Author's response to reviews

Title: Prevalence and Predictors of Cervicitis in Female Sex Workers in Peru: an Observational Study

Authors:

Simon Pollett (spollett@med.usyd.edu.au)
Martha Calderon (marthacalderonsilva@yahoo.com)
Kristen Heitzinger (heitzk@u.washington.edu)
Vicky Solari (solarivicky@yahoo.es)
Silvia M Montano (Silvia.Montano@med.navy.mil)
Joseph Zunt (jzunt@u.washington.edu)

Version: 2 Date: 22 March 2013

Author's response to reviews: see over
Dear Sir,

Please find attached the revised manuscript titled ‘Prevalence and Predictors of Cervicitis in Female Sex Workers in Peru: an Observational Study’.

We have very much valued the revisions suggested by the two reviewers, and agree it has improved the quality of the manuscript. Please find below our point-by-point responses to these suggested revisions.

This revised manuscript has also been reviewed by three coauthors with English as a first language (including myself) and all are satisfied with the grammar and level of English herein.

We thank you for your time and ongoing consideration of this manuscript.

Respectfully,

Dr S. Pollett (corresponding author)

MBBS, BMedSci, DTMH

Centre for Infectious Diseases and Microbiology, Westmead, Sydney, Australia

Phone: 61-0412525637

E-mail: spollett@med.usyd.edu.au.
Reviewer's report
Title: Prevalence and Predictors of Cervicitis in Female Sex Workers in Peru: an Observational Study
Version: 1 Date: 31 October 2012
Reviewer: Marissa Becker
Reviewer's report:
General:
The authors conducted a cross sectional study evaluating the prevalence and etiologies of cervicitis in female sex workers in Callao-Lima, Peru. This is an important area of research and has significant programmatic implications. The authors found a high prevalence of cervicitis among FSWs who participated in the study, yet a very low proportion of women with cervicitis had an etiology identified. I did have a number of questions and concerns though and would suggest that the manuscript undergo further revisions.

Major Compulsory Revisions:

1. Abstract, Results: The denominator for CT and GC in the abstract is 87 however in the manuscript the denominator is 99. Please confirm which is the correct sample size.

We thank you for identifying this transcription error in the written text of the results page. The total number of FSW with cervicitis is 99. However, CT and GC were not tested on 12 of these participants due to logistic/operational issues, thus the denominator for CT and GC is 87.

2. Introduction, paragraph 2: It is not clear to me what the authors mean regarding understanding of the mechanism- does this refer to the pathophysiology of cervicitis or etiology or otherwise?

We agree that ‘mechanism’ is an ambiguous term. We were referring to the etiology and pathogenesis of cervicitis, and this has been amended in the manuscript.

3. Introduction, paragraph 3: please provide a reference for the statement that FSWs typically receive only intermittent health care.

This reference has now been added. In addition, we have amended the statement to “FSW may receive only intermittent healthcare” as there are subgroups of FSW that undergo regular STI screening and thus receive regular health care.

4. Introduction, paragraph 3: It would be good if the authors can discuss some of the challenges with syndromic management.

We agree it is important to discuss some of the challenges with syndromic management, and this has now been added to the introduction.

5. Methods, Setting, paragraph 1: Can the authors please describe the monthly
health assessment which the FSWs undergo? Do they receive presumptive treatment for STIS or are they screened symptomatically?

This has now been described in the methods section. Such monthly assessments include genital examination and collection of cervical and vaginal swabs for basic onsite microbiology (including gram stain, wet mount and KOH staining) in addition to gonococcal culture. Syphilis screening by RPR is performed quarterly and HIV testing is performed twice per year. If required, much of the treatment is syndromic (based on symptoms and clinical signs), as per the National STI Guidelines.

Is treatment free of charge?

Assessment (including treatment) is free of charge. This has now been emphasised in the methodology.

6. Methods, Setting, paragraph 1: Who conducts the genital examination during the monthly health check ups and were these same individuals the ones who conducted the examination during the study?

Peruvian Ministry of Health clinicians conduct the monthly check-ups. One of these clinicians conducted the examination during the study, as an assigned study physician and co-author. This has been clarified in the methodology.

Also, please explain how the FSWS that were not registered were identified and recruited.

This has now been clarified in the methodology. CSAB provides mobile clinic services twice weekly to unregistered FSW who do not seek care at CSAB. Approximately 45 unregistered FSW receive care each month via the mobile clinic, and identify themselves as FSW as part of the routine assessment and care. From these women seeking care, participation in the study was offered and consent acquired upon agreement to participate. The same exclusion criteria applied as per registered FSW. Please note that registration status was not determined for a significant proportion of FSW.

7. Methods, Study procedures, paragraph 2: Please clarify in what instance the Amsel criteria was used for BV diagnosis and when Nugent scoring was used

A diagnosis of BV was made when both Amsel criteria and Nugent scoring were positive. We have reanalysed based on this updated definition of BV. Before these revisions, we had defined BV as Amsel or Nugent positivity, however we believe this should be amended in accordance with recent standardised BV definitions for research purposes. Please see below.

Please also explain and justify why two different methods of scoring were used for BV diagnosis.
We thank you for raising this important methodological question. As described above, we had defined a diagnosis of BV if the participant met Nugent positivity or Amsel criteria. We had originally justified this definition as both methods of BV diagnosis have been used in the clinical and research setting.

We have now become aware that the suggested definition of BV for research purposes is that of Amsel and Nugent positivity [Marrazzo et al. Sex Transm Dis. 2010 December ; 37(12): 732–744] and that researchers have been encouraged to use this standardised definition so that their findings may be more comparable to those of other BV-related research.

To meet such standardisation, we have redefined a diagnosis of BV where participants met Amsel criteria and were positive by Nugent scoring. Analyses have been suitably readjusted, as have relevant areas of discussion.

8. Methods, Study procedures: Where were the diagnostics conducted? Please clarify where the laboratory was located and whether one lab was responsible for performing all the diagnostics.

The locations in which diagnostics were undertaken have now been specified in the methods section.

9. Results, paragraph 1: Can the authors indicate how many of the 467 women recruited were from registered and how many were from the mobile clinic? Also, do these women differ in terms of their socio-demographic characteristics?

We have now indicated in Table 1 how many of the recruited women were registered or unregistered. Please note that in many cases registration status was unable to be determined. We have also performed further analysis (Table 2) to determine if there was any statistically significant association between registration and cervicitis. There was no statistically significant association between registration and cervicitis by univariate or multivariate analysis. If such an association was found, we agree that presenting how FSW differ in terms of socio-demographic (and other) characteristics would be important. But as no such association has been found, we do not believe presenting an extra table which compares the characteristics of registered/unregistered FSW will be helpful in answering the study question. As such, we respectfully request that we do not present how registered FSW differ from unregistered FSW in terms of socio-demographic characteristics.

10. Discussion, paragraph 3: The authors correctly state some of the limitations of the study. Specifically, they did not test for HSV or M. genitalium-important causes of cervicitis. Further, they did not collect information on use of spermicides or douching and so it is difficult to comment on potential contribution of non-infectious causes of cervicitis.

We agree these are important limitations, as stated in our discussion.
11. Discussion, paragraph 3: The authors correctly identify that the method of detection used for trichomoniasis in this study was not very sensitive. This is an important limitation of the study and one that needs further consideration particularly given the high rates of NSC in this study.

We agree these are important limitations, as stated in our discussion. Future studies should consider using alternative methods such as immunochromatographic or molecular techniques.

12. Discussion, paragraph 5: The authors identify that prior treatment may have impacted the ability to identify a causative pathogen but unfortunately information on prior treatment was not collected. This is an important limitation.

We agree this is an important limitation, as stated in our discussion.

13. Discussion, paragraph 5: The authors state that the monthly health checks for FSW appears to be effective for reducing rates of cervicitis but the justification for this statement is not clear. What were the baseline rates for this population? Where is this information? This sentence seems out of place. Not enough information on the program is provided for the reader.

We acknowledge this important point and agree that the wording of this statement should be changed. We do not have earlier rates of cervicitis to present, but on multivariate analysis, regular clinic attendance (i.e. receipt of regular medical care) was associated with a 46% reduction in risk of cervicitis. In addition, CT, GC and TV were less common in regular clinic attendees (OR = 0.39 [0.15, 0.99], p=0.04), and BV was also less common in regular clinic attendees (OR=0.39, 95% [0.24, 0.62] p<0.001).

This generates a hypothesis that regular attendance to free sexual health clinics may reduce the risk of cervicitis, GC, BV, CT or TV in these women. We agree that the above results do not prove that a system of monthly health checks is effective in reducing rates of cervicitis and certain genital tract infections in these FSW. Further research would be needed to explore such an association.

We thus have altered the statement to:

‘Regardless of the mechanism, the current Peruvian Ministry of Health program of free monthly health checks for FSW may be effective for reducing rates of cervicitis, BV and cervicitis-causing STI noted in FSW with regular clinic attendance’.”