Reviewer's report

Title: Long-term consistency of vaginal gel use among HIV-1 sero-discordant couples in a phase III double blind trial (MDP301), in rural SW Uganda

Version: 1 Date: 31 August 2012

Reviewer: Jael Obiero

Reviewer's report:

1. Major compulsory revisions
   a) Authors contribution
      This paper was written in haste and it is highly unlikely that all the co-authors indicated on the manuscript (Wrote the paper: AA AC SM SW JL ANA RH MG ZA AN AK) read the paper and gave their input. All co-authors should spend considerable time to re-write this manuscript.
   b) There are several short paragraphs in each section of the paper e.g four short paragraphs on background, six short paragraphs on results and eight short paragraphs on discussion. These many short paragraphs make the paper appear cumbersome, and here is lack of adequate flow of the contents of the paper. I recommend that the paragraphs be merged in a way that allows for proper flow of the contents of the paper.

2) Abstract
   a) Methods
      Second sentence
      Remove “remaining”. If you remove 299 from 840, what remains is 611women.
      Re-write to read
      The PRO2000 arm that had enrolled 229 women was stopped early due to futility and data were analysed on 544 women who ........
   b) Results
      Insert “gel” line 4
      ........independently associated with reported gel use.
   c) Conclusion
      Insert “positively” line 3
      Privacy could positively influence gel use.

3) Methods
   a) You need to focus on the experimental design and describe the participants. Do not discuss results here.
   b) First paragraph, first line.
Correct spacing “Uganda- Masaka” to “Uganda-Masaka

c) Remove “HIV negative”. You have mentioned it in the inclusion criteria

Second paragraph, first line
d) Replace “was” with “were”

7th line
e) Re-write to read “……placebo gel, but the 2% was stopped early on 14th February 2008 on recommendation by the Independent Data Monitoring Committee that is was unlikely to show benefit. However, 37 (4.4%) women on this gel arm had either sero-converted or completed 104 weeks of follow up. This analysis was therefore limited to the 0.5% PRO2000 and placebo gel arms.

Third paragraph, fifth line
f) Delete “e.g.” insert “factors such as”

…..visits due to factors such as sero-conversion or pregnancy.

4) Results

a) Note that you need to include only the results of what appears in experimental design under methodology.

First paragraph, second line
b) Delete the second sentence that begins with “The reasons…….. Re-write the sentence to read “Those who were HIV-positive, pregnant or not sexually active at screening were considered ineligible”.

Fifth line
c) Insert (Figure 1) at the end of the paragraph

Second paragraph
Insert (Table 1) at the end of the paragraph
d) “ I recommend that you merge the first and second paragraphs”

Fourth Paragraph
e) It is not clear where these results are originating from. HIV infection is not an outcome of your interest and does not fall within the scope of your objective. In addition, the methodology section does not have any description on HIV assessment.

HIV incidence was a primary outcome already reported in the main trial. Reporting it here does not add any value to this paper.

Fifth paragraph
f) Insert (Table 1) at the end of the paragraph
g) Other factors such as education, etc, that appear in table1 are not mentioned in the results section.

Note that you need to include only the data from experimental design described
under methodology.

5) Discussion

a) Note that you should only discuss what appears in the experimental design and in results.

b) Your discussion should focus on your results and implications for up coming studied

First paragraph

c) Fourth line

Insert (Table 1) after (67.8%)

Third paragraph

Sixth line

d) “Perceived sexual experience evaluation”? This appears under discussion, but it is not described under methods or results section.

Ninth line

e) Insert (Table 1) after “significant”

Tenth and eleventh line

f) Are there any data to support this?

Fourth paragraph

First line

g) Delete “was” insert “were”

Fourth line

h) Insert (Table 1) after “consistently”

Sixth line

i) Delete “applicator”

Paragraph seven

j) As in results section, age and privacy have been extensively discussed for reported consistent gel use. Some of the factors mentioned in table 1 such as level of education, etc seems to have been ignored.

Paragraph eight

k) Are you suggesting that gel based microbicides are not necessary since ART is available? Could you suggest how future studies should be designed for gel based microbicides given that ART is in use?

Line one

l) Write ART in full and put abbreviation in bracket

**Level of interest:** An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that i have no competing interest