Author’s response to reviews

Title: HIV status disclosure and associated outcomes among pregnant women enrolled in antiretroviral therapy in Uganda: a mixed methods study

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Dear Editor,

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“HIV status disclosure and associated outcomes among HIV infected pregnant women enrolled on lifelong antiretroviral therapy in Uganda: a mixed methods study”

Thank you for giving us an opportunity to revise and resubmit our manuscript. We have made revisions in line with all the comments that we received. Below is a point-by-point response to all the comments.

Sincerely,

Rose Naigino
Response to reviewers’ comments

Reviewer 1

1.0 Abstract

In the ‘’Background’’ section describe lack of information in the study setting, which leads logically to the aim of the study. Example: ‘’However, little has been explored about…’’

Response: We have adjusted the background section of the abstract to highlight the gaps in evidence. (see page paragraph 1 on page 2)

Methods: Authors should also specify in the method how the participants were sampled for the quantitative technique.

Response: We have included a statement on the sampling for quantitative data (See the methods section of the abstract on page 2).

Key findings from qualitative study must be incorporated. Response: We have included a summary of the qualitative findings to the abstract(refer to the last sentence under the results section on page 3).

2.0 Background

The literature has been cited and given sufficient consideration with novel research avenues. However, the prevalence of HIV among pregnant women in Uganda should be included.

Response: In the background section on page 5, we have included a statement which highlights the prevalence of HIV among pregnant women in Uganda, as cited from the Uganda HIV and AIDS country progress report (June 2015).
3.0 Methods

3.1 The authors have described the setting of the current study which is, Mityana, Masaka and Luwero districts in Central Uganda. However, no information has been given to justify the rationale for choosing these districts over the other districts (which provide lifelong ART, too) if any.

Response: We have included an explanation for choosing Masaka, Luwero and Mityana districts over the other districts which provide lifelong ART in Uganda (Please refer to the first sentence under the methods section on page 6).

3.2 How many districts are there in this setting, Uganda? The authors should articulate a little bit more on this. Response: We have addressed this within the first sentence under the methods section on page 6, where the number of districts in Uganda is indicated.

3.3 Please explain how you selected the six health facilities among the others. What were your selection criteria? The authors are required to unequivocally explain the ‘inclusion criteria’ used in the study Response: We have included an explanation for the criteria used to select the six health facilities included in the study (Please refer to the last paragraph on page 6).

3.4 Authors should also specify in the methods how:

- The samples (507) were determined

- The participants were sampled for the quantitative technique.

Response: We have modified the section on sample size (page 8) by providing a detailed explanation on how we arrived at 507 as our sample size for the quantitative component including the relevant assumptions that were involved in determining sample size.
We have also adjusted the section under sampling procedure on page 8 to clearly specify the procedure used to sample participants for the quantitative component of the study (see the past paragraph on page 8).

3.5 I understand that the questionnaire was pretested among a sample of clients. Did the authors assess reliability of the questionnaire?
Response: The pretesting included assessment for reliability of the tools and those that had issues, were revised after pre-testing.

4.0 Data collection and measurement
4.1 Define clearly the primary and secondary outcome variables.
Response: We have modified the section under measures to include a statement which specifies the primary and secondary outcome variables within the last paragraph under measures on page 10.

4.2 Some information about the interviewer could be important like: number of interviewers, their profession and training for the data collection process.
Response: We have adjusted the section under data collection tools on page 10 by adding a paragraph that covers interviewer information including their number, profession and training for data collection.

5.0 Data analysis (Quantitative)
5.1 Which statistical software was used for data analysis? In general, the description of methods and statistical analyses should be improved.
Response: We have generally modified the entire section on quantitative data analysis on page 11 and 12. The statistical software used for data analysis is specified as follows; ‘All statistical analyses were conducted using STATA version 12’ (see page 12).

6.0 Results

6.1 The results and discussion were presented in an appropriate fashion in line with the research objectives.

It was supported by sufficient relevant literature, The discussion included findings from other related studies that support or contradict their own present study.

However, qualitative findings have not been discussed sufficiently.

Response: We have strengthened the discussion for the qualitative component (see page 20).

6.2 Limitation of the study was mentioned although generalization of the findings to the source population is not appropriate. The sample size may limit the findings of this study to be generalized to all HIV positive pregnant women in Uganda.

Response: We have included a statement under study limitations to acknowledge this limitation (refer to page 23).

Reviewer 2

1.0 Abstract

- The numbers are confusing. For instance how is n under line 40 related to the total sample of 507 or those who had disclosed under line 38, page 2? Check for consistency.

- Under the conclusion- what specific interventions do you recommend to address stigma and violence?
Response:

- We have reviewed the abstract section to ensure consistency in the results section (see page 2).

- We have included a statement which suggests some of the interventions that could help address stigma and violence in the era of lifelong ART (see page 21).

2.0 Background

The background is generally well written. However, it should be strengthened.

Response: We have generally strengthened the background section by indicating more recent statistics as well as more relevant information to help orient the reader; including details on the prevalence of HIV among pregnant women in Uganda (see page 5).

3.0 Essential revisions

3.1 Page 4, authors should use more recent statistics from WHO and Ministry of Health /Uganda AIDS Control programme reports on eMTCT.

Response: On page 5, we have included more recent statistics on eMTCT, which have been cited from the Uganda HIV and AIDS country progress report (June 2015).

3.2 Para starting Lifelong….authors state that: ‘Enrolment of HIV-infected pregnant women into care continues to increase but their retention remains poor’. How poor is this retention and compared to what? We also know women are not a homogeneous group so for which women is retention poor?

Response:

We have provided clarification for this statement as follows:

….. As enrolment of HIV-infected pregnant women into care increases, their retention remains a concern (refer to page 5).
3.3 Authors should do a more critical analysis of women’s retention in eMTCT. Some studies show high retention even over a long time in Option B+. See for instance; Haas, Andreas., Lyson Tenthani, Malango T, Msukwa, Kali Tal, Andreas Jahn, Oliver J. Gadabu, Adrian Spoerri, Frank Chimbwandira, Joep J. van Oosterhout and Olivia Keister. “Retention in care during the first 3 years of antiretroviral therapy for women in Malawi’s Option B+ programme: an observational cohort study”. The Lancet HIV 3, no. 4(2016).

Response: Retention in care was not our primary outcome variable for this particular analysis, which is why our analysis did not focus on women’s retention in eMTCT.

3.4 Lines 45-50

How low were rates of maternity and PMTCT service utilization among women who had not disclosed?

Response: We have added the proportion to specify how low these rates were for women who had not disclosed. (refer to the last sentence on page 5)

3.5 Authors should review and discuss some of the documented outcomes of HIV sero-status disclosure and why the current study was necessary.

Response: We have strengthened the discussion section on page 20.

4.0 Methods

Major revisions

Description of the study sites should be strengthened to make it better to contextualize findings.

For instance;
4.1 How and why the study sites were selected?

4.2 How similar or different are these areas to the rest of Uganda? For example in terms of HIV prevalence, drivers, past success/gaps with provision of PMTCT including availability or lack of implementing partners, promotion of male involvement.

4.3 How long have these sites been providing PMTCT, ARVs?

4.4 What is the environment like in which lifelong ART is delivered at these sites? Is it routine, What is the ANC attendance like? What population do these facilities serve? What cadre of staff and numbers deliver these services? Do these sites have outreach services for PMTCT? These contextual factors have a bearing on the support women get, disclosure and related outcomes.

One way is to summarize some of this information in a table.

Response: We have modified the section under study sites on page 6 to include a detailed description of the context and the rationale for selecting the six health facilities. (see page 6 for more details)

We have also created a new table (Table 6) on page 34 of the revised manuscript. This table summarizes the context in which provision of PMTCT services varied across the three recruitment study sites to help the reader understand the environment in which lifelong ART is delivered at these sites.

Essential revisions

4.5 What was the rationale for mixed methods? How did the mixing happen?

Response: A mixed methods paper was appropriate for triangulation purposes. The qualitative component provided an explanation for some of the key quantitative findings. See the discussion section on page 20. For example, the barriers to HIV sero-status disclosure are exposed in our qualitative data.
The sampling procedure on page 8 shows how the mixing/sampling was done for both the quantitative and qualitative component.

4.6 Sample size of 507. How was this arrived at? Response: We have modified the section on sample size (page 8) by providing a detailed explanation of how the 507 sample size was determined.

4.7 Under sampling procedure clarify:

- How study participants were enrolled in the study

- Did you include all or some?

- For qualitative interviews, respondents were purposively selected, what was the basis for this purposiveness?

- What did you do for HIV negative women?

- How was the number of in-depth interviews determined?

- Describe the people who conducted the interviews

- Why were key informants not included in the study? Would have added value to the study. Authors should discuss this in limitations.

Response: We have adjusted the section under sampling procedure on page 8 to clearly specify the procedure used to sample participants for the quantitative component of the study (refer to the last paragraph on page 8).
We have included a statement to explain the basis for the purposive selection of respondents for qualitative interviews. (refer to page 9 for the statement below):

‘Respondents were purposively selected based on provider judgment of the client’s history of ART adherence/acceptance for option B+ over the past 4 months or longer, since we believed that these had a longer story to share’.

We have added a statement on page 8 to demonstrate what we did for the HIV negative women (refer to the last paragraph on page 8).

We have also adjusted the section under data collection tools on page 10 by adding a paragraph that covers interviewer information including their number, profession and training for data collection process.

Key informant interviews were conducted to help address an objective to explore health system challenges and successes in the implementation of Option B+ as part of the larger cohort study. However, we have provided an explanation on paragraph 2 under study sites (page 6).

4.8 Explain why analysis was limited to 2 visits not the entire follow-up period?
Response: We have modified the section on sample size (page 8) to include an explanation why our analysis was limited to 2 visits.

4.9 Ethical clearance - Consider renaming this to- Ethical Considerations
Response: We have replaced the word ‘clearance’ on page 24 with the word ‘considerations’, as suggested.

5.0 What did the team do for those who experienced negative outcomes of HIV status disclosure?
Also those who had not disclosed?
Response:  This study did not integrate any interventions and was purely observational. However, the women who experienced challenges were encouraged to reach out to their providers for support.

Results (Essential Revisions)

6.1 Include a study profile starting with screening, exclusion…

Response:  We have modified the first paragraph under the results section on page 13 to include details on screening and eligibility procedures (page 13).

6.2 Across the results section, be consistent in the presentation of %ages and absolute numbers.

In some cases, %s are presented first and numbers next and in other areas, the reverse. This is confusing!

6.3 Also refer to your tables in the text

Response:  Consistency in presentation of all figures has been checked through the entire manuscript. Absolute numbers now come before %ages in the revised manuscript.

We have adjusted our text to refer to our tables (see last paragraph on page 14)

6. 4 Page 11, under HIV-sero-status disclosure and spousal support

-Why is this section limited to spouses yet disclosure was studied beyond spouses?

-Remove/or reduce section on general support not linked to HIV status disclosure.

Response:  That section is limited to spouses only because the question on support following disclosure was only specific for women who had disclosed to spouses. Any form of support following disclosure to any other person (such as a relative/family member) is captured in the qualitative component, as indicated on page 16 (Refer to the 3rd quote on page 16 of the revised manuscript).
6.5 Under results, pg 12- section on women’s experiences disclosing should be revisited. The current form is more on how disclosure has helped or is difficult for some women.

- Do authors have data on the pathways to disclosure by these women? How did women go about disclosing? Were the paths different for disclosure to partner and other people?

- What helped women to disclose.

Response: We have modified the qualitative section on page 15 under ‘Women’s experiences disclosing their HIV positive sero-status’, by describing the processes women undertook in an attempt to disclose including the factors that enhanced/facilitated disclosure (page 15).

However, pathways to disclosure to partner differed (page 16) from those involving other persons (page 16).

Discussion (Essential revisions)

7.1 Pg 17-Authors state that: Interventions to enhance HIV-sero-status disclosure and partner support should address women’s fears and support for partner testing. What interventions have worked/or do you recommend?

Response: We have added a sentence next to the said statement to recommend some interventions that could address women’s fears and enhance support for partner testing (see page 20).

7.2 Pg 18- the discussion on gender, power, motherhood, poverty, young age of women as barriers to disclosure should be strengthened. Also review other Ugandan studies eg. Rujumba J et al. ‘‘Telling my husband I have HIV is too heavy to come out of my mouth”: pregnant women’s disclosure experiences and support needs following antenatal HIV testing in eastern Uganda Journal of the International AIDS Society 2012.
Response: We have included this citation (by rujumba et al) to help strengthen our discussion. (see page 20).

Strengths and limitations

8.1 Being a health facility based study- selection bias? Could any loss to follow-up in care and what this would mean for disclosure?

Response: This study was intended to explore disclosure and its outcomes among women enrolled on lifelong ART, which would mainly be those that attended the facilities and initiated treatment. We agree that a facility based enrolment may miss a small proportion of women who do not attend ANC but such women would not be on lifelong ART in the first place. MOH recommends that all women attending ANC be tested at first ANC (>95% of women in Uganda attend first ANC)—we enrolled HIV+ women including those tested on the same day.

8.2 The lack of male perspectives to check reported disclosure?

Response: We have adjusted our study limitations on page 23 to include a statement to acknowledge this as one of the weaknesses in our study.

8.3 Could you have overestimated disclosure and positive outcomes owing to social desirability?

Response: Male perspectives could have helped to double check. However, we do acknowledge this limitation to our study on page 23.

8.4 Key informants could have helped to triangulate

Response: Yes, we agree. However, we have provided an explanation for not including key informants in this analysis, much as data on key informants was collected as part of the larger
cohort to address an objective on health system challenges and successes in the implementation of Option B+ (page 6).

8.5 Table 1: Present characteristics by study site and add P-values. Are there site variations?
Response: We created table 6 on page 34 to help the reader get a feel of the variations in the model of care at the sites. However, we have maintained table 1 because we believe that confidence intervals are more informative than p-values.