Reviewer's report

Title: Population awareness of risks related to medicinal product use in Vientiane Capital, Lao PDR: a cross-sectional study for public health improvement in low and middle income countries

Version: 2
Date: 27 January 2015

Reviewer: Jo Durham

Reviewer's report:

Major Compulsory Revisions

Methods
1. Please explain a little more about the sampling of districts and village’s and why 30 villagers per district required. What alternatives were considered instead of including 16 year olds?

2. Were the number of households the same in each cluster in the villages were there was not a village list?

3. Please explain more about the translation and back-translated process and the characteristics of the translator(s) Were there discrepancies and how were they resolved?

4. Please explain more about the pilot and how did you check how terms such as ADR and Pharmacovigilance system were understood?

5. How did you determine the questions you used to determine whether a villager was unaware of medicine risks? Please expand on this. What if the respondent answered negative for one question but not the other?

6. It is not clear if this is a validated instrument or one developed for this study. Can you expand on this?

7. Please explain the steps you took to ensure meaningful informed consent from the 16 year olds and why parental consent was not obtained. Please comment on gatekeeper consent and how this was obtained. Also where did the interviews take place and how was confidentiality assured or were there any issues of confidentiality and if so how were these managed?

8. Can you comment on the 100% response rate? High response rates are not unusual in Lao PDR but how and by who were the respondents in the villages where a list of the households was available approached in the first instance? Could this have affected the response rate? And the quite large difference in male and female respondents? Was this a feature of the survey design – e.g. the time you went to the village?

9. Please provide a reference or evidence to support the claim that ‘The majority of the Lao population in the province of Vientiane Capital considers traditional medicines as safe or has no opinion about their risks.’
10. The section ‘Implications and reflections for policy and research is too simplistic and does not flow well. More innovative solutions are needed and more concrete examples – how do patients transform for example from passive recipients to active partners? What would it take to achieve adequate labelling and package inserts? How would this be regulated? Pharmacists are often the preferred sources for drug safety information (and sometimes diagnosis) what would it take to engage these actors in training and engage them to pass on information? As you mention labelling of medicines will be insufficient for the purpose of raising awareness of rural patients (also the most vulnerable based on your study) on drug safety.

11. Achieving universal health coverage and effectively regulating the pharmaceutical industry (formal and informal providers) are important but long term objectives – what can be done in the interim? What are the risks for pharmacists and how can these be mitigated?

12. It is partly because prescription drugs are readily available that people self-medicate but also because of failures of and a lack of trust in the health system – again while a long term project this needs to be acknowledged

Discretionary Revisions

1. Was there any mention of perceived differences in efficacy between medications from China, Vietnam and Thailand

2. There are likely to be other reasons as well that explain why urban residents have better access to information on medicinal products – can you discuss these too

3. The discussion can be more concise and focus on the key points and interpretation

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

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

Declaration of competing interests:

declare that I have no competing interests