of the rule that the profit made out of the investment in healthcare cannot be distributed to the shareholders and owners. Profit from healthcare can only be reinvested to develop healthcare further. Private medical colleges are also not-for-profit in nature. In the words of Ono, "the Japanese healthcare is primarily not for profit in nature". There are some exceptions to this rule- for example where industrial houses have hospitals that provide healthcare to their employees- but these are few. In insurance too, all social health insurance is provided by statutory agencies: which are autonomous but with government leadership. There are private insurance agencies but these largely provide additional/supplementary insurance coverage.

Public system and coverage:

Public hospital facilities are managed by central government, local governments, the national university, local universities or special agencies such as Japanese Red Cross (HSDP). The prefectural (local) government is in-charge of starting a new hospital. In Japan, a healthcare establishment having more than 20 beds is known as a hospital, while those having beds in the range of 0-19 are known as clinics. For opening a clinic, a notification has to be submitted to the Prefecture. Although the providers enjoy the choice of location, the number of facilities in the region is decided by the local government. The local government is involved in regulation of the public and private health services in order to ensure that people are provided appropriate care. The public health doctors cannot do private practice.

Financing of Health Care:

The Employees' health insurance system (social insurance schemes) provides coverage for about 60 % of the population in Japan. The National Health Insurance system provides for about 40% of the population, the self-employed, unemployed and retired. OECD estimates show that 8% of GDP is spent on healthcare. Health insurance is the source of funds for 50 % of total spending, 36% from taxation and the rest 14% out-of-pocket (Tatara and Okamoto.2009).

There are three types of statutory health insurances in Japan: (1) occupation based, (2) municipality based and (3) separate system for persons of 75 years and above. The system was mandatory in nature, and the municipalities were expected to give health insurance. The insurance companies are not-for-profit and they collaborate with public and not-for-profit healthcare providers for service delivery. The cost of medical care is financed through tax revenues, insurance premiums and co-payments. However we see a principle of solidarity in the system that it exempts the elderly- above 75 and the infants and low-income from co-payments, while the productive age class and employed have to pay 30 % as copayments.

The NHI does not cover prevention. Health insurers get freedom to offer preventive care or to have copayment for top up or supplementary insurance (Tatara and Okamoto. 2009). The National Health Insurance Scheme fixes a fee schedule at the central level, which the private sector has to accept. The public health services focused more on rural areas that

are less densely population. It is also involved in treating patients with rare diseases and is financed through tax based insurance.

Social insurance schemes are compulsory. The Prefecture (local government) is the insurer. All large employers have the duty to provide insurance protection to their employees through their own not-for-profit health insurance schemes. For smaller organizations, Japan Health Insurance Association provides the same through a collective health insurance. This is also a not-for-profit public health insurance, also called the 'Association Managed Health Insurance' (Social Security in Japan.2014).

The range of contribution rate as percentage of monthly wage is 3.12% to 9.62%. (HSDP). Major companies and the defense run their own insurance schemes and assure financial protection of their employees. The sector has therefore been characterized as a price-controlled, fee-for-service basis. (Leflar, 2008).

For those who are not covered by occupation-based health insurance and are below the age of 75, the National Health Insurance provides protection. The contribution to the National Health Insurance is proportional to the salary. The burden of copayments tended to be large for the elderly and chronic patients. Hence from the 1960s the municipalities subsidized the care of the elderly. The fast escalation of expenses made the government to revise and introduce the new Health Service System for the Elderly in 1983 with per diem copayment (Social Security in Japan.2014).

Prefectural health care plans document the service delivery model in each prefecture (HSDP.2012). But the patients are left with their freedom to choose from among the providers. There is no gate keeping for advanced medical treatment. If they pay surcharge, patients can receive treatment at Special Functioning Hospitals or Regional Support Hospitals without a referral letter. (HSDP.2012).

Regulation of facilities and services:

Regulation of Japanese health care system is two dimensional: human and capital resources are regulated by Medical Care Act, and financing is regulated by Health Insurance act. Regulation is implemented at three levels: central government, prefecture government and major city governments. The national government regulates financing, while human re-

sources are by the prefecture governments. The Ministry of Health regulates insurance schemes and benefits as well as the national uniform fee schedule.

Although Japanese healthcare is private-public mix, there are stringent regulations set by the national government. Private facilities can start hospitals or clinics only if they satisfy the criteria in the Medical Care Act (HSDP.2012). There are certain specifications in terms of human resources. As reported by Iwasa (1996), the director of a hospital is specified to be a medical doctor by law. The law requires one nursing professional for every four patients (Iwasa.1966). The Medical Care Act sets staffing numbers for physicians and nurses for each type of hospital bed as a quality measure, but there are not enough staff to meet the standards. Nurse specialist for cancer was started from 1994 with 4 nurses trained in the specialty and by 2012 the number was 327 (HSDP.2012).

The private sector has the freedom to choose the location for starting the new health facility; however its number is controlled by the prefectural government. The public system focus on equitable distribution and basic as well as specialty care. But advanced treatments are available with the private providers, often not covered by health insurance. “Prohibition of mixed treatments” acts as a mechanism to assure that the schemes are not abused by the providers and receivers as well. However there are no regulations directly restricting the selection of medical institutions by patients (Chino.2007). The law also says that the administrators of smaller hospitals must not keep their patients longer than 48 hours except when there are unavoidable circumstances (Iwasa.1966). But it is observed that many elderly patients are admitted for long days in many hospitals, mostly to bridge the gap in revenue. There are no mechanisms to strictly monitor this.

The public sector organizations can receive public subsidies and contributions, while private institutions run by medical corporations and individuals should rely on revenues for medical services for management as well as for income. Price incentive effect of medical treatment will differ depending on the type of ownership. The decisions made by private institutions result in a phenomenon called ‘cream skimming” and lead to differences in market structures between private and public institutions, resulting in regional differences in supply conditions. Private institutions play a particularly large role in the hospitalization and treatment of senior citizens (Chino 2007).

Pricing and profitability :

Medical fees are revised by the government every two years and uniform reimbursement to providers is one reason for Japan's control of medical expenditure. Private providers must deliver services according to the fee schedule where they are covered by insurance, but may set prices only for services not covered by the insurance (HSDP.2012). There is disparity in the prices faced by patients and doctors. Hidden costs are being imposed on patients, an important one is the cost of waiting time at a medical institution for consultation, the queuing cost. Although medical fee schedule is a way of controlling, the elements that are regulated for price control are inputs (Chino 2007).

Japan has a not-for profit private sector in health. However, if a private company engaged in healthcare makes profit then it has to be spent only for improvement of medical services. The private stock-based companies are not allowed to engage in the provision of health care services. Japan has Medical Services Law that provides the framework for establishment of medical and health services in the country. It also governs the number of human resources in the health facility, as said by Ono.

Three key issues are identified by Chino (2007) in the context of institutional economics:

(1) The fee schedule which represents the official price of medical services plays an important role in income distribution and resource allocation. There is tendency for rent-seeking activities of interest groups to develop in the political process. The current medical fee structure reflects the political bias that result from involvement of the doctors in decision-making.

(2) Almost of all medical institutions are reimbursed under the medical care insurance system, without considering the transaction costs and scale of services.

(3) The current medical fee schedule imposes severe constraints on the production process of medical care, because the providers will get paid only if they limit the treatment appraised in the schedule.

Extra bed charges and clinical trials for new drugs which are not covered by insurance but permitted together with insured treatments.(Chino 2007).

Legislation:

The Medical Services Law and health insurance law are the main laws that regulate health care services. Other than this, the School Health Law, Industrial Safety and Health Act, and Infectious Disease Control Law regulate provision of healthcare services to the needy. The Act on the Protection of Personal Information (2005) legally obliges patients to be informed and prevents medical records to be disclosed except with specific conditions (HSDP.2012).

Unregulated aspects:

The Japanese traditional medicine 'Kampo medicine' is based on oriental traditional way. In addition to Kampo, herbal medicines, acupuncture, moxibustion, and others are used in Japan. There is neither national program nor national expert committee related to traditional medicine in Japan. A study in 2005 indicated that 32% of the population used acupuncture during their lives. Kampo medicine can be sold with prescription or as non-prescription over counter medicines. (HSDP.2012)

Quality Accreditation:

Post-war Japan is known for its quality improvement movement across manufacturing and service sectors. But the pioneering effort in quality improvement is not much reflected in the Japanese healthcare. Japan Council for Quality Health Care (JCQHC) was founded in 1995 (HSDP.2012). Institutional structures to monitor quality of care have been weak. Voluntary accreditation system does exist, but accreditation is unnecessary to qualify for reimbursement (Leflar. 2008). Quality assurance is voluntary in nature but every health facility has to follow some minimum standards mandated by the prefectures.

Professional Regulation: Doctors are the members of the Medical Associations that determines the code of ethics for their practice. There is also a Nurse Association. Malpractice liability premiums in Japan are lower and more stable than in the United States. There is a nationwide risk pool for all physicians in private practice, covered by the Japan Medical Association (JMA) indemnity insurance system. (Leflar. 2008)

Professional licensure and discipline authority is exercised by the Ministry of Health, Labour and Welfare, but it seldom inquires into failures of medical safety.

Challenges:

1. In 2012, there were 8,565 hospitals, 10,052 clinics and 68,474 dental clinics in Japan. The number of beds in hospitals is 1,578,254 (12.4 beds/1000 people) and the number of beds in clinics is 125,599 (0.99 beds/1000 people). Role of community clinics is not well defined. Treatment can be availed from any healthcare facility of the choice of the patient. Clinics and hospitals compete for patients as there is little functional differentiation between them. Gate-keeping mechanisms are weak. (Ikegami.1992)

2. Coordination between medical care and long-term care is an issue in Japanese healthcare. The average length of stay in the hospitals is 31.2 days and in clinics the average stay is 17.5 days, while it is 8 days average in OECD countries. (SSJ 2014). Hospitals have taken the role of nursing homes. 45% of in-patients over the age of 65 have been hospitalized for more than six months (Ikegami.1992). GDP spending on healthcare in Japan (2008) is 8.5 %.

3. All providers are paid exactly the same amount, regardless of the physician's expertise or facility's characteristics or geographical location. (Ikegmai.1992)

4. Income of the employed is well disclosed, but that of the self-employed is difficult to find out. Hence the burden of copayment is not easy to be evaluated. (Ikegami.1992)

7. COUNTRY : UNITED KINGDOM

Healthcare in the United Kingdom:

The emergence of the welfare state in the United Kingdom played an important role in its economic reconstruction after the Second World War. The Keynesian model of welfare state aimed at state intervention not only in economy but also in social services particularly health care and education (Doyal and Pennell 1979). The Beveridge Committee Report of 1942 called for comprehensive healthcare as a part of post-war government master plan for promoting education, housing, employment and social security. The Beveridge Report planned for a taxed based National Health Service (NHS) as a public good that provided access to healthcare as individual rights and which was freely available to all. This led to the establishment of NHS in July 1948 that provides universal, comprehensive health care to all its citizens free of cost at the point of use (Leys 2001). Except for some prescription charges, optical and dental services NHS largely provides free of charge medical care to it population. Thus, NHS was based on the core principles of providing good healthcare to all regardless of the ability of pay and these principles have guided the growth and development for the past 70 years.

NHS is largely public funded based on general taxation. In the early 1970s, the provision of health services by the state was severely hampered with the world-wide economic recession. These resulted in the increased debates around cost cutting particularly reducing the expenditures on social services such as health (Crinson 2009). In the 1980s private markets in the NHS changed rapidly because of the policies adopted by conservative government. These changes created conducive conditions for the growth of the private sector in NHS.

The internal market reforms introduced by the policies of Margaret Thatcher in the 1990s transformed the NHS from a public service to a public system of purchasers and providers (Light 2003).

Over the years, NHS has continued to dominate the British health care systems. 83% of all the UKs health spending is on NHS.

Structure of Health Sector in UK:

The Secretary of State for Health heads the Department of Health. The Department for Health sets policies as well as provide leadership, funding and advice for public health. Under the NHS, a hierarchy of regional and district health authorities acts as agents for the Department of Health. For administrative purpose there are Health Authorities based on geographical locations that are in-charge for operation and management of the hospitals and other health facilities.

The NHS comprises of two different sections focussing on Primary and Secondary Care. Primary care is the first point of contact for patients to access medical care provided by the NHS. The provision of primary care is the responsibility of the Primary Care Trusts (PCTs). PCTs also have to ensure that health care services are provided within a local area. Working in alliance with the local authorities, PCTs also play an important role in commissioning of secondary care as well as providing community care services. It is the responsibility of the PCTs to manage the services of the General Practitioners and Dentists under the NHS. Around 80% of the NHS budget is controlled by the PCTs (Tritter; Koivusalo; Ollila and Dorfman 2010).

Secondary care also known as acute health care includes both elective and emergency care services. Ambulance trusts provides emergency access to patients in case of any acute healthcare. In 2002 saw the establishment of Strategic Health Authorities that were responsible for performance, managing and improving the health services in local area(ibid: 96).

One of the major organisational changes in the NHS was introduced in 1991 when reforms were initiated to create internal markets. These reforms were justified as necessary to make NHS more efficient and responsive to patients needs, reduce waiting time and offer choices to patients (Crinson 2009).

With these changes the Health Authorities became the purchaser of services known as "Trusts".

Clinical Commissioning Groups:

In April 2013, the Primary Care Trusts were replaced with Clinical Commissioning Groups. This led to the abolition of Strategic Health Authorities and the Primary Care Trusts. The statutory responsibility for commissioning of health services was taken over by the CCGs. The CCGs are clinically led statutory bodies that are responsible for planning and commissioning of healthcare services in the local area. General Practitioners, Clinicians, Nurses and Consultants are the members of the CCG. The Clinical Commissioning Group plays an important role in providing secondary care services as well as commissions the services of the General Practitioners. Some of the important secondary care services provided by CCG includes planned hospital care, rehabilitative care, urgent and emergency care, community health services and mental health services. In 2013, there were around 209 Commisioning groups. In simple terms it is purchasing of the services on behalf of the population from hospitals or clinics. The responsibility of the improving the health of the local population which ranges from 90000-100000 rests with the CCGs. CCGs are membership bodies and the GPs are its members. CCGs are independent and accountable to the Secretary of State for Health. If any service provider be it a NHS Hospital or private sector providers meet the NHS standards and costs, then it can be commissioned by the CCG. However, CCG has to be assured of the quality of services commissioned and that the providers take into consideration that guidelines issued by the NICE and the CQC. It is necessary for the CCG to involve patients and the public in the decisions they make about commissioning.

Health and Social Care Act, 2012:

The Health and Social Care Act 2012 became effective from 1st April 2013. This Act has made changes in the accountability and funding of the NHS. It is one of the most recent reforms introduced to restructure the NHS since its establishment in 1948. The major reforms introduced under this Act were outlined in a July 2010 paper titled ‘Equity and Excellence: Liberating the NHS’. One of the important objectives of this was to limit the role of the Central Government in the control of NHS and thereby emphasis on decentralisation of the NHS. This was mainly undertaken by involving doctors in the commissioning of health services. Another stated objective of these reforms was to provide greater choice to the patients.

Regulation in the NHS:

Since 1999, with an objective to improve the performance and management of NHS, government has created around five new national agencies for its regulation. This includes the National Institute for Clinical Excellence, Commission for Health Improvement, Modernisation Agency, National Patients Safety Agency and National Clinical Assessment Authority. Prior to this, there were different acts, schemes and organisations that performed the regulatory functions. These included the Mental Health Act Commisssion, Health Service Commissioner, Clinical Negligence Scheme for Trusts, National External Quality Assessment Scheme for Junior Medical Staff, Clinical Pathology Accreditation Scheme etc. These resulted in duplication and overlapping regulatory functions. The new agencies created did not focus on the regulation of the organisation as a whole instead; they dealt with single facets of the NHS such as the regulation of health and safety, medical education or the administration of mental health legislation (Walshe 2002). The regulatory bodies plays an important role in setting standards, monitoring organisations to ensure compliance with the standards as well as enforce consequences in case providers fails to meet the standards (Cylus, Richardson, Findley etal 2015).

There are two main types of regulation in the health sector of UK. The first is for governing the behavior of organizations and second for individuals in the health care system. The legislative framework within which NHS operates as well as the regular guidelines issued by Department of Health, governs the organisations working within the health system of UK. While General Medical Council, the Nursing and Midwifery Council and the Health Professions Council regulates the individual professionals within the health system (Maybin and Harrison 2008). The Care Quality Commission, Monitor and NICE are the main bodies that focus on ensuring and promoting the quality and safety of health services under the NHS (ibid). These come under the department of health, but their relationship is typically described as ownership but at arm's length.

The first white paper of the Government on Health in 1997 emphasized on the need for the system of regulation for quality and safety. Till the late 1990s there was no national policy that addressed the question of quality and safety in NHS. Improvements in the NHS were envisioned by setting targets such as those for waiting time as well as by introducing

Performance Assessment Framework that focused on improving quality and efficiency in delivery of services (ibid). The following section briefly discusses the different organisations involved in the regulation of NHS.

Care Quality Commission:

CQC was established in March 2009 by merging together three different organisations. This included the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. Monitoring, inspecting and regulating the quality and safety of health and social care services is the responsibility of Care Quality Commission. CQC makes sure that patients receive quality care from hospitals, dentists, ambulance and care homes (Doheny S, 2014). It also ensures that health and social care services provide people with safe, effective, responsive, compassionate, high-quality care. CQC is an independent health regulator of health and adult social care in England. The Care Quality Commission registers, monitors, inspects and regulates health services in England to ensure that they meet the core standards on safety and quality. This includes services under NHS and all other private services in England. The findings and performances rating Its findings are published, including performance ratings are published in the public domain. The Care Quality Commission sets the minimum standards of care. "If services fall below the minimum standards, the Care Quality Commission has the power to define what providers need to do to improve the quality of care or, if necessary, can limit a provider's activities until the necessary changes have been made. Its regulatory powers include issuing cautions and fines, and where patients have been harmed or put at risk, they can also prosecute."

It ensures that all the new care services must duly complete the registration process as well as inspects and monitors different data sources which will give an indication of the problems with the services provided (Care Quality Commission, 2012).

Charges of neglect and mismanagement at a Mid Staffordshire NHS Foundation Trust led to a high-profile inquiry which report was published in 2013. The main conclusions of what is known as the Francis Report were that the health care system required more effective regulation and a culture of care. One key outcomes was the inclusion of ratings for specific

services in the Care Quality Commission's reports. The Commission has developed five quality domains – safety, effectiveness, caring, responsiveness and well led for this purpose.

National Institute for Health and Care Excellence (NICE):

NICE was established in April 1999 as an independent organisation responsible for providing advice and guidance on clinical standards, promotion of good health and prevention of ill health. The proposal for NICE was one of the several new NHS institutions announced in the White Paper tilted: The New NHS: Modern, Dependable. NICE was envisaged as an important vehicle for influencing the practice of clinicians in line with research evidence (Hann, 2007). One of the major roles of the NICE is to undertake 20-30 evidence based appraisals every year of the new or existing clinical interventions. NICE have developed guidelines for different clinical procedures for Clinical Commisioning Groups and local authorities.

Monitor:

Monitor is the economic regulator in the health sector in UK. It was established under the provision of Health and Social Care Act, 2003. Monitor was transformed as a sector regulator for health under the Health and Social Care Act of 2013. The main function of Monitor is to set and enforce the regulatory framework for providers and commissioners as well as licensing NHS providers. Monitor is a non-departmental body that is accountable to the parliament (Cylus, Richardson, Findley etal 2015). One of the major duties of Monitor is to promote and safeguard the patient's interest in the NHS. (Doheny. S 2014) It ensures that if a provider runs into serious problems, essential services are maintained for patients. By 2013, Monitor is also the economic sector regulator for all providers both private and not-for-profit groups that provide NHS funded care (Cylus, Richardson, Findley etal 2015). Monitor works with the Care Quality Commission, NHS England and other bodies to make sure that the procurement, choice and competition elements of provision work in the best interests of patients. Monitor is one of the agencies involved in setting prices.

Since 1st April 2017, Monitor is a part of NHS Improvement. One of the major responsibility of NHS Improvement is to supervise the work of Foundation Trusts, NHS Trusts and Independent Providers that provide care under the NHS. Monitor assists in preparing

hospital trusts to transition into becoming foundation trusts. Foundation trusts must meet the licensing rules set by Monitor, which include how they are governed, what services they provide, the amount of money that the trust is permitted to borrow from private sources, and the number of assets the trust is allowed to sell. Monitor works with the Competition and Markets Authority (CMA) to make sure foundation trust mergers and acquisitions are not anti-competitive, in keeping with the regulations passed following the Health and Social Care Act 2012, although this means Monitor is responsible for both mergers and competition.

The NHS Trust Development Authority (TDA) was established in 2012 in order to assist trusts in reaching foundation trust status. If a trust will not be able to meet Monitor's standards for foundation trusts, the Trust Development Authority will help the trust find a different organizational form. The Trust Development Authority ensures safe, quality services from trusts by overseeing planning, clinical quality, performance and finance.

Regulation of Health Human Resources:

The regulation of healthcare professionals is guided by professionally led statutory bodies. Protecting and promoting the safety of the public by setting standards of behaviour, education and ethics is the main responsibility of these regulators. The regulators maintain a register of individuals who have qualified the standards of training. It is the responsibility of the regulators to establish standards of practice as well as codes of conduct. They are authorise to take actions against the health professionals who are not fit to practices and do not fulfil the minimum standards necessary for providing care. Some of the key regulators for health human resources are:

1) General Medical Council established as early 1858 that regulates the doctors.
2) Nursing and Midwifery Council that regulates nurses and midwives and health visitors
3) General Dental Council, General Optical Council and Health Professional Council.

In addition to all the above there is an NHS Outcomes Framework that provides an overview of how well the NHS is performing, to hold NHS England accountable for its use of public funds, and promotes increased quality throughout the NHS by encouraging a culture

change. The five domains of the Outcomes Framework, which were enshrined in the Health and Social Care Act 2012, are:

- to prevent people from dying prematurely;
- to enhance quality of life for people with long-term conditions;
- to help people recover from episodes of ill health or following injury;
- to ensure that people have a positive experience of care;
- and to treat and care for people in a safe environment and protect them from avoidable harm.

Indicators are purposely not changed too much from year to year, to ensure continuity. They may change when outcomes become more reliably measurable.

Scotland, Wales and Northern Ireland:

The above description applies largely to England. The other nations within UK similar features with some important differences. Scotland regulation is based on Healthcare Improvement Scotland (HIS), formed in 2011, which oversees quality of care delivered by both the NHS and the independent sector. Healthcare Improvement Scotland does not have enforcement powers against NHS boards, although it does have such powers against independent health care providers. NHS boards are expected to adhere to a set of Scotland specific guidelines issued by a Scottish guideline network. Healthcare Improvement Scotland includes several sub-groups that work on specific projects, such as the Healthcare Environment Inspectorate and the Scottish Health Technologies Group. Healthcare Improvement Scotland works according to the Healthcare Quality Strategy (2010) The Audit Scotland also has a role to play. The NHS boards in Scotland report to the minister.

Wales is similar to Scotland. Healthcare Inspectorate Wales (HIW), like its counterpart in Scotland, monitors NHS and private health care organizations, in order to ensure safety and quality. HIW focuses on improving patient experience and strengthening the voice of the public in reviewing health services.

In Northern Ireland, the Regulation and Quality Improvement Authority (RQIA) monitors the availability and quality of health and social care services to ensure that services meet

standards and are easy to access. RQIA was established by a law that created a statutory duty of quality for health and social care organizations, and required setting quality standards.

In all three territories however, NICE and the professional councils have their mandate as such- and there is no alternative proposed. In regulation alone there is an alternative since the move to commission and purchase care as different to only NHS board organizations providing care, is not on their agenda. Northern Ireland has trusts, but unlike England does not have a policy of promoting competition between them.

8. COUNTRY : FRANCE

Health and Healthcare in France:

The French Republic consists of mainland France and a collection of overseas islands and territories on other continents. France is the second populous country in the European union after Germany and 5th largest economy in the world too. French population is about 63.7 million inhabitants in metropolitan France and 2.1 million inhabitants in other territories.

Health status of France with a life expectancy of 82 is acknowledged as much healthier even in comparison with other European states and industrialized nations. Health inequalities across socioeconomic and geographical groups are higher in France when compared to other European countries. This is mainly due to disparities on access to health services. The main preventable risk factors are Smoking, harmful consumption of alcohol and road accidents which together are the largest causes of avoidable deaths in France.

The French health system has developed into a mix of Beveridge and Bismarckian model. Different Social Health Insurance Schemes covers the resident population. Providers of Out Patient Care are largely private and hospital beds are largely in government or not for profit sector. Besides health and social sectors there is a health and social care sector known as 'third' sector which caters to the needs of elderly and differentially abled population.

Government expenditure has been increasing because and Statutory Health Insurance's deficit is high.

Organization and governance:

Policy formulation and regulation powers of the health care system are divided between the state's bicameral parliament and the executive, the social health insurance scheme at national levels and local authorities at the regional level.

Laws and regulations are divided into 60 different codes in France. The codes that are directly related to health care are the social security code, the mutual societies code, the public health code and the social action and families code. The health care also falls under labor code and the commercial insurance code indirectly. Social Health Insurance schemes are su-

pervised Directorate of Social Security. The Directorate of Social Security proposes an annual Social Security Financing Act, which is then approved by the parliament. This Act establishes the basis of the provisional health care budget. Policy of decentralization of power started in 1990s resulted in fragmentation of planning especially in healthcare. To overcome this Hospital, Patients, Health and Territories (HPST) Act passed in 2009 merged most of the institutions into a single regional health agency (ARS). ARS's functional areas are very broad inclusive of healthcare, public health and the social sector. ARS aims to meet the health needs of entire population within domestic health expenditure.

Application of the health laws in the French overseas territories varies. For example, French Polynesia and New Caledonia are autonomous with respect to health matters, while Saint Pierre and Miquelon and Wallis and Futuna rely on the French national health authorities.

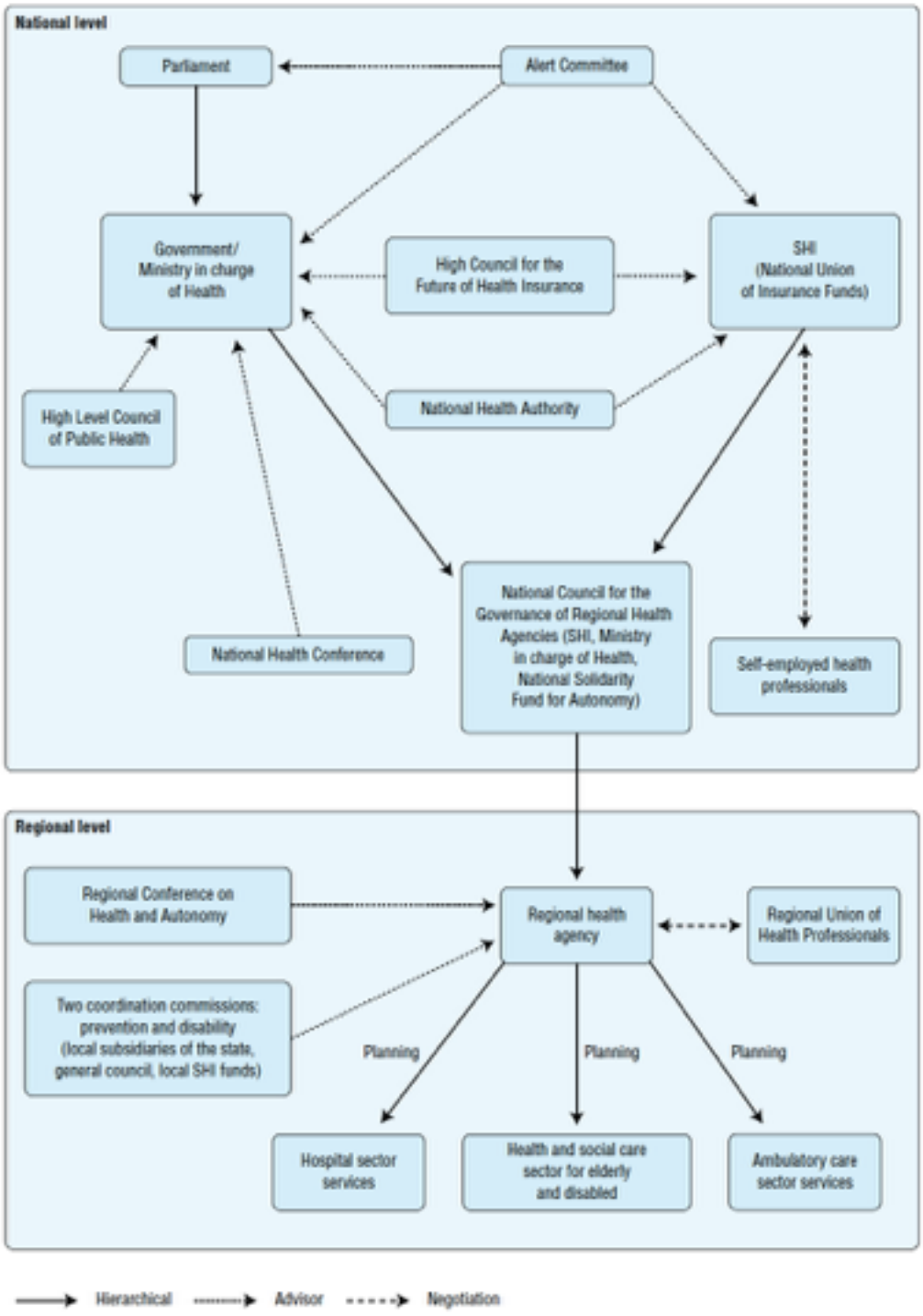
France has signed several treaties with direct or indirect impact on health, including the General Agreement on Tariffs and Trade and the European Convention on Human Rights.

The Social Health Insurance:

SHI started with the 1930 Act on Social Insurance, which paved the way for compulsory insurance to workers who are below a certain level of income. Illness, maternity, disability, old age and death were covered under this act and by 1939, two-thirds of the French population was covered for illness by mutual benefit associations, with free choice of the organization providing coverage. After second world war SHI was created within the social security system and earlier associations disappeared or changed into VHI. Beveridge report influenced most of the founders of the SHI to ensure uniform rights to all but certain social groups opposed it because earlier one was more favorable to them. The shift from an employment-based system towards the Universal Healthcare System was nearly achieved with the 1999 Universal Health Coverage Act which instituted a residency-based right to SHI coverage and created the Universal Health Care Fund to provide free public coverage for individuals whose incomes fall below a certain level. Residents above this threshold who are not entitled to SHI on an occupation basis must pay a share of their income to be covered on a voluntary basis by SHI. From 1990s the financing became more tax based rather than SHI contribution.

Fig. 2.1

Overview of the health system in France, 2014



SHI schemes are under the supervision of the Directorate of Social Security. SHI schemes sign a three-year contract with Health Ministry on the objectives, the management and the governance of SHI. It includes measures to improve efficiency in the management of SHI, reduce inequities in access to health care services and develop risk management. National Union of Health Insurance Funds represents the SHI funds in negotiations with the state and health care providers. Collective agreements with doctors and other organizations of professionals in private practice are negotiated and signed by the director-general of SHI alone, illustrating the withdrawal of employee and employer unions from the management of SHI. SHI is, therefore, fully responsible for the economic consequences of the agreements that it negotiates and signs. SHI can also set the level of user charges, although this power is limited to a certain extent by the political acceptability of the proposals. In order to qualify for SHI coverage, a drug must be included in the so-called "positive list" of reimbursable drugs established by ministerial decree on the advice of the HAS Transparency Commission and the CEPS pricing committee.

Voluntary Health Insurance:

Three types of VHI providers are in France. Mutual Insurance companies are regulated by mutual insurance code, commercial insurance companies by commercial insurance code and provident fund institutions by social security code. All VHI are supervised by Prudential Control and Resolution Authority. VHI influences governance through National Union for Health Insurance Funds, through negotiations for benefit packages, medical devices prices etc.

Regulation in the Health Sector:

France wants universalism in provision of health care using its health system which is a complex mix of social health insurance, tax and private financing with a significant role for private delivery in ambulatory care. French politicians have defended their health system as an ideal synthesis of solidarity and liberalism in which financing is done by SHI,VHI and payroll taxes and provisioning is a complex public private mix but with dominant private independent physicians. Cannot define boundaries of 'private' and may in fact be better characterized as quasi-public with overlay of extensive regulations.

Regulations are made mainly to provide universal health care and contain health care costs within SHI and its budget limits. Regulation are also meant to address issues of accessibility in rural and difficult terrains of the country.

Purchasing as Regulation: Since the major part of private hospitals need to be contracted into the purchasing of care by the government, there is a greater ability of the government to ensure that norms are followed – which include norms related to investment, quality, and ethics. Licensing is required to start a new hospital- but after than contracting and quality accreditation become the main form of regulation.

Quality Accreditation of Hospitals as Regulation French National Health Authority(HAS) ensures standards of competence through a certification process in every four years. Certification is a two-step process, at first hospitals do a self-appraisal then HAS visit the hospital to conduct certification review. Hospital quality assurance and risk management are monitored by the Ministry in charge of Health through Scope Santé. Hospital quality indicators are also compiled through the Coordination for the Measurement of Hospital Performance and Improvement in Quality of Care. Incentives methods to boost quality of care was started in 2012 on an experimental basis.

Quality assurance also applies to public hospitals, which are struggling to fulfil it due to resource constraints.

Regulation of Human Resources: The number of doctors, and to some extent their areas of specialization, is regulated by the numerus clausus, which is set by the government annually and controls access to the second year of study in medical schools. By this government regulates the total number of physicians and other health professionals and their distribution across the country. This numerus clausus is then applied at the regional level, taking into account current inequalities in the geographic distribution of doctors. Registration by their professional association is mandatory for practicing doctors, pharmacists, dentists, midwives, physiotherapists and nurses. It is usually granted upon request after the initial training and recertification is not needed after it. Moreover, registration in the national information system on health professionals (ADELI) in the ARSs is also mandatory for almost all health professionals.

Professionals Regulation: Professionals practice under the regulations of Public Health Code. Two third of the practicing health professionals are independent and self-employed providers. They have the freedom to practice wherever they wish. The National Union of Health Professionals negotiate with payers at the national level. At regional level, regional unions negotiate with the ARSs. Professionals have to undergo Continuing professional development (DPC) to ensure lifelong quality but no re-certification or renewal of licenses needed. Within the DPC process, accreditation exists for a limited number of high-risk medical specialties. The accreditation process includes a registry of adverse events, use of practice guidelines and review criteria and participation in educational sessions in risk reduction.

Regulation in Pharmaceuticals: As said earlier, Pharmaceuticals has to be in the "positive list" so as to be included in the beneficiary b package of SHI. All drugs have to get the market authorization either at European or national level before coming to market. Price is negotiated by CEPS an inter- ministerial committee under the social security code. The price must be set according to the ASMR i.e. added benefit of the drugs compared to the existing ones , the price of other drugs with same therapeutic indications and the estimated volume of sales. Pharmacies have the monopoly in dispensing the medicines but SHI,VHI also can open retail shops. Medicine sales are is highly regulated in terms of advertisements, prescription drugs, sale over internet etc. Financial incentives are there for generic prescriptions. All these are regulated by 'numerous clausus' too. Medical devices are also regulated by similar way but much less than the drugs.

Patient Rights: The principles of health democracy were instituted by the 2002 Act on Patients' Rights and Quality of Care, which included representation of users; the right of patients to directly access their full medical records; and principles of professional liability and compensation for victims of medical malpractice. The public health code states that a patient's right to choose a health professional and hospital is a fundamental principle of France's health law. Implementation of a gatekeeping function has not significantly limited that right, as patients may designate the treating physician of their choice and, once a specialist referral is made, may visit any professional in that specialty even if it is not the specialist identified by the gatekeeper. The 2002 Patients' Rights and Quality of Care Act enumerated

the general rules for patient complaint and compensation procedures, which differ depending on the setting in which care is delivered.

Challenges:

Decentralization provides opportunities in regional planning but curtails larger level planning and policy implementation. It also hinders the efforts to reduce geographical disparities in service provision.

With the implementation of Quality assurance and accreditation process the public sector hospitals had to take loans and their deficits are increasing because they can't charge as private hospitals and provide much of the care.

The physicians are mostly paid through fee for services and private specialists get much higher fee than in the SHI. Regulation of fee for service for doctor visits is challenge with the stiff resistance from various stakeholders. Introducing Gatekeepers to reduce specialist visits are being carried out but found to be very challenging in its implementation.

Complementary insurance is not regulated in France, high percentage of complementary insurance is provided by employers. There is a large disparity among its quality and benefit packages.

9. COUNTRY : AUSTRALIA

Healthcare In Australia:.

This is one of the leading examples of universal insurance coverage. Basic insurance is provided by the government for all through Medicare. But higher insurance need to be purchased. Medicare is the government insurance machinery. Everybody has to pay one percent of their tax to Medicare. The 30 percent population who buy private insurance also have to do it and they are also eligible for public services. Mental health services, Drug and alcohol services (de addiction) are covered by Medicare. Dental care is not provided by Medicare. So also the cosmetic services. Public facilities give free dental care to pregnant women. But all others have to rely on private sector for dental care and it is very expensive.

Australian healthcare has a mix of both public and private providers. About 60% of beds and inpatients are seen by the public sector hospital. The affluent prefer private healthcare and either use private medical insurance or pay out of pocket. There are government incentives to promote even private insurance in the form of tax breaks, and the largest private insurer is government owned. Everyone is linked to a GP to whom they have to go for consultation. The GP may suggest a few doctors from his list if specialist support is required.

In addition to medical services, mostly specialty services, complementary medicine practices are allowed in Australia. Acupuncture, Chiro and Naturopathy are in practice. Almost 80 percent of women use acupressure. License is required for acupuncture. Massage, Podiatry etc. are unregulated.

Regulation in the health sector:

Quality Accreditation and Licensing: The Australian Quality Accreditation system has a high credibility and is considered one of the best. The standards are set by a separate institution and measurement of achievement is taken on by another. The responsibility to act on it, and whether it would attract sanctions would go to the ministry itself. The information on quality scores , with details on issues like waiting time, and patient satisfaction are put up in the public domain.

The Australian Council on Healthcare Standards, which undertakes this function accredits hospitals for varying periods- full 4 years which is the maximum, or two years with correctives to be taken in a year, or conditional one year with improvements to be shown or refusal to accredit. But despite this there are concerns. The number who get full 4 years accreditation could vary widely even within consecutive years- and there are many other pressures at work. Public hospitals, especially in difficult areas, would have a different threshold on the measurement of standards and on sanctions.

The standards on the basis of which measurement is done, is set down by the Australian Medical Research Council. The decision to impose sanctions for non-achievement of standards is upto provincial governments.

Purchasing Care: One of the important avenues of regulation is that over 65% of all health care expenditure is by government and few private hospitals can opt out of it. The terms could be separate for public and private health sector and the rate of increase in costs is certainly less in the former. Different forms of co-payment are allowed, most of which could be covered by complementary private insurance. Even in government hospitals private insurance has a role, and those in special wards could be seen by a doctor of their choice as against as hospital assigned doctor. Private insurance would not however be covering some of the costlier procedures like liver transplants. Adherence to clinical guidelines is said to be better in the public sector. The public sector adhere better to standards, requirements, policy reforms etc, while in the private sector this is more difficult. The prices are unregulated in private sector.

Professional Regulation: Professional bodies regulate the practice of their members. The Medical Board, Nurses Board, Midwives Board, Dentists Board, Physiotherapist Board and such 12 different boards function under the one umbrella of AHPRA (Australian Health Practice Regulatory Authority). Foreign doctors who come to practice in Australia also must be approved by the board. The boards are also being influenced by the politics.

Medical and Nursing training is by the public sector. Very limited private medical schools are present. Doctors require registration and license from the Medical Board to practice. Government doctors can practice in private hospitals also as VMO (Voluntary Medical Offi-

cer). Hence many of the doctors practice in one government hospital and one or at the most two of the private hospitals.

14 months training is required for a nurse to become midwife. ANMC (Australian Nursing and Midwives Council) also has a role to play in this. The training process can be said to be supervised by three agencies: first the university has to offer the training, then ANMC has to approve it and registration from Nurses Board required for practice.

Pharmaceuticals : No advertisement of medicine, healthcare services and complementary food anything of health effect is allowed in Australia.

Information and Patient Rights:

Australia has laws that ensure patients rights to information over their records. These were so restrictive, that it was relaxed to include provisions for making it available for research and public health purposes. There are also mechanisms of grievance redressal in place.

10. COUNTRY : UNITED STATES

The US Health Care System:

The U.S. does not have a uniform health system, has no universal health care coverage, and only recently enacted mandatory health coverage through Affordable Care Act (ACA) which has since been repealed. There is however a strong government role in creating conditions favourable to robust healthcare industry which is seen as the solution for much of healthcare needs.

Private sector stakeholders play a stronger role in the US health-care system with the wider insurance system, pharmaceutical and medical devices industry, physicians with fee-for-services. Despite this, public sources of financing constitute 48% of health-care expenditures in the United States- which is much larger than most LMICs- but much less than in all other industrialized high income nations. Private third party payer sources- health insurance accounts for 40% of healthcare expenditure with the remaining 12% being paid by individuals out-of-pocket.

The majority of Americans (54%) receive their coverage from private health insurance, with most privately insured individuals obtaining coverage through an employer. Most health care, even if publicly financed, is delivered privately. In 2014, 89.6 percent of the U.S. population had some type of health insurance, with 66 percent of workers covered by a private health insurance plan. Among the insured, 115.4 million people, 36.5 percent of the population, received coverage through the U.S. government in the form of Medicare (50.5 million), Medicaid (61.65 million), and/or Veterans Administration or other military care (14.14 million). People may be covered by more than one government plan. In 2014, nearly 32.9 million people in the U.S. had no health insurance. There is also a large category of close to about 39 million people who are considered under-insured. This refers to having some insurance coverage but inadequate to pay for their specific needs.

There are two dominant forms of private insurance in USA. Fee-for-service plans in which doctors are reimbursed for the services they give. Deductibles and co-payments are applicable according to various plans people chooses. Other form of Private insurance is Health Maintenance Organisations (HMOs) in which patients pay a fixed annual fee known

as Capitation fee. In these schemes persons can visit doctors only through HMOs. HMOs are now on decline and their position is taken over by the Preferred Provider Organisations (PPOs). Drug manufacturing in USA is entirely provided by the Private sector and no price control is imposed. As a result, drugs prices are twice as compared to other OECD countries.

Health Care Regulation in the United States :

In USA regulations cover third party payers, professional practice and human resources for health, service providers, capital investments in the health sector and patient privacy rights. There are also laws on pharmaceuticals, clinical research, public health, food safety, environmental pollution.

Regulation of Insurance/third party payers:

The McCarran-Feruguson Act affirms the power of states to regulate and tax insurance products of third party payers. The major regulation on insurance is ERISA enacted by Congress in 1974. It focuses on federal level and sets standards for private sector employee benefit plans by public or private which only apply to worker's compensation, disability and unemployment, grievance redressal and patient rights. ERISA allows pre-emption of state regulatory laws on employer insurance mandates, financial reserve requirements, premium taxes, and managed care standards which curbs states power to regulate third party payers. The reasoning for the same was to avoid multiplicity across the states so as to make uniform administration of employees insurance programs across the country. The COBRA Act of 1985 has made provisions for giving health protection some workers and families the right to continue their insurance coverage for a limited period of time after a job loss or some specific events. Subsequently pre-existing illness and mental illness were added on by other acts.

As per 2010 Affordable Care Act (Obamacare) health plans are required to offer and renew coverage to everyone and cannot charge more with persons having pre-existing conditions. This now stands repealed and if this is confirmed in the Senate some 23 million of those with coverage would effectively become uninsured once more. Clearly the focus on regulation in the USA is on private insurance – and there are strong pressures against much government intervention in this domain.

Regulation of Professional Practice:

- Professional Education**:** All physicians must be licensed to practice medicine in the USA., at a minimum: completing medical school, passing of licensing exams and completing at least 1 year of GME, and meeting ethical standards. The licensing exam consists of a three part exam: the first two parts of the exam are completed during medical school and the final portion is taken at the end of the first year of GME.
- Health care human resources are also get accredited by licensing boards in the state. State license boards sets educational credentials, renew licences and enforce basic standards through their power to suspend or revoke licenses to practise.
- Physicians are also regulated at the federal level by CMS imposing criteria for reimbursing providers especially in Medicare program.
- One important law to note is the STARK law which prohibits payment to physicians for referrals to services in which they or their family members have a financial interest.
- The Physician Payments Sunshine Act (PSSA) is a government initiative that requires all biomedical companies to publicly disclose payments to physicians through the Open Payments Program (OPP). The goal of this study was to use the OPP database and evaluate all non-research-related financial transactions between plastic surgeons and biomedical companies.
- Compliance with clinical guidelines with respect to standard clinical protocols have little regulatory effect. A non-profit Patient-centred Outcomes Research Institute (PCORI) studies the comparative effectiveness of medical treatments, including drugs. However, the ACA stipulates that the comparative effectiveness findings from this institute "may not be construed as mandates, guidelines, or recommendations for the payment, coverage, or treatment or used to deny coverage" (Kaiser Family Foundation, 2011a).
- No laws exist in the United States preventing drug companies from advertising prescription drugs to consumers directly, the FDA can prosecute manufacturers for advertising that is false or misleading. Drug promotions are widespread across TV channels- and usually end with a message asking the patient to ask his or her doctor to give them that option.

Purchasing as Regulation:

- In the context of the US, most regulation of physician behaviour is through the mechanisms of payment. Thus the emphasis is on payment through capitation, pre authorisation, gatekeeping and so on.
- The HMOs and PPOs also regulate physicians behaviour- but in line with their priorities. It was expected that the incentive environment for insurance business is such that it will regulate provider behvious adequately. Which it does with respect to excessive care, but not necessarily with respect to inadequate care, or care for which co-payments can be charged. Hospitals have their standard operating protocols and credentials committees and they conduct review board meetings to influence the functioning of physicians.

Hospitals:

Hospital regulation in US occurs via certification, the Non-Governmental Joint Commission, federal laws, and rules for reimbursement by the CMS.

The Joint commission is a non-governmental body that does voluntary accreditation programme for quality. It has 4000 hospitals as its members. Auditors of joint commission do re accreditations every three year for all hospitals.

Certification is needed in most states for establishing a hospital. The state or district authority has to issue a certificate of need. There are other legal compliances that has to be met.

Conditions of Participations (CoPs) and Conditions for Coverage (CfCs) under CMS regulate wide spectrum of all hospital activities and also applicable to nursing homes, psychiatric hospitals etc.

The Emergency Treatment and Active Labor Act (EMTALA) requires all hospitals to provide emergency care even without insurance. It is compulsory for all hospitals participating in medicare.

Regulation on Capital Investment:

In 1946 a Federal-level regulation on capital investment referred to as the Hill–Burton Act – and also in the National Health Planning Law of 1974.made a provision for funding

for infrastructure and support to develop hospitals where they are needed and there is a gap – but in return they had to provide uncompensated services for vulnerable sections in local community and later changed to participating in Medicare and Medicaid. There is a lot of comment that implementation of the act was weak- and fell far short of its expectations.

Regulation of patient privacy and access to information:

Regulations regarding the privacy of health information came through HIPAA Privacy and Security Rules passed by Congress in 1996. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. The security portion has administrative, physical and technical safeguards to ensure the confidentiality of patients' electronic information. It is enforced by Office of Civil Rights under HHS. The Patient Safety and Quality Improvement Act of 2005 (PSQIA) protects "identifiable information being used to analyze patient safety events and improve patient safety" (U.S. Department of Health and Human Services, 2011c).

Health Informatics:

The HITECH Act established the digitzation of information in law and provides the U.S. Department of Health and Human Services with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health IT, including electronic health records (EHRs) and private and secure electronic health information exchange. Institutions engaging in most HHS-supported human subject research must have an approved assurance of compliance with protective HHS regulations.

SECTION IV

CROSS - COUNTRY ANALYSIS

I. Meaning and Purpose of Regulation- In Contexts:

At first glance, regulation, that too of the private sector seems an obvious word with a singular meaning. On closer examination both at the level of academic prose and in the practice of nations it could mean very different things. According to Ensor and Weinzierl (2007), a traditional and narrow view of regulation is to see it primarily as a preserve of government, implementing control of the health system through legislation and bureaucratic methods. This view may still dominate public understanding of the word, but in practice it is passé.

A more modern definition of regulation would " the legitimate institutional frameworks that set permissible activities for participating stakeholders and involves informal constraints or practices that guide or encourage or restrict their activities" (Prakash 2015). This definition is more in line with how we have used the term in this text except that we have included both formal and informal constraints.

Regulation could thus refer to any "imposition of external constraints upon the behaviour of an organization or an individual." This implies that the organization to be regulated is capable of at least some degree of autonomous or independent decision-making (Morgen and Ensor 2016). Thus while the first and second definition seem very similar, on closer examination the latter definition makes it less required to have regulation on public organizations directly managed by the government subject to regulations- since the government administratively controls these viz has internal controls in place.

The central rationale of regulation in a capitalist economy and liberal theory is market failures. In competitive market situations when industries or enterprises fail to serve public goods, regulations become imperative for stability and assurance (Prakash 2015). The unique character of healthcare as both social and private good reinforces the importance of active government regulation in health sector (WHO 2014). Imperfections of the healthcare market justified the need for government's intervention in healthcare industry in most nations studied. In other public services one expects, that ''the magic of the market place" would ensure a proper allocation of resources and access to services. Prices would fall if demand is low and

products would appear that are more suited for those who can pay less. Prices would rise if demand is high and/or willingness to pay is high. Thus if there are too many private investment in hospitals in one urban area, some of them would fail and thus disciplined by the market, private investors would have to shift investment in hospitals to smaller towns and rural areas. Market theory does recognize that there would be some too poor to pay, but the government can purchase the care on their behalf through suitable contracts and modes of payment with private providers. However from as far back as 1963, and Kenneth Arrow's seminal paper in this regard, even this limited level of market function is not happening with respect to healthcare. Further this paper makes clear, that market failure is not only with respect to health as a public good, or a good with high degree of externalities. It is applicable even where health care behaves like the usual commodity in that it both excludable and rivalrous viz. even with curative healthcare.

The causes of market failure have been identified to lie in a) high degrees of information asymmetry between provider and patient b) high degrees of uncertainty on outcomes and even on process c) nature of professional practice and professional power and d) different and conflicting principal- agent relationships.

If market failures is the central rationale for regulation then the nature of regulation changes accordingly. The objectives of regulation would then be : Control market entry and distribution of hospitals (the quantity of care and access to care); Improve and maintain good quality services within hospitals (the quality of care) ; Improve efficiency in health service provision within private hospitals (the cost effectiveness of care, when purchased for the poor); and ensure health service provision within private hospitals is provided equitably (access to care, with non-discrimination, no exclusions and denials). In this understanding, what to regulate is to be determined by the market failures identified. (Morgen and Ensor, 2016; Ensor and Weinzierl,2007).

The private markets of the United States there is a slew of regulations that attempt to do this. Their focus is on addressing information asymmetry through putting in place patients right to information, addressing uncertainty in outcomes by making outcomes more public as well as accreditation process, addressing professional power by tight rules of entry and membership. The legal and enforcement route to equity however is a non-starter with laws like the

Hill Burton act remaining more on paper- but here through Medicaid and Medicare which are state managed purchasing mechanisms, there is some negotiations possible- for provision of emergency care for example.

In nations like Japan, France, Australia where public purchasing accounts for over 70% of all health care expenditure we see a different set of both ethical principles and objectives for regulation. Provisioning is private, but private providers contribution can vary anywhere from 30% to about 70% . In all of these nations there are extent and intensity of legislative and administrative regulation increases with shift to purchasing. Thus in Japan by law, no surplus from healthcare can be distributed as dividends, shares or profits. They necessarily have to be re-invested into health infrastructure. Though there is no restriction on foreign investment, the clause is so clearly restrictive that it becomes completely unattractive for private equity of any sort- but particularly foreign direct investments. Further there are number of clearances, including a certificate of need from local prefecture needed for setting up a hospital. Further minimum human resource standards are insisted upon- and prices are fixed centrally- the pace being set by the government owned national insurance scheme. We see such intensity of regulation in France and Australia also, though the proportion of public providers is higher here than in Japan (about 25% public providers in Japan, whereas about 60% are public providers in Australia). In France too the regulation framework is such, that many so called private institutions would be public in character. In Australia where there is a greater mix of public providers separate regulations apply to private sector. In other words- the aim of regulation in these settings is to remove the influence of prices, market and competition- and have much of the decisions on this pass to the state. The state through statutory bodies sets prices and defines market entry. In both France and Australia the state through statutory bodies which engage professional associations sets quality standards and enforces achievement of it. The focus of Japanese regulation is on regulating entry, prices and profits- and while quality is important and gaining ground, not the main focus of regulation.

However if the architecture of the health sector has a much larger mix of public providers, the notion of regulation changes. In Cuba for example where there is no significant markets in healthcare and no private providers all regulation is internal- a part of the organization of healthcare services. There is no purchasing of care. The discourse in such a context is of so-

cial accountability of providers and organizations. This is so even in Sri Lanka where hospitals are mostly in the public sector and there is little dependence on private health care making it possible to have strict regulation regimes.

In many LMIC nations which are good performers- defined as much further advanced on the road to UHC- like, Brazil, Thailand, Sri Lanka, public sector provisioning dominates. Some of these like Brazil have also got a robust private sector. In Sri Lanka the private sector is largely limited to ambulatory care where it has a close to 60% share whereas in in-patient care it is as low as 5%. In Thailand private sector would account for only about 20 to 30 % of all care. The trend in all such nations is to have one system of regulation for public sector and another for the private sector. In the private sector a clear differential exists between private sector which are empanelled and part of public purchasing and those who are not. Amongst those who are not there is a soft approach- built around quality accreditation – which begins by being voluntary, but insisted upon over time. Judicial processes also intervene.

Where there is a large private sector, not dependent on public purchasing, like in South Africa and in India, well intentioned laws are on paper, but implementation lags far behind. It is worth noting that most such nations equate regulation with licensing and there are strong sanctions against failure to qualify by centrally set standards. However these are usually contested and there is then a failure to implement. However despite vast differences in systems all nations are increasingly into promotion of quality accreditation systems- especially in the public sector.

Regulation seems to be an increasing concern only with a change in the role of the state from providing services to purchasing from private sector. An interesting case study is in United Kingdom where there is a differential and gradient between England, Northern Ireland, Wales and Scotland. England is pushing reforms to shift state role from providing services to purchasing services and also has mechanisms in place to ensure that private providers have an equal chance to participate in securing contracts. But as a consequence it has a strong and intrusive regulatory regime with powers for a central quality commission to issue sanctions and de-license if quality standards and protocols are not maintained. There is

in addition a large organization to just define standards- the National Institute of Healthcare and Clinical Excellence (NIHCE) , and an empowered body called "Monitor" to supervise the purchasing and contracting process itself. Its explicit purpose is to ensure adequate competition in the purchasing, and fairness, since it is far too easy to win the bid for providing services by compromising quality or denying services. Scotland, which finds little merits in purchasing is the other pole. It has only a recommendatory body on quality standards- which it adopts from the central standards with supervision by the ministry. But its emphasis is on different forms of vertical and horizontal accountability. Northern Ireland has agreed to putting trusts in place for purchasing but decreed them to be not for profit and is not designing them to encourage competition in providers, but only ensure quality. Wales lies between Northern Ireland and Scotland.

Thus while common sense and popular discourse seems to propose strategic purchasing as an alternative to regulation, we find that intensity and scope of regulation intensifying with shift of government role to purchasing. And this shift is more extreme in that regulatory regimes get even more intrusive and rigorous once strategic purchasing is defined as ensuring fair competition amongst providers to win contracts from the state purchaser. This is the view in published literature as well. (Doherty 2015). On the other hand where public providers dominate, the focus of regulation is as an accountability mechanism for the public hospital, and to ensure that the supplemental purchase from the private sector is a fair deal which the private sector cannot game or cheat on.

II. The Scope of Regulation:

Across nations, the scope of regulation include the following:

a) Professional – Certification and Licensing : Entry into the profession, Periodic certification of skills; Professional practices and ethics, Actions against malpractice and negligence

b) Market Regulation- Entry- Licensing as permission and Conditions to set up a practice and stay in practice; Regulation of prices, Public purchasing; Pro-competition or anti-competition measures:

c) Quality of Care: As Accreditation and as Licensing

d) Access to Information- both as patient rights-; and with respect to digitization

e) Medicines and Devices- access and quality (not discussed in the report)

f) Public Health Laws- laws that are primitive of positive health or health related practices.(This is not discussed in this paper)

Professional Entry & Professional Practices:

Healthcare regulations aim to shape behavior of the providers to produce services as per patient criteria (Prakash 2015). They do this in a number of ways.

One way- the traditional is professional regulation. Professional regulation everywhere is concerned with professional standards and entry into the profession. It has a role in ensuring ethics and preventing malpraxis, but this is weak.

The other, increasing way of regulation is a licensing examination conducted by government, with requirement for re-accreditation every few years. Where the latter is in place, it is usually acquiring a set of credits through continuing education processes- except in some high skills areas in some nations where they have to demonstrate that they have been in practices and successfully executed a number of procedures in the interim.

France seems a best practice in this area. Professionals in this nation, have to undergo Continuing professional development (DPC) lifelong but no re-certification or renewal of licenses needed. Within the DPC process, accreditation exists for a limited number of high-risk medical specialties. The accreditation process includes a registry of adverse events, use of practice guidelines and review criteria and participation in educational sessions in risk reduction.

In most nations where there is a robust system in place for regulating professionals the process is such that it is not done without involvement of professionals- but it is not internal to their councils alone. In UK alone is it completely left to professional councils.

In many nations professional councils also set up a professional enclosure. There are laws which specify who can be certified and by which institutions and illegalize other providers. The experience with regulating non allopathic health care providers is varied, but in general there is considerable latitude.

Market Regulation:

This is with reference to nations where purchasing care is a major or dominant aspect of the healthcare system. There are many forms this takes:

a) Permission required to set up practices : This happens only in intensively regulated environments often with strong purchasing arrangement. Most often local bodies are involved in giving the certification. Though by nature this is an anti-competitive measure, the understanding is that even if they qualify for entry, too many providers in a given area would make all of them unviable. A certificate of need has to be provided to establish a clinical establishment.

b) Market Entry Regulations: Qualifications and rules specify the nature of players. Many developed nations, Japan for instance, have statutes that ensure that only not for profit agencies can participate. Most nations have rules that specify conditions for being contracted with public purchasers of care. Where the private sector is not dependent on government of employer purchase such regulation is effective. But where it is only a small part of the health markets, private players exit when it suits them

c) Price regulation. Where public financing pays for the greater part of total health expenditure some form of price regulation is de facto or de jure in place. Most often there are for a, and sometimes laws that specify how these prices are set and revised. Where out of pocket expenditure dominates regulation of prices is most required but almost impossible to create. Iran is an interesting exception with the prices being specified by the Iranian Medical Council.

d) Managing Competition- 1: Most nations build mechanisms to ensure that purchasers are not for profit agencies but that such agencies purchase care from providers on terms where competition is encouraged. Usually this takes the form of not for profit statutory agencies set up by the government for undertaking purchasing. This is one meaning of strategic purchase- where the efforts is to make markets work to provide higher quality of care. This was based on the understanding that competition would reward those providers since they would attract more patients and that they would be charging less. Legislating or administratively guaranteeing patient choice is one important element of such an eco-

system. This is an important element in England and France, and to some extent in USA- where Medicare or Medicaid is doing the purchasing. There is no evidence yet that this is working. (Firth, 2016).

e) Managing Competition- 2: In another meaning of strategic purchasing there is a view to use purchasing and prices to encourage growth of private services in certain geographic areas and for certain diseases and procedures. This approach to strategic purchasing is also meant to help align private providers with public health priorities. There have been efforts in this direction (like the Hall- Burton Act of the US) but it is not clear that it is working except in nations where public provisioning dominates. In Australia and Japan, in the other territories of the UK and in Thailand, Brazil etc there are many elements of this.

f) Managing Competition – 3: One important aspect of regulation where private markets dominate like in the USA is the banning of practices which interfere with fair competition. The most important is to prevent kickbacks on referrals and prescriptions for drugs and diagnostics. The USA law prevents prescription or referrals that favour a company where any family member has an interest. Most industrialized nations have some elements of such kick back statutes but along with further restrictions on pharamecutical promotion.

g) Managing Competition – 4 : All nations provide for choice of providers for patients. But this is on personal preferences, or due to migration. Thailand limits it to four times per year- but registration is with the neighborhood clinic and change is only in context of migration. In UK such patient choice is projected as essential to competition, but there are no instances of contracts lost due to inadequate enrolment by beneficiaries. Instead, drawing upon institutional economics, purchasing is decentralized to Clinical Commissioning Units at the county level where patients are represented as state-holders. In United States, where purchasers are largely private, affordability is the major issue in joining any health plan. Medicare and Medicaid is meant to act as a state purchaser to pay for those who cannot afford insurance, but close to 30 million people do not have any insurance cover whatsoever and another 36 million people are under-insured since they do not quality for medicare and are unable or unwilling to pay for their own insurance.

Quality of Care:

Almost all nations are giving increasing importance to quality of care- but there is a gradient in how far quality is a voluntary process of opting for accreditation, and to how far it is mandatory and a necessary criteria for being allowed to function.

In USA and Japan it is mostly voluntary. In Japan, quality assurance body is not only voluntary in nature and every health facility has to follow minimum standards mandated by the prefectures and be monitored by the same. So also in Indonesia and India. In Thailand and Brazil it is a necessary condition for empanelment- but in the un-contracted private sector it is voluntary. In contexts where public purchasing dominates health expenditure and there are both public and private providers, insistence on quality across public or private facilities is the rule.

Nations that do not encourage competition and market forces through strategic purchasing tend to have separate standards for private and public. Weak public healthcare may be considered as an incentive for weak and poor quality private healthcare. Maureen Mackintosh and colleagues argue that a good quality and accessible public sector system will lead to a private health system with similarly desirable characteristics. But this is not achieved through legal or purchasing measures. (Lancet editorial June 26, 2006).

A recently published comparison between Australia and Indonesia in setting up quality accreditation systems and its uses as regulation or licensing systems (Judith Healy, 2016) points to 6 states in the development if this relationship. In the basic stage it is only voluntary or self- regulation. This stage is marked by the onset of professional engagement in quality improvement programs. At the next level, there is a focus on public information with the advantage it provides in that an informed public could potentially choose accredited facilities. In the third level there is professional self- regulation where external accrediting agencies assess and accredit facilities. At the fourth level, the financial incentive kicks in with insurance agencies making payments only to accredited facilities or providing a higher rate of reimbursement if they are quality improved. At the fifth level, meta-regulation independent agency sets standards and oversees accreditation. And finally at the apex we have an Aus-

tralia like situation where Government sanctions non-performers and government mandates regulation for permission to operate (Healy and Dugdale, 2009).

There is two important learnings from this framework.

Firstly we can now perceive every nation as on a path to universal quality assurance, but at different stages of progress on that road. In all LMICs examined, even those very far from universal health coverage, some elements of quality accreditation as a voluntary process and some engagement with quality in purchasing of care has emerged. Secondly it is desirable that not only each nation, but each stakeholder and each region within a nation experience these different stages without jumping prematurely to the last stage. Or trying to do so. At any given time, in a nation like India, there would be different states at different levels of understanding and different degrees of subjective and objective readiness and state capacity to undertake this. But on the positive side, at all times, there is always something we can do about it.

Information Asymmetry and Public Information:

The USA has the most well developed laws in the right to information of patients, along with laws that assure privacy and confidentiality. The USA has also a well-developed scheme for digitization of the health sector including incentives for providers to switch over to interoperable electronic health records. This is in line with the ideological understanding that as information asymmetry is the problem a better access to information would help. The Japanese, French, Australia and UK also have legal provisions for safeguarding privacy and ensuring access to information for the patient.

Most of the developed nations also have similar measures in this area, though not necessarily with the same scope and effectiveness. The situation in LMICs examined however is weak. We need to examine the details in nations like Brazil further. Indonesia reports indicate adequate laws in this area, but this too needs to be examined.

Greivance Redressal Systems: One area of intervention relates to enforcement of patient rights. Some nations have far more robust grievance redressal systems than others. The most innovative is the Thailand no fault system which has support in law. When there is a failure to provide care or negligence, then without establishing who is at fault and the punishments that

necessarily follow that route, a compensation is paid. There is a budget ear-marked for payment of compensation and every year a sum- about 1% of the budget is paid out in this form. But the government has provided direct line and contact number for all patients to seek assistance if they have grievances.

Iran also has a grievance redressal system in place which patients can approach and if that fails they are free to approach the medical council if they have complaints of unethical practices and to the court in case of negligence.In most nations however the effective venues of redressing grievances especially on negligence and malpraxis is the courts.

Medicines and Devices-

Access and quality:

All nations necessarily have extensive regulations with respect to the manufacture, procurement, prescription and quality assurance of pharmaceuticals and medical devices. In medical devices whereas industrialized nations have relatively better systems, most LMICs have still relatively weak systems- except to some extent in Brazil. All of them have drug regulatory authorities and most have authorities for clinical research in place- but the degree of autonomy and effectiveness they have were not the focus of this study.

III. The Institutions of Regulation:

Across nations there are at least three sets of governance institutions. One that deals with the administration of health care services, another which deals with purchasing services- usually in the form of a national insurance agency. And a third set of institutions, the professional councils which govern the professions.

Professional Councils:

Professional councils of doctors in all countries have different committees for ensuring scientific and ethical practices. Thiers is the responsibility to prevent and to investigate negligence and unethical practice. However in most countries either these are less than effective or have required judicial intervention for action. . Most countries report their boards are as being ‘’influenced by the politics”.

In most nations these councils enjoy various degrees of autonomy, but across nations the degree of autonomy is in the decline, and state intervention is on the increase- even in the British Council which was the prototype for all professional councils and easily the most effective in regulation.

In Australia the many autonomous professional specific boards come under one common board. There is a Medical Board, Nurses Board, Midwives Board, Dentists Board, Physiotherapist Board and such 12 different boards function under the one umbrella of AHPRA (Australian Health Practice Regulatory Authority). Foreign doctors who come to practice in any country also must be approved by the board or board defined procedures.

The emerging regulation regime for professionals seem to be that councils would certainly have professionals playing an important part, but it would not be exclusively a professional domain, and in both its structure and function, governments would have a larger say.

***Quality Accreditation and Facility Licensing*:**

When it comes to institutions to regulate clinical establishments- this varies- and almost no two nations have the same set up. Licensing is usually a compulsory process that requires universal adherence to minimum standards as a condition of practice. Accreditation is defined as a voluntary process.

Some nations have 'evolved' to the level where quality standards are the basis of licensing. In such nations – there are two or three institutions: one to set the standards, another to measure and monitor compliance with the standards, and a third that can recommend action on them and so on. Compliance and enforcement are better in such contexts. There is also far less chances of regulatory capture (i.e where the regulatory mechanisms become subservient to interests of powerful interest groups). The balance between quality, access and equity can be maintained. This also means that while quality standards are the same, the state commitment to helping facilities to achieve these standards and sanctions against non-achievement and even measurement thresholds for these standards could vary with objective circumstances. Most important is the difference between facilities vying to achieve quality certification as a one time status objective, and putting in place a quality improvement programme. It is the latter that needs to be encouraged.

Most nations are at the level of introduction of quality accreditation as a wide spread process and there is limited state role in it. Regulatory authorities and accreditation authorities could be different and work with different objectives and perspectives. Much of the evidence in low- and middle-income countries where private sector dominates provisioning of services is that state capacity to regulate is low. One agency, usually the ministry itself takes on all three functions- setting standards, measuring achievement and certification, and all of it with limited resources. (Ensor and Weinzierl 2007

In Iran medical universities have an important role to play in regulation, by monitoring clinical establishments within the province and ensuring compliance with standards. Applications for establishment of medical facilities have to be approved by chancellors of medical universities in provinces. They make periodic inspections and issue or renew licenses. Certificate and accreditation from the university in the area are mandatory to start a healthcare facility. This regulation works as licensing as well as quality accreditation

Regulation of insurance also requires a separate institutions- and these are not the same that regulate the facilities. In almost all nation's social insurance or government funded insurance is by a statutory agency managed by the government. In such instances quality accreditation has a separate body with different degrees of state control. In some nations private insurance has a major role to play, and in these nations institutions and methods have been developing for regulating insurance. Brazil has developed a major state sponsored system for this. But in many states comparisons between insurance plans remains a private entrepreneurial functions.

Judicial intervention and its helpfulness varies. In many nations it ensures that quality standards are enforced. So too for action against negligence. But judicial intervention could lead to unnecessarily high levels of professional certification or enclosure, and thereby reduce access to care. In Brazil for example, we find examples of both trends.

Limitations of our study approach:

One central problem is with this study, and indeed in this as a study domain is the lack of any evaluations, or even a well-articulated method of evaluation. Thus what we have pre-

sented is essentially a description of the purpose, scope and institutions of regulation. We cannot say how effective they have been in achieving their objectives.

We do have a limited number of studies on evaluation quality accreditation and even on that there is no clear conclusion. Some studies have shown an improvement in quality- but few have shown that quality accreditation improves effectiveness, efficiency or even patient centeredness across a health care system.

SECTION V

LEARNINGS AND RECOMMENDATIONS

Indian Experience with Regulation:

The context of this study is India's efforts at regulation of the private sector and the limited results it is yielding. This forces a re-look at the approach.

The Clinical Establishments Act (CEA) was notified by the Government of India on August 19, 2010. The situation with respect to its implementation is that 9 States and 6 UTs have adopted the CEA. In addition 8 States and 1 UT have notified alternative regulatory mechanisms. The rest have no regulations in place. Of the states that have adopted the CEA, rules have been notified in 6 States and 4 UTs; but even here there are problems in implementation.

A recent study by NIHFW attributes it "to variable political will, inadequate Centre-State coordination, non-congenial funding, and lower priority." It also blames lack of clarity in state government officials and devalues in notification of rules and making implementation plans. There are in the words of the NIHFW report "no periodic reviews to assess progress and course correction as well as provision of adequate infrastructure, ICT equipment, human resource (HR) and institutional capacity. The existing state and district nodal officers are already overburdened with other routine work, lack appropriate technical capacity and the support staff is scarce, untrained and those on contract receive low in-hand emoluments."

As a result, so far even in the states with the best record, only provisional registrations of CEs are being done under the Act whereas permanent registrations have yet not started. Standards too are not in place. Paradoxically, while basic quality standards are not in place, small providers and not for profit providers are facing pressure from regulators to meet standards which cannot be met in rural and remote areas and which are more forms of enclosure and monopoly.

Quantum of renewal registrations is also declining due to lack of robust control mechanisms and recurrent fees being levied for renewing provisional registration instead of issuing permanent registration. Since there is no robust census of private health facilities, its hard to gauge the progress of registration. Besides there are practical problems in scrutiny of health

providers' qualifications, many CEs could not have been registered whereas some unqualified persons (quacks) have managed to get registered in some States.

Clearly much of the poor implementation is due to the pressure from the medical profession and the healthcare industry. The Indian Medical Association, has contested the Act, raising objections to provisions for fixation of rates of charges by the government; lack of flexibility in minimum standards related to infrastructure and HR (no consideration for old CEs, costly or difficult locations or scarcity of qualified staff); the mandatory clause for stabilization of emergency patients, the insistence on adherence to Standard Treatment Guidelines and maintenance of electronic health records and the risk of harassment in the name of inspection.

Not surprisingly an examination regulatory mechanisms introduced in some States shows acts which are even is narrower in scope and content (mainly on standards, guidelines and accountability). Implementation of these state specific regulations is also weak.

The Indian experience with professional regulation of ethics, or in positively guiding practice has also had minimal impact. Professional practice abounds with irrational prescriptions, kick backs, conflicts of interests and even malpractice. Consumer protection laws have made an important though limited impact- but this is no substitute for legislation. Though India has a robust right to information, in the health sector, access to information on treatment, guarantees of privacy and confidentiality are all very limited and unprotected by legislation.

The last two decades have seen a major expansion of purchasing of care. Over 300 million persons are projected as being covered by publicly funded insurance programmes. But it has not made regulation easier. There is also no evidence that it has significantly altered provider behavior in the private sector- though there is a greater interest in quality accreditation because of this, or perhaps independent of it. What is more inexplicable in the context of our study, is the failure to link such widespread purchasing of health care with either quality accreditation or with regulation.

To break this deadlock with respect to clinical establishments act in particular and to regulation in general, the Indian government could do well to re-conceptualize the areas of regulation. We give below 6 key learnings from this study and 6 domains of regulation – in each of which government could show progress.

Learnings from the study:

1. **Licensing of facilities:** A sole dependence upon regulations that emphasize only registration, licensing with entry and exit from practice as the main effector mechanism works almost in no country. There is a role for licensing and approvals in most countries, but this is effective only in contexts when public health expenditure forms the major part of total health expenditure,(like in England or Australia) and therefore there is a felt need by private hospitals to be on board with the government. In a context where public expenditure dominates, private sector agrees to accreditation and licensing even if not part of purchasing contracts, because of the need to mobilize external revenue through medical tourism- like in Thailand. Where it does not, like in India and most African nations, licensing cannot be carried through.

   Where licensing and de-licensing has a significant role (which seems to be the exception) it could be on based on holistic assessments of quality (in England) or based on input criteria like meeting basic infrastructure and HR stipulations. The latter is far more common. Some nations have requirements for periodic re-licensing, and others have it only at entry.

   In no nation studied would licensing as a concept apply to public hospitals. Compliance with statutory regulations and public health laws would however be called for (eg. fire safety). In fact when it comes to public hospitals the discourse shifts to *accountability* as different from regulation.

2. **Shaping Market Behavior**: Where private players dominate in the provision of care, there are efforts to shape how markets behave. These are broadly to limit forms of competition that are deemed harmful and promote forms of competition that are considered desirable. Market entry conditions for private sector play a big role. Many nations like Japan are able to prevent entry of any for-profit entity by declaring that no profits can be distributed as stocks or dividends and must necessarily be re-invested in healthcare. In most nations where permission is required to set up a hospital, it requires a certificate of need which the local government has to provide. In Iran medical universities have this role. It is not clear how wisely the local governments exercise this power and how it contributes.

Similarly some nations have mandated that insurance agencies have to be not for profit.

One important pro-competition device is laws and strict regulations against conflicts of interests and kick-backs in any referral or prescriptions. This is present even in USA, the most extensively privatized of the health markets studied. But this is a norm in most developed nations. The contrast with India cannot be more stark, for in India many successful business models are based on commissions paid for referrals and prescriptions of diagnostics and drugs.

Yet another pro-competition device, reported only from England is monitoring to see that contracting agencies do not exclude private parties from bidding for primary care contracts. The other constituents of UK: Northern Ireland, Scotland and Wales however do not have this policy direction of enforcing competition amongst providers, much less between public and private providers.

There is a mixed response to how private practice by public practitioners- though this is one of the most common forms of conflict. Some welcome it, some look the other way, while many actively ban it. This is obviously more of a problem where there is a mix of public and private providers with private providers having much more unregulated terms of service.

3. **Purchasing as Regulation:** In most nations where it is successful large scale contracting in of private hospitals is the main form of influencing provider behavior. In every instance studies this goes along with much better regulation of standards, and ethics of care and in most situations also includes pricing of services as well. However these are also nations where licensing, quality accreditation and other forms of regulation are robust. Clearly public purchasing plays a major role only where private sector regulation is robust- but it is a chicken and egg relationship. Is widespread public purchasing possible because there is good regulation, or is effective private sector regulation possible because private sector depends on public purchasing and cannot opt out of this without adverse economic consequences for its own viability. There is no doubt some truth in both contentions- and the dominance of which is the driver of change would depend on context. In nations like Japan the ground rules itself elimi-

nated profits, and brought about a tough regulatory regime, where both inputs and prices were regulated. Other quality standards however are more voluntary. But in nations like Thailand and Sri Lanka the dominance of the public sector amongst contractees meant, that the private sector had to enter on its terms or exit and in such circumstances the private sector had limited growth. In Brazil, it could woo a considerable part of the private sector into a regulated behavior- but a sizeable section remained outside to whom only voluntary quality accreditation could reach out.

One corollary of our above discussion is that strategic purchasing does not appear as an alternative to private sector regulation- but dependent on it.

4. **Quality Accreditation:** In all nations there is a growth of quality accreditation, but its links to regulation and even its own effectiveness in improving quality of care varies widely. In many nations which vary widely in their health systems like USA and Japan and in the private sector of most LMICs, quality accreditation is completely voluntary and not linked to licensing. Two caveats- First quality refers to quality of processes and measures of outcomes, patient safety and responsiveness- and not only to input criteria of infrastructure and human resource stipulations. Licensing is often linked to the latter in most nations where it exists, but the question is whether it is linked to the former. Secondly quality standards as an entry barrier or regulatory device is in most nations not applicable to public hospitals, only to the private sector. This is justified on the basis that private hospitals are external and autonomous from government and quality accreditation is one of the few tools available to ensure outcomes, safety and responsiveness. On the other hand, when it comes to public hospitals, while there are huge benefits to be reaped from implementing quality improvement programmes, these can be done by administrative will- and undone by it. The government needs to be held accountable for poor quality and be forced to improve it- rather than use it as an excuse to shut it down.

   Extensive private sector participation in quality accreditation also seems to occur best where public sector provisioning is robust and can participate in purchasing. Brazil has an interesting innovation of scoring and ranking the private facilities as a mandatory measure and putting these in public domain.

Universities play a major role in quality accreditation in Iran. In most nations there are separate quality councils that do so.

It is only in England that we find in operation the concept of quality as setting a level playing field for competition in purchasing, so that providers cannot price lower by compromising quality. Like with most innovations that we uncover, we have no objective information that this works.

One strong positive for using quality accreditation as an approach to regulation is that it has a better understanding of human resources and institutional capacity for achieving it. One important lesson is that the organization that sets the standards can be different from that which does the accreditation, and a third organization, usually the ministry itself can decide on licensing. A quality inspection by the accrediting agency is followed by instructions to the facility for improvements that they must necessarily comply with, failing which the license could be revoked. But the actual revoking of the license must take affordability and feasibility within that context into account- and this is best left to the Ministry.

There is also a clear six levels of achievement in the relationship between improvements in quality accreditation and their use of regulation. In the first level it is self-regulation, but is useful to secure professional engagement in quality improvement programs. Then a focus develops on public information with the advantage it provides in that an informed public could potentially choose accredited facilities. In the third level there is professionalization of quality with external accrediting agencies assessing and accredit facilities. Then financial incentives kick in with insurance agencies making payments only to accredited facilities or providing a higher rate of reimbursement if they are quality improved. At the fifth level, meta-regulation independent agency sets standards and oversees accreditation across all facilities, and finally at the apex we have a situation where Government sanctions or de-licenses. There is a need to go through one or more of these levels sequentially. Jumping straight to the highest level, does not work. (at least in most political circumstances).

5. **Information and Patient Rights:** There are four main areas where patient rights to information need to be addressed.

First are rights for patients access to information on the care they are receiving. This should include providing them with information before the treatment for them to make informed choices and after the treatment for them to be empowered for follow up with the same provider or elsewhere

Second is the need for laws that guarantee privacy and confidentiality. Amongst the countries studied USA had robust laws. Laws in the Scandinavian and Baltic countries are also known to be robust in this regard.

Third are arrangements, preferably backed by law, related to grievance redressal. The Thailand no-fault liability system is an outstanding example in this area.

Fourth is related to the performance of the facility. This relates largely to their achievement of quality standards but is also important to indicate prices. A corollary of these above needs- but which have also independent rationale – for IT governance- so that the required information is generated, access and kept confidential.

6. **Human Resources-** Certification and Licensing**:** All nations have mechanisms of certification and licensing of professionals. In some nations it is only at the entry level with no subsequent process. In some nations it is periodic but with flexibility so that acquiring a prescribed minimum of credit points on continuing education is adequate for re-certification. In some nations it is periodic with some process of examination and skill testing. This is very rare- and if present relates to only a sub-set of skills.

   In all nations professional councils are involved. But it varies between whether they are in autonomous control over this function, or whether they need to have other stakeholder participation and be bound by state laws in this regard, or whether they also participate, but effectively the action is with a government nominated body.

   The nature and depth and use of autonomy by professional councils also vary. In many nations like in Australia an overall council for all human resources in health supervises the professional councils and sets the scope of their action. In others they do not.

   The regulation of professional practice as different from entry certification and periodic licensing varies. All professional councils are charged with having to address

malpraxis and ethical violations but in most instances it is ineffective in this regard. It is the judiciary that plays this role. We need to understand better and more objectively the scope and effectiveness of professional councils. There is a dearth of information in this regard.

Professional councils also play a major role in defining professional practice by either being a part of evolving, establishing and implementing standard treatment guidelines and protocols. In practice this is best done by autonomous agencies like the example of NIHCE in the United Kingdom with participation of professional councils but not left exclusively to them.

The Judiciary and Justiciability:

In many areas of healthcare and especially in patient rights, on action against malpractice and ethical violations by individuals or by organizations, and even on scope and effectiveness of regulations the presence of a pro-active judiciary and a necessary legal framework for seeking redressal makes a large difference. Literature is patchy in this area. We do know that where this becomes the main or even an important form of intervention there are both desirable and undesirable consequences. Undesirable consequences take the form of rising costs of care due to both indemnity insurance and defensive medicine. They could also take the form of stringent forms of quality control that compromise access or equity. But the main desirable consequence of this is the strengthening of regulatory frameworks

One way forward, that nations have used, is to put in place a government and professional council supported Code of Conduct. While this could be imposed on public hospitals and be part of contract terms, it would not automatically cover private hospitals. However enabled by this judiciary could step in, and give it a greater legal presence. For this, it would have to be well evidenced and legally argued and defended. There are many areas like kickbacks, transparency, right of patients to information and privacy, notification of diseases and information of public health relevance, denial of care to patients who are eligible for care under the contract etc… which such a code of conduct could facilitate.

Options in the Indian Context:

1. **Licensing of Facilities:**

Considerable published literature supports the view that banning and heavily regulating private sector may be neither possible nor fully practical in countries with weak governments or weak governmental institutions (Lancet editorial June 26, 2006) The ability to regulate private health sector has not kept up with its growth. The major challenges are – lack of government institutional capacity, the large size of the sector, lack of resources, and corrupt relationship between state and private actors (Morgen and Ensor2016).

Public expectations of regulation are reasonable prices, and protection from exploitative or irrational care, and from negligence or even lack of competence. Most licensing systems are limited to defining adherence to minimum levels of infrastructure and human resources which does not quite capture the public requirements of regulation. It could even go counter to public expectations by increasing costs further. Adherence to standard treatment guidelines are difficult to monitor in any situation unless it is part of a purchasing contract. If regulation is to be effective in the Indian context, the emphasis should be on registration and not on licensing.

The purpose of registration should be providing adequate information of public health value to government and information of value to patients to know the treatment, what it costs and their options and to promote use of rational drug and diagnostic use and the use of standard treatment guidelines. In addition adequate information about provider performance is needed, and systems need to be put in place to collect and monitor this information. This information would then be put in the public domain. This could include median prices on key procedures. No doubt web-sites would emerge that would provide tools for comparison. But unless legal provisions are breached through criminal action, or patient safety is seriously compromised, the option of shutting down facilities is not on the table. Which is then an insistence on registration as different from licensing. In many ways this is what the CEA intends, but its permanent registration clause reads like licensing, its standards are unlikely to be friendly to affordable care and there is already enough examples of misuse of the law for political purposes and anti-competition reasons against small providers. (a number of mis-

sion hospitals and not for profits have reported high degrees of intervention and closure of their establishements to either favour local competitors or on political grounds).

Licensing would exist as an entry criteria, where there is an undertaking for ensuring a code of conduct which has a list of to-dos and not to dos. Registration is an active process, with administration responsible for registering all. Administration should be empowered to collect the minimum information required from each clinical establishment.

2. Use of Strategic Purchasing as instrument of altering provider behavior:

In contrast to weakening a command and control licensing role to regulation of private facilities, when it comes to purchasing care from private facilities, the efforts can be to strengthen this regulatory provisions much further.

The conditions of empanelment should include adherence to standards and codes of conduct in a strict way. These standards are to be laid down by a national standards organization which would also have the powers to relax them for specific administrative blocks where the density of providers (both public and private included) is sub-critical it comes in the way of access to care and affordability of care. District administrations would be authorized to move for such relaxation of standards.

Regulation of prices in an empanelled provider should possibly apply to all patients (excluding hospitality components). Even if it is difficult to mandate this information on prices should be available. Co-payments charged or incurred by insurance covered patients should be reported.

The list of empanelled (contracted) hospitals and reasons for non-empanelment could be displayed. The list of possible reasons could include non-application for empanelment, lack of minimum quality scores, lack of empanelment criteria etc.

Our reading of international experience shows that this moves together and there is reasons from within India also. Not for profit ethical providers find the financial provisions quite adequate. If purchasing was consciously to be used as a form of altering provider behavior, it would have an impact not necessarily by changing the behavior of established providers, but by providing an advantage for ethical and affordable care

providers to flourish. It would encourage new graduates to move to hitherto unremunerative and difficult areas to establish services. Over time as the number of such providers and their bargaining power increases it would become easier to use strategic purchasing in a much more extensive way.

But without clear stipulations on the code of conduct and quality of care, purchasing from the private sector, would shape the private health sector with an advantage to those who see health care merely as an investment opportunity. In this context purchasing care becomes a form of economic stimulus.

3. Legislating Health Information and Patient Rights:

Legal and administrative measures must be fast forwarded to achieve patients right to information and their own case records, and the right to privacy and confidentiality.

Information on prices and performances and quality achievements of private and public hospitals could be collected and put on the public domain. These could be part of the mandatory code of conduct of empanelled private hospitals and of all public hospitals and a desirable code of conduct for the rest.

Knowing the difficult in expressing prices, the code of conduct could specify what cost elements are to be included and further specify that the median and mean averages of costs for the last 50 patients who had this diagnosis be made available. Alternatively they could be categorized into five levels of charges based on a package of 5 tracer procedures (eg c budget hospitals, low cost, median cost, high cost and very high cost hospitals). Industry would certainly come up with better names for these categories- but the importance of knowing prices should be emphasized. This is what much of the public wants with regard to regulation.

It is important to put in a place a grievance redressal mechanism for complaints from the private sector along with legal aid where necessary. For all public hospitals and for empanelled private hospitals some measure on the lines of Thailand no fault liability compensation could be considered.

4. Quality Standards and Accreditation:

a. Pro-active promotion of quality accreditation by both public and private sector is one of the most feasible ways for altering provider behavior. Its effectiveness is not beyond doubt- but state intervention helps improve its effectiveness in many ways.

b. One form of state intervention is to provide a differential in repayments to those which are quality accredited private sector. Another is public information on scores and ranks.

c. We do not recommend de-licensing on the basis of quality scores. Failure to adhere to quality standards could attract a range of actions- from time given to make improvements, to penalties, to public dissemination of scores and of gaps- but not as a rule to de-licensing. However where purchasing contracts are concerned there could be monetary penalties or even de-empanelment.

d. There is a need to define quality standards with flexibility, allowing district administrations to ask for relaxation where it intervenes with access or affordability of care. A national or state level council for setting down standards and for allowing flexibility where required must be constituted with legal backing for the same. The council should have representatives of the profession and government but at least half of those representing the profession should be professionals practicing in rural areas and/or familiar with their concerns.

5. Monitoring adherence to quality:

It also requires its own autonomous institutional arrangement. This institution should be delinked from management contracts and consultancies for improving quality. The organization measuring adherence to quality standards, recommends action, but its enforcement, especially if it is related to licensing is a function of governance.

6. Strengthening legal accountability:

a. There is a need for separate legal frameworks for public and private sectors. The focus in public sector is on accountability mechanisms, and this could be built into essential services maintenance act. The quality standards are already defined by the National Quality Accreditation Scheme (NQAS) and the direction of movement would be to

make government officers accountable for achievement of the NQAS minimum standards.

b. The focus in private sector act is both the clinical establishments act and the consumer protection forum. Whereas the first would address issues of information asymmetry, and quality and specify entry criteria, the second would address malpractice and ethical violations.

c. Contracting under purchasing arrangements too would need legal support for enabling a more regulated provider behavior as well as to safeguard the contracted provider especially the small provider from undue harassment and ensure the sanctity of the contract.

d. Kick backs and commissions and other conflict of interests including referring from ones one public practice to a private practice where one has a vested interest would have to be illegalized using provisions similar to laws for this purpose in other nations.

e. To give greater scope for judicial action and to clearly indicate the required behaviours of private sector, with respect to ethics and to quality and information a Code of Conduct for HealthCare Providers must be out in place as part of government policy. These would be actionable with regard to government partnerships, but on private players who have no contracts with governments, judicial action could help.

7. Human Resources for Health :

a. This is a vast areas and this report has limited focus on this aspect. Two key principles however emerge

   i. All professional councils should be supervised by a common human resources for health regulation council which is constituted as a body with more direct public accountability.

   ii. Most regulatory functions that councils perform should be done by the councils through empowered committees or organizations where council representatives have a major presence, but there is presence of civil society and services user associations.

Industry is as a rule not represented in these committees. This particularly applies to professional regulation of ethics in practice, and certification as license to practice.

iii. Continuing professional education must be mandatory with renewal of accreditation/ license to practice, once in five years- but in a non-threatening manner , where the acquisition of a number of credit points through CME programme, attendance in conferences, and online courses are taken as adequate.

In conclusion:

The Clinical Establishments Act is one tool, but not the only tool available to national and state governments for regulation of health care. There are many others which must be leveraged better- and it is only in the context of a much wider understanding of regulation that even the objectives of the clinical establishments act can be met.

The purpose of regulation would vary with context. With respect to public healthcare delivery, accountability mechanisms are the idiom rather than regulation. But mechanisms of achieving quality of care and patient rights is an urgent requirement and will have overlaps with private sector regulation.

With respect to public purchasing of health care from the private sector, there is a much wider scope to introduce most measures of regulation that are desirable in the long run. The emphasis should be on ethics of care, and prevention of exploitation as expressed in a code of conduct. While quality of care would be important, it is a mix of mandatory quality accreditation/scoring using the NQAS (rather than the NABH) with scores placed in the public domain, better patient and public information and positive financial incentives for better quality scores, rather than a threat of sanctions and de-licensing that would be important. Contracting periods and contract renewal could however be based on a process similar to how sanctions and licensing linked to quality scores are done in Australia- four year contracts if quality requirements are fully met, two year contracts with conditions that have to be complied within that time frame, one year contracts with conditions to be complied with at once, and non renewal of contracts. Since the number of the private sector seeking empanelment could be four to five times the numbers empanelled in such government funded programmes, such an approach could work. The measurement thresholds for quality scores would change for under-serviced areas. Institutions would need to be built up, even for implementing this.

With respect to the private sector which has no contractual obligations to the state, one could put in place a code of conduct and facilitate judicial processes to give it appropriate legal teeth. The focus of this is on ethics and against exploitative processes and on public and patient information. Would this be a model code of conduct or something more binding- would need to be worked out.

All of this is not as a substitute to the clinical establishments act, it is in addition to it.

Concluded:

Fig 1: WHO FRAME WORK TO ASSESS REGULATION OF PRIVATE SECTOR HEALTH-CARE

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Annexure 1:

List of some key informants (Note – list is not complete)

Sr.No	Name of the Person	Details
1)	Dr Somsak Chunharas (Thailand)	Somsak Chunharas is the former Deputy Minister for Ministry of Public Health of Thailand. Chunharas' expertise in public health policy has allowed him to assume directorship positions throughout his career. Presently, Chunharas holds various positions in several committees including the Steering Board Member of Routine to Research Project, Faculty of Medicine, Siriraj Hospital, Mahidol University and Vice President to the National Health Foundation, Thailand.
2)	Dr Kalipso Chalkidou (United Kingdom)	She is the Director of the Global Health and Development Group at the Institute of Global Health Innovation, Imperial College London, helping governments build technical and institutional capacity for improving the value for money of their healthcare investment. She is interested in how local information, local expertise and local institutions can drive scientific and legitimate healthcare resource allocation decisions whilst improving patient outcomes. She has been involved in the Chinese rural health reform and also in national health reform projects in the USA, India, Colombia, Turkey and the Middle East, working with the World Bank, PAHO, DFID and the Inter-American Development Bank as well as national governments.

		Between 2008 and 2016 she founded and ran NICE International, a non-profit group within the UK's National Institute for Health and Care Excellence (NICE).
3)	Dr Taichi Ono (Japan)	Mr. Taichi Ono is a Professor at the National Graduate Institute of Policy Studies (GRIPS). Ono has a degree in law from the University of Tokyo and Master of Business Administration from University of California at Berkeley. Before coming to the Institute, he has worked at the Ministry of Health, Labour and Welfare for about twenty years, where he assumed various responsibilities for health care policy making. He has written extensively on topics pertaining to social security, social insurance and policy.
4)	Dr Osvaldo García González:	Professor, Cuba's Sports Medicine Institute. Osvaldo Garcia is a physician with specialties in family medicine and sports medicine and a doctorate in physical education and sports.
5)	Dr Maziar Moradi-Lakeh(Iran)	Associate Professor, Department of Community Medicine, Preventive Medicine and Public Health Research Center, Gastrointestinal and Liver Disease Research Center, Iran University of Medical Sciences, Iran, and the former head of the department of Community Medicine at Tehran University of Medical Sciences.

		Being in-charge of the research track of global health, his current research interests include burden of diseases and risk factor studies, health equity analysis and health service researches with a focus on the countries in the Middle Eastern region.
6)	Dr Ajay Mahal (interview on Malaysia and on Australia)	Mahal: Finkel Chair of Global Health at the School of Public Health and Preventive Medicine and an Adjunct Professor in the Department of Economics at Monash University. Ajay Mahal is also an Adjunct Professor of International Health Economics at Harvard University. He has worked as a health economics advisor in Gaza and the West Bank, and as a consultant to the Indian Government. He is an expert on issues including the health financing, the social determinants of health, and the economics of HIV/AIDS.
7)	Dr Hannah Dahlen (Australia)	Australia: Professor of Midwifery/Higher Degree Research Director, School of Nursing and Midwifery, Western Sydney University.
8)	Dr Karine Chevreul (France)	Karine Chevreul is presently working as a Professor, Public Health Economics and Health Services Research Unit, University of Paris. A researcher in health economics, she has participated in several studies of international comparisons on health policies and the organization of care. She has also worked as a technical advisor to the Minister of Health and the Minister of Social Security, France, in the areas of healthcare for elderly, disabled and their families

9)	Dr Denise Mary Leonard (United States)	Mary Denise Leonard is currently working as Advisor with Open Health Systems Laboratory. She is retired Director International Finance Corporation(IFC) New Delhi office in the early 1990s presently based at Washington. Denise has three decades of experience in international finance and project finance, and has spent most of the last decade advising governments globally on the structuring and international competitive tender of large Public-Private Partnership projects relating to infrastructure and social services
10)	Prof. Lynn Freedman (United States)	Professor-Population and Family Health at the Columbia University Medical Centre- Has served a UN commissioner for maternal right/health rights.
11)	Dr Nalini Vishwanathan(United States)	Currently Independent Reseacher – New York. Formerly consultant on health policy and faculty in US university.
12)	Dr Manju Karmacharya (Nepal)	UNFPA
13)	Purna Shrestha (Nepal)	Senior Legal Adviser (Asia), Centre for Reproductive Rights
14)	Rondi Anderson (Bangladesh)	UNFPA
15)	Dr. Shankar Prinja	School of Public Health, PGI Chandigarh

16)	Mr. M. Siva Kumar	Aravinda Eye Hospital

Indian Nationals with Global Health Experience who were data sources: Dr. AmitSen Gupta; Dr.Ravi Duggal, Ms Sarojini, Dr. Bhujang: Dr. VR Muraleedharan, Dr. Sundararaman