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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Author's response to reviews: see over
Response to reviewer comments

Reviewer's comments:

The authors have done a good job of revising the manuscript and addressing my concerns in their comments. I now appreciate that their intent was simply to determine if there was compliance with regulations, but not to determine if these regulations were essential to the public's health.

Response

We thank the reviewer for their kind words.

I still believe, however, that the following statement in the article, which is found in the abstract (and similarly in the conclusion) needs to be modified. Currently, the authors state: "Under such a system, rural SDSs operating in low-resource setting, and selling a limited range of medicines, would be exempted from certain regulatory requirements."

I still believe that this is not an acceptable conclusion. No SDS should be allowed to operate in a way that could be injurious to the public's health. Rather than issue blanket "exemptions" to SDSs in low-resource settings, it would be far better to first review and revise the existing regulations, determining which are essential and which are optional/advisable, based on consumer safety. Then the new regulations could be sent to the SDSs and inspectors could be re-trained.

For example, if it is determined that a nurse has sufficient capacity to dispense pharmaceuticals safely, this could be inserted into new regulations. However, if there are some pharmaceuticals that only a trained pharmacist can safely dispense, the regulations should note that this class of drugs cannot be dispensed by a nurse but only by a trained pharmacist (or by a nurse who obtains a certain certificate).

Response

We agree with the reviewer that maybe our conclusion may be misleading to the reader. What we meant was that certain exemptions may be allowed, but that these must only be allowed where practice in rural locations is limited to certain essential services only.

We have made this correction in the abstract and manuscript conclusion.

See the following text in the last paragraph of the abstract:

'This suggested the need for policy to introduce levels of practice in recognition of the variations in resource availability. Under such a system, rural SDSs operating in low-resource setting, and
selling a limited range of medicines, may be exempted from certain regulatory requirements, as long as their scope of practice is limited to certain essential services only.’

Reviewer comment

Lastly, I think that the authors need to note in their introduction that the intent of their research was not to assess the usefulness/value of the existing regulations, but only the current compliance.

Response

We agree fully with the reviewer, and have gone through the manuscript to clarify in certain sections that the focus is on compliance to regulations, not the usefulness or relative importance of the regulations.

We have added a statement in paragraph 2 of page 8 that:

‘We recognize that the regulations selected for the study may not be reflective of public health importance, and that other regulations with higher public health significance may have been omitted for logistical reasons. However, we also observe that the primary objective of the study was to measure regulatory compliance, and not the relative merit of different regulations.’

We have also added in the conclusion (page 19 paragraph 1), the statement that:

‘Policymakers need to reexamine the list of regulations and decide whether all requirements should apply across the board, or whether regulatory requirements should be linked to the scope of practice and the location of the practice. Such an approach may reduce the number of SDSs operating unlawfully, and allow more shops to seek formal registration.’