Case Study

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Stakeholder Participation Analysis in healthcare regulation: The case of amendment of Karnataka Private Medical Establishment Act, 2017

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Introduction

Health care regulation is a complex process. Regulation refers to the diverse set of instruments by which government sets requirements on enterprises and citizens. Regulations include laws, formal and informal orders, and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers (OECD, 1997)[1] . Robert et.al in his book "Getting health reforms right" has explained, "regulation refers to the government's use of its coercive power to improve constraints on organization and individuals."[2] Under this definition only legal rules and not incentives or behaviour changes were included. Regulation is vital to ensure equity and access to quality services within the health sector since health sector is prone to market failure mainly due to asymmetry of information. The consumers of medical services are always at a disadvantage due to asymmetry of information[3]. The recognition of health care services under the consumer protection act 1986 has provided an additional forum to address the grievance of the patients[4]. The recent amendments though do not specify health services is not excluded; medical services continue to be under the ambit of consumer protection act 2019[5].

Private sector is the predominant provider of health care in India but is poorly regulated[6,7]. As different states expand access to health care to achieve Universal health coverage, the role of private sector as complementary to public health needs to be recognized. They have a critical role in filling gaps in health care especially in the secondary and tertiary care level. Their partnership in implementation of key public health initiatives is also important, hence a balance has to be maintained and both over and under-regulation should be avoided. The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services. This has not been adopted by all states. Some states have their own medical establishment act, which is applicable in some instances only for private (Karnataka) or both public and Private facilities (Kerala).

[1] OECD, Paris 1997, the organization for economic co-operation and development report on regulation reform synthesis, Paris 1997, available from: http://www.oecd.org/gove/reglatory-policy/2391768.pdf
[2] Roberts MJ, Hsio W, Berman P, Reich MR, Getting health reforms right Oxford; Oxford university Press 2002.
[3] Iszaid I, Hafizan A.H, Muhamad Hanafiah Juni (2018), Market failure in health care: A review, International Journal of Public Health and clinical Sciences 5 (5): 16-25.
[4] Indian medical association Vs VP Shantha case judgement, https://indiankanoon.org/doc/723973/
[5] Consumer protection act 2019, http://egazette.nic.in/WriteReadData/2019/210422.pdf
[6] Hester W, Rhia R, Arthika S, Gianluca F, Joachim M, Ara D(2017), How to harness the private sector for Universal Health coverage, Lancet, , vol 390, issue 10090, E-19-20,
[7] Morgan, R and Ensor, T (2016) The regulation of private hospitals in Asia. International Journal of Health Planning and Management, 31 (1). pp. 49-64. ISSN 0749-6753

Even before the Clinical Establishment Act 2010[8] was approved nationally, Karnataka a southern state in India, had a legal mechanism for private medical establishments (PMEs). It had enacted the Nursing Homes act in 1976 but had not implemented it. Following the recommendations of the taskforce (2001)[9] on the health sector and the Chikungunya/Dengue outbreak in 2006 when the Government realized the need for mobilising private sector for health, the Karnataka state government repealed the old Nursing Homes Act and enacted the Karnataka Private Medical establishment act (KPME) in 2007[10]. The act mandates registration prescribes minimum standards and imposes certain obligations on all types of private health care facilities. The act underwent minor changes in terms of the composition of the KPMEA district registration authority in 2010 and 2012 (Fig 1). Significant revisions were made in KPMEA in 2017 after tough negotiations with private hospitals and medical professional associations.

This case study gives an overview of the amendment process of the KPMEA 2017 and stakeholder analysis and participation in the policy reform process which brings out important learnings for future reforms in health sector.

Brief description of the KPME Act 2007

The main objectives of the Act were to provide for monitoring of private medical establishments in the state of Karnataka. The key provisions under the act were:

1. The registration of private medical establishment
2. Constitution of local inspection committee
3. Laying down the standards for private medical establishments
4. Verification that the private medical establishment conformed to requirement of infrastructure and human resources.
5. Requirement to notify the schedule of charges payable for different medical treatment and other services in the form of brochures or booklets.
6. Prescribing statutory obligations to be performed by private medical establishment.
7. Maintenance of clinical records
8. To make available to the persons or his family member a copy of the gist of observations, treatment, investigation, advice and diagnostic opinion pertaining to the person.
9. Process for suspension or cancellation of registration
10. Penalties for violation of the provisions of the act and cancellation of the registration. and other relevant matters.

[8] Government of India. The Clinical Establishment (registration and regulation) Act, 2010. Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi. 2010.
[9] Government of Karnataka. Final report of the Task Force on Health and Family Welfare: Towards equity, quality and integrity in health. Bengaluru: Government of Karnataka; 2001.
[10] Karnataka Private Medical Establishment Act of 2007, Karnataka Act No. 01 (Jan 06, 2018).

Need for Amendment:

Though the KPME act 2007 was in force it was not effectively implemented. There were many clinics/hospitals in operation without KPMEA registration in Karnataka and the department of health database on the private health sector was incomplete and not updated. Despite the objective of the act to ensure quality of care, in reality the scope of the act was limited to registration of the health facilities which were often dependent on self-reporting by the private medical establishments.

Some reasons for poor implementation of KPMEA, 2007[11] were:

- **Lack of clarity on certain provisions of the act**: It was mentioned that the act is applicable for practitioners of alternate medicine also, which was misused by quacks to get registered under KPME. The penalties for all types of deviations were not specified. The rate list must be displayed in a conspicuous place in the hospital, but a clear definition of this was not provided.
- **Inadequacy of the act**: The act falls short of important aspects like regulation of health care costs, kickbacks and commission practices of doctors with the pharmaceutical and diagnostic industries. It had become more of a license issuing authority and the key aspects of ensuring quality of care were not adequately specified.
- **Poor coordination between implementing actors/bodies**: There is no dedicated body to implement the act and the district registration authority do not routinely conduct inspections unless a complaint is registered.
- **Human resource constraints:** The number of hospitals in some districts was too large, especially in urban areas and the district health officers/Ayush officers are not adequate to handle the workload without additional staff.
- **Political interference** and especially during the raids on the fake clinics was an issue to take action against erring hospitals.

In mid-2015 one of the civil society organizations found that many private hospitals performed medically unwarranted hysterectomies on women in one of the districts in Karnataka. The civil society mobilized the victims and held protests. This incident gained wide media coverage and the state government conducted an enquiry on the incident. Towards the end of 2016, the state cabinet of ministers was also reshuffled, and a new Health Minister took office. Thus, with the renewed political momentum and further, with the pressures building from the High Court of Karnataka, State Women's commission and the National Human Rights Commission to act on the private hospitals involved in the incident of the medically unwarranted hysterectomies, the state government, in 2016, realised the need to give more teeth to KPMEA.

[11] *Putturaj M. Demystifying the enigma of policy implementation: The case of Karnataka private medical establishment act. [dissertation]. Antwerpen: Institute of Tropical Medicine;2018.*

The Amendment Process:

The government followed a consultative approach with variety of stakeholders and had a series of discussions. The consultative committee was co-chaired by retired Justice & Health secretary. There was a move to be exhaustive in the inclusion of stakeholders in the consultation. At least 4 different sub-committee were formed. The private hospital associations and medical professional associations especially from the allopathic sector were well represented in the committees and sub-committees. While the researchers and the civil society organizations worked in silos, the medical professional associations and the private hospital associations worked together and adopted a number of powerful strategies to influence the content of KPMEA. A platform called Federation of Hospital Association of Karnataka was used to ensure coordination between the actors opposing the policy. They secured support from the legislators belonging to the opposition political party, to raise their concerns in the assembly when the KPMEA amendment bill was tabled in the legislature. They held large scale protests across the state by shutting down the private health facilities for five days and holding people's health at ransom. This forced the government to hold discussions with the Private Hospital associations and Indian Medical Association representatives to iron out the contentious issues.

The private hospital associations also held knowledge events like seminars to further reiterate their stand on KPMEA. During the process, one critical recommendation given by the committee was to include the government institutions also in the purview of the act and have the act renamed as Karnataka Medical Establishment Act. This was not considered by the Government which led private hospitals insisting on it and bringing it up repeatedly. The health minister himself participated in most of these consultations highlighting the priority of the initiative.

Proposed Amendments:

- Increasing the fines and maximum period of imprisonment in the Act. For instance, the fine for running a non-registered private medical establishment was proposed to be enhanced from Rs.10,000 to Rs.5,00,000. It was also suggested that if the application for registration is not acted upon by the concerned authorities within 90 days the application is to be deemed approved.
- The fine and term of imprisonment for non-adherence to the rules regarding maintenance of clinical records, and payments was planned to be increased from 6 months and Rs. 2,000 to three years and Rs.1,00,000.
- The amendment also suggested to make it mandatory to provide lifesaving or stabilizing emergency measures without insisting on advance payment.
- It added that every PME should display prominently the Patient's rights Charter and Private Medical Establishment's Charter and that in the event of death, the mortal remains of the deceased should be released immediately without insisting on payment of dues.
- PME were required to display schedule of charges and suggested that expert committee to set minimum standards of infrastructure, qualifications to provide care, protocols and fix charges to be constituted.
- Separate grievance redressal committee with the involvement of the higher rank police official at the district level.

Reactions of the private sector:

The hospitals were satisfied with some of the provisions like auto-approval of registration if application was not processed within 90 days and inclusion of patient responsibilities also in the charter. But they had major concerns regarding the penal provisions, composition of the grievance redressal committees at the district level and intent to cap prices.

The private sector reacted sharply and initiated a massive media campaign on the policy labelling the amendments as antidemocratic and draconian in nature Fig 3. They argued that if these amendments were brought to effect it will lead to the collapse the health systems in Karnataka and undermine the future of medical professionals[12]. The smaller hospitals and nursing homes took the lead to put pressure on the Government not to table the amendments in the June session of the Assembly, 2017. Instead, the government went ahead and scheduled discussion on the bill in the assembly. But the hospitals and professional associations developed cohesive policy networks by collaborating with other professional associations and also managed to garner support from opposition parties especially those having their own hospitals/medical institutions to stall the passage of the KPMEA amendment bill when it was tabled in the legislature in June 2017. The bill was discussed in the assembly at length but was sent to joint select committee for further deliberations. The joint select committee after making some changes by removing the imprisonment clause and reducing the fine gave assent to the bill to be placed in the upcoming assembly session in November 2017.

Some of the demands of private hospitals were not met by the Joint select committee such as, free hand to fix charges except hospitals for providing care for beneficiaries under the government schemes and not to have separate grievance redressal committee. Hence during the assembly session in November 2017, they mobilized key medical professionals and also held large scale protests across the state by shutting down the private health facilities for five days. This stressed the public facilities causing lot of inconvenience to the public and put pressure on the Government to concede more relaxations. The pro-amendment activists also mobilized the public and tried to create an impression of profiteering by the hospitals and doctors, but it failed to gather momentum as public were not able to fully appreciate the benefits of the amendments.

The final outcome of the amendment

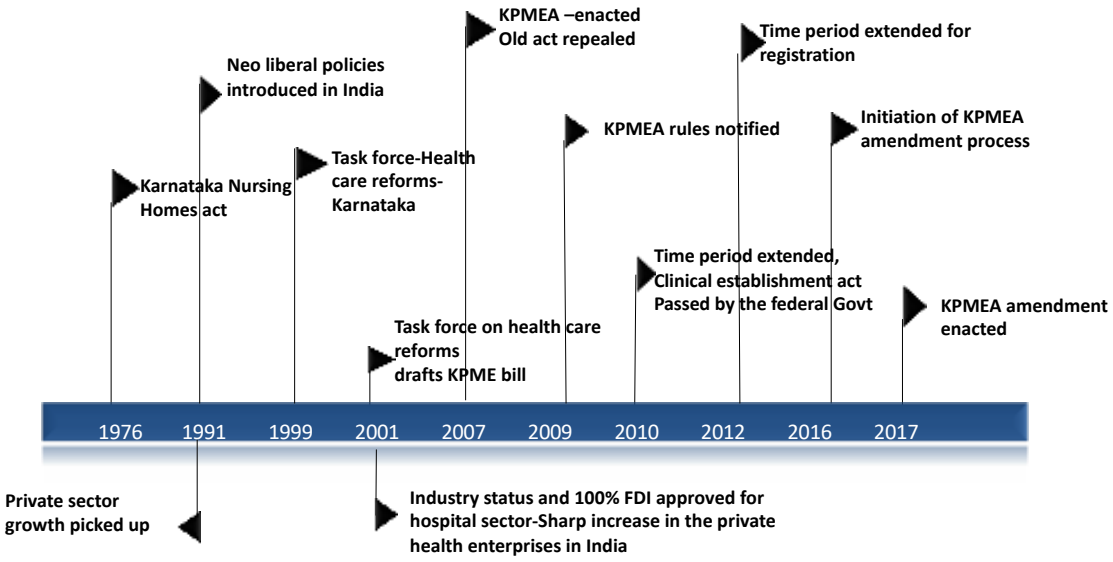
Since it was an election year there were pressures on the ruling party too which forced the government to hold discussions with the private sector and to reconsider certain provisions. Further there was key bureaucratic shuffle (change in health secretary and commissioner health) around October 2017 just before finalization of the recommendations of the joint select committee and presenting the revised bill in the upcoming assembly session. This did create some disconnect in deliberations that were held earlier and also the civil society which were fighting throughout could not get enough access to share their concerns with the new lead in the Government. On the other hand, the organized hospital and medical professionals could navigate the system to get sufficient time to represent their side of requests. After tough negotiations with health minister leading from

[12] Bhojani U, Rao V N, Putturaj M & Munegowda CM. Karnataka Private Medical Establishment Act: health policy analysis using political perspective. Bengaluru: Institute of Public Health:2016

the front the bill was revised and provisions such as imprisonment were omitted, fines were reduced to Rs. one lakh from proposed Rs.5 lakh (Amendment 19 sub-section (1) and Rs. 25,000 for first time and compounded to 50,000 from the proposed one lakh sub-section (4) for running an establishment without registration. Further the price capping was restricted only for government schemes. District registration authority and grievance redressal were combined instead of a separate grievance redressal authority with addition of one women member and representative of Indian medical association also was added as member in local inspection committee and a provision to levy monetary penalty for patients and their family members if they make false allegations on the hospitals and the treating physicians was also included in the final amendment. However, after several rounds of negotiation, the state managed to include certain patient centric clauses like the patients' rights charter and entrusted civil court powers to the District Registration and Grievance Redressal Authority. Thus, to some extent there was dilution, but it was passed in Nov 2017 just six months from the scheduled date of state government elections. The final amendments were notified in the Karnataka Gazette dated 6th January 2018 (Annexure-1). The process and timelines and the amendments proposed and accepted is presented in Fig 2 & Fig 4.

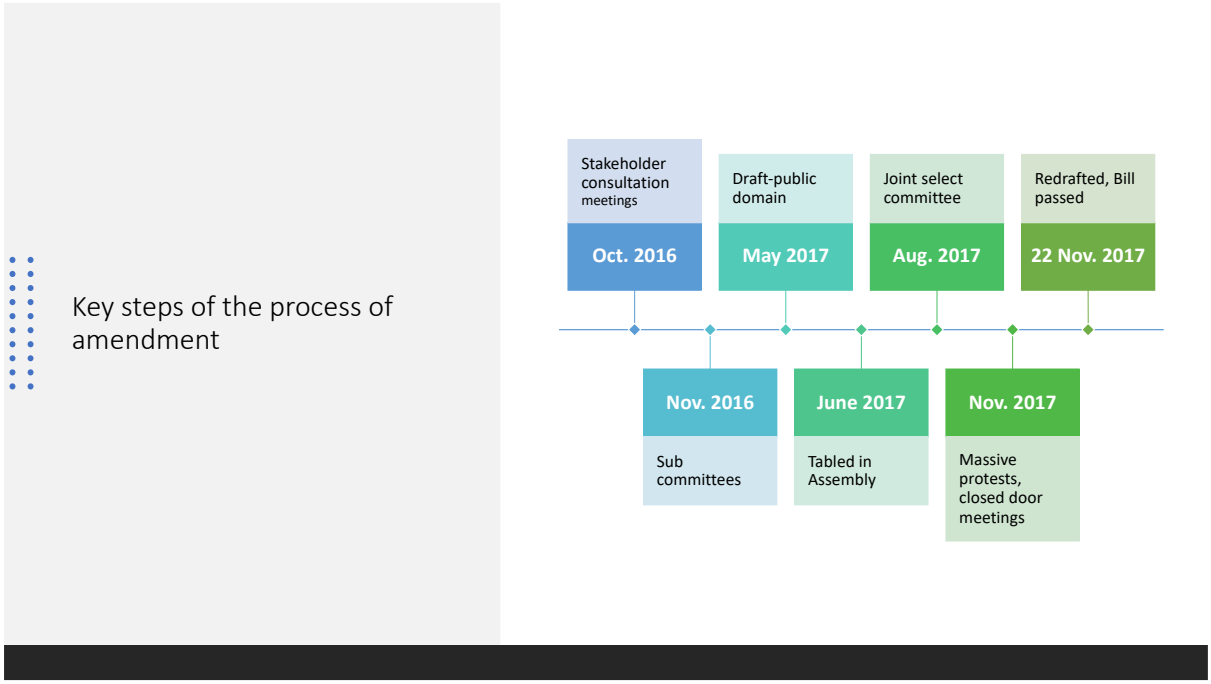
EXHIBITS: KPME CASE STUDY

Fig 1: The evolution of Karnataka Private Medical Establishment Act



Source : Putturaj M et al, 2018

Fig 2: Process and timelines of KPME 2017 amendment



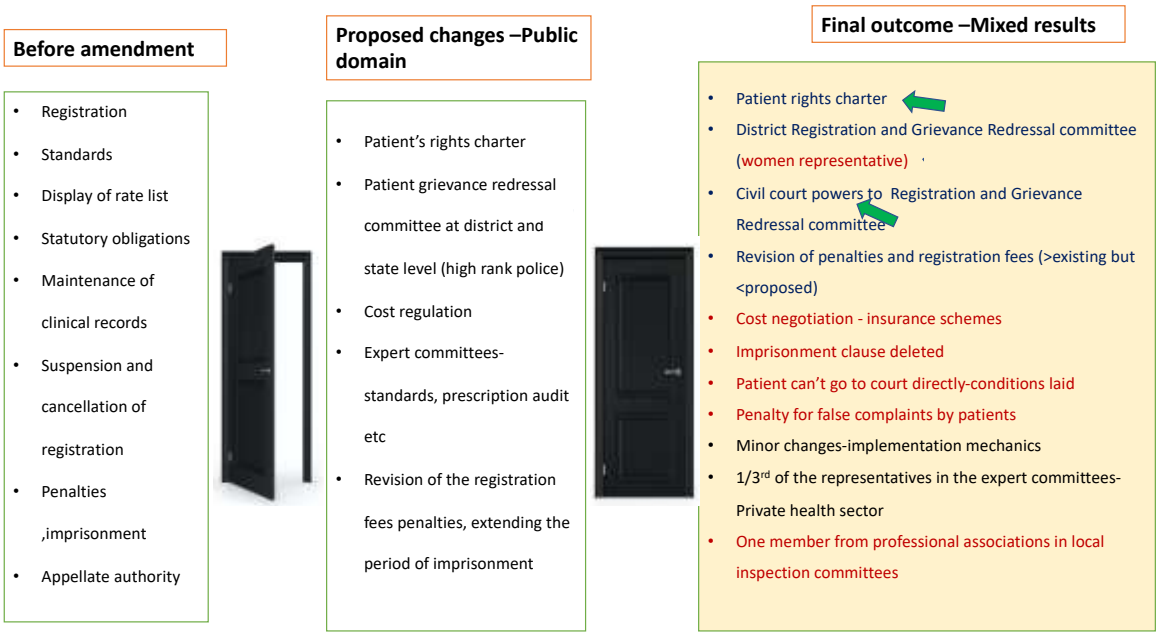
Source : Adapted from Putturaj M et al,2018

Fig 3: Media campaign against the amendments

17

Source: Putturaj M, 2018

Fig 4: Proposed changes and final amendments



18

Source : Putturaj M et al, 2018

Session Overview - Student Handout

Stakeholder analysis in policy reform process of health care Regulation:
Case Study on the Karnataka Private Medical Establishment Amendments Act (KPMEA) 2017

Group work:

Considering the case study on the amendment of KPME Act 2017, please discuss the following questions in your allotted groups.

Learning objective

1. How to conduct stakeholder analysis to assist policy reform?
2. Discuss the lessons learned from case study example of KPME reform.

Stakeholder Mapping and Analysis Exercise

1. Who are the key stakeholders in the case study?
2. Which stakeholders are the influencers and have power? (Positive influencers, Negative influencers, Neutral, Power low to high)
3. Assess which stakeholders could be interested (positive/negative) in the amendments to the act? (Interested to involve, interested to support, and Not interested)
4. Map stakeholders as per their levels of power and interest in the following diagram
5. Suggest measures to make the influencers who are neutral to take a stand and consider the concerns of those influencers who are negative.
6. What are the key lessons that we can learn from this example of the policy reform process using regulation?

Figure 5: Stakeholder mapping matrix[#]

Level of Influence/power

Latent/Neutral- **High/low power but interest medium:** Need to build interest on priority	**Enablers-** Top Priority, Supportive **High power and highly interested:** Sustain efforts of involve them throughout
Apathetic-Low priority **Less power and less interested:** General communications, least focused	**Opposing** **High power and highly interested:** Handle with care and negotiate

Levels of Interest ⟶

 # The diagram is suggestive. Participants are encouraged to map through innovative diagrams/using other methodologies.

Two axes of the matrix: Influence- Power to non-powerful/ Interest-positive to negative

Required reading: KPME Amendment 2017, Gazette notification.

Background reading: Keshri, VR (2018), Government Stewardship for Health Care: A Scoping Review of Regulatory Frameworks for Health Care Providers. Working Paper 03/2018. The Centre for Health Policy, Patna, Bihar, India

Teaching note- KPME case study

Case Synopsis:

This case study would discuss on stakeholder analysis to support health system reforms in regulation as an important policy lever. It provides insights on the role of Government intervention in health care not only as a provider but also as a regulator to ensure equity and access to quality care. Ineffective regulation may be worse than no regulation, so governments may need to think strategically before they intervene. Here, we present a specific experience of amendments to Karnataka Private medical establishment act. A political stakeholder analysis (Ministry, hospital associations, public, professional associations, media, civil society organizations) of the process during the amendments would be discussed. It also examines factors that could facilitate and hamper policy reform and how the information asymmetry between persons whose private benefit is threatened and the general public whose welfare is expected to increase by the legislation could influence policy reform.

Target Audience: Policy makers, researchers, professionals involved in health system reforms.

Objectives

- To emphasize the role of regulation in health care and the need for government intervention
- To describe the policy processes for health care regulation
- To discuss the role of interest groups in the regulation processes
- To discuss on the strategies/approaches for fair and just regulatory processes/policy reforms and policy making processes
- To demonstrate stakeholder mapping and analysis in health policy reforms/processes

Session outline

1. Introduction to the KPMEA 2017 will be provided and the Key changes proposed will be presented.
2. Time for quick reading of the case study will be provided.
3. Participants will be divided into 4 groups and each group will discuss in detail the questions listed.
4. Each group will identify the stakeholders in the case study and conduct stakeholder mapping and analysis.
5. Groups will present their key points to the larger group.
6. Participants involved in similar exercise of regulation in their states will be asked to share their experience and also the process adopted, challenges faced and how they were circumvented.
7. Would attempt to bring in the Health minister who championed the amendments/Secretary/Commissioner health during that period to provide comments and as a discussant to the session from Karnataka.
8. The session presenter will summarize the discussions of the group.

Main Messages

- Policy reform is a complex political endeavour and often comes with a limited window period to work upon hence the pace of reform is important.
- Co-ordination with all stakeholders, building policy networks, transparency, trust and timeliness can ensure better outcomes.
- Aligning support groups and detailing a well laid out strategy, anticipating and countering the moves of persons opposed to the reform.
- Negotiation and ceding ground on a few issues may salvage an important legislation.
- The role of champions in stewarding the reform process.

Stakeholder mapping – Actual analysis findings

Stakeholder	Involvement in the policy issue	Interest	Power	Position
Government actors				
Minister of Health and Family Welfare	Initiated the amendment process. Very much keen regulate the private health facilities.	High	High	Supportive
Health Secretary and other bureaucrats	Steering the policy change process. Organizing the stakeholder consultation meetings and drafting of the bill	High	High	Supportive
AYUSH department officials	Seeking legitimacy for the AYUSH doctors to practice allopathy in the name of integrated medicine. Offered clarification of the terms in the act.	High	Medium	Supportive
Karnataka Medical Council-Regulatory body for medical practitioners	How to link certain provisions of KPME with the Karnataka medical council act? Part of stakeholder consultation meetings.	Low	High	Neutral
Professional/private hospital associations				
Private hospital association, (Diagnostic centers, pharma companies, medical equipment companies, Insurance companies-invisible)	The target group of the policy. The policy will impose restrictions on various aspects of the service delivery. Provisions like price control, infrastructure standards have cost implications for the private health facilities.	High	High	Opposing

Karnataka integrated medical practitioners, AYUSH Federation of India	Tried to promote or legitimize integrated medicine (AYUSH + allopathy) through KPMEA.	High	Medium	Neutral
Indian Medical Association	Sizeable proportion of its members are in the private health sector. Policy has implications on their autonomy to practice and some provisions of the policy are not conducive for their profit logic	High	High	Opposing
Association of health care providers in India	Target group of the policy. Conglomeration of entire health care providers like hospitals, diagnostic centers, medical equipment companies, insurance providers etc., (national level). Policy imposes restrictions and has cost implications on its members	High	High	Opposing
Karnataka Government medical officers Association	Government doctors also own private health facilities. Dual practice is common in India.	High	Medium	Opposing

Academicians and Researchers				
Institute of Public Health	Conducted a study on the development and implementation of KPMEA. The organization is committed for health system strengthening and interested in health governance issues.	High	Medium	Supportive
Public health foundation of India	Reputed organization for education, training, research, policy development in the area of public health in India	High	Medium	Supportive
National law school India university	Have legal expertise on drafting public policies. Hence involved in drafting the amendment bill. Mandate to provide legal jargon to the act.	High	High	Supportive

Karnataka Health system resource Centre	Supposed to support the government in the decision-making processes by generating evidence.	Low	High	Neutral
Civic/interest groups				
Karnataka Jan Arogya Chaluvali, JAAK	KJC first to reveal the unwarranted hysterectomies on women by private hospitals in Gulbarga- an activist group fighting for strong regulation of private sector and strong public health system.	High	Medium	Supportive
Alternative law forum	Provides legal services to marginalized groups and conducts research on laws. Attended stakeholder consultation meetings initially. Ideas were similar to Karnataka Jan Arogya Chaluvali.	High	Low	Supportive

Lessons for future policy reforms

It is evident that a policy reform endeavor is an intensely political activity. In order to reduce opposition, it is important to treat all hospitals (government, private not-for-profit, private for profit) equally and not have regulation only for private hospitals. If quality is the objective it has to be ensured for all hospitals, irrespective of ownership.

The case of KPMEA amendment clearly proves that the window of opportunity for reforms are short and sometimes the various stakeholders can either push the reforms or stall it by mobilizing support even at the last minute. Many times the policy makers are pre-occupied with the content of the reform and fail to engage the stakeholders well in the process which may lead to failure of even well intentioned policies[13]. Power, interest and engagement of the stakeholders determine the provisions of the policy and so the implementation structures of the policy[14,15]. The pace of reform is important. When dragged over a long period, powerful opponents from vested group have an advantage as they will remain focused for the entire period while supporters without personal stakes might find it difficult to sustain the effort needed to counter the vested interests. When such well organised groups have access to a fundamental flaw – not treating all hospitals alike irrespective of ownership – it becomes difficult to defend the legislation.

[13] Gill W and Lucy G (1994), Reforming the health sector in developing countries, the central role of policy analysis, Health Policy and Planning, (4): 353-370.

[14] GrindleSM,ThomasWJ.Publicchoicesandpolicychange.Thepoliticaleconomyofreformin developing countries. Baltimore: John Hopkins University Press; 1991.

[14]SabatierP,MazmanianD.Theimplementationofregulatorypolicy:Aframeworkofanalysis.Davis: Institute of Governmental Affairs; 1979.

Strong policy networks and well-organized structures facilitated the creation of informal and formal spaces for the private hospitals and medical profession's associations while the same was not possible so quickly to the pro-amendments group. When public interest faces off with private profit, it is helpful to mobilise as many interested groups as possible. While private hospitals were able to bring in other support groups such as media and opposition parties, the pro supporters do not appear to have mobilised the larger society in support of a measure that would have improved public welfare. There is an asymmetry of information and effort between persons directly affected and those who do not have a direct interest. Private hospitals and physicians were directly affected by the reform and fought passionately to fend it off, while the supporters, mainly community service organizations and administrators, did not bring in the same level of strategic thinking and effort. Thus understanding the different stakeholder interests, perspectives and the influence they bring in is necessary to steer the reform process.

The government also has to move fast and ensure the reforms are brought in within a defined timeline and provide all stakeholders the same opportunity to air their concerns. Further, the changes in bureaucrats during crucial time in the policy process gives advantage to destabilize lot of ground gained for all stakeholders which could be detrimental to the process. It is important to have champions for a reform to succeed. Health minister's persistence appears to have been the main driving force. The change of health secretary seems to have adversely affected the level of ownership and thrust in implementation.

Negotiation and ceding ground on a few issues may salvage an important legislation if the core issues are not diluted and is worth the effort as any steps that strengthens the legal tool is useful. Though the legislation is passed into an act, if implementation does not see the same focus the opponents will achieve their objectives by creating difficulties in implementation.