Decoding the black box of health policy implementation: A case of regulating private healthcare establishments in southern India

MEENA PUTTURAJ, UPENDRA BHOJANI, NEETHI V. RAO, BRUNO MARCHAL

ABSTRACT

Background. Implementation of healthcare regulatory policies, especially in low- and middle-income countries where the private health sector is predominant, is challenging. Karnataka, a southern state in India, enacted the Karnataka Private Medical Establishments Act (KPMEA) with an aim to ensure quality of care in the private healthcare establishments. After more than a decade the implementation of KPMEA is suboptimal.

Methods. We used a case study design. The case was 'implementation of KPMEA'. The case study site was Bengaluru Urban district in Karnataka. Data from key informant interviews, focus group discussions held at the state, district and subdistrict levels and key policy documents, minutes of the meetings, data from the State Department of Health and Family Welfare, district level KPMEA data and litigations at the High Court of Karnataka were analysed using a framework.

Results. The policy (KPMEA) content is inadequate and requires clarity in certain provisions of the Act. There was a lack of coordination between the implementing agencies. Workforce shortages were evident. Factors that impede the enforcement of the Act include poor knowledge and lack of competency of the officials on the content and the implementation mechanics of the policy, insufficient policy oversight from the state on the districts, corruption, political interference and lack of support from the local public, especially during raids on illegal establishments.

Conclusions. A regulatory policy such as KPMEA needs a clear, comprehensive content and directions for operationalization. However, improving the content of the policy is not easy as some aspects of the policy remain contentious with the private healthcare providers/ establishments. Addressing health governance issues at all levels is key to effective enforcement.

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INTRODUCTION

There is a growing discourse on regulation of private healthcare providers and establishments. It is a complex phenomenon. The complexity is owing to the interplay of the different levels of the government, multiple stakeholders, contextual factors and the inherent tensions that exist between different stakeholders in the design and implementation of the healthcare regulatory policies. There is a general consensus on the need for healthcare regulation, but most of the questions are raised on the structure and implementation of healthcare regulatory policies. In general, in low- and middle-income countries (LMICs) implementation of public policy is problematic because of ineffective governance systems,[1] and India is a typical example where it is a struggle to implement healthcare regulatory policies.

The regulation of healthcare providers and their establishments in India broadly consists of three main approaches: (i) self-regulation through the professional councils that regulate the individual healthcare providers' education and their conduct; (ii) (voluntary) accreditation; and (iii) specific legislations targeting a health condition/technology application/ specific aspect of healthcare, for example, the Pre-Conception and Pre-natal Diagnostic Techniques (prohibition of sex selection) Act 1994. There are also broader legislations such as the Consumer Protection Act 1986 (health services are covered under this Act since 1995), the Nursing Homes Act 1988 and the Clinical Establishments Act 2010. Despite the plethora of legislations, we do not have a realistic estimate on the number of private health facilities in India.

Karnataka, a southern state in India, had enacted a legislation, the Karnataka Private Medical Establishments Act (hereinafter referred as KPMEA) in 2007. The Act mandates registration, prescribes minimum standards and imposes certain obligations on all types of private healthcare facilities.[2] However, even after more than 10 years of KPMEA in operation, the implementation of the policy is suboptimal.[3,4] No matter how perfectly a policy is designed, a defective implementation will spoil the intent of the whole policy.[5] What happens to the legislation after the parliamentary processes often remains a 'black box'.

The healthcare-related legislations in India such as the Consumer Protection Act, the Pre-conception and Pre-Natal Diagnostic Techniques (prohibition of sex selection) Act, the Drug and Cosmetic Act and the Indian Medical Council Act have been comprehensively examined for their effectiveness and were found to be fraught with challenges in implementation such as corruption, lack of workforce, apathy of state governments, technical incompetence, lack of monitoring and ill-designed implementation structures.[6–9] However, no research has systematically examined the content and the implementation of KPMEA.

There is a scarcity of primary research on health policies, especially in LMICs and the literature on health policy processes are dominated by perspectives of scholars from the global north.[10] Empirical research focusing on health policy implementation processes is also scanty. Thus, research on health policy-related issues in LMICs is deemed relevant.

We undertook a policy analysis of KPMEA between December 2015 and January 2016 to better understand its evolution, concerned agencies, their engagement with the policy processes and the resultant policy design and

Institute of Public Health, 3009, II-A Main, 17th Cross, KR Road, Siddanna Layout, Banashankari Stage II, Banashankari, Bengaluru 560070, Karnataka, India
MEENA PUTTURAJ, UPENDRA BHOJANI, NEETHI V. RAO

Durham University, Durham, UK
UPENDRA BHOJANI Department of Anthropology

Institute of Tropical Medicine, Antwerp, Belgium
BRUNO MARCHAL Department of Public Health

Correspondence to MEENA PUTTURAJ; *meenaputturaj@gmail.com*

implementation in a given context. We focus on a specific aspect of the larger study, i.e. implementation of KPMEA at the district/subdistrict level using the case of Bengaluru urban district in the state of Karnataka in India.

We aimed (i) to assess the actual implementation processes of KPMEA at the district and the subdistrict levels against the KPMEA policy on paper; (ii) to identify specific barriers to the implementation of KPMEA; and (iii) to draw lessons for the implementation of regulatory policies pertaining to private healthcare establishments.

METHODS

Study design

Case studies are useful when the phenomenon under study is context-sensitive, context-related and the boundaries between the phenomena and the context are not clear.[11] Contextualization is key to understanding various policy implementation processes. Therefore, we used the case study design in this enquiry.

The case was 'the implementation of KPMEA'. We had three subunits of analysis to examine the relationship between the macro level (state) policy decisions, the meso level (district) and the micro (subdistrict) level of the organizations through which the policy is enforced. The Bengaluru Urban district was the site of the case study.

Description of the case study district

Bengaluru Urban district has the highest number (6182 as on March 2015) of private health facilities registered under KPMEA compared to other districts in Karnataka. Hence, it offers a good opportunity for studying the KPMEA implementation processes. The district has a total population of around 9.62 million.[12] For administrative purposes, the district has been divided into five subdistricts (referred to as taluks in India). Bengaluru Urban is the capital of Karnataka state and is the major metropolitan city. It is referred to as the 'Information Technology capital of India' and the economic epicentre of Karnataka. Despite its economic achievement, Karnataka lags behind in social sectors such as health, education and poverty eradication among its counterparts such as Kerala and Tamil Nadu in southern India.[13]

Data collection methods and data sources

The data collection took place from February 2016 to September 2016.

Key informant interviews: Stakeholders at the state and district levels for the key informant interviews were purposively selected. The interviews lasted for 40–60 minutes. When the stakeholders did not give consent for recording, detailed notes were taken. The audio recorded interviews were transcribed. A semi-structured interview guide was used.

Focus group discussions (FGDs)*:* We conducted one FGD involving bureaucrats at the state level. In the other FGD, the subdistrict officials were involved.

Document review: We applied to the concerned authorities of Bengaluru Urban district seeking information under the Right to Information Act (2005) regarding the composition of the KPMEA district registration authority, local inspection committees, KPMEA implementation outputs (no. of registrations, complaints and penalties under KPMEA) and also minutes of the district level KPMEA meetings. The authorities responded but provided incomplete information. Yet, whatever information was received was used in the analysis.

Documents from the Department of Health and Family Welfare pertaining to KPMEA implementation outputs were also analysed. The transcripts of all the high court judgments from September 2007 to December 2015 where KPMEA was cited were retrieved from *www.indiankanoon.org*. The purpose of these litigations was to understand the impact of the court decisions on KPMEA implementation processes.

Theoretical framework

The conceptual framework for the present study was inspired by the two models developed by Grindle and Thomas[14] and Sabatier and Mazmanian.[15] We adopted the framework post data collection as we found it more appropriate for analysing the data (given our focus on implementation).

Ethical clearance

The study was approved by the Institutional Review Board of the Institute of Public Health (IPH-IRB:26/01/2016). Permission was sought from the Government of Karnataka (HFW 94 FPR 2015: 05/02/2016) to conduct the study and interview government officials. Informed consent was obtained from all the respondents of the interviews and FGDs. Only the research team members had access to the collected data.

OUR FINDINGS AND THEIR INTERPRETATION

This section has two parts. Part 1 consists of the description of the KPMEA policy, implementation status of KPMEA and key stakeholders' perspectives on private healthcare providers and establishments regulation. Part 2 explains the barriers to effectively implement KPMEA.

PART 1

Description of the KPMEA policy

Evolution of KPMEA. An Act to regulate the private health sector in Karnataka existed in 1976, but it was hardly implemented. The Health Task Force in 1999 emphasized the need for regulating the private health sector, and it drafted the Karnataka Private Establishments Bill in 2001.[16] After 6 years, in 2007, the KPMEA was enacted. The rules to operationalize the Act were notified in 2009. Several private health facilities remained unregistered under KPMEA, so the period for registration was extended twice (in 2010 and in 2012). The patients' rights charter, patient grievance redressal mechanism, civil court power to the district registration committee and a few other minor changes were incorporated in the Act and the amended Act was passed in 2017.

Targets groups of KPMEA. The policy covers both Allopathy and a few recognized non-allopathic systems of medicine in India such as Ayurveda, Unani, Homeopathy, Yoga, Naturopathy, Siddha, Acupuncture, Acupressure and Integrated Medicine (where an Ayurveda medical practitioner practises Allopathy as well). The rules of the Act are applicable to all medical establishments where promotive, preventive, curative and rehabilitative care is provided, which means even diagnostic centres, blood banks and all kinds of therapy centres are covered under the Act.

Major provisions in KPMEA. KPMEA attempts to regulate a diverse set of behaviours of private healthcare enterprises. All private health facilities are supposed to register themselves under the Act, and renew the registration once in every 5 years. The Act also prescribes minimum standards for infrastructure and staffing. It imposes a few obligations on health facilities that

they should share the data of public health importance with government authorities and cooperate in the implementation of national and state health programmes. Further, the Act says that no private health facility can insist on advance payment for initiating emergency treatment and should hand over, in the event of the death of a patient, the body of the deceased immediately without a demand to pay the dues. The Act demands the display of the contact details of the owner of the establishment, the system of medicine that the facility is authorized to practise and the patient rights and responsibilities charter.

Status of implementation of KPMEA and its outputs. The main objective of the Act is to ensure quality of healthcare in private healthcare establishments. However, KPMEA in its current form is reduced to mere registration of private health facilities. KPMEA in principle regulates who can/cannot enter the healthcare market but does not seem to have any grip over private health facilities after their entry into the healthcare market. In the words of a senior bureaucrat, 'KPMEA is like "book-keeping" mainly about the private sector reporting information. And it is mostly self-reporting. The standards also focus more on infrastructure and people and not so much on the quality of health care services per se.' (KI1)

KPMEA is not adequate to address all dimensions of quality healthcare in private establishments.

'KPMEA is just a bare bone Act…You are only issuing a licence. I mean you are not doing anything about the quality of care.' (KI15)

Consolidated data from the State Health Department of Health and Family Welfare indicate that the number of private health facilities registered under KPMEA, as on March 2015, ranges from as high as 6182 in Bengaluru Urban district to as low as 90 in Chickballapur district. Small private health enterprises (formal and informal) run by solo practitioners account for 71.3% of private health institutions in India.[17] Unauthorized medical practitioners who are not eligible to get a licence under KPMEA usually run single doctor clinics. An official gave an estimate of at least 10 000 illegal clinics in the Bengaluru Urban district alone. Hence, we can say that there are many establishments in operation without KPMEA registration in Karnataka. The health department does not have a complete database on the private healthcare establishments. In the words of a government official, 'Unless you catch any bike rider, you never know whether they are having a licence or not. KPMEA has got the same fallacy. You will never know until you raid a clinic and check for registration.' (KI18)

A few unintended effects of the policy were also perceived by government officials at the district and state levels. Some of them felt that a few doctors have personal enmity and use KPMEA as an instrument to take revenge on their fellow doctors by filing complaints to the district registration authority. The officials also had an impression that the owners of the establishments (especially the ones that belong to unrecognized non-allopathic systems of medicine) who are not permitted to function under KPMEA, use the judicial system to delay action taken by the enforcement officials. During the trial period, the KPMEA enforcement officials cannot act upon the establishments that are not compliant with KPMEA but have to wait for the court judgment to initiate any punitive action. Among the 86 KPMEA-related court cases retrieved for analysis, 99% were from the non-allopathic medical practitioners whose qualifications are not recognized as the official systems of medicine by the Karnataka state regulating body for non-allopathic systems of medicine education and practice. Due to administrative reasons, the district registration authority and the state appellate authority took much longer than what is stipulated in the Act to dispose of the applications and the appeals made under KPMEA.

Key stakeholders' perspectives on the regulation of private healthcare providers/establishments

The state and non-state functionaries have different perspectives on regulation of private healthcare providers and their establishments, which have implications for KPMEA design and implementation.

The Indian Medical Association (IMA) has a substantial role in the implementation of KPMEA. However, it is advocating for self-regulation.

'We don't require any external body to regulate us. We will regulate ourselves because medical profession is supposed to be a noble profession…we ourselves can do it…in fact we do have some sort of self-regulatory mechanisms.' (KI10)

Civil society organizations felt that involvement of representatives of the private health sector in the implementation

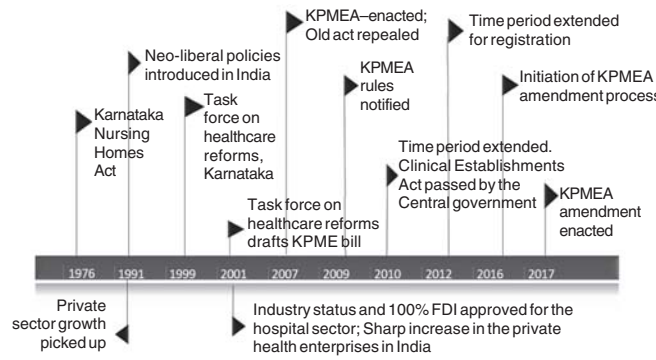

FIG 1. Evolution of the Karnataka Private Medical Establishments Act (KPMEA) FDI foreign direct investment

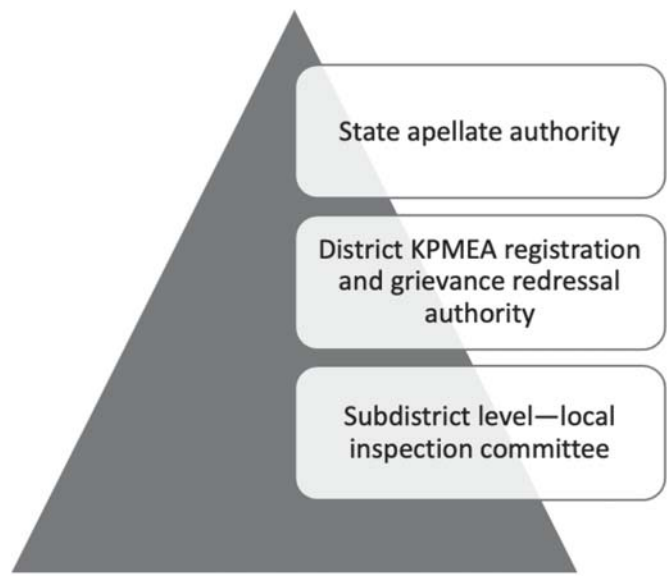

FIG 2. Implementation structure of the Karnataka Private Medical Establishments Act (KPMEA)

processes of KPMEA led to a conflict of interest. However, some policy-makers (FGD1) believed that involvement of the private health sector in the regulatory processes will ensure better communication and it is considered to be a way of winning confidence and coordination from private healthcare establishments for implementing KPMEA.

There is also a perspective that involvement of non-medical people will result in better implementation of KPMEA.

'Doctors cannot regulate their own fraternity, because they have a soft corner for those who belong to their own profession. We can't be asking permission of the chicken to cut its own head. Such attitude will be there in any profession.' (KI7); however, the IMA opposes this view.

PART 2

So, what is impeding implementation of KPMEA? To understand this, the policy context, the power of private allopathic private practitioners/establishments is elaborated and then the issues with the policy characteristics, implementation agencies' and resource requirements for KPMEA are presented.

The policy context

Policies are designed and implemented in a context. On the economic front, Karnataka state is the third largest contributor to India's gross domestic product (GDP). The GDP of the state stands at 8% at constant (2011–2012) prices. Among the districts in Karnataka, Bengaluru Urban has the highest per capita income. The state has many industry-friendly and liberal policies to attract private business investments.[18] In addition, since 2002, there has been a paradigm shift, particularly in terms of healthcare financing. The interest of the government has shifted from tax-based financing of the public health system to achieve financial protection through social health insurance schemes.[17] The allopathic private healthcare establishments have a substantial role in the implementation of these social health insurance schemes, and they are powerful in health policy circles. The Karnataka state is no exception to this. Hence, we see that KPMEA is implemented in a context where the state is increasingly reliant on the private (allopathic) healthcare establishments, which are dominant in terms of service delivery and power to influence policies.

Power of private practitioners/establishments

The policy design spells out the implementation strategy/processes of the policy. During the design stage, various stakeholders depending on their interest and power, influence the policy content. In the case of KPMEA, organized groups of private practitioners/establishments, especially those of the modern medicine sector were engaged during formulation of the policy. The private allopathic practitioners and private allopathic hospitals in Karnataka have well organized and active associations. The most influential are the state branch of the IMA, the Private Hospitals and Nursing Homes Association and the Association of Health Care Providers India. Apart from these, there are specialized doctors' professional associations, for example, Bengaluru Society for Obstetricians and Gynaecologists, Cardiological Society of India, etc. These bodies align themselves to form a cohesive policy network and use their collective bargaining power to deal with health policy issues that impact them. See for instance the following quote: 'IMA is in constant touch with the health ministry (on various issues) not only in this state at the national level as well.' (KII9)

Considering the availability of human, financial, technical and political resources, the non-allopathic medicine practitioners' associations such as the National Integrated Medical Practitioners Association and the AYUSH Federation of India (AFI), folk/traditional healers association (Paramparika Vaidyara Parishad) are less powerful than the IMA (professional association for allopathic practitioners) and the Private (allopathic) Hospitals and Nursing Homes Association.

Even though not very prominent in the health policy circles, by making petitions to the state Ministry of Health and Family Welfare, the AFI was able to secure a place in the district KPMEA registration committee since 2010 and include the term 'integrated medicine' in the legislation. Another representative of non-allopathic medical practitioners' associations expressed that they were never consulted during the KPMEA formulation or adoption stage in 2007. In fact, that representative perceived that the infrastructure standards prescribed in KPMEA are difficult to apply to single doctor clinics and KPMEA was thought to be a tool for big corporate hospitals to scuttle solo practitioners.

'KPMEA is the conspiracy of the big corporate chain hospitals. They did this with the intention of curbing small private medical establishments who are considered to be their potential competitors in the healthcare industry. The big corporate chains pressurized the government to formulate such an Act in their favour.' (KI14)

Scholars in high-, middle- and low-income countries have also documented the power of (allopathic) medical professional associations in health policy-making processes.[19–21] The term 'medical power' is used to highlight the dominance of medical professional associations in various stages of designing the health policy.[20] Strong policy networks and well-organized structures facilitate the creation of informal and formal spaces for private hospitals and medical profession's associations within the policy environment.

Issues with the content of KPMEA

Need for clarity in certain provisions of KPMEA. Certain provisions/terms of the Act seem to be lacking clarity. While the Act does not mention a word about alternative medicine, the rules framed under the Act incorporate the term alternative medicine. Some unauthorized/informal healthcare providers who practise non-allopathic systems of medicine not recognized by the state regulatory body claimed themselves to be practitioners of alternative systems of medicine and tried to get registration under KPMEA citing the term included in the KPMEA rules. However, applications from such establishments are rejected by the district KPMEA registration authority. These applicants usually approach the judiciary to resolve such disputes. Of the 86 court cases related to KPMEA analysed, 99% of litigations were from the clinics run by people claiming to be practitioners of alternative medicine.

KPMEA says that medical establishments should not deny care for patients with emergency conditions and are expected to administer at least first aid. However, recognized non-allopathic practitioners feel that 'emergencies are something that they cannot handle' (KI14). They demand a specific mention in the Act as to who should handle the emergencies.

Inadequacy of the policy

The Act technically falls short of important aspects such as regulation of healthcare costs and kickbacks (commission

TABLE I. Categories of respondents involved in the interviews and focus group discussions (FGDs)

Category of respondents	*n*	Code
Government officials from the Ministry of Health and Family Welfare, Directorate of Health and Family Welfare, Directorate of AYUSH, Karnataka Ayurveda Unani Practitioners Board, elected representatives	9+3 in FGD	KI1*, KI2, KI3, KI4, KI5, KI6, KI7, KI8, KI9, FGD1
Allopathic and non-allopathic practitioners' associations, traditional healers' association, civil society organization, private hospital associations	7	KI10, KI11, KI12, KI13, KI14, KI15, KI16, KI17
District KPMEA registration committee members and clerical staff	5	KI18, KI19, KI20, KI21, KI22
Government officials at the subdistrict level	7 in FGD	FGD2

* Key informant KPMEA Karnataka Private Medical Establishments Act

received by doctors for referrals of patients to diagnostic centres, surgeries, check-ups or medical shops). This leaves the policy implementers with a feeling of helplessness. The policy implementers also felt that the Act is toothless as it is not always possible to file cases against erring hospitals under KPMEA. In their opinion, no direct judicial action can be initiated under KPMEA on registered clinics (FGD2).

Hence, it seems there are issues with the content of the KPMEA policy. Inadequacy of the existing legal frameworks for healthcare regulation were also documented in other states of India such as Delhi and Madhya Pradesh.[22] Similar struggles to regulate prices in the for-profit private health sector exist in Zimbabwe and Tanzania.[23] With the amendment of KPMEA in 2017, the district KPMEA registration committee is vested with powers of a civil court to deal with any violations with the patients and the private medical establishments charter stipulated in KPMEA. This could probably enable the enforcers to take judicial action on the establishments non-compliant with KPMEA.

Issues with those implementing KPMEA

Implementation of the KPMEA policy requires coordination of people belonging to at least six/seven different organizations. Among these, two are non-state officials (local branches of the IMA and AFI). The implementation happens at the district level. The district registration authority under the Act consists of the Deputy Commissioner, District Health Officer (DHO), District AYUSH Officer and representatives from the local branch of the IMA and AFI. All the members in the team except the AFI representative are signatories in the KPMEA registration certificate. Since the amendment of the Act in 2017, the district registration authority also holds the responsibility for addressing grievances of patients and private healthcare establishments. While dealing with the grievances, the district authority should include additionally a woman representative. Establishments that are aggrieved by the decisions of the district registration authority can approach the state appellate authority.

Ideally, as per the Act, before issuing the licence to a private health facility, the registration authority needs to confirm that the private health facility fulfils the prerequisites for registration. This can be checked by the local inspection committee constituted by the district registration authority. However, in reality, inspections do not seem to be happening regularly because of poor coordination between the team members in the local inspection committee. Inspections are conducted only when there is a complaint raised against a private health facility.

'Nowadays, so many establishments are there, the committee may not go there, they might sit and tick.' (FGD1)

'As per the Act (KPMEA), the committee should inspect, not just the Taluk Health Officer or even the DHO. But it does never happen. Everybody is never available at the same time…people (members of the registration authority) put their signatures based on trust on their fellow government officer.' (FGD2)

'…Too difficult. IMA people are also busy. Usually they will not come. Some people will insist that they have to come, then only they will sign (in the registration certificate). Here we have not done inspection.' (FGD2)

Securing coordination outside the health department (e.g. police) at the district level was also problematic.

'If we have to book a police case, the police are also not knowledgeable and it is very difficult to explain…police people should also be made aware so that there is good coordination.' (FGD2)

These findings are aligned with the results of a study conducted in two other Indian states, which also identified poor inter- and intra-organizational coordination to be an issue in healthcare regulatory policy implementation.[22]

Issues regarding resource requirements for implementation

Human resource constraints. Officials felt that in districts such as Bengaluru Urban where private health facilities are concentrated, additional staff might be required. In other districts of Karnataka, with the current human resources, it should be possible to implement KPMEA. What matters the most is the willingness of the DHO who plays a key role in implementation.

'DHOs are multi-tasked. But it doesn't mean that a DHO will spend 24 hours because of any particular policy. If he is able to manage his time well, I don't think human resource is a constraint. It is the lack of will that is a constraint. Definitely, no officer is idle, but officer is not straight-jacketed by the government that you have to do this and this. There is a package of duties that you have to do, but you schedule your duties, you schedule your time.' (KI2)

'Once it is fully digitalized, it is not much work. The DHO can do it.' (KI18)

However, there was a lack of workforce for conducting inspections on the AYUSH health facilities. On analysing the human resource data of the State Health and Family Welfare Department regarding sanctioned posts, as on 1 January 2016, 50% of District Ayush Officers and 18% of Subdistrict Health Officers were vacant across Karnataka. An official observed, 'Like for Allopathy, AYUSH department doesn't have government officials at the subdistrict level. There are only 13 government AYUSH doctors in Bengaluru Urban. If they are taken for KPMEA inspection, the dispensary work will get affected.' (KI22)

Frequent turnover of bureaucrats at the Ministry of Health, Directorate of Health Services, District Health Office Bengaluru Urban was a barrier to effective enforcement. During the data collection of the study (2015–2016), the key officials of KPMEA,

holding positions at the state and district levels (Bengaluru Urban) were transferred at least three times. Frequent transfer of government officials is a major deterrent as it gives less time for the officials to gain mastery over the content and implementation mechanics of KPMEA.

Enforcement officials reported that they have to learn about KPMEA on their own. No training was conducted on KPMEA. Officials at the state level felt the need for strengthening competencies of the policy implementers in law enforcement.

'Our doctors and staff up to the DHO level have to be sensitized about all the Acts, rules and how to enforce them…so many of them will be calling "sir this is what happened, what should we do?" There should be a workshop to teach them.' (FGD1)

'…I doubt DHOs' abilities as they are clinicians not oriented to administration.' (FGD1)

The findings indicate that there is a need for training state, district and subdistrict officials involved in implementation of KPMEA. According to best practices in regulatory enforcement, training and competency frameworks would enhance the skills set of regulators and help in achieving regulatory policy objectives.[24]

Insufficient political resources. Policy implementers indicated political interference in enforcement of KPMEA.

'Even if we give notice to the clinic, within half an hour, we get a call from big political people, requesting us to stop taking action on the clinics.' (KI21)

'If I had to enforce law in a private hospital where a politician is taking treatment, the politician says "No, my hospital, my doctor…"; you need to handle with finesse and delicately.' (KI2)

The district officials reported that some illegal clinics have the support of the public since such clinics are offering services at very low cost and the services are available when they need. Officials at the state, district and the subdistrict levels reported incidents of attack by the local people on the KPMEA enforcement team while raiding some fake clinics. The demands of the public are not irrational. In the absence of accessible and affordable formal healthcare, people especially the poor tend to accept the services provided by informal healthcare providers. The evidence from other studies shows that unauthorized healthcare providers are mostly sought for primary care needs. They are often socially embedded and are regarded with high esteem by the communities they cater to.[25,26] In order to gain public support for implementation of a regulatory policy like KPMEA, improving overall access to formal healthcare especially strengthening of the primary healthcare system is the key.

Insufficient managerial resources

Policy implementers have less opportunity to share the concerns and their grievances related to implementation of KPMEA as review meetings on KPMEA at the state level are few. There is insufficient policy oversight. Only when there are some pressing needs, state officials discuss about KPMEA or collect data from the districts. A senior official said, 'Answer to your question is we have not done even one (KPMEA meeting). Only this firefighting, whenever there is a question in the session or issue comes in the media, we (get) active in that district.' (FGD1)

Even communication between the district and subdistrict officials seemed to be problematic.

'We will make recommendations but we will not know what has happened. Only DHO can seize (the clinic). We cannot do that. We don't have the power. We can recommend, that's all.' (FGD2)

'…depends on the person. To some we can give suggestions, others are not open. They (DHOs) are like boss, so we have to keep quiet.' (FGD2)

The chairperson of the KPMEA district registration authority is the head of the general administration of the district. So, he rarely finds time to check how the KPMEA inspections are happening.

The subdistrict officials had concerns about the authoritative nature of a few higher authorities.

'We can log in and see which hospitals we have to inspect. But we will not know how many in total have been registered in our subdistrict. Only (a higher officer) knows. We don't have access to that data.' (FGD2)

'If requested by a higher officer, we go for inspection and submit report. We are not even communicated about the action taken. Once the report is submitted, it is left to the higher officer to take action. What can we do?' (FGD2)

Furthermore, a few stakeholders (KI18, KI14, KI3) indicated the possibility of corruption especially at the district and subdistrict levels in issuing licences. Frequent transfers of bureaucrats at the state and district levels provide less time for them to learn the content as well as the implementation mechanics of KPMEA. High bureaucratic turnover acts as a barrier to ensure coordination as it provides less opportunity to build trustworthy working relationships between the implementing agencies. Iyer and Mani also show in their study that frequent transfers are a feature of Indian bureaucracy.[27] Issues such as poor monitoring, corruption, frequent transfers of officials in the health department of Karnataka, political interference in policy enforcement activities are indicators of serious deficiencies in the overall governance of the health sector. Our findings correlate with the investigation of Huss *et al*. who exposed the existence of corruption in the health sector at all levels in Karnataka.[28] Governance-related problems are rampant and impede the implementation of other healthcare-related Acts in India.[6–9,29]

Strengths

We reached out to a diverse set of stakeholders (government officials at the state, district and block levels, civil society representatives, allopathic private hospital associations, allopathic medical practitioners' association, non-allopathic professional practitioners' association and politicians) to understand their perspectives on implementation of KPMEA. The diversity of stakeholders helped to corroborate various findings. We validated the findings of the study with multiple data sources (interviews, FGDs, analysis of litigations pertaining to KPMEA at the High Court of Karnataka, information from district authorities on KPMEA received through RTI and KPMEA data received from state authorities). Further, the conceptual framework grounded in the scholarly literature on public policy implementation theories guided the data analysis on KPMEA implementation.

Limitations

We are aware that in policy studies, it is nearly impossible to describe (as a researcher) what exactly transpired and what were the precise intentions of all the stakeholders. Our interpretations are based on the information we had access to. It is possible that

during the interviews some officials would have felt that their performance was being appraised when we asked specific questions on the way they do inspections and issue licences to health facilities under KPMEA. This perception would have led to socially desirable responses. We used different data sources and data collection methods to mitigate this problem. Furthermore, we did not explore the general awareness of the public about KPMEA and also the exact role of the media in implementation of KPMEA. The 2017 amendment of KPMEA might have some implications on the implementation processes of KPMEA. Our study does not capture these changes as the data for the study were collected in 2016. However, we have attempted to assess the implications of the amendment on implementation wherever possible.

Conclusions

A regulatory policy such as KPMEA needs clear, comprehensive policy content and directions for operationalization. However, improving the content of the policy is not easy as some aspects of the policy remain contentious with the private healthcare providers/establishments. For effective enforcement of KPMEA, addressing the key governance issues such as corruption, ensuring coordination between the implementing agencies, policy oversight, training, achieving stability in the tenure of bureaucrats in the health department and insulating policy implementation from political interference could be useful. There is a need for additional human resources for enforcement activities especially in urban areas and for inspection of facilities run by non-allopathic practitioners. The potential for engaging civil society in the implementation processes can be explored to foster social accountability. Further, a functional formal primary care system might generate public support for implementation of KPMEA.

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