Reviewer’s report

Title: Factors Associated with Vaccination Completion and Retention among HIV Negative Female Sex Workers Enrolled in a Simulated Vaccine Efficacy Trial in Kampala, Uganda

Version: 0 Date: 06 Jun 2019

Reviewer: Monika Doshi

Reviewer's report:

General Comments:
1. The authors tackle an important and timely issue. Suggest modifying title to more tightly fit the crux of the investigation (i.e., factors associated with retention and vaccination completion...).

2. General flow and connections between paragraphs need to be strengthened further. Suggest linking paragraphs more tightly throughout the manuscript.

3. Given that the scientific inquiry is timely and important, the authors may consider strengthening the manuscript by highlighting the Ugandan context in relation to FSWs and sex work. That is, the literature review can be strengthened with additional examples from the African context generally and the Ugandan context more specifically.

4. Correct for typos

5. The acronym list does not include all the acronyms from the body of the text. For example, the following (among others) are missing: AVD, MRC, UVRI. Suggest updating.

6. Consider revision of formatting, especially section headers, of the manuscript to conform to an existing template.

Specific Comments:

Introduction
Clarifications are required for the following:

1. Lines 65-69: How does HVTN702 relate to RV144? The mention of these together seems a bit disjointed -- recommend making the needed connections.

2. Lines 71-77: What are the other interventions being referred to here?

3. Lines 77 & 80: How is "good retention" defined? It would be helpful to specify this.

4. Lines 83-84: What is meant by preparedness education? And what types of studies specifically?
5. Line 87: The current literature specifies terminology such as MARPs (most-at-risk populations) or key populations. Consider using one of these and providing reasons for why FSWs are more at risk. If the choice is to stay with characterizing FSWs as having high HIV incidence then consider providing related statistics.

6. Line 90: Consider providing characteristics of FSWs in Uganda as opposed to India. The mobility of FSWs varies by context as well as by sex work type in India (e.g., street-based, brothel-based, home-based, etc.). It will be more important to characterize the context in Uganda.

7. Line 92: Consider elaborating on the criminalization and discrimination of FSWs specifically in the context of Uganda. It will be important to ground the introduction more specifically to the Ugandan context. This is largely missing from the manuscript.

8. Line 99: It is unclear what is meant by site operational tools.

Methods

1. The clinic visit schedule is unclear. Consider using a table or some sort of a graphic to facilitate understanding.

2a. For more clarity and to improve flow, consider combining the sections on "Study setting and source population" and "Sampling and eligibility criteria".

2b. Line 123: Mention of ART causes confusion since the study is focused on HIV negative FSWs. Consider revising.

3. What about determining/calculating sample size? There is no mention of this.

4. Line 134: It is unclear what is meant by baseline safety assessments.

5. Line 154: Was transportation provided? This is unclear. If so, how did the honorarium differ between those who received transportation and those who did not?

6. Line 155: What was the amount of the honorarium? This should be included.

7. The laboratory methods section may not be required. Consider removing/deleting.

8. Primary study outcomes: This section needs to be more clear. It is unclear, for example, how a volunteer would be categorized (retained or not retained) if they completed 2 of the 3 vaccination visits and the 12 months. That is, the primary study outcomes can be more clear here -- they become more clear as one reads on but that's a bit too late.

9. Consider elaborating further on independent variables including whether any preexisting instruments/measures were used. How were the independent variables chosen/informed by literature? Why those and not others, for example?

10. Line 205: Unclear what is meant by total expected.
11. Lines 207-211: More details need to be provided regarding the statistical analysis for both the bivariate and the multivariate analysis. What models were tested and how?

12. Overall this section needs to strengthened. Currently, there is information here that is not essential (e.g., laboratory methods) while pertinent information is missing (e.g., sample size calculation).

Results

1. Line 217: Unclear what 'citing frequent blood draws' means. This can be made more clear.

2. Line 219: Consider providing the age range of the sample instead of IQR.

3. Line 221: How has the volunteer not reporting exchanging sex for money, gifts, etc been categorized? As a FSW? How is the current study defining FSWs?

4. Table #1: Consider breaking down the age group "35+" further as this will give a better descriptive sense of the study population.

5. Line 232: Addresses 18 volunteers. What about the remaining? Consider combining with the sentence that follows to facilitate flow and ease of understanding.


7. Table #2: Consider inserting into the body of the manuscript as opposed to the Appendix/end of manuscript.

8. Consider reporting other findings, including those that are insignificant as this is the "Results" section.

Discussion

1. Line 244: How can the retention rate of this study be explained further? It is on the lower end of the ranges reported by other studies. What does this mean or imply for the way forward?

2. Lines 253-257: The current study's retention strategies don't seem to support or counter the named barriers to retention. So, this begs the question, what did the study do differently?

3. Overall: The discussion section highlights were the study's findings converge with past findings. However, it is unclear what new knowledge or current gaps in extant literature have been filled by this study. The authors should consider being more pointed and direct about how their study advances scholarship. It may also be important to contextualize to the Ugandan context and also provide related discussions and explanations.

Limitations

1. Consider elaborating on this section. For example, how does context and study design shape
limitations, including generalizability?

2. The authors have also included study strengths in this section. Consider revising the header to "Limitations & Strengths".

Conclusions & Recommendations

1. This section needs more information. Consider summarizing key study findings, their implications and related implications in more depth.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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