Author's response to reviews

Title: An Integrated Individual, Community, and Structural Intervention to Reduce HIV/STI Risks among Female Sex Workers

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Version: 3 Date: 31 May 2013

Author's response to reviews: see over
May 30, 2013

RE: Manuscript ID-2112575577845665: An Integrated Individual, Community, and Structural Intervention to Reduce HIV/STI Risks among Female Sex Workers

Dear Editors,

Thank you so much for offering us the revision opportunity to improve the manuscript. We are grateful to the reviewers for their insightful comments. Following your guidance, we have revised the manuscript in light of the reviewer’s suggestions. We have provided point-by-point responses to all issues raised by the reviewers.

Reviewer #1:

MAJOR COMPULSORY REVISIONS:

Point1.1 General comments: Revise language
This paper reports on the results of a large cross sectional study among female sex workers from 16 counties, including six intervention and 10 non-intervention counties, in Shandong province, China. The aim of the study was to evaluate the Global Fund AIDS Program in the six counties. Overall, many parts of the paper are too general and should be much more specific (see further). The methodological limitations should be more extensively discussed. In addition, the language of the paper needs improvement and English editing.

Many thanks for the reviewer’s comments. We made the further revision on the paper according to reviewers’ suggestion. The Background and Discussion sections were revised accordingly. Our native English-speaker has gone through the paper with a fine-tooth comb to ensure that all of the spellings and word idioms are correct.

Point1.2 Title: “Making efforts to reduce the heterosexual transmission of HIV/STIs: The Global Fund AIDS Program in Shandong Province, China” is not specific enough. The title should be revised in order to indicate the target population and some hint of the study’s design.

The title was revised.

Point1.3 Background, general:
It would be interesting as background information to mention the HIV and STI (syphilis) prevalence in the general population in Shandong province.

We added the HIV epidemic and surveillance data in Shandong province in the background section following the reviewer’s suggestion. The HIV/syphilis prevalence
in the general population in Shandong province was still at low level. Data from the sentinel surveillance in Shandong showed that the HIV and syphilis prevalence among the general population was 0.03% and 0.20% respectively in 2011.

**Point 1.4** Background, line 10. Part from “…changing sexuality (4,5) until next paragraph “At the 1990s…” is not readable in the pdf file.

The sentence was revised.

**Point 1.5** P.28, line 3 from bottom: “Six pilot counties of Shandong Province accelerate its response…” What were the selection criteria for the 6 pilot counties? Were there differences in the general socio-demographic characteristics between the selected pilot counties and the other counties?

Thanks for the reviewer’s excellent suggestions. The revision was made in the “Study design” and “Intervention components” in the Method section.

**Point 1.6** P.29, line 1: “… large scale promotion of sexual transmission interventions among HIV-related high-risk groups” The description of the intervention strategy is rather vague, it would be good to have a more specific description of the program components to better understand the intervention. Another important part of information which is missing considers the baseline prevention activities in the non-intervention counties. What was the difference exactly between intervention and the rest in terms of prevention activities?

Thanks for the reviewer’s excellent suggestions. The revision was made in the “Study design” and “Intervention components” in the Method section.

**Point 1.7** Methods, Study site, line 2: “ Random cluster sampling was applied…” Why random cluster sampling of the control counties, if the pilot counties were not randomly chosen (I presume). Can the authors discuss the possibility of selection bias with this method? Have the investigators thought of matching the intervention counties with non-intervention counties based on certain socio-demographic characteristics? Could this limit a selection bias?

Thanks so much for the reviewer’s insights. We apologize for the mistakes in the initial draft. We have revised it as “The Ten control counties including four counties (Huaiyin, Longkou, Rushan, Zhiwu) were selected from developed areas and six counties (Decheng, Dongming, Gaomi, Jvxian, Pingyin, Yanggu) were selected from less developed areas of Shandong province in 2009. The cut of value between economically developed and less developed counties was $2500 of average per capita income of its residents. The sampling frame of control sites was to ensure that the background characteristics of the selected control sites are similar in the baseline to the intervention sites including the sociodemographics, geographic location,
economical development, migration of population, transportation, and the status of HIV/STI epidemics. The six intervention sites hosted 7.2 million with 103 cases of HIV/AIDS reported through the year of 2004 compared with 10.9 million population and 32 diagnosed and reported cases of HIV/AIDS in the 10 control sites. During the intervention period from 2004 to 2009, the integrated individual, community, structural intervention supported by the Global Fund AIDS Program was only implemented in the six intervention sites of Shandong as described in the following “Intervention components”. The 10 control sites and all other counties or cities across the province provided the “standard of care”, the routine testing, prevention, care and treatment services for HIV and STI, but not the integrated individual, community, and structural intervention. We recognized the limitations of this study. Selection bias existed in this study; we added selection bias in the limitation of Discussion Section.

Point1.8 P. 29: Recruitment and participants: “… venue-based recruitment was applied…” What type of sampling was used: probability or non probability sample? Can the authors describe more specifically how the recruitment was done: how were the venues selected, what methodology was used to select the participants in the venues, …

Stratified sampling method was applied in this study. A detailed geographical map with roads, key streets, markets, shops, hotels, and bus depots was developed in each county. The numbers of FSWs in each establishment and street were numerated or estimated. All establishments and streets were listed and stratified for sampling. Participants were randomly selected from randomly selected establishments or streets. A maximum of 25 participants were recruited from the large selected establishments; for smaller selected establishment with \( \leq 15 \) FSWs. Revisions were made in the recruitments and participants part of Method section.

Point1.9 P.33, HIV-related knowledge and HIV-related service utilization. This paragraph is quite confusing, because outputs and outcomes are used as determinants instead of independent variables. For example peer education is used as a determinant for intervention group. It is not because a FSW has peer education that she belongs to an intervention group, but she has peer education because she belongs to an intervention group. The analysis should be revised, with the correct outcomes and determinants.

All counties across the province provided HIV/STD prevention, care, treatment services among FSW and other HIV-related high risk groups as “standard care” in Shandong. Only the 6 “intervention counties” carried out the well designed intervention program supported by The Global Fund AIDS Program since 2004. This study was designed to evaluate the intervention impact of the integrated individual, community, structural interventions supported by Global Fund AIDS Program in Shandong province. We compared the variables of the HIV-related knowledge score and HIV-related service utilization to evaluate the intervention impact among FSW
post-4 years intervention. The revisions were made in the Method section.

**Point1.10** Discussion, P34, line 7: “... suggested that the indicator rates of knowledge-related HIV/AIDS increased from...” One of the limitations of the study is the absence of baseline data in both intervention and non-intervention counties. This implies that no conclusions can be taken about trends in knowledge or other indicators. Can the authors comment on this?

In the Discussion section, we included some information that our previous report on FSWs showed the trends in knowledge and condom use.

**Point1.11** P.35, line 11: “Strengths of this study include its estimation of the size of the targeted population and mapping strategy” What do the authors mean by this? To our knowledge, nothing has been mentioned about the size estimation and the mapping until now. If these are methods used for sampling purposes, can the authors explain why this is a strength of the study?

We described more specifically how the recruitment was done in the revised method section. A sociodemographic mapping strategy was applied with venue-based recruitment, community outreach and peer referral techniques in this study. A detailed geographical map with roads, key streets, markets, shops, hotels, and bus depots was developed in each county. The numbers of FSWs in each establishment and street were numerated or estimated. All establishments and streets were listed and stratified for sampling. Participants were randomly selected from randomly selected establishments or streets. Efforts on investigating the venue and preliminary estimates in each establishment strengthen the mapping strategy and size estimation to reduce selection bias.

**Point1.12** P.35, 2 last lines: “… In spite of these limitations, we feel the data gave us better understand the progress of intervention program…” In the light of the limitations in study design mentioned earlier, how can the authors be certain of the progress caused by the intervention program?

Thanks for this reviewer’s insights. This study was a post-intervention cross-sectional survey. The findings of this study found the significant lower rate of syphilis, higher score of HIV knowledge, and the higher rates of condom use, HIV testing and the utilization of HIV prevention services in the intervention sites, compared to that in the control sites. These findings are consistent with our previous findings.

The higher score of HIV knowledge among FSWs demonstrated in intervention sites is consistent with our previous study. Our previous study targeted FSWs in the same 6 sites from 2004 to 2008 showed the rate of correct answer of three HIV/AIDS transmission routes increased from 59.36% at baseline in 2004 to 97.21% in 2008, and increased from 32.76% in 2004 to 82.76% in 2008 for correct answer of
non-transmission routes. The higher rate of condom use found in the intervention sites is also consistent with our previous report. Our previous data suggested that the proportion of consistent condom use with clients in the last three months significantly increased from 38.75% at baseline in 2004 to 71.67% in 2009. In addition, the overall low HIV prevalence indicated from surveillance system and lower syphilis prevalence in intervention sites compared to the control sites indicated the integrated individual level intervention, community mobilization and structural intervention prevention program with multi-sectoral cooperation and strong societal participation made the difference. The revisions were made accordingly in the Discussion.

Point1.13 Conclusion, P36: “The results of the study indicated that remarkable progress…” Same comment as before. This statement is too strong and should be put in the right (methodological) context.

Many thanks for reviewer’s suggestion; we made revision to soft the tone of this sentence.

Point1.14 Table 2. See previous comment: outputs and outcomes are used as determinants instead of independent variables. Please revise analysis and adapt the table.

See the point 1.9.

MINOR ESSENTIAL REVISIONS:
Point1.15 P.32, HIV/syphilis prevalence and sexual /drug use behaviors, line 5: “…77.7% and 51.7%...” and others. Please add p-value for easier interpretation.

The revision was made following the reviewer’s suggestion.

Point1.16 Table 1: P values. Please show actual P values if # 0.001

The revision was made.

Point1.17 There is no need to show X2 in this table, as P values are shown.

The revision was made.

Point1.18 Table 1, P.40: Some factors are rather vague and should be better explained. Please specify following factors in the table:
- HIV counseling and/or testing: does that mean “access to HIV C&T”? or “used HIV C/T services once” or …?
- STD examination and/or treatment: does that mean “has been treated for an STD in the last 12 months”?
- Free condom: access to free condoms?
• Peer education: access to peer education, active participation in a peer education program?

Thanks so much for the reviewer’s suggestions, the revisions were made as the following:

• HIV counseling and/or testing means ever received HIV volunteer counseling and testing or just received counseling in the last year.
• STD examination and/or treatment means ever received STD examination or treatment in the last 12 months.
• Free condom means ever received free condoms in the last year.
• Peer education means ever received peer education or took part in peer education program in the last year.

Reviewer #2:
Major Compulsory Revisions:
Point2.1 It is always better to provide some information about the baseline data on HIV and syphilis prevalence or sexual behaviors before intervention in both the intervention and non intervention areas. Without this, one can not conclude the higher knowledge and better condom use rates in the intervention area are because of intervention as the difference might have existed between both the areas even before intervention.

Shandong province situated along the east coast is the second most populous provinces in China, with 92 million people. The first HIV cases in Shandong was identified in 1992, and 31 HIV cases were reported by the end of 2002, only about one fifth of total 140 counties reported HIV case by the end of 2002. The Shandong provincial department of HIV/AIDS control and prevention was established in 2003, and since then, the department of HIV/AIDS control at county level was established to develop HIV-related activities. We didn’t develop the baseline survey at all 140 counties in 2004, and only the 6 intervention counties supported by The Global Fund AIDS Program developed the baseline survey in 2004. Our previous report revealed the increasing trends in knowledge and condom use in the 6 intervention counties. The 10 control counties (4 from developed and 6 less developed economically) were selected based on the similarities of economic status and HIV/STI epidemic. We recognize the limitations of this study. Limitations were added in the Discussion section.

Point2.2 There can be social desirability bias in the responses provided by the participants especially in the intervention areas as they are more aware of the positive behaviors for preventing HIV/AIDS even though might not actually practicing them. May be the HIV testing rates obtained from the Program data may be compared between the intervention and non intervention areas to support the data obtained by participant interviews.
We completely agree with the reviewer’s thoughts. The sensitive nature of the questions may have lead to information bias due to the social desirability of certain answers. The indicators of ever having a test for HIV in the last year were compared between the intervention and control counties. The rate of ever had a test for HIV was 69.0% in intervention, significantly higher than the rate of 33.6% in control group. Revisions on Discussion section were made accordingly.

*Point2.3 What was the non response rate of the study? Was there any difference in the sociodemographic characteristics or risk behaviors among participants and non participants?*

Non-response information were not collected, but based the interviewers’ estimates and our past experience that the rates are similar in both intervention and control counties very limited. We acknowledged this as a limitation of the study, although since our well experienced interviewers always ensure to the confidential, non-judgmental, friendly environment during the interview.

*Point2.4 Did all the participants who agreed for the study provided consent for HIV testing?*

Verbal informed consent was obtained from all participants, and serospecimens were collected from all participants to test their status of HIV and syphilis.

*Minor Essential Revision:*

*Point2.5 Selection of study sites: It should be cluster random sampling rather than random cluster sampling.*

Many thanks for this reviewer’s suggestion. The revision was made.

Again, we are grateful to the revision opportunity. We are looking forward to your reviewing our revised manuscript. If you have any questions, please feel free to contact Meizhen at liaomz161@126.com/ 011-86-186-1528-1775 (Beijing Time) or Yujiang at jiayj@aol.com/ 615-482-1512 (U.S. Eastern Time).

Sincerely,

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