

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Randomised trials in maternal and perinatal health in low- and middle-income countries from 2010 to 2019: a systematic scoping review
<b>AUTHORS</b>	Eggleston, Alexander; Richards, Annabel; Farrington, Elise; Tse, Wai Chung; Williams, Jack; Sella Hewage, Ayeshini; McDonald, Steve; Turner, Tari; Vogel, J

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Kotlar, Bethany Harvard University T H Chan School of Public Health, Social and Behavioral Sciences
<b>REVIEW RETURNED</b>	14-Feb-2022

<b>GENERAL COMMENTS</b>	<p>Dear BMJ Open Editorial Team,</p> <p>Thank you for the opportunity to review this paper: “Randomised trials in maternal and perinatal health in low-and middle-income countries from 2010 to 2019: a systematic scoping review.” This paper contributes to the field of maternal health by identifying trends in research in LMICs over time and identifying current gaps in the literature pertaining to maternal mortality. This manuscript is of high quality, with clear and appropriate presentation of well-founded methods and analysis. I recommend the acceptance of this paper and have no major revisions to suggest.</p> <p>Sincerely,</p> <p>Bethany Kotlar, MPH Associate Director, Maternal Health Task Force</p>
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<b>REVIEWER</b>	Hussain-Shamsy, Neesha University of Toronto
<b>REVIEW RETURNED</b>	23-Feb-2022

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to review your interesting manuscript. I have a few comments and suggests which could be used to improve your manuscript and add clarity for the reader:</p> <ol style="list-style-type: none"> <li>1. When discussing eligibility criteria for studies, inclusion criteria is listed narratively, whereas exclusion criteria is provided in list form. It would be helpful for these to be consistent (either both narrative or both in list form).</li> <li>2. You state that the search was applied to CENTRAL, which includes records from ClinicalTrials.Gov, yet you also state that trial registration from ClinicalTrials.gov were not included in the records retrieved. Can you clarify? Excluding records from ClinicalTrials.Gov would be a significant limitation.</li> <li>3. A minor point, but in the Results it would be helpful if you were very clear on whether you are reporting year of publication, or the year in which the trial was conducted. This could be an important point if there are significant delays in publication.</li> <li>4. Could you comment more in-depth on possible reasons for the lack of focus on community-level interventions and whether you feel, given available evidence, there should in fact be greater importance placed on these types of interventions?</li> <li>5. I note that the role of funding sources in the outcomes described in the paper is only noted briefly at the conclusion. I would suggest a more comprehensive inclusion of this point in the text of the discussion. Is there a reason why funding source was not included in data extraction? This information could provide important insight to explain the nature of trends.</li> <li>6. In the PRISMA Flow Chart of Screening (Fig 1), the 68 articles that were excluded because the full-text could not be located are currently included in the number of articles assessed for eligibility by full text. This should be corrected as those articles were not assessed for eligibility by full text.</li> </ol>
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### VERSION 1 – AUTHOR RESPONSE

1. When discussing eligibility criteria for studies, inclusion criteria is listed narratively, whereas exclusion criteria is provided in list form. It would be helpful for these to be consistent (either both narrative or both in list form).

Response: The exclusion criteria (page 7) has been changed to narrative form, in line with the formatting of the inclusion criteria

2. You state that the search was applied to CENTRAL, which includes records from ClinicalTrials.Gov, yet you also state that trial registration from ClinicalTrials.gov were not included in the records retrieved. Can you clarify? Excluding records from ClinicalTrials.Gov would be a significant limitation.

Response: Thanks for this comment. The reviewer is correct in that the primary aim of the scoping review was to assess published trials of maternal health interventions conducted in LMICs. We acknowledge that trial registries such as ClinicalTrials.gov would be a useful source of additional information with regards to trials that are registered or ongoing, though we are also aware that many trials are registered are ultimately not conducted nor completed. In the interests of focusing this review on completed, published trials we opted to use the specified databases.

We have clarified this in the last sentence of the Introduction: "As such, we sought to assess all *published* maternal health trials conducted in LMICs in the past 10 years..."

To acknowledge the potential limitation of this approach, we have added the following sentence to the first paragraph of the Strengths and limitations section: " While we focused this analysis on published randomized trials, we acknowledge that further insights could be gleaned from analyses of registered trial protocols on platforms such as ClinicalTrials.gov or the WHO International Clinical Trials Registry Platform. While exploring registered trial protocols was beyond the scope of this analysis, we intend to update and expand this database in the future.

3. A minor point, but in the Results it would be helpful if you were very clear on whether you are reporting year of publication, or the year in which the trial was conducted. This could be an important point if there are significant delays in publication.

Response: The word "published" has been inserted into relevant parts of the results section to help clarify that our findings are based on the year of publication, and not necessarily the year the research itself was conducted.

4. Could you comment more in-depth on possible reasons for the lack of focus on community-level interventions and whether you feel, given available evidence, there should in fact be greater importance placed on these types of interventions?

Response: we agree with the reviewer that that the relatively fewer community-level interventions is itself an interesting finding. It was not possible for us to draw firm conclusions based on the data in this dataset, and several factors might have contributed to this pattern. We have speculated further on this Interpretation, para 4:

"Over 90% of trials were conducted at either a facility or primary care level, a finding consistent with Chersich et al, in which only 5% of studies involved a community service component.<sup>24</sup> This is perhaps not surprising considering that trials of health system or community-wide interventions can be larger-scale and complex endeavours, and hence more challenging and resource-intensive to conduct. Conversely, our findings may reflect that the relative scarcity of community-level intervention trials is a missed opportunity, and that greater investment in such trials are warranted. Strengthening community-based approaches are particularly important in resource-limited settings where maternity care facilities and services are scarce."

5. I note that the role of funding sources in the outcomes described in the paper is only noted briefly at the conclusion. I would suggest a more comprehensive inclusion of this point in the text of the discussion. Is there a reason why funding source was not included in data extraction? This information could provide important insight to explain the nature of trends.

Response: Thanks for this great point. We agree that trial funding is an important consideration and worthy of exploration. In our preparatory work, we observed a number of inconsistencies in the reporting of trial funding, including absence of reporting/lack of data, and use of multiple funding sources, complicating consistent coding and analysis. In light of this, we elected to - as a first step - focus on our primary objective as to how trial questions aligned with international maternal health research priorities. In light of this, we are not in a position to make specific comments on trial funding practices in maternal health trials in LMICs, but anticipate being able to do so in the future.

Our plan is to update and expand this database to answer other questions such as trial funding practices, as well as differences in trial quality, trial protocol registration practices, and other important methodological aspects of trial conduct and design. We have modified the “future research” section to better reflect this:

“This database of randomized trials will be used to conduct further analyses of the maternal health trial literature, such as exploring variations in study quality between countries and over time, trial protocol registration and trial funding practices, and bibliometric analyses to identify the most impactful individuals, institutions, and collaborations.”

6. In the PRISMA Flow Chart of Screening (Fig 1), the 68 articles that were excluded because the full-text could not be located are currently included in the number of articles assessed for eligibility by full text. This should be corrected as those articles were not assessed for eligibility by full text

Response: Thank you for pointing this out. To amend this, we have utilised the updated 2020 PRISMA flowchart diagram for Figure 1, which contains an extra step in the process (reports sought for retrieval) and separate box allowing for those which could not be retrieved. We have updated the first paragraph of the results section to reflect this.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Hussain-Shamsy, Neesha University of Toronto
<b>REVIEW RETURNED</b>	12-Apr-2022

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to once again review this interesting manuscript.</p> <p>With respect to the original comments provided:  RE: Excluding records from ClinicalTrials.Gov  I appreciate the clarification in the introduction around the assessment of published trials and the additional acknowledgement of this limitation in the S/L section. While I still do believe that including records from ClinicalTrials.Gov (which can specify trials that have concluded but perhaps not published yet) would have made your review more comprehensive, I can appreciate that this would be resource intensive and perhaps not feasible.</p> <p>All of my other comments have been addressed to my satisfaction. In reading the revised manuscript, I have no further comments to add.</p>
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