Author's response to reviews

Title: The policy-practice gap: describing discordances between regulation on paper and real-life practices among specialized drug shops in Kenya

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Response to reviewer comments

Overall comment

We thank the reviewer for the comments. However, we feel some of the reviewer’s views extend beyond the scope of our work.

For one, we didn’t set up our study to judge the value of different regulatory provisions, or decide what is important, and what isn’t. Rather, we set out to show the effect blanket regulatory policies have on compliance, especially across rural and urban locations. The study showed that even inspections may not improve compliance if contextual factors are not considered when designing regulations, suggesting that policymakers rethink how they approach regulation overall.

We also recommended that more effort go into understanding why compliance was poorly associated with inspections. We (two of the authors) have since published a follow up qualitative study looking at this in detail (See Wafula, F. Molyneux, S, Mackintosh, M, Goodman, C. Protecting the public or setting the bar too high? Understanding the causes and consequences of regulatory actions of front-line regulators and specialized drug shops in Kenya (Social Science and Medicine 2013, DOI: 10.1016/j.socscimed.2013.08.020)).

The reviewer’s suggestion that we identify regulations that focus on patient safety, and analyze and discuss these only, is a useful one, but extends beyond the scope of this project. This, we feel, is the next level, building from our study. Such a process should entail getting stakeholders together to discuss and prioritize regulations, and decide which provisions should be exempted in rural areas for instance. Our work was to show whether there are gaps in policy and practice, and we believe we showed that.

For that reason, we insist on keeping the focus broadly on regulatory compliance, rather than introducing quality of care/patient safety angles. However, we included some discussion on whether all regulations are equally important (see for instance page 16 paragraph 2), and have recommended that future studies examine the relative importance of different regulatory provisions on patient safety and quality of care.

To specifically address the reviewer’s comments:

Reviewer: A [locked] cupboard for narcotics is only required IF the SDS is dispensing narcotics.

Response: Cupboards for narcotics were required for ALL SDSs, not just the ones which stock narcotics. However, in practice, some regulators used discretion to ignore the provision for SDSs that did not stock narcotics and psychotropics. On the other hand, some inspectors used such opportunity to elicit bribes from non-compliant SDSs (see the Wafula et al qualitative study referenced above).
Reviewer: A prescription book is only required IF the SDS is dispensing prescription drugs. (By the way the authors need to define what they mean by prescription book and how it should be kept. Unfortunately, the failure to actually examine the prescription books is a serious flaw of the study, because what if they are poorly or wrongly kept?)

Response: Prescription books are a requirement for ALL SDSs. As we explain in the introduction, all SDSs in Kenya are licensed to sell all types of medicines, and are therefore expected to meet similar requirements. We don’t have SDSs that are only licensed to sell specific medicines.

We didn’t examine prescription books or licenses due to the sensitive nature of the study. From our piloting, we found that asking the SDSs to share this level of detail caused discomfort, leading to some level of hostility, and worse still, SDSs calling to warn each other of a team of people moving around looking at records and licenses. We tried to make the study be as less intrusive as possible, but still faced major challenges dealing with suspicion within the communities.

Reviewer: A [working] refrigerator is only required IF the SDS is stocking drugs that require refrigeration. (Did the authors determine if this was occurring? Did they check the status of the fridges?)

Response: 3- A refrigerator was a regulatory requirement for setting up an SDS. Like the narcotics cupboards, inspectors used discretion to decide whether one was necessary. We didn’t attempt to check the status of the very few refrigerators we found.

Reviewer: Having a pharmacist on staff is only required IF the SDS is dispensing prescription drugs. I also wish that the authors had assessed if the SDS had an up-to-date pharmaceutical manual so that they would ensure that they are prescribing properly based on age/weight and condition of the patient, as well as to avoid prescribing inefficacious drugs or those that would be contra-indicated. I also wish they had determined which SDSs had a copy of the Pharmacy and Poisons Act, rather than just ask if they knew what Act was important to their work.

Response: 4 – Having a pharmacy qualified staff is required for ALL SDSs. Again, this was explained in the introduction. ALL SDSs in Kenya have similar requirements. Any shop that is not an SDS in Kenya is simply a general shop selling groceries and other household items, and some prepackaged medicines (usually fever medicines). We did not include the latter in our classification of SDSs.

Our study was not set up to gauge knowledge, but we felt that a simple question asking staff in charge whether they know the Pharmacy and Poisons Act would suffice. Our thinking was that even if they don’t keep a copy of the Act in their shops (and most pharmacists wouldn’t keep a copy of the Act, from our experience), they should at the very least, know of its existence.

On the license issue, we determined it would be inappropriate to check, and possibly, unsafe for our field staff. Our study focused specifically on regulatory compliance, a very sensitive topic among Kenyan inspectors and SDS operators. Most respondents became uncomfortable just after reading the consent forms for the study, and we even had an incidence where field staff were arrested by the community for ‘causing disturbances’, simply because they were perceived as undercover inspectors (inspectors
characteristically ask to see licenses and records during inspections). The reviewer needs to understand that there is a reason few studies have ventured into this area of research, especially among rural communities that tend to be very protective of their few providers (regardless of the registration status). The decision to take this step was well thought out and discussed with regulatory inspectors beforehand.

Responses to other comments

Reviewer: 1 What is the difference (if any) between outlets with a trained pharmacist and those who did not have a trained pharmacist? (This would help the Kenyan government determine if it needs to require a trained pharmacist in its SDSs and/or whether its pharmacists are following regulations. It may be the case that the pharmacists have grown lax and this would be important to know.)

Response: We have this in table 4. However, we did not separate the pharmacists from pharmaceutical technologists, as both are equally recognized by the law as legitimate operators of SDSs. We combined them in one category called ‘Pharmacy Qualified Staff’. We describe the two cadres in the introduction.

Reviewer comment: 2. What is the difference (if any) between outlets with an inspection in the past year and those that did not? (Presumably, inspectors should be ensuring that hazardous outlets are closed or improved. If there is no difference, this would suggest that Kenya is wasting money on inspectors or may need to re-train them.)

Response: Again, we have this in the table 4. The table has data showing the odds of SDSs that have had an inspection complying with specific regulations compared to those that did not have an inspection.

Reviewer comment: The authors never explicitly tell the reader what constitute the principal pharmaceutical regulations of Kenya, other than the requirement to have registered pharmacists. They also never spell out the provisions of the Pharmacy and Poisons Act. Instead of Table 1, which is not really relevant to this paper, they should spell out all of these key provisions of the Act.

Response: The Kenyan pharmaceutical sector isn’t just governed by the Pharmacy and Poisons Act. It is governed by several pieces of legislation and policy guidelines. That is the reason for table 1. We have, however, added table 2, listing regulations, as requested by the reviewer. These are numerous, and we have made effort to present them in a summarized form.

Reviewer comment: Table 3 has a number of items that seem irrelevant to the public health and safety. Why is it necessary to have the shop be of bricks/stone? Why do we care if other household merchandise is sold? Why is a separate dispensing room necessary or desirable?

Response: Again, we feel the reviewer has strayed from the purpose of our paper. Our objective was to describe the policy-practice gap, not the merits of different policies, or why they were selected by policymakers, or what should or should not go into policy. This is an important issue, but it is not the purpose of this paper, and it requires separate engagement between the researchers and policy.
Reviewer: Following from the previous comment, it is not clear how these particular regulations were chosen. Rather than take two from each category, wouldn’t it have been better to have chosen those that are important to public health and safety?

Response: We wanted a combination of structural, practice and knowledge related tracer regulations. We also wanted regulations that could be easily ascertained, given the sensitive nature of the study. We wanted to show whether SDSs were complying with regulations, and what factors were associated with compliance (or non-compliance). Obviously, the debate as to whether we should have selected items that focused on patient safety has merit, but we did not, as part of our study, set out to decide why having a separate dispensing area is less important than some other regulations.

It’s important that regulation be seen as one of the ways of improving quality/patient safety, but the two are not synonymous. Regulation plays a larger role in health, including (some have argued) protecting the professionals by creating entry barriers and restricting practice, and quite often, there are regulations that have been criticized as having no direct patient safety role. That doesn’t mean they carry less weight (or penalties) in the eyes of enforcers. This, we feel, is a central feature of regulation, and perhaps the one thing that differentiates it from continuous quality improvement (CQI) and total quality management (TQM), both of which are solely directed towards improving patient safety. It’s important to us that the reviewer recognizes our focus was purely on compliance to rules, not their merit.

Reviewer: The authors need to better define the different personnel. For instance, what is a pharmacy technician licensed to dispense?

Response: Licensed pharmacists and technologists are both allowed to dispense all types of medicines. Indeed, there is no difference in retail practice between the two. We have added this sentence on page 5.

Reviewer: The authors need to comment on why regulatory compliance may be low. Possible reasons are: costs (for a refrigerator or cupboard), lax enforcement, bribes of inspectors, poor quality of inspectors, transient nature of some SDSs, etc.

Response: We have tightened bits of the discussion section a bit more to include possible reasons (see for example page 13 paragraph 2).

Reviewer: The term provider survey has been used quite extensively in this literature (see for instance, reviews of SDSs by Wafula et al). Dispenser survey has not been used as much. However, to avoid confusion, we have corrected as advised

Reviewer: Lastly, while the authors have an extensive bibliography, they do not seem to have read all the articles thoroughly and cited them correctly. For instance, they don’t seem to be aware that other researchers in Kenya have used “mystery clients” as a strategy for determining if regulations are being followed during actual dispensing. So they should revisit their literature and reclassify it.

Response: We recognize the mystery clients method has been widely used, but usually confined to understanding quality aspects of practice (for instance, compliance to treatment guidelines when dispensing, or questions asked, both of which are not regulatory issues, but are quality of care issues).
Again, this is different from compliance to regulation, although there may be some overlaps. Again, we would refer the reviewer to the Wafula et al review of SDSs to understand the differences a bit more.

Authors’ final comment: We did a systematic review of specialized drug shops in 2012 (Wafula, F. Miriti, E., Goodman, C. Examining characteristics, knowledge and regulatory practices of specialized drug shops in Sub-Saharan Africa: a systematic review of literature (BMC Health Services Research 2012, 12:223). Out of 61 Sub-Saharan African studies reviewed, none set out to look specifically at compliance to regulation. To the best of our knowledge, this is the first publication for a study that set out to explore this very sensitive area in the region. While we recognized limitations, and highlighted these in the discussion, we see this as an important first step towards understanding regulatory compliance in Sub-Saharan Africa by measuring the policy-practice gap with reference to the legal and regulatory frameworks. Hopefully, more studies will follow with more innovative ways of measuring this.