EPOC Qualitative Evidence Syntheses:
Protocol and review template

27th September 2019
Cochrane Effective Practice and Organisation of Care Group (EPOC)


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## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TEMPLATE</strong></td>
<td></td>
</tr>
<tr>
<td>[Title of qualitative evidence synthesis]</td>
<td>3</td>
</tr>
<tr>
<td>Abstract</td>
<td>3</td>
</tr>
<tr>
<td>Plain language summary</td>
<td>5</td>
</tr>
<tr>
<td>Background</td>
<td>5</td>
</tr>
<tr>
<td>Objectives</td>
<td>6</td>
</tr>
<tr>
<td>Methods</td>
<td>6</td>
</tr>
<tr>
<td>Results</td>
<td>18</td>
</tr>
<tr>
<td>Discussion</td>
<td>21</td>
</tr>
<tr>
<td>Authors’ conclusions</td>
<td>22</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>23</td>
</tr>
<tr>
<td>Contributions of authors</td>
<td>23</td>
</tr>
<tr>
<td>Declarations of interest</td>
<td>24</td>
</tr>
<tr>
<td>Differences between protocol and review</td>
<td>24</td>
</tr>
<tr>
<td>Published notes</td>
<td>25</td>
</tr>
<tr>
<td>Characteristics of studies</td>
<td>25</td>
</tr>
<tr>
<td>Summary of Qualitative Findings tables</td>
<td>26</td>
</tr>
<tr>
<td>Additional tables</td>
<td>27</td>
</tr>
<tr>
<td>References</td>
<td>27</td>
</tr>
<tr>
<td>Figures</td>
<td>28</td>
</tr>
<tr>
<td>Sources of support</td>
<td>28</td>
</tr>
<tr>
<td>Appendices</td>
<td>28</td>
</tr>
<tr>
<td><strong>Template Examples</strong></td>
<td></td>
</tr>
<tr>
<td>Example 1. Title and Objectives</td>
<td>30</td>
</tr>
<tr>
<td>Example 2. Background / Why is it important to do this review?</td>
<td>31</td>
</tr>
<tr>
<td>Example 3. Methods / Criteria for considering studies for this review</td>
<td>32</td>
</tr>
<tr>
<td>Example 4. Methods / Sampling of studies</td>
<td>33</td>
</tr>
<tr>
<td>Example 5. Methods / Data management, Analysis and Synthesis</td>
<td>34</td>
</tr>
<tr>
<td>Example 6. Integrating the review findings with the Cochrane</td>
<td>38</td>
</tr>
<tr>
<td>Example 7. Review author reflexivity</td>
<td>39</td>
</tr>
<tr>
<td>Example 8. Results / Methodological limitations of the studies</td>
<td>41</td>
</tr>
<tr>
<td>Example 9. Results / Confidence in the review findings</td>
<td>42</td>
</tr>
<tr>
<td>Example 10. Results / Review findings</td>
<td>43</td>
</tr>
<tr>
<td>Example 11. Example of Discussion / Overall completeness and</td>
<td>50</td>
</tr>
<tr>
<td>applicability of the evidence</td>
<td></td>
</tr>
<tr>
<td>Example 12. Examples of “Authors’ conclusions / Implications for</td>
<td>51</td>
</tr>
<tr>
<td>practice”</td>
<td></td>
</tr>
<tr>
<td>Example 13. Examples of “Authors’ conclusions / Implications for</td>
<td>53</td>
</tr>
<tr>
<td>future research”</td>
<td></td>
</tr>
<tr>
<td><strong>Template references</strong></td>
<td>54</td>
</tr>
</tbody>
</table>
[Title of qualitative evidence synthesis]

Your QES title should be brief, but should closely reflect your main objective.

Your title should always end with “a qualitative evidence synthesis”.

Where your QES is linked to a single published Cochrane intervention review, consider using terms similar to those used in that review.

See examples of EPOC qualitative evidence synthesis titles in Appendix 1.

Abstract

Background
[text]

Summarize the rationale and context of your qualitative evidence synthesis. Consider using the same text that you have prepared for the background section of your Plain Language Summary.

Where relevant, mention here or in the Objectives section that the review is linked to one or more Cochrane intervention reviews of effectiveness.

Possible text: [This review links to a Cochrane review assessing the effect of [...].]

Objectives
[text]

State the main objective(s), preferably in a single concise sentence. Make sure the objective in the Abstract matches exactly the Objective in the main text of the review.

Search methods
[text]
Provide the date of your last search for studies, and the databases and other sources that you searched.

For more guidance, see the MECIR standards for intervention reviews:

**Selection criteria**

[text]

Summarize your criteria for selecting studies for inclusion in the review, including information on study design, population and setting.

**Data collection and analysis**

[text]

Summarize your methods for selecting studies, sampling studies (when applicable), collecting data, evaluating methodological limitations and synthesising findings.

**Main results**

[text]

Follow the same guidance given for presenting Plain Language Summary findings: How to write a plain language summary of a Cochrane EPOC Qualitative Evidence Synthesis.

**Authors' conclusions**

[text]

State the key conclusions that can be drawn from your review. Authors' conclusions can include both implications for practice and implications for future research.

**Do not make recommendations.**

Consider using the same text that you have used in the “Key findings” section of your Plain Language Summary.
Plain language summary

[See: How to write a plain language summary of a Cochrane EPOC Qualitative Evidence Synthesis.]

Background

Description of the topic

[text]

Describe the topic covered by your review. This would usually include a description of the health intervention or health condition and what this review seeks to understand, explain or describe.

For guidance from the Cochrane Qualitative and Implementation Methods Group on formulating a research question for a qualitative evidence synthesis, see Harris 2018 [1]

How this review might inform or supplement what is already known in this area

[text]

Describe the ways in which the topic/intervention/theory you are examining might inform, extend, enhance, or supplement what is currently known in this area.

This includes a description of how your review might inform or supplement evidence of effectiveness. This is particularly relevant where your review is linked to a Cochrane intervention review.

How the intervention might work / How the health condition might affect people

[text]
Where your review focuses on a healthcare intervention or a health condition, provide an overview of relevant evidence describing theoretical and empirical reasoning for why and how the intervention might work, or how the condition might affect people’s lives, including how this might differ for different populations.

To describe how and why the intervention might work or how a health condition might affect people’s lives, and to show where the qualitative evidence synthesis fits in, you may want to include a framework or logic model.

If you plan to include sub-group analyses in your review, you should also include relevant background information that can justify your choice of sub-groups here.

Why is it important to do this review?

[Text]

Explain the importance of the review question, with reference to relevant policy documents, systematic reviews, health technology assessments, or other reports.

Describe how this review differs from other reviews on similar topics See example of a description of how this review differs from other reviews in Appendix 2: Background / Why is it important to do this review?

For EPOC guidance on how to identify relevant systematic reviews, see Identifying Cochrane and non-Cochrane reviews relevant to your EPOC topic.

Objectives

[Text]

State the main objective(s), preferably in a single concise sentence.

For some syntheses, you may also want to include secondary objectives. For example, you may want to explore:
- whether the data shows differences across different population groups or settings
- how the review informs, extends or enhances a Cochrane intervention review

See examples of Objectives in Appendix 1.

For guidance from the Cochrane Qualitative and Implementation Methods Group on formulating a research question for a qualitative evidence synthesis, see Harris 2018 [1]. For additional guidance on formulating a research question for a qualitative evidence synthesis, see Booth 2019 [2]

Methods
Criteria for considering studies for this review

Types of studies

Specify which study designs you plan to include. Justify your choice of study designs where you think this information might be helpful to readers.

If you plan to exclude primary studies because of their publication date, publication status or language of publication, describe and explain this decision here.

Possible text:

[We will include primary studies that use qualitative study designs such as ethnography, phenomenology, case studies, grounded theory studies and qualitative process evaluations. We will include studies that use both qualitative methods for data collection (e.g., focus group discussions, individual interviews, observation, diaries, document analysis, open-ended survey questions) and qualitative methods for data analysis (e.g. thematic analysis, framework analysis, grounded theory). We will exclude studies that collect data using qualitative methods but do not analyse these data using qualitative analysis methods (e.g., open-ended survey questions where the response data are analysed using descriptive statistics only).

We will include both published and unpublished studies and studies published in any language (See also section on Translation of languages other than English" below).]

Specify whether you will include data from mixed method studies.

Possible text:

[We will include mixed methods studies where it is possible to extract the data that were collected and analysed using qualitative methods.]

If you only plan to include studies that are directly associated with the studies included in any linked Cochrane intervention review(s), state this.

Possible text for reviews that only include qualitative studies directly associated with the studies included in the linked intervention review(s):

[We will only include studies directly associated with the studies included in the Cochrane intervention review of the effectiveness of [specify the intervention and cite the intervention review]. This will include qualitative studies conducted before the effectiveness studies as part of the intervention design process, qualitative studies (e.g., process evaluations) conducted alongside or within the effectiveness studies, and qualitative studies that were...}
conducted after completion of the effectiveness studies but utilising the same groups of participants (e.g., studies of people’s views of the intervention received).]

**Possible text for reviews that include qualitative studies regardless of whether they are directly associated with studies included in the linked review of effectiveness:**

[We will include studies regardless of whether they were conducted alongside studies of the effectiveness of [Specify the intervention. Cite the intervention review] or not.]

Specify whether you will use a 'quality threshold' for including studies in your review (i.e. after you have assessed the methodological limitations of the included studies, do you plan to exclude studies that are do not meet certain standards or levels?). If you plan to use a quality threshold, you need to justify this decision and describe how you will implement this threshold in your review.

**Possible text where you are using an additional quality threshold for included studies:**

[We will include all studies that are graded C or higher on the [specify the tool] for assessing the methodological limitations of qualitative studies [reference the tool], and are therefore assessed as not having important limitations (see 'Assessing the methodological limitations of included studies' for more details). This will ensure that we do not include studies with important methodological limitations that may compromise the credibility or trustworthiness of the review findings.]

**Possible text where you are not using an additional quality threshold for included studies:**

[We will not exclude studies based on our assessment of methodological limitations. We will use this information about methodological limitations to assess our confidence in the review findings.]

For guidance from the Cochrane Qualitative and Implementation Methods Group on types of studies to be included in a qualitative evidence synthesis, see Harris 2018 [1]

**Topic of interest**

Specify and describe the topic that the studies need to cover to be included in the review. This description would usually (but not always) include the types of:

- participants (e.g., adolescents aged 11 to 19 years)
- settings (e.g., primary health centres for adolescents and youth)
- health issues (e.g., sexual and reproductive health)
- interventions (e.g., provision of family planning information)

Remember to define key terms (e.g., what is meant by ‘adolescent’?)
Consider whether it would be helpful to justify your inclusion criteria. Also list exclusion criteria where you think this would be helpful. (E.g. “The review will focus on primary health centres as this is where most family planning information is provided to adolescents. We will not include studies of family planning provision in hospital settings”).

See examples of Methods / Criteria for considering studies for this review / Topics of interest in Appendix 3.

For guidance from the Cochrane Qualitative and Implementation Methods Group on specifying and describing the topic of interest in a qualitative evidence synthesis, see Harris 2018 [1].

Search methods for identification of studies

Even if you plan to search for studies on your own or have the support of an information specialist, you should seek advice from EPOC Information Specialists Paul Miller (paul.miller@ndph.ox.ac.uk) or Marit Johansen (Marit.Johansen@fhi.no) before you choose databases and develop and run searches.

For further guidance from the Cochrane Qualitative and Implementation Methods Group on search methods in a qualitative evidence synthesis see Booth 2011 [3] and Harris 2018 [1].

See also EPOC guidance on how to develop and report a search strategy (EPOC 2017 [4]).

Electronic searches

Possible text:

[The EPOC Information Specialist will develop the search strategies in consultation with the review authors.]

Approaches to searching sit on a spectrum from, on the one end, deciding in advance on the search strategy and databases to be searched and not deviating from this to, on the other end, planning an iterative search process. In an iterative search process, the search strategy may be adapted as the review progresses, or new strategies developed, with the aim of ensuring that all available themes are concepts related to the review question are identified.

You should discuss with the EPOC Information Specialist which kind of approach is best suited to your review question, your synthesis approach and the resources available for searching and screening. To date, most EPOC qualitative evidence syntheses have specified in advance their search strategy and the databases to be searched and at present it is unclear what the trade-offs are between this approach and a more iterative approach. Please also note that the EPOC Information Specialist will not be able to design more than one search for your review.

Refer to the selected approach for developing the search strategy here. Make sure you have described and explained the reasons for the selected approach.

Possible text:

[We will search PDQ-Evidence (pdq-evidence.org) / We will search Epistemonikos (www.epistemonikos.org) for related reviews in order to identify eligible studies for inclusion, as well as the following electronic databases:}
You may also want to include other, topic-related databases. Some examples are listed below. Discuss with an Information Specialist which databases you should search:
- Embase Ovid
- AIM (African Index Medicus)
- ProQuest Dissertations and Theses Global database
- LILACS (Latin American and Caribbean Health Sciences Information) database
- PAHO (Pan American Health Organization) database
- Science Citation Index and Social Sciences Citation Index
- Web of Science, Conference Proceedings Citation Index - Science
- WHOLIS (World Health Organization Library Information System).
- British Nursing Index and Archive, 1985 to May 2011, OvidSP
- Global Health, Ovid
- POPLINE K4Health
- PsycINFO
- AMED
- AJOL
- Anthropology Plus (EbscoHost)
- ProQuest Dissertations and Theses
- Web of Science Conference Proceedings Citation index, ISI Web of Knowledge
- World Health Organization Reproductive Health Library
- World Health Organization Global Health Library for WHO databases (Regional Indexes)

Your search strategy may include filters that specifically exclude certain types of studies. For instance, you may plan to use methodological filters, language filters, filters for country income setting, or publication date limitations. Refer to these filters/limitations here. Make sure you have described and explained the reasons for these limitations under "Criteria for considering studies for this review".

Possible text:

[We will develop search strategies for each database. We will not apply any limits on language or publication date. We will search all databases from [date] to the date of search [date]. We will include a methodological filter for qualitative studies. We will include a filter for low- and middle-income countries (EPOC 2017). See [Appendix #] for the MEDLINE search strategy, which we will adapt for other databases. We will provide appendices for all strategies used.]

Searching other resources

Whether you should search other resources depends on your review topic. Discuss this with your Information Specialist.

Possible text:

[We will review the reference lists of all the included studies and key references (i.e. relevant systematic reviews). We will conduct a cited reference search for all included studies in ISI Web of Science and Google Scholar.]
[We will check the bibliography of studies that were included in the intervention review in order to identify any qualitative studies that were associated with these studies.]

[We will contact authors of included studies to clarify published information and to seek unpublished data. We will contact researchers with expertise relevant to the review topic to request studies that might meet our inclusion criteria.]

**Grey literature**

The sources listed below are examples. Whether you should search the grey literature depends on your review topic. Discuss this with your Information Specialist.

Possible text:

[We will conduct a grey literature search in the following sources to identify studies not indexed in the databases listed above:

- [OpenGrey (www.opengrey.eu; to date of search)]
- [Grey Literature Report (New York Academy of Medicine; www.greylit.org; to date of search)]
- [Agency for Healthcare Research and Quality (AHRQ; www.ahrq.gov; to date of search)]
- [National Institute for Health and Clinical Excellence (NICE; www.nice.org.uk; to date of search).]
- [Eldis: http://www.eldis.org]

**Selection of studies**

Describe how the review authors will reach a decision about which studies to include, the process by which review authors (at least two) will be involved, whether they will work independently, and how they will deal with disagreements.

See the "Characteristics of excluded studies" section below for more information about which excluded studies you should list.

Possible text:

[Two] review authors [or more; initials here] will independently assess the titles and abstracts of the identified records to evaluate eligibility. We will retrieve the full text of all the papers identified as potentially relevant by one or both review authors. Two review authors will then assess these papers independently. We will resolve disagreements by discussion or, when required, by involving a third review author. Where appropriate, we will contact the study authors for further information.]
We will include a table listing studies that we excluded from our review at full text stage and the main reasons for exclusion.

Where the same study, using the same sample and methods, has been presented in different reports, we will collate these reports so that each study (rather than each report) is the unit of interest in our review.

We will include a PRISMA flow diagram to show our search results and the process of screening and selecting studies for inclusion.

Language translation

Include primary studies irrespective of their language of publication, unless exclusion is explicitly justified.

Your review team should include people who are fluent in those languages that are most relevant for your topic (for instance, we would expect a review team working on the zika virus to include Spanish- and Portuguese-speaking members). However, you may still have to assess abstracts and publications in other languages. Describe how the review team will assess and translate studies in languages they are not fluent in. A quick, automated translation using tools such as Google Translate of only parts of the study is likely to be sufficient when assessing whether a study should be included. However, if you do decide to include the study in your review, you should ideally translate the full paper as information about context may be included in different parts of the paper. Ensure that your translation is of a sufficient quality. Tools such as Google Translate may not be a sufficient resource for translation of full texts.

Possible text:

For titles and abstracts that are published in a language that none of the review team are fluent in (i.e. languages other than X, Y, Z), we will carry out an initial translation through open source software (Google Translate). If this translation indicates inclusion, or if the translation is inadequate to make a decision, we will retrieve the full text of the paper. We will then ask members of Cochrane networks or other networks that are fluent in that language to assist us in assessing the full text of the paper for inclusion. If this cannot be done for a paper in a particular language, the paper will be listed as ‘studies awaiting classification’, to ensure transparency in the review process.

If we decide to include studies published in languages that the review team are not fluent in, we will (specify if and how you will translate the whole paper (recommended), or justify if you will translate only specific sections of the paper. You may not be able to report this at the protocol stage, but this should be reported at the final review stage).

Sampling of studies

If you anticipate that you will identify a large amount of data and that a sampling approach is likely, describe this here.
What constitutes a “large amount of data” is a judgment, and depends on the number of studies that you identify as eligible and the amount of data within these studies. For instance, a few lengthy dissertations with rich data may be the limit for what you reasonably can synthesise, while a higher number of journal papers with less rich data may be a reasonable amount (In addition, some review topics may require in-depth, rich data that can only be found in longer papers or dissertations, while other review topics may be sufficiently covered in shorter papers).

Refer to studies that you identify as eligible as “eligible studies” or “studies that meet our inclusion criteria”. Refer to studies that you include in your review after purposive sampling as “sampled studies”.

Describe all of the eligible studies in your Characteristics of Included Studies table, regardless of whether they were sampled. But make it clear whether they were sampled or not.

See examples of Methods / Sampling of studies in Appendix 4

Possible text:

[Qualitative evidence synthesis aims for variation in concepts rather than an exhaustive sample, and large amounts of study data can impair the quality of the analysis. Once we have identified all studies that are eligible for inclusion, we will assess whether their number or data richness is likely to represent a problem for the analysis, and will consider selecting a sample of studies. (Then describe the sampling approach you will use).]

For further guidance, see the EPOC guidance on study sampling –

For guidance from the Cochrane Qualitative and Implementation Methods Group on sampling studies in a qualitative evidence synthesis, see Noyes 2017.

Data extraction

Describe the type of data that you plan to extract from each study. This usually includes:
- descriptive information about study objectives, participants, settings, health issues and interventions
- information about how the study was designed and conducted, providing you with the basis for your assessment of methodological limitations
- the study findings (for instance, qualitative themes/findings/supporting quotations, and conclusions)

Where your QES is planned alongside an intervention review, explore whether you can extract similar types of descriptive data. This will make it easier for you to evaluate later on whether the study populations, settings, and interventions are similar in the QES and the intervention review (See section on “Integrating the review findings with the Cochrane intervention review”).
The software ‘Covidence’ is available for free to all Cochrane review authors and can be used for screening and for some aspects of data extraction. Go to www.covidence.org where you can log in using your Cochrane ID.

Assessing the methodological limitations of included studies

Describe which approach you will use to assess methodological limitations, how many authors will be involved and the process by which they will be involved, including whether they will work independently and how you will deal with disagreements.
- If you have specified under “Criteria for considering studies for this review” that you will use a quality threshold as part of your study inclusion criteria, make sure that the methodological terms and concepts you describe in that section match what you say here.
- Remember that you will also be using your assessment of methodological limitations when you carry out your CERQual assessment of confidence in the findings. Make sure that the approach you choose to assess these limitations does not include items that overlap with the other CERQual components (relevance, coherence, data adequacy), leading you to “double-count” problems with the included studies.
- If members of your review team are also authors of any of the included studies, we suggest that they do not assess the methodological limitations of their own studies.

Possible text:

[Two] review authors [or more; initials here] will independently assess methodological limitations for each study using [name of tool, e.g. CASP tool] [Reference]. We will resolve disagreements by discussion or, when required, by involving a third review author [initials here]. We will assess methodological limitations according to the following domains [list domains included in chosen tool]:

- [domain]
- [domain]
- [domain]
- [domain]

We will report our assessments in a Methodological Limitations table.

For guidance from the Cochrane Qualitative and Implementation Methods Group on assessing methodological limitations in a QES, see Noyes 2017

Data management, analysis and synthesis

Describe and reference your proposed analytic approach, how you will conduct your analysis, and how you will synthesise your findings into a final output (line of argument, logic model, or...
The approach you choose at the protocol stage will be influenced by the study data and may therefore change. You should, however, describe the approach that you intend to use, or state that you will postpone your final decision about which approach to use until you have familiarised yourself with the study data.

If you have suggested in your background section that findings may differ for different groups, settings, or other factors, explain how you intend to address this, for instance through carrying out sub-group analyses.

If your background section includes a conceptual model (such as a framework, logic model, or hypothesis), state if you plan to use your review to update this model. If you have not already referred to an existing model, state if you are planning to develop one.

If you plan to use software for data management or analysis, mention and reference this here.

Once you have described your approach, read through it critically - would another person be able to follow what you did and follow the same approach? This is particularly important when preparing your report of the final review. Consider using a figure if you think this is helpful.

See example of Methods / Data management, analysis and synthesis in Appendix 5

For guidance from the Cochrane Qualitative and Implementation Methods Group on synthesis methods, see Noyes 2018 [5].

Assessing our confidence in the review findings

Cochrane expects its QES teams to use the GRADE-CERQual approach (www.cerqual.org) to assess confidence in each of the review findings.

Mandatory text:

[Two [or more] review authors [initials] will use the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach to assess our confidence in each finding (Lewin 2018b[6]). CERQual assesses confidence in the evidence, based on the following four key components.

1. Methodological limitations of included studies: the extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to an individual review finding.
2. Coherence of the review finding: an assessment of how clear and cogent the fit is between the data from the primary studies and a review finding that synthesises those data. By cogent, we mean well supported or compelling.
3. Adequacy of the data contributing to a review finding: an overall determination of the degree of richness and quantity of data supporting a review finding.
4. Relevance of the included studies to the review question: the extent to which the body of evidence from the primary studies supporting a review finding is applicable.
to the context (perspective or population, phenomenon of interest, setting) specified in the review question.

After assessing each of the four components, we will make a judgement about the overall confidence in the evidence supporting the review finding. We will judge confidence as high, moderate, low, or very low. The final assessment will be based on consensus among the review authors. All findings start as high confidence and will then be graded down if there are important concerns regarding any of the CERQual components.]

For guidance on assessing confidence in qualitative synthesis findings using GRADE-CERQual, see the Implementation Science series from 2018.

Summary of Qualitative Findings table(s) and Evidence Profile(s)

(Guidance regarding how to prepare Summary of Qualitative Findings tables and Evidence profiles is available further on in this document.)

Mandatory text:

[We will present summaries of the findings and our assessments of confidence in these findings in the Summary of Qualitative Findings table(s). We will present detailed descriptions of our confidence assessment in an Evidence Profile(s).]

Integrating the review findings with the Cochrane intervention review(s)

Most EPOC QES link to one or more Cochrane intervention reviews of effectiveness. Your approach when integrating your findings with an intervention review will be influenced by whether your review is carried out before, alongside or after the intervention review.

Describe the aim of this integration. For instance, do you plan to use your review findings to:
- understand the findings from an existing intervention review (why the intervention was or was not effective)
- explore how the interventions that were assessed in an existing intervention review might be better designed or implemented in the future
- suggest how future intervention reviews or future updates of intervention reviews could be designed (for instance, how the intervention should be defined, the outcomes that are important to stakeholders, suggestions for sub-group analyses)

Then describe how you plan to carry out this integration. Some options include developing a matrix (a table that compares your findings with the programme elements in the intervention review)[7]; analysing programme theory (for example based on mid-range theory arising from your review findings); developing a logic model or other conceptual framework; testing hypotheses; or carrying out a qualitative comparative analysis [8].
Your approach when integrating your findings with an intervention review will also be influenced by the findings of the intervention review, and your assessment of what is most useful and practical. For instance:

- Is the intervention review out-of-date? If so, it may be most useful to use your findings to inform future updates of the intervention review.
- Do the results of the intervention review show unexplained heterogeneity? If so, it may be useful to use your findings to suggest future sub-group analyses.
- Does the intervention review have a large number of studies? If so, it may be challenging to develop a matrix based on 100 or more trials as you will have to collect data on all of these trials as well as any related publications. You may therefore want to consider other options than a matrix approach.
- Are you integrating your review findings with several intervention reviews, and do these reviews represent a wide range of primary outcomes? If so, the development of a logic model may be complicated, and you may want to consider other options than a logic model.

The approach you choose at the protocol stage may change when you reach the analysis stage, depending on what studies you include. You should, however, describe the most likely options.

See examples of “Integrating the review findings with the Cochrane intervention review(s)” in Appendix 6.

For guidance from the Cochrane Qualitative and Implementation Methods Group on ways of integrating qualitative evidence syntheses with intervention reviews, see Harden, 2018 [8].

## Review author reflexivity

Reflexivity is concerned with the ongoing, mutually-shaping interaction between the researcher (in this case, the review team) and the research (in this case, the review) [9]. It can be useful to distinguish between prospective and retrospective reflexivity [9]:

- “Prospective reflexivity” refers to the influence that the review authors have on the review. It involves considering how your views and beliefs could influence the choices you make in terms of the scope of the review and your review methods; your interpretation of the data; and your interpretation of your own findings (for instance when developing implications for practice and implications for future research). This gives you an opportunity to reflect on and acknowledge this influence and to describe this influence to readers of the review. It may also lead you to decide that you need to modify your influence on the review, for instance by using a range of review authors with different perspectives.
- “Retrospective reflexivity”, on the other hand, refers to the influence that your review has on you as review authors, and gives you an opportunity to reflect on how the review process and findings can have influenced your prior positions.

We suggest that you:

1. include a reflexive statement in the Methods section of your protocol where you describe your review team’s prior positions; how they may influence the decisions you make at various points of the review; and, where relevant, any strategies you will use to address these issues.
2. include a reflexive statement in your Results section, summarising how you think your positions influenced the review; and whether your positions changed during the review.

See examples of “Review author reflexivity” in Appendix 7.
Results

Results of the search

Describe the number of studies that met your inclusion criteria, and when these were published. Provide a link to the flow chart.

If you used a sampling strategy, also describe the number of studies that were included in the review, but not sampled. Provide a link to an additional table that lists these studies (see below “Additional tables / Studies included but not sampled”).

Ensure that the numbers you report here are consistent with the numbers in your flow chart, your abstract and your plain language summary.

Possible text where you are not using a sampling strategy:

[We included [X#] studies in our review (Figure 1: Flow chart). These studies were published between [Date] and [Date]].

Possible text where you are using a sampling strategy:

[We found [X#] studies that met our inclusion criteria. We sampled [X#] of these studies for inclusion in the analysis (Figure 1: Flow chart). All of the sampled studies were published between [Date] and [Date]]. For an overview of the studies that were not sampled, see Table [X#].

Description of the studies

Describe the studies that you included in your review. If you used a sampling approach, describe the sampled studies only:

- Focus on study characteristics related to your inclusion criteria and any other characteristics that you have systematically gathered information about and that are important for the topic of your review. It may help the reader if you present this information under separate subheadings
- If you have translated any of the included studies, mention this here and reference which studies were translated
- Include references to each study

Methodological limitations of the studies
Give a brief (1 to 2 paragraphs), overall description of the methodological limitations of the studies included in your review.

Present individual assessments for each study in a Methodological Limitations table.

Include this table as an appendix to the review and provide a link in this section of the text.

See examples of “Results / Methodological limitations of the studies” in Appendix 8.

Confidence in the review findings

Give a brief (1 to 2 paragraphs), overall description of your assessments of confidence in the review findings.

(You will present more detailed descriptions of each assessment of confidence in the CERQual Summary of Qualitative Findings table/s (SoQF); and the CERQual Evidence Profiles. Guidance regarding how to prepare Summary of Qualitative Findings tables and Evidence profiles is available elsewhere in this document.)

See examples of “Results / Confidence in the review findings” in Appendix 9.

Review findings

This part of the Results section is where you describe the findings of your review in detail (as opposed to the summaries in your Summary of Qualitative Findings table).

We define a review finding as ‘an analytic output from a qualitative evidence synthesis that, based on data from primary studies, describes a phenomenon or an aspect of a phenomenon’ [10]. Within EPOC qualitative evidence syntheses, findings may range from more descriptive/aggregative to more interpretive and may be presented in many different ways.

When presenting your findings, use an approach that is congruent with your review approach. You may present:
- The themes that you have identified
- A framework, if you used one to guide your analysis or developed one as part of your analysis
- A logic model emerging from your findings [11, 12]
- A diagram or figure that shows how your findings link to one another
- A line of argument

Your review might present themes as well as a framework or logic model.

Whatever approach you use, make sure that you use a structure that readers can follow easily. You also need to adhere to the following principles:
- Aim for brevity: When reporting findings of more than 100 words in length, you should include a summary first, followed by a more detailed description of the finding. The summary should allow readers to quickly understand the main elements of your finding and can also be used in the Summary of Qualitative Findings table
- Ensure consistency: Make sure your findings are reasonably consistent across different sections of your review (for example, across the Results section, the Plain Language Summary and the Summary of Qualitative Findings table)
- Indicate level of confidence in your findings: Make sure each finding refers to the CERQual assessment of confidence for the finding. See Appendix 10 for options of how to do this. At present, our experience in applying CERQual to more interpretive or explanatory review findings is limited – see Additional file 2 in [13] for further guidance on this.
- Ensure traceability: Make sure the reader can trace each finding back to the primary studies that contributed to it. This ensures an ‘audit trail’ for the review findings and enhances transparency.

We encourage you to include extracts (for example, a participant quotation or primary author interpretation) from one or more of the contributing studies in your findings. These data extracts can be used to illustrate the theme or issue that the finding describes, provide support for the finding and give readers a sense of the voice of the primary study participants. When using data extracts, you should do the following [14]:
- Explain why the data extract has been included – for example, note that the extract shows how a particular group of people experienced the intervention
- Make sure that you are not using extracts from only one or two papers included in the review or one or two study participant groups. Rather you should try to use extracts from a range of papers and participant groups
- Keep the extracts succinct – they should be used to supplement your description of the findings and not replace this description
- Indicate which participant group / and or setting the extract was drawn from (e.g. ‘Adolescent male seeking care at primary care clinics’)
- Ensure that the reader can trace each extract back to the primary study from which it was drawn by including the study ID and page number

See examples of “Results / Review findings” in Appendix 10

For further guidance on what constitutes a review finding, see Lewin 2015 [10]. For further guidance on synthesising and reporting findings, see Noyes 2018 [5].

**Results of integrating the review findings with the Cochrane intervention review(s)**

(If your review does not link to an intervention review, you can ignore this section.)

As described in the Methods section, most EPOC QES link to one or more Cochrane intervention reviews of effectiveness. Present the results of your linked analysis here.

See examples of "Integrating the review findings with a Cochrane intervention review" in Appendix 6.

**Review author reflexivity**

As described in the Methods section, we encourage reflexivity at different stages of the review. Use this section to include a reflexive statement, summarising how you think your positions influenced the review; and whether your positions changed during the review. The review team needs to consider these issues carefully. It would be unusual for the prior views and beliefs of the review author team to have no influence on a review, or for the team to only find exactly what they expected to find – indeed, this might suggest that reflexive accounting has not been undertaken with enough rigour.
See examples of “Review author reflexivity” in Appendix 7.

Discussion

Summary of the main findings

Your main findings should already be summarised in your abstract and Plain Language Summary. It should therefore be sufficient to refer to this text. E.g. "For a summary of the main findings, see the Plain Language Summary."

Comparison with other reviews and implications for the field

Discuss the following (as appropriate):
- What we know now that we didn’t know before
- How your review advances or contributes to existing theories, hypotheses, debates, etc.
- How your review informs or supplements existing intervention review(s). If you have linked your review to an intervention review, briefly summarise the main results of this linkage
- How your review informs or supplements other relevant reviews (Cochrane and non-Cochrane). Consider to what extent the findings presented in this review confirm or refute the findings of other reviews conducted in similar areas. For example, this may consider other non-Cochrane qualitative evidence syntheses or mixed-methods reviews

Overall completeness and applicability of the evidence

Briefly describe the overall body of evidence included in your review and reflect on any gaps in this evidence. It may be helpful to look at the “Criteria for considering studies for this review” section of the methods (e.g. what did we look for) and the “Description of studies” section of the results (e.g. what did we find) to consider gaps in the types of studies, perspectives, or contexts that were included in the review. Consider how these gaps may influence the interpretation of your results. Also consider whether there are points made in the “Implications for future research” section that you want to elaborate on here.

Also briefly describe any limitations in the body of evidence that you did find. Specifically, assess whether your confidence in the findings were often downgraded for the same reasons, including lack of data, missing perspectives, or methodological limitations.

If you have used sampling methods in your synthesis, consider how your sampling approach may have influenced your review findings. For example, reflect on each of the sampling criteria and how they may have influenced your findings and confidence assessments.

See examples of “Discussion / Overall completeness and applicability of the evidence” in Appendix 11.

Limitations of the review
Discuss possible limitations of your review, for instance:
- The possibility that the most relevant studies were not identified (e.g. the possibility of dissemination bias, potential weaknesses with your search strategy)
- Whether the methods you used could have influenced the results in a particular way (e.g. because of your decisions regarding study selection, data collection, sampling or data analysis)

Authors' conclusions

Implications for practice

Implications for practice are meant as prompts or suggestions to people responsible for designing or delivering the intervention in question or otherwise affected by the topic.

Review all of your findings. This includes the output emerging from integrating your findings with the intervention review findings. Assess the extent to which they represent an issue that might affect practice. For instance, think through whether your findings point to:
- aspects of a healthcare service that stakeholders may like or want
- aspects that they may find unacceptable or difficult to use
- particular problems that implementers may need to overcome, and any solutions

Think through how this information could be useful to people designing or delivering health services:
- Present prompts or suggestions, not recommendations
- Consider basing these suggestions on findings that have high or moderate confidence assessments. Be more cautious with low or very low confidence findings
- Keep in mind that Cochrane reviews are intended for a broad international audience - avoid making suggestions that are intended for specific settings

Once you have prepared this section, read through it critically. Would you be able to print this and hand it to a person responsible for designing or delivering the intervention?

See examples of “Authors' conclusions / Implications for practice” in Appendix 12.

See also Glenton et al 2019 for a discussion of how findings from qualitative evidence syntheses can be prepared in the context of guidelines [15]

Implications for future research

Describe any important gaps in the research that your review has identified as well as limitations of the existing research. To do this:
- Assess the extent to which you found studies that covered the scope of your review. For instance, did you find studies that covered the topic, populations, settings or time points that you were interested in or were there gaps?
- Assess whether your confidence in the findings was often downgraded for the same reasons. For instance, was there often a lack of data, were certain perspectives often missing; were studies mostly conducted in very specific settings or with particular population groups, or were they often poorly designed or conducted?
If your review aimed to test or create models, frameworks or hypotheses, are you missing certain types of data that could have helped you test or build these models?

Then consider and describe what the implications of these issues are for future researchers.

Once you have prepared this section, read through it critically. Does it contain the main messages that you would want to hand to a researcher or research council?

See examples of “Authors’ conclusions / Implications for future research” in Appendix 13.

Acknowledgements

List any people or organizations that you wish to acknowledge. This would include any previous authors of the Cochrane protocol/review; or any people or organisations that have previously given support to the review. It might also include the contributions of the editorial team, information specialist, and peer reviewers. Remember to obtain permission from the persons acknowledged.

For protocols supported by the EPOC editorial base in Oxford, the following acknowledgment must be included in the protocol:

[National Institute for Health Research (NIHR), via Cochrane Infrastructure funding to the Effective Practice and Organisation of Care (EPOC) Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS), or the Department of Health.]

Additional text for satellite in Melbourne:

[The Australasian Satellite of the Cochrane EPOC Group is funded by the Australian Government National Health and Medical Research Council (NHMRC); it is a partnership between the Cochrane EPOC Group and Monash University.]

For protocols supported by the EPOC satellite in Oslo, the following acknowledgment must be included in the protocol:

[The Norwegian Satellite of the Effective Practice and Organisation of Care (EPOC) Group receives funding from the Norwegian Agency for Development Co-operation (Norad), via the Norwegian Institute of Public Health to support review authors in the production of their reviews.]

Contributions of authors

Describe the contributions of the current review authors to the protocol or review. Identify one author as the guarantor of the review. All authors should discuss and agree on their
respective descriptions of contribution before the review is submitted for publication. When the
review is updated, this section should be checked and revised as necessary to ensure that it is
accurate and up to date.

Declarations of interest

Report any conflict of interest that might be perceived by others as being capable of influencing
your judgments (see Cochrane’s conflict of interest policy (https://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-
considerations/conflicts-interest-and-cochrane-reviews)).

Each review author should, in the protocol and in the review, declare their interests in relation
to the following:
- Financial conflicts of interest, and how these have been addressed
- Whether you have been involved in a study included in the review and how you have dealt
  with this

You will also be asked to complete a separate declaration of interest statement required by all
Cochrane review authors. The information you provide in this statement should be consistent
with the information you provide here.

In addition:
- Other potential interests to declare include personal, political, academic and other
  issues
that may influence judgements made in a review (concerning, for example, the inclusion or
exclusion of studies, assessments of the validity of included studies or the interpretation of
results). You are likely to have provided much of this information earlier, when discussing
review author reflexivity. We therefore suggest that you refer to your sections on reflexivity
when referring to these types of non-financial issues.

Possible text:

- [Author initials] declared no financial conflicts of interest. He was a co-author on [X#]
of the included papers and was therefore excluded from the screening process of
these papers.
- [Author initials] declared no financial conflicts of interest
- “[Author initials] declared the following financial conflicts of interest: [Describe and
discuss how this was dealt with].

A number of non-financial issues, including personal, political and academic factors, could
have influenced the review authors’ input when conducting this review. The review authors
have discussed this further in the sections on reflexivity in the Methods and Results
sections.”

Differences between protocol and review

It is sometimes necessary to use different methods from those described in the original protocol.
This could be because you could not apply the methods in the protocol (for example, due to
insufficient data or a lack of information required to implement the methods); or because you
changed your methods because you identified a preferable alternative.
Some changes are acceptable, but must be fully described in this section. Explain any changes from the protocol to the review, state when they were made and provide the rationale for the changes.

Published notes

Published notes will appear in the review in the CDSR. They may include editorial notes and comments from the CRG, for example where issues highlighted by editors or referees are believed worthy of publication alongside the review. The author or source of these comments should be specified (e.g. from an editor or a referee).

Published notes must be completed for all withdrawn protocols and reviews, giving the reason for withdrawal. Only basic citation information, sources of support and published notes are published for withdrawn protocols and reviews.

Characteristics of studies

Characteristics of included studies

When you upload a reference into Revman as an included study, Revman automatically creates a ‘Characteristic of Included Studies’ table for that study.

Characteristics of included studies tables can be very useful for people wanting to know more about each of the included studies. Consider what information end users such as guideline developers, policy makers or others might need or find relevant. For instance, people may want more information about country (including income level), setting (e.g. urban or rural; level of care), study aim; participant information; where there was an intervention, how this was delivered; study designs, including methods of data collection and analysis. Ideally, you should be able to find most of this information in your data extraction sheets.

- These tables can have maximum of 8 rows. You can add your own headings within these tables (but they will be the same for all Characteristics of included studies tables within a review)
- If you have used a sampling strategy, remember to include all studies that meet your eligibility criteria in these tables. Make it clear in the table’s top row whether each study was sampled or not sampled.

Characteristics of excluded studies

When you upload a reference into Revman as an excluded study, Revman automatically creates a ‘Characteristic of Excluded Studies’ table for that study.

You are likely to screen a large number of studies during the process of your review. It is not practical or helpful to list all of the studies that you excluded as this number is likely to be very large for most reviews. In your characteristics of excluded studies table, we suggest that you
focus on studies that you excluded at the full-text stage, and that readers might plausibly expect to see among the included studies, for example:

- Studies that are likely to be thought relevant by some readers, but that did not meet all of your inclusion criteria
- Studies that you excluded because you had a quality threshold
- Studies included in another review that addresses a similar or related question
- Studies where you needed to obtain missing information from the primary study authors to determine that the study did not meet your inclusion criteria

The reasons you list for excluding studies should link directly to the inclusion / exclusion criteria for your synthesis, and might include:

- Study design: e.g. “the study did not use both qualitative methods of data collection and qualitative methods of analysis”
- Topic of interest: i.e. the study did not include relevant participants, settings, interventions or health issues

### Characteristics of studies awaiting classification

The ‘Characteristics of studies awaiting classification’ table has the same structure as the ‘Characteristics of included studies’ table. It should be used for two categories of study:

- Studies for which an inclusion or exclusion decision cannot be made because sufficient information is not currently available. These could include, for instance, studies in languages that cannot be understood by the review team or its wider networks; or studies only published as abstracts, where the study authors cannot be contacted for the full study report, and you are unable in other ways to obtain the full text. You should make all reasonable attempts to obtain information on a study before you add this to the table of ‘Studies awaiting classification’. However, your review should not be delayed excessively waiting for this information.
- Studies that have been identified as eligible for inclusion in the review but are awaiting an update to the review to be fully assessed and potentially incorporated into the review. This could include, for example, studies identified during the final phases of the review, where the review author team and EPOC agree that attempting to include these will substantially delay publication of the review. Studies that are likely to have important impacts on the overall review findings should ideally not be listed in this table but rather incorporated into the review. If you are unsure how to proceed, please discuss this with the Managing Editor or your Contact Editor.

### Characteristics of ongoing studies

List here any potentially relevant studies that are underway but not yet published.

### Summary of Qualitative Findings tables
CERQual Summary of Qualitative Findings (SoQF) tables and Evidence Profiles must be included in all EPOC qualitative evidence syntheses:

- **The SoQF** includes a summary of each review finding, the overall CERQual assessment of how much confidence can be placed in each finding, an explanation of each overall CERQual assessment and references to the studies contributing to each review finding. The SoQF table facilitates the use of your review findings in decision processes. In the final, published version of your synthesis, the SoQF will automatically appear near the front of the review – i.e., this is one of the parts of the review that readers are likely to look at first. **The SoQF** includes a summary of each review finding, the overall CERQual assessment of how much confidence can be placed in each finding, an explanation of each overall CERQual assessment and references to the studies contributing to each review finding. The SoQF table facilitates the use of your review findings in decision processes. (In some cases, you may choose to create several SoQF tables. Discuss with EPOC’s editorial team where in the review it makes most sense to present these).

- **The Evidence Profile** includes the same information as the SoQF. In addition, it includes your judgments for each CERQual component underlying the overall CERQual assessment. The Evidence Profiles should be included as appendices.

The reader should be able to easily move between the full review findings in the Results section, their summarised versions in the SoQF table, any logic models or other representations of the findings, and the full explanation of their CERQual assessment in the Evidence Profile. To help them to do this, we recommend that you give each review finding a unique identifier and use this identifier consistently throughout your synthesis, including in any relevant tables or figures.

When preparing your SoQF table, write a summary finding for any review finding that is more than approximately 100 words long. Shorter findings can be presented unedited.

You may want to split your findings into several SoQF tables, for example by broad categories or themes.

For further guidance from the GRADE-CERQual group on developing Summary of Qualitative Findings tables and Evidence Profiles, see Lewin 2018 [13]. Templates for creating these tables are available on request from your EPOC managing editor.

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Additional tables

References

**References to studies included in this review**

**References to studies excluded from this review**
References to studies awaiting assessment

Additional references

Other published versions of this review

Figures

PRISMA flow diagram
Your review should include a PRISMA flow diagram to show your search results and the process of screening and selecting studies for inclusion in your synthesis. The flow diagram should present:
- The number of unique records identified by the searches
- The number of records excluded after preliminary screening (e.g. of titles and abstracts)
- The number of records retrieved in full text
- The number of records or studies excluded after assessment of the full text, with brief reasons
- The number of studies meeting eligibility criteria for the review (and thus contributing to the findings)
- When a sampling approach is used, the number of studies sampled

If you are using Covidence for screening, a PRISMA flow diagram can be generated automatically within Covidence and then included in your Revman review.

Further guidance is available here http://www.prisma-statement.org/PRISMAStatement/FlowDiagram.aspx

Sources of support

Internal sources

External sources

Appendices

1 MEDLINE search strategy

2 GRADE-CERQual evidence profiles

Before submitting your protocol for editorial approval:
- Complete a validation check in RevMan (File menu > Reports > Validation report), and make corrections where possible. Check there are no Errors and review the Warnings and address as needed. Note that protocols cannot be published with validation errors.
- Complete a spell check in RevMan (Tools menu > Check spelling).
- Proof read the Cochrane Protocol carefully in accordance with the Cochrane Style Manual.
- See to it that all the authors listed have had a chance to read and approve the final version and take full responsibility for the accuracy of the contents, and that the Contribution of authors section is completed.
- Check that the authors are listed in the correct order, and with correct affiliations. Note: authors can at any time log into Archie and update their own contact details; if you have problems accessing Archie contact your Managing Editor (ME).
- Complete the 'Date next stage expected' (which refers to when the full review will be submitted for publication), which ideally should be no longer than 12 months from the publication of the protocol – this can be adjusted in the protocol nearer to the publication date.
Example 1. Title and Objectives

Example 1 (adapted from Odendaal et al. 2015 [16])

Title: Healthcare workers’ perceptions and experiences on using mHealth technologies to deliver primary healthcare services: a qualitative evidence synthesis

Objectives:
- To synthesise qualitative research evidence on healthcare workers’ perceptions and experiences regarding their use of mHealth technologies to provide and support the delivery of primary healthcare services
- To identify hypotheses, for subsequent consideration and assessment in effectiveness reviews, about why some technologies are more effective than others

Example 2 (adapted from Karimi-Shahaniarini et al. 2019 [17])

Title: Barriers and facilitators to the implementation of doctor-nurse substitution strategies in primary care: a qualitative evidence synthesis

Objectives:
- To identify factors influencing the implementation of interventions to substitute doctors with nurses in primary care
- To explore how our review findings related to, and helped to explain, the findings of the Cochrane intervention review of the effectiveness of substituting doctors with nurses
- To identify hypotheses for subgroup analyses for future updates of the Cochrane intervention review

Example 3 (adapted from Cooper et al. 2019 [18])

Title: Factors that influence parents' and informal caregivers' acceptance of routine childhood vaccination: a qualitative evidence synthesis

Objectives:
- To synthesise qualitative studies exploring: parents’ and informal caregivers’ views, experiences, or decision-making regarding routine childhood vaccination; or the factors influencing acceptance of routine childhood vaccination arising from parents’ and informal caregivers’ accounts
- To develop a conceptual understanding of what and how different factors influence parental acceptance of routine childhood vaccination
- To explore how the findings of this review can enhance our understanding of the related intervention reviews
Example 2. Background /Why is it important to do this review?

Example of a description of how the review differs from other reviews on similar topics, including a section of the table (from Cooper 2019 et al. [18])

Various reviews have focused on the demand-side of childhood vaccination (see Table 1 for a summary of these reviews). Many of these reviews are out of date, limited in geographical scope (i.e. include studies only from HICs), focused on specific vaccines or broader populations than children, and are not ‘systematic’ in their approach. In addition, few existing reviews include qualitative studies, and amongst those that do, in most cases the results were synthesised quantitatively or in a narrative summary. Carrying out an up-to-date qualitative review that systematically explores the factors influencing vaccination acceptance from the perspective of parents and informal caregivers, across a variety of regions and vaccines, will provide a single point of access for synthesised qualitative evidence on vaccination acceptance to inform immunisation decision-making and strategies.

**Table 1. Summary of related published reviews focused on the demand-side of childhood vaccination (beliefs, attitudes, perceptions, decision-making, acceptance, hesitancy, confidence/trust)**

<table>
<thead>
<tr>
<th>Author/ date</th>
<th>Title</th>
<th>Focus</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mills 2005</td>
<td>Systematic review of qualitative studies exploring parental beliefs and attitudes toward childhood vaccination identifies common barriers to vaccination</td>
<td>Focuses on parental beliefs and attitudes toward childhood vaccination and associated barriers to paediatric immunisations. Only includes studies from HICs.</td>
<td>Qualitative</td>
</tr>
<tr>
<td>Karafyllakis 2017</td>
<td>The benefit of the doubt or doubts over benefits? A systematic literature review of perceived risks of vaccines in European populations</td>
<td>Focuses on perceptions of the benefits and risks of vaccines. Only includes studies from Europe and considers vaccines for all age groups.</td>
<td>Mixed methods, includes both quantitative and qualitative studies</td>
</tr>
<tr>
<td>Carlsen 2016</td>
<td>The swine flu vaccine, public attitudes, and researcher interpretations: a systematic review of qualitative research</td>
<td>Focuses on attitudes towards a vaccine given in response to a pandemic and also considers all age groups.</td>
<td>Qualitative</td>
</tr>
<tr>
<td>Yaqub 2014</td>
<td>Attitudes to vaccination: a critical review</td>
<td>Focuses on vaccination attitudes among the public and healthcare professionals. Only includes studies from Europe and considers vaccines for all age groups.</td>
<td>Mixed methods, includes both quantitative and qualitative studies</td>
</tr>
<tr>
<td>Etc......</td>
<td>Etc......</td>
<td>Etc......</td>
<td>Etc......</td>
</tr>
</tbody>
</table>
Example 3. Methods / Criteria for considering studies for this review / Topics of interest

Example of a description of the review’s topic of interest (adapted from Glenton et al. 2013 [19])

**Topic of interest**

We will include studies where the primary focus is the experiences and attitudes of stakeholders towards lay health worker programmes.

**Types of participants**

We will include studies that focus on the experiences and attitudes of stakeholders about lay health worker programmes in any country. Participants can include lay health workers, patients and their families, policy makers, programme managers, other health workers, or any others involved in or affected by the programmes.

**Types of interventions**

We will include studies of programmes that are delivered in a primary or community healthcare setting; that intend to improve maternal or child health; and that have used any type of lay health worker, including community health workers, village health workers, birth attendants, peer counsellors, nutrition workers and home visitors.

For the purpose of this review, we define a lay health worker as any health worker who:

- performs functions related to healthcare delivery,
- is trained in some way in the context of the intervention, but
- has received no formal professional or paraprofessional certificate or tertiary education degree (Lewin 2005).

We define maternal and child health care as follows:

- child health: health care aimed at improving the health of children aged less than five years
- maternal health: health care aimed at improving reproductive health, ensuring safe motherhood, or directed at women in their role as carers for children aged less than five years (Lewin 2010)

We will include studies where services are delivered in a hospital setting if they also include a primary or community health care component.
Example 4. Methods / Sampling of studies

**Example 1:** In this example from a protocol, the review authors describe their planned sampling strategy (adapted from Odendaal et al. 2015 [16])

As qualitative evidence synthesis aims for variation in concepts rather than an exhaustive sample, and because large numbers of studies can impair the quality of the analysis, we will select a sample of studies if large number of studies are eligible for inclusion. To allow for the broadest possible variation within the included studies, we will use maximum variation purposive sampling to select from the eligible studies. Key areas of variation that we may consider will include the study methods, the cadre of healthcare worker, the technology used and the purpose of its use, and the geographical setting. Once these variables have been determined, we will create a sampling frame and will map all eligible studies onto the frame. We will then review the studies in each frame, including their number and level of detail, and reach a decision regarding how many studies in each cell we will include in the review.

**Example 2:** In this example from a review, the review authors describe the sampling strategy they used (from Ames al 2017 [20])

Large numbers of studies can threaten the quality of the analysis in qualitative evidence syntheses. In addition, syntheses of qualitative studies aim for greater variation in concepts as opposed to an exhaustive sample that avoids risk of bias. Therefore, since seventy-nine studies were eligible for inclusion, we decided to sample from the eligible studies. As in primary qualitative research (Silverman 2013), we utilised purposive sampling to select from the eligible studies. We used a type of purposive sampling approach called maximum variation sampling with the aim of achieving the broadest possible variation within the included studies (Suri 2011). We decided on three key sampling criteria that would enable us to capture rich data from all settings that would best answer our review objectives. These became our three-step sampling frame. First, we sampled all studies from low- and middle-income country (LMIC) settings, as most studies took place in high-income country (HIC) settings. Second, we created a simple 1 to 5 scale for assessing the richness of data, with 1 corresponding to very few or thin qualitative data (for example, from an open-ended survey question); 3 being an average qualitative article in a peer-reviewed health services journal; and 5 being very rich data (for example, from an ethnographic study). We sampled all articles that scored a 3 or higher for data richness. Finally, we examined the remaining studies after applying the first two elements and sampled studies that most closely matched our review objectives. After applying our sampling frame, we selected 38 studies for data extraction. The findings from these studies are the basis for the review findings reported here. For a list of included but not sampled studies see Table 2.
Example 5. Methods / Data management, Analysis and Synthesis

**Example 1:** In their report of the final review, the review authors describe how they analysed and synthesised the data. As their approach was relatively complex, they also included a flowchart to describe the process (adapted from Downe et al. 2019, forthcoming).

**Data management, analysis, and synthesis**

A flowchart illustrating the stages of the analytic process is shown in Figure 2.

Following the principles of meta-ethnography (Noblit 1998), we undertook data extraction and analysis simultaneously for each included study in turn. Meta-ethnography uses an approach based on the grounded theory method of constant comparative analysis, where the analysis is built up study by study. The process requires the researcher to be open to the emergence of new themes, and to ensure that unexpected phenomena can be captured and examined, by subjecting the initial assumptions about what is in the data to both confirmation (‘reciprocal analysis’) and disconfirmation (‘refutational analysis’) against each study in turn. This ensures that the product of the review is continually refined as each study is included. However, as this was not a primary grounded theory study, but a qualitative evidence synthesis (QES) (Booth 2016), we did not start from a position of no knowledge. We were explicitly looking for factors influencing both uptake of ANC by women and provision of good-quality care by staff. We also had some prior beliefs about behavioural change theories. We therefore used framework analysis (Gale 2013) as a supplement to meta-ethnography. We used the findings to test the explanatory power of our original theoretically-informed logic model of the theory of planned behaviour (Azjen 1991), given in Figure 1 (the ‘framework’), and where necessary to amend it.

Starting with the earliest published paper, we read each included study in detail, and extracted the relevant verbatim text, along with the codes/themes/theories/metaphors used by the study authors, initially marking them as likely barriers, facilitators, or potentially both barriers and facilitators. We mapped the data from each subsequent paper against this coding structure. Where new data from subsequent papers could not be explained by this emerging taxonomy, we added new categories. Over time, conceptual similarities between some codes in the framework became evident, and these were merged. This resulted in the generation of findings that explained the data at a descriptive level and that were presented in a ‘Summary of qualitative findings’ table (SoQF), along with the relevant CERQual gradings (see below for details of this process).

We then undertook a higher-level thematic analysis, to generate transferable explanatory thematic domains that could be predictive of uptake of ANC. These were translated into two lines of argument syntheses: one to explain the service user data, and one to explain the healthcare provider data. This allowed for theoretical explanations of what might underpin perceived factors influencing women's intended and actual use of local antenatal care, or
providers’ capacity to provide good-quality care, in terms of social, behavioural, and control beliefs, and the contextual factors that interact with these factors to prevent or enable an intention for care uptake or quality care provision.

We then tested the explanatory power of the findings in three logic models (full uptake of routine ANC; partial uptake of routine ANC; no uptake of routine ANC), built on our original hypothesis that the theory of planned behaviour would be a good theoretical model for use or non-use of ANC. The logic models incorporated the key elements of the theory of planned behaviour, namely: 'What do people believe in this context (behavioural beliefs)?'; 'What is normal in this context' (normative beliefs)? and 'How much control do I have over what happens here' (control beliefs)?; the attitudes and perceptions predicted by these beliefs; the intended behaviour that could result; and the actual experiences, all linked to a feedback loop (see figures 4 to 6).

All authors contributed to the final findings, domain structure, lines of argument, and development of the logical models. We made final decisions by consensus, throughout the extraction and analysis process.

**Example 2:** In their report of the final review, the review authors describe how they analysed and synthesised the data. They also added a table to explain their approach (based on Glenton et al. 2013 [21]
**Data synthesis**

We analysed and synthesised qualitative evidence using the framework thematic synthesis approach ([Booth 2012](#)). Thematic synthesis is one of several approaches recommended by the Cochrane Qualitative Review Methods Group ([Noyes 2011](#)) and may be particularly appropriate where evidence is likely to offer only thin description and is likely to be largely descriptive as opposed to highly theorised or conceptual. In the framework approach, the thematic synthesis is guided by an a priori theoretical framework. Framework synthesis has five stages:

- **Familiarisation**: immersion in the included studies with the aims and objectives of the review.
- **Identifying a thematic framework**: Rather than develop our own a priori framework after reading the included studies, we opted to use the SURE framework described above ([The SURE Collaboration 2011](#)) as an a priori framework of themes and categories. We used this framework to guide our analysis for two reasons. Firstly, it provided us with a comprehensive list of possible factors that could influence intervention implementation. Secondly, the current synthesis is one of four syntheses of qualitative research that have informed the World Health Organization's OPTIMIZEMNH Guidelines ([WHO 2012](#)). The use of the SURE Framework across these syntheses made it possible to carry out an overarching analysis of factors influencing optimisation among different health worker groups.
- **Indexing**: Four review authors independently read and re-read the selected studies and applied the SURE framework, moving between the data and the themes covered by the framework, but also searching for additional themes until all the studies had been reviewed. The definitions and boundaries of each of the emerging themes were discussed among the authors. The SURE framework was then revised in line with the ideas and categories that emerged.
- **Charting**: We then developed the thematic synthesis further by rearranging data according to the appropriate part of the thematic framework to which they related, and formed charts. Our charts contained distilled summaries of evidence from different stakeholder perspectives and involved a high level of abstraction and synthesis. At the charting and mapping stage we used a cross-case analysis approach ([Miles 1994](#)) to explore whether there were differences between high, middle and low income countries in the barriers and facilitators we identified, and whether studies of trained traditional birth attendants differed from studies of other types of lay health workers. Any differences that were identified were indicated in the text of the results.
- **Mapping and interpretation**: Using the charts we then defined concepts, mapped the range and nature of phenomena, created typologies and found associations between themes as a way of developing explanations for the findings. The process of mapping and interpretation was influenced by the original review objectives as well as by the themes that have emerged from the data.

See [Table 3](#) for an overview of the data synthesis process.
Table 3. Data synthesis approach

<table>
<thead>
<tr>
<th>Main elements of the data synthesis</th>
<th>Purpose</th>
<th>Tools and frameworks used</th>
</tr>
</thead>
</table>
| Identifying a theoretical model of barriers and facilitators to health systems intervention implementation | - To inform the synthesis of the included studies  
- To enable an overarching analysis across several syntheses of qualitative data within a broader, but relevant theme | The SURE framework |
| Developing a synthesis of the included studies | - To identify and list the barriers and facilitators to implementation reported  
- To explore the relationships between reported barriers and facilitators | Framework thematic synthesis |
| Exploring differences across contexts | - To explore possible differences in barriers and facilitators between high, middle and low income countries and between studies of trained traditional birth attendants and other type of lay health workers | Cross case analysis |
| Assessing the certainty of the findings | - To assess the quality of the individual studies  
- To assess the certainty of the evidence for drawing conclusions about barriers and facilitators to lay health worker programme implementation | Elements of the CASP tool CERQual tool |
| Integrating the findings of the synthesis with the Cochrane review of LHW programme effectiveness | - To suggest how specific chains of activities and events identified in the synthesis of qualitative studies could lead to the outcomes described in the review of effectiveness | Logic model approach |
Example 6. Integrating the review findings with the Cochrane intervention review(s)

**Example 1:** In this example from a protocol, the review authors describe their plans for a logic model approach (adapted from Xyrichis et al. 2017 [22])

“Findings will be used to complement and contextualise a subset of the conclusions of the Flodgren 2016 Cochrane intervention review on interactive telemedicine by looking at CCT in particular. The refined CFIR framework developed through this review will be used to explore the appropriateness of linking the review findings with conclusions and outcomes drawn by Flodgren 2016. In particular, using CFIR as a starting point, we will deploy a logic model approach (see Glenton 2013) to develop a logical flow of theoretical connections/hypotheses through which implementation factors could affect CCT effectiveness and outcomes. At least two review authors will work together to develop this. This logic model could allow identification of specific combinations of factors that could lead to the results described in the Flodgren 2016 review. This could help explain variability in effectiveness of CCT, identify factors that need to be considered in future trials and inform the development of future CCT interventions and evaluations.”

**Example 2:** In this example from a protocol, the review authors describe their plans for a matrix model approach (adapted from Ames et al. 2017 [23])

“As part of data synthesis, we will explore how we can integrate the findings from our review with those of related Cochrane intervention reviews (Kaufman 2013; Saeterdal 2014; Oyo-Ita 2016). We will explore whether the interventions studied in these reviews contained the features of vaccination communication that parents and caregivers identify as important in this synthesis. To do so, we will use a matrix model approach similar to one used by Candy 2011. To create the matrix we will undertake the following steps: First, we will go through each of the review findings and identify features of communication interventions that parents and informal caregivers perceive as positive or important. Secondly, we will create a table, listing these features, and will then assess whether the interventions in each study included in the intervention reviews reflected these features.”

Examples from final reviews:

- For examples where the review authors used a logic model approach specifically to link their review findings to the findings of an intervention review, see Glenton et al. 2013 [21] and Bohren et al. 2019 [24].
- For examples where the review authors used a matrix model approach specifically to link their review findings to the findings of an intervention review [7], see Ames et al. 2017 [20]; Munabi-Babigumira et al. 2017 [25]; Bohren et al. 2019 [24]; and Karimi-Shahanjarini et al. 2019 [17].
Example 7. Review author reflexivity

**Example 1:** In this example from a protocol, the review authors give a “prospective” reflexive statement in their methods section (adapted from Xyrichis et al. 2017 [22])

We will maintain a reflexive stance throughout the stages of the review process, from study selection to data synthesis. Progress will be discussed regularly among the team and decisions made explored critically. As a review team, we all have clinical backgrounds: in nursing (AX, NM, SB, JP), medicine (MT) and midwifery (JS). In addition, three review authors have received advanced training in implementation science (NM, SB, JS) and are well versed in relevant theory. NM, AX, MT and JS have been part of a project examining the implementation of CCT at a UK site, but SB and JP are independent of that research. Based on our collective and individual experiences (as clinicians, academics and researchers), we anticipate the findings of our review to reveal a combination of organisational, professional and individual factors influencing the implementation of CCT. We will as a team remain mindful of our presuppositions and support each other to minimise the risk of these skewing our analysis or the interpretation of our findings. As the lead author, AX will keep a reflexive journal throughout the review process in which to document and reflect on progress and decisions made.

**Example 2:** In this example from a review, the review authors give a “prospective” reflexive statement in their methods section and a “retrospective” reflexive statement in their results section (adapted from Odendaal et al. 2019 (forthcoming)):

*From Methods section:*

**“Researchers’ reflexivity**

The author team represents diverse professional backgrounds with a range of research experiences and expertise that could have biased their input in conducting this review. All of them are experienced qualitative researchers. Except for one author [KD], everybody has had previous experience in conducting primary mHealth research in the context of PHC services in low-income settings in South Africa, and have published on this (Coetze 2017; Leon 2012; Neupane 2014; Watkins 2018). FG has also experience in conducting telemedicine research in high-income contexts (Griffiths 2017). Our experiences in conducting effectiveness studies and process evaluations of mobile health programmes, included positive, negative, and mixed results. This provided us with a good platform for engaging and understanding the complexities and nuances of qualitative research of mobile health interventions.

During the screening, both during abstracts / titles and full texts, the team constantly referred to each other to resolve conflicts, which was an effective counter measure to the bias they respectively may have had. In many instances a team decision was called upon,
which further countered our biases. As is standard practice within qualitative research, the
two review authors [KD, WO] who did the data coding, extraction, and synthesising, and
wrote the findings, constantly discussed with each other how their own background and
position, may have affected their analysis and writing of the findings. WO realised that at
times his research experiences resonated strongly with some of the included studies, to the
extent that he may give these data more importance than what was due. Inversely, he was
aware that he may be more dismissive towards data which contradicts his experiences. KD
questioned the weight he attributed to certain data, ensuring that all data were equally
represented in the final set of findings. To minimise their biases, they repetitively questioned
each other’s interpretation of the data and how it fitted with the existing findings. They also
called upon other members of the author team to verify that the findings were true
reflections of the supporting data. The same process of constant discussion and being aware
of their personal biases, applied during the appraisal of confidence in the findings which was
done by JAW, KD, and WO. A final measure to counter possible biases in the review findings,
was consultations with the contact editor of this review. She had a close reading of each
finding and its supporting data, and on many occasions pointed to a mismatch between the
supporting data and finding. In other instances, she questioned our interpretation of the
data, which led to a refinement of our analysis and writing of the findings.”

*From Results section:*

“**Review author reflexivity**

We described our initial positioning earlier (see Review author reflexivity above). Our views
remained the same during the review, though our continued team discussions led to more
nuanced definitions regarding mobile health, whether it is used to deliver or support
healthcare services, and primary health care. During writing the discussion and the
implications for practice and recommendations, we were particularly aware of the risk of
overlooking data that refuted our own experiences that mobile health intervention
outcomes are usually a mix of having positive and no effects.”
Example 8. Results / Methodological limitations of the studies

**Example 1.** A brief, overall description of the methodological limitations of the studies included in the review (adapted from Ames et al. forthcoming)

In some of the included studies, there was poor reporting of the participant voice. For example, many studies included limited first order constructs or data extracts and these were often not labelled with an identifier of the participant. We also found poor reporting of researcher reflexivity across many of the studies. All studies gave some description, even if very brief, of the context, participants, sampling, methods and analysis. Details of the assessments of methodological limitations for individual studies can be found in Table 1.

**Example 2.** The methodological limitations of each individual study, presented in a table (adapted from Karimi-Shahanshanjari et al. 2019 [17])

“**Table 2. Methodological limitations of included studies based on modified Critical Appraisal Skills Program (CASP) tool**”

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Was the context described?</th>
<th>Was the sampling strategy appropriate and described?</th>
<th>Was the data collection strategy appropriate and described?</th>
<th>Was the data analysis appropriate and described?</th>
<th>Were the findings supported by evidence?</th>
<th>Is there evidence of researcher reflexivity?</th>
<th>Have ethical issues been taken into consideration?</th>
<th>Overall assessment of methodological limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott 2013</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor to moderate</td>
</tr>
<tr>
<td>Albers-Heitner 2011</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor</td>
</tr>
<tr>
<td>Bailey 2006</td>
<td>Yes</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor</td>
</tr>
<tr>
<td>Basaleem 2009</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor to moderate</td>
</tr>
<tr>
<td>Basaleem 2011</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor to moderate</td>
</tr>
<tr>
<td>Bennett 2013</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Minor</td>
</tr>
</tbody>
</table>
Example 9. Results / Confidence in the review findings

Example of a brief, overall description of an assessment of confidence in the review findings (adapted from Munabi-Babigumira et al. 2017 [25])

Out of 51 findings, we graded two as high confidence, 16 as moderate confidence, and the remaining findings as low or very low confidence using the CERQual approach (see Summary of findings for the main comparison). Our explanation of the CERQual assessment for each review finding is shown in the Evidence Profiles (see Table 2 to 8).
Example 10. Results / Review findings

Example 1: This example shows how themes emerging from a synthesis can be grouped for presentation, and how the review authors used a short introductory paragraph to explain to the reader how the results section is organised (adapted from Bohren et al. 2019 [24])

Themes and findings identified in the synthesis

From the thematic synthesis, we developed 10 overarching themes, which we organised under three domains using the following structure:

- Factors affecting implementation
- Companion roles
- Experiences of companionship

We explore each review finding under these themes and domains in depth in the following sections. At the end of the results section, we bring together the results of this qualitative evidence synthesis and the related Cochrane systematic review of interventions.

Example 2: This example also shows the use of a short text to introduce the review findings. Here the review authors provide an overview of the confidence in the evidence identified and the domains into which the findings were organised. The reader is provided with links to the relevant Summary of Qualitative Findings tables (adapted from Downe et al. 2019 [26])

Findings of the review

Our primary analysis generated 31 findings relating to women’s experiences and views (17 moderate to high confidence), and 21 relating to maternity care providers (14 moderate to high confidence). Three thematic domains encompassed all of the findings across both groups. These were: Socio-cultural context; Design and provision; and What matters to women and staff. The third domain was sub-divided into two conceptual areas; personalised supportive care, and information and safety. Summary of findings table 1, Summary of findings table 2, Summary of findings table 3, and Summary of findings table 4 list all the findings in detail, with their CERQual ratings.

Eleven findings were present for both service users and providers (see Table). They indicate that both service users and providers were conscious that antenatal care was provided in a social context, in which the local social norms could operate either to enhance or resist uptake. Resource issues are also noted, as well as the need for well-organised services that offer safety, appropriate information, and positive interpersonal relationships, notably through continuity of care/carer. A summary of the findings, organised according to the three domains, is discussed below.

Example 3: This example shows the use of a short summary for each review finding, followed by a more detailed explanation of the finding. The GRADE-CERQual assessment of
confidence in the evidence is clearly indicated as are the primary studies contributing to each finding. Each finding is numbered so that it is easy to move from the finding text to the details of the GRADE-CERQual assessment in the Summary of Qualitative Findings table (adapted from Bohren et al. 2019 [24])

Findings

In the sections below, we report each review finding. For each finding, we start with a short, overall summary and then present the detailed results. The CERQual evidence profile table supporting the assessment of confidence in that finding is available in an Appendix.

Factors affecting implementation

Awareness-raising among healthcare providers and women

Finding 1: The benefits of labour companionship may not be recognised by providers, women, or their partners (moderate confidence; Abushaikha 2013; Afulani 2018; Alexander 2014; Brüggemann 2014; Coley 2016; Pafs 2016). Some providers viewed companionship as a low priority in their setting because of the lack of clear benefit to the woman (Brüggemann 2014). Some women and male partners believed that the partner was unable to do anything to help the woman during labour (Abushaikha 2013; Alexander 2014). When potential tasks or responsibilities for the labour companion were identified (e.g. holding her hand, rubbing her back, encouraging her), it was perceived that this was the role of the clinical staff or that the woman could persevere without this support (Abushaikha 2013; Alexander 2014; Coley 2016).

Finding 2: Labour companionship was sometimes viewed as non-essential or less important compared to other aspects of care, and therefore deprioritised due to limited resources to spend on 'expendables' (low confidence; Akhavan 2012b; Brüggemann 2014; Lagendyk 2005; Premberg 2011). For example, some health facilities required labour companions to wear hospital-issued clothing, but clothing for labour companions may not always be available (Brüggemann 2014). Where labour companions were allowed, health facilities faced difficulties to provide adequate material resources, such as bed or chair space (Brüggemann 2014; Premberg 2011).

Example 4: This example shows how findings can be introduced in a short paragraph. It also shows the use of a short summary for each review finding, followed by a more detailed explanation of the finding. The GRADE-CERQual assessment of confidence in the evidence is clearly indicated as are the primary studies contributing to each finding. Each finding is numbered so that it is easy to move from the finding text to the details of the GRADE-CERQual assessment in the Summary of Qualitative Findings table (adapted from Ames et al. 2019, forthcoming)
Findings and categories identified in the data

From our synthesis, we developed a set of individual findings, and then organised these findings into six overarching categories related to (1) the general acceptability of and preferences around digital health interventions; (2) the varying degrees of access to network services, phones and messages; (3) communication delivery and format preferences; (4) communication content preferences; (5) privacy and confidentiality regarding personal health information; and (6) perceptions of intervention impact.

General acceptability of and preferences around digital targeted client communication

Summary of qualitative findings table for findings 1-4 (see Table)

Finding 2: In discussing the pros and cons of digital targeted client communication, compared to in-person meetings with a health care provider, some participants perceived interacting with a health care provider as preferable, warmer and something to which they were accustomed. Participants also felt that people could receive a faster response using digital communication and that the messages were more convenient and less judgemental. However, some participants liked having direct access to both health care providers and digital targeted client communication. (very low confidence)

A few studies (Naughton 2013, Smillie 2014, Nachega 2016, Calderón 2017, Sloan 2017) described participants’ preferences for digital health interventions compared to in-person visits to health care providers. However, some participants liked having direct access to both health care providers and to digital health interventions as each played a different role (Naughton 2013, Smillie 2014, Sloan 2017). Some participants felt that the digital health interventions were more convenient, reliable, flexible, faster and provided more frequent support (Naughton 2013, Smillie 2014, Nachega 2016, Sloan 2017). Participants who were pregnant and trying to quit smoking often preferred the SMS interventions as they felt health care providers judged them and made them feel uncomfortable (Sloan 2017). Participants in some studies liked the digital health interventions but still felt it was important to have access to in-person visits with health care providers or speaking with someone when needed (Naughton 2013, Smillie 2014, Calderón 2017).

Example 5: This example shows the use of a figure to illustrate the conceptual framework emerging from the review findings. The figure is described in a short paragraph (adapted from Munabi-Babigumira et al. 2017 [25])

Review findings

In this section we have reported the categories identified in the synthesis and the findings from the synthesis that belong in each category. As described above, our analysis was guided by Graham’s conceptual framework for skilled birth attendance at delivery (Graham 2001). We did not make major changes to the categories in Graham’s framework. However, while
Graham grouped these categories as either "structure", "inputs", "outputs", or "outcomes", we chose not to group the categories in this way. This was because we experienced overlap of some categories (e.g. referral processes and mechanisms could be categorised as inputs or outputs), and because grouping the categories in this way downplayed the interrelationships between the categories. We instead chose to group the categories according to the level at which they operate; namely, the macro-environment or the meso- or microenvironment. We did not use two of Graham’s categories. We did not find any studies that reported data on the “financing” category. We did not consider the second category, “technical quality of care”, to be a separate category, as it is relevant to all other categories as an immediate outcome of the process of providing care. The Figure below represents our adaptation of Graham’s conceptual framework for skilled birth attendance at delivery (Graham 2001), and reflects the findings from this synthesis as well as the categories for which we had no data. Factors tied to the macro-, meso-, and microenvironment may influence available quality of care and health worker performance and motivation; maternal experiences of care; as well as health facility functionality or capability. Some of the maternal experiences of care included satisfaction and participation in decision-making. These factors are discussed further in the section below.

Figure 3. Factors that influence the delivery of intrapartum and postpartum care by skilled birth attendants.
Example 6: This example shows how the review findings were used to develop a ‘line of argument’ synthesis which, in turn, led to hypotheses about the mechanisms of effect of the intervention. The example also shows how the review authors used a theoretical model of behaviour change selected at the start of the review process to develop theoretical logic models to explain uptake of the health service of interest. These logic models were illustrated in a series of figures (adapted from Downe et al. 2019 [26])

The line of argument and hypothesised facilitative mechanisms of effect

The line of argument emerging from the analysis of the data relating to pregnant women was as follows: For women, initial or continued use of antenatal care depends on a perception that doing so will be a positive experience. This is a result of the provision of good-quality local services that are not dependent on the payment of informal fees and that include continuity of care that is authentically personalised, kind, caring, supportive, culturally sensitive, flexible, and respectful of women’s need for privacy, and that allow staff to take the time needed to provide relevant support, information and clinical safety for the woman and the baby, as and when they need it. Women’s perceptions of the value of antenatal care depend on their general beliefs about pregnancy as a healthy or a risky state, and on their reaction to being pregnant, as well as on local socio-cultural norms relating to the advantages or otherwise of antenatal care for healthy pregnancies, and for those with complications. Whether they continue to use antenatal care or not depends on their experience of antenatal care design and provision when they access it for the first time.

For healthcare providers, the line of argument was similar, but with a different emphasis. The capacity of healthcare providers to deliver the kind of high-quality, relationship-based, locally accessible antenatal care that is likely to facilitate access by women depends on the provision of sufficient resources and staffing, as well as the time to provide flexible, personalised, private appointments that are not overloaded with organisational tasks. Such provision also depends on organisational norms and values that overtly value kind, caring staff who make effective, culturally-appropriate links with local communities, who respect women’s belief that pregnancy is usually a normal life event, but who can recognise and respond to complications when they arise. Healthcare providers also require sufficient training and education to do their job well, as well as an adequate salary, so that they do not need to demand extra informal funds from women and families to supplement their income, or to fund essential supplies.

The three facilitative mechanisms of effect arising from these lines of argument were:

- Treating pregnancy as a fundamentally healthy state while monitoring for complications
- Ensuring authentically accessible and affordable access to skilled care provision and required resources throughout the antenatal episode
- Creating the conditions to enable positive staff attitudes and behaviours.
**Testing the findings with 'theory of planned behaviour' logic models**

To test the utility of the findings for future use in practice, we developed theoretical logic models based on these findings, to explain no uptake, partial uptake, and full uptake of antenatal care services by women, in the context of our a priori behavioural theory (the theory of planned behaviour). Each input box was populated by statements based directly on the findings. The three models derived from this process are given in the figures below [one of these figures is included here as an example]. Text in regular font relates to pregnant women, and text in bold font relates to providers of antenatal care. Superscript text refers to the finding numbering in the Summary of Qualitative Findings tables. For this theoretical exercise, we only used findings of moderate or high confidence. If the logic models and findings are to be used to understand mechanisms of effect for implementation projects in specific settings, they may need to be re-rated for those specific settings. For example, we rated some findings as low or very low confidence on the grounds of coherence or relevance, because all the data only came from particular settings, or because there was incoherence between different types of settings, or both. Both relevance and coherence may be increased for very specific settings. For example, the low-confidence rating for ‘Only visit antenatal care to get an antenatal care card’ is due to lack of relevance and coherence for all settings, since all five included studies were from Africa. For African settings, however, there is high coherence and relevance for this finding.
Figure: Logic model of full antenatal care uptake, using findings relating to beliefs (superscript letters and numbers refer to the Summary of qualitative findings table)

**Behavioural beliefs**
- Health providers should understand and respect local health beliefs, including that pregnancy is a normal healthy state for most, while recognizing and dealing with problems if they occur \( (M.1, 2, 3) \)
- My family/local community think that attending ANC is useful \( (N.1, 2, 4) \)
- Benefits of regular ANC visits outweigh costs (time/money) \( (W.1, 3, 12) \)
- Flexible appointments, continuity of care, warm and caring staff, and ease of access to the clinic are important \( (F.1, 2, 4, 6, 7, 13) \)
- Pregnant women should try to find knowledge and information \( (W.1, 2, 4, 7, 13) \)
- Staff should work with local community beliefs and practices \( (P.1, 4) \)
- Staff should be kind, caring, flexible, and warm-centred \( (P.1, 2, 3, 6) \)
- Staff should feel valued, well-trained, and adequately resourced \( (P.1, 3, 4, 6) \)

**Normative beliefs**
- Pregnancy is a normal healthy event \( (N.1, 2) \)
- People trust/depend on support ANC attendance \( (N.1, 4, 6) \)
- Local women are always involved in the way ANC is organised/ran and it is usual for peer support to be available \( (W.1, 3, 10) \)
- ANC should be easy to get to/attend. Female providers be present/have plenty of space/have kind staff who spend time with you/ listen to you/people shouldn’t have to pay extra/walk long times should be short \( (O.1, 2, 3, 4, 5, 10, 11, 22, 26) \)
- ANC provides good quality information and medical safety for women, and when they need it \( (W.1, 3, 10) \)
- Local community members/TVAs are good advocates \( (P.1, 4) \)
- Local beliefs (eg pregnancy is a healthy state) can be helpful \( (P.1, 4, 6) \)
- ANC visits should be flexible and long enough, providing tests, treatments, and support with privacy, continuity of care, kindness, and respect \( (P.1, 4, 6, 10, 16, 18) \)
- Providing good antenatal care depends on there being enough well-paid, staff, with good resources, training, management support and working conditions, and low staff turnover \( (P.1, 4, 6) \)

**Attitude to behaviour**
- I trust local health providers: they understand and respect our local health beliefs, and they treat pregnancy as a normal state, as well as finding and sorting out problems if they occur \( (M.1, 2, 3) \)
- I’m sure my family will approve of me going to ANC \( (M.1, 2, 3) \)
- The time and costs of regular ANC attendance are worth spending \( (W.1, 3, 10) \)
- Flexible appointments and kind, caring staff mean that it is easy and enjoyable to attend ANC \( (W.1, 2, 4, 6, 7, 13) \)
- ANCs provide me with the information I need, and when I need it \( (W.1, 2, 4, 6, 7, 13) \)
- Locally, it is a pleasure to work with the community \( (W.1, 2, 4, 6, 7, 13) \)
- We enjoy working in a kind, caring, and woman-centred atmosphere \( (W.1, 2, 4, 6, 7, 13) \)
- Our managers support us to do a good job, and we feel part of a valued team \( (W.1, 2, 4, 6, 7, 13) \)

**Control beliefs**
- Pregnant women should have control over their choices and finances \( (W.1, 2, 4, 6) \)
- Women should be able to negotiate timing, privacy, and length of clinic visits, the cadre and gender of health providers, the timing and nature of the information they receive, and the attitude of staff \( (W.1, 2, 3, 13, 16, 17, 22, 26) \)
- It is important for women to have some control over the design and running of ANC, and to be able to set up/access effective peer support \( (W.1, 2, 3, 13, 16, 17, 22, 26) \)
- Women should be able to accept or decline ANC medical costs and treatments \( (P.1, 2, 3, 10, 11) \)
- Staff should have the freedom to work with local communities/TVAs \( (P.1, 4) \)
- Staff should be able to negotiate the condition of the clinic, the design/delivery patterns/philosophy of ANC provision, and staffing levels, resources, and training provision \( (P.1, 2, 3, 10, 11) \)
- Staff can call disrespectful colleagues to account \( (P.1, 2, 3, 10, 11) \)

**Perceived norms**
- I trust my baby will be healthy if we attend ANC \( (M.1, 2, 3) \)
- People like me go to clinic and are fine, and people I depend on think ANC is worth the time/experience in terms of information, support, tests, and treatments \( (W.1, 2, 3, 4, 6, 7, 13) \)
- Our local clinic is close by. We can be involved in it and it is set up and run, and we know what to expect. Appointments are flexible, we don’t have to wait, and the visits are long enough. Staff are respectful, they remember us, and we have a female provider and peer support \( (W.1, 2, 3, 4, 6, 7, 13) \)
- We work with local community members/TVAs and peers \( (W.1, 2, 3, 4, 6, 7, 13) \)
- We offer flexible visit time, privacy, and enough time \( (W.1, 2, 3, 4, 6, 7, 13) \)
- We provide continuity of care, and we monitor women’s views and experiences and act on any issues that arise \( (W.1, 2, 3, 4, 6, 7, 13) \)
- Staff are here to be paid and trained. We always have enough people, training, and resources to do a good job, and staff usually stay for many years \( (W.1, 2, 3, 4, 6, 7, 13) \)

**Perceived control**
- I have the resources/transportation to get to ANC easily \( (M.1, 2, 3) \)
- I can negotiate the timing, nature, and content of my ANC visits, and the gender and cadre of my care provider, and I expect respectful competent care provision from them \( (M.1, 2, 3) \)
- I can contribute to the design and running of ANC, and I can choose to be a peer supporter \( (M.1, 2, 3) \)
- I can call to ask for a change in the treatment I receive \( (M.1, 2, 3) \)
- I can prevent disrespect and interruptions during ANC visits \( (M.1, 2, 3) \)
- I can work with local communities/TVAs \( (M.1, 2, 3) \)
- I am involved in decisions about resources and the clinic environment, and staff training, and about the design, delivery, and philosophy of local ANC care \( (M.1, 2, 3) \)
- Colleagues will support me if I challenge disrespectful staff attitudes \( (M.1, 2, 3) \)

**Behaviour**
Full engagement with ANC
- Provision of woman-centred care
- Respectful ANC provision that prioritizes the health and wellbeing of pregnant women and their unborn babies, and in which staff support each other to do this.

**INTENTION**
I will attend ANC regularly
- I will go above and beyond what is required of me, as I really enjoy my job and I want the best for women and babies

**BEHAVIOUR**
Full engagement with ANC
- Provision of woman-centred care
- Respectful ANC provision that prioritizes the health and wellbeing of pregnant women and their unborn babies, and in which staff support each other to do this.

**+/− Actual control (positive feedback loop)**
- High desire for control over ANC attendance reinforced over time: ANC attendance continues to be normalised by the individual and the local community
- High control over resources, space, workload, work patterns/high control over flexible, collegial and innovative working over time – women-centred care seen as central to job satisfaction. Respectful, kind, competent care is normalised.
Example 11. Example of Discussion / Overall completeness and applicability of the evidence

Example 1. Adapted from Bohren et al. [24]

A majority of the included studies included the perspectives of women or male partners. Only four included studies focused on the perspectives of healthcare providers (midwives and nurses only). Given that the introduction of companionship requires a restructuring of service provision to include the presence of an additional support person, the inclusion of more provider perspectives could have added important information about factors that may influence sustainable and successful implementation. Additionally, understanding the perspectives of healthcare administrators or policy-makers would add an important dimension of higher-level decision-making and contexts that may influence the implementability of the programme.

Seventeen of the 47 studies included in this qualitative synthesis were conducted in low- or middle-income countries, and of these, only three studies were conducted attached to an intervention or evaluation (Campero 1998; Kabakian-Khasholian 2015; Khresheh 2010). As researchers implement labour companionship programmes or trials in low- and middle-income country settings, it may be useful to conduct qualitative research to assess the feasibility, acceptability, values, preferences and experiences of populations in those settings (including women, partners, and healthcare providers).

Lastly, almost all of the qualitative studies used interview or focus group methods, which rely on the self-report of the individual participants. It may also be useful to use other qualitative methods of data collection, such as participant observation of the labour ward or longer-term ethnographic research with providers, in order to better understand actual practices and changes over time.
Example 12. Examples of “Authors’ conclusions / Implications for practice”

Example 1. In this review on intrapartum and postnatal care by skilled birth attendants, the review authors defined the review’s main audience as health system or programme managers. The review authors went through the findings they had assessed as being of moderate or high confidence and then developed a set of questions that could act as prompts for this audience (Based on Munabi-Babigumira et al 2017 [25])

Implications for practice

Below are a set of questions that may help health system or programme managers when implementing or planning for obstetric health services. These questions were drawn from the findings for which we had high or moderate confidence.

1. At your facility, what is the staffing situation in relation to the workload, for instance for providing 24-hour care? Where task-shifting strategies or increasing health workers' scope of practice are suggested as options to improve the staffing situation, how will this impact on health workers' workload and on the overall quality of care? Would recruiting more health workers be a better option than moving people around?
2. For facilities that deliver emergency obstetric care, are specialists available when needed? If no specialists are available and tasks have been transferred to non-specialist health workers, have these health workers been provided with training, supervision, and linkages to other centres, for instance for referral or support by telephone?
3. How do health workers at your facility perceive their working and living conditions? Could these be the underlying reasons for absenteeism, decreased morale, poor retention, and recruitment?
4. For managers at district or higher programme levels, are sufficient funds available for the recruitment of health workers? Is the recruitment process responsive to the local needs with minimal bureaucracy? Recruitment arrangements need to take into account facility arrangements, e.g. 24-hour opening.
5. Do health workers' salaries reflect their training, experience, actual workload and responsibilities, and the need for reasonable living conditions?
6. What are health workers’ pre- and/or in-service training needs? Can they manage complicated pregnancies, alternative delivery positions (practice), among others? When planning for in-service training, consider how training is organised, e.g. scheduling of classes, availability of tutors, selection of trainees according to health facility, or individual training needs, etc.
7. What are the reasons why women may be reluctant to accept referral to higher levels of care? When exploring how to improve the referral process, health system managers may
need to consider these issues in order to make the referral system more responsive to women’s needs, e.g. their need of financial support or the need to manage their fears.

8. Does your health facility have a regular and reliable supply of electricity and water all year round? Consider how intersectoral collaboration could help resolve problems with this supply.

9. Does your health facility have the necessary equipment such as cord clamps, complete delivery kits, as well as sterilising equipment required for good-quality maternity care?

10. If your health facility occasionally runs out of the supplies necessary to provide maternity care, what are the underlying reasons for stock-outs and how can these problems be addressed?

11. Is the physical environment at your health facility optimally organised to facilitate health workers’ delivery of good-quality care? For instance, what is the location of the postnatal ward in relation to the labour ward for health workers who need to monitor mothers in labour as well as mothers in postpartum and their newborns? Consider collaborating with health workers to organise the available space in view of the number of mothers served.
Example 13. Examples of “Authors’ conclusions / Implications for future research”

**Example 1.** Adapted from Bohren et al 2019 [24]

**Implications for future research**

Implications for research have been developed based on the overview of studies included in this review and our CERQual assessments of the review findings.

Better reporting is needed in qualitative studies, particularly around sampling methods, researcher reflexivity, and data analysis. Future qualitative studies on this topic, and more broadly, should transparently report their research methods, including reflection on the researchers’ roles and how they may influence the conduct and results of the study.

More research about implementing labour companionship models in different contexts, particularly in low- and middle-income countries, is needed to understand how different models may improve outcomes for women and babies. Understanding how different cadres of healthcare providers, such as midwives, nurses, obstetricians, and healthcare managers, perceive labour companionship and factors that may affect implementation would provide valuable evidence to scale-up implementation. Implementation research or trials conducted on labour companionship should include a qualitative component to evaluate the process and context of implementation, in order to better interpret results and share findings across contexts. This aligns with the “WHO Standards for improving quality of maternal and newborn care in health facilities,” where every woman “is offered the option to experience labour and childbirth with the companion of her choice” (World Health Organization 2016).

Further research is needed to understand the most appropriate ways to engage lay companions during antenatal care, including the content of training programs. Similarly, more research is needed to understand how labour wards in lower-resource settings may be physically designed to allow labour companionship, while maintaining privacy and confidentiality for women.


4. How to report the search process in EPOC protocols, reviews and updates. EPOC Resources for authors [epoc.cochrane.org/epoc-resources-review-authors]  


