Author’s response to reviews

Title: Contraceptive use and pregnancy rates among women receiving antiretroviral therapy in Malawi: A retrospective observation cohort study

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Dear Editor,

RE: REPH-D-17-00161- Contraceptive use and pregnancy rates among women receiving antiretroviral therapy in Malawi: A retrospective observation cohort study

On behalf of the authors, I would like to thank you for the favourable review and decision of the above mentioned manuscript. We have addressed all the issues raised by the reviewers by indicating the changes using track-changes in the manuscript. Below is the point-by-point response to the issues.

We hope that this revised manuscript is now suitable for publication in your journal, and look forward to hearing from you in due course.

Regards,

Hannock Tweya
Reviewer reports:

Reviewer #1: The results were predictable (offering effective contraceptives reduce pregnancy rates) and the generalizability of the findings is limited. However, the study is very well-written - authors acknowledge most of the limitations - and the results are still interesting.

Thank you for the comments

I have only one minor comment

- Please, define ART in the abstract.

We now have written ART in full at first appearance.

Reviewer #2: Comments:

1. In Plain English summary section: Line # 16-23, by what aspect HIV positive women differ from the general population in terms of accessibility to family planning services? What challenges HIV-infected women are facing in accessing a preferred contraceptive methods unlike the general population?

We have addressed the two questions as follows:

Women living with HIV appear to have a higher rate of unintended pregnancy (51–90 %), compared to global unintended pregnancy estimates (38%).

Most frequently, family planning services are not integrated into HIV services; therefore, HIV-positive women typically must visit separate family planning and HIV clinics to access both services.

2. In Abstract section:

2.1 The background should show the knowledge gap

We have added the following sentence:

To date, no previous study evaluated pregnancy rates among HIV-positive women after the integration of FP services into HIV-related care.

2.2 In the method subsection: you didn't say about the analysis method except mentioning the study design.
Thank you for the observation. We have revised the method section by including the following sentences:

Pregnancy rates, frequencies and proportions were calculated. Trends of contraceptive use and pregnancy rates were analyzed using chi-square ($\chi^2$).

3. Introduction section:

3.1 Use consistent term! In the abstract, you used the term 'Background' while the term 'Introduction' here.

Thank you for the observation. We have replaced introduction with background in the main text.

3.2 It is good to use the latest report on HIV instead of using the 2013 report.

We have now used the 2016 UNAIDS report.

3.3 Line # 27: what reference style did you use?

Thank you for the observation. We have updated the reference style.

3.4 Line # 47: You noted that "Efforts to implement more integrated FP services within MPC were initiated, by mid-2013" but this is not consistent with the first sentence of the background section of the abstract.

Thank you for the observations. We have revised the introduction and abstracts accordingly.

MPC introduced provider-initiated FP service following the implementation of the 2011 Malawi integrated clinical HIV guidelines. Accordingly, MPC began to routinely provide condoms to all adults in ART clinics and offer, at least the standard injectable contraceptive (depot medroxyprogesterone Acetate (DMPA)) during ART visit to women [11]. Women who preferred other contraceptives were referred to a neighboring, external reproductive health unit for contraceptives. Efforts to implement more integrated FP services within MPC were initiated in early 2015, resulting in an array of FP methods (including oral contraceptive pills, DMPA, copper intrauterine devices, etc.) offered within the ART clinic setting.
3.5 Line # 59: You said "We compared pregnancy rates among women on ART to (i) pregnancy rates observed in the previous MPC study". Do you mean you have made a comparison with others study (which is not a component of this study)? If yes, is it appropriate because there may be methodological difference? Why you compared your finding with the finding observed in urban women in the country? because your study participants (HIV positive women) are different by different characteristics for instance birth intention and residency.

Yes we qualitatively compared pregnancy rates observed in this study with those observed in a previous study conducted at the same facility before family planning services were integrated. This adds context to the findings to better inform the reader about the effects of integration.

The study clinic, MPC, is located in in Lilongwe, Malawi, the capital city and a large urban area. For this reason, we compared with urban women in the general population as their fertility preferences are likely similar in a similar setting.

4. Methods section:

4.1 You didn't explain about the study design in the main body of the method section. Readers may be confused whether it is a retrospective cross-sectional or cohort.

We have revised the sentence as follows:

This retrospective cohort study used routine programme data collected at a public ART clinic, MPC, at Bwaila Hospital situated in urban Lilongwe, Malawi.

4.2 line # 19/20, you noted "....for management of ART patients." What do you mean by 'ART patients'? Rewrite it.

Now the sentence reads as follows:

The clinic uses a real-time, point of care, electronic medical record system (EMRs) for management of HIV positive people who are receiving ART.

4.3 What is you exclusion criteria? Did you exclude HIV positive clients who did not start ART? If yes, why? because both those who are on pre-ART and ART services at ART clinic are equally important in reducing unintended pregnancy and paediatrics HIV/AIDS.

We did not include HIV positive women who did not initiate ART because data collection of pregnancy information was not consistent for them. We have included this information in the
method sections (paragraph 1 line #4): We excluded (i) all HIV positive women who registered for HIV care, but did not start ART, due to inconsistent pregnancy information among pre-ART patients, (ii) women who had fewer than 1 month of ART follow-up and (iii) women who were pregnant at ART registration and were lost from care within 3-month after delivery.

4.4 Who should be the study and/or the sample population? Why did you consider all HIV-infected women to assess contraceptive use rate? The denominator should be only sexually active HIV positive women. The contraceptive is not an issue for those who are not sexually active.

We calculated the proportion of contraceptive use as the number of women reported using contraceptives at the time of their ART clinic visit (numerator) over the total number of non-pregnant women who accessed ART care during each quarter (denominator). The denominator included some women who may not be sexually active because (i) sexual activity status may change within a short time and (ii) women might have falsely reported not being sexually active due to the cultural sensitivity of discussing their sexual life. We have updated the methods section to reflect this in the first paragraph under data management and statistical analysis as follows.

Women who were not sexually active were included in the denominator because (i) sexual activity status may change within a short time and (ii) women might have falsely reported not being sexually active due to the cultural sensitivity of discussing their sexual life. Use of long-acting reverse contraceptives (intrauterine devices and implants) and permanent contraceptives (tubal ligation and vasectomy) were classified as “more effective contraceptives” and other contraceptives were condoms, DMPA and oral contraceptives.

4.5 Look references style in Line # 33/34-Ref [19-21] and Line # 37/38-Ref [11][14], the reference style is not consistent.

Thank you for the observation. We have updated all the referencing format.

4.6 In data management and statistical analysis section, it is clinically important to focus on modern contraceptives excluding the traditional ones because they are less effective and are not recommended.

We have revised the analysis to focus on modern contraceptive methods. The method and result sections are now updated accordingly.
4.7 line # 10-14 It says "Use of intrauterine devices, tubal ligation and vasectomy were classified as "more effective contraceptives". What is the definition of 'more effective methods'? Don't you think there are other contraceptives which are highly effective which are not included in your case? Please review it. Please cite references for the definition;

Thank you for the observations. The more effective contraceptives refers to long-acting reverse contraceptive and permanent contraceptives. But the use of “more effective contraceptives” was not consistent in the method and result section. We have therefore revised the method and result section to reflect this. Now, the sentence reads as follows:

Use of long-acting reverse contraceptives (intrauterine devices and implants) and permanent contraceptives (tubal ligation and vasectomy) were classified as “more effective contraceptives” and other contraceptives were condoms, DMPA and oral contraceptives. (Under data management and analysis, line # 4).

We did not include other equally effective contraceptive methods (such as Contraceptive Patch, Vaginal Ring etc… ) in the study. These options were not offered at the clinic or the nearby reproductive health unit for women receiving services at MPC.

5. Results section:

5.1 You have excluded 3,093 (23%) of women on ART but you said nothing about the exclusion criteria in the method section.

We have added a sentence for this as exclusion criteria: “We excluded (i) all HIV positive women who registered for HIV care, but did not start ART, due to inconsistent pregnancy information among pre-ART patients and (ii) women who had fewer than 1 month of ART follow-up and (iii) women who were pregnant at ART registration and were lost from care within 3-month after delivery.”

5.2 Please rewrite the result after considering the comments given on the definition of "more effective methods".

We have revised the results section accordingly

5.3 pregnancy rate, Line # 56, you mentioned that the pregnancy rates remained stable at 3.1 per 100 person-year however you noted a varied pregnancy rate which as low as 1.6% at 6 months and as high as 10% at 36 months. How do you see it.
The two rates present values for two different concepts. Pregnancy rates (incident) is the rate at which new pregnancies are occurring at any particular moment while cumulative incidence is the proportion of a women at risk of becoming pregnant in a given period of time. They are expected to be different.

5.4 In the result section, you are not expected to compare your findings with others but you compared your TFR result with previously done one. It is expected in the discussion section. Instead, note you findings (TFR, # of births...)

Thank you for your observation. We have not removed the sentence from Results and used in in discussion as follows:

The TFR of women in the study was also lower than both the TFR of the general population of urban Malawian women[4] and the TFR among pre-intervention women in 2010 (TFR 3.1)[17], suggesting the impact of the integrated, comprehensive FP services in HIV-infected women. (Discussion, paragraph 1)

6. Discussion

6.1 Well written but it is good to enrich it mainly the contraceptive rate by comparing with the results of many other similar studies.

We have added a paragraph that compares recent contraceptive use among HIV positive women receiving ART in sub-Saharan Africa. Below is the paragraph

We found an overall contraceptive use of 62% in 2016. As compared to our result, some recent studies among women receiving ART in Ethiopia, Nigeria and Ghana reported a lower contraceptive rate, 44%, 36% and 42%, respectively[18][19][20], while a study in Zambia reported higher contraceptive use of 69%[21]. Unlike our study, however, family planning services were not fully integrated in HIV clinical care in these studies and most preferred methods were male condoms, except in Ethiopia. These comparisons highlight variations of contraceptive service delivery and contraceptive uptake among HIV positive women who are receiving HIV-related care in sub-Saharan Africa.

6.2 Consider the reference style

Thank you for the observation. We have addressed the reference style.
7. Table-2

7.1 Reconsider the proportion of more effective contraceptives based on the comment given. Thank you. We have revised the table accordingly.

7.2 It is good to show the trends in graph

Thank you. We replaced Table 3 with a graph.