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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Author’s response to reviews:

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Dear Editor,

Manuscript No: REPH-D-16-00017

“HIV status disclosure and associated outcomes among HIV positive 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

1.0 Background

1.1 You don't mention where the study took place/when

Response: We have included a sentence that indicates where and when the study took place.(refer to the last sentence under the background section of the abstract on page 2)

1.2 Delete the word PMTCT (repetitive)
Response: We have deleted the word PMTCT to make it less repetitive.

1.3 ‘We analyzed cohort data for 507 women initiated on lifelong ART in three districts in Uganda, to determine HIV sero-status disclosure and associated outcomes’

This sentence doesn't belong in the background instead include a sentence stating the study objective.
Response: We deleted this sentence and have instead included a statement highlighting the overall study objective.(refer to the last sentence under the background section of the abstract on page 2).

2.0 Methods

2.1 Methods’

We have changed this word from methods’ to methods.
2.2 It is typically advised to describe subjects/patients with a condition rather than infected, consider the below suggestion: 507 pregnant women with HIV OR 507 HIV positive pregnant women.

Response: Within the first sentence under the methods section on page 2, we have changed the description of subjects/patients from 507 HIV infected pregnant women to 507 HIV positive pregnant women. We have actually replaced HIV infected with HIV positive across the entire document.

2.3 followed up for four months when? after enrolment? after diagnosis, identification, conceptions?

Response: We have clearly specified after when?

We have indicated .followed up for four months after enrolment. (Please refer to the second line under the methods section on page 2).

2.4 Negative events

This is too vague

Response: We have addressed this by deleting the phrase ‘including spousal support and negative events’(see page 2)

2.5 In the methods you state 6 facilities
Response: We have inserted a new statement on page 2, which further clarifies on the number of health facilities included in the study. This statement is consistent with what is now stated in the methods. It is phrased below:

The quantitative sample was drawn from three recruitment sites while the qualitative sample was derived from six sites including the three quantitative sites. (see page 2)

2.6 ‘PR’ remove abbreviation

The abbreviation ‘PR’ has been removed. (see page 2)

2.7 ......‘Indepth..... inappropriate capital

The word ‘Indepth’ has been appropriately changed to small letters …indepth…. (see page 2)

3.0 Results

3.1 About eight in ten women who had sexual partners reported receipt of spousal support at the first; [330/407, (81.1%)] and second follow up [320/389, (82.2%)], which was more common among women who disclosed to their spouses (adj.PR =1.17; 95%CI: 1.02-1.34). This sentence is not clear

Response: We have modified this sentence to make it clear. Refer to the revised statement below on page 2:

Among women who had sexual partners, 330/407 (81.1%) reported spousal support at the first and 320/389 (82.2%) at second follow up. The majority of women who reported spousal support had disclosed their HIV status to their spouses (adj.PR =1.17; 95%CI: 1.02-1.34).
3.2 Overall, negative outcomes (HIV-related stigma, discrimination or violence) were high (20%)…….

According to what? self-report? it is not clear how you came to this conclusion.

Response: We have adjusted this statement to illustrate how we came to this conclusion by including the phrase ‘the proportion of self-reported negative outcomes’. The revised sentence is indicated below. (see page 3)

Overall, the proportion of self-reported negative outcomes (HIV-related stigma, discrimination or violence) was high (20%).

3.3 but 11% lower among women who disclosed relative to those who did not (adj.PRR=0.89; 95%CI: 0.56-1.42).

..........‘women who disclosed relative’ - what does this mean?

Response: To improve on the clarity of this statement, we have replaced the phrase ‘relative to’ with ‘compared to’. (see page 3).

4.0 Plain English Summary

4.1 ……sero-status….delete ‘sero’

We have deleted the word ‘sero’. (see page 4)

4.2 with the scale up of lifelong antiretroviral therapy (ART) for HIV infected pregnant women.

..........use lay language.......... 

Response: We have modified this statement to make it clear for the lay audience.........

The revised statement reads:

‘with the scale up of lifelong HIV treatment for pregnant women’. (refer to page 4)

4.3 We analyzed cohort data for 507 women initiated on lifelong ART in Uganda
Response: We have modified this statement to make it clear for the lay audience as indicated below:

‘We examined longitudinal data for 507 women initiated on lifelong HIV treatment in Uganda’. (refer to page 4)

4.4 Women on ART were followed up for four months to determine HIV sero-status disclosure and associated outcomes, including persons whom they commonly disclosed to. In-depth interviews were conducted with 57 women to document their lived experiences.

This is the exact same to your scientific abstract, please edit for a lay audience

Response: We have modified this statement to make it clear for the lay audience as indicated below:

‘Women on ART were studied over a period of four months after enrolment to determine disclosure of HIV positive status and associated outcomes, including persons to whom they often disclosed. One-on-one in-depth interviews were conducted with 57 women to explore their experiences with HIV status disclosure. (refer to page 4)

4.5 In order to reap the full benefits of HIV positive sero-status disclosure, efforts should integrate interventions to reduce negative outcomes

……what benefits….  

Response: We have deleted this statement and replaced it with a summarized sentence highlighted below;

Interventions to reduce negative outcomes could enhance HIV status disclosure. (refer to page 4)
5.0 Background

5.1 According to the Uganda HIV and AIDS country progress report (June 2015), out of a total of 1,493,164 pregnant women who were tested during ANC and received their results or knew their positive status, 8% (122,753) were found to be HIV positive. 

Response: We have deleted the opening phrase. According to the Uganda HIV and AIDS country progress report (June 2015)........and instead included a reference at the end of this sentence. The revised sentence has been phrased below:

Out of a total of 1,493,164 pregnant women who were tested during ANC and received their results or knew their positive status, 8% (122,753) were found to be HIV positive [2]. (refer to page 5)

5.2 ARV regimens for HIV-infected pregnant women have changed over time. Define ARV and delete ‘HIV-infected pregnant women’

Response: We have defined ARV regimens by removing the abbreviation and subsequently deleted ‘for HIV-infected pregnant women’. The revised sentence reads:

In an effort to eliminate mother-to-child transmission of HIV, antiretroviral regimens have changed over time. (refer to page 5)

5.3 Previous studies have shown that most women disclose their HIV status prior to child birth and their decisions to disclose are influenced by levels of internalized stigma...

What do you mean by internalized stigma?

Stigma placed on oneself? clarify

Response: We have deleted the phrase ‘internalized stigma’ and replaced it with the word ‘perceived’ which we’ve further defined in the brackets as stigma felt by oneself. Refer to the revised statement below on page 6.
……and their decisions to disclose are influenced by levels of perceived stigma (stigma felt by oneself).(see page 6)

5.4 Last sentence under the background section…

Include the aim/objective of the study We have modified the last paragraph under the background section to include the overall objective of the study. (refer to page 6)

6.0 Methods
6.1 Study sites
6.1.1 The study was conducted at six health facilities

This doesn't match with the abstract.

Response: We have inserted a statement to provide clarification on page 6. See revised statement below:

The quantitative sample (N=507) was drawn from three health facilities: Masaka regional referral hospital, Mityana district hospital, and Luwero HC/IV. The qualitative sample (N=57) was derived from these same three facilities, as well as three additional sites: Kyanamukaka HC/IV, Ssunga HC/III and Katikamu HC/III.

6.1.2 Inclusion of both hospital and lower level facilities (III and IV) was intended to address another objective of the larger study……What larger study?

Response: This study was nested within an ongoing prospective cohort of HIV positive pregnant women. However, to be able to address this comment, we have deleted the phrase another objective of the larger study to make this statement less confusing. The revised statement is indicated below:

Inclusion of both hospital and lower level facilities (III and IV) was intended to explore the differences in experiences by facility level.
6.1.3 These facilities were also selected because they were the first to implement Option B+ in their respective districts you already stated this above.

Response: We have deleted this statement since it’s a repetition of what is already mentioned above.

(see page 6)

6.2 Study design

6.2.1 This was a mixed methods study utilizing quantitative data from a prospective cohort of 507 HIV positive pregnant women who were attending ANC services at the selected health facilities and qualitative interviews

Interviews of who? How many?

Response: We have modified this statement:

This was a mixed methods study utilizing quantitative data from a prospective cohort of 507 HIV positive pregnant women who were attending ANC services at the selected health facilities and 57 in-depth interviews with women who had been initiated on lifelong ART for four months or longer.

6.2.2 Women were offered lifelong ART during pregnancy as per the Option B+ guidelines although some were deferred when not ready. Were these all newly diagnosed women? Were some women already on treatment before pregnancy?

Response: Our eligibility criteria included women who were either ART naïve (not yet initiated ART for the current pregnancy) or recently initiated 4 weeks at the time of study enrollment. Women on treatment before pregnancy were excluded.

6.2.3 Women were followed up every two months to determine disclosure of HIV sero-status, retention in care and adherence to ART for those who had initiated treatment.
every two months for how long? For four months? if so they were only followed up twice. what did 'follow-up' entail?

Response: We have adjusted this statement to make it clear. See statement below on page 7.

Women initiated on lifelong ART were followed upto four months (every two months after enrollment) to determine HIV sero-status disclosure and associated outcomes.

6.2.4 In-depth interviews were conducted with selected women to document their journey to initiating ART…..

when? by who? about what? how were they selected?

Response: We have modified this statement to answer the highlighted questions;

We also conducted in-depth interviews between February and May 2014 with purposively selected women to document their journey to initiating ART…………

6.3 Sample size

6.3.1 A total of 507 HIV infected pregnant women were enrolled between October 2013 and August 2014 at Luwero HCV, Masaka and Mityana hospitals. I thought it was at 6 facilities.

Response: Refer to the correction on page 6 above under the section on study sites.

6.3.2 The Kish-Leslie formula for proportion was used to estimate the sample size for the primary objective of the larger study…… What larger study? this is alluded to multiple times but not described or referenced.

Response: We have further clarified by adding a phrase at the end of this sentence as indicated below:
The Kish-Leslie formula for proportion was used to estimate the sample size for the primary objective of the larger study in which this study was nested.

Refer to the correction on page 7 under the methods section.

6.3.3 Written informed consent was sought from eligible study participants before administration of the baseline survey. This is the first mention of a baseline survey? what did this include? where was it administered? by who? to who?

Response: The word survey was incorrectly used. We have deleted it and replaced it with the word interview to make it clear.(refer to page 8)

6.3.4 ……respondents were purposively selected from among the HIV positive women in care, with the help of the health workers……..Was ethical approval provided by each facility?

Response: Yes, formal letters were written to the head of each facility to introduce the study. At the start of data collection, a meeting was held with staff at each participating facility to explain the different components of the study and as well communicate their role in supporting the study. Permission to conduct the study was obtained from the head of each participating facility.

6.3.5 After enrolment, follow-up surveys for cohort participants were scheduled…………Surveys are not interviews, which was done?

Response: We have deleted the word surveys and replaced it with the word interview to make it clear.

(refer to page 9)

6.3.6 After enrolment, follow-up surveys for cohort participants were scheduled every two months up-to month 6 post-recruitment (3 interviews per woman) and then every four months up-to month 18 (an additional three interviews, postpartum)………Describe only those methods that are included in this analysis
Response: We have modified this statement to include only the methods used in this analysis. The revised sentence is stated below (Refer to page 9).

After enrollment, follow-up interviews for cohort participants were scheduled every two months up to the fourth month.

6.3.6 Three well-trained and experienced study interviewers conducted the quantitative interviews.

Interviews or questionnaire?

Response: We have modified this statement as shown on page 10.

Three well-trained and experienced study interviewers administered the questionnaire.

6.4 Quantitative data management and analysis

6.4.1 Questionnaires were edited at the sites………

The questionnaires were edited or the responses?

Response: We have adjusted this statement to make it clear. See page 10: The responses were edited on site and reviewed by the study coordinator.

6.4.2 Double data entry was conducted using CSPro version 5 by two independent data entry clerks

On all the data or a subset?

Response: Double data entry was done on all the data not just a subset. We have adjusted this statement clearer to the reader. (refer to page 10)

Double data entry was conducted for all the data using CSPro version 5 by two independent data entry clerks.

6.4.3 In the multivariable analysis, other factors included in the model were women’s age, education level, marital status, employment, partner testing, type of visit (antenatal or postnatal),
health facility, and use of either alcohol or drug. Some of this detail can be mentioned when the findings are presented in the next section.

Response: We have moved this statement to the results section. (see page 18)

6.5 Qualitative data analysis

6.5.1 For the qualitative data, narratives were transcribed and transcripts coded independently by two researchers.

All transcripts were coded by two researchers or only a subset?

Response: All transcripts were coded by two researchers.

We have inserted the word all to make this clear to the reader. (see page 13)

6.5.2 We documented women’s experiences in dealing with HIV-related stigma and how this impacted on their disclosure decisions after initiating ART. Quotes were identified and presented verbatim to support some of the key findings.

Response: We have deleted this sentence. (see page 13)

7.0 Results

7.1 Socio-demographic and clinical characteristics of the sample...

Response: We have deleted the highlighted words (refer to page 14).

7.2 Almost all of the women were married (41/57, 71%) and had carried at least one previous pregnancy (54/57 women). Reference Table 1
Response: We have referenced table 1 at the end of the last sentence under the results section on page 14.

7.3 Other forms of spousal support included money to pick drugs……..to pick drugs? is this related to the choice of treatments or to retrieving the medications themselves?

Response: This statement is related to retrieving their ART supplies/medications from the health facilities themselves.

We have modified this statement for clarity (refer to page 14).

7.4 ART adherence support for women who disclosed included being escorted to pick drugs……..and reminders to swallow their drugs on time….Strange wording

Response: We have improved on the wording in this statement (see page 14).

ART adherence support for women who disclosed included being accompanied to the health facility to retrieve their medications……..and reminders to take their prescribed drugs on time.

7.5 In contrast to the good adherers, almost all the poor adherers and delayed acceptors (30/36) had not disclosed their HIV status to their spouses for fear of domestic challenges including separation. What about those who do not have spouses?

Response: Reasons for non-disclosure among women who did not have spouses included; fear of breach of confidentiality and perceived stigma. Others viewed their HIV positive status as a secret while some felt they needed more time to prepare to disclose. (These findings are presented on page 15 of the revised manuscript).

7.6 In the adjusted analysis, the risk of HIV-related negative events was 11% lower among women who had disclosed than those who did not disclose; after adjusting for age, occupation, type of visit and alcohol/drug use (adj.PRR=0.89; 95%CI: 0.56-1.42)

In the previous section you describe how the overall rate of negative outcomes is low, so are you confident in the associations below?
Response: Yes, we are 95% confident with these associations because our multivariate model was built after adjusting for any potential confounding variables.

8.0 Discussion

8.1 On the other hand, lack of disclosure and stigma were major barriers to ART adherence. But I thought they were uncommon?

Response: We agree with your observation and have therefore modified this statement as indicated on page 20 of the revised manuscript.

Although relatively uncommon, lack of disclosure and fear of stigma were major barriers to ART adherence.

8.2 Our qualitative data shows women who had not disclosed struggling with keeping clinic appointments and taking their drugs…….Why might this be?

Response: They acted this way probably because they did not want their spouses to find out that they were HIV positive for fear of the negative outcomes (such as divorce) that could potentially result from knowing their HIV positive status, while others thought they would lose financial or social support from their spouses if they disclosed. (refer to the quotes below on page 17)

I feared because I did not want the man to see me taking the drugs. He told me that, if they test me for HIV and am found with the HIV virus, we will divorce.--Delayed ART Acceptor (Mityana hospital).

Even if he knows that he is the one who brought that thing [meaning infected you with HIV], he will say that it is the woman who brought it. That’s why majority of women keep quiet saying that if I tell the man he will chase me away. Who will look after me at home? -- Good ART Adherer (Katikamu HC/III).
8.3 This is similar to the rates reported in a systematic review of studies done in developing countries where less than 15% (3.5% - 14.6%) of women were reported to experience a violent reaction from a partner following disclosure.

A violent reaction from a spouse is much more severe than stigma, so are these rates comparable?

Response: Yes, these rates are comparable because in this study, our composite variable for negative outcomes combined stigma, discrimination and violence which were initially captured independently as stated below:

Have you experienced stigma, discrimination or violence because of your HIV status? (Circle all that apply).

As such, we were able to tease out the proportion of self-reported negative outcomes that were attributed to violence (3.7% - 3.9%), stigma (7.6% - 10.8%) or discrimination (5.3% - 5.4%); thus making these rates comparable.

(Refer to the results presented on page 18)

8.4 Simple screening measures could identify and target such women while interventions to reduce negative outcomes (stigma and violence) should include efforts to scale up male involvement. Is there evidence that this would reduce the negative outcomes?

Response: See evidence provided from two studies (South Africa and Uganda).

Both studies showed reduced intimate partner violence among participants in the male engagement intervention arm (page 23).

9.0 Study limitations

In the quantitative analysis, we were unable to differentiate the type of stigma, whether felt or perceived stigma. Are felt and perceived different?
Response: ‘Felt and perceived’ refer to the same type of stigma (stigma inflicted upon oneself. We have therefore provided clarification by deleting the word perceived and replaced it with the word enacted to mean the type of stigma inflicted by others. (see page 24)

10.0 Presentation of Tables

10.1 Table 1: The difference between Table 1 and 2 is not clear.

Response: Table 1 provides a description of the socio-demographic and clinical characteristics of the sample in terms of their numbers and percentages.

Table 2 describes (by study visit) the primary independent variable (HIV status disclosure) and associated outcomes (spousal support and negative events) including the mode of HIV testing for women and their spouses.

Age category
15-24, 25-29, 30-34

It is strange to present three categories that are not equivalent. The first represent 10 years and the others are 5. None were older than 34?

Response: We have maintained these categories and instead provided an explanation as a footnote right below table 1 (page 29). Our explanation is stated here.

Age categories were based on definition of young women (up to 24 years) and fertility across age groups (based on Uganda UDHS data).

We certainly had women older than 34, thank you for highlighting this. It was a typing error. We have made the correction below in tables: 1, 4 and 5.

15-24, 25-29, 30-44.

10.2 Table 2
There are many tables provided that are not mentioned in the text, all tables that are included must be referenced.

Response: We provided 6 tables and have now referenced all of them in the text.

For instance; Table 1 is referenced on page 14; Table 2 on pages 14, 15, 18; Table 3 on page 15; Table 4 on page 15 & 16; Table 5 on page 19 and Table 6 on page 7 of the revised manuscript with track changes.

How partner tested (during ANC, outside ANC, individually)

How is this different from outside ANC?

Response: We have modified these responses for clarity. Refer to table 2 on page 30 for the revised responses: tested together during ANC, tested together outside ANC, tested individually.

HIV-related stigma, discrimination, violence

What about it? It is not clear what this field represents.

Response: This field represents the negative outcomes of disclosure of HIV positive status. We have renamed this field as:

‘Ever experienced HIV-related stigma, discrimination or violence, to make it clear to the reader. (Refer to table 2 on page 30)

10.3 Table 4

Marital status:

Never married, married, widowed/separated

What about women who are in a committed relationship but not married?
Response: We have maintained these categories as stated because women who reported being in a committed relationship (co-habiting) were considered married.

Occupation:

Unemployed, home maker, business/wage. What is this? employed?

Response: We’ve removed the word business/wage from table 4 and instead replaced it with employed to make this category clear. In the analysis, we re-categorized this variable. All those who mentioned peasant farmer / salaried / business / casual-worker / wage as their primary occupation were collapsed into one category which was redefined as employed.

In this study, we defined occupation as where one spent most of their time irrespective of whether they received a salary/wage or not.

Education level

None/primary, O’ level, A’ level + vocational training, University

Level O and A are not categories common to all audiences, these must be changed or explained.

Response: In Table 1 (page 29), 4 (page 29) and 5 (page 33); we have renamed these categories (O’ and A’ level) to help all audiences understand them better.

O’ level category has been renamed as Lower secondary (ordinary level) while A’ level has been renamed as Advanced secondary.

Type of visit:

Antenatal, postnatal, subsequent postnatal

Why not group postnatal together?
Response: We have maintained these categories because in our study, postnatal and subsequent postnatal visits were defined differently. We actually administered different questionnaires at the 1st postnatal visit and subsequent postnatal visits. We have provided clarification in table 4.

By postnatal visit, we mean the very first postnatal visit that the mother made to the clinic soon after delivery.

Subsequent postnatal visit refers to all other postnatal visits that subsequently followed the initial postnatal (1st PNC visit), which is why we wouldn’t group these two categories.