Title: Introduction of a sexual health practice nurse is associated with increased STI testing of men who have sex with men in primary care.

Authors:

Anthony F Snow (asnow@mshc.org.au)
Lenka Vodstrcil (lvodstrcil@mshc.org.au)
Christopher K Fairley (cfairley@mshc.org.au)
Carol El-Hyak (carol@burnet.edu.au)
Rosey Cummings (rcummings@mshc.org.au)
Lousie Owen (louise.owen@dhhs.tas.gov.au)
Norman Roth (norm@prahranmarketclinic.com)
Margaret E Hellard (hellard@burnet.edu.au)
Marcus Y Chen (mchen@mshc.org.au)

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Author’s response to reviews: see over
Dear Ms Harris,

Manuscript ID 1243652698868545 entitled “Introduction of a sexual health practice nurse is associated with increased STI testing of men who have sex with men in primary care”

We thank you for the opportunity to prepare a revised manuscript in response to the reviewers’ comments. We believe we have addressed all the issues raised by the reviewers as outlined below, and that the changes have significantly improved the manuscript.

We hope the manuscript will now be suitable for publication.

Yours sincerely,

Anthony Snow and Lenka Vodstrcil on behalf of the authors.

Please find our responses to the reviewers’ comments in the requested format below.

**Reviewer One**

Referee: 1, Darren D Russell

We thank the reviewer for their careful reading of the manuscript and have answered their comments below.

**Reviewer Comment 1**

*Under Methods, could you provide us with information as to whether Clinic B is also a Medicare-billing clinic (similar to Clinic A)?*

**Our Response**

We recognise that there are differences between the operation of each clinic and have moved the following statement from the introduction to the methods section on page 4 and expanded it to explain the situation at Clinic B: “Clinics A operated utilizing the Australian government universal insurance scheme, Medicare, with no direct costs to clients. Although Clinic B also used Medicare, clients had to pay some additional consultation fees.”
Reviewer Comment
It may be useful and of interest in a future paper to assess the cost-benefit of Introducing a nurse to a general practice setting.

Our Response
We agree with the reviewer and we have included the following sentence on page 10 of the discussion. “Furthermore, a cost-benefit evaluation needs to be undertaken, to assess the sustainability of this intervention”.

Reviewer Two

Referee: 2, Kirsty Smith
We thank the reviewer for their careful reading of the manuscript and have answered their comments below.

Reviewer Comment 1- Abstract
Methods: Primary outcome needs to be clearly stated. Also need to define ‘complete testing’ — which tests, which anatomical sites, all men who attended, only men who had one of the tests, complete set of tests in a single encounter, or anytime in the period?

Our Response
We have included the definitions as suggested by the reviewer in the abstract (page 2); “This observational study compared the proportion of men who have sex with men (MSM) tested for HIV, syphilis, chlamydia (urethral and anal) or gonorrhoea (anal), or all of the above (defined as a complete set of tests at a single visit)…. ”

Reviewer Comment 2a- Abstract
Results: Mentioned in Clinic B there was no significant increase in testing – need to define if this refers to complete testing, uptake of testing, and if in HIV-negative and/or positive men.

Our Response
The authors recognise the reviewer’s comments and have replaced the sentence on page 2, ‘In Clinic B there was no significant increase in testing in MSM over the same time periods’, with, ‘In Clinic B there was no significant increase in testing in the proportion of either HIV negative or HIV positive men who had a complete set of tests over the same time periods.’

Reviewer Comment 2b- Abstract
Results: The uptake of testing results should be included as this appears to be the primary aim/outcome.

Our Response
We apologize if we have caused any confusion but we did not measure the uptake of testing in our study. Our primary objective was to determine the number of HIV and STI tests ordered as a proportion of men seen before and after the introduction of a sexual health nurse. We have made this clearer in our study objective in the abstract.
Reviewer Comment 3-Abstract
Conclusion—significant increases in STI testing mentioned, but would be good to clarify that this was an increase in complete testing rather than more men being screened.

Our Response
The authors agree with the reviewer’s suggestion and have changed the sentence from, “The introduction of the sexual health practice nurse resulted in significant increases in STI testing among MSM”, to “The introduction of the sexual health practice nurse resulted in significant increases in episodes of complete STI testing among MSM.”

Reviewer Comment 1-Background
First sentence – needs a reference

Our Response
We thank the reviewer for highlighting this omission and have included a reference.

Reviewer Comment 2-Background
Would be useful to mention other studies which have examined whether existing practice nurses can increase chlamydia testing in general practice (Bowden MJA 2008) and also a study in the UK where a GUM health advisor was placed in a general practice clinic to provide advice (Armstrong, STI journal, 2003)

Our Response
We acknowledge the potential for the manuscript to be enhanced by including the literature suggested by the reviewer, however we have decided not to include these references as we want to keep our manuscript concise and because we believe these studies are not directly relevant for reasons listed below.

The study by Bowden et al (2008) is a randomized controlled trial, which randomized general practices into two groups. Doctors in the intervention clinics were asked to offer combined chlamydia and Pap testing to eligible women; and doctors in the usual care/control clinics were asked to implement chlamydia screening guidelines based on risk assessment of the individual patient. The main outcome measure was chlamydia screening rate per visit. Their study specifically focused on chlamydia screening among women, and did not employ or utilize general practice nurses with the aim of enhancing screening in MSM which is the focus of our paper.

The study by Armstrong et al (2003) investigated the impact of a health advisor in genitourinary medicine as a training and support resource on the management of Chlamydia trachomatis in a large inner city health centre. It is important to note that practice nurses (registered nurses) perform a role that is distinctly different to that of a health advisor. For instance, in our study the nurse was able to initiate and carry out HIV and STI screening, whereas a health advisor could not. Furthermore, the sexual
health nurse in our study was not employed into the clinic for training purposes; the clinic was already a specialist general practice in gay men’s health. Finally, in the study by Armstrong et al, the vast majority of chlamydia testing was offered to women, which is clearly distinct from the population of MSM in our study.

**Reviewer Comment 3-Background**
The aim of introducing the nurse is not clear from the introduction– to increase the proportion of men tested, to improve the completeness of testing, or both?

**Our Response**
We apologize for any confusion, although we state the aim of the intervention was to enhance HIV and STI testing, our study objective was to determine the effect of this intervention, and we did this by evaluating the number of tests performed as proportion of men attending the clinic. We have clarified this in the manuscript at the end of the background section (page 3-4). “The overall objective of the current study was to determine the effect the introduction of the sexual health practice nurse (i.e. the intervention) had on HIV and STI testing. We evaluated the number of HIV and STI tests as a proportion of MSM who attended the clinic before and after the intervention.”

**Reviewer Comment 4-Background**
It may also be useful to reference a paper by Holt et al (ASHM conference 2012) which showed completeness of testing among gay men in Australia is low, due to low uptake of rectal swabs

**Our Response:**
We thank the reviewer for this suggested reference and have included the following sentence at the end of the first paragraph in the background section(page 3) and referenced the suggested conference abstract by Holt et al “Furthermore MSM in Melbourne and Sydney self-report lower rates of complete/comprehensive HIV and STI testing compared with being tested for any STI test.”

**Reviewer Comment 5-Background**
Would be useful to highlight the proportion of gay men attending GPs for STI screening (Gay Community Periodic Surveys and Futures Study reference) and therefore the importance of interventions being conducted in this setting

**Our Response**
We acknowledge the relevance of the point made by the reviewer. However, we wish to keep the length of the manuscript manageable and do not believe this additional detail is required.

**Reviewer Comment 6-Background**
A brief description of the training, roles, medicare eligibility etc of sexual health practice nurses would be useful.
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**Our Response**
The authors acknowledge the usefulness of the points made by the reviewer, however, we believe to include such detail is beyond the scope of the manuscript. We believe we have addressed the issue of the role of the nurse by stating the aim of the intervention and also their role in HIV chronic disease care.

With respect to the training of the nurse, in the background section (third paragraph page 3) we have changed the following sentence from “In October 2008; we introduced a sexual health practice nurse into an urban Melbourne general practice specializing in gay men’s health”; to, “In October 2008, an experienced sexual health nurse was introduced into an urban Melbourne general practice specializing in gay men’s health.”

The authors are reluctant to include practice nurse eligibility for Medicare rebates/funding for two reasons. First since the project was undertaken Medicare funding of practice nurses has changed significantly. Second, we are aware that the manuscript has the potential to reach an international audience, and the funding and employment of practice nurses will be dependent local health care systems.

**Reviewer Comment 1- Methods**
Consider adding some subheadings to the methods such as setting, study design, data extraction, analysis

**Our Response**
We have added the sub-headings as requested by the reviewer.

**Reviewer Comment 2-Methods**
Could the authors describe the setting in more detail and compare the two clinics – the size of the clinics, staffing (e.g. did Clinic B have a practice nurse?), who collected pathology, billing (did Clinic B charge additional fees?), location, population seen, operating hours, how funded, affiliations (if any), routine testing practices (self vs clinician collected rectal swabs). Would recommend including a table which shows the differences in the characteristics of these clinics.

**Our Response**
We acknowledge the importance of the points raised by the reviewer. We concur with the reviewer and have added the following sentence about specimen collection by patients, “At each clinic the routine practice was for patients to self-collect anal and urine samples.” (paragraph 1, page 4). However, we believe that we have provided a sufficient description of the clinic settings (Methods section, Paragraph 1). If the editor would like more information included then we are happy to redress this point.

**Reviewer Comment 3-Methods**
Could more information about the intervention at Clinic A be provided e.g specific goal/s of the nurse, who paid their salary, funding for the project, did the sexual health nurse promote self-collected swabs?

**Our Response**
We thank the reviewer for their comment and refer to the Introduction for a description of the aim of the nurse introduction. We have also altered the first
sentence of the Methods section (Settings, page 4) to make the goal of the nurse introduction clearer “..We undertook a study comparing the proportion of men who were tested for HIV and STIs before and after a sexual health practice nurse was introduced into a clinic (Clinic A) with the aim of increasing HIV and STI testing…” and we have included a description of specimen collection in Reviewer Comment 2-Methods.

However, we believe the additional information requested by the reviewer regarding nurse salary and funding diverges from the original intent of the manuscript to report the effect of the intervention, as we have discussed in “Reviewer Comment 6-Background”. If the editor would like this information included we are happy to redress this point.

Reviewer Comment 4-Methods
The clinics appear to specialise in gay men’s health, so should the study population be gay men, rather than MSM?

Our Response
The authors cannot be certain that all the men included in our study identify as gay men. Therefore, the authors use the term MSM to encompass any man who has sex with other men, regardless of how an individual man identifies his sexual orientation.

Reviewer Comment 5-Methods
First paragraph mentions ‘HIV chronic disease care’ does this mean HIV monitoring, or chronic disease management in those with HIV?

Our Response
Within the text of the Methods section (Setting, page 4), in the same sentence as ‘HIV chronic disease care’ we believe we have explained what is meant by the term: “In addition, the sexual health nurse provided HIV chronic disease care, whereby HIV positive MSM could visit the nurse every three months for a range of services, including, but not limited to, the collection of routine HIV serologic monitoring tests and STI testing.”

Reviewer Comment 6-Methods
The frequency of testing would be another important outcome in high risk men. Although the testing rates were lower in Clinic B and didn’t change, it is possible they increased the frequency of testing in those considered higher risk i.e 2+ tests in high risk men, or 3+ syphilis tests in HIV positive men?

Our Response
The HIV and STI testing data for our study were obtained from the Victorian Primary Care Network for Sentinel Surveillance of STIs and Blood Borne Viruses. The sentinel surveillance network is a third party who receives testing data from the relevant testing laboratory. Clinics A and B do not provide the sentinel surveillance network with sexual behaviour data. Therefore we would not be able to determine if individuals deemed to be high risk had altered frequency of testing over the time period.
Furthermore in the interests of patient privacy and confidentiality the sentinel surveillance network receives data where patient identifiers have been re-coded. Neither the sentinel surveillance network nor the authors were aware of the code to re-identify patients. Also, as a condition of the research ethical approval the authors were precluded from re-identifying patients, which would be necessary to conduct these further analyses highlighted by the reviewer. Therefore, it is impossible for the authors to determine much of the information suggested by the reviewer from the dataset or clinic records.

**Reviewer Comment 7-Methods**

2nd paragraph: suggest rewording this sentence. ‘Periods 1 and 2, were included to establish whether any changes in testing rates detected were occurring naturally over time ...’ to: ‘whether there was a background increase in testing due to other factors...’

**Our Response**

We have changed the wording of this sentence in the Methods section (Study Design, page 5) to read, ‘The two periods prior to the intervention, Periods 1 and 2, were included to establish whether there was a background increase in testing prior to the introduction of the nurse.’

**Reviewer Comment 8-Methods**

Could the authors describe where the information on the HIV viral loads used to estimate the HIV-positive MSM was obtained from?

**Our Response**

The authors concur with the reviewer’s comment that it is not clear where the HIV viral load tests were obtained from. The authors have amended the sentence in the Methods section (Data Extraction, page 5) to ‘HIV viral load tests, and the number of HIV and STI tests undertaken during these periods and at both clinics was obtained from the Victorian Primary Care Network for Sentinel Surveillance of STIs and Blood Borne Viruses.’

**Reviewer Comment 9-Methods**

In regards to ‘men with a viral load being classified as HIV positive unless they had a negative HIV antibody test at an earlier visit’, could the authors explain the situation when HIV-negative men would have a HIV viral load? I assume occasionally in a suspected HIV seroconversion illness? The authors should comment on any misclassification bias that may arise from this and the extent of the issue. If men are incorrectly misclassified as HIV negative but are HIV positive then it may underestimate HIV testing rates.

**Our Response**

We thank the reviewer for their comment and apologise if our statement was confusing. No men who were deemed HIV-negative had a HIV viral load in our retrospective audit. What we meant by our comment was that some men went from being HIV-negative to HIV-positive during the study and so were counted as HIV-
negative until we had a viral load indicating otherwise. We have clarified this by including the following description in the Methods section (Data Extraction, page 5):

“Men who had an HIV viral load test performed at any visit over the three periods were included as HIV positive. However, if an individual had a negative HIV antibody test at an earlier visit before they had HIV viral load tests, they were deemed to be HIV negative for any prior visits.”

**Reviewer Comment 10-Methods**
Could the authors please explain why data on throat gonorrhoea were not available?

**Our Response**
The authors have changed the following sentence in the Methods section (Data Extraction, page 5) from ‘Data for testing of pharyngeal gonorrhoea were not available’, to, ‘The Victorian Primary Care Network for Sentinel Surveillance of STIs and Blood Borne Viruses does not routinely collect data for pharyngeal gonorrhoea testing, therefore it was not included in the analysis.’

**Reviewer Comment 11-Methods**
Re following statement (last paragraph): ‘If an individual attended more than once in the same period he was only counted once.’ Does this mean that if he had a test on one occasion, and not another, the former was counted?

**Our Response**
We apologise if our statement was not clear. What we meant was that if a man was tested more than once within a period only his first test within that period was counted. We have altered the sentence to make this clearer (Analysis, page 6): “If an individual attended and was tested more than once in the same period he was only counted once.”

**Reviewer Comment 1-Results**
Some subheadings would be useful: 1) client characteristics at baseline (sample size, median age of men, risk behaviour, previous positive tests, proportion of new and existing clients, reason for presenting- sexual health related or other etc), 2) testing uptake, 3) completeness of testing, etc.

**Our Response**
The HIV and STI testing data for our study were obtained from the Victorian Primary Care Network for Sentinel Surveillance of STIs and Blood Borne Viruses. The sentinel surveillance network is a third party who receives testing data from the relevant testing laboratory. In the interests of patient privacy and confidentiality the sentinel surveillance network receives data where patient identifiers have been re-coded. Neither the sentinel surveillance network, nor the authors were aware of the code to re-identify patients. Also, as a condition of the research ethical approval the authors were precluded from attempting re-identifying patients. Therefore, it is impossible for the authors to determine much of the information suggested by the reviewer from the dataset or clinic records. We are unable to determine why men presented, if they chose to be tested or were recommended to have test or any of the
client characteristics. Furthermore, the sentinel surveillance network does not routinely collect behavioural data from the clinics in our study.

However, as suggested by the reviewer, we have included sub-headings to separate our results for HIV negative and HIV positive men.

**Reviewer Comment 2-Results**
*In the first paragraphs could authors please clarify if the increases are absolute or relative increases, and add to the methods?*

**Our Response**
Please refer to our next response.

**Reviewer Comment 3-Results**
*I assume the p values in the results related to the differences in the proportion between periods, rather then the % increase. This could be made clearer. For example 'the proportion tested for syphilis in period 2 was x% compared with x% in period 3 (p<0.05), representing a x% increase.'*

**Our Response**
We apologise for any confusion. We have changed the relevant sentence (HIV and STI testing in HIV Negative Men, page 6) to now read “When Compared with Period 2, the introduction of the sexual health nurse in Period 3 (see Table 1) was associated with significant increases in the proportion of HIV negative MSM who had HIV, syphilis, urine, anal, or complete sets of tests with absolute increases of 5% (p=0.026), 7% (p<0.01), 5% (p=0.024), 7% (p<0.01), and 6% (p<0.01) respectively.”

The p values stated relate to the difference in proportion between period 2 and 3, however the difference in proportion has been expressed as a percentage. In essence they are one and the same, whether expressed as raw number or a percentage, the p value does not change. The reporting of percentages has been done so to aid readability and is also consistent with tabulated results.

We would like to thank the reviewer for the suggested formatting of reporting changes in the percentage tested between periods. For the sake of brevity and to avoid repetition of reporting of results within the manuscript, we decided to maintain our original format. We have however, added ‘(Table 1)’ to the new sentence outlined above. This addition is designed to draw the reader’s attention to the tabulated results that can be read in conjunction with the text.

**Reviewer Comment 4-Results**
*Although contained in Tables 1 and 2, please add to the text some brief results on the actual proportions at the different clinics, as at Clinic A the % of HIV-positive men having a STI test seems very low, and this issue is mentioned in the discussion*
Our Response
Again we thank the reviewer for their suggestion. For reasons of brevity and conciseness, as outlined in Reviewer Comment 3-Results (above), we draw the reader’s attention the tabulated results to be read in conjunction the text.

Reviewer Comment 5-Results
One important confounder is that the demographics or risk behaviour of men attending the clinics was different, or these characteristics changed between time periods. The baseline characteristics of the men could be compared in regards to the different clinics and before and after period in Clinic A. If there are differences, they should be adjusted for in assessment of the primary outcome.

Our Response
Our study design was a retrospective analysis of previously collected data which (as previously outlined in ‘Reviewer Comment 1-Results’), that did not include the collection of demographic or sexual behavior data. Therefore analysis suggested by the reviewer could not be performed.

Reviewer Comment 6-Results
Could the testing done by the sexual health nurse be analysed separately if available, or at least report what proportion of testing was done by the nurse?

Our Response
As previously outlined in ‘Reviewer Comment 5-Methods’ the data set obtained from the Victorian Primary Care Network for Sentinel Surveillance of STIs and Blood Borne Viruses contained coded patient identifiers. The authors did not have the ‘key’ to re-identify patients and were precluded from do so as a condition of the ethics approval. Therefore it is impossible to distinguish whether a doctor or the nurse initiated or undertook testing of an individual.

Reviewer Comment 7-Results
In regards to completeness could the results for the individual tests/anatomical sites be added? E.g. were rectal swabs most incomplete at baseline, and then improved the greatest?

Our Response
The authors agree that the reviewers suggestion would enhance the manuscript and have added the following comment to the end of the first paragraph in the section STI testing In HIV Positive Men (page 7): “The significant increase in the proportion of anal swabs performed is likely to be the main cause of the subsequent increase in complete episodes of testing.”

Reviewer Comment 8-Results
Could the results of tests be included, specifically in relation to completeness? Did the increase in completeness result in a greater yield of HIV/STIs?

Our Response
We thank the reviewer for the suggestion, however we do not have the results of the tests to report. In paragraph 4 of the discussion (page 9) we have added the sentence
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“This is important because increased STI screening of MSM has been shown to increase detection of infections [16],” to explain the significance of this finding.

**Reviewer Comment 9-Results**
Could Tables 1 and 2 be restructured to avoid repetition of ‘period 1,2,3’?

**Our Response**
We believe it is important to keep this level of detail in the table so that the distinct time periods are clear. We refer to the periods in the Methods section, results section and tables in the same way for consistency.

**Reviewer Comment 1-Discussion**
Mentions in the second paragraph that ‘increased by 1% (p=0.31)’ but not significant. This could be reworded to say ‘no significant change’

**Our Response**
We have amended this accordingly.

**Reviewer Comment 2-Discussion**
Could the authors comment on why they think there is a difference in the baseline testing rates at Clinic A compared with B? Also is the baseline completeness in Clinic A greater than B because of the way the doctors order the test e.g. a common group of tests set up in their patient management system?

**Our Response**
Our data reflects the number of tests ordered as a proportion of men who visited each clinic. While both Clinic A and B have a high proportion of clients who are MSM, Clinic B also has a high caseload of other clients. It may be that as a result, Clinic B might see men for reasons that do not call for STI testing. It is difficult therefore for us to speculate as to why the difference was present.

**Reviewer Comment 3-Discussion**
Could the authors also comment on why they think there was a significant increase in testing in HIV negative men between period 1 and 2 at clinic B and the significant decrease between periods 2 and 3?

**Our Response**
We acknowledge these differences however we can only speculate why there was a variation in HIV testing in this period. Therefore the authors have not passed comment.

**Reviewer Comment-4- Discussion**
Describes that among HIV positive MSM, the proportion of men tested for syphilis actually decreased after the sexual health nurse was introduced. However these results aren’t included in the results section.

**Our Response**
We thank the review for pointing this out. We have amended the third paragraph in the discussion section (page 9) to now read, “Among HIV positive MSM in the intervention clinic, there was no significant change in syphilis testing (p=0.20) after the sexual health nurse was introduced. There was a small but statistically
significant (p=0.02) decrease in syphilis testing among HIV positive MSM at the control clinic over the same period.” However, this decrease may not be of clinical significance, given the high portion of HIV positive men tested for syphilis across all three periods in both clinics. The most likely reason for the high proportion of HIV positive men tested for syphilis is that prior to the commencement of this study, and throughout the study periods, both clinics had a policy in place to testing HIV positive MSM for syphilis with each routine blood test taken as part of HIV monitoring. This policy was in line with the recommendations of Australian National Gay Men’s Syphilis Action Plan [15].”

Reviewer Comment 5-Discussion
Further discussion about the infections missed due to incomplete testing in other studies in the US could be noted.

Our Response
Please refer to our response in ‘Reviewer Comment 8-Results’, where we have added a sentence that increased screening of MSM increases detection of infection.

Reviewer Comment 6-Discussion
Mentions the decline in syphilis testing was because of the clinics having a policy prior to the nurse, but does this mean the policy was removed when the nurse was introduced? Could it be because there was a decline in viral load testing and thus less opportunity for syphilis testing in these men?

Our Response
Please refer to our response in ‘Reviewer Comment 4- Discussion’.

Reviewer Comment-7 Discussion
Other than social marketing, are there any other external factors to be considered which may have influenced testing, such as promotion of guidelines, or initiatives undertaken by the doctors which were unrelated to the introduction of the nurse i.e. doctors grouping their pathology so all tests are automatically ordered. For example the paper by Holt et al at ASHM showed a general increase in all gay men in regards to completeness.

Our Response
Holt et al (2012) analysed self-reported STI testing data from the Melbourne and Sydney Gay Community Periodic Surveys between 2003-2011. They found increases in testing for any STI and for comprehensive testing over this period. Holt et provide no detail about factors that may have driven (self-reported) increases in STI testing behaviours, nor do they differentiate where the testing occurred (i.e. general practice or sexual health clinic). We are reluctant to compare our findings with that of Holt et al because it is self-reported data and the type of clinic men were tested in is uncertain. If we were to do this then it would be with caution and overall we believe it would not enhance the manuscript.

Furthermore, the national MSM STI testing guidelines were in existence years before the study period commenced. Given the clinical focus of the intervention clinic, and
that some, but not all of the, general practitioners were also sexual health physicians, then we believe there was a high awareness of the recommended testing guidelines amongst the doctors prior to the implementation of the nurse.

**Reviewer Comment 8-Discussion**
Was there any assessment of the acceptability of a sexual health practice nurse to the GPs/clients? If not this should be noted as a limitation. The authors could also refer to any other patient acceptability studies of nurse only sexual health screening clinics.

**Our Response**
The authors have included a reference [17] on page 9, relating to the general practitioners acceptability of the sexual health practice nurse. We did not specifically comment on this in the current manuscript for this reason. To our knowledge there are no patient acceptability studies of nurse-led sexual health screening for MSM in the sexual health clinic setting.

**Reviewer Comment 9-Discussion**
Finally the authors should comment on how this could be translated to other GP clinics in Australia or overseas. For example should practice nurses receive more specialist sexual health training, should more sexual health practice nurses be placed in GP clinics, how would this be funded (is it cost effective for clinics to employ a sexual health practice nurse)?

**Our Response**
We thank the reviewer for their comment. The practicalities of how nurses could be placed in primary care practices to undertake STI screening is an important consideration, however we are aware that BMC has an international readership across many different types of health systems and service models so it would be best to leave out detailed discussion because it may not be generalizable across different settings.