Author's response to reviews

Title: Increase in condom use and decline in prevalence of sexually transmitted infections among high-risk men who have sex with men and transgender persons in Maharashtra, India: Avahan, the India AIDS Initiative

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Version: 3 Date: 21 June 2013

Author's response to reviews: see over
To,
The Editor,
BMC-Public Health

Dear Editor,

We thank you for proving us an opportunity to resubmit our paper (MS: 1457241132880259) after modifications, based on comments from reviewers. The comments from reviewers were insightful and helped us address gaps in the manuscript. We have replied to each of the comments below and have incorporated the suggested revisions. We edited the complete manuscript to improve the flow and readability and sections with major changes have been highlighted.

We hope we have satisfactorily addressed the concerns of the reviewers, and the paper can now be considered for publication. Please let us know, if any further clarifications are needed.

Sincerely,

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Reviewer's report

Title: Increase in condom use and decline in prevalence of sexually transmitted infections among high risk men who have sex with men and transgender in Maharashtra, India: Avahan, the India AIDS Initiative

Version: 2 Date: 14 February 2013

Reviewer: Tooru Nemoto

Reviewer's report:
Major Compulsory Revisions:
The study presented evaluation results of a large scale community intervention project in India targeting high risk men who had sex with men and transgender persons; however, the manuscript needs to clarify a number of issues.

1. Abstract page 2

a) Please clarify HR-MSM/TG: What does “high risk” mean? Do transgender persons include both male-to-female and female-to-male transgender persons? If it means hijra, please state and explain to readers.

As suggested, we have now included following sentences in the abstract:

“Based on Avahan’s evaluation framework, the present study assessed coverage, changes in condom use, and prevalence of HIV and other STIs among high-risk men who have sex with men (HR-MSM; highly visible, recruited from cruising sites/sex venues) and transgender (TG; male-to-female transgender persons, also called hijras) in the Indian state of Maharashtra”.

Additional details have also been included in the introduction section of the main manuscript.

b) Methods: Were there any duplicates in study participants in Round 1 and 2? It seems that the study did not assess changes in behaviors and STIs of the same participants, but assessed changes in the prevalence of these.

We have adopted probability based sampling and the proportion of respondents who participated in both rounds of survey was negligible i.e. 2% & 3% in two districts.

c) Results: Clarify “denominator”. It seems an estimate. If it’s so, please show how the denominator was calculated.

We have changed the term denominator to estimated total population for clarity and the details are explained in the methods section in the main manuscript.
d) Clarify “regular” male partner.
   Spell out “IBBA”

   As suggested, the terminologies have been defined and acronyms spelt out.

2. Page 4 1st paragraph

   a) It does not seem HIV/AIDS epidemic is heterogeneous; concentrated on FSWs, MSM, transgender persons, and IDUs. The background section needs to address the previous literatures on HIV/AIDS specific to MSM in the region and India. The manuscript described the background of the project implementation which could be in the methods section.

   As suggested, the background section has been revised to present a context of the previous literature on HIV/AIDS specific to MSM in the region and India. However, the background of the project has been retained in the introduction so as to provide a broad perspective of the program for which the evaluation was conducted and has also been recommended by the second reviewer.

3. p.7 1st paragraph

   “80% of the estimated denominator” needs clarification.

   We have now clarified what 80% of the estimated denominator means as below in the manuscript

   “Avahan’s target for saturated coverage (defined as providing services to at least 80 percent of the estimated total population) in selected districts/catchment areas, assessed through participatory mapping and site assessment, was the benchmark against which the adequacy of coverage was assessed. The estimated size of the HR-MSM/TG population as of March 2009 (10,240) was used as the denominator for analysis”.

4. p.8 3rd paragraph

   a) What are “scale-up, intensity, and quality”?

   As suggested, the indicators presenting scale and intensity of the Avahan program are explained in the methods section as below:

   “The coverage indicators included whether a high-risk group member was ever contacted by peer educators and had ever visited a program STI clinic. Avahan’s target for saturated coverage (defined as providing services to at least 80% of the estimated...
total population) in selected districts/catchment areas, assessed through participatory mapping and site assessment, was the benchmark against which the adequacy of coverage was assessed. The estimated size of the HR-MSM/TG population as of March 2009 (10,240) was used as the denominator for analysis. The service indicators examined were monthly peer contacts and quarterly clinic visits against Avahan's established targets [outreach: one contact per month; clinic visits: once per quarter]. Measures of program intensity included ratio of program staff (peers and outreach workers) to target population (against a target of 1:50 HR-MSM/TG) [see Table 2 for additional indicator details]. Detailed description of CMIS indicators and estimation process is available elsewhere.

b) Also, please clarify “association between intermediate outcomes and exposure to the Avahan program”

Here we are referring to condom use and STIs as intermediate outcomes and Avahan's contribution to these changes over time. This has now been clearly stated in the manuscript and table 2 elaborates on each of the indicator used in the evaluation.

5. p.9. 2nd paragraph

The authors need to provide a rationale for creating a composite indicator. These seem to be qualitatively distinct and the data of each intervention exposure seems to be meaningful and helpful for developing future intervention services and projects.

The Avahan program provided a package of services to the MSM and therefore three core services provided by the Avahan partners were considered to create a composite indicator and assess impact of exposure to prevention interventions.

6. p.10. 3rd paragraph

The authors need to provide a rationale for creating a category of MSM/TG. In general MSM include men who have sex with men and women. Men who have sex with transgender women may be different from MSM.

We agree with the reviewers concern. The sample of MSM in Pune included TGs as the programme have covered TG population along with the MSM population and due to the inadequate number of TGs in Pune, it was difficult to conduct a separate survey among TGs in Pune. The TG covered are male-to-female transgender persons, also called hijras.

7. p.11.

a) Clarify “panthis”. Is this person “bottom”?

Panthis is a locally used term for a male partner who mainly penetrates; this has now been mentioned in the manuscript
b) The percentage of STI clinic visit may not be reliable because the “denominator” was fixed and estimated without reliable and valid data.

The estimates presented are based on the MIS data from the Avahan program compiled, aggregated and updated using computerised management information system (CMIS). The denominators were fixed as it was the benchmark against which the adequacy of coverage was assessed. This is now mentioned in the manuscript.

8. p.12. 2nd paragraph

a) The number of peer educators/outreach workers was increased from 13 to 192. Itseems obvious that more funds were available in the later stage of the project. In general, these data for the implementation of the project seem to be asummary to the funding agency; does not seem to be results of the “research” study.

We have now revised the write up to describe the change in coverage and scale over time.

b) 4th para.

a) Please clarify “sex act with a paying partner”. Is this “sex with a man with whom a person paid for sex” or “sex with a man from whom a person was paid for sex? Also, clarify “a paid male/hijra partner”

We have now clearly stated the different types of partners in the methods section:

“Consistent condom use was defined as condom use during every act of anal intercourse with different types of male partners (such as, main regular male partners [lover/boyfriend/spouse], paying male partners [receiving cash or gifts when selling sex], paid male partners [giving cash or gifts to male partner or hijra when buying sex], and other casual male partners]

b) Table 3. The percentages of condom use with regular and paying male partner were 91% and 98%, respectively. These seem to be really high. The authors needs to present validity of these data. Also, the authors need to explain a negative and significant change in condom use with paid male/hijra partner from 84% to 57%.

We agree with the reviewers concern. The condom use with regular and paying male partners during last sex is high but the same is not true when we see the trend for reported consistency in condom use with these partners. Condom use with male partners increased considerably in the second round of IBBA as compared to round 1, which is largely due to the scale up of the Avahan program and it may also be due to social desirability bias as it is a self-reported measure. This has now been included as a limitation in the manuscript. In the discussion
section we have also attempted to explain the plausible reasons for the negative and significant change in condom use with paid male/hijra partner.

9. p.15 1st paragraph
“A higher than 100% coverage, as reflected in the CMIS data, may be due to highly mobile nature of the population;....” Please clarify this sentence. Also, what is “Similar results”?
As suggested, the sentence has been clarified.

10. p.17 1st paragraph
The authors presented findings for lower rates of consistent condom use with female partners among MSM participants compared with those with male partners. It is commended that the authors recommended future prevention programs to focus on increasing MSM’s condom use with female partners.

We have now included a discussion on the negative and significant change in condom use with paid male/hijra partner.

11. P.18
Conclusion needs to include lessons learned from the project and study, as well as recommendations for future HIV prevention projects for MSM in India.

The conclusion has now been revised to include lessons learnt and recommendations for future HIV prevention projects as below:

“The Avahan program in Maharashtra for HR-MSM/TG was successfully scaled up to achieve its targets through outreach, condom distribution and STI clinical services. The current evaluation shows that Avahan program effectively covered the target group, improved accessibility to condoms and reduced risk behaviours with male sexual partners. Syphilis prevalence declined; however HIV prevalence did not change and therefore a major concern. However, the evaluation also suggests that additional tailored and innovative behaviour change interventions are required to increase condom use behaviours with all types of partners, so as to reduce risk among HR-MSM/TG. Continued strengthening of core programmatic strategies will help bring sustained reductions in HIV risk in HR-MSM/TG and check its onward transmission”.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being Published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:** I declare that I have no competing interests
Reviewer's report

**Title:** Increase in condom use and decline in prevalence of sexually transmitted infections among high risk men who have sex with men and transgender in Maharashtra, India: Avahan, the India AIDS Initiative

**Version:** 2  **Date:** 20 February 2013

**Reviewer:** Eric Nehl

This research “Increase in condom use and decline in prevalence of sexually transmitted infections among high risk men who have sex with men and transgender in Maharashtra, India: Avahan, the India AIDS Initiative,” aims to explore sexual risk behaviors, condom use, related characteristics / psychosocial constructs and change based upon the Avahan India AIDS Initiative among MSM and transgender individuals in India. The article makes a useful contribution when considering the potential for continued HIV/STIs and related behavioral/psychosocial /program dynamics. However, there are some limitations of the research that greatly diminish enthusiasm for the current paper.

**Major Compulsory Revisions**

1. **Introduction**

   a) More description of the Avahan initiative components targeted for MSM and transgender participants would be helpful.

   As suggested, description of the Avahan initiative’s components targeted for MSM and transgender persons has been added in brief.

   “Avahan’s strategies were designed to achieve high coverage (80 % of the total estimated target population) through delivery of a package of proven prevention services that would address proximal and distal determinants of HIV risk [20,21]. The key elements of the combination prevention program for HR-MSM/TG included peer-led outreach to promote behavior change, clinical services to treat STIs, provision of commodities (condoms and lubricants) for safe sex, support for community mobilization, and advocacy to reduce structural barriers to safer sexual practices [18].”

   b) The last paragraph in the introduction could provide a better framework to the article. It could be organized in terms of some sort of groupings such as Aim1, 2,or data sources, etc. This is of particular importance in this article with the large number of data sources, predictors, analyses, and results. Using a format such as this throughout the paper would greatly improve the flow and the ability to interpret the results.

   As suggested, the last paragraph has been modified to clearly state the specific objectives of the article.
“The present analysis, using multiple data sources, was conducted to assess the overall effect of the Avahan program on HIV prevention in Maharashtra's HR-MSM/TG population. The specific objectives of this paper are to examine the scale-up and coverage of the Avahan program, changes in condom use patterns and prevalence of HIV and other STIs, and the association between these outcomes and exposure to Avahan program among HR-MSM/TG in Maharashtra”.

2. Methods
a) The description of the data collection is somewhat vague in terms of lack of specificity. It is understandable to point a reader to an article to a related article in which methods are fully explained, but a description could be used to give the reader a sense of the structure and how these data sources fit together. For instance, a data triangulation or synthesis statement would be helpful.

We appreciate the reviewer’s concern. We have added information on data collection in the CMIS and IBBA. We have provided details on the type of sampling, numbers, and dates when the data were collected.

3. Analysis
a) Again, this should be organized under aims, hypotheses, or even preliminary/main analyses. What was done and for what purpose?

We have now reorganized the section on data management and analysis to systematically explain what was done. Given the framework that was developed for the evaluation, we have tried to answer each question related to the program’s logic model to build the evidence.

4. Results/Discussion
a) It is difficult to read the results without a description of the sections by aim, hypothesis, or how the data sources fit together to give a picture of the program as a whole. The authors should emphasize how this all fits together.

As per the framework used we have organized the results section to first present the scale up and coverage of Avahan, followed by changes in behavioral and biological outcomes (condom use and prevalence of STIs) which were the core indicators assessed.

**Minor Essential Revisions**

The manuscript does have some minor problems with flow, clarity, and grammar.
We have now reviewed the manuscript to correct problems with flow, clarity and grammar

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.
Reviewer's report

Title: Increase in condom use and decline in prevalence of sexually transmitted infections among high risk men who have sex with men and transgender in Maharashtra, India: Avahan, the India AIDS Initiative

Version: 2 Date: 19 February 2013

Reviewer: Patrick S Sullivan

Reviewer's report:

This is an important manuscript, and highly relevant to the field. This is why it is important to make sure that the results reported are in the strongest possible position. I would ask the authors to address the following concerns, understanding my view of the importance of their work:

Major Compulsory Revisions:

1. The IBBA needs to be described at least briefly in the text. It appears from the online reference provided that potentially both Venue Time Location and RDS were used to collect data. If so, then the authors need to address how they combined these data, and if they just treated all observations as though they comprise one big convenience sample, that is a major methodologic limitation and must be justified and implications explored. If only RDS was used, then the authors need to state how they used the weights in the analysis -- this currently is not mentioned. Although implied, it is important to state that the same areas were surveyed in both rounds.

   As suggested, we have discussed briefly on IBBA in the methods section. Time location cluster sampling method was used to recruit respondents in Maharashtra. Same methodology was adopted in both IBBA rounds and now has been clearly stated in the manuscript. RDS method was not used for data collection for this target population.

2. The logistic regression analyses report odds ratios, although the underlying conditions for which the odds ratio is a reasonable estimate of risk are almost certainly not met. Did the authors consider using prevalence ratios, and if not, how would they justify the use of odds ratios as superior to prevalence ratios in this case?

   We agree with reviewer that prevalence ratio is a better measure considering the design of the study especially for behavioural outcomes. We also understand that the prevalence of the biological indicators is low and condom use indicators are high, however, we used a common approach to conduct the analysis. We used odds ratios; we used logistic regression models to present the association between consistent condom use and STIs as outcomes and the round of IBBA and composite exposure to Avahan program interventions as explanatory variables, adjusting for profile and other contextual variables. We calculated odds
ratio to test strength of association between the exposure and outcome variables and to measure odds of exposure to a particular factor in those with the outcome of interest and those without the outcome. Most of the STIs have a prevalence of <5% in both the rounds (potentially fitting the rare disease assumption). However, we do agree that in some these scenarios the POR > PR which and this may be a potential limitation of the study.

3. The limitations section fails to mention the most prominent limitations, which are that the samples used to report the behavioral data are not representative. They don't address the fact that there were important differences between the characteristics of the two samples that they are comparing. Although they controlled for these factors in the model, one wonders whether the differences in demographics are underlain by more important, unmeasured differences in who was recruited in these rounds. It is not acknowledged that the comparisons made are ecological in nature, and that differences between the two rounds can't necessarily be related to the intervention described.

We agree with reviewers and we have now revised the limitation section to include the prominent limitations as below:

“Nonetheless, the present study does have a number of limitations. The first round of IBBA was conducted one year after the initiation of the Avahan intervention and therefore not a true baseline. Avahan’s evaluation design did not include a control group, given the ethical considerations to be applied for large-scale public health programs. However, the used evaluation framework did follow program logic, and data from multiple sources (both program monitoring and independent survey data) was used to suggest plausible evidences for the effectiveness of the intervention, as alternative to randomised controlled trials, which are now considered less suitable for large public health interventions [40-43]. Although Avahan was a pan-Maharashtra intervention, the IBBA surveys were restricted to three districts; while the CMIS data shows the scale up and coverage of the program across all districts, the IBBS data provides outcomes in a sample of districts, providing confidence on validity of the monitoring data. Another limitation in IBBA was that gonorrhoea and chlamydia were tested based on urethral samples, as rectal samples could not be collected in the given field conditions. Other studies from India, where throat or rectal swabs were collected, prevalence of oropharyngeal and rectal gonorrhoea was 4.7% and 7.4%, respectively [44]. Other limitations include those applicable to cross-sectional studies. For example, there were changes in population profile over the two rounds of the survey; however, these were accounted for by controlling for changes in multivariate models. Social desirability bias for self-reported behaviors (such as condom use) is a limitation, but it was presumed that such bias was similar for both rounds of IBBA.”

4. The authors note that HIV prevalence decreased between the two IBBAAs, and this seems to be presented as evidence of programmatic impact. However, without substantial mortality rates, it seems unlikely that even large reductions in HIV transmission would result in such large decreases in prevalence over such a short period of time. This is further reason to be concerned that the two IBBA samples were
different in important, unmeasured ways, but probably should not be implied to suggest better outcomes related to program without more correlative evidence.

We agree with the reviewers concern and have reviewed and revised the write up.

**Minor essential revisions:**

5. Means are presented; are the ages normally distributed? If not, medians are preferable.

   Age is normally distributed and therefore means are presented.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:** I declare that I have no competing interests