Author's response to reviews

Title: Long term virological, immunological and mortality outcomes in a cohort of HIV-infected female sex workers treated with highly active antiretroviral therapy in Africa

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Author's response to reviews:

05/01/11
Dear Editor
We provide here below a point by point response to the first reviewer’s comments, and we thank Reviewer 2 for accepting our previous changes.
We have made most recent changes in track mode in the manuscript.
We thank you for the opportunity to revise our work and re-submit our manuscript.
Philippe Mayaud (on behalf of co-authors)

Reviewer's report

Version: 2 Date: 30 November 2010
Reviewer: Brian Montague
Reviewer's report:
Major Compulsory Revisions
1. Need to better delineate the type of sex work in the composition of the cohort and specifically address the discrepancy between the number of sexual partners in their survey (which is low) and prior studies of the high risk group which indicated much high numbers of partners. The presumption is that they have missed the highest risk group in their cohort which, if not the case, needs to be clearly addressed and refuted by the data presented and subsequent discussion.
REVIEWER’S COMMENT ON REPLY 1: I appreciate the authors’ thoughtful discussion of the issue above. For the purposes of the article, noting lower risk does not seem sufficient to clarify the issue for the reader who will not have the benefit of reading this elaboration. Since the conclusion is that introducing HAART into a hard to reach and marginalized population is maintainable or sustainable over the long-term, it is important that the paper and the discussion clearly identifies the cohort and critically assesses that issue. The noted collection of risk data at time of HAART initiation rather than at intake into the education and prevention programs seems to be an important limitation of this study that should be addressed.

AUTHORS REPLY 2: We have further clarified the differences in behaviour at time of cohort enrolment and at time of HAART initiation and the likely causes of divergence. See Discussion, pp 16 (yellow highlights).

2. Unless cost-effectiveness and sustainability data is presented, conclusions regarding sustainability need to be dropped as they are not substantiated. All available data in the article suggests that this cohort has received a level of monitoring and intervention that may not be sustainable in most national HIV programs in sub-Saharan Africa without a commitment of additional resources based on their being a high risk group.

REVIEWER’S COMMENT ON REPLY 1: I am not sure that the substitution of 'maintain' for 'sustain' significantly changes the meaning. The concern is not with the terminology but rather with the conclusions drawn. Essentially the authors conclusion is that with a cohort intervention including high degrees of prevention services, counseling, laboratory monitoring, and resource investment similar to what is provided in more resource plentiful environments HAART can be given with acceptable adherence and immunologic and virologic outcomes that reflect the regular use of medications. That is a very different statement than HAART is an attractive option for use in marginalized populations which reflects a generalization of the above observation to a context in which the high level of intervention is not feasible or maintainable over the long-term. Is the goal of this paper to advocate for high level investment of resources in these populations? Clearly there is no difference in the biology of these patients so the conclusion that if you get them to take meds they will respond to treatment is neither interesting nor novel. The interest and the importance of your valuable study lies in the point that the authors are downplaying, namely what does it take from a systems of care point of view to sustain this level of response. That is what would seem to be most relevant in the discussion and what is missing even with their modifications.

AUTHORS REPLY 2: We have been careful to stick to the main conclusion that can be derived directly from our findings, i.e., as the reviewer notes, that it is possible to elicit a sustained biological response to HAART even in this marginalised population given a fairly high level investment, which we believe is
feasible and worthy. However, because we of the noted study population
limitations and lack of economic or health systems evaluation data we have been
careful to not make claims of generalisation, replicability or sustainability, as the
reviewer indicated.

Discretionary Revisions

4. Unless data on transmission events can be presented, I would suggest
deephasizing the impact on transmission in the discussion since the rate of
sexual activity in your cohort is low and you have no data to refute the contention
that targeting this group will have minimal impact on the spread of the epidemic.

REVIEWER’S COMMENT ON REPLY 1: This discussion remains outside of the
scope of a cohort intervention study. Modeling studies require outcomes from
treatment in the broader population. The very limitations that the authors cite
regarding the generalizability of their cohort, the unfeasibility of the interventions
for large scale use given the expense, make the data obtained from this sample
less relevant for modelling. If the authors can demonstrate that the observations
of durable response could be achieved with a sustainable level of resource
investment, then the example provided by this cohort would be of great value to
modelling the potential impact of increased use of HAART in these communities.
Overall, the inclusion of this paragraph raises more questions than it answers.

AUTHORS REPLY 2: We have now removed this paragraph from the Discussion
(p16) and considerably reduced the corresponding paragraph on possible
transmission effects in the Background (p5). We have simplified our conclusions
(p16 and in the Abstract).

The revised word count is reduced to 2981 and abstract 282 and 42 references
(no changes to tables and figures).