



STUDY PROTOCOL

REVISED **A protocol for a systematic review of standardised tools used in perinatal death review programmes [version 2; peer review: 2 approved]**

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Abstract

Introduction: Perinatal mortality encompasses stillbirths and early neonatal deaths. A perinatal death surveillance and response cycle has been recommended by the World Health Organization for use in the review of perinatal deaths. The main components of the cycle include identifying and reporting perinatal deaths, and reviewing the deaths, including potentially modifiable factors, in order to measure and improve quality of care provided to women and infants. There is no consensus on the best way to design, implement and conduct perinatal death reviews. This systematic review aims to identify standardised tools that are used to review perinatal deaths.

Objectives: The primary aim of this protocol is to describe methodology for a systematic search of the literature to identify standardised tools that are used to review perinatal deaths in upper-middle to high-income countries. Review tools may include standardised checklists, forms, frameworks or other structured documents used to review perinatal deaths. Review tools will be appraised to see if they incorporate the identification of modifiable factors in perinatal deaths and establish recommendations for improvements to quality of care provided.

Methods: A systematic review of the literature will be performed to identify peer-reviewed publications and grey literature describing the use of perinatal mortality review tools without date restrictions. The eligibility of review tools for inclusion will be based on inclusion and exclusion criteria applied to the SPIDER framework. Data will be extracted based on the structure and content of included review tools, and the tools will be appraised using the Appraisal of Guidelines Research and Evaluation Health Systems (AGREE-HS) instrument.

Conclusion: This systematic review protocol for identifying and appraising standardised perinatal mortality review tools may help to establish the optimal way to structure a standardised review process

Open Peer Review

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- Rachidatou Compaoré** , Institut de Recherche en Sciences de la Santé, Ouagadougou, Burkina Faso
 - Collette N Ncube** , Boston University, Boston, USA
- Ruby Barnard-Mayers** , Boston University, Boston, USA

Any reports and responses or comments on the article can be found at the end of the article.

for perinatal mortality in middle- to high-income countries.

PROSPERO registration: CRD42022326877

Keywords

Perinatal mortality, stillbirth, neonatal death, review tool, surveillance and response, protocol



This article is included in the [Maternal and Child Health](#) collection.

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REVISED Amendments from Version 1

Please see below detail on the changes and updates made to the manuscript on this updated version:

- Further clarity on the Sustainability Development Goal 3.2 and absence of a clear reference to Stillbirth has been included in paragraph 1.
- The primary aim of the review and objectives have been re-structured as per reviewers suggestion.
- Information regarding the ways in which the process of perinatal death review may contribute to the reduction in PMRs has been included in paragraph 3.
- Further clarity on how/why the MPDSR perinatal death review might be better suited for application to upper-middle- and high-income countries has been provided.
- The reference to Republic of Ireland as target population has now been removed.
- The rationale for including only high- and middle-income countries as been explained in the 3rd paragraph of the "Eligibility criteria" section.
- Information on search strategies for each database has been updated as outlined in the section "Search strategy". Table 3 has also been replaced with a supplementary table with a more detailed example of the search strategies developed.
- Further detail regarding methodology in analyses of the data, use of Rayyan and use of quality assessment tool has also been included.

Any further responses from the reviewers can be found at the end of the article

Introduction

"The day of birth is potentially the most dangerous day for both mothers and their babies" according to the World Health Organisation (WHO)¹. While significant reductions have been made in neonatal mortality in the last two decades, there are still an estimated 2.7 million neonatal deaths every year. It is worth noting that there are also an estimated 2.6 million stillbirths every year, a fact that does not feature as prominently in the Sustainable Development Goals (SDG) published by the United Nations in 2016². Although the SDG 3.2 includes a target reduction in neonatal mortality to 12/1,000 livebirths by 2030, there is no clear reference to a reduction of stillbirth rates in this document².

Perinatal mortality includes stillbirths (both antepartum and intrapartum stillbirths) and early neonatal deaths (death of a live born infant occurring within the first seven days of life). The perinatal mortality rate (PMR) of a country is a key indicator of the quality of maternity services available in that country^{3,4}. In 2019, a stillbirth rate of 3.0/1000 livebirths and a neonatal death rate of 2.9/1000 livebirths was reported^{5,6}. Perinatal death surveillance is a powerful approach towards monitoring and improving healthcare services⁴. A perinatal death is considered in many countries to be a sentinel event, which is defined in the United States (US) by the Joint Commission as a patient safety event that results in death, permanent harm, or severe temporary harm⁷. In an Irish context, a perinatal death is considered a serious reportable event, which is defined as a subset of incidents which are either serious or that should not occur if the available preventative measures

have been effectively implemented by healthcare providers⁸. In recent years, there has been a greater focus on auditing and reviewing the circumstances surrounding the perinatal death with particular emphasis on the role of system factors in the death^{1,8-10}.

In support of this, and to emphasise the importance of multi-factor review of perinatal deaths, the WHO published guidance on the establishment of maternal and perinatal death surveillance and response (MPDSR) committees at a local level in 2021⁹. The value of comprehensive review of perinatal deaths has already been established in several high-income countries around the world^{10,11}. This includes the United Kingdom (UK), where the perinatal mortality rate (PMR) has reduced by 18% from 2012–2018 with the introduction of several targeted measures, one of which is a perinatal mortality review tool (PMRT)¹². Review tools, as part of this process, allow for a more streamlined approach to identification of risk factors and care-related issues. Similarly, the Netherlands established the Foundation National Perinatal Audit (PAN) programme in 2010 (now known as PERINED), which standardised the perinatal death review process, and helped to reduce their PMR by 18% during the years 2010 to 2015¹³.

While it is extremely important to capture data on number and causes of perinatal deaths, it is also of vital importance that review of perinatal deaths encompasses the identification of modifiable factors in those deaths. Modifiable factors are defined by the WHO as a factor "that may have prevented the death had a different course of action been taken"^{1,9}. Identification of remediable factors forms part of the WHO's MPDSR cycle. It is only through reviewing quality of care that quality improvements and changes to clinical care can be enacted, thereby completing the cycle¹. The importance of evaluating the quality of care through structured review has been highlighted repeatedly by MBRRACE-UK, whose confidential enquiry and national audit is often viewed internationally as a gold standard¹⁰. The quality of institutional review was more recently emphasised in the Ockenden Report, which reviewed the maternity services at a hospital group in the UK¹⁴. Recommendations from this report included strengthened accountability amongst senior maternity staff, timely implementation of changes in practice following review of care and improving family engagement in investigations.

There is no international consensus on the optimum way to conduct perinatal death reviews that factor in all of the above-mentioned aspects of the review cycle. A 2020 Cochrane systematic review of death audits for reducing maternal, perinatal and child mortality concluded that more research is required in order to identify how death reviews should be designed and implemented in order to achieve maximum effectiveness in different contexts globally³.

While there are some support materials for maternal and perinatal death review included in the MPDSR guidance document published by the WHO in 2021, many of the examples given focus largely on maternal death reviews and surveillance⁹. Included information on perinatal death reviews, for example the sample stillbirth and neonatal death case review form, provides limited information and lacks the detail

required to identify risk and contributory factors, which is possibly not as suited to countries who may have access to larger dataset and information on each perinatal death.. There is a need to identify what standardised tools (if any) are in use internationally for the review of perinatal deaths that may be more suitable for use in high-income, resource-rich settings.

The evidence for appraisal or comparison of review tools for perinatal deaths is lacking in the literature. This is particularly the case for review tools in use in high-income settings that incorporate the development and implementation of recommendations for clinical practice and governance. In addition, this analysis may aid policy-makers and stakeholders who seek to implement a standardised review tool to evaluate perinatal deaths in their own institution or country.

Primary aim

The primary aim of this systematic review is to examine standardised tools used to review perinatal deaths.

Objectives:

- Identify tools or other standardised checklists, forms, frameworks or other documents that are currently in use or have been piloted for use in reviewing perinatal deaths.
- Describe the structure of identified perinatal review tools and if they generate data or information on modifiable factors contributing to perinatal deaths.
- Assess if identified facilitators and barriers to the implementation of standardised perinatal mortality review tool.
- Examine evidence of validation or accreditation of the tool identified

As part of this systematic review, we will also study the development of recommendations for clinical care generated as part of the use of standardised tools to review perinatal deaths and examine the evidence that employing these tools may contribute towards a reduction of perinatal mortality rates at institution, region or country-level.

Protocol and registration

This protocol has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (protocol number: CRD42022326877) and is reported in accordance with the reporting guidance provided in the Preferred Reporting Items for Systematic review and Meta-Analysis – Protocols (PRISMA-P) 2015¹⁵; the completed checklist is available as part of the extended data for this project.

Eligibility criteria

The eligibility of review tools will be based on inclusion and exclusion criteria applied to the SPIDER framework (S: sample, PI: population of interest, D: study design, E: evaluation, R: research type), developed by Cooke *et al.* and outlined in Table 1¹⁶.

The definition of stillbirth varies widely internationally. The WHO identifies the following definition for stillbirth: “death before birth, among fetuses that are, by order of priority, of at least 1000g birthweight, and/or at least 28 weeks gestation, and at least 35cm long.”⁹ Some countries use lower thresholds for both gestational age and weight at birth to define stillbirth (for example, a fetus that has reached greater than or equal to 24 weeks’ gestation or weighing greater than 500g at birth)¹⁷. As the term “perinatal mortality” is generally accepted to encompass stillbirths (antepartum and intrapartum) and early neonatal deaths, this definition also varies internationally.

Table 1. SPIDER framework for eligibility criteria.

SPIDER Framework	Eligibility Criteria
S: Sample	<ul style="list-style-type: none"> – Review of perinatal deaths (stillbirths and/or early neonatal deaths) occurring in maternity units or hospitals – Standardised review tools used, in use or piloted for use at local, regional or national level – Upper-middle-income to high-income countries as defined by the World Bank 2022 (N=135)¹⁸
PI: Phenomenon of Interest	<ul style="list-style-type: none"> – Perinatal mortality: stillbirths (antepartum and intrapartum) and early neonatal deaths – Definition according to each country
D: Study Design	<ul style="list-style-type: none"> – Any study, report or other publication detailing the current use or trial of use of a standardised review tool to review individual perinatal deaths or perinatal mortality as a whole – No language restriction – No date restriction
E: Evaluation	<ul style="list-style-type: none"> – Structure, content and format of perinatal mortality review tools – Standardisation or validation of the review tool – Development of recommendations based on identified remediable factors based on the review of perinatal deaths – Evidence of reduction in perinatal mortality rate (PMR) in the relevant institution, region or country – Facilitators and barriers encountered in the implementation of the perinatal mortality review process
R: Research type	<ul style="list-style-type: none"> – All relevant study types involving the use of a standardised tool to review perinatal deaths will be included, including both quantitative and qualitative studies – Grey literature including publications from national or international scientific societies, professional colleges, charitable organisations, and government organisations

For the purposes of this systematic review, a country's own definition of perinatal mortality, stillbirth and early neonatal death will be used when searching for tools used to review perinatal deaths.

Literature focused on tools from upper-middle-income to high-income countries to allow better comparability and ensure that the tools apply to settings with somewhat similar characteristics and level of resources.

In addition, the search will not be restricted by language, date of publication or type of study.

Information sources

The identification of relevant perinatal mortality review tools will encompass a multi-tiered approach. Systematic bibliographic database searching will identify review tools that are in use or have been piloted for use at a local, regional or national level by individual hospitals, hospital groups or committees. This includes identifying review tools published in journals, through professional medical associations and organisations, or identified through searches of grey literature.

A systematic literature search will be performed to identify publications describing the use of perinatal mortality review tools using the following databases: PubMed, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science and OpenGrey. Websites of international scientific institutes, organisations & professional

societies, listed in [Table 2](#), will also be searched. Other professional organisations will be added to this table if applicable as the search progresses.

Search strategy

A search strategy will be developed by the study investigators. The search strategy will include suitable keywords relating to perinatal mortality reviews. The terms will be followed by the truncation symbols * and will be refined using Boolean operators such as AND/OR. The initial search will be limited to screening titles and abstracts rather than full bibliographic records. The search strategy will be similar for all databases (with the same search terms and combinations) with exceptions for where a specific database criteria requires a tailored approach. An example of search strategies developed for use in scientific databases is included in Supplementary File 1. The search strategy will be piloted before the final searches are executed.

Study selection

For the bibliographic database search, two reviewers will screen titles and abstracts against the inclusion and exclusion criteria outlined below.

Inclusion criteria:

- Perinatal mortality review tools from upper-middle- to high-income countries as classified by the World Bank Country and Lending Groups 2022 (N=135)¹⁸

Table 2. Scientific institutes, organisations & professional societies.

Scientific Institutes, Organisations & Professional societies	Country/Region
National Perinatal Epidemiology Centre (NPEC)	Ireland
Mothers and Babies: Reducing Risk through Audits and Confidential Enquires across the UK (MBRRACE-UK)	U.K
French Society of Neonatology	France
Dutch Society of Obstetrics and Gynecology	The Netherlands
German Society of Perinatal Medicine	Germany
European Society of Human Reproduction and Embryology (ESHRE)	Europe
European Association of Obstetricians and Gynecologists	Europe
European Association of Perinatal Medicine	Europe
European Board and College of Obstetrics and Gynecology (EBCOG)	Europe
Union of European Neonatal and Perinatal Societies (UENPS)	Europe
Perinatal Society of Australia and New Zealand (PSANZ)	Australia & New Zealand
National Perinatal Association	U.S.A.
Canadian Perinatal Network	Canada
Society for Maternal-Fetal Medicine (SMFM)	International
World Association of Perinatal Medicine (WAPM)	International
The International Federation of Gynaecology and Obstetrics (FIGO)	International

- Review tools for perinatal deaths currently in use or review tools that have been piloted for use in individual maternity units or hospitals, or in hospital groups
- Review tools for perinatal deaths in use at local, regional or national level
- Review tools for perinatal deaths that include a recommendation section for changes to clinical practice, guidelines, and/or governance
- Tools that are used in the review of individual perinatal deaths or tools that are used for reviewing a grouping of perinatal deaths (e.g. intrapartum stillbirths or stillbirths caused by placental abruption)
- Review tools available in any language
- No date restrictions

Exclusion criteria:

- Tools previously used to review perinatal deaths that are no longer in use or have been decommissioned or replaced
- Lower-middle- and low-income countries as classified by the World Bank Country and Lending Groups 2022
- Publication does not include the review or audit tool nor enough relevant information on this in the published material, or the review tool cannot be accessed by other means (e.g. direct contact with the study authors, or the governing group)

For screening of websites, two independent reviewers will screen the websites for the scientific institutes, organisations & professional societies outlined above. The titles and abstracts (where applicable) will be reviewed against the inclusion/exclusion criteria outlined above. The methodology for this website screening follows the process previously described by Hennessy *et al.* (2021) in their research¹⁹.

Results from both the scientific databases and the website screening will be imported using Rayyan software²⁰ and duplicates will be removed. Title and abstract (or summary) screening will be carried out in this software using the blinding feature during the review period. When abstracts are not available, the summary of the document will be used. If summaries or preliminary information on the document is not available, a brief screening of the full record will be carried out. The SPIDER framework will be applied broadly during the initial screening to ensure relevant perinatal mortality review tools are not excluded. Full text articles of publications identified through screening of titles and abstracts will be retrieved and assessed independently for eligibility by the two reviewers. Disagreement between the two reviewers regarding the eligibility of any study will be resolved following discussion and consensus. If consensus on eligibility is not reached, the opinion of a third reviewer will be sought.

A PRISMA flow diagram will be used to illustrate the search process. This diagram will map out the process for review tool selection and the number of records identified at each stage based on the inclusion and exclusion criteria.

Data collection

Once the review tools for inclusion have been obtained, all associated supplementary documents will be retrieved by the reviewer (EOC) prior to data extraction and quality assessment. If links to these documents are not provided within the article, website or other source, EOC will conduct a search to locate them. All supplementary documents will be verified by a second reviewer to ensure completeness and correct document pairing.

Data extraction

Data extraction will be completed by one reviewer (EOC) and will be independently verified by a second reviewer for accuracy and completeness. A standardised, pre-piloted form in Microsoft Excel will be used to extract data from the identified perinatal mortality review tools for assessment of quality and data synthesis. Discrepancies will be resolved through discussion and consensus. If consensus cannot be reached, the opinion of a third reviewer will be sought. Any missing information from the review tools will be recorded as 'not described' in the data extraction form.

The following information will be extracted from identified perinatal mortality review tools:

- General Information
 - Title
 - Author & year of publication
 - Language
 - Developing/publishing organisation and/or authors/funding
 - Country/countries of publication
 - Version
- Description of document provided by the authors (e.g. guideline, review tool, audit tool)
- Composition of tool development group, if applicable
- Evidence of peer review or validation
- Target user of the review tool
- Type of perinatal death reviewed by the tool (e.g. all perinatal deaths, intrapartum stillbirths only, or early neonatal deaths only)
- Document structure (including subsections, type of data collected, length of document)
- Development process (evidence based and/or consensus-based)

- If a recommendation development section is included, data extraction will include the structure of the recommendation section
- Appraisal of recommendations based on SMART principles (Specific, Measurable, Achievable, Relevant, Time-bound)²¹
- Framework used for the development of recommendations, e.g. the Yorkshire framework²²
- Validity period, if specified

Quality assessment

The quality of the included review tools will be appraised using the Appraisal of Guidelines Research and Evaluation Health Systems (AGREE-HS) tool²³. This tool was developed by the AGREE research team to systematically appraise health systems guidance (or guideline) documents produced by countries, governing bodies or committees at national, regional or local level. Two reviewers will independently conduct the quality assessment of the review tools using AGREE-HS. This tool focuses on five key domains that form part of the development of health systems guidance:

1. Topic
2. Participants
3. Methods
4. Recommendations
5. Implementability

Each domain is applied to the guidance document (in this case, the perinatal mortality review tool) and scored using a 7-point Likert scale, with scores ranging from 1 (lowest quality) to 7 (highest quality). A final score for the overall quality of the review tool will be calculated by totalling the individual scores for the five domains. If consensus cannot be reached during appraisal (i.e., if individual scores from each reviewer differ more than 2 points), a third reviewer (KOD) will assist with the appraisal process. The final scores will be used to help interpret the guidance documents being appraised by identifying review tools of higher and/or lower quality. The quality appraisal outcomes will not affect the literature that will be included in the data synthesis.

Data synthesis

Data synthesis will involve a descriptive approach to appraisal and examination of perinatal mortality review tools. The

appraisal will be conducted using the AGREE-HS tool, as described above. There will be a narrative description of the data extracted from the perinatal mortality review tools, as well as a specific focus on those tools that include a section on the development of recommendations based on the review findings (if applicable).

Conclusion

The aim of this systematic review is to identify and appraise standardised review tools that are currently in use or have been piloted for use in reviewing perinatal deaths. Consistent review of the modifiable factors around perinatal deaths and implementation of recommendations developed from the review may help to prevent future perinatal deaths and reduce a country's PMR. There is a need to identify what standardised review tools are being used to review perinatal deaths, particularly in a high-income, resource-rich setting and appraise and compare the tools. The findings from this systematic review may help in the implementation of a targeted perinatal death review program.

Dissemination

We plan for this systematic review of perinatal mortality review tools to be disseminated through peer-reviewed publication and presentation at relevant professional and scientific events.

Data availability

Underlying data

No data are associated with this article.

Extended data

Open Science Framework: A protocol for a systematic review of standardised tools used in perinatal death review programmes, <https://doi.org/10.17605/OSF.IO/PVKX7>²⁴.

This project contains the following extended data:

- Supplementary File 1 Sample Search Strategy.pdf

Reporting guidelines

Open Science Framework: PRISMA-P checklist for "A protocol for a systematic review of standardised tools used in perinatal death review programmes", <https://doi.org/10.17605/OSF.IO/PVKX7>.

Data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

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<http://www.doi.org/10.17605/OSF.IO/PVKX7>

Open Peer Review

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Ruby Barnard-Mayers 

Boston University, Boston, Massachusetts, USA

No further comments

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Epidemiology, Maternal and Child Health

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 08 September 2023

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Rachidatou Compaoré 

Institut de Recherche en Sciences de la Santé, Ouagadougou, Burkina Faso

I assessed the authors' revision, and I would like to confirm through this email that I am happy with the changes and have no additional comments.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Public health, sexual and reproductive health, quality of care, health policy and systems research, process evaluation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 01 August 2023

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Thank you for the opportunity to review this study protocol aimed at identifying standardised tools used in perinatal death review programmes in high- and middle-income countries. In addition to summarizing the tools identified, the authors are particularly interested in describing facilitators and barriers to implementation of these tools, and determining whether the tools are structured to support the development of recommendations for change to clinical practice based upon identified modifiable factors contributory to perinatal deaths.

Introduction

1st paragraph: The authors allude to the existence of a Sustainable Development Goal related to neonatal death (SDG 3.2 which includes a target reduction in neonatal mortality rates) and the absence of an SDG target for stillbirth. However, this is not mentioned explicitly. We would recommend that the authors provide more clarity to their statement.

3rd paragraph: This paragraph could be strengthened by the addition of information regarding the ways in which the process of perinatal death review has led to the reduction in PMRs in the identified countries. It can be inferred from the manuscript that clinical policy recommendations may result from this exercise, and that perhaps it is the goal of the authors to determine whether that is the case by conducting this review. It would be helpful to the reader to know the hypothesized or empirically identified mechanisms by which perinatal death review contributes to reductions in perinatal deaths.

6th paragraph: Additional information is required regarding the inadequacy of the MPDSR perinatal death review for application to upper-middle- and high-income countries. The authors indicate that the MPDSR perinatal death review requires less information for the conduct of the

review. This alone does not make it “unsuitable for use in high-income, resource-rich settings” as we could assume that information would be readily available in resource-rich settings. The authors might consider excluding the comparison between low-income and high-income countries and focus instead on the value such a review could provide to upper-middle- and high-income countries.

7th paragraph: The authors mention the Republic of Ireland as the target population for policy change following this review, however the introduction is not focused on this country. It might be better to exclude this statement and bring it up for discussion in the following paper discussing results from the review.

Primary Aim

No comments.

Objectives

No comments.

Protocol and registration

No comments.

Eligibility criteria

Please include the rationale for including only high- and middle-income countries.

We recommend moving the definitions of stillbirth given in this section to the introduction.

Information sources

No comments.

Search strategy

The SPIDER search tool proposed by Cooke, Smith & Booth (2012) is one of a number of variations to the PICO approach for formulation a search strategy in a literature review of qualitative studies. We think rationale is required for choosing the SPIDER search tool/framework to define the literature review eligibility criteria and, assumedly, the search strategy that will be developed for this systematic literature review. Among the number of variations to the PICO approach, the PICOS tool appears to be the recommended tool for literature reviews of qualitative research (Methley *et al.* (2014)¹ and Booth (2016)²).

The protocol could benefit from some clarity regarding the number of reviewers who will be involved in title and abstract review of citations from electronic databases (such as PubMed and Embase); specific mention of the use of Rayyan for title and abstract review of citations from electronic databases, if applicable; and any blinding during review of titles and abstracts. The process by which the websites will be screened lacks the level of detail required to replicate the review. We would suggest that the authors describe this aspect of the review in more detail, referencing any prior work describing the process for such a review if any exists. The authors mention that the “Results will be imported using Rayyan software.” Some specificity would be helpful regarding the results referenced here; particularly, whether this includes websites. Since websites are less likely to have titles and abstracts as do peer-reviewed journal articles, it is unclear how their content will be evaluated alongside the citations within Rayyan.

Quality Assessment

The authors describe the scoring system for the AGREE-HS quality assessment tool, which would result in a total score for each review tool identified via this systematic literature review process ranging from 10-70 (score of 1 * 5 items * 2 reviewers; score of 7 * 5 items * 2 reviewers). We would recommend that the authors include an explanation of what consensus looks like in this case where the outcome is a total score across the two reviewers (i.e., do the individual scores have to be identical or can they vary by 1 or 2 points).

References

The URL link for Reference 6 link is invalid.

Supplementary files

Inclusion of the sample search strategy for the CINAHL database permits reproducibility of the literature review. It would be helpful to include a sample search strategy for all databases to be searched in this review.

References

1. Methley AM, Campbell S, Chew-Graham C, McNally R, et al.: PICO, PICOS and SPIDER: a comparison study of specificity and sensitivity in three search tools for qualitative systematic reviews. *BMC Health Serv Res.* 2014; **14**: 579 [PubMed Abstract](#) | [Publisher Full Text](#)
2. Booth A: Searching for qualitative research for inclusion in systematic reviews: a structured methodological review. *Syst Rev.* 2016; **5**: 74 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Epidemiology, Maternal and Child Health

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 18 Aug 2023

Sara Leitao

Thank you for your review of this Systematic Review Protocol. we hope to have addressed all the comments and suggestions in the new draft and we outline, below, an itemized response and clarification on each of the comments by these reviewers.

Introduction

1st paragraph: The authors allude to the existence of a Sustainable Development Goal related to neonatal death (SDG 3.2 which includes a target reduction in neonatal mortality rates) and the absence of an SDG target for stillbirth. **However, this is not mentioned explicitly. We would recommend that the authors provide more clarity to their statement.**

Response

Thank you for highlighting this, further clarity on SDG3.2 and absence of a clear reference to SB has been included in paragraph 1.

3rd paragraph: This paragraph could be strengthened by **the addition of information regarding the ways in which the process of perinatal death review has led to the reduction in PMRs in the identified countries.** It can be inferred from the manuscript that clinical policy recommendations may result from this exercise, and that perhaps it is the goal of the authors to determine whether that is the case by conducting this review. It would be helpful to the reader to know the hypothesized or empirically identified mechanisms by which perinatal death review contributes to reductions in perinatal deaths.

Response

This has been clarified further in paragraph 3.

6th paragraph: **Additional information is required regarding the inadequacy of the MPDSR perinatal death review for application to upper-middle- and high-income countries.** The authors indicate that the MPDSR perinatal death review requires less information for the conduct of the review. This alone does not make it “unsuitable for use in high-income, resource-rich settings” as we could assume that information would be readily available in resource-rich settings. The authors might consider excluding the comparison between low-income and high-income countries and focus instead on the value such a review could provide to upper-middle- and high-income countries.

Response

Thank you for highlighting this. We have rephrased this paragraph to clarify the argument being made.

7th paragraph: The **authors mention the Republic of Ireland as the target population for policy change following this review, however the introduction is not focused on this country.** It might be better to exclude this statement and bring it up for discussion in the following paper discussing results from the review.

Response

The reference to Republic of Ireland as target population has now been removed.

Eligibility criteria

Please include the rationale for including only high- and middle-income countries.

Response

This has now been included in the 3rd paragraph of the "Eligibility criteria" section.

Eligibility criteria

We recommend moving the definitions of stillbirth given in this section to the introduction.

Response

We appreciate the suggestion and have given thoughtful consideration to this. The definition of stillbirth is placed in this section to provide clearer context on the criteria that will be used within the systematic review and hence we believe it is of greater value in the current location.

Search strategy

The SPIDER search tool proposed by Cooke, Smith & Booth (2012) is one of a number of variations to the PICO approach for formulation a search strategy in a literature review of qualitative studies. We think rationale is required for choosing the SPIDER search tool/framework to define the literature review eligibility criteria and, assumedly, the search strategy that will be developed for this systematic literature review. Among the number of variations to the PICO approach, the PICOS tool appears to be the recommended tool for literature reviews of qualitative research (Methley *et al.* (2014)¹ and Booth (2016)²).

Response

SPIDER was considered more relevant for this SR as it does not look at interventions specifically, not in a changed/comparison of outcomes. This review looks at the various tools available to review Perinatal Deaths (the Phenomenon of Interest) and hence a tool focussed on outcomes would not be the most applicable. As per CASP: "PICO mostly focuses on intervention (or therapy) clinical questions. It can be less suitable for other question types (such as qualitative research) as it doesn't account for some complexities like considering feasibility, context, and sociocultural acceptability " (<https://casp-uk.net/pico-framework/> 02 Aug 23)

The protocol could benefit from some **clarity regarding the number of reviewers who will be involved in title and abstract review of citations from electronic databases** (such as PubMed and Embase); **specific mention of the use of Rayyan for title and abstract review of citations from electronic databases, if applicable; and any blinding during review of titles and abstracts.** The **process by which the websites will be screened lacks the level of detail required to replicate the review.** We would suggest that the authors describe this aspect of the review in more detail, referencing any prior work describing the process for such a review if any exists. The authors mention that the **"Results will be imported using Rayyan software."** **Some specificity would be helpful regarding the results referenced here; particularly, whether this includes websites. Since websites are less likely to have titles and abstracts as do peer-reviewed journal**

articles, it is unclear how their content will be evaluated alongside the citations within Rayyan.

Response

Further detail on the items listed above has been included in paragraph 4 and 5 of the "study Selection" section.

Quality Assessment

The authors describe the scoring system for the AGREE-HS quality assessment tool, which would result in a total score for each review tool identified via this systematic literature review process ranging from 10-70 (score of 1 * 5 items * 2 reviewers; score of 7 * 5 items * 2 reviewers). **We would recommend that the authors include an explanation of what consensus looks like in this case** where the outcome is a total score across the two reviewers (i.e., do the individual scores have to be identical or can they vary by 1 or 2 points).

Response

Thank you for highlighting the need for this further clarification in the manuscript, this has now been included.

References

The URL link for Reference 6 link is invalid.

Response

This has now been corrected and the correct URL provided.

Supplementary files

Inclusion of the sample search strategy for the CINAHL database permits reproducibility of the literature review. It would be helpful to **include a sample search strategy for all databases to be searched in this review.**

Response

This has now been included as supplementary file.

Competing Interests: None to declare

Reviewer Report 04 July 2023

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Rachidatou Compaoré 

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This article is a systematic review protocol for a study on standardised tools used in perinatal death review programmes. The study aims to identify the best practices for reviewing perinatal deaths and improving the quality of care provided to women and infants. The review will be conducted using a comprehensive search strategy and will include studies that evaluate the use of standardised tools in perinatal death review programmes in high income countries.

The rationale for, and objectives of, the study clearly described, The rationale is well presented with a justification to conduct the study. It would be interesting to precise the perinatal rates in high income countries.

The authors were also careful to specify their general and specific objectives for this study. However, the general objective is not well formulated, containing three verbs for a single objective. There are too many specific objectives: some of the specific objectives could be grouped together. In addition, the authors could try to present the specific objectives in a more organised way, for example everything concerning the structure of the tools should be grouped together, and everything concerning the actions taken following the generation of information grouped together too. Some specific objectives go beyond the general objective, which seems more descriptive, whereas some specific objectives refer to actions taken to correct situations leading to deaths and improve mortality rates.

The authors presented their methods in a structured manner. It would be necessary to describe the databases that the authors intend to screen and also add the search strategies for each of the database.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Public health, sexual and reproductive health, quality of care, health policy and systems research, process evaluation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 18 Aug 2023

Sara Leitao

Many thanks for the review and comments on our manuscript

As per your suggestion, a reference to the perinatal rates in high income countries has now been included in the second paragraph of the introduction.

We have also rephrased the primary aim and re-structured the objectives as per reviewer's suggestion.

In relation to the suggestion to describe the databases to use and add the search strategies for each of the database: the databases to use in the literature search are listed in the second paragraph of the section "Information sources". Information on search strategies and for each database has been updated as outlined in the section "Search strategy". Table 3 has also been replaced with a supplementary table with a more detailed example of the search strategies developed.

Competing Interests: None to declare