Author’s response to reviews

Title: Factors in the HIV Risk Environment Associated with Bacterial Vaginosis among HIV-Negative Female Sex Workers who Inject Drugs in The Mexico-United States Border Region

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Author’s response to reviews:

Dear Editor in Chief,

We were pleased to receive the reviewers’ comments for our manuscript entitled “Sociostructural Factors Associated with Bacterial Vaginosis among HIV-Negative Female Sex Workers who Inject Drugs in the Mexico/United States Border Region.” All of the comments have been addressed in our re-submitted manuscript, and highlighted throughout so each edit can easily be located. Additionally, I have included below a detailed list of all of the comments that we received and a description of how each comment has been addressed.

We are thrilled that you are considering our manuscript for publication and look forward to hearing from you soon regarding your final decision.

The comments we received are listed below with each corresponding edit(s) made to incorporate the helpful recommendations from each reviewer.
1. How was the screening test (OSOM BVBlue rapid test) performed? What is the nature of the specimen tested? Blood? Serum? Urine? Saliva? Vaginal discharge? Under what circumstances/environment was it collected? I presume that this information has to appear in the methodology.

Author’s Response: Thank you for asking such relevant questions, we agree that these details are important. There were at least two female field nurses with extensive experience collecting biological samples and providing pre and posttest counseling to high-risk women including sex workers, available at each site. Study nurses facilitated BV testing in a private setting outfitted with an exam table. Using a vaginal swab from the BVBlue kit, vaginal fluid from the lower one third of the vaginal wall was collected. Immediately afterwards the specimen was tested. All study staff were well trained on laboratory testing procedures, and detailed standard operating procedures that were accessible to study staff for reference. All specimen collection and testing procedures were developed in accordance with the Center for Disease Control and the Mexican Health Department’s guidelines at the time of data collection. Detailed study procedures and protocols have been published elsewhere (Vera et al, 2012). The following details have been added to the methods section on page 6: “As described elsewhere [25], screening and treatment for BV was performed in accordance with the guidelines set for by Mexico’s Ministry of Health the time of data collection. Study nurses facilitated the screening process in a private setting using the OSOM BVBlue® Rapid Test (Genzyme Diagnostics, San Diego, CA).”

2. Unless sex work is not as stigmatizing as it is in my culture I think its worth to add a few sentences on ethical issues like confidentiality and the comfortability zone of conducting such research (e.g. where was it conducted).

Author’s Response: All research activities were conducted in private office based setting in each city respectively. During the informed consent process and at the beginning of each interview, participants were reminded that their participation was voluntary and that their information would be kept confidential. Furthermore, participants were reminded that participant identification numbers were used all study documentation when appropriate. Finally, all study documents were stored in locked offices. Field staff at both sites had extensive experience working with the target population. Prior to initiating recruitment activities, all project staff underwent cultural sensitivity and ethical conduct of research activities training. The following has been added to the study sample section on page 5: “Participants provided written informed consent during which study staff explained the details of confidentiality and the protection of
personal information.” Further, the text in the measures section on page 6 has been edited as follows: “Participants completed surveys in a private setting administered by trained interviewers with extensive experience working with FSW-PWIDs in the Mexico/US border region. All staff underwent cultural sensitivity and ethical conduct of research trainings prior to engaging with participants. Surveys collected information on individual-level factors, as well as micro- and macro-level components of the physical, social, economic, and policy HIV risk environment.”

3. Page 5; the methods section; last sentence on study sample feels ectopic and it repeats itself in the ethical clearance section.

Author’s Response: Thank you we agree that this is redundant and it has been removed.

4. The study setting is not described in the methodology section. Its good to know what is so interesting in this boarder that attracted your attention to do research on this area.

Author’s Response: Thank you for asking us to reiterate the to reader the relevance of HIV prevention work in the Mexico/United States border region. In order to highlight this to our reader the following text has been added on page 5 of the manuscript under study sample and setting: “Given the dual impact of sexual and injecting risk among FSW-PWIDs, and the elevated rates of HIV and other STIs in this population along Mexico’s northern border [16], this study targeted FSW-PWIDs in this region.”

5. Who exactly prescribed metronidazole? MD? Pharmacist? Research nurse? What was the dose? Was there any precaution/health education on the disease as to how to prevent, signs and symptoms of BV, its complications, drug reactions, resistance to treatment, risk of contracting other STIs including HIV and where to get help in case of anything?

Author’s Response: In Mexico, antibiotics can only be prescribed by a registered medical doctor (MD). In our study, we had a registered MD onsite who was responsible for prescribing Metronidazole. Then study nurses provided the medication to participants with detailed instructions on how to use it, upon detection of BV via the BVBlue rapid test (Vera, et al. 2012). The text on page 6 under BV Screening and Treatment has been edited as follows: “Women who tested positive for BV were provided free treatment (oral metronidazole), ordered by a medical doctor onsite at the time of diagnosis.”
Mantwa Chisale Mabotja, MBchB (Reviewer 2): This was a good written paper addressing an important public health issue. However I have few comments on this manuscript:

1. The title is rather long and confusing, I think one can work on it to shorten it while still keeping the aim of the study.

Author’s Response: The title has been revised to include ‘sociostructural’ instead of microenvironmental, as this may be easier for a lay audience to interpret: Sociostructural Factors Associated with Bacterial Vaginosis among HIV-Negative Female Sex Workers who Inject Drugs in The Mexico/United States Border Region

2. The abstract is a bit confusing, making the methodology sound like it was a RCT while it is a cross sectional study, maybe try to explain this a bit better for the readers of abstracts

Author’s Response: Thank you for bringing this to our attention. The wording in the abstract has been revised to address this concern. Please view on page 2 of the manuscript new language which states: “Utilizing baseline data, we applied logistic regression to identify correlates of BV in the physical, social, economic, and political HIV risk environments stratified by study site (Ciudad Juarez vs. Tijuana).”

3. The survey included questions that could be traumatic for the respondents, such as question on childhood abuse. Were you offering any kind of counseling for the respondents should it be deemed necessary?

Author’s Response: All study staff were well trained on how to respond to participants in the event of a trauma-induced reaction. There was a psychologist onsite available in case any participant needed further assistance that could be provided after the interview. Most of the interviewers were registered psychologist and so professionally trained to address any situation that could arise as a result of the issues addressed during the behavioral interviews. All study participants received a list of referrals for social and psychological services available in the community. Further, this study was reviewed by a Data Safety and Monitoring Board comprised of experts in the field that are familiar with the challenges that women who inject drugs face and engage in sex work face. There were no safety issues identified during the study period. The following has been added to the manuscript on page 6 under the measures section: “Furthermore, a psychologist was present onsite at all times to respond to any additional needs or concerns of participants.”
4. Results: The only results for Tijuana on the number of hours spent on the street was reported a significant finding, however the 95% CI includes 1 [1.00-1.10], which basically deems the results statistically insignificant. This finding cannot be included as a significant finding when it is not, thus your whole discussion and results needs to change and remove that finding. Removing this finding basically mean there was not significant finding for Tijuana, thus only one site had significant findings.

Author’s Response: Thank you for your attention to such detail. We agree that this finding is marginal and modest and have changed the language in the manuscript to reflect this. Although this finding is not highly significant, and the 95% confidence interval (CI) while not equal to one practically contains one, we feel as though it is still important to discuss this association for the following reasons; the 95% CI in full is 1.000767-1.096055 and we don’t expect this interval to be very large given the continuous nature of the exposure variable (hours spent on the street). Further, the corresponding point estimate 1.047328 (rounded up to 1.05) is the most accurate estimate, and we hesitate to use the 95% CI as a surrogate test of significance (Rothman, Greenland & Lash, 2008). However, the association is still modest, and we happily acknowledge that. The language in the abstract has been changed to: “In Tijuana, BV was marginally associated with the number of hours spent on the street daily in the past six months looking for, using, or dealing drugs, engaging in other income generating activities, or sleeping (aOR=1.05, 95% CI: 1.00-1.10, p=0.046).” The text on page 10 of the results section has been modified as follows: “Finally, for women in Tijuana BV was marginally associated with the number of hours spent on the street, such that for every one-hour increase spent on the streets the odds of BV increased by 5% (aOR=1.05, 95% CI=1.00-1.10, p=0.46).” The following sentence has been added to the limitation section on page 13: “Finally, the association between the number of hours spent on the street and BV among FSW-PWIDs in Tijuana, warrants further investigation to better understand how impactful this finding is given its modest association with BV”. The text on page 12 of the discussion has been modified as follows: “In Tijuana, the association between the average number of hours spent on the street looking for, using, or dealing drugs, performing other activities to obtain money, or sleeping and BV may have several important public health implications. This association, although marginal, may capture the impact of street-based sex work, economic marginalization, and increased dependence on illicit substances on the reproductive health of FSW-PWIDs.” Finally the text on page 12 toward the end of the discussion has been modified as follows: “Taken together, this finding – albeit modest- is consistent with the implications of the aforementioned associations between BV and women in Ciudad Juarez which highlight the need to address structural and microenvironmental factors in interventions for FSW-PWIDs in the Mexico/US border region.

5. Limitations: I wonder if this being an interviewer-administered survey does not introduce some form of bias and social desirability in the response of participants? I would think the
answer is yes. Please clarify how you controlled for this bias, if not, then it should be highlighted under your limitations.

Author’s Response: Thank you, we agree that this is an important limitation to acknowledge. In order to address this concern I have added the following text to the limitations section on page 13 of the manuscript: “This study relies on self-reported information of sensitive behaviors (e.g. substance use and sex work), which may have led to underreporting of behaviors considered socially undesirable.”

References
