Reviewer's report

Title: Antibiotic sales in rural and urban pharmacies in northern Vietnam: an observational study

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Reviewer: Kathleen Holloway

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Overall comment
This is an important and interesting paper. It quantifies the profit from antibiotic sales and so highlights the profit motive for selling antibiotics over-the-counter. One weakness is that the only solutions suggested are education of retailers and the community, and there is no discussion of other interventions to curtail inappropriate antibiotic sales such as enforcing regulation or implementing pricing policies. All this should be mentioned in the discussion. The paper should be published after the revisions are made in accordance with the suggestions below.

(1) Major compulsory revisions

Background
Please include 1-2 global references that highlight the types of inappropriate use of antibiotics e.g. Medicines Use in Primary Care in developing and transitional countries, WHO Geneva 2009, or others. Reference 6 does not fit well in refs 4-8 on antibiotics being sold for ARI without prescription, since Zimbabwe has low OTC use.

Methods
Study sites: please state how many private pharmacies and outlets exist in the rural area so that one may understand the sampling frame in the rural as well as the urban area.

In-pharmacy observation: it is mentioned that the observer recorded all drugs available at the site on the first day. Was this just antibiotic products or all products? If all products, this could be thousands of products in some shops - was this so? Please provide some information on this.

Also, it is my experience that in many shops large numbers of customers come to shops simultaneously. In observing drug sales to one patient, several other customers may come and go having been served by another sales assistant. Please describe how you managed this problem.

Focus group discussion: This is mentioned in the discussion but not the methods. Please include a description of the FGD in the rural area and some explanation about why FGD was done in the rural area but not the urban area and why in-depth interview was done in the urban but not the rural area. Please also
described the 5 in-depth interviewees and comment on whether they were substantially different or not from the other pharmacy workers.

Data Analysis

Please explain what descriptive statistics were generated.

When calculating the mark-up for the 20 most commonly sold antibiotics, were the top 20 antibiotics different for each shop or were they chosen from data across all shops?

Results

Pharmacy characteristics: the first sentence talks of 13 pharmacies while the methods talk of 30 pharmacies. Please clarify. Also please include either here or in the methods a description of Good Pharmacy Practice in the Vietnam context and what is required of a shop owner to get a certificate.

Observation of drug sales: please explain the denominators for % of antibiotic transactions that had a prescription vs those that did not have a prescription in shops with and without a pharmacist - it does not seem to tally with the total number of antibiotic transactions - or are these results only for the urban area? Similarly, please clarify the denominator for this indicator in shops with and without GPP. On page 9, paragraphs 2 and 3, please clarify what the p-values denote - significant differences between urban vs rural areas or significant differences between antibiotics and other drugs.

Economic indicators of antibiotic sales: mark-ups are referred to as means - means of what? Please report on % mark-ups.

Causes for inappropriate antibiotic selling: The information in this section could be put into a table format for easier reading. Does this information come from the baseline pharmacy questionnaire completed on day 1 of observation? Please clarify. Once again it is not always clear to what differences the p-values are referring to. Is it the urban/rural difference that is referred to?

Proposed solutions: Are these solutions only those proposed by the in-depth interviewees and the focus group discussion participants? If so, the relatively few number of participants may account for the relative paucity of solutions. Please explain what pharmacy workers understand by GPP here.

Discussion

Please include a paragraph on the relative paucity of solutions suggested and discuss the problems of enforcing regulations and implementing pricing policies. 1-2 relevant examples from the literature can be taken e.g. enforcing prescription-only regulations in Chile [Bavestrello et al, Rev Med Chile 2002, 130(11): 1265-1272] and separating prescriber and dispenser function as in Korea [Park et al, Health Pollicy & Planning 2005, 20(5): 302-309. Even if such solutions are deemed impossible in Vietnam, there should be some discussion on this. Also the experiences of other parts of the world, particularly in Europe on public education could be mentioned. In this regard the reference [Huttner et al Lancet Infectious Diseases 2009, 10(1), 17-31] should be used.
Please also include a paragraph on the limitations of the study particularly with regard to the methodology. In many shops, a multitude of customers often come at the same time. Were you able to "catch" all customers buying drugs or not? If not what proportion were you not able to observe or is this unknown? How well were the structured observation forms filled in? Is the Hawthorne Effect likely i.e. that drug sellers changed their behaviour because they knew they were being observed? These and other problems in the methodology need discussion.

Please give a reference for the statement that in India 53% of pharmacies dispense antibiotics without prescription. Here, is it meant 53% of pharmacies or 53% of antibiotics? My experience of India is that almost all pharmacies dispense some antibiotics without prescription.

Page 15, para 2: reference 22 is a regulation - does this regulation state that self-medication is more affordable and convenient? If not it should not be included as a reference here. Rather it should be included as a reference when referring to what regulations exist. In this respect how do refs 11 and 22 differ - and should not ref 22 also be referred to in the introduction?

Page 16, para 2: please clarify the situation with regard to focus group discussion as previously mentioned.

Page 17: as mentioned previously please ensure that GPP is explained.

References
Please state the journal or publisher in reference 3.
Please state the publisher in reference 25.

Table 2: the mark-ups appear to be in terms of USD but the price is not mentioned so one cannot judge the percentage mark-up. Please put in the % mark-ups.

Minor Essential Revisions
Page 7, line 1: please clarify "...(2) knowledge and government regulations..." Does this mean knowledge of government regulations?

Page 9, last line of first para: is it meant that 28.4% of rural clients self-medicate?. Please also insert the nuermator and denominator here.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.