




# Is it possible for drug shops to abide by the formal rules? The structural determinants of community medicine sales in Uganda

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## ABSTRACT

The medicines retail sector is an essential element of many health systems in Africa and Asia, but it is also well known for poor practice. In the literature, it is recognised that improvements in the sector can only be made if more effective forms of governance and regulation can be identified. Recent debate suggests that interventions responsive to structural constraints that shape and underpin poor practice is a useful way forward. This paper presents data from a mixed-methods study conducted to explore regulation and the professional, economic and social constraints that shape rule breaking among drug shops in one district in Uganda. Our findings show that regulatory systems are undermined by frequent informal payments, and that although drug shops are often run by qualified staff, many are unlicensed and sell medicines beyond their legal permits. Most shops have either a small profit or a loss and rely on family and friends for additional resources as they compete in a highly saturated market. We argue that in the current context, drug shop vendors are survivalist entrepreneurs operating in a market in which it is extremely difficult to abide by policy, remain profitable and provide a service to the community. Structural changes in the medicines market, including removing unqualified sellers and making adjustments to policy are likely prerequisite if drug shops are to become places where individuals can earn a living, abide by the rules and facilitate access to medicines for people living in some of the world's poorest countries.

## INTRODUCTION

In many countries in Africa, and South and Southeast Asia, the medicines retail sector (MRS) constitutes an essential element of the health system.<sup>1–3</sup> Its role in enabling access to medicines is well recognised<sup>2,4</sup> but so too are the regulatory infringements and poor practices (the over and underdosing of prescription only medicines and sale of poor quality or degraded pharmaceuticals) that are commonplace.<sup>5–7</sup>

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Drug shops are an essential element of many health systems in Africa and Asia but is also well known for poor treatment practice. Improvements in the sector can only be made if more effective forms of governance and regulation can be identified.

## WHAT THIS STUDY ADDS

⇒ This study describes the structural determinants of medicine sales at the community level. Drug shop vendors are survivalist entrepreneurs despite being trained professionals. They work in highly constrained markets, making minimal profit and occasionally losses, relying on family members, and lending circles to provide financial inputs to keep the shops afloat. Addressing these structural constraints is a necessary condition for creating effective long-term change.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The difficulties of working within saturated medicine markets severely limits drug shop vendors' ability to improve practice in the long term. Any changes that threaten profitability are likely to be unworkable. Long-term improvements hinge on finding feasible ways to restructure the market, limiting the participation of untrained medicine sellers and supporting trained drug shop vendors who have the professional capacity to be rule abiding.

Interventions to improve practice within the MRS have had mixed results. Some programmes have enhanced the diagnosis of fever and pneumonia in drug shops,<sup>8,9</sup> but research suggests that this has not impacted on unindicated sales of antibiotics<sup>10–13</sup> and in some instances has increased their sales<sup>14</sup>. Forms of inspection for private sector health facilities that take social relations and trust into account have yielded some benefits.<sup>15</sup> Schemes often seen as critical to improving

practice in the MRS such as social franchising and step-wise regulation have not, however, and have shown negative (and inconclusive) results in randomised trials.<sup>16</sup>

Twenty years of research on medicine sellers suggests that the difficulty of governing this sector is related to the widespread rule breaking among the inspectors, regulators and the sellers themselves.<sup>14 17–19</sup> Despite this, no effective strategies have been designed to manage rule breaking and rent seeking in the market. Policy makers have very little work to build on, as anticorruption interventions across the health sector, for the most part based on ‘good governance’ frameworks, have not been successful.<sup>20 21</sup>

In the last 10 years, however, a new generation of approaches to governance have emerged. These offer promising new directions for public health research and policy.<sup>22 23–26</sup> Turning away from the adoption of universal blueprints to improve accountability and transparency, these new approaches have a deep concern with the context in which corruption takes place.<sup>25 27–31</sup> They have explored the ways in which power, social networks, social norms and economic conditions shape rule breaking and rent seeking across sectors. Those that focus on front-line providers within health and education ask about the roles that rule breaking plays in the face of severe structural constraints and whether, in some contexts, it is possible to be rule abiding and provide a service. This has led to an examination of ‘problem-solving corruption’, which are understood to be driven by the inadequacies of the system rather than the private interests of immoral individuals.<sup>26 32 33</sup> One approach, which draws on Khan’s political settlements theory and ideas of developmental governance, has been seen as particularly useful for health systems and policy research.<sup>22 23 27 34–36</sup> It argues that improvements in governance begin by identifying and working with actors who are currently rule breaking but who have the capacity to become rule abiding and then identifying policy changes that would support them to change and improve their practice. Such an approach demands research that situates people in their economic context, social and political networks; and examines how an ‘enabling environment’ to improve regulation and governance can be created.

The first wave of research in health that draws on developmental governance focused on publicly funded health systems.<sup>22 23 27</sup> It identified the structural constraints that drive some junior medical doctors and nurses to be absent from their rural posts, and sought to identify which of these could be addressed through policy.<sup>23 27</sup> This paper is the first to apply a developmental governance framework to private sector health providers. It explores rule breaking in class C drug shops in Uganda (see **box 1**); the professional capacity of those running drug shops; and the economic, social and political context in which they provide services. Focusing on qualifications, social networks and the profitability of shops in one district, it asks whether it is possible for drug shop vendors (DSVs) to abide by the rules and maintain a profitable business,

### Box 1 Current regulations governing drug shops

Class C drug shops are retail medicine outlets that are registered, licensed and regulated by Uganda’s National Drug Authority (NDA). These drug shops should be operated by a pharmacy technician, nurse or midwife who must be in the shop during opening hours. Their class C classification means that they are permitted to sell a restricted list of over-the-counter medicines including malaria treatment but excluding antibiotics. They are not meant to provide in-patient care. In August 2022,<sup>42</sup> the Ugandan NDA listed 11 371 registered drug shops.<sup>53 65</sup>

and what the potential is for changes in regulation in these medicine markets.

### Study setting and methods

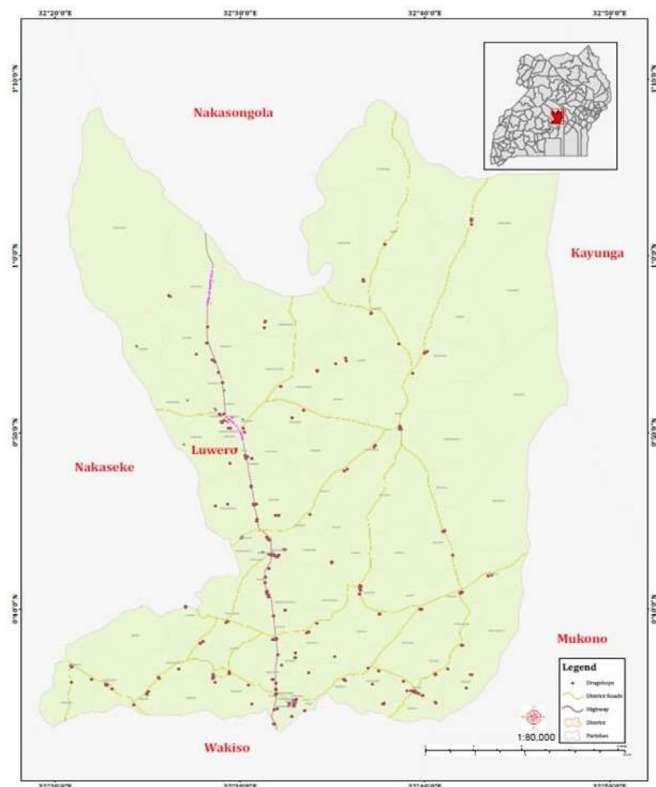
The study was based in Luwero district, in the central region of Uganda. It is 60 km to the north of Kampala, the administrative and commercial capital of Uganda. The district is estimated to have a population of 535 000.<sup>37</sup> It is predominantly a rural district, covered with savannah vegetation. Agriculture is the main economic activity, with coffee and bananas constituting the major cash crops.<sup>38</sup> Luwero has 10 subcounties and 3 towns. The healthcare infrastructure was severely damaged during the guerrilla war (1981, 1986) but has since been redeveloped.<sup>39</sup> As of 2018, there were 41 government health facilities in Luwero, the overwhelming majority were lower level of health facilities offering outpatient and primary care services. These were supplemented by 18 private-for-profit and 26 private-not-for-profit health facilities.<sup>40</sup> For the year 2020, 194 drug shops<sup>41</sup> and 57 pharmacies<sup>42</sup> were registered with the National Drug Authority (NDA).

The study used a mixed-method approach, employing a convergent parallel design.<sup>43</sup> The research began with a mapping and survey, followed by in-depth interviews (IDIs) (n=30) and focus group discussions (FGDs) (n=3). The majority of data was gathered by two experienced Ugandan researchers with bachelor’s degrees in social science (SM, LPA), a senior anthropologist based in the UK who travelled to Uganda for data collection (EH) and a senior academic pharmacist based in Uganda (FEK). These researchers (EH, SM and LPA) had previously conducted 13 months of ethnographic fieldwork in the district and were known to some DSVs and the district health team.

#### Quantitative drug shop survey

##### *Mapping and selection of drug shops*

The project sought to include all drug shops in the district. A list of shops was provided by the district health office and supplemented with a more extensive list compiled by the national drug shop membership group, the National Drug Shop Advocacy Initiative (NDAI). Each shop on the combined list was asked to identify any other drug shops in their area for inclusion. Drug shops were included if they had been in existence for at least 6 months and had



**Figure 1** Distribution of drug shops in Luwero district.

attendants aged 18 years and older, who had worked in the drug shop for 3 months or longer. At the time that they were visited, their Global Positioning System (GPS) coordinates were taken and inputted into a map of the area (see figure 1).

#### Quantitative data collection and study variables

Trained interviewers obtained consent from those who sold medicines ‘for at least half of the opening hours’ and collected data using a preprogrammed structured electronic questionnaire with Open Data Kit (ODK) software (Get ODK). Data were gathered on: age, professional background and years of experience of the respondent; the legal status of the drug shop; revenue and profitability. For the latter, respondents were asked to provide details of expenditure (rent, water, electricity, staffing costs, purchases of medicines, other expenditure categories) for the calendar month preceding the day of the interview. Certain expenditure categories were paid on an annual basis (eg, licence or fees for town council). We asked for the annual expenditure and calculated a monthly equivalent. In addition, respondents were asked about the total sales income from all products for the previous month. DSVs were also asked to identify their five most profitable drugs (specified as those with largest margin between price purchased and price sold), and to name the six most frequently sold drug products and provide their manufacturer, dosage form details, quantity sold in the 7 days preceding the survey, quantity in stock, purchase price and selling prices of pack.

#### Quantitative data management and analysis

The study dataset was transferred from the ODK software to Microsoft Excel 2016, checked for completeness and cleaned. We derived additional variables from sales and expenses. First, we calculated the gross monthly profit as the income from sales minus total expenditure for the month preceding the survey. Second, the differences in purchase and selling prices of the six most sold drugs and the amount of the drugs sold in the 7 days preceding the survey were used to calculate the total contribution of these drugs to each drug shop’s profit in absolute amounts (UGX). Third, we calculated the mean and SD, median and IQR of these profit indicators. Additional, quantitative data analyses were done in Stata V.13.0 (StataCorp). Categorical variables were summarised as proportions and frequencies and presented in a table. The association between age categories of DSVs in years (20–25, 26–35, 36–45 and above 45 years) and whether they were qualified to work in drug shop or not was tested by using the  $\chi^2$ , reporting the crude OR and p value.

#### Qualitative research: IDIs and FGDS

##### Selection of respondents

IDIs (n=30) were conducted by (SM, LPA and EH) with DSVs to elicit the social and economic networks supporting their business. FGDS were conducted by (SM and LPA) to identify the structural factors that were driving rule breaking among a group of DSVs who had the professional capacity to be rule abiding.

##### Sampling strategy

For the IDIs, we purposively sampled interviewees with (n=9) and without up-to-date registration documents (n=21) for the shops that they worked in. IDI participants were identified from the survey; disruptions to the research caused by COVID-19 meant that they were only recruited from one subdistrict of Luwero for the network charts. Three FGDS were conducted with 18 DSVs following the IDIs. FGD participants were purposively selected to include only those with the professional capacity to run a rule abiding shop (nurses and midwives).

##### Data collection strategy and tools

The IDIs drew on Wallman’s network charts which were developed to examine social and economic networks in London.<sup>44</sup> To ascertain their social, economic and political networks, each DSV was asked to provide a list of individuals who had been important to the establishment of their business and its ongoing activity. As suggested by Wallman, these were divided between family and non-family and placed on a ‘map’ with concentric circles, those with the circles closer to the centre of the chart represented individuals who had been most important to the business and those who were least important on the outer rings. The interviewees then described in detail the role that each had played in the business.

FGDS focused on relationships with regulators, the former and current economic context of the market in

the district, and the DSVs' perspectives on the potential to change regulatory practices in the sector. The IDI and FGD questions were drawn up by EH, SM and LPA. The IDI tool was piloted with three participants before the questions were finalised. The FGD was piloted and changes in questions were made for FGDs 2 and 3.

#### Data collection procedure

IDI and FGD participants were approached in person in their shops, the interviewer informed them about the project and asked for their interest in participating in the interview/FGD. A time was then set to conduct the interview/FGD. IDIs were held in the participants' shops at a time that they specified. FGDs were held in a church hall in the district. At the beginning of the IDI or FGD, the researchers read out the information sheet, asked the participants if they agreed to participate, and if they did to sign the consent form. With the consent of the interviewees and FGD participants, all qualitative data were recorded. Where necessary text was translated from Luganda into English using meaning-based translation.<sup>45</sup> Transcripts were checked for completeness by (SM and LPA).

#### Qualitative data analysis

FGDs and IDIs were analysed in NVivo V.12. The Ugandan social scientists (SM and LPA) coded one IDI each and one FGD which they used to draft a coding tree. With support from the senior anthropologist (EH), this was combined with data driven codes to create the final coding tree which was used to code the remaining IDIs and FGD.

No patients or members of the public were involved in the design of the study. We have set out the roles of and relationships between the different members of the research team in the reflexivity statement (see online supplemental file 1).

## RESULTS

A total of 296 drug shops participated in the survey of which 295 provided information on sales and expenditure. Figure 1 provides the location of the shops, showing that most are located along the roads and the majority are clustered in the main commercial centres of the district. Table 1 provides their characteristics. The survey respondents were divided almost equally between those who owned the drug shops that they worked in (48.0%) and those who did not (52.0%). The overwhelming majority of DSVs were women (82.8%).

All the DSVs (n=30) invited to participate in the IDIs accepted. One DSV refused to participate in the FGDs, stating that she was too busy to attend. Of the thirty DSVs who participated in the IDIs, there were 16 nurses, 8 nursing assistants, 3 laboratory assistants, 2 business women with no formal training or education in health and one clinical officer. One of the laboratory assistants and one of the nurses worked in the local public health system as well as owning a shop. Two other health workers

**Table 1** Participant characteristics from the survey (N=296)

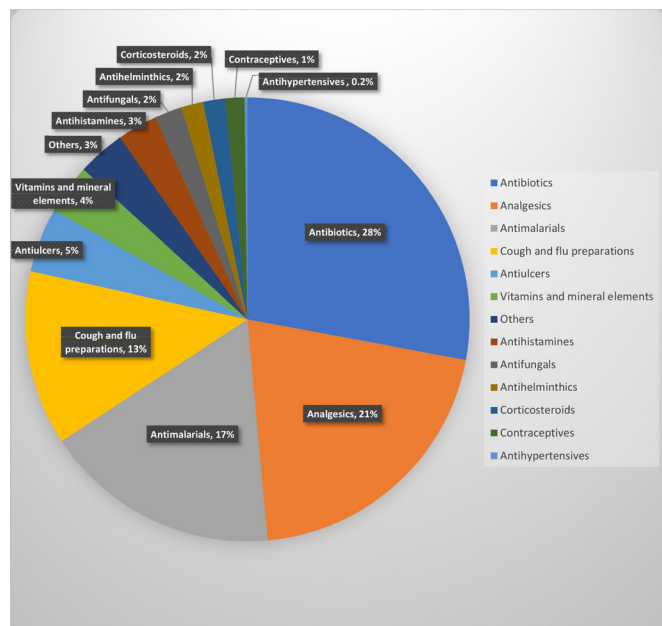
Characteristic	Frequency (%)
<b>Age</b>	
20–25 years	99 (33.5)
26–35 years	146 (49.3)
36–45 years	37 (12.5)
Older than 45 years	14 (4.7)
<b>Gender</b>	
Women	245 (82.8)
Men	51 (17.2)
<b>Professional background</b>	
Nursing aide/assistant	96 (32.4)
Nurse/midwife	178 (60.1)
Clinical officer or medical assistant	10 (3.4)
Pharmacy technician or assistant	2 (0.7)
Pharmacist	1 (0.3)
Laboratory technician	6 (2.0)
Other*	3 (1.0)
<b>Years of experience</b>	
Less than 5 years	137 (46.3)
5–8 years	79 (26.7)
9–12 years	42 (14.2)
More than 12 years	38 (12.8)
<b>Owner of the drug shop</b>	
Yes	142 (48.0)
No	154 (52.0)
*Other: tailor, clinical medicine student.	

interviewed had previously had regular employment as a health worker (one for 3 months in a private not for profit hospital and another with an NGO for 2 years).

#### Forms of rule breaking in drug shops: licences, unqualified staff, unlicensed sales of medicines

During the survey, we asked about rule abiding behaviour by asking about (A) the licensing status of the shop, (B) the qualifications of the person who ran the shop and (C) the medicines that they sold. Only 11.2% of drug shops had an up-to-date licence that was presented to the researchers. A further 58.8% stated that their licence was in process and had paperwork (mostly a receipt for the payment of the licence fee) to demonstrate that this was the case. Almost one-third of drug shops (30.1%), however, had made no effort to get a licence and had no plans to get a licence in the future.

A similar proportion of the shops to those that were unlicensed were run by poorly or unqualified individuals. More than one-third of health workers (32.4%) were nursing assistants or nursing aids with 3 months of training or less. According to policy, these individuals should not run drug shops.



**Figure 2** Proportion of categories of the top 5 most profitable medicine products in 295 drug shops in Luwero (N=1475).

The final and most common form of rule breaking was found in the medicines sold (as reported among the top five profitable and top six frequently sold drug products). Drug shops are prohibited from selling prescription only medication including systemic antibiotics. In the survey, however, 71.9% of drug shops (n=212/295) reported selling antibiotics as at least one of their top five most profitable medicines. Twenty-eight per cent (n=411/1475) of those listed in the top 5 profitable medicines by the 295 drug shops were antibiotics (see figure 2).

The majority of antibiotics listed by the DSVs are classified by the WHO as ‘access’ antibiotics, those that should be more easily available to those who need them (including amoxicillin and metronidazole).<sup>46</sup> ‘Watch’ list antibiotics, however, whose use should be more curtailed were also reported and ciprofloxacin was identified as the third most profitable antibiotic sold in drug shops. Furthermore, ampicillin and cloxacillin capsules, a non-recommended fixed dose combination was also observed among the medicines sold.

### Rule breaking among the regulators

The IDIs and the FGDs identified informal rules that shaped everyday practice and governed the relationship between the DSVs, the district assistant drug inspector (the regulator based at the district health office) and the NDA regulators based outside the district who would come to inspect drug shops.

District officials were identified as a critical source of information by 21/30 of the DSVs interviewed. They provided newcomers with details about which rules it was possible to break, which informal practices incurred more serious punishment. For a small fee, they would inform DSVs ahead of time about (supposedly ad hoc)

regulatory visits by the NDA. This would provide DSVs time to hide equipment and medicines that they should not be stocking. DSVs warned one another of visits by NDA whose car had a distinctive capsule picture on its side (eg, ‘We are united. We alert each other, you can call your colleague and ask, have you seen *the capsule*’, FGD 2, participant 4). They also kept their knowledge about unlicensed shops and informal medicine sellers secret from both the district and the NDA inspectors.

Although it was against regulations for DSVs to stock antibiotics, many described regulators as disinterested in the antibiotics they stocked (‘I had Amoxicillin on the counter, the NDA official pretended that he had not seen it, he wrote in the book, gave it back to me and left’ (FGD 1, participant 2); ‘I always have antibiotics at my drug shop but they [the NDA] never say anything to me’ (FGD 2, participant 5). In contrast, injectable medicines and associated health supplies had to be well hidden, a factor that meant that they were not always disposed of safely (‘they know that we inject but you must avoid having a sharps safety box because the moment that they see it they just know.’ (FGD 1, participant 2).

The NDA inspectors were reported to confiscate medicines and close premisses when drug shops had no licence. These were described as profoundly unpopular; community members had attacked NDA inspectors in the district on at least one occasion when they confiscated medicines from an unlicensed shop.

Clinic regulators (who according to policy are not meant to regulate drug shops) further complicated the governance of the market in Luwero. These clinic regulators were reported to search for drug shops run by unqualified staff when they visited the district and ask for costly bribes in exchange for not reporting them to the district officials. Finally, during the research period the DSVs described the arrival of fake regulators in the district. These individuals were reported to have come to the district and demand payments when the district official drug inspector was away. As one DSV explained,

When I had just started, a woman came and pretended to be very serious. I got scared. She told me, ‘The NDA are here. But you know what I am going to do, if you don’t want to get arrested bring me UGX 200,000 (US\$ 55).’ She had an identity card and put it here on her chest. She said, ‘I am from the district, the NDA are here in town, and they are coming, hurry’. I was about to call my boss, but the woman took my phone and said ‘No, don’t call anyone’. Now [the district drug inspector] told me ‘Be careful of the fake people’. (FGD 3, participant 5)

### Do DSVs have the capacity to become rule abiding? Professional qualifications, economic structures and social networks

#### Education and training

As reported above, findings from the survey suggest that there are many trained health-workers working in drug shops in this district. The majority of DSVs interviewed for the survey (61%) were either nurses, midwives or

**Table 2** Age of qualified versus unqualified DSVs

Variable	Qualification to work in a drug shop		Unadjusted OR	P value
	Unqualified*	Qualified†		
Age				
20–25 years	35 (35.4)	64 (64.6)	1.00	
26–35 years	72 (49.3)	74 (50.7)	0.56 (0.33–0.95)	0.031
36–45 years	20 (54.1)	17 (45.9)	0.46 (0.22–1.00)	0.050
Older than 45 years	3 (21.4)	11 (78.6)	2.00 (0.52–7.67)	0.309

\*Nursing aide, nursing assistant, other nurse, laboratory technician and other profession.  
†Nurse and midwife, pharmacy technician/assistant, pharmacist.  
DSVs, drug shop vendors.

pharmacy assistants who by law are allowed to own and operate drug shops. Many of the DSVs described the arrival of these qualified individuals as one of the changes in the market (eg, ‘In the past, you find somebody with quack practices but now we are qualified people.’ (FGD 2, participant 1) and described how they worked in or had established their drug shop as a pragmatic response to the difficulty of finding work elsewhere. For example,

There are so many reasons [why I started the drug shop], but the most important one is that at that time I had no job. I tried looking for a job in public and private facilities but up until now I am still applying, so I decided to start this drug shop with the little money I had saved. (DSV in-depth interview #3, nurse)

When I finished school, there were no jobs, I went to work in different private clinics. Some didn’t pay me, and others were rude. After a while, I went to the market in Kampala to buy T-shirts. I sold the T-shirts and managed to raise 3million shillings and so I started up the drug shop. (DSV in-depth interview #5, nurse)

The survey data suggest that there are more trained health workers coming into the market. The younger entrants (those up to the age of 25 years) were better qualified than older DSVs, those aged 26–35 years were 44% less likely to be qualified to work in the drug shops as compared with those under the age of 25 years old (p=0.031) (see [table 2](#)).

#### Economic context: profitability and sustainability of the drug shops in the district

While many health workers were drawn to these markets as a place in which they could earn an income, the survey findings on the profitability of the shops suggests that it was not easy to make a reasonable profit from a drug shop in this district. When we asked DSVs about whether their business had been profitable or had made a loss over the last 6 months, just over half (52.4% or 155/295) reported having returned a positive profit for all of the months during this time. The mean profit reported for the month preceding the interview among the drug shops was low, UGX194 000 or US\$52 and UGX259 000 (or US\$70) if credits were included

([table 3](#)). A similar trend was observed with the median monthly profit. Monthly profit was reported to be positive in 60.3% (178/295) of the drug shops increasing slightly to 63.1% (186/295) of the drug shops if credits were included. [Figure 3](#) shows a large variation in profits among drug shops and that profits were low or modest for most drug shops; as many as 64% of the drug shops in the study had earned UGX300 000/US\$81 (excluding credits) or below per month.

Another indicator of profitability was the contribution to individual drug shop profit from the six most sold drugs over 7 days calculated as the total sales multiplied by the difference between purchase price of individual drug shops and their selling prices. The mean contribution among the surveyed drug shops was UGX82 300 or US\$22. All drug shops had a positive contribution from their six most sold drugs, but the distribution of this indicator was right-skewed ([figure 4](#)) with 77% of the drug shops making UGX100 000 (US\$27) or less.

The tables and figures above show a large variation in profitability among drug shops in Luwero. Out of 295 drug shops, 117 were barely breaking even, 133 drug shops reported a monthly profit of UGX200 000 or less and only 5 drug shops made profits just above UGX200 000. Three drug shops seemed to be outliers, reporting a profit of UGX 400,000 or greater. Thirty-six drug shops registered losses of up to UGX200 000 and one drug shop had loss of UGX400 000. This suggests that a large proportion of drug shops (79%) barely make a profit, of whom 37 drug shops actually incur losses. Many of the DSVs that we interviewed and who attended the FGDs were very aware of the difficulties of having a profitable drug shop in the area and linked this to the high numbers of shops in the market.

There are some new drug shops that have come up and our daily sales have reduced. Because if at all you have been selling a packet of paracetamol and competitors come, you will not manage to sell that packet. So, in one way or the other profits are being affected profits somehow now lower down. (FGD 3, participant 4)

For those who had been in the district for a longer time, many considered that the potential to have a profitable

**Table 3** Profit in Uganda shillings in the calendar month preceding the interview for individual drug shops, Uganda shillings, 2020 (N=295)

Estimate	Monthly profit in UGX	Monthly profit in UGX, including value of credits
Mean (SD)	194 305 (876 301)	258 879 (888 206)
Median (IQR)	118 000 (-174 458 to 510 380)	168 000 (-122 413 to 619 151)

business was increasingly difficult as there were so many newcomers to the district.

While we explored the importance of the role of antibiotics in the overall profitability of the market, we were also interested in the role of antibiotics in the profitability of individual shops. Above, we reported that antibiotics were the largest group in the list of five most profitable medicines. When we asked DSVs to identify their six most sold medicines in the last 7 days, 46% identified antibiotics among these commodities. Many DSVs argued that it was impossible to operate within the formal policy guidelines on the medicines that they are legally allowed to stock and continue to operate their businesses. For example:

.... We can't live selling only paracetamol or anti-ulcers; if you only sell paracetamol, you will make no profit. That is why some of us resort to giving injections and [selling] antibiotics to earn a living and survive. (FGD 2, participant 2)

### Social networks

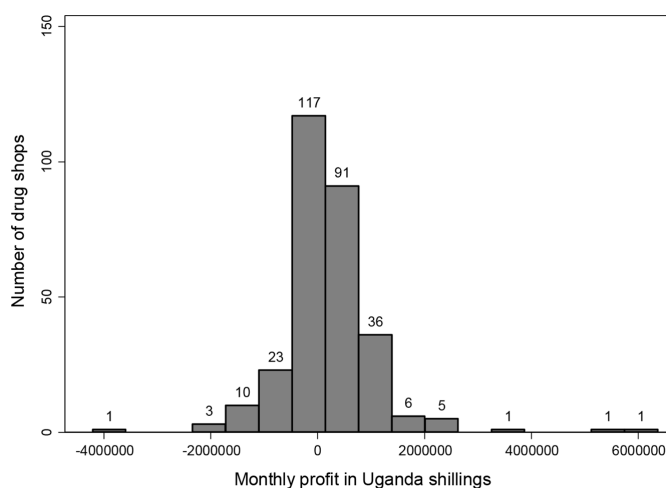
The lack of profits that were made through the sales of commodities and services in the drug shops begs the question as to how it was that these businesses were able to continue to function. During the IDIs, DSVs described family networks as critically important for both the establishment and ongoing survival of their businesses. Twenty-eight of the thirty DSVs who completed network charts described how parents, siblings and partners (husbands and boyfriends) provided business advice, the financial capital that enabled DSVs to rent space for drug shop premises, purchased shelving and medicines

and provided ongoing support to pay rent and purchase medicines when stock was low. For those with a wide family network, there were often a range of people who were relied on to provide support. For example,

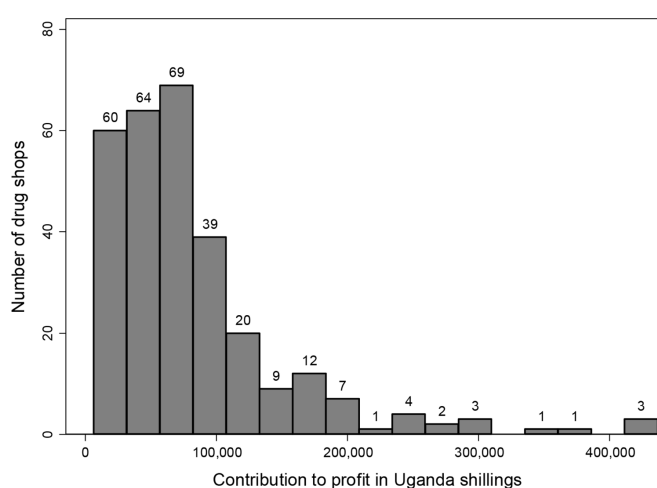
My Brother-in-law Christopher stays in [another district], he is property agent. He supported me financially in the start of the business. He visits me here and still gives me finances up to now. My sister Mary is a teacher in Dubai, she gives me financial support. Steven, my boyfriend is a lab technician. He can give me health information, but he also gives me financial support for food and also money to restock the business. Finally, my aunty who does some poultry farming advises me on business issues and also relationships. Sometimes she also helps me out financially. (DSV in-depth interview, #18 nurse)

In addition to the family networks, almost all the DSVs interviewed (28/30) described medical-entrepreneurial networks made up of nurses, clinical officers and doctors who were former employers and colleagues who provided financial support and business guidance. These networks were often knowledgeable about licensing rules and regulations around the establishment and running of drug shops and provided advice on which medicines to stock, how to establish a good reputation among the local and how to treat clients with more complex problems.

Henry stays in [another subdistrict in the area]. He is 40 and a pharmacist. He supports me on health matters because I consult a lot from him. He is more qualified than me. Normally, if I get a patient and, the way you know studying does not end... I normally call him in cases of consultations. So, he tells what to do. He also supports me



**Figure 3** Profit in the calendar month preceding the interview (excluding credits) for individual drug shops, Uganda shillings, 2020 (N=295).



**Figure 4** Contribution to individual drug shop profit from the sales in the 7 days before the interview of the six most sold drugs, Uganda shillings, 2020 (N=295).

financially by lending me money. We pray together [at the same church] that's how I came to know him. (DSV in-depth interview, # 12 laboratory assistant)

Lending circles including church groups, 'SACCOs' (a Savings and Credit Cooperative Organisation, supported by a non-governmental organisation (NGO) based in the district) and more informal groups of farmers would also provide financial support to enable drug shops to stay in business ('there are times when stock reduces and there is low income so when that happens, I go and borrow, and I maintain my job.' (DSV in-depth interview # 10).

Political networks (connections with local, district level or national politicians or powerful bureaucrats) were, however, noticeably absent among the DSVs. Only one of those interviewed identified local councillors as supportive of their business. The only connections to political processes was via the NDAI. Approximately 30% (n=91) of those who owned or worked in the drug shops in the district were, however, members of the NDAI, a nationwide membership group that lobbied government and the NDA in interests of drug shops. The NDAI was seen by many DSVs as important in protecting the drug shops against new policies that were detrimental to their businesses.

## DISCUSSION

This paper explored rule breaking in class C drug shops in Uganda (see [box 1](#)) and the professional, economic social and political context in which DSVs provide services. It found three main forms of rule breaking: failure to licence the business, allowing unqualified individuals to work in shops and making sales of medicines beyond the licensure. We found that some regulators simply ignore some forms of rule breaking (sales of antibiotics), while corruption between regulators and DSVs enabled some unlicensed shops, unqualified individuals and sales of medicines beyond the licence to continue without sanction.

The regulatory infringements that we have described in this paper are well known in the literature and researchers have repeatedly shown the widespread nature of rule breaking regarding the stocking of medicines and the existence of unlicensed drug shops in both East and West Africa.<sup>19 47–52</sup> Difficult working relationships between regulators and DSVs has previously been reported in Uganda.<sup>53</sup> Findings in this paper, however, stand in marked contrast to many other studies in identifying many trained health workers as both employed in and running these shops. This concurs with recent ethnographic findings by this research team which have highlighted the importance of drug shops for employment of midwives and nurses who are unable to find work in the formal institutions of the health system in Uganda.<sup>54</sup> Future research should ascertain the extent to which this is replicated in other districts in the country, and whether the numbers/proportion of trained health workers in

drug shops are similar in urban and rural settings. If it is, then, findings from this and similar studies provide a platform for a range of policy options for involving DSVs directly in primary healthcare.

As far as we are aware, our research is the first to examine the political networks that DSVs operate within. Most DSVs had few options open to them by systems of patronage, through which resources are often distributed in Uganda.<sup>55</sup> Instead, in common with other entrepreneurial businesses in the country,<sup>56</sup> family members and friends constituted an important network that ensured that there were inputs into the business when poor profits made it difficult to pay the rent or restock the shop. The only recourse to political power for DSVs was through their membership group, the NDAI. Research suggests that this group is able to successfully contest some potentially detrimental policy changes<sup>54</sup> but they have yet to be involved in strategies to improve practice in these markets. Patent medicine sellers in Nigeria have similarly organised themselves into local associations that challenge policy.<sup>57</sup> To date, no intervention has worked with these new organisations as part of a strategy to improve regulation and governance.

Our research suggests that the high numbers of drug shops in Luwero district means that most businesses provide a poor income for those who work in and own them. These findings contrast with work on Tanzania, which has shown little competition among medicine sellers,<sup>58</sup> but are similar to those on informal sector women workers in Africa more generally. These studies show that women working in small enterprises compete for trade in highly saturated 'survivalist' rather than growth-oriented markets.<sup>59</sup> Studies of survivalist markets are often concerned with their (in)ability to provide an income for those working in them. For public health, they also raise concerns about whether, when competition is fierce, these types of market provide space for improvements in practice if they threaten the meagre profits that many of these businesses provide.

Our findings suggest that the sales of antibiotics are important for drug shops' economic survival. Previous research has shown that the government of Uganda relies on these shops to distribute antibiotics,<sup>54</sup> but the nature of anti-microbial resistance makes unregulated sales of antibiotics a global concern.<sup>60</sup> Those calling for stricter regulation and enforcement of antibiotic sales<sup>60–62</sup> need to attend to structural factors that drive poor practice.<sup>63</sup> They may wish to consider whether or the extent to which medicine markets like those in Luwero offer room for the kinds of adaptations that they wish to implement.

Future research could assess which structural changes to the market would support the uptake of new technologies (diagnostics), medication, education and regulatory programmes. Policy makers may wish to focus their efforts on the surprisingly high number of trained health professionals who have the educational capacity to deliver high-quality services. In contexts like Luwero, complex intervention trials could ascertain whether if shops run



by untrained personnel were closed those remaining could have more market space to change and improve practice. If regulators were able to work with qualified medicine sellers and their membership body to identify adaptations to practice that could be introduced with the support of all these actors, then long-term improvements to practice might be more forthcoming. Interventions with such outcomes would rely on the incentives attendant from optimising the existing effective demand for health commodities and care to fewer drug shops run by trained personnel.

### Limitations

The generalisability of our study is limited by only focusing on one district in Uganda. We developed a novel tool to establish the financial viability of drug shops by collecting multiple data points of their revenue sources and expenses. Using these data, we estimated the profitability of each study drug shop. Some drug shops did not have records of the relevant data points. This may have affected our study estimates of total expenses, revenue and profitability. Whereas the authors did not observe any systematic trend in the missing records, this limitation may explain the heterogeneity of the profit estimates reported in the study. We think, however, that there are important lessons from our findings. We know from the literature that rule breaking is widespread and this has not been managed by inputs of new technologies, diagnostics and education programmes. Our study provides evidence of the importance of understanding the economic and financial constraints underlying the observed behaviour and practices of the actors in drug shops particularly. It also calls for more innovative tools and approaches to capture the revenue and sales data in these medicine outlets. Mixed-methods studies have been shown to be particularly important when researching social, economic and cultural contexts<sup>43</sup> and broad, complex and multifaceted phenomena.<sup>64</sup> Triangulating our data between survey, IDIs and FGDs suggests, however, that many DSVs realise that their shops are unprofitable and have a number of ways of managing to keep the business open. This reinforces the notion that the *raison d'être* for some of the drug shops contradicts the obvious reason of profit motivation advanced by many commentators. Exploring these reasons opens up new areas of research in medicine retail sector and calls for new ways to construct interventions to order and mobilise these actors towards contribution to societal goals.

### CONCLUSION

Policy makers wishing to improve regulation and governance of the drug shops are stymied by a lack of evidence of effective long-term interventions. New approaches to governance in the public health literature argue that regulation and anticorruption must be responsive to the structural constraints in which actors operate. Many DSVs working in Luwero district are qualified health workers

with the professional capacity to provide good quality services but they work in saturated medicine markets that severely limit their abilities to improve practice in the long term. Going forward, improvements in these markets will hinge on finding feasible ways to restructure them, including limiting the participation of untrained medicine sellers and supporting trained DSVs to improve their profitability and rule abiding behaviour. In Uganda, the next step is the co-creation of a regulatory intervention with multiple stakeholders, including the DSVs themselves, to ascertain if a lasting and effective solution can be found.

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## **Appendix S1 – Reflexivity Statement**

### **1. How does this study address local research and policy priorities?**

The medicines retail sector delivers approximately half of the essential health commodities to those in need in Uganda and is a critical part of the health system in many low- and middle-income settings. The delivery of quality-assured, essential medicines is a key component of the government's health plans. The difficulties of effectively governing drug shops and the role that they should play in providing health care is often the subject of debate at the Ministry of Health and in the national media in Uganda. Understanding the underlying mechanisms that would influence uptake of interventions to improve the function of medicine retail sector and its contribution to achievement of set societal targets is a national priority.

### **2. How were local researchers involved in study design?**

This study was conducted in the context of a long-standing collaboration between researchers and academics at the London School of Hygiene and Tropical Medicine and Makerere University, respectively. The collaboration has conducted research and capacity building activities in drug shops and the medicine retail sector in Uganda since 2011. The late Prof Anthony Mbonye, a co-investigator based in Uganda with a team that included Dr Freddy Eric Kitutu, Ms Sunday Mundua and Ms Lydia Peace Ocheru were involved in development of the proposal for research funding and eventual design of the study. Prof Mbonye had dual assignment as a senior policy maker in the Uganda Ministry of Health and an Honorary Professor at Makerere University School of Public Health. Dr Freddy Eric Kitutu is a senior lecturer at Makerere University and a member of national technical committees on pharmaceutical systems strengthening and occasionally provides technical support to Uganda Ministry of Health. Prof Mbonye's deep concern to facilitate effective, long-term changes in the market underpinned the key questions in this research project. Dr Kitutu took on additional roles as the Ugandan based co-investigator at the start of the data collection process and brought his deep knowledge, experience and scholarship in the medicine retail sector to the study. Dr Eleanor Hutchinson of the London School of Hygiene and Tropical Medicine (LSHTM) is the Principal Investigator, and she is joined by Prof Sian Clarke (LSHTM), and Prof Kristian Hansen, a health economist (National Research Centre for the working Environment, Denmark) on this study, in collaboration with the Ugandan team named above.

### **3. How has funding been used to support the local research team?**

Dr Freddy Eric Kitutu worked extensively with Prof Kristian Schultz Hansen on the conceptualization and data collection tool to explore and examine the financial performance of the study medicine outlets. Ms Jacquelyn Nambi Ssanyu, Ms Sunday Mundua and Ms Lydia Peace Ocheru were junior members of the study team in Uganda and were supported by the investigators to understand the study and acquire skills to conduct the fieldwork, manage and participate in the analysis, interpretation and write up of the findings. The project facilitated their attendance of a course in qualitative research methods offered by the University College London. They participated in preparation of the manuscript and they are co-authors, in accordance with the ICMJE guidelines.

### **4. How are research staff who conducted data collection acknowledged?**

Jacquellyn Nambi Ssanyu, Sunday Mundua and Lydia Ochero collected the data and are co-authors on this paper.

**5. Do all members of the research partnership have access to study data?**

All members of the partnership have access to data.

**6. How was data used to develop analytical skills within the partnership?**

Sunday Mundua, Jacquellyn Nambi Ssanyu and Lydia Peace Ochero were trained by Eleanor Hutchinson in Nvivo and worked with her to code the qualitative data in this project.

**7. How have research partners collaborated in interpreting study data?**

All researchers were involved in interpreting the data for this study and are co-authors on this paper. In addition, we have presented the key findings of the project to officials of the National Drug Authority, the Luwero District Health Team, the Ministry of Health and other organisations that we consider stakeholders in this market.

**8. How were research partners supported to develop writing skills?**

The early career researchers (Jacquellyn Nambi Ssanyu, Sunday Mundua and Lydia Peace Ochero) were supported by senior academics within study team to develop and refine their writing skills.

**9. How will research products be shared to address local needs?**

Findings from this study have been disseminated to the study District Health Teams and national stakeholders in dissemination workshops. The participants in these workshops include representatives from Department of Pharmaceuticals and Natural Medicines and Health Sector Partners and Multi-sectoral Coordination of the Ministry of Health, National Drug Authority, medicine outlet owners and attendants, Allied Health Professional Council, Pharmaceutical Society of Uganda, Uganda Medical and Dental Practitioner's Council, Uganda Pharmacy Owners Association, National Drug Shop Association Initiative, representatives of research institutes and civil society organizations and researchers. This paper will be published as open access. Once successfully published, it will be distributed at a workshop with members of the MRS in Luwero district and among national stakeholders in Uganda. We will use this to underpin discussions with the different policy makers and stakeholders at district and national level in Uganda.

**10. How is the leadership, contribution and ownership of this work by LMIC researchers recognised within the authorship?**

Authors, Dr Eleanor Hutchinson and Dr Freddy Eric Kitutu worked as part of the senior authorship team in developing this manuscript, and their contribution has been recognised as first and last authors respectively.

**11. How have early career researchers across the partnership been included within the authorship team?**

We have included early career researchers Sunday Mundua, Lydia Peace Ochero and Jacquellyn Nambi Sanyu as authors . They attended all the workshops, contributed to the data analysis.

**12. How has gender balance been addressed within the authorship?**

Six authors are female, two are male (Freddy Eric Kitutu and Kristian Schultz Hansen).

**13. How has the project contributed to training of LMIC researchers?**

Sunday Mundua and Lydia Peace Ochero have received extensive training in the collection of ethnographic, qualitative and quantitative data by the research team.

**14. How has the project contributed to improvements in local infrastructure?**

This project has not directly contributed to improvements in local infrastructure.

**15. What safeguarding procedures were used to protect local study participants and researchers?**

We have anonymised the participants in the text, ensured that all participants provided informed consent.