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Drug shop regulation and malaria treatment in Tanzania—why do shops break the rules, and does it matter?

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Regulatory infringements are extremely common in low-income countries, especially with respect to retail pharmaceutical sales. There have been few practical suggestions on public policy responses other than stricter regulatory enforcement, which governments are often unable, or unwilling, to do. This paper explores the challenges of regulating retail drug sellers, and potential solutions, through a case study of malaria treatment in rural Tanzania where small drug shops are a common source of medicine.

Infringement of health-related regulation was extremely common. Most stores lacked valid permits, and illegal stocking of prescription-only medicines and unpackaged tablets was the norm. Most stocked unregistered drugs, and no serving staff met the qualification requirements. Infringements are likely to have reflected infrequent regulatory inspections, a failure of regulatory authorities to implement sanctions, successful concealment of regulatory violations, and the tacit permission of local regulatory staff.

Eliminating regulatory infringements is unlikely to be feasible, and could be undesirable if access to essential medicines is reduced. Alternatives include bringing official drug regulation closer into line with locally legitimate practices; greater use of positive incentives for providers; and consumer involvement. Such a change in approach has the potential to provide a firmer platform for public-private collaboration to improve shop-based treatment.

Keywords Regulation, shopkeepers, drugs, private sector, malaria

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KEY MESSAGES

- Infringement of regulations related to drugs stocked, staffing and permits are extremely common in retail drug stores in Tanzania.
- Regulatory infringements are likely to reflect a combination of infrequent regulatory inspections, a failure of regulatory authorities to implement sanctions, successful concealment of regulatory violations, and the tacit permission of local regulatory staff.
- Eliminating regulatory infringements is unlikely to be feasible, and could be undesirable if access to essential medicines is reduced; alternatives include bringing official drug regulation closer into line with locally legitimate practices, greater use of positive incentives for providers, and consumer involvement.

Introduction

Regulation of the private health care sector in low-income countries is argued to be highly ineffective, with common practices including the use of under-qualified staff, illegal provision of certain drugs and services, and a failure to meet quality standards and obtain official registration (Bennett *et al*. 1994; Kumaranayake 1998; Hongoro and Kumaranayake 2000). Particular concern has been expressed about regulation of drug retailers, where regulatory enforcement is reported to be especially inadequate (Kumaranayake 1997; Tawfik *et al*. 2002). However, the retail sector is very widely used, accounting for a high proportion of care for common health problems such as malaria, acute respiratory infections, sexually transmitted infections and tuberculosis (Uplekar *et al*. 1998; Brugha and Zwi 1999; Berman 2000; McCombie 2002). In a review of studies of the treatment of childhood febrile illness in Africa, the median percentage using the retail sector was roughly 50%, with rates as high as 70 or 80% in some settings (Brieger *et al*. 2004). Care-seekers reportedly choose the retail sector over health facilities because retailers are more accessible, provide quicker service, have more reliable drug stocks, are courteous and approachable, and in some cases are less costly (Williams and Jones 2004). Moreover, there has been growing interest in the potential to use retail providers to expand coverage of appropriate care for key health problems (Smith *et al*. 2001; Tawfik *et al*. 2002; Brieger *et al*. 2004).

Pharmaceutical retailers in sub-Saharan Africa include a very limited number of formal pharmacies, and numerous general stores that sell a range of groceries and household products. Medicines are also sold by small drug shops in many areas of East and West Africa, including Tanzania, Uganda, Eritrea, Ghana, Nigeria and Cameroon (Van der Geest 1987; Oshiname and Brieger 1992; Adome *et al*. 1996; Murray *et al*. 1998; Nsimba *et al*. 1999; Dzator and Asafu Adjaye 2004; Goodman *et al*. 2004). Drug shops generally stock a range of medicines for common ailments, basic first aid supplies and toiletries. They have been argued to provide a suitable entry point for government intervention to improve retail sector treatment, as they form an established network in both urban and rural areas, and their staff generally have some medical training or experience (Goodman *et al*. 2004).

However, there is widespread concern that drug shops frequently flout pharmaceutical regulations and prioritize profit-making over good quality treatment, leading to poor quality care, unsafe practices and behaviour that encourages the development of antimicrobial drug resistance. In many countries, calls for a more active role for retailers have met with resistance from at least some government health personnel, who favour stricter law enforcement or an outright ban of such commercial drug sales (Reynolds Whyte and Birungi 2000; Brieger 2002). In other settings, drug stores are tolerated, but their frequent abuses of regulations may compromise the willingness of government agencies to engage in formal collaboration.

In this paper we explore challenges involved in drug store regulation through a case study of malaria treatment in rural Tanzania. Rates of infringement of key health-related regulations are evaluated. A combination of quantitative and qualitative data is used to develop an in-depth understanding of the reasons for these infringements and their likely impact on public health outcomes. Finally, potential policy responses are proposed for improving retail regulation and public-private collaboration in low-income settings.

Background: pharmaceutical regulation in Tanzania

At the time of data collection in 2001, pharmaceutical regulation in Tanzania was the responsibility of the Pharmacy Board, through the 1978 Pharmaceuticals and Poisons Act and the 1990 Pharmaceuticals and Poisons Regulations. In 2003 these responsibilities were taken over by the Tanzania Food and Drugs Authority (TFDA), with the passing of the Food, Drugs and Cosmetics Act. However, in practice the implementation of drug retailer regulation has remained broadly unchanged.

There are two types of drug-specific retailer in Tanzania: Part I and Part II pharmacies. A limited range of medicines is also available in some general stores. Part I pharmacies have to be run by a registered pharmacist, and are allowed to sell both prescription-only and over-the-counter (OTC) medicines. In 2003 there were 344 Part I pharmacies in Tanzania, 60% of which were in the commercial capital, Dar es Salaam, with the rest distributed unevenly throughout the regions, always in urban areas (Battersby *et al*. 2003).

Drugs are much more widely available from Part II pharmacies, known as *maduka ya dawa baridi* or drug shops. Drug shops were established in the 1970s to address the lack of access to medicines for much of the rural and peri-urban population. In 2003 the Pharmacy Board had records of 5666 drug shops,

although the total number may be considerably higher (Battersby *et al*. 2003). They are required to obtain a Pharmacy Board (now TFDA) permit each year, and to meet certain conditions related to the premises, qualifications of the seller and products stocked (Ministry of Health 1998). Drug store owners do not need any specific qualifications, but all staff serving customers are required to have basic medical knowledge, which is interpreted by regulatory staff to mean a minimum of 4 years training (e.g. pharmacy assistant or nurse). They are allowed to stock basic medical supplies and OTC medicines only, known as *baridi* drugs. *Baridi* literally means cool or cold, or could be translated as weak or mild. Medicines are classified as *baridi* because they are relatively safe, used for minor and self-limiting conditions, and their use is believed to be well understood by the public. Drug shops are not permitted to sell any prescription-only drugs, including all non-topical antibiotics and injectables of any kind.

In terms of antimalarials, the regulations were amended following the change in national antimalarial drug policy in August 2001, when high levels of resistance led chloroquine to be abandoned as first-line treatment in favour of sulphadoxine pyrimethamine (SP). SP remained the first-line drug until 2006, when it was in turn replaced by artemether-lumefantrine. Before the 2001 policy change, drug stores were permitted to stock oral formulations of chloroquine and amodiaquine, the first- and second-line drugs. Between 2001 and 2006, amodiaquine remained the second-line drug, and was still permitted, but chloroquine was withdrawn. There was some confusion over the regulatory position of the new first-line, SP, as many expected it to be given OTC status, but in fact it remained prescription-only. All injectable antimalarials and all formulations of other antimalarials such as quinine and artesunate have always been designated as prescription-only.

All drugs on sale should be registered in Tanzania, although locally manufactured drugs have been exempted from registration for a given period while domestic manufacturing standards are improved. All medicines sold in drug shops are required to be sold in unit packs, i.e. packaged as single doses accompanied by the manufacturer's instructions for use. From a public health perspective, packaged tablets are preferable to those sold loose for several reasons. The consumer is more likely to take away information on the name and dosing of the drugs; tablets are less likely to be damaged or subject to degradation; and shopkeepers are less likely to decant tablets into other containers.

Drug shop inspection has two components. Firstly, drug shops should be inspected on a quarterly basis by a drug regulatory inspector. Regional Pharmacists and Regional Medical Officers are designated as inspectors, and collaborate with District Medical Officers and District Pharmacists in implementation. The inspectors' remit includes looking for prohibited products, and checking drug expiry dates, the permit and the competence of the seller. In addition, all retailers, including drug stores, should be inspected regularly by an environmental health officer, generally a health assistant based at the local health centre, known locally as *Bwana Afya* (literally 'Mr Health'). Their remit is to approve the outlet premises and inspect the safety and appropriate storage of products, including expiry dates on drugs and foodstuffs.

Methods

Study site

The study took place in the rural districts of Kilombero, Ulanga and Rufiji in southeastern Tanzania, where the main economic activity is subsistence farming, and median monthly per capita expenditure is under US$10 (Household Budget Survey 2002). Data were collected in the areas of each district covered by a demographic surveillance system (DSS) which undertakes continuous monitoring of births, deaths and migrations. The areas contained populations of 73 839 in Rufiji and 66 503 in Kilombero/Ulanga in mid-2001. Use of the DSS areas allowed a detailed census of drug retailers to be conducted by local DSS field staff who lived in the areas and knew them well (government records of retailers were highly incomplete). The DSS covered only rural areas, where the malaria burden is most severe (Schellenberg *et al*. 2003). Ifakara Town is located a few kilometres from the start of Ulanga and Kilombero DSS areas, but providers in the town were rarely used for fever/malaria treatment seeking (96% of visits took place within the DSS area of residence) (Goodman 2004).

The areas suffer intense and perennial malaria transmission, and malaria is the leading diagnosis for outpatient visits. The symptoms of mild or uncomplicated malaria include fever, chills, headache and nausea, and patients are generally treated on an ambulatory basis. Prompt access to appropriate treatment is essential because malaria can rapidly progress to severe disease, with a high case fatality rate (Greenwood *et al*. 1987). The recommended treatment consists of prompt access to a course of antimalarials, supplemented by antipyretics to help reduce fever and pain. The vast majority of cases are treated presumptively, on the basis of fever alone, although many febrile patients are not parasitaemic (Font *et al*. 2001; Kachur *et al*. 2006).

Malaria treatment is provided through a network of public and church-run dispensaries, health centres and hospitals. The DSS areas contained 18 government facilities (4 health centres and 14 dispensaries), and 9 private facilities (7 mission dispensaries, 1 mission hospital and 1 commercial dispensary). In 2001 there were no Part I pharmacies in the DSS areas, but there were 32 Part II drug shops; 30 were commercially owned, and 2 were recently opened not-for-profit village-run stores. Drugs were also available from numerous general stores and kiosks, which sold a wide range of household goods. However, this analysis focuses on commercial drug stores, which were responsible for 88% of retail sector antimalarial drug volumes (Goodman 2004).

Drug stores typically consist of a single building, with cement or brick walls and a tin roof. Most owners employ just one regular seller, who usually works full-time at the shop. The shops are generally located in the more populous areas, and typically open from 7.30/8am to 9pm, 7 days a week. In 2001 they accounted for 31% of provider visits for reported fever/malaria, compared with 34% for general shops, 26% for government facilities, 7% for private facilities and 2% for traditional healers or other providers (Goodman 2004). The high use of drug shops was linked to their long opening hours and friendly service, lack of consultation and laboratory fees, perceived staff expertise, and the reliability and range of their drug stocks, especially compared with government

facilities (Goodman 2004). However, a number of problems with the appropriateness of treatment were reported (Goodman 2004). An antimalarial was obtained at only 55% of drug store visits for fever/malaria, and 29% of antimalarials obtained were dispensed as under-doses. Injectable antimalarials were purchased at 5% of drug store visits, and antibiotics at 13%, although in many cases it was not clear that these drugs were justified by reported symptoms.

Data sources

Data were collected from shops using three tools. In each case we aimed to interview the person most involved with day-to-day management, which in some cases was the owner and in others the main seller. First, a census of all private sources of manufactured drugs in the DSS areas was conducted in mid-2000 and updated in mid-2001 (the 'outlet census'), for which methods are described in detail elsewhere (Goodman *et al*. 2004). The outlet census provided basic data on the number, location and drug stocks of outlets, and was used as the sampling frame for the remaining data collection activities, which were conducted between August and December 2001. Secondly, more detailed representative data on shop characteristics, inspection visits and compliance with regulations were collected through a structured survey of all 30 commercial drug stores in the DSS areas (19 in Rufiji, 9 in Kilombero and 2 in Ulanga). Of the interviewees, 3 were drug store owners and 27 were employed as sellers; 29 served regularly in the shop and 1 occasionally. The majority (26) were female. Thirdly, in-depth qualitative data on providers' perceptions and behaviour were gathered through semi-structured interviews with staff at five purposively selected drug stores (three in Rufiji and one each in Kilombero and Ulanga). These in-depth interviews involved four female sellers and one male owner (who was also the main seller). Although the number of qualitative interviews was small, the shops selected encompassed the range of staffing, stocking patterns and general operation observed in the study sites. These data were supplemented by key informant interviews with three government officials responsible for overseeing pharmaceutical regulation at the district, regional and national level, respectively.

Informed consent was obtained for all interviews with shop staff, which were conducted in KiSwahili. Qualitative interviews were subjected to manual content analysis, based on a preliminary coding scheme, which was refined throughout the process. Quantitative data were double-entered using FoxPro 2.6a, and checked for logical consistency and coding errors, and analysis was performed using STATA 8 (Stata Inc. 2003).

Compliance with a number of health-related regulations was assessed during the structured survey, focusing on those most likely to affect the quality of fever/malaria treatment and the potential for future public/private collaboration or interventions. The assessment covered the presence of a Pharmacy Board permit, the qualifications of selling staff, and stocking of prohibited products such as prescription-only drugs, unpackaged tablets and unregistered or expired antimalarials. We also assessed the appropriateness of dosing instructions on tablet packaging for the first- and second-line antimalarials, SP and amodiaquine. Potential reasons underlying regulatory contraventions were explored using data from the structured survey and qualitative interviews. All verbatim quotes are from the qualitative interviews.

Questions concerning regulation and illegal behaviour are inevitably highly sensitive and there was therefore a risk that shop staff would decline to participate or fail to provide full and truthful answers. We addressed this issue in several ways. First, our field team were introduced by local DSS staff, who knew the communities well and were able to corroborate our assurances that we were unconnected with any regulatory body. Secondly we complemented the quantitative survey with qualitative interviews which provided a more conducive forum to discuss sensitive issues in depth. Finally, sensitive questions on regulation were asked towards the end of the interviews, once a reasonable rapport had been developed. As a result, no drug stores refused to participate in any data collection activities, it proved feasible to raise sensitive regulatory issues, and many interviewees were very open in their discussion. However, participants will still have had strong incentives to conceal certain information, so reported rates of illegal behaviour should be considered a minimum.

The study received ethical approval from the institutional review boards of the Ifakara Health Research and Development Centre, the Tanzanian Medical Research Coordinating Committee, and the London School of Hygiene and Tropical Medicine.

Results

We first present data on the degree of compliance with regulations, followed by an assessment of the likely causes of the infringements observed.

Compliance with regulations

Regulatory violations were common (Table 1). Pharmacy board permits were displayed in only 19 of the 30 drug stores. Of the nine stores with permits in Kilombero and Ulanga, two permits were out-of-date, and in seven shops the seller specified on the permit was not working there (the Rufiji permits did not display these details). An owner explained that it was easier to get a permit renewal if you did not change the name of the owner or seller. Only one of the 37 staff serving regularly had no health qualifications at all. However, none had the required minimum of 4 years health-related training. The mean was 1.4 years, with most staff being Nurse Assistants (a 1 year course).

Stocking of prescription-only medicines was very common. Interviewees reported that 16 drug shops stocked prescription-only painkillers, and all but one stocked prescription-only antimalarials. Even excluding SP, for which the status was unclear, 27 stocked other prescription-only antimalarials, predominantly quinine. In addition, 24 out of 26 drug stores interviewed during the initial outlet census stocked antibiotics.

Unregistered imported antimalarials were found in 19 drug shops, including unregistered brands of SP tablets and syrup, amodiaquine tablets and syrup, and quinine and artesunate tablets. Expired antimalarials were found in four shops. Each shop had only one expired product, representing 2% of all antimalarials stocked. Three of the products were less than

Table 1 Infringement of health-related regulations in drug shops

	Number of drug shops infringing regulations ($n = 30$)
Pharmacy Board permit not displayed	11
Regular selling staff not appropriately qualified[a]	30
Stocked prescription-only antimalarials[b]	27
Stocked prescription-only painkillers	16
Stocked unregistered imported antimalarials[c]	19
Stocked loose antimalarials	22
Stocked loose painkillers	29
Stocked expired antimalarials	4

[a]Defined as having less than 4 years' medical training.
[b]Excluding oral chloroquine formulations because they had been removed from the OTC list only 3–4 months before the survey, and shops were still using up their remaining stocks during this transition period.
[c]Excluding all chloroquine formulations as they were not included in the new registration system.

Table 2 Adequacy of dosing instructions on packaged antimalarial products stocked in drug stores

	SP[a]	Amodiaquine
Number of products identified	14	7
Children under 5 years:		
Any dosing guidance	4	0
Dosing guidance consistent with national guidelines	1	n/a
Adults:		
Any dosing guidance	5	4
Dosing guidance consistent with national guidelines	4	1

[a]SP includes formulations of both sulfadoxine-pyrimethamine and sulfamethoxypyridazine-pyrimethamine.

a month past their expiry date, but one was over a year. For a further 3% of products no expiry date was shown.

All drugs sold in shops should be in unit packs, but the sale of loose painkillers and antimalarials from pots was found in 29 and 22 drug stores, respectively. Loose tablets were generally taken away in home-made paper envelopes, labelled with a handwritten abbreviated drug name and dose.

Even on packaged drugs, dosing instructions were inadequate and inconsistent (Table 2). Of the 14 packaged SP tablet products stocked, nine gave no guidance on dosing, or just stated 'as directed by your physician'. Of the five products with dosing instructions, only one gave dosing information for children consistent with national guidelines. Similarly, of the seven packaged amodiaquine tablet products, none had dosing information for children, three had none for adults either, and three specified an adult dose inconsistent with national guidelines. Finally, few people spoke fluent English in the study sites, yet there were no instructions in KiSwahili on any of the tablets.

Table 3 Regulatory inspection: visits by Environmental Health and Drug Inspectors recalled by interviewees

	Ever visited (out of 29 who recalled whether a visit had occurred)	Visited in previous 3 months (out of 26 who recalled whether a visit had occurred and the date)
Environmental Health Inspectors	22	8
Drug Regulatory Inspectors	24	4

Explaining infringements of pharmaceutical regulations

Five potential causes for these frequent infringements of health-related regulations were identified, based on previous literature and analysis of the data collected: poor knowledge of regulations, lack of inspections, lack of sanctions, successful concealment of regulatory violations, and the tacit permission of inspectors.

Knowledge of regulations

Only a minority of drug store staff had copies of the Pharmacy Board regulations (and such copies were often outdated), and neither drug store staff nor district-level regulators had lists of registered medicines. There was considerable confusion among drug shop staff about which drugs they were allowed to stock. All sellers knew they were allowed to sell *baridi* drugs only, but they were not clear which products this included. Staff knew that common painkillers were *baridi*, and that antibiotics were prohibited, but were unclear on the status of antimalarials. As one seller said:

> ''They're not antibiotics, so that's OK isn't it?''

Confusion over antimalarials may have been heightened by the recent change in drug policy. This may have explained to some degree the widespread availability of SP and to a lesser extent oral quinine, but antibiotics were also widely stocked, although all sellers knew they were prohibited.

Frequency of regulatory inspection

Environmental health and drug regulatory inspections were reported to take place, although not as regularly as specified in the regulations (Table 3). Over three-quarters of drug shops recalled being visited by *Bwana Afya*. Of the 26 interviewees who recalled the date of the visit, 8 reported a visit within the previous 3 months, and 19 within the previous 6 months. Interviewees in 24 shops recalled drug regulatory visits. Of interviewees recalling the visit date, 4 reported a visit within the previous 3 months, 15 within the previous 6 months, and 18 within the last year.

No clear patterns were detected to indicate that either type of regulatory inspection had a constraining impact on regulatory violations.

Imposition of sanctions

In theory a failure to comply with regulations could lead to the drug store being fined or closed down. Interviewees at five

of the 30 drug stores said that inspectors had reprimanded them for stocking prescription-only drugs during their most recent visit; in two stores such drugs had been confiscated, and one store had been fined. At the time of the study the maximum fine for drug stores was still set at the nominal level of Tsh 5000 (about $5) specified in the 1978 Pharmaceuticals and Poisons Act. During qualitative interviews, none of the interviewees said they knew of specific examples of shops being closed down for regulatory violations. A regulatory official commented that court convictions were very difficult to obtain, and could take several years. In sum, it appeared that the penalties of being caught were low because no heavy sanctions were implemented, and the cost of confiscation of, for example, a few bottles of antibiotic syrup was small compared with the profits to be made from selling relatively high-value and popular products.

Concealing regulatory violations

Some regulatory violations may have been difficult to detect during an inspection visit, such as verifying whether the current seller was the person registered on the permit. Similarly, while prescription-only products were sometimes openly displayed, they were usually concealed from view in a side room or in a box under the counter. However, the availability of prescription-only drugs was well known by the customers who regularly purchased them. In addition, all the regulatory officials interviewed were aware of widespread regulatory infringements, such as the use of under-qualified sellers and stocking of prescription-only products. As one drug store interviewee said:

> ''I sell them (antibiotics) via the back door, and they know that we sell via the back door. In fact you can tell someone openly that you sell them.''

Tacit permission

It therefore appeared that drug inspectors were at least partially aware of regulatory violations, but still allowed them to continue. This may have reflected the links between drug stores and the formal health care system. Of the 30 drug stores, nine owners and one server had jobs in the formal health sector, the majority being health care workers at local government facilities. Inspectors may also have been personal acquaintances of shop staff, as in the case of this owner:

> ''When they come I know how to deal with them . . . I know the Regional Pharmacist, I know the District Pharmacist well. We have eaten *ugali* and beans together . . .''

Perhaps more importantly, inspectors may have given their tacit permission, recognizing that shops met a genuine need in communities without Part I pharmacies, in particular acting as a reserve drug source for government facilities. As one seller noted:

> ''I normally have (antibiotic) syrup because it is prescribed to many people and it is not available in the health centre.''

A district-level regulatory official commented that, although he was concerned about dispensing by insufficiently trained staff, he did not mind too much about the availability of prescription-only medicines as it served the interests of the community. Moreover, he believed that drug stores needed to sell such medicines in order to make a profit.

In fact, the referral of patients to drug shops by health care staff to purchase both prescription-only and OTC medicines when government facilities had stockouts had been semi-formalized through the use of *cheti*, informal prescriptions from government staff. These were normally written in exercise books, and described the drug and dose required. During qualitative interviews all drug stores reported getting many customers with *cheti* for painkillers, antimalarials and antibiotics. In one store such patients made up around half of their customers, and two stores linked their weekly sales patterns to patients directed from government facilities, with sales peaking on the days when the facility had most patients.

Finally, regulatory officials reported severe constraints in regulatory implementation due to insufficient manpower and transport. Inspectors may therefore have recognized that eliminating such a widespread and popular practice would have been infeasible. As one drug store owner said:

> ''They should make changes because they forbid things which cannot be forbidden. For instance, they say Part II drug stores should not sell antibiotics, but the truth is that people are selling them and they are bought a lot.''

Discussion

Infringement of health-related regulation was extremely common. Many drug stores lacked Pharmacy Board permits and several others had permits which were invalid in some way. Stocking prescription-only medicines and loose tablets was the norm, most stocked unregistered products, and a minority had expired antimalarials. No serving staff met the qualification requirements.

Similar regulatory violations have been reported from other studies of drug sellers in Tanzania and elsewhere, particularly the illegal stocking of prescription-only medicines (van der Geest 1987; Oshiname and Brieger 1992; Adikwu 1996; Adome *et al*. 1996; Murray *et al*. 1998; Nsimba *et al*. 1999). For example, in Dar es Salaam, 85% of undercover caretakers obtained prescription-only drugs without a prescription from drug stores and pharmacies (Kumaranayake *et al*. 2003). In Uganda, all drug shops were found to stock prescription-only drugs (Adome *et al*. 1996), and in Nigeria, only 13% of patent medicine vendors (drug retailers) believed that the law on prescription medicines was being obeyed (Adikwu 1996). In addition, many studies have documented poor quality antimalarials available on the private market (Shakoor *et al*. 1997; Ogwal Okeng *et al*. 1998; Taylor *et al*. 2001; Risha *et al*. 2002; Minzi *et al*. 2003; Amin *et al*. 2004; Basco 2004).

On the other hand, although pharmaceutical regulation fell short of its targets, the retail drugs market in rural Tanzania remained relatively well ordered. For example, nearly all drug store staff had some health-related qualifications, and the availability of prescription-only medicines outside drug stores

was relatively low; of general stores stocking drugs, only 1% stocked prescription-only antimalarials, and none stocked prescription-only painkillers (Goodman 2004). Drugs were not available from market traders, itinerant vendors or unofficial and unqualified 'street doctors', as they are in some other locations (van der Geest 1987; Fassin 1988; Adome *et al*. 1996). Moreover, household survey data indicated that the quality of treatment obtained was no worse at drug stores than at government facilities. For example, an antimalarial was obtained at 55% of drug store visits for fever/malaria, compared with 52% for government facilities, and of antimalarials obtained, 29% were dispensed as under-doses at both drug stores and government facilities (Goodman 2004).

However, the high rate of regulatory violations remains a cause of concern and potential constraint on public-private collaboration. This raises two key policy questions. Firstly, should the government aim to clamp down by increasing the resources allocated to enforcing existing regulations? Secondly, are there more cost-effective approaches for improving retail drug dispensing than the current legal tools?

Policy options

Major questions surround the feasibility of increasing regulatory enforcement. The evidence base on regulatory interventions in low- and middle-income countries is very limited (Goel *et al*. 1996; Kumaranayake 1998; Waters *et al*. 2003). In Vietnam and Lao Peoples' Democratic Republic, interventions to improve regulatory compliance in drug stores had a significant impact, although a similar intervention was much less successful in Bangkok (Stenson *et al*. 2001; Chalker *et al*. 2005). The long-term impact of these interventions is not known, and no comparable studies were identified in Africa, where regulatory capacity may be particularly weak (Kumaranayake 1997). In the study districts, regulation was the responsibility of the District Health Management Teams, who had many other competing demands on their resources. Moreover, even if the government ordered more frequent regulatory visits and harsher penalties, it is likely that some regulatory violations would continue, as drug stores have strong financial incentives to operate partially outside official regulations, and to make a good living may be obliged to do so. By contrast, the incentives for district staff to enforce regulations were likely to be relatively weak, especially for less 'visible' aspects of their work, such as the strictness of inspections and the appropriateness and harshness of penalties (Meyers and Vorsanger 2002).

Even if greater enforcement were feasible, one could also question its desirability. In some areas, improving enforcement would be clearly beneficial, such as improving the packaging, labelling and chemical quality of medicines. In general, this would be achieved most efficiently by working with manufacturers and importers at the national level, using the leverage of the registration process. At a local level, providing local inspectors with up-to-date checklists of registered products could reduce the prevalence of unregistered antimalarials on the market, and potentially improve drug quality. It is also possible that eliminating all prescription-only medicines from drug stores would limit inappropriate use and reduce drug pressure and, thereby, the growth of antibiotic and antimalarial drug resistance.

However, tighter enforcement of some regulations could have a negative public health impact. Eliminating all prescription-only medicines from drug stores could restrict the access of poor rural populations to effective medicines, particularly when government facilities are out of stock. Hammer has argued that this would be most damaging for products where enforcing prescription-only status means that a high proportion of people will fail to access the drug and the health consequences of not obtaining the drug are high, but the difference in appropriate use with and without a prescription is small, and the consequences of inappropriate treatment are not severe (Hammer 1992). He argues that first-line antimalarial treatment provides a good example of a drug meeting these criteria, implying that it might be appropriate to remove the prescription requirement for first-line antimalarials and possibly some antibiotics.

Enforcing the health-related qualification requirement of 4 years' training for drug store sellers might improve the knowledge of sellers, but could also raise costs due to the higher wages needed to attract such sellers, and potentially put upward pressure on prices. It is anticipated that scaling-up priority interventions in the areas of HIV, TB and vaccination, for example, will require a significant increase in Tanzania's facility-based human resources over the next 5 to 10 years (Kurowski *et al*. 2004). It is therefore unlikely that staff with appropriate qualifications will be available in sufficient numbers to fulfil drug store regulations, meaning that many stores would be forced to close. This would inevitably drastically reduce drug availability in rural areas.

Enforcing the regulation that only drugs in unit packs be sold over-the-counter has the potential to guard against tablet contamination and degradation, and to improve labelling and dosing instructions, which in turn has been demonstrated to improve treatment adherence (WHO 2004). However, this could increase substantially the cost of antimalarials to consumers as, for example, packaged SP was on average 1.8 times the retail price of loose SP tablets (Goodman 2004). Although packaged drugs may be perceived as better quality, such an increase in price would run the risk of further reducing the proportion of patients who purchase an adequate antimalarial dose. On the other hand, enforcement of this regulation might increase competition between packaged products, eroding the often high mark-ups on these drugs.

Similar gaps between stated policy and practice on the ground have been documented throughout the literature on policy implementation (Pressman and Wildavsky 1973). It has been argued that emphasis on this implementation gap in enforcing existing regulations derives from a 'top down', hierarchical model of policy implementation (Hill and Hupe 2002). Implementation can also be seen as a 'bottom up' process, where policy is adapted during implementation, with 'street level bureaucrats' who deliver services or enforce regulations being key players in this process (Lipsky 1980). Where these front-line workers have considerable discretion in the execution of their work, they may even function as 'de facto bureaucratic policymakers' (Meyers and Vorsanger 2002). It has been argued that such behaviour is not only inevitable but may also be desirable in promoting local democratic control and tailoring policies to local needs (Meyers and Vorsanger 2002).

It could be argued that the gap observed in the Tanzanian study sites between the official *de jure* regulations and a locally legitimate *de facto* version reflects the success of bottom-up adaptation of centrally set rules to the realities of drug availability in remote rural areas. A similar approach to regulatory infringements has been documented among pharmacy inspectors in Sri Lanka, who took a 'passive role' in their dealings with unlicensed pharmacies in remote areas because they felt the service had important social benefits (Attanayake and Siyambalagoda 2003).

However, allowing selective non-compliance of this nature to continue could signal that compliance is optional, damaging the credibility of government regulation in general and potentially exerting wide-ranging ill effects in a number of sectors. One could therefore argue that, instead of clamping down more harshly, it would be more appropriate to bring the *de jure* regulations more in line with their *de facto* counterparts by, for example, lowering the official qualifications required for drug store sellers, and widening the range of legal drug stocks to include more antimalarials and some oral antibiotics. This could reduce uncertainty for drug retailers, lead to more supportive supervisory interactions during visits by district officials, and provide a more positive environment for public-private collaboration, including initiatives to encourage appropriate use of shop-bought antimalarials and other drugs.

However, it would be unrealistic to assume that the current state of implementation is necessarily optimal. In tacitly accepting infringements, inspectors may have failed to consider other public health consequences of weak regulatory enforcement, such as the impact on antimicrobial resistance. Moreover, they are unlikely to be motivated purely by the interests of the community. Failure to implement regulation may also reflect a desire to reduce their own workload, avoid unpleasant confrontation and protect their own business interests in the drug retail sector. The important influence of inspectors on regulatory implementation points to the need for further qualitative research to understand their motivations and incentives, and the constraints within which they operate.

Legal restrictions are not the only tools for regulating private providers. In fact, Mackintosh and Tibandebage argue that 'Effective regulatory intervention is only possible in Tanzania if the resource constraint on inspection and enforcement can largely be side-stepped' (Mackintosh and Tibandebage 2002). They argue for a move towards 'collaborative regulation', where non-government providers and the general public are seen as regulatory partners with government. Alternative mechanisms include informal regulation through professional bodies, the use of provider incentives, and indirect regulation through consumers (Kumaranayake *et al*. 2000), considered in turn below.

Professional associations are common for groups such as doctors or pharmacists, but rare for retailers such as drug stores. There are exceptions, such as the Nigerian Association of Patent and Proprietary Medicine Dealers, founded in 1951, but no equivalent body currently exists in Tanzania.

Positive incentives to induce appropriate provider behaviour could be provided via accreditation. This occurs when an independent agency defines and monitors the standards of facilities which voluntarily participate in the scheme. Incentives frequently include provider training, subsidies and promotion activities (Smith *et al*. 2001). The approach has been used for services such as diagnosis and treatment for sexually transmitted infections and tuberculosis, voluntary counselling and testing for HIV, and maternal and child health care packages (Smith *et al*. 2001). However, successful accreditation is resource intensive, involving establishing a brand, monitoring compliance with standards and maintaining quality assurance systems, and requires an accreditation body with a high level of capacity (Smith *et al*. 2001). In low-income countries the costs of set-up and on-going monitoring have generally been funded by external agencies, and there is little evidence on long-term sustainability (Smith *et al*. 2001).

It could be argued that consumers themselves may be effective regulators, as they have the greatest incentive to achieve a high-quality outcome. This could take place through community organizations or through individual purchasing power (Bennett *et al*. 1994). The capacity of consumers to undertake this role could be enhanced through large-scale, ongoing communications campaigns, providing information to enable consumers to judge provider competence, recognize danger signs, and choose safe and effective medicines (Bloom and Standing 2001), although the evidence base on these interventions is currently very limited (Brieger *et al*. 2004). However, the limits of this approach should be recognized. Even following a communications campaign, consumers will be poor judges of certain aspects of treatment, such as drug quality. Moreover, their capacity to demand appropriate care will remain constrained by affordability.

An intervention combining enhanced enforcement, accreditation and consumer information has been piloted in the Ruvuma Region of Tanzania since 2003, through the establishment of Accredited Drugs Dispensing Outlets (ADDOs). Part II drug stores can become ADDOs if they meet specified quality criteria, including a training programme of 26 days for sellers and 6 days for owners (Sigonda-Ndomondo *et al*. 2004). The shops are then allowed to sell a limited range of prescription-only essential medicines, and receive additional support through regular supervision, refresher training, marketing of the ADDO brand, and commercial incentives such as business skills training and access to microfinance. Some regulatory responsibilities have been transferred from district to ward-level officials, who it is hoped will be more aware of the shops' day-to-day operation. Improvements in services have been documented in the pilot areas with, for example, reductions in the number of unregistered medicines on sale and the frequency of inappropriate sales of antibiotics (Mbwasi 2005). The government plans to scale up this initiative and eventually eliminate all non-accredited Part II stores, replacing them with ADDOs.

However, the ADDO programme has substantial financial and managerial capacity requirements, and the feasibility of implementing the piloted intervention nationwide in Tanzania's 6000-plus Part II stores is open to debate. There is evidence that the Ministry of Health currently struggles to provide appropriate supervision and commodity supplies to its own primary care facilities (National Malaria Control Programme 2002); such an ambitious drug store programme could distract attention from the government's core responsibility of ensuring good

facility care. There is therefore a need for evaluation of a range of strategies, with a focus on the potential to scale them up and sustain them in the face of existing capacity constraints.

Conclusions

Drug stores in rural Tanzania frequently infringe pharmaceutical regulations. It is the norm to find that shops lack valid permits, their staff do not meet the qualification requirements, and they stock prescription-only medicines, unregistered products and unpackaged tablets. Infringements are likely to reflect a combination of relatively infrequent regulatory inspections, a failure to implement heavy sanctions, successful concealment of regulatory violations, and the tacit permission of local regulatory staff. However, drug stores are important treatment providers for fever/malaria, providing a potentially life-saving source of medicines in many remote areas.

The challenge is to define the mix of interventions that build on this important role, while safeguarding public health. To date, most attention has focused on the use of legal controls to restrict the availability of medicines to outlets with suitably qualified staff, although implementation is clearly highly inadequate. Successfully eliminating regulatory infringements is likely to be infeasible, due to the incentives faced by drug store staff and inspectors, and the capacity constraints of the latter.

Moreover, we should be alert to situations where increased regulatory enforcement could actually do more harm than good, by restricting access to much-needed medicines. Drug regulation should address societal objectives, meaning that it should serve to protect and promote public health. These goals may be best served by revising official drug regulation to bring it closer into line with current locally legitimate implementation. Moreover, change in drug store operation may be more effectively achieved through positive incentives and/or consumer involvement, with the proviso that unreasonable demands on implementation capacity be avoided. Such a change in approach has the potential to provide a firmer platform for public-private collaboration to improve shop-based treatment of malaria and other priority health problems.

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