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Compliance to Private Healthcare Facilities and Services Act and Regulations amongst Primary Care Private Clinics in a State in Malaysia

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Abstract

Introduction: The private healthcare facilities and services act and regulations had been gazette in 2006. This act contains seven areas, which evaluates compliancy among clinics to these areas. Hence, it posed as a safety indicator to the act and regulations.

Methodology: A cross-sectional study was done among the private healthcare medical clinics in an urban state in Malaysia. A convenience sampling among 515 clinics were done whereby direct observation and inspection were according to the domains in the act.

Results: Among the 515 private healthcare clinics studied, only 45.0% were categorized as having good compliance, 31.8% moderately compliance and 23.1% as poor compliance level. There were significant associations between level of compliance with owner's ethnicity (Malays), place of graduation (local graduates) and years of working experience (shorter years of service).

Conclusion: The compliance level among the private primary care providers have place for improvement. While determinants are owners ethnicity, graduated local or abroad and years of services. Regular scheduled inspection and enforcement by state managers are to instill provider's compliance to new Act, especially on areas of emergency services to the community.

Keywords: Private clinic; Healthcare act and regulations; Level of compliance; Healthcare providers

Introduction

Over the last few years, there has been increasing interest globally in the issue of patient safety including primary care. Patient's safety issues arise not mainly from provider's negligence but also from failures in the healthcare system to have sufficient safeguards embedded to protect patients.

Despite decades of public investment to assure public provision for basic services especially in healthcare, private provision is still significant and often dominant [1]. In many countries, private healthcare is expanding very rapidly. In most of developing countries, private healthcare providers play a large role in health provisions. The private health cares are most prominent in delivery of primary and curative care, mainly cited due to lower capital requirements, high demand and patient's willingness to pay [1]. Despite widespread concern about the clinical quality they can offer, patients often bypass public facilities to utilize private providers for reasons of convenience and responsiveness [2]. In particular, the private providers have always been credited for being more 'sensitive' of local circumstances, more flexible and less politicized in operation [3].

Private providers are defined as those who fall outside the direct control of the government [4]. Private ownership generally includes for-profit and non-profit providers, although in Malaysia it's more for profit making. There are not many non-profit clinics available. These are usually private healthcare operated by religious missionaries and other non-governmental organizations (NGO's) [1]. There are many functions of health services regulation in Malaysia. The aim of regulations is to improve equity and access through geographic redistribution, or protect the public by controlling the quality of the healthcare services clients received [5]. Thus, these in return protect the public by socially oriented regulation. The most familiar type of regulation consists of legal restrictions or controls that require providers to conform to legislative requirements. If they do not abide by these laws, then providers are liable to punishment. Types of local regulations that are usually done via control include health facility licensing, heath care facility accreditation, health personnel credentialing, utilization reviews and medical audits, outcomes research, practice guidelines and clinical protocols [5].

The Private Healthcare Facilities Services Act and Regulations is a formulation of public policy toward private healthcare providers and their services. Private healthcare is an important component of Malaysia's healthcare system and has received intense policy attention. Dominating the out patients services, majority of state public attend private clinics as an alternative to the slower pace and heavily burdened public primary care centers. A striking setback of this and gathered attention in many developing countries are the lack of basic data available on private health care provision [1,5]. Due to this deficit, policy makers lack evidence to identify and implement positive rectification process or address problems associated with the private provision. The state and local governments are strengthening their roles in reinforcing regulations together with research and development to identify shortfalls and to find ways of improvements.

Effective regulatory systems are able to create high public esteem in which the medical profession is held. But regulation is a dynamic process and must be scrutinized, challenged and improved to ensure it takes account of our changing society and health care environment.

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All regulated healthcare professionals are required to prove their competency and facilities safety, so as that they remain up to date and fit to practice [6]. In Malaysia, there have been a limited number of studies on private healthcare showing this important component of the health system may need extra attention. Aggressive efforts are focused on the development of policy and legislative frameworks that shape the private healthcare service quality.

This study are to identify and evaluate compliance and its' influencing factors to the Private Healthcare Facilities Services Act and Regulations. This was done amongst private healthcare clinics in a highly urbanised state in Malaysia. Data from 2008 till 2010 were utilised and we hope, this information will assist policymakers to develop strategies to identify risk areas and improve areas of weaknesses in the system.

Methodology

This was a cross-sectional survey conducted using data from 2008 till 2010 among registered medical private healthcare clinics in one of the fourteen states in Malaysia. Data was taken from the Private Medical Practice Unit (UKAPS), Health Department. Sampling of clinics was done conveniently. A total of 515 private healthcare clinics were being studied with total coverage of 25% from total private healthcare clinics in that state. Private healthcare clinics included in this study are those providing primary care services and outpatients specialist care.

Six months before the inspection date, the selected private healthcare clinics were informed regarding the clinics' impending inspection by letter and notification via e-mail. The checklist on items to be evaluated, were also given in order for owners and staffs to make early arrangement and improvisation. One day prior inspection, they will be reminded again by phone. Clinic evaluation and inspection were done by two officers from the UKAPS consisting of one medical officer and one paramedic personal.

Study factors measurement

The private healthcare evaluation can be divided into two parts: documents inspection and facilities and services inspection. There are seven domains being evaluated.

- Organizational and Management of clinic
- Policy and Procedures
- Infection Control
- Special Requirements for Emergency Care Services
- Special Requirements for Pharmaceutical Services
- Special Requirements for Radiological or Diagnostic Imaging Services
- Facilities Requirement

Outcome factors measurement

The level of compliance can be divided into three outcomes, based on the total scoring either good, moderate or poor compliance. For further analysis, the moderate and poor comply are pooled and categorised as non-comply.

Method of analysis

In the analysis, the descriptive characteristics and clinic ownership such as gender, ethnicity, owners' place of graduation and years of experience were analysed. The frequencies and percentage distribution of private healthcare clinics based on compliance level and the associations between the compliance level and various factors were compared. In subsequent analysis, association of compliance level with five domains under study were determined.

Statistical analyses were performed using the Statistical Package for the Social Sciences 20.0 (SPSS 20.0). Data analysis were done using chi-square, t-test and logistic regression. Statistical level of p less or equal to 0.05 was taken as significant.

Results

Characteristics of private healthcare clinics

As shown in Table 1, from 515 private healthcare clinics being studied, majority (95.9%) were categorized as general outpatient clinics. Only 4.1% offered specialty services. Type of specialist services offered was medical services, paediatrics, obstetrician and gynaecologists and family medicine. Majority are solo practices at 81.0%, while only 19.0% were owned by group practice. Solo practice clinics are defined as clinics which are wholly owned by only one individual doctor. All the equity in the clinics is owned by an individual but he/she may employ other doctors as assistant but they do not hold any equity of share in the practice. A group practice is defined as clinic which are owned by more than one doctor, each of them hold some equity in the clinics [7]. This study showed a tremendous increase in proportion of solo ownership, in contrast of a previous study that elucidated about 64.7% were solo practitioners owned, while the other 35.3% were owned via group practice [7]. Only 7.2% of these clinics operated 24 hours while majority 92.8% operated less than 24 hours. These findings were similar with a previous study by Al Junid et al. [7].

Characteristics of clinic ownership

Table 2 shows the characteristics of clinic owners. A vast majority are owned by male doctors at 70.9%, while 29.1% are female owners. There is an imbalance among providers in term of gender. The male practitioner dominated the clinic ownership in the ratio of 70:30. The findings of male domination in private healthcare clinics are similar in many other countries. This gender maldistribution might cause difficulty and unsuitability to the female populations needs due to gender barrier especially concerning with cultural or religious barriers concerning women and maternal issues [8]. Therefore, policy for equal gender distribution among private healthcare clinics should be formulated.

Even though the Indian ethnicity group makes up only 8% of the whole Malaysian populations [4], however they owned 33.8% of private healthcare clinics. It is almost equal number with the Malays (35.9%) who made up 65% of the Malaysian populations [9]. Chinese contributed to 21.6% of the clinic ownership. This represented the similar proportion of Chinese in Malaysia. The exceeding number of Indian practitioners and less of Malay practitioners in proportion to the populations should not lead to any disparities since Malaysia consist of multi ethnics and most of the areas are categorised as urban or suburbans. Urbanites have less language barrier within races as compared to rural. From a study by Sharifa Ezat et al [7], it was concluded that 90% of the private healthcare clinics in Selangor were located in the urban areas. Among the clinics owners, 60.2% graduated overseas. Majority experienced more than ten years in the medical field, only 5.8% had working experience of less than ten years. It also shows the compliance level among the clinics. Unfortunately, even though six-months prior notices were provided to clinics, only 45.0% of clinics were categorized as good compliance. As high as 31.8% were categorised as being moderately comply and 23.1% was considered poorly comply (Table 2).

Characteristics	Frequency	Percentage, %
Type of Services:		
General Outpatient	494	95.9
Specialist Services	21	4.1
Type of Practice:		
Solo	417	81.0
Group	98	19.0
Operating Hours:		
Non-24 hours	478	92.8
24 hours	37	7.2

Table 1: Characteristic of private healthcare clinics in Selangor, Malaysia.

Characteristics	Frequency	Percentage, %
Gender:		
Male	365	70.9
Female	150	29.1
Race:		
Malay	185	35.9
Chinese	111	21.6
Indian	174	33.8
Others	45	8.7
Graduated from:		
Local	198	38.4
Oversea	310	60.2
Missing data	7	1.4
Years of Experience:		
≤ 10 years	30	5.8
11 to 20 years	218	42.3
≥ 20 years	262	50.9
Missing data	5	1.0
Category of Compliance:		
Good	232	45.0
Moderate	164	31.8
Poor	119	23.1

Table 2: Characteristics of clinic ownership.

Variables	Categories	Compliance		Chi-square	p-value
		Good Comply	Non Comply		
Type of Services	General Outpatient Specialist Services	223 (45.1%) 9 (42.9%)	271 (54.9%) 12 (57.1%)	0.042	0.837
Type of Practice	Solo Group	181 (43.4%) 51 (52.0%)	236 (56.6%) 47 (48.0%)	2.390	0.122
Operating hours	Non 24 hours 24 hours	217 (45.4%) 15 (40.5%)	261 (54.6%) 22 (59.5%)	0.327	0.567
Gender	Male Female	171 (46.8%) 61 (40.7%)	194 (53.2%) 89 (59.3%)	1.642	0.2
Race	Malay Chinese Indian Others	102 (55.1%) 45 (40.5%) 70 (40.2%) 15 (33.3%)	83 (44.9%) 66 (59.5%) 104 (59.8%) 30 (66.7%)	12.641	0.005*
Graduation	Local Overseas	107 (54.0%) 122 (39.4%)	91 (46.0%) 188 (60.6%)	10.525	0.001*
#Experience (mean, years)		20.86 ± 8.04	23.52 ± 9.89	-3.284	0.001*

*significant, p<0.05
t-test
Table 3: Comparison on level of compliance among private healthcare clinics.

Private healthcare clinics characteristic and compliance level

Table 3 shows the relationship between compliance and clinic characteristics. There was no difference between levels of compliance with type of services. Among the general outpatient clinics, 45.1% have good compliance while 54.9% were non-compliance. Among the specialist providing services clinics; 42.9% have good compliance while 57.1% were noncompliance. Among solo type of practitioners, good compliance is lower (43.4%) than non-comply (56.6%). While group practitioners, good compliance are higher (52.0%) than those non-comply (48.0%). However, the difference is not significant. There are no significant associations between operating hours and compliance. Both operating less than 24-hours and 24-hours are mostly noncompliance (54.6% and 59.5%). On gender ownership; both male and female owners were predominantly noncompliance (53.2% and 59.3%) (Table 4). Only 46.8% of male and 40.7% of female owners had good compliance. There is a significant association between level of compliance and ethnicity. Among the Malay owners, the prevalence of good compliance exceeds the non-comply (55.1 and 44.9%). While for the other ethnicity the prevalence of non-comply exceed the good compliance level (59.5% and 40.5% for Chinese, 59.8% and 40.2% for Indian and 66.7% and 33.3% for others).

Further analysis via multiple logistic regressions revealed the risks for noncompliance among Chinese owned clinics was 1.802, Indian 1.826 while 'others' 2.458 (as shown by Table 5) using Malay as the reference group and the associations is significance (p value <0.05). There is significant association between compliance and owners graduation venue i.e. graduated locally or abroad. Those who graduated from local medical institutions were seen as owners with better compliance at 54.0% while the remaining 46.0% were non-compliance. Among those who graduated overseas, only 39.4.0% was compliance while majority at 60.6% were non-compliance (Table 3). Among the good compliance group, the mean years of service was shorter at 20.86 ± 8.04 years, while for the non-compliance group, they had longer duration of services at 23.52 ± 9.89 years. This difference in experience was significant (p=0.001). Longer service doctors may be seen as being complacent or have learned of ways and means of bending the rules while avoiding penalties. In Table 6, it showed significant association between providers' ethnicity and place of graduation. Among Malays, majority (76.5%) graduated from local institutions compared to Indian ethnicity when majority (94.7%) graduated overseas.

Adherence to compliance areas

The following table illustrated (Table 5) the significant associations between the five domains under the act and compliance level. In the organization and management domain, as high as 82.7% possessed good compliance; while under policy and procedure, 79.3% had good compliance. Clinics area of infection control practice, 62.9% had good compliance and on emergency care services, those who had good compliance were the least at only 53.8%. This showed the major deficit area under study, which was considered the emergency care services that may not be well-equipped enough. Under the area of infrastructures and facilities, 60.0% had good compliance. The area under organisation and management had highest adherence to the act and as shown had the highest prevalence of compliance. The chi square analysis also presented that the area of policy and procedure had the highest percentage of noncompliance at 94.2%.

Discussion

The Private Healthcare Facilities and Services Act and Regulations, 2006 [10] was formulated and implemented to provide guidelines

	Odds Ratio	p-value	CI 95%
#Malay	1	0.006*	
Chinese	1.802	0.015*	1.119-2.904
Indian	1.826	0.005*	1.201-2.777
Others	2.458	0.010*	1.240-4.872

Reference group
*Significant, p<0.05

Table 4: Association between prevalence of non-comply among private healthcare clinics owner by ethnicity.

Domain		Compliance		Chi-square	p-value
		Good Comply	Non Comply		
Organization and Management	Good Comply Non Comply	134 (82.7%) 98 (27.8%)	28 (17.3%) 255 (72.2%)	135.463	<0.001*
Policy and Procedure	Good Comply Non Comply	218 (79.3%) 14 (5.8%)	57 (20.7%) 226 (94.2%)	279.213	<0.001*
Infection Control	Good Comply Non Comply	210 (62.9%) 22 (12.2%)	124 (37.1%) 159 (87.8%)	121.986	<0.001*
Emergency Care Services	Good Comply Non Comply	219 (53.8%) 13 (12.0%)	188 (46.2%) 95 (88.0%)	60.160	<0.001*
Infrastructures and Facilities	Good Comply Non Comply	129 (60.0%) 103 (34.3%)	86 (40.0%) 197 (65.7%)	33.330	<0.001*

*significant, p<0.05

Table 5: Compliance level by domain.

Ethnicity	Place of Graduation		Chi-square	p-value
	Local	Overseas		
Malay	140 (76.5%)	43 (23.5%)	213.410	<0.001*
Chinese	47 (43.1%)	62 (56.9%)	-	-
Indian	9 (5.3%)	162 (94.7%)	-	-
Others	2 (4.4%)	43 (95.6%)	-	-

*significant, p<0.05

Table 6: Association between provider's ethnicity and place of graduation.

for healthcare providers regarding the mandatory and standard requirements in areas of its' organisation and management, policy and procedure, infection control, emergency care services, pharmaceutical services, radiological services and standard facilities [11]. The aim of the regulations is to improve and protect the public by controlling the quality of the healthcare services received [5].

The percentage of clinics that comply with the act and regulations are worrisome since out of 515 clinics, only 45.0% fall under that category of good compliance, while 31.8% were categorised as moderate and 23.1% categorised as poor. According to the level of compliance set by the UKAPS, good compliance also implied as 'safe'. Moderate compliance clinics will receive a warning within three months period of rectification while poor compliance indicates a pending revoke cor (based on further recommendation of the Ministry of Health and approval from the Director General of Health's' directive). The term 'safe' do not signify the true 'safety'. Since it is the prerogative and responsibility of the Malaysian Medical Council (MMC), to further determine whether a practitioners' practice as ethical, acceptable and safe professional practice (mandated under Medical Act 1971) [12]. The UKAPS sole responsible is for monitoring, licensing and registration of private healthcare facilities as regulated by the act [13]. However, all the seven domains investigated in the checklist are a prerequisite for safe practices among the healthcare provider. Early prior six months notification together with guidelines was already given prior inspection. Clinics which continue to poorly adhere to the act signify lack of attitude and recalcitrant behaviour of its owners. Place of graduation might be a good indicator in determining the quality and attitude of providers, since difference in teaching scope, teaching methods and syllabus between different centres of training may play some role in this. This signifies the importance of introducing local safety policies before accrediting any medical teaching institutions and prior acceptance by this country accreditation board. All the five domains evaluated are important in primary care, since failure to adhere to any domain may lead to overall clinic 'failure' as manifested by noncompliance. All these requirements are the basis that must be fulfilled by providers ensuring higher quality of services are provided to the community. This is extremely important if we are to compete with international clinics that have a foot hold in Malaysia's healthcare. The health tourism is also important in obtaining all players adhere to the act and regulations no matter how difficult and taxing they may be.

In Malaysia, so far we cannot found any studies that determine the compliance level to the act and regulations among the private healthcare facilities. Thus reference using local studies is minimal. This study is not without its shortcomings. This study analyzed only secondary data just two years after the introduction of the act. Hence many open ended and response of owners can't be assessed. The findings also only conformed to a portion of a highly urbanised state, and cannot being generalised to the whole country, where proportions of rural areas may far exceed the urban. A wider study coverage and qualitative study can provide useful information to policy makers in order to formulate better strategies to ensure higher quality of services delivered to the community at large.

Conclusion

The compliance level among the private healthcare providers were still far from satisfactory level. Regular scheduled inspection must be taken seriously and implemented. A more strict actions and enforcement in the scope of licensing and registration must be taken without prejudice following evaluations. The effect of penalties such as closure or monetary fine may induce better compliance to acts and regulations deployed by the government.

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