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Protecting the public or setting the bar too high? Understanding the causes and consequences of regulatory actions of front-line regulators and specialized drug shop operators in Kenya

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ABSTRACT

The problem of poor regulatory compliance has been widely reported across private health providers in developing countries. Less known are the underlying reasons for poor compliance, especially with regards to the roles played by front-line regulatory staff, and the regulatory institution as a whole. We designed a qualitative study to address this gap, with the study questions and tools drawing on a conceptual framework informed by theoretical literature on regulation. Data were collected from specialized drug shops (SDSs) in two rural districts in Western Kenya in 2011 through eight focus group discussions, and from regulatory staff from organizations governing the pharmaceutical sector through a total of 24 in-depth interviews.

We found that relationships between front-line regulators and SDS operators were a strong influence on regulatory behaviour, often resulting in non-compliance and perverse outcomes such as corruption. It emerged that separate regulatory streams operated in urban and rural locations, based mainly on differing relationships between the front-line regulators and SDS operators, and on broader factors such as the competition environment and community expectations. Effective incentive structures for regulatory staff were either absent, or poorly linked to performance in regulatory organizations, resulting in divergences between the purposes of the regulatory organization and activities of front-line staff.

Given the rural-urban differences in the practice environment, the introduction of lower retail practice requirements for rural SDSs could be considered. This would allow illegally operated shops to be brought within the regulatory framework, facilitating good quality provision of essential commodities to marginalized areas, without lowering the practice requirements for the better complying urban SDSs. In addition, regulatory organizations need to devise incentives that better link the level of effort to rewards such as professional advancement of regulatory staff.

Introduction

Regulating the private sector allows the government to share out responsibility for health service provision whilst maintaining some control over quality and distribution (Afifi, Busse, & Harding, 2003; Baldwin & Cave, 1999). Until recently, private health services faced relatively little scrutiny, with regulating health providers being seen as part of the process of entrenching professionalization. This has changed for various reasons, including increased demand for regulation due to increased numbers of health professions, more awareness that regulation can lead to monopolization, and increased realization that certain aspects of health care bear similar features to other markets and can be regulated similarly (Graddy, 1991; Kumaranayake, 1998).

Health care regulation aims to control some or all of the following: market entry, competitive practices, remuneration, and standards and quality, and, to ensure safe use of health care services

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more broadly (Afifi et al., 2003). While debate on health care regulation has become more open in developing countries, the evidence base on which regulations and enforcement strategies work best, and what factors contribute to observed outcomes, remains weak (Kumaranayake, Mujinja, Hongoro, & Mpembeni, 2000). Some argue that regulation in developing countries either reflects the governments' unrealistic expectations of what is achievable, or the desires of professional bodies (Blevins, 1995; Ensor & Weinzierl, 2007). Some evidence, for instance, suggests that while regulation plays a role in protecting the public, certain aspects appear to serve the objectives of professionals and limit competition (Blevins, 1995; Graddy, 1991; Paul, 1984).

Specialized drug shops

Specialized drug shops (SDSs) play an important role in provision of health services in Sub-Saharan Africa because they provide quick and convenient access to medicines, and in some cases, flexible payment terms to clients (Goodman et al., 2007). The scope of SDSs varies across countries, but will usually include registered and unregistered pharmacies and registered and unregistered drug shops (Wafula, Miriti, & Goodman, 2012). Studies have shown SDSs to be popular sources of treatment for fever and malaria, diarrhoea, respiratory diseases, and sexually transmitted illnesses, as well as for chronic conditions such as hypertension (Chuc et al., 2001; Garcia, Gotuzzo, Hughes, & Holmes, 1998; Hetzel et al., 2007; Oparah, Adje, & Enato, 2006). There is increasing interest in how policy makers can work with SDSs to strengthen health systems. However, there are concerns over their performance, with studies showing practices such as dispensing without prescription being common. Interventions to improve their practices have been limited mainly to training, with little effort going towards strengthening regulation (Wafula & Goodman, 2010).

Specialized drug shops are an important part of the Kenyan health system; with estimates suggesting 26–69% of the population visit them for fever (Amin, Marsh, Noor, Ochola, & Snow, 2003; Chuma, Gilson, & Molyneux, 2007; Molyneux, Mung'Ala-Odera, Harpham, & Snow, 1999). In Kenya, pharmacies are the only cadre of SDSs that is recognized by law; however, unregistered SDSs have been widely documented (Barnes et al., 2009). For this reason, we use the term SDSs to refer to both registered and unregistered pharmacies. However, pharmacies that are joined to a clinic and do not serve walk-in clients (clients who have not been seen by the clinician), are not included in the SDS categorization.

Because SDSs are a component of the health system, they are regulated in ways that are similar to other providers. In Kenya, the pharmaceutical sector is governed by several pieces of legislation, the main one being the Pharmacy and Poisons Act of 1959. Others include the Public Health Act of 1961, the Food, Drugs and Chemical Substances Act of 1965, the Narcotic Drugs and Psychotropic Substances Act of 1994, as well as Guidelines for Good Wholesaling and Retail Practice (details on regulations and compliance level published elsewhere) (Wafula, Abuya, Amin, & Goodman, 2013). Two cadres of pharmaceutical qualifications are recognized in Kenya: degree (pharmacists) and diploma in pharmaceutical technology (pharmaceutical technologists). Pharmacists practice following a four year degree course and one year internship, whereas technologists study for three years and undertake a six month internship. The two cadres play a similar role in the retail sector; however, only pharmacists are allowed to engage in pharmaceutical wholesale or importation.

Regulatory enforcement is done by pharmaceutical inspectors (PIs) and public health officers (PHOs). The PIs are employed by the Pharmacy and Poisons Board (PPB, a semi-independent government body that serves as the medicine regulator) to enforce pharmaceutical regulations specifically, and will usually have a degree or diploma in pharmacy qualification. Public health officers, on the other hand, are employed directly by the Ministry of Public Health to enforce a wider range of regulations governing the health sector, including those governing SDSs, as well as community hygiene practices (such as pit latrines) and hotels. The PHOs typically have a diploma qualification in public health, although some have university degree qualification. The PI and PHO roles are defined by the Pharmacy and Poisons Act and the Public health Act respectively, hence the overlap in roles. Professional ethics are enforced by the professional bodies for pharmacists and technologists, but there is no active association for PHOs.

In 2009, we conducted provider and mystery shopper surveys of SDSs in two Kenyan districts. The results showed most SDSs were not complying with regulations, for instance, over half did not keep prescription records, have a refrigerator, or have staff with pharmacy qualifications (survey findings reported elsewhere) (Wafula et al., 2013). Non-compliance was higher in rural locations, for instance, only 12% of rural SDSs had a designated dispensing area, compared to 43% for urban SDSs. However, regulatory inspection frequencies were similarly high in rural and urban areas (over 80% for both). These findings pointed at inadequacies in regulatory enforcement, suggesting a need for a detailed understanding of what happens during inspections, and how this translates into practices. This study sought to understand how the interaction between front-line regulators and SDS operators influences regulatory practices, and how organizational factors influence behaviour of regulatory staff.

Regulation theory: the conceptual framework

Scholarly work on regulation has evolved mainly along the politico-economy pathway, where regulation was seen as either serving the public interest (the public interest theory) or individual groups (interest group theories) (Den Hertog, 2000; Ogus, 2004). While the public interest theory saw regulation as a tool for correcting market failure, interest group theories depicted it as a tool for serving the interests of politicians, bureaucrats and regulated entities. The latter group include regulatory capture, the Chicago theory, and the public choice theory (Posner, 1974). However, these older theories have increasingly lost ground, with more interest going towards understanding the ingredients of effective regulation (Balleisen & Moss, 2009). There is increasing interest, for instance, in understanding influences on regulatory enforcers, and the interaction between regulators and private providers. Some of the ideas that have shaped recent debates were reviewed and developed into a conceptual framework for the study (see Fig. 1).

At the heart of the conceptual framework is the relationship between front-line regulatory staff and SDS operators. We drew on insights from the responsive regulation theory to examine this relationship. Responsive regulation defines regulation, not as a rigid set of rules, but as a tool for addressing the diverse objectives, structure and operations of the regulated entities (Ayres & Braithwaite, 1992). The theory proposes that enforcement should respond to variations in the industry, with severity of sanctions varying with compliance. We chose the theory based on the observation that the SDSs operated in vastly different environments, and that regulatory compliance was varied, despite both rural and urban SDSs having frequent inspections. However, while the responsive regulation theory is a normative presentation of alternative ways of enforcing regulations, we apply its insights to examine whether and how variations in the SDS market environment elicit different regulatory responses.