Author's response to reviews

Title: Scaling up HIV counselling and testing for pregnant women to the community level: experiences from a community-based study in Northern Vietnam

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Author's response to reviews: see over
Responses to reviewers' comments

Authors of:
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First of all, we would like to thank the Editor and our Reviewers for their constructive criticisms. Below, please find our responses to the reviewers' comments. Please note that the page numbers given refer to page numbers in the revised and resubmitted version of the paper.

Responses to Reviewer 2 (Gita Sinha)
1. Is the question posed by the authors well defined?
I believe the study question is generally clear, but could be revised to be more precise. The term “quality” is a very general term; defining it in the study’s context would be very important. In this study, the term “quality” appears to refer to overall “characteristics” rather than to the indicators for a standard of service or care. For example, are there standard HCT quality indicators in the literature or among policymakers that are a guide? It may be necessary to acknowledge the limitations of the study to capture all indicators of quality, and/or to justify why the specific indicators were chosen in this study. (Major Compulsory Revision) I would suggest defining “quality” in the background and methods section, including clearly stating the outcome variables of interest in the description of analytic methods.
(Discretionary Revision) I would also suggest, in the discussion/limitations section, based on this study’s findings and some of the existing literature, to describe whether there are additional aspects of uptake and quality that should be addressed as other HCT programs scale up in Vietnam or globally.

Response: To address the comments of the Reviewer, we have revised the objective of the paper: “To describe the uptake of HIV counselling and testing among pregnant women at different levels of health facilities; and to investigate how gestational week at first HIV test and counselling provision vary between levels of health facilities”. With this overall objective, we now focus on the early uptake of HIV testing and the provision of counseling at different levels of health facilities, rather than on ‘quality’.

2. Are the methods appropriate and well described?
a. Regarding the study setting: (Major Compulsory Revision) Because the authors refer to their findings in the context of scaling up HCT into more local HF’s, I suggest they provide more background details on the history of HCT services in the study setting. For example, how many HF’s offered HCT at the start (2004), how many and what type (primary/secondary/tertiary) were offering HCT at the time of the study.

Response: On p4, in the sub-section ‘Study site’ of the Methods Section, we have added more information about the history of HCT services in Quang Ninh province and Ha Long city.

b. Please see the additional comments above regarding defining quality as used in the analysis section.
Response: Please see response to comment 1.

3. Are the data sound?
   a. Background descriptive data: It is at times confusing to go to the HF-stratified data directly to get an idea of the characteristics of the overall study sample.

   (Major Compulsory Revision) Table 1 should be made more informative with the sample’s background socio-economic characteristics, and also specifically the distribution of HCT by HF type (see b) below) and by gestational age (see c) below. Beyond adjusting for socioeconomic variables, this would help clarify that there are no distribution biases in the study sample that might impact/confound the statistically significant differences in primary versus higher HF level HCT utilization findings (Table 3).

   Response: We have revised Table 1, adding socio-economic characteristics of the women and HIV testing related factors. After presenting frequencies of selected socio-economic characteristic of women, we have added variables of antenatal care and HIV testing.

   b. (Major Compulsory Revision) I would recommend incorporating statistical testing for significant difference in the distribution of HIV testing by HF type (Table 1). For example, a comparison of proportion of the sample using testing at primary levels versus higher levels: is there a significant difference? Could this or did this impact the ensuing findings of the characteristics or quality of the testing? My initial presumption reviewing the data is that there is no significant difference or impact, but I think the authors should include the relevant statistical testing to help justify this.

   Response: We do not fully understand the reviewer’s comment, in this version as well as in the previous version of the manuscript, crude ORs of the association between health facility level of first HIV test and socio economic characteristics were calculated together with
adjusted OR were all socio-economic characteristics studied were included in the model. This has been described in the method section and in a table footnote both in the previous and the present version of the manuscript. However, in the present version we have tried to express this more clearly to avoid any misunderstanding.

c. (Major Compulsory Revision) I would also recommend including in Table 1, the proportion of women who were tested according to gestational age (i.e. <34 wks, >34wks, or at L&D), with relevant statistical testing, to clarify its distribution in the overall sample.

Response: Please see our response to 3a.

d. (Major Compulsory Revision) The description of the analytic approach in the text of the Methods section must be made clearer. On reviewing the data, it appears to me that the authors did an analysis of the crude odds of primary versus higher HF-level HCT, by subgroup category only. For example, primary education level was compared against university level education, but not against the other categories of education, in both the crude and adjusted odds ratio analyses. Logistic regression models were used to adjust within each of these sub-categories in a pairwise fashion, it appears, after adjusting for some socio-economic variables. After confirming this with a PhD level statistician in our group, I would say that this is not a sound approach to the analysis. Rather, logistic regression analysis should be used within each characteristic category, to calculate crude and adjusted odds ratios for all subcategories of the listed characteristic. (Major Compulsory Revision) A more sound approach would be to construct logistic regression model(s) incorporating all of the indicators (rather than just paired sub-categories) and determine whether the characteristics are statistically significantly associated with primary versus higher HF-level utilization.

Response: On p.5, in the sub-section: “Data analysis” of the Methods section, we have tried to describe the analytical approach more clearly and in more detail: “The socio-economic characteristics (age, marital situation, number of children, educational level and monthly income) of women who were tested at first level HFs and women who were tested at higher level HFs were compared. To adjust for possible confounding, multivariate logistic regression analysis was performed where all variables under study was included in the regression model [19] (Table 2). Crude odds ratios (ORs) and adjusted odd ratios (aOR) were calculated with 95% confidence intervals (CI).

e. Regarding the presentation of “quality” indicators in Table 3: pre- and post- Test counseling is listed as separate categories. Most HCT policies state that an HCT quality indicator would be the receipt of both, rather than just one or the other. (Major Compulsory Revision) The authors should include a measure of the proportions of women who received both, by facility type, and make some ensuing conclusions on how
that reflects on the quality of HCT received. The alternative is that the authors provide statements/established guidelines to indicate that their chosen quality indicators are otherwise justified.

Response: We have responded to this comment through the construction of a new variable ‘Counselling provision’ which combines the two variables “pre-test counselling” and “post-test counselling”. Women who stated they had received both pre- and post-test counselling were computed as ‘Yes’, women who either received pre- or post-test counselling, or none of these, computed as ‘No’. (Table 4)

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
This is overall an observational comparative study with a convenience sample design, rather than a trial design that would warrant adherence to existing reporting and data deposition guidelines. However, there are some issues with the presentation of the data for which I would make the following comments/suggestions.

a. (Major Compulsory Revision) I would recommend in the text describing the Results to clearly “walk the reader” through the Tables and include the relevant statistical testing for Table 1 as well as the subsequent Tables, in the text itself. For greater clarity, and because there are no major space considerations, it is useful to include text-described data in the tables, and vice-versa. (See points in #3 above).

Response: On p.5, in the Results section, we have added the sub-section: “Background characteristics of study population and HIV testing related factors” and highlight the main findings in the text. However, we do not agree with the reviewer that statistical testing should be provided both in the text and in the tables since, too many numbers in the text may make it more cumbersome to read.. We would like to have comments from the Editors of the Journal regarding this point.

b. (Major Compulsory Revision) The authors need to either correct or clarify Table 2 for the referent category in income level. All the sub-categories have odds ratios listed to them, rather than a referent sub-category against which all the others are compared for HCT utilization.

Response: We corrected this typo.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

a. As the analytic approach does not appear to be sound, it is difficult to say the ensuing conclusions are supported. I think the authors need to be a bit more objective in any conclusions, because their study lacks a comparison group to demonstrate clear differences in uptake of HCT, and as stated there are potentially significant differences in
both the study community and sample from other populations in Vietnam. Also, they did not include a comprehensive list of quality indicators in their analysis. (Major Compulsory Revision) I would suggest that the authors revise their analysis to confirm their conclusions, and clearly explain how their data support their conclusion but also include a discussion of future issues/indicators/research that would be needed to better prove that the scale up in accomplishing its goals.

Response: We revised the Discussion and Conclusion following the reviewer’s comments.

6. Are limitations of the work clearly stated?
   a. (Major Compulsory Revision) Limitations of the study sample: In addition to the limitations described, the lack of an external, community-based comparison group also limits the ability to generalize the findings. For example, what is the overall antenatal/HCT utilization and characteristics among pregnant women who are not part of a “scaling up” community? Are there historical confounders or external confounders that may be influencing pregnant women to seek testing in higher numbers, even in places where primary facility testing is not available? This warrants additional discussion by the authors.

Response: On p.8, paragraph 4 of the Discussion section, we have added the following information: “Against this background it is encouraging that nearly 80% of the women in our study had been tested for HIV before or at the 34th week of gestation. This high rate of early HIV testing suggests that the antenatal care program in Quang Ninh province is functioning well, an assumption that is supported by the fact that 82% of pregnant women attend antenatal care (90% at urban sites, 80% at rural sites), and that the vast majority come for antenatal care during the first trimester [5]. Thus, excellent conditions exist for an efficient PMTCT service which, in the setting studied, has been backed up by massive investments in both the quality and the quantity of PMTCT”.

Further, on p.9, we added the following in the Conclusion section, “Although it may be questioned whether the present study can be generalized to settings where less massive investment in PMTCT is made, it is argued that the findings may serve as an important inspiration for the future expansion of the PMTCT program in Vietnam as well as in other low income countries. To shed further light on the uptake of PMTCT in resource poor settings it is recommend that additional studies are performed in sites where other conditions for PMTCT prevail”

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
   The cited references are appropriate to the authors’ discussion points.

8. Do the title and abstract accurately convey what has been found?
(Discretionary Revision) The title could more clearly convey the key findings from the study, depending on what a revised analysis reveals. The title could describe the study’s key findings, such as “increased and earlier uptake of HCT among women accessing primary versus higher-level antenatal care during pregnancy in Vietnam” --- a title that conveys the key findings would more directly convey the importance of the study. (Major Compulsory Revision) I suggest that “quality” as a term, if it is still used in the revised manuscript, needs to be very clearly defined in the abstract as well as throughout the paper. An alternative approach would be to define the key outcome variable(s) of interest, (such as utilization of testing, etc.), in the abstract’s methods/analyses description, rather than refer to “quality” as one of the studied outcomes.

Response: We agree with the comments of the Reviewer and have revised the title of the article. This reflects the revised objective.

9. Is the writing acceptable?
(Minor Essential Revisions) Overall the writing/language is clear; a few minor grammatical English corrections should be made throughout the paper. The use of the term “quality” should be clarified, as I referred to above. Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore) Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct) Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached). Please refer to my comments above for suggestions for revision and their relative importance.

Response: We have gone through the paper and revised the language. Regarding the term ‘quality’, please see our response to the first comment.

Responses to Reviewer 1 (Karin Minnie)
1. Logic - Problem not clear from background (also abstract) as previous policy only stated in first sentence of fourth paragraph of discussion. This must be explained earlier in the abstract and background. The first sentence, fourth paragraph of Background also states that expansion of service provision is recent, but its not clear from what is was expanded.

Response: We have revised the Abstract, Background and Discussion sections following the Reviewer’s comments in order to clarify our points regarding the expansion of the PMTCT programme and the scaling up of services to HFs at primary level as well as policy of routine HIV testing at the time of labour for pregnant women.

2. Logic - Abstract - last sentence of Results: Increased pre-test and post-test counselling not necessarily an indication of the QUALITY of HIV counselling and testing.
Response: On p.2, we have revised this sentence in accordance with the contents of the other sections.

3. Language - First sentence, second paragraph of Background: ..... where prevalence of 5-37% has been reported.

Response: On p.3, we have revised the language of this sentence.

4. Logic - Ninth sentence, second paragraph of Background: However, there is a lack of studies examining health facilities (HF) at different levels of the health care system as an important predictor for the early uptake of HCT among pregnant women. What about the health facilities is an predictor for early uptake and need to be investigated?

Response: On p.3, in the Background section, the last sentence of paragraph 2, we have revised this sentence: “However, there is a lack of studies examining the early uptake of HIV testing and counselling provision at different level health facilities (HF) of the health care system”.

However, we do not understand what is meant by the comment “What about the health facilities is an predictor for early uptake and need to be investigated” and have thus not addresses this comment in the revised manus

5. Third sentence of Data analysis: change martial to marital.  
Response: On p.5, we have corrected this spelling mistake.

6. Last sentence under Uptake of testing during pregnancy under Results: change no of children to number of children.

Response: On p.6, we have corrected this term.

7. Fifth sentence, third paragraph under Discussion: 'One of' the advantages of a community-based design is ....

Response: On p.7, we have revised this sentence.

8. Third sentence, fourth paragraph under Discussion: .... have documented that 85% of pregnant women were tested late ...

Response: On p.8, we have revised the discussion and this sentence. Then we put this sentence under the fifth paragraph, counted as the third sentence.

Discretionary Revisions
9. Language - .... all levels of health facility / at different levels of health facility.
Change to .... all levels of health facilities / at different levels of health facilities. Change right through document.

Response: We found the terms and changed them throughout the document.

10. Third sentences - However, that strategy will only be effective .... Change to However, this strategy will only be effective ....

Response: On p.2, we have revised this sentence.

11. Fourth sentence - include abbreviation (PMTCT) after first use of term ‘Prevention of Mother to Child transmission’

Response: In the Background section, we have included the abbreviation of this term.

12. First sentence, second paragraph under Discussion: The study population comprised 'of' women from ..... 

Response: On p.7, we have corrected this mistake by adding the word “of”.

Other change:

We add one reference, number 19:

We have added this reference [19] in the text, on p.5, under the sub-section: “Data analysis” of Methods section. We have revised the number of reference over the paper.

Thanks for attention and hope that our paper will be considered for publication.
With the best regards,

Vibeke Rasch, Tine Gammeltoft and Nguyen Thi Thuy Hanh