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Regulation, quality reporting and third-party certification of healthcare providers

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REVIEW ARTICLE

Regulation, quality reporting and third-party certification of healthcare providers

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Abstract

The newly established provincial healthcare commissions in Pakistan have started certification of healthcare providers. The policy-makers perceive that without third-party certification or licencing the healthcare quality will be suboptimal in the country. This paper reviews the current literature on third-party certification and studies objectives and progress of the largest healthcare commission in Pakistan. It analyses the certification role of the Punjab Healthcare Commission and draw lessons for future regulation and strengthening of the quality reporting process. It also documents the short-term and long-term trade-off resulting from the enforcement of quality certification in the absence of appropriate alternative investment in medical training and care provisions in the country for uncertified providers. The paper concludes with a roadmap for future research to improve healthcare regulation in Pakistan.

Keywords: Healthcare provider, Regulation, Care quality, Third-party certification.

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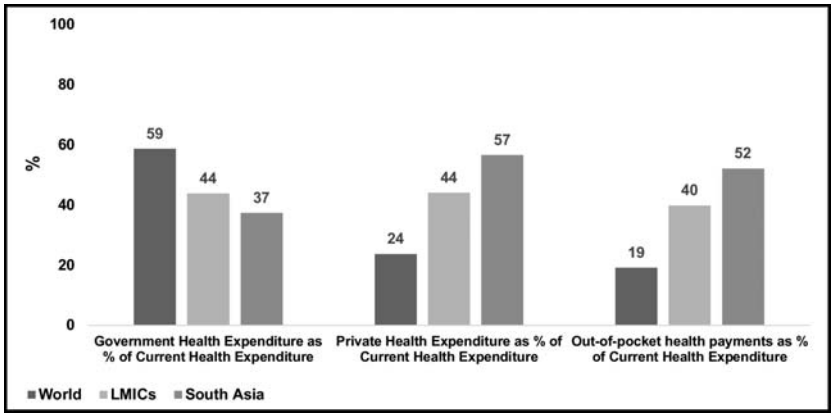
Introduction

The regulation of healthcare industry in low- and middle-income countries (LMICs) is minimal.[1] LMICs in general, and South Asia in particular have mixed health systems where private and public healthcare services exist in parallel. There is a large government-funded national health system in many LMICs which is in some sense regulated due to standard operating rules and government ownership, but the substantial portion of demand of health services fall on private and non-government health system, and this fact can be validated by comparing out-of-pocket expenses on healthcare in South Asia, LMICs and high-income countries (HICs).[2] The private expenditures make up 57% of the total spending in South Asia compared to 24% in HIC, and out-of-pocket payments represent almost half of the current health expenditures in South Asia (Figure-1). Given the nature and extent of mixed health system, the regulation of private healthcare is an important agenda item in healthcare policy in LMICs, including South Asia.



Source: Authors compilation from, Global Health Expenditure Database.[26]

Figure-1: Health finance stylised facts.

In addition, the transactions in healthcare industry involve imperfect information, where supplier of the service (a doctor) has different set of information than the consumer (patient) or in majority of the cases has more knowledge (asymmetric information) about the type of treatment required.[3] In the context of poor countries, asymmetric information in medical care generates incentives for the healthcare practitioner to oversubscribe or wrongly subscribe (e.g. quackery). This practice will have consequences for both prohibitive cost and low quality, or unnecessarily high quality, for the patients with limited information about the given treatment's effectiveness or diagnosis. In a large mixed health system, it is virtually impossible to monitor each transaction in the market. Therefore, the regulation of healthcare

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establishments is inevitable if a level playing field is intended in the healthcare markets of LMICs. The regulation of health industry includes the certification of staff, regulation of pharmaceuticals sales, actions against quackery and issuance of license to healthcare establishments to enter or operate in the market. There is a dominant view that without third-party certification or licencing the healthcare quality in the industry will be suboptimal.[4]

Since the start of the current century, public policy focus in many countries has been shifted from the cost of healthcare to the quality of service provisions. Although universal access of healthcare at an affordable cost is a still priority for many governments, the regulatory authorities in the mixed health systems, like in Pakistan, have started raising concern on the quality of healthcare. Third-party health certifiers play a pivotal role in quality regulation enforcement in medical care. Third-party certification affects both the demand for healthcare and the incentives to improve healthcare quality.[4] Health report cards and pay for performance (P4P) compensations are two popular policy options in this regard. The report cards provide information about a health facility to patients and decision-makers, while P4P compensations link pay incentives to performance quality of a healthcare worker.

The regulation of healthcare sector and third-party certification of providers is not common in LMICs, where healthcare bodies to regulate service provisions are in early stages.[1] In Pakistan, Healthcare Commissions (HCCs) were established during the first of half of the last decade in most of the provinces to regulate quality of healthcare provisions. After the devolution of the health sector to the provinces, provincial governments in Punjab, Sindh and Khyber Pakhtunkhwa (KP) established HCCs in their respective domains through provincial legislation to regulate public and private healthcare providers.[5,6] One of the main functions of HCCs is to issue licences to all public and private healthcare organisations (HCOs) for providing healthcare services. According to the Punjab Healthcare Commission (PHC), an HCO or health establishment is defined as: "a hospital, diagnostic centre, medical clinic, nursing home, maternity home, dental clinic, homeopathic clinic, 'tibb' clinic, acupuncture clinic, physiotherapy clinic or any other premises or conveyances wholly or partly used for providing healthcare services".[6]

To regulate large private establishments along with public providers looks like an ambitious government plan. There is significant investment involved in the establishment of quality care regulation. However, once effective quality regulation is in place that can improve the service delivery quality for millions in the country. Therefore, a parallel research agenda needs to be established to evaluate the current interventions by HCCs and to study how this investment in third-party regulatory bodies benefit the public and healthcare providers. To generate proper understanding of third-party certification in the current context in Pakistan requires research. The current reviews was planned to study the current relevant literature and to study the objectives and progress of PHC, which is the largest HCC in Pakistan. PHC was selected as a case study for the purpose. Also, PHC was selected because the other provincial HCCs in the country are still in the formative stage, while PHC is well-established since the approval of the act by the provincial assembly in 2010. This paper analyses third-party certification role of PHC and draws lessons for future policy-making and strengthening of the quality reporting process. We also planned to analyse the gap resulting from forcing quality certification in the absence of appropriate alternative investment in medical training and care provisions in the country.

This paper is divided into three further parts. The first section below discusses the current state of third-party certification in healthcare in selected markets around the world, and documents the objectives of healthcare certification and progress to date. The next section analyses the case of third-party certifiers and documents PHC's progress with the focus of the role of regulators in collecting information from providers and practitioners and the process of making this information available for patients and public. The last section synthesises the findings from international practice of third-party certification and the current practice of licensing by PHC. We analyse how HCCs can achieve the intended targets of certification practice and how better quality data can be generated to improve the current processes. Lessons are also drawn for future policy and further research.

Third-party certification in healthcare

Third-party certification, regulation, and quality reporting are interlinked topics in the economics of quality reporting in healthcare. The apparent link is that certification and reporting will require enforcement through an authority such as a regulator or a healthcare commissioner. The exact nature of the institutions which enforce quality control and regulation differs across countries. For example, in the United Kingdom, the National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care, while Care Quality Commission (CQC) functions as the independent regulator of all health and

social care services.[7,8] Both NICE and CQC are non-departmental public bodies and are in contrast with the National Health Service (NHS). In India, the National Accreditation Board of Hospitals and Healthcare Providers (NABH) was established in 2006 for the accreditation of public and private healthcare providers.[9] NABH is employing patient and provider-based quality measures for the accreditation of quality standards. Given the nature of healthcare market where asymmetric information is prevalent, quality control in healthcare is central to the regulatory bodies. The essential role of monitoring and reporting quality is to provide appropriate information to the decision-makers, including patients and practitioners, that will generate better incentives and increase efficiency of service delivery in the health system.

Third-party certification falls under the realm of quality assurance in healthcare. The two key instruments used in this context, in sequential order, are licencing of providers, like hospitals and doctors, and disclosing information to the patients. Both activities are interlinked, as data collection is not possible without a formal registration process at the first stage. Licensing is a regulatory process which allows a firm's entry into the market; without a licence the healthcare establishment cannot operate legally. Licencing involves a certification activity in a sense, as the licencing authority collects data on the quality from a provider and then confirms that the quality exceeds a certain quality threshold. After certification, the licencing authority or a third-party evaluates and repots data about quality to the public. For instance, Healthgardes collects and reports extensive data on United States healthcare market for decision-making to connect patients and providers.[10]

Licencing healthcare establishment sends signals to patients regarding the quality of the services. But given that a licence is essential to operate in the market, it is not easy to differentiate healthcare providers merely based on licensing. The licencing alone will not solve the limited information problem because provision of healthcare is an "experience good" by nature. Alongside formal certification, the report cards have been adopted as main quality assurance mechanism in many markets around the world. Dranove discussed other quality assurance mechanisms in detail and has listed shortcomings of other leading mechanisms, such as branding, personal experience, and warranties in the context of healthcare.[4] The key finding is that where other quality assurance measures failed to work in healthcare, the space was captured by healthcare report cards or consumer report cards. The regulation in Pakistan is so far focussed on licencing of providers and certification of professionals. The implementation of health report cards might benefit the public depending on design and utilisation of these cards.

Although inputs, processes and outcomes are three important components, most of the report cards are based on the clinical outcome (Table-1). The key questions regarding the definition and measurement of a health report card are worth having a look at (Table-1). In the US, 'Medicare' reports death rate for heart attack or rate of readmission as outcome measures relative to US national rate for a given hospital.[11] As the evidence shows in the US market, the selection of outcome measures for reporting is not problem-free. The choice of outcome measures affects healthcare provider behaviour depending on the nature of adverse selection, multitasking problem, and quality distortion problem. Dranove reviewed these challenges and reported results on report card performance.[4] The literature so far has focussed on evaluation of the programmes and not much has been done on designing an optimal scheme.[4]

Previous studies have addresses three broad type of questions that are relevant to measure the effectiveness of third-party certification and licencing in healthcare industry.[4] First, do healthcare providers provide the right information to regulators or patients? Second, does more information and knowledge effect the choice of patients while selecting the healthcare? Third, does providing more information to patients and third-party reporting

Table-1: Economics of healthcare provider quality reporting: taxonomy.

Goal	What to measure?	Challenges
Provision of more information through report cards for the patients, the doctors the regulator for better incentives to enhance efficiency and improve decision making.	◆ Outcomes or changes in clinical outcomes: mortality rates, surgical complications ◆ Process: Implementation of SOPs adoption of accepted processes and guidelines. ◆ Inputs: Human capital, staff development, trained nurse ratios.	◆ Health outcomes are hard to measure or poorly measured at provider level ◆ Adjusting for health status risk is difficult. ◆ The healthcare provider will report or pick the measures that shows all is good.

Source: Dranove (2011).[4]

Table-2: Summary of selected studies on third-party certification.

Study [Year/Country]	The impact of exposure to information
Brown et al [2013/US][20]	No evidence of substantial use of public reporting of cardiac surgeon report cards, no substantial use of publicly available information by doctors at the time of discussion or referral for cardiac surgery.
Chen & Meinecke [2012/US][21]	No evidence on patient selection by providers, only minor decline (0.05 percentage points) in mortality rate for patients with bypass surgery.
Chou et al [2014/US][13]	Yes: After the availability of online report cards, hospitals in more competitive markets used more resources per patient and achieved lower mortality among more severely ill patients.
Kraska et al [2016/Germany][14]	Yes: Results indicate a positive effect of public reporting on hospital care, independent of a hospital's profit orientation. Improvements in the quality of care were registered for all observed quality indicators over time, but public reporting stimulated a faster improvement in quality.
Maggard-Gibbons [2014/US][18]	Yes: Findings show that feeding outcomes back to healthcare providers, along with real-time comparisons with other hospital rates, leads to quality improvement, better health outcomes, cost savings and overall improved patient safety.
Paddock et al [2015/US][22]	No: Current information not useful due to low variation in the report cards score. Analyses illustrate the need for further innovations in the design of public report cards to enhance their utility for consumers
Pesis-Katz et al [2013/US][23]	Yes: Evidence on choice consideration in nursing home selection. Consumers choose a nursing home based on the quality dimensions that are easy for them to observe, evaluate, and apply to their situation.
Scanlon et al [2015/US][24]	Yes/No: Investment in care quality information provisions results in modest change in awareness about physician quality among patient with long term conditions. But no significant increase in awareness of hospital quality was observed in the study.
Shi et al [2017/US][15]	Yes: Among those who were not aware of physician quality at the baseline the likelihood of physician quality awareness increased by 3.8 percentage points once physician information was available in community.
Sinaiko et al [2012][16]	No: Authors found broad agreement that public reporting has been disconnected from consumer decisions about providers because of weaknesses in report card content, design, and accessibility.
Werner et al [2016/US][25]	Yes: The nursing home star rating system significantly affected consumer demand for high- and low-rated nursing homes.

improve quality of healthcare? The answer to these questions can be useful in evaluating new licencing and certification initiatives in Pakistan and other LMICs. Literature has answered the above questions regarding report cards in recent years. For the current review, studies were selected after search on Medline database at Elton B. Stephens Co (EBSCO) with key words "report cards AND healthcare OR "health care" for the period between January 1, 2012, to December 31, 2017.

Do healthcare providers disclose quality of service provisions? Most scholars start with Grossman's 1981 theory of unravelling which suggests that under certain assumptions, providers will disclose information even in the absence of third-party certification.[12] However, the two important assumptions for theory of unravelling are untenable in most situations prevailing in LMICs. The first assumption says that in a given market healthcare providers are fully aware of quality of each other. The second assumption says that beliefs about quality held by consumers are consistent with provider quality. Under the second assumption, a provider will declare quality only if it is certain that quality is higher than the general belief held by the consumers.[4] Healthcare professionals also voluntarily declare some information, like their professional qualifications which are prominently displayed in the clinics.

Studies show a mix evidence for the certification of providers and provision of care quality to patients and community. Based on the evidence collected from the review, some findings require attention. There is conflicting evidence on the impact of quality disclosure on hospital mortality rates. There is some evidence of positive health gains in more competitive markets.[13] This finding is important for healthcare markets with the presence of large number of private providers as these providers will be competing for consumers in a giver market, and disclosure can result in potential vertical sorting.

There is also evidence that providers improve quality reporting standards after the implementation of third-party certification requirement which is accompanied by more consumer awareness about comparative hospital quality.[14,15] The improvement in hospital reporting of quality is not free of problem if there are incentives in the reporting of the listed indicators. Hospitals can also improve the reporting on indicators which shows a better picture of the hospital rather than improvements in actual care experience of the patients. Finally, studies show that there is need to improve the reporting standards and better-designed health reporting system for the certification process.[4,16]

Quality regulation and licencing in Pakistan

The regulation of healthcare sector and third-party certification is not common in LMICs and the quality care regulators are in their early stages in many countries.[1] Lack of regulation of health industry is considered a major

challenge and the absence of checks in health system results in low quality and inequitable health service delivery.[5] The current research on the economics of healthcare also demonstrate that since the last decade, public policy focus has shifted to quality considerations from cost considerations.[4] The reporting of medical negligence, maladministration and malpractice cases is common in LMICs.[1,17] Similar realisations have led provincial governments in Pakistan to put in place legal provisions for installing healthcare quality regulators. These organisations are formed to improve quality of healthcare and ban quackery in medical practice. We planned to focus on the Punjab province only as the care commissions in other provinces are in very early stages of formation while in Punjab, the commission is functional since 2010. The framework of quality regulation is quite similar in other provinces as well, where all the regulatory bodies are formed through provincial legislation.

The experience of PHC and related analysis are based on data from published and official PHC sources, including PHC's social media account and its website.[6] The analysis is conducted to address two fundamental questions; how PHC collects and processes the information related to quality of providers; and what are the actions by PHC that might signal or directly provide information about provider's quality to the public and patients.

In Punjab, the third-party certification process consists of key components of registration and licensing of the providers. Registration and licensing are two interlinked but distinct concepts. According to the PHC Act, "an unregistered healthcare service provider shall not provide healthcare services". Licencing is the second stage of third-party certification. The mechanism of registration and licencing is public knowledge (Figure-2). It is evident that without PHC registration, no one can provide healthcare services in the medium to long run otherwise penalties will be implemented by the commission for any violation of the PHC Act 2010.

The coverage of registration and provisional licence data compiled by PHC shows that in total 57,221 healthcare providers are registered with the PHC.[6] The private providers account for 91%, which highlights the scale of private healthcare in the provision of overall health services in the most populous parts of the country. The nature of limited information problem in medical practice and existence of private healthcare provision at such a large scale requires an effective regulatory regime. Therefore, the establishment of regional HCCs in Pakistan looks like a step in the right direction. About 71 % of the registered providers have been issued the provisional licences by the PHC. Disaggregated data shows that only 54% of the registered public healthcare providers are provisionally licensed, while this figure is 73% for the

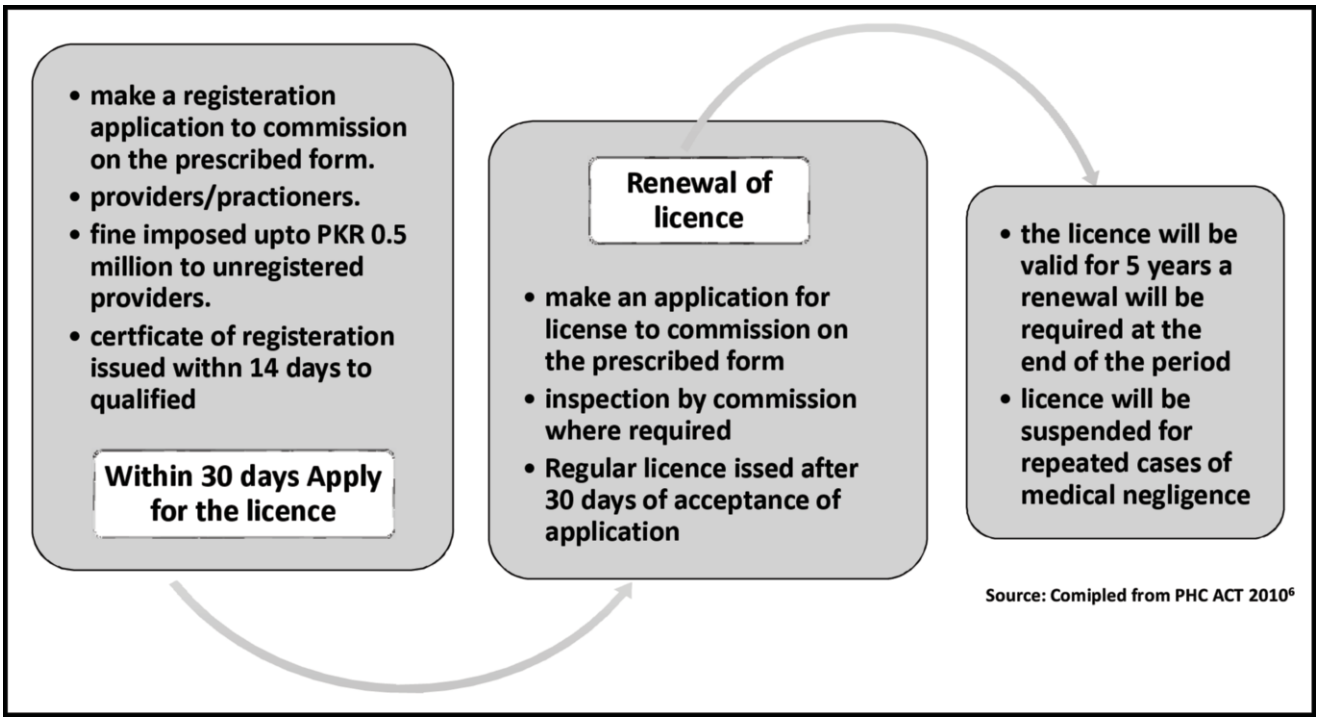
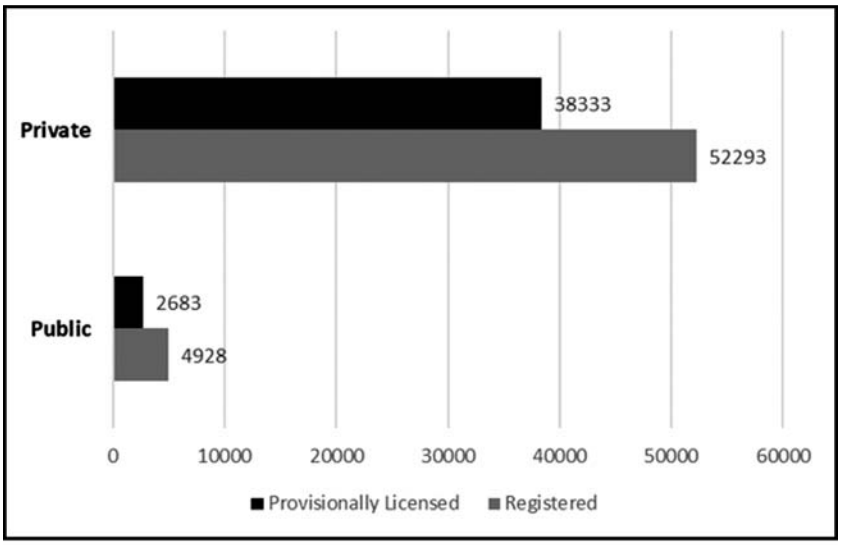
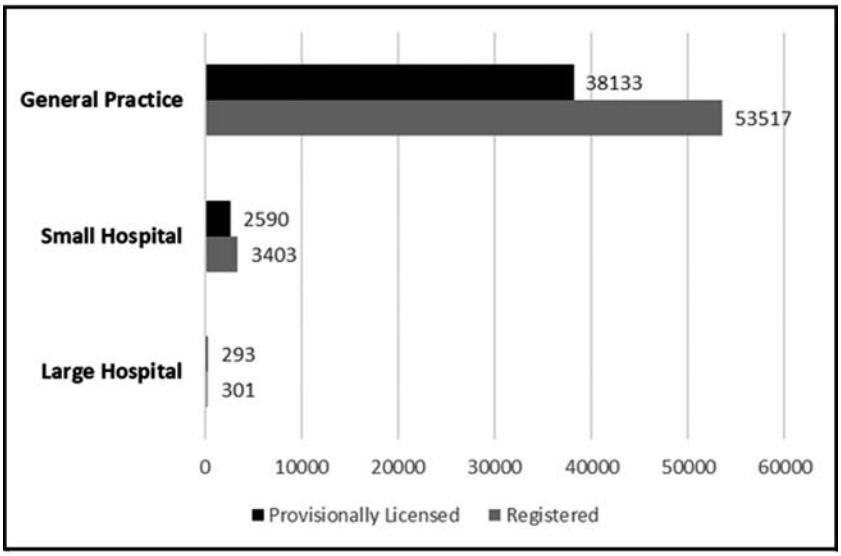


Figure-2: Healthcare commission's registration and licencing mechanism.



(Panel a: Private and Public Providers)



(Panel b: Types of Providers)

Source: Authors compilation from PHC (2019)[6]

Figure-3: Number of registered and licenced healthcare providers in Punjab.

private providers (Figure-3).

The issuance of provisional licence is a signal of quality of healthcare in terms of data collected by PHC. The provider licence is usually displayed along with certification of healthcare staff at the site and a visiting patient can observe and consider it as a minimum quality (e.g. signalling) at a provider. Although it is not clear why regular licence has not been issued to any healthcare provider so far, as according to the PHC policy, the regular licence has to be issued within 30 days of the acceptance of the application.

According to the PHC Act, "the commission may, before issuing the license, inspect the healthcare establishment which is to be licensed…". It means providers with provisional licences are subject to a regulator visit to verify the "information about provider services" and, if validated, the regulator then issues the regular licence. The non-verification of providers by PHC and not confirming regular licence to majority of providers raises quality concerns and underlines the prevalence of poor-quality healthcare service delivery at a wider scale in the country.

Recently, PHC has launched a helpline for public to report any fake healthcare establishment, and has encouraged patients to approach only the licenced providers. It means licence will be a signalling for quality certification and will improve the service delivery. Further, PHC is providing information on the anti-quackery actions through print, electronic and social media. PHC has closed more than 6,000 clinics run by quacks and this process continues.[6] The quackery prevalence appears quite high in the region; in size equal to one quarter of the total licenced private providers. More than 70% of these quacks were operating in conventional medical care. The geographical concentration of sealed clinics appears to be high at about 75% happened to be in just 4 districts of the province. Therefore, a further understanding of nature and extent of anti-quackery actions is required to analyse the regional variation in the prevalence of quackery. According to the PHC Act, the commission works "to improve quality of healthcare services and ban quackery in the Punjab in all its forms and manifestations". Apart from the quality assurance action of PHC, policy actions described below will have far reaching implications for the largest healthcare delivery system in the country.

Lessons learned and way forward

The discussion thus far raises relevant questions. First, the licencing of large number of private providers in Punjab confirms the high prevalence of private medical care in Punjab which shows that substantial healthcare demand

falls on private providers. If the private providers are competing for patients in a competitive market, then disclosure of medical care quality will increase patient welfare.[18] The better knowledge about quality of providers can lead to sorting of patients over providers, where the share of patients with high-quality providers will increase after the disclosure of the information. This hypothesis needs to be tested in Punjab in the context of PHC's current and proposed interventions. Second, as literature shows that lack of variation in quality reporting at provider will not be of much attraction for patient decision making, the current licencing practice by PHC will not create substantial variation in reporting, as either a provider will be licensed or not licensed. The current practice of licencing in Pakistan need to be augmented with further quality reporting on providers. Although PHC is implementing the minimum service delivery standards, further research is required to understand the impact of this practice on quality of reporting to patients.[6] Designing the report card and appropriate instruments in the local context shall be high on the future research agenda.

Third, how to motivate people to attend licenced provider? This shall be a key arear of research. For the time being, PHC advertises and announces through social media and encourages public to report fake providers and to attend licenced providers only. How effective are these current quality reporting measures? And how the digital revolution, smartphone, and internet access can be capitalised to provide information on quality of the providers to patients and stakeholders? Further research is required to address these questions.

Finally, there is little knowledge available on the extent and uptake of various service providers. The government data in Punjab shows that about 80% demand of primary care nature is catered to by private healthcare providers, potentially including informal providers, like quacks.[19] In this context, anti-quackery intervention by PHC will have substantial consequences on the healthcare market and the welfare of patients in the region. So far, PHC has closed down 6,000 clinics where healthcare services were provided by non-qualified staff. The closure of providers at such a large scale will burden the licenced providers (particularly public) or will suppress the healthcare demand. Although, PHC is running training workshops, it is not clear how far untrained staff form closed facilities will benefit from these limited trainings. Further research is required to understand this balance between training the untrained staff at non-licenced facilities and restricting healthcare care provisions to only licenced providers.

Conclusion

Over the last decade, health policy focus has shifted from cost considerations to quality concerns in the delivery of medical care. HCCs are established to regulate healthcare quality at the provincial level in Pakistan by providing third-party certification. The evidence on number of licenses issued by PHC showed that private providers were operational at a large scale in Punjab in a competitive market. Literature review also found that the disclosure of the quality leads to better healthcare provisions in competitive healthcare markets. Therefore, a provider level health quality information reporting mechanism in the shape of a report card can potentially impact the quality of care in a competitive healthcare market like Punjab. Licencing or certification reveals healthcare provider quality. However, to differentiate among providers for quality requires reporting of health outcomes along with the licencing practice by PHC. There is need of further evidence collection to test many policy-related hypotheses proposed in the paper.

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