

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Methods and Quality of disease models incorporating more than two sexually transmitted infections: A protocol for a systematic review of the evidence
AUTHORS	Sailer, Fabian; Rait, Greta; Howe, Alice; Saunders, John; Hunter, Rachael

VERSION 1 – REVIEW

REVIEWER	Theresa Ann Sipe, Statistician and Team Lead CDC, USA
REVIEW RETURNED	31-Oct-2017

GENERAL COMMENTS	<p>This is an interesting protocol for a systematic review to summarize the literature on modeling of 2 or more STIs and report on the methodology and quality. The protocol is fairly comprehensive and complete. There are a few gaps or sections out of order. Below are my suggestions</p> <ol style="list-style-type: none"> 1. Abstract - change multiple STIs to 2 or more STIs 2. Paper - Please add potential limitations. There are some as reflected by the decisions that were made in methods. 3. Under methods and analysis there is a general inclusion and exclusion criteria section but then there are many other inclusion/exclusion items grouped by a subhead. Suggest adding a subhead such as 'Other Inclusion/Exclusion criteria by Characteristic' and have each of the types of inclusion/exclusion criteria listed below this subhead. 4. for 'Type of study' delete 'being included and excluded. Add a comma after 'information'. 5. Change 'Population' subhead to 'Populations' 6. Add more information under 'Selection Process'. 7. Move 'Search strategy' to follow 'Information sources' as it seems out of order. Move 'Selection Process' to follow 'Search strategy'. 8. Move 'Information sources' to follow 'Outcomes' 9. Add a section on 'Analyses' before 'Subgroup analysis' and describe how you will summarize the results. Add the sentence 'all reviewed studies will be reported in the final report, including their calculated percentage scale value'. Add 'of the quality assessment' to that sentence. 10. Under subgroup analysis, consider analyses by low versus high quality, type of modeling, and published versus grey literature. 11. p.6, line 43, change 'all articles' to 'remaining articles'.
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REVIEWER	Matthew Chico London School of Hygiene & Tropical Medicine
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REVIEW RETURNED	13-Nov-2017
GENERAL COMMENTS	<p>BMJ Open</p> <p>Sailer et al. have prepared a protocol for a systematic review of the methods and quality of disease models that incorporate more than two sexually transmitted infections (STIs). The topic is of importance and the protocol may merit publication. However, there are some changes the authors should consider.</p> <p>Main points</p> <ol style="list-style-type: none"> 1. Page 1 & 2 – It is not clear from the 'Strengths and Limitations' section at the bottom of page 1 (section heading) and the top of page 2 (four bullet points) which points are strengths and which points are weaknesses. 2. Throughout – The authors misspell or misuse the terms for STIs in many parts of the manuscript and would benefit from reading a paper by Low et al. entitled, "Mind your binomials: a guide to microbial nomenclature and spelling in Sexually Transmitted Infections" 3. Page 3 – In the 'Rationale' section, the authors should cite a few studies that have previously demonstrated STI interventions impacting on several STIs at one time. 4. Page 4 – Be clear where pregnant women will be included. Although sexual activity may decline for some women during pregnancy, this is not universal. Moreover, being pregnant is evidence of sexual activity. 5. Page 4 – Some of the 'Outcomes' listed are vague and should be described in greater detail, including 'Input', 'Output', and 'Customisability'. 6. Page 5 – The year(s) when the study was conducted should be extracted – not just the year of its publication; the year when the study was conducted should receive emphasis in the resulting analyses instead of the publication year. 7. Page 5 – Bias assessment should involve a funnel plot assessment to determine whether positive versus negative studies have been equally reported, as well as large versus small studies. 8. Page 6 – Search terms in appendix A should be listed using all combinations of search terms for each database. The purpose, after all, of publishing a protocol is to enable other researchers to reproduce the same results if the same processes are followed. It is true data bases are always expanding their content (both past and present) but this is the purpose of publishing the protocol. 9. Page 6 – FS appears to be extracting data while AH will conduct quality checks on 10% of studies. This itself is not standard practice. Ideally, a quality systematic review first involves two individuals who independently of each other conduct the same database searches using the same search terms. The highest quality systematic reviews will blind reviewers to publishing journal and authors. This may not always be feasible, but the searches should be done by separately by two people. If that is not done, then at a minimum, one person should carry out the searches and data extraction and the second person reviews the initial Endnote library (before any duplicates were removed) and then follows the inclusion and exclusion criteria in the protocol to produce a dataset that is then compared to the one prepared by the first person. Where there are discrepancies, whether by inclusion or exclusion, a senior person acts as a tie-breaker to determine whether a paper is to be included. In this protocol, AH is only going to review 10% of studies that FS has included. This is poor practice and, arguably, would be fine for a student paper, but not a publication. AH (or someone else)

	<p>should start with the original Endnote library proceed as described above.</p> <p>Minor points</p> <ul style="list-style-type: none"> • Abstract (line 39): Public Library of Science (PLOS) is mentioned (and elsewhere in the manuscript) with a dated abbreviation. The journal now uses PLOS; the authors have written PLoS. • Abstract (line 43): The authors use 'and al' rather than 'et al' or 'and all'. English or Latin is fine, but not a mix of both. • Page 3 (rows 5-8): The word 'patient' is used three times in the first sentence between rows 5-8 on page three. Can this be re-written to communicate the same idea without such repetition? • Page 3 – The 'Methods and analysis' section contains the inclusion and exclusion criteria. However, the lists need a close copy-edit. Start each bullet with a relevant verb, for example. <p>Articles will be included if they:</p> <ul style="list-style-type: none"> o Examine STIs at a population level... o Cover at least two STIs o Contain and English title... <p>Also, the third bullet listed is not really a criterion The exclusion criteria are very repetitive. The authors should re-write to remove 'will be excluded' from three of the five bullets.</p>
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VERSION 1 – AUTHOR RESPONSE

Comments of the first reviewer:

1. Abstract - change multiple STIs to 2 or more STIs

Thank you for the suggested text. We have updated the document to read "2 or more STIs" in the two occasions that the text "multiple STIs" occurred.

2. Paper - Please add potential limitations. There are some as reflected by the decisions that were made in methods.

We acknowledge that the limitations of our research were not listed clearly in the first submission. Therefore we added three paragraphs at the beginning of the "Discussion and dissemination" section to provide detail regarding the limitations.

3. Under methods and analysis there is a general inclusion and exclusion criteria section but then there are many other inclusion/exclusion items grouped by a subhead. Suggest adding a subhead such as 'Other Inclusion/Exclusion criteria by Characteristic' and have each of the types of inclusion/exclusion criteria listed below this subhead.

We have added a subheading to "Inclusion Criteria" and "Exclusion Criteria" to increase the clarity of the "Eligibility criteria" section.

4. for 'Type of study' delete 'being included and excluded. Add a comma after 'information'.

5. Change 'Population' subhead to 'Populations'

We have made the recommended changes.

6. Add more information under 'Selection Process'.

We have increased the detail provided in the section "Selection Process". We moved content from the "study records and data management" section into "selection process" in order to increase the coherence of both sections.

7. Move 'Search strategy' to follow 'Information sources' as it seems out of order. Move 'Selection Process' to follow 'Search strategy'.
8. Move 'Information sources' to follow 'Outcomes'

We changed the order of the sections so that they are now in a more logical sequence.

9. Add a section on 'Analyses' before 'Subgroup analysis' and describe how you will summarize the results. Add the sentence 'all reviewed studies will be reported in the final report, including their calculated percentage scale value'. Add 'of the quality assessment' to that sentence.
We added another section to the protocol. We lay out the plan of our data analysis in this section and explain all summary measure we will report on.

10. Under subgroup analysis, consider analyses by low versus high quality, type of modeling, and published versus grey literature.
We appreciate this suggestion and think that these subgroup analyses will enhance the quality of outcome of this review, which is why we decided to add further planned subgroup analyses to the protocol.

11. p.6, line 43, change 'all articles' to 'remaining articles'.
We have made this change.

Comments of the second reviewer:

1. Page 1 & 2 – It is not clear from the Strengths and Limitations' section at the bottom of page 1 (section heading) and the top of page 2 (four bullet points) which points are strengths and which points are weaknesses.
We changed the wording in this section to be more precise.
2. Throughout – The authors misspell or misuse the terms for STIs in many parts of the manuscript and would benefit from reading a paper by Low et al. entitled, "Mind your binomials: a guide to microbial nomenclature and spelling in Sexually Transmitted Infections".
Thank you for forwarding this paper. We used it as a guidance to edit the document.
3. Page 3 – In the 'Rationale' section, the authors should cite a few studies that have previously demonstrated STI interventions impacting on several STIs at one time.
We added three more references to the protocol [17-19] which give example for interventions, which increase condom use and their effects on multiple STIs at the same time.
4. Page 4 – Be clear where pregnant women will be included. Although sexual activity may decline for some women during pregnancy, this is not universal. Moreover, being pregnant is evidence of sexual activity.
We changed the wording of this paragraph and added two more sentences in order to make it more precise.
5. Page 4 – Some of the 'Outcomes' listed are vague and should be described in greater detail, including 'Input', 'Output', and 'Customisability'.
We put some of the information from the appendix into the main protocol to explain these vague point in more depth.
6. Page 5 – The year(s) when the study was conducted should be extracted – not just the year of its publication; the year when the study was conducted should receive emphasis in the resulting analyses instead of the publication year.

We completely agree with this point and added another item to the list of data items. We also amended the appendix to explain what will be covered using this data item. We also added the year when study was conducted into one of our summary measure described in "Analyses".

Page 5 – Bias assessment should involve a funnel plot assessment to determine detect whether positive versus negative studies have been equally reported, as well as large versus small studies. We understand that this is standard practice and if possible would have reported a funnel plot. Unfortunately as this is a review of the quality and quantity of the literature and not a single outcome measure we will not be able to produce a funnel plot. We have added this as a potential limitation of the study.

7. Move 'Search strategy' to follow 'Information sources' as it seems out of order. Move 'Selection Process' to follow 'Search strategy'.

We changed the order of the sections so that they now are in a more logical sequence.

8. Page 6 – Search terms in appendix A should be listed using all combinations of search terms for each database. The purpose, after all, of publishing a protocol is to enable other researchers to reproduce the same results if the same processes are followed. It is true data bases are always expanding their content (both past and present) but this is the purpose of publishing the protocol. We enhanced appendix A and show all search strategies there. We explain the changes to the strategies which are necessary to search each database in a short paragraph before the strategy.

9. Page 6 – FS appears to be extracting data while AH will conduct quality checks on 10% of studies. This itself is not standard practice. Ideally, a quality systematic review first involves two individuals who independently of each other conduct the same database searches using the same search terms. The highest quality systematic reviews will blind reviewers to publishing journal and authors. This may not always be feasible, but the searches should be done by separately by two people. If that is not done, then at a minimum, one person should carry out the searches and data extraction and the second person reviews the initial Endnote library (before any duplicates were removed) and then follows the inclusion and exclusion criteria in the protocol to produce a dataset that is then compared to the one prepared by the first person. Where there are discrepancies, whether by inclusion or exclusion, a senior person acts as a tie-breaker to determine whether a paper is to be included. In this protocol, AH is only going to review 10% of studies that FS has included. This is poor practice and, arguably, would be fine for a student paper, but not a publication. AH (or someone else) should start with the original Endnote library proceed as described above.

We would like to thank the reviewer for their helpful suggestions. We are aware that both reviewers screening all articles is best practice. The PRISMA guideline though offers the possibility to let the second reviewer screen only a sample of paper. As stated in PRISMA: "Similarly, some detail should be reported on who participated and how such processes were completed. For example, a single person may screen the identified records while a second person independently examines a small sample of them"[1]. We sought advice from Dr Andrew Booth, Reader in Evidence Based Information Practice at University of Sheffield, as to what is a reasonable percentage of papers screened by two. He advised us that 20% is acceptable, but that other processes should be put in place to ensure quality and that this should be reported as a limitation. Based on this plus the PRISMA guidelines we have increased the percentage of papers screened by two reviewers to 20%. We have also included a process for what will happen when there are conflicts (If the second and third reviewer find that the first reviewer is over exclusive and has missed some papers we will increase the percentage of papers reviewed by two reviewers by 10% and repeat the process).

- Abstract (line 39): Public Library of Science (PLOS) is mentioned (and elsewhere in the manuscript) with a dated abbreviation. The journal now uses PLOS; the authors have written PLoS.

We were not aware of this change of acronym, and would like to thank the reviewer for pointing this out. We now used the correct acronym throughout the whole protocol and in the appendix.

• Abstract (line 43): The authors use 'and al' rather than 'et al' or 'and all'. English or Latin is fine, but not a mix of both.
We now use the Latin abbreviation.

• Page 3 (rows 5-8): The word 'patient' is used three times in the first sentence between rows 5-8 on page three. Can this be re-written to communicate the same idea without such repetition?
We edited the sentence to avoid this repetition.

• Page 3 – The 'Methods and analysis' section contains the inclusion and exclusion criteria. However, the lists need a close copy-edit. Start each bullet with a relevant verb, for example. Articles will be included if they:

- o Examine STIs at a population level...
- o Cover at least two STIs
- o Contain an English title...

Also, the third bullet listed is not really a criterion

The exclusion criteria are very repetitive. The authors should re-write to remove 'will be excluded' from three of the five bullets.

We edited this section to avoid repetitions and deleted redundant word.

The second submission for the protocol and the appendices have been attached to this letter. "Track changes" mode has been activated in both documents to follow up each change we made to the protocol and the appendix since our last submission. We used comments in the documents to point out where and how we addressed each of the issues raised by the reviewers.

We would like to thank the reviewers for their detailed feedback which has helped us to reflect on the protocol and as a result improved its quality.

We greatly appreciate the opportunity to respond to the reviewer comments and look forward to further correspondence from you on the publication of our article.

Best wishes,
Fabian Sailer

1. The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration. 2017.

VERSION 2 – REVIEW

REVIEWER	R. Matthew Chico London School of Hygiene & Tropical Medicine
REVIEW RETURNED	05-Jan-2018
GENERAL COMMENTS	Thank you for addressing my concerns. The protocol is much improved with the revisions provided.

VERSION 2 – AUTHOR RESPONSE

Comments of the editor:

1. Please include the dates of the search in the abstract.

We included the search date in the abstract.

2. Did you use a tool to assess bias?

We specified that we will use basic statistic methods to analyse potential bias.

3. Please include the search dates in the methods section.

We specified the search date in the method section.

4. The 'Discussion and dissemination' section should be renamed 'Ethics and Dissemination', as per guidelines for protocols.

We amended the title of this section.

5. Please include the full PRISMA-P checklist, with the recommendations still in it, as well as your page numbers.

We included the recommendations and updated the page and line numbers mentioned in the checklist.

Comments of the second reviewer:

1. Thank you for addressing my concerns. The protocol is much improved with the revisions provided.

We would like to thank you for your very detailed review which helped us to reflect on the design of the systematic review and hence wise improve it.

The latest submission for the protocol has been attached twice to this letter, a version with activated "Track Changes" mode and a clean copy. We used comments in the marked copy to point out where and how we addressed each of the issues raised by the editors.