ORIGINAL ARTICLE

Challenges in Regulating Private Primary Health Care in Malaysia: Perceptions from Key Informants.

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Abstract
Introduction: Malaysians can access primary health care services from public or private facilities. The Ministry of Health regulates the public services, and to a lesser degree, the private practices via the Private Healthcare Facilities and Services Act 1998. With the mushrooming of private medical clinics, issues of accessibility, inequity, and quality of care arise. Currently, there is limited data on the assessment of regulatory performance and this study aims to assess the challenges in regulating private primary health care to assist policy makers in addressing problems associated with private primary healthcare provision.
Methods: A total of 23 key informants categorised into the regulator (7), provider (6), academia (5), media (2), and consumer (3), were interviewed. They were purposively selected through recommendation by research team members, participants or information searching from websites. All transcribed interviews were analysed in accordance with the principles of qualitative thematic analysis, using the manual method in identification and analysing the themes.
Results and Discussion: There were five major themes explaining the challenges in regulating private primary health care pertaining to the regulator, regulations, provider, facility, and the market. Among the main challenges were uncoordinated and fragmented enforcement by multiple regulatory bodies, poor enforcement of the private sector due to resources constraint of the main regulatory authority, and gaps in the regulations for provider competencies, facility monitoring and third-party administrator regulation. The main recommendations to improve the regulation of the private sector included alignment of the policy environment to foster coordinated enforcement for efficiency, strengthening of the main regulatory body, addressing the gaps in the regulations for congruency with the current health landscape in the country, data sharing for policy formulation, and to consider economic aspect of the regulations within the health market.
Conclusion: Regulations for setting standards in providing primary health care in Malaysia have been fulfilled to some extent, however revision of the current regulations and the enforcement mechanism, involving relevant stakeholders, is timely, to achieve equitable and sustainable primary healthcare system.
Keywords: primary health care, private practice, regulations, enforcement, Malaysia.

Introduction

The core of health services delivery in Malaysia is through primary health care (PHC), developed over several medium term Malaysia Plans, with the 11th Malaysia Plan (2016-2020) focusing on achieving universal access to quality healthcare.[1] PHC is a broader whole-of-society approach to health which includes multisectoral policy and action, as well as people and community empowerment.[2] In Malaysia, PHC services are delivered by the public health clinics (HC) and private general practitioner clinics, commonly known as private medical clinics (PMC). PMC are often located in urban areas and they outnumber HC, totalling 7,988 in 2019 as compared to 3171 HC.[3] PMC services are usually utilised when the cost is handled by a third party, as part of health benefit package.[4] Rapid growth of private PHC services has raised concerns on issues of accessibility, inequity and quality care.[5] While the public sector is governed by administrative instruments, the private sector is governed by the Private Healthcare Facilities and Services Act 1998 (PHFSA or Act 586), together with its Regulations 2006; enacted to achieve the national objectives of improving accessibility, equity and quality healthcare in the private sector.[5]

Malaysia has five major acts that directly regulate private providers and 20 other health-related acts.[6] Act 586 provides guidance on seven areas of standard requirements, namely, infection control, emergency care services, organisation and management, pharmaceutical services, policies and procedures, diagnostic services and standard facilities with a total of 194 requirements for compliance.[7]

A local study amongst 515 private medical clinics to identify the compliance to the Act 586 using secondary data from 2008 to 2010 showed that only 45% private medical clinics were categorised as having good compliance.[8]

Malaysia still faces many challenges regarding private health sector regulation including: a lack of incentive to ensure quality of services, accreditation is on voluntary basis without clear benefit to the providers and inspection is usually done upon registration and follow-up inspections are not required unless there are complaints from the public.

Currently, there is limited data on the assessment of regulatory performance of private PHC provision. This study addresses the limited study on assessment of regulatory performance to assist policy makers in addressing problems associated with private primary healthcare provision. This study is part of multi-country regulatory assessment by the Joint Learning Network's (JLN) Private Sector Engagement (PSE) Collaborative, using a country regulatory assessment guide developed by the collaborative members, including Malaysia. The aim of this paper is to explore issues related to implementation of current regulations for PMC.

Materials and methods

Study Design

Utilising the phenomenological approach of qualitative research methodology; the lived experience of relevant stakeholders on how they perceive the regulations of private primary healthcare provision in Malaysia were explored. This study approach enables us to understand about others' experience, knowledge, belief and opinion about the performance of health sector regulations. [9,10]

Participants

Participants from various relevant stakeholders in the healthcare sector were chosen and categorised into five groups: regulator, provider, academia, media, and consumer. Twenty-three participants consisted mainly of regulators (7), providers (6) and academics (6), in almost equal numbers, while only about 20% of them were laypersons [media (2) or consumers (3)]. They ranged in age from early 30s to the 70s and 65% were males. Purposive sampling was chosen because it could yield rich information to answer the research question.[11] They were purposively selected

through recommendation by research team members who knew the key persons representing private PHC in Malaysia, participants or information searching from websites.

Data collection method

Face to face interviews with the key informants were conducted. Participant information sheet were given, and written consent were obtained prior to the interview. This study was registered with National Medical Research Register and approved by Medical Research and Ethics Committee.

Data analysis

All audio recordings were transcribed verbatim, and thematic analysis was conducted Working in pairs, first, the research team members read and reread the transcripts to reach an overall understanding of the main issues in regulating PMC.[12] Next, important codes were addressed, organised, and compared in terms of similarities and differences; and assigned to each cluster of codes. Categories were developed based on similar cluster of codes. The researcher team members then discussed and explored various interpretations of the categories and came to a consensus on the themes. Once the themes were refined, a story line was developed to explain the challenges in regulating PMC. The interviews were concluded with a close ended question, "to what extent do you feel the regulation is fulfilling its mandate?" Participants were asked to rank their response using the scale 1 (strongly disagree) to 5 (strongly agree).

To the concluding question, the regulators ranked higher at 3-4, followed by the academics and laypersons at 2-3, and the providers at 1-4.

Results

The challenges in regulating private primary healthcare delivery in Malaysia can be illustrated in the Figure 1. Five themes with twelve sub-themes emerged to describe the phenomenon.

Theme 1: Regulator

There are many regulations that govern service delivery by PMC, imposed by different agencies, including within and outside the Ministry of Health (MOH), the local councils and the professional boards.

Some of these laws were, as perceived by both providers and regulators, to be overlapping and its implementation contradictory at the different service delivery levels because of uncoordinated and fragmented enforcement by the different regulatory bodies, as well as different requirements under various regulations by different agencies.

"We have the Local Council Act, Poisons Act, then we have the Private Health Care and Facilities and Services Act… and then we have the DOE, Department of Environment, check our sharp bins and all… environment have come and check our clinics …and we also have the local councils coming, checking whether we have our license" (provider)

Sub-theme 1a: Overlapping regulations

Providers and regulators agreed about the overlaps in the regulations because there is no coordination between the regulatory bodies and the enforcement was done in silos and fragmented. Maintenance of cold chain, radiology and personal data protection are the common examples given.

"Sometimes they do not know what the other one is doing, so we've got overlap now. Example, the Personal Data Protection Act (PDPA). PDPA is another regulatory thing which we have to follow now, and under that, the way, they have written out their regulations, it's very different from medical acts again… we are actually being governed by the Medical Act, which is actually even more stringent, as far as the personal data is concerned. And yet, we have to again subscribe to this one" (provider)

Sub-theme 1b: Contradicting regulations

Regulations by multiple agencies are acknowledged to be contradictory by the regulator. For example, laws under the city council which contradicts the infrastructure requirements of the PHFSA. The PHFSA sometimes has more stringent requirements than the other relevant agencies, for example, the fire safety door.

"The Local Government Act is under the city council's sub-regulation and others. That one has many contradictions with our Act. The simplest example I can give is on the ramp. For wheelchair access to the clinic, there must be a ramp from the corridor into the clinic. Certain city councils do not allow the building of this ramp. Many things in the Local Government Act is conflicting with ours. Sometimes, in order to make partitions you have to pay. For us, no need to pay. Sometimes advertisement license, we don't need, but they want. The Fire Department fire resistant door on level one, 0.9 is sufficient, but we ask for 1.2 which impact upon the primary health care clinics" (regulator)

Sub-theme 1c: Costly to comply

Complying to the different agencies' regulations incur cost to the provider.

"In order to comply with the Private Health Care Act and its room allocation and so forth, we have to end up with multiple panels and we end up paying RM 4000, RM 5000, RM 10,000 even," (provider)

Theme 2: Regulations – The Private Healthcare Facility and Services Act (PHFSA)

Overall, respondents felt that there were gaps in the regulations and enforcement of the law is still weak and require urgent attention to human resources constraints.

Sub-theme 2a: Poor enforcement of regulations

The lack of enforcement officers leads to multi-tasking of conflicting roles in educational and punitive enforcement.

"I need to issue compound to you." "Eh, just now you didn't compound me?" This leads accusations." (regulator)

Interpretation of the Act at different service delivery levels is influenced by the competency and experience of the enforcement officer, some of whom are junior, and perceived to be procedural to the letter of the law, not its spirit.

"You put in the same application to let's say 5 different UKAPS centres around the country, you'll get 5 different responses. Because the interpretation is different" (provider)

Sub-theme 2b: Regulations micromanaging

The perception that the PHFSA micromanage was specifically referring to the infrastructure requirements, for example the size of the entrance and toilet door. This view consistently surfaced in the interviews because most of the clinics were not custom made and utilised existing buildings approved by local councils.

"I don't understand why the toilet must be 0.9, we had to break down. The original door is small because the original design is like that. So, we have to break down the brick wall to make it bigger. And we have to increase the size of the toilet to fulfil. So, for me, it's troublesome" (provider)

Sub-theme 2c: Outdated regulations

Regulators raised concerns that the current regulations have not kept pace with advancements in medicine and technology, as exemplified by the lack of regulations on aesthetic medicine and telemedicine in PMC.

"Say for example like nowadays we have apps where doctors can sign up and provide services through apps. But the regulatory mechanism does not cope up with it…does not address that" (regulator)

Theme 3: Provider registration

For registration as a medical practitioner in Malaysia, medical graduates must undergo at least two years of housemanship training at public hospitals followed by two years compulsory

service with public sector facilities. After which, they can leave the public service and open their own private practice.

Sub-theme 3a: Lack of regulatory in requirements for set of competencies of private PHC providers

The participants acknowledged the lack of regulatory requirements for postgraduate training in primary healthcare although there exists postgraduate training in family medicine through the Master programme in the public universities and the alternative membership in the Academy of Family Physicians, which both lead to specialist qualification. The implied lack of competency among private providers surfaced in the discussion as incidents related to botched circumcision in the last few years which had not been reported before among the general practitioners.

"For years we had no problem, suddenly last year we had 2 or 3 problems…It happens either this one is losing competency" (regulator)

Academics admitted that the current undergraduate medical curriculum is geared towards training future doctors who are housemanship-ready, rather than hospital-ready or clinic-ready. The current regulations need to be reviewed to be in alignment with the country's need for more competent providers.

"Our system, we train them to be in hospital. 3 years of clinical work out of which 8 weeks in Family Medicine…whereas the reality of the fact is in a true developed country, 70% of medical graduates should be in primary care" (academia)

It was expressed that more stringent requirement on experience working in the public service before private practice is needed. Comparison with a developed country was made, where a minimum five years' experience of working under a fellow GP and passing an examination was required before they can operate a GP practice independently.

"We want some kind of standard for the GPs. At least a diploma in family medicine. Or master… the only organization that is offering this is AFPM (Academy Family Practice Malaysia). And they have been offering this course for 40 years... they have only produced about 400 of Family Medicine Specialist." (provider)

The current regulation in the Medical (amendment) Act 2012 and Medical Regulation 2017, enforcement of minimum continuing medical education points of 20 for renewal of annual practising certificate (APC) is perceived to be inadequate to ensure that providers have the required competency to practice in primary care.

"What is the CPD point? You gain numbers. It is based on your attendance and all that. What if I go there, sign and left then come back again. My number is there it is still going to be submitted" (regulator)

Sub-theme 3b: Lack of regulations for supporting personnel

While under the PHFSA, only fully registered medical doctor can be the license holder or owner of a private practice and is held accountable for all PMC activities, there is no requirement under the current regulations for them to hire qualified allied health personnel for nursing, laboratory, or dispensing activities. Many examples surfaced during the interview on untrained personnel normally seen at the dispensing counter at the private clinics.

"The person who is dispensing the medicine is not trained. So, we have had complaints, wrong medicine with wrong labelling, because the person filling out is not trained" (consumer)

Theme 4: Facility

Act 586 requires only a one-off registration for private GPs. A private GP is mandated two visits by the regulator, once prior to approval of registration, and a second monitoring visit within one year after the registration. Subsequent visits are ad-hoc, depending on complaints received.

Sub-theme 4a: No requirement for continuous monitoring visit

This lax enforcement is perceived to be an opportunity by the private provider and as a weakness by other stakeholders.

"Local council every year they check the license and all. And then the pharmacy also they will visit every year. CKAPS and UKAPS, they will only come initially when the clinic is open, they will come once. Then after approval, after a few months, they will come again. And after that they will only come based on complaints" (provider)

Sub-theme 4b: No zoning policy

There is conflicting opinion on the need for zoning policy for PMCs. While the independent private providers, academics and regulators agree on the need, group practice providers have expressed their opinion against zoning policy, opting for free market approach as they believe whoever are willing to take the risk, will compete to survive.

"There has to be some zoning… Because right now, they can even open next to another GP also… once the zoning is there, then you can say, we need GPs here and here" (regulator)

Theme 5: The Market

Currently, PMC in Malaysia operate in a free market with less government control in medicine pricing, from manufacturer down to the retailer.

Sub-theme 5a: Third party administrator (TPA) unregulated by Ministry of Health

Third party administrator (TPA) is a growing market in Malaysia and currently the only legal instrument between PMC and TPA is an agreement signed when the clinic becomes a panel under the TPA. TPA had been growing after the year 2000 and PMC received 80% of their business via TPA. There are two types of TPA, insurer and non-insurer, which operate quite differently and are regulated by different regulatory bodies. The main complaints towards TPAs are related to fee splitting, low capping treatment bill, renewal or registration fees, different reimbursement mechanism and interference with treatment regime.

"If they feel that the TPA will be victimizing them or bullying them or whatever later on, or controlling them, they should not sign up. But the fear is that they may not get the panel patient… inverted comma, "forced to" sign up to get more patients" (regulator)

Sub-theme 5b: Transparency in price regulation

There were mixed perceptions on transparency in price regulation. The provider felt the consultation fee was too low and there was a need to review the fee schedule. However, they acknowledged that a higher consultation fee would not be feasible because of the competition among them. There was disagreement on the quantum between the provider and the academics, the former suggesting a higher fee. There is no financial incentive given for promoting wellness as billing is made based on diagnosis. In term of drug pricing, there are price differences among the pharmacies and even the manufacturers. This is attributed to the absence of national drug pricing to regulate prices for both local and imported drugs. The consumers expressed their dissatisfaction about limited information on prices of services at the PMC.

"I don't see the healthcare industry being as open because they are providing the service for me, they have never actually asked me what I wanted. In the sense that they are building a house for me, … they never ask me where I want the house, but I will be involved in paying for it" (consumer)

Sub-theme 5c: Biased complaint mechanism

The existing complaint mechanism was perceived as biased as complaints are handled by fellow doctors. This may lead to conflict of interest. Through the professional society, the identified problematic provider would be consulted before enforcement. It was perceived that there was no standardized complaint management process, with more serious ones, like death, undergoing more rigorous processes as compared to other issues like overcharging.

"Medical profession is very well represented, Director General, the ministers, they're all doctors. So, they tend to have more of an opinion that favours the medical profession" (consumer)

Sub-theme 5d: Lack of data sharing system

Currently, data from PMC that are crucial for policy development are fragmented as there is no unified system to consolidate them. Data that were shared between the public and private sectors were perceived to be aggregated, for example, number of pregnant mothers and number of immunisations given. Granular data on effectiveness of services, such as children who have completed their booster immunisation or diabetes patients with complications were not available.

"We don't know what sort of patients that are coming to the private clinics. We roughly know the communicable diseases, non-communicable, that would be the top on the list. But how good are their management? Why are these patients having a lot of complications, are we keeping these patients too long because of the ability to pay? Are we turning some patients away because they are not able to pay? We're not sure. And we don't have that data" (academia)

Discussion

Regulating private health sector is challenging and may lead to bias in quantity, quality, price, type of services and competition in the market, due to a tension between profit and achieving social and national objectives of an equitable and sustainable health system.[13] Challenges faced by Malaysia are similar to other upper-middle income country (South Africa)[13,14] and low- and middle-income countries (Ghana, Kenya, Mongolia, Morocco, Indonesia, Tanzania, Zimbabwe, Yemen and India) that actively engage with the private sector to improve delivery.[6,15–18]

Private primary healthcare providers in Malaysia are currently under standard setting requirements for registration and licensing from three to eight authorities depending on the personnel hired and services provided.[6] As pointed out by the providers in this study, the multiplicity of regulators leads to overlaps in regulations between the different regulatory authorities, and uncoordinated and fragmented enforcement, which have cost implications for compliance by providers. Therefore, existing licensing and registration Acts need to be coordinated under one umbrella to improve efficiency and alleviate fragmented policy environment [13], while factoring in the complex interactions between the multiple actors within this sector and their engagement with political leadership at different levels.[18]

The key problem in enforcing existing regulations is a weak main regulatory body, as perceived by the providers, regulators, and the academics in this study. MOH has 77 main regulatory staff and 336 clinical and nonclinical staff responsible for regulating private PMC, which is too low a number to effectively enforce the regulations and legislations. Resource constraints afflict effective inspections, handling of complaints as well as manage continual public awareness, which are the foundations of enforcing regulations in many low- and middle- income countries (LMIC).[16] Resources constraint in MOH should be addressed not only through further investment, but also through organisational streamlining and training for enforcement capacity and capability. This would alleviate the dissatisfaction currently expressed by the providers on the conflicting roles, competencies, and experience of the regulators. Better monitoring indicators, more reflective of regulatory performance (e.g., compliance rate improvement), should be introduced as compared to the existing process indicator of number of PMC inspected after registration.

The landscape of the health sector is fast changing while governance for private health sector, through the PHFSA and Regulations, has not kept pace with the changes. Like other countries, existing regulations in Malaysia are outdated and deficient for the medical and technological advances. As expressed by the regulators and the providers in this study, the current regulations need to be reviewed to be in alignment with the country's current health landscape. The review

also needs to address the gap in the regulations on mandatory monitoring of PMC after registration.

Within Malaysia's dichotomous healthcare system, inequalities exist in primary healthcare provision with the geographic distribution of PMCs mainly in the urban areas and primarily run by doctors in facilities which are less well-equipped and with less certified supporting staff. Only 15% of rural PMC hired certified nurses and this is even lower in the urban PMCs. Only 7.6% of the GPs have postgraduate qualifications.[19] This reflects laxity in the current regulations and thwart access to quality services. The academics strongly recommended an urgent review of the provider registration standards, like countries with more stringent requirements for primary care providers and their supporting personnel. This was also a concern raised by the consumers, fearing medical errors.

Similar to the findings from studies in Africa, there is agreement among the participants of this study that regulations to monitor location and distribution of private health facilities, their quality and prices for health services, are inadequate.[13,15,16] The recommendations from the providers and academics included a review of the consultation fees, financial incentive for wellness intervention and national drug pricing to control drugs prices, while the consumers wanted more transparency in the prices of services.

The consumers raised their concern on the complaints mechanism as they perceived the current self-regulation of providers by the professional bodies to be potentially biased.

National policy development is affected by the lack of data from the private sector and a unified data sharing system was recommended by the academics.

Markets result from the interaction of buying and selling health services between user, provider and third party administrator (TPA), requiring economic roles of regulation for promoting competitive practices and consumer protection.[13,14,15] Mushrooming of TPA to handle medical claims make them an important player to be regulated in the market. In 2017, the number of PMC registered with TPA was at 78%.[4] Unfortunately, TPA has not been a good player, with more than half of the GPs alleging meddling in clinical decisions, reimbursements falling short of actual charges, with 69% experiencing non-reimbursement and the majority agreed market competitiveness is increasing for the last five years.[20] Similar to previous studies done locally, the providers demanded for regulation of TPAs in Malaysia. [4,20]

Free market for healthcare might induce market failure and further increasing costs create difficulty for the poor to access.[21,22] While health is seen as a public utility, with universal access to quality services, policy makers should keep pace with emerging market and form effective legal mechanism on marketization process as it is much harder to do it later after the private sector develops and become more formalized.[14,15]

Conclusion

Challenges in governing PMC in Malaysia have been identified and found to be similar to other developing countries. They include uncoordinated and fragmented enforcement by multiple regulatory bodies, poor enforcement of the private sector due to resources constraint of the main regulatory authority, gaps in the regulations pertaining to registration of competent providers, facility monitoring, data sharing and regulation of TPA. Other challenges include transparency in price regulation and a biased complaint mechanism, which were concerns of consumers.

Recommendations to improve the regulation of the private sector included alignment of the policy environment to foster coordinated enforcement for efficiency, strengthening of the main regulatory body, addressing the gaps in the regulations for congruency with the current health landscape in the country and for policy formulation through data sharing, if we are to achieve equitable quality care in our dichotomous system. There is a need to consider economic

aspect of the regulations within the health market, including regulation of TPAs, financial incentives for wellness and price regulation.

Regulations for setting standards in providing primary health care in Malaysia have been fulfilled to some extent, however revision of the current regulations and the enforcement mechanism, involving relevant stakeholders, is timely, to achieve equitable and sustainable primary healthcare system.

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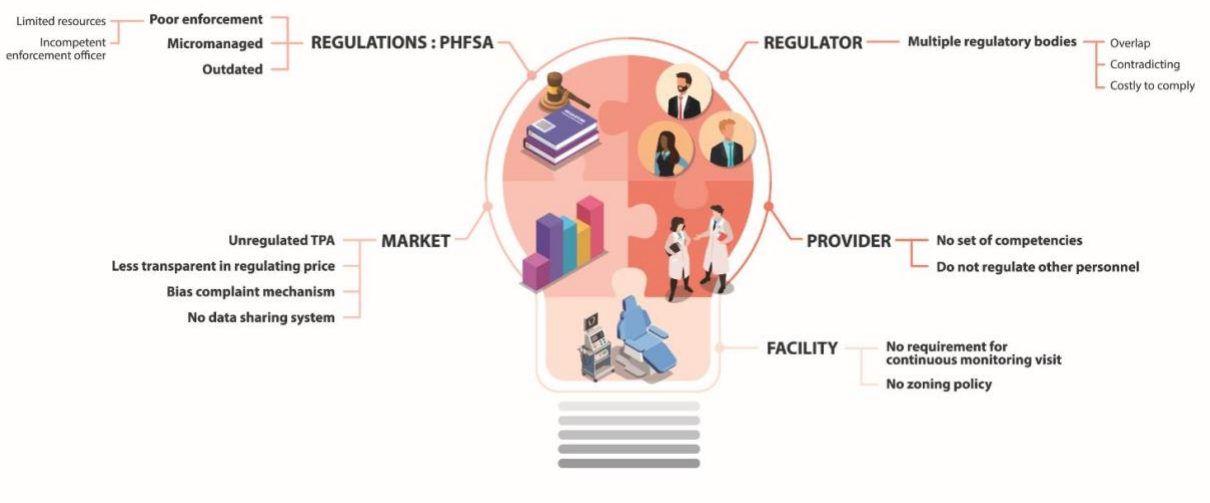

Figure 1. Themes emerged to describe challenges in regulating the private PHC in Malaysia

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