Selecting Studies and Assessing Methodological Limitations

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With Acknowledgements to Dr Heather Ames Co-Author of Cochrane QIMG Handbook Chapter on Sampling (2022)
Conflict of Interest Statement

We have no actual or potential conflicts of interest in relation to this presentation.

Andrew Booth & Jane Noyes
Overview of whole program

1-2 pm 28th October, 2021
Introduction to qualitative research and qualitative evidence
Jane Noyes, Professor in Health and Social Services Research

15th November, 2021
Question formulation and searching for qualitative evidence
Dr Andrew Booth, Reader in Evidence Based Information Practice

13th December, 2021, 14:00 UTC [Check the time in your timezone]
Selecting studies and assessing methodological limitations
Jane Noyes, Professor in Health and Social Services Research

20th January, 2022
Making Sense of Framework and Best Fit Framework Synthesis
Dr Andrew Booth, Reader in Evidence Based Information Practice & Director of Information, University of Sheffield, UK.

Thematic Synthesis – Thursday 24th February 2022 at 09:00 am - Angela Harden and James Thomas

Meta-ethnography – Thursday 17th March 2022 at 14:00 pm - Kate Flemming

GRADE CERQual – Monday 25th April 2022 at 14:00 pm - Megan Wainwright

Integrating qualitative and quantitative syntheses – Monday 16th May 2022 at 14:00 pm - Angela Harden and James Thomas
Study selection begins once you’ve completed database searches and [supplementary] searches. Using the inclusion and exclusion criteria, at least two reviewers select articles that merit critical appraisal from all the identified citations (usually stored in an electronic library such as EndNote). Ensuring the transparency and reproducibility of this part of the process is vital.

(Porritt et al, 2014)
Ruling In: “to identify those articles that help to answer the questions being addressed by the review” (CRD Guidance)

Ruling Out: Speedily and efficiently eliminating (interesting?) papers that do not address the review questions.
More complex in QESs compared to reviews of trials…decisions on whether to include all studies or to select a sample of studies depend on…general and review specific criteria that Noyes and colleagues (2019) outline in detail.

The number of qualitative studies selected needs to be consistent with a **manageable synthesis**, and the contexts of the included studies should enable integration with the trials in the effectiveness analysis.

The **guiding principle is transparency** in the reporting of all decisions and their rationale.
Processes used to identify studies for QES... similar to those of other systematic reviews. Studies should be screened and selected based on the **predetermined inclusion and exclusion criteria highlighted in the protocol**.

Careful consideration of these criteria and their relevance to the study objectives will help to focus the scope of the review and limit the number of papers selected to a manageable amount.

Reviewers should make every effort to ensure that the search strategy optimises the opportunity to locate the maximum number of studies from the full range of contexts and participants for which/whom [findings are] intended to apply

(Downe et al, 2020)
Unlike the techniques used to identify quantitative studies for systematic reviews or meta-analyses, it is **not essential to identify and include every available relevant study.**

The purpose of QES is **interpretive rather than predictive.** Important, transferable concepts (or themes) are unlikely to change substantially in subsequent studies once they are consistently found in a body of papers from a **wide range of participants and contexts.**

The **number of studies** included in any specific QES will therefore depend on the **variety of concepts identified, the range of sociocultural contexts of interest…, and the degree of agreement between studies on the emerging concepts and themes.**

(Downe et al, 2020)
Typical Study Selection Process

Step 1: Apply Inclusion/Exclusion Criteria to Titles and Abstracts

Step 2: Eliminate Studies That Clearly Meet One or More Exclusion Criteria (RULING OUT)

Step 3: Retrieve the Full Text of the Remaining Studies

<Sampling Strategy>

Step 4: Evaluate Remaining Studies for Inclusion and Exclusion (RULING IN)

Step 5: Include Studies That Meet All Inclusion Criteria and No Exclusion Criteria

Step 6: Exclude Studies From QES With Reasons

Step 7: Accept Studies for QES
Theoretical or Purposeful Sampling

Source: Ames H, Booth A, Noyes J Chapter 5 - Study selection and sampling in “Cochrane QES Handbook” (forthcoming 2022)
Formulate Selection Criteria

Setting: Universal?, Criterion-Based (e.g. LMICs)? Selective? [Sampling?]

Perspective: Single?, Multiple?, All? [Sampling?]

Interest, Phenomenon of: Single Popn/Intn/Exp?, Multiple Popn/Intn/Exp [Sampling?]

Comparison: Subgroups?

Questions such as:

- Is the article published in the **time period** covered in the protocol?
- Is the article published in a **language** specified in the inclusion criteria?
- Does the **population studied** meet the inclusion criteria (such as adults or children or both)?
- Does the study look at the **phenomena** stated in the review question?
- Has the **study design** been reported? Is it relevant to the review question?
- Does the study include **qualitative data** in the form of findings (from author; participants or both)?
FAQ: How Many Sifters?

Double Sift – All Stages
Double Sift – Either Ti, Ab or Full Text
Single Sift – Plus Random Sample (10% or 20%)
Double Sift during Pilot, Single once Inter-Rater
Reliability is Acceptable
Text Mining as a Second Sifter
Covidence – Screening Tool used by Cochrane
Multimorbidity, defined as the presence of 2 or more chronic conditions, is common among older adults with cardiovascular disease. These individuals are at increased risk for poor health outcomes and account for a large proportion of health care utilization. Clinicians are challenged by the heterogeneity of this population, the complexity of the treatment regimen, limited high-quality evidence, and fragmented health care systems. Each treatment recommended by a clinical practice guideline for a single cardiovascular disease might be rational, but the combination of all evidence-based recommendations can be impractical or even harmful to individuals with multimorbidity. These challenges can be overcome with a patient-centred approach that incorporates the individual's preferences, relevant evidence, the overall and condition-specific prognosis, clinical feasibility of treatments, and interactions with other treatments and coexisting chronic conditions. The ultimate goal is to maximize benefits and minimize harms by optimizing adherence to the most essential treatments, while acknowledges trade-offs between treatments for different health conditions. It might be necessary to discontinue therapies that are not essential or

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<tr>
<td>1</td>
<td>Population Setting</td>
<td>Condition</td>
<td>Interest</td>
<td>Population Setting</td>
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<td>INCLUDE - INCLUDE - UK</td>
<td>INCLUDE - MULTI INCLUDE - MEDICATION MANAGEMENT INCLUDE</td>
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<td>3</td>
<td>QUERIY - 6 INCLUDE - RELEVANT HIGH INCOME</td>
<td>QUERIY - +1 CON QUERIY - OTHER MEDICATION ISSUE INCLUDE</td>
<td>EXCLUDE - EXCLUDE - LMICS</td>
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<td>6</td>
<td>EXCLUDE - EXCLUDE - NONRELEVANT POPULATION (i.e. Indigenous Populations)</td>
<td>EXCLUDE - NOT CHRONIC</td>
<td>EXCLUDE - NOT CHRONIC</td>
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<td>12</td>
<td>RandGW</td>
<td>Kim DHiri</td>
<td>Patient-Centred Care of Older Adults Canadian Journal of Aging</td>
<td>Multimorbidity, defined as the presence of two or more chronic conditions</td>
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<td>13</td>
<td>RandGW</td>
<td>ClarkeSmith</td>
<td>Educational and Interpersonal Factors in Cochrane Database of Systematic Reviews</td>
<td>Population Setting</td>
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<td>15</td>
<td>Serra</td>
<td>RAM Study on the Efficacy of Surgery vs. the International Wound Wound Management: The Mainstay of Treatment of Chronic Venous Ulcers</td>
<td>Population Setting</td>
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<td>17</td>
<td>Doucette</td>
<td>Initial Development of the System's Research In Socio-Economics</td>
<td>Population Setting</td>
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<td>18</td>
<td>Ballester</td>
<td>Counteracting Learning Non-Use in Journal of Alzheimer's Disease</td>
<td>Population Setting</td>
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<td>19</td>
<td>Emanuel</td>
<td>Cardiovascular Risk Assessment and Heart. 102(24):195-203</td>
<td>Population Setting</td>
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<tr>
<td>20</td>
<td>Vellone</td>
<td>Self-Care Confidence may be more important than International Journ Background</td>
<td>Population Setting</td>
<td></td>
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</tbody>
</table>
Poll

Which software is your preferred option for study selection?
Take home message:

Give thought to **sequencing of eligibility criteria** – quickest/easiest first (e.g. is it qualitative?)

Remember **Title/Abstract Screening** is to **Rule Out**, **Full Text Screening** is to **Rule In**

In practice “**Include**” and “**Full Text**” both equal “**In**” for **Title/Abstract Screening**. However you may want to **prioritise Probables over Possibles** (e.g. for piloting or a rapid review)
A Case for Sampling:

Sampling is...warranted theoretically, in that the focus in interpretive synthesis is on the development of concepts and theory rather than on exhaustive summary of all data.

A number of authors suggest drawing on the sampling techniques of primary qualitative research, including principles of theoretical sampling and theoretical saturation, when conducting a synthesis of qualitative literature”.

Dixon-Woods (2006) CIS
Patton’s 16 Sampling Strategies

- Typical cases
  - Random
  - Criterion
  - Snowball or Chain
  - Random purposeful

- Politically important cases
  - Extreme or deviant cases
  - Homogenous
  - Theory based
  - Intensity
  - Maximum variation
  - Confirming and disconfirming cases

- Opportunistic or emergent
  - Stratified purposeful
  - Convenience

- Critical Case
“Systematic reviews of trials attempt to locate every possible study on a given topic or intervention and some authors advocate a similar approach for qualitative syntheses.

In keeping with the methods of primary qualitative research, other methodologists suggest the use of theoretical sampling until data saturation is reached. **Key difficulties with this approach include how to establish the population of studies from which to sample without first identifying all relevant studies**.”

Sampling Papers ≠ Sampling People

“it has to be acknowledged that sampling research papers is fundamentally not like sampling people. Unlike people, research papers have a vested interest in being different from one another, and are (in theory at least) only published if they are saying something new. Missing out some papers may therefore risk missing out potentially important insights”.

Dixon-Woods, Bonas, Booth et al, 2006
Two main types of qualitative syntheses

**Aggregative qualitative synthesis** (e.g. Joanna Briggs Institute method) - similar to a quantitative systematic review – aim to comprehensively identify relevant research, to quality assess it, and to meta-synthesise it (instead of meta-analysis)

**Configurative (interpretive) qualitative synthesis** (e.g. meta-ethnography) - purposively (selectively) sample from available qualitative research, privilege contribution over quality *per se*. Methods resemble primary qualitative research, more than a conventional systematic review
Things to consider (when planning your sample)

- Is the review intended to be **aggregative or interpretive**?
- Is **theory** expected to play an important part in the review?
- Are **differences in context** important to understanding the phenomenon?

(Sutton et al 2019)
How much of this can we interpret?
The missing piece could be critical – depends upon sampling!
“Conventional systematic review methodology limits the number of papers... by having tightly specified inclusion criteria for papers. Effectively, this strategy constructs the field to be known as having specific boundaries, defined as research that has specifically addressed the review question, used particular study designs and fulfilled the procedural requirements for the proper execution of these.”

“Interpretive reviews might [see] the boundaries as more diffuse and ill-defined, as potentially overlapping with other fields, and as shifting as the review progresses.” (Dixon-Woods et al, 2006)
Overall Sampling Strategies

Strategy One – Aggregative

1. Conduct **Scoping**
2. Define all concepts (i.e. population, intervention, comparison, outcomes)
3. Finalise Sampling Frame
4. Conduct Exhaustive Searches

Strategy Two – Interpretative

1. Conduct **Scoping**
2. Construct Preliminary Sampling Frame
3. Identify Appropriate Sampling Strategies
4. Conduct Appropriate Searches
5. Revisit Sampling Frame, Strategies and Searches *as required*
Matching Sampling to Synthesis

A ‘Dual Heritage’ for QES

Table 2 - Synthesis Methods with Appropriate Sampling Methods

<table>
<thead>
<tr>
<th>Synthesis Method</th>
<th>Sampling Method</th>
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<tbody>
<tr>
<td>Critical Interpretive Synthesis</td>
<td>Purposive Sampling (Dixon-Woods et al, 2006)</td>
</tr>
<tr>
<td>Meta-Ethnography</td>
<td>Purposive Sampling (Doyle, 2003)</td>
</tr>
<tr>
<td>Meta-Interpretation</td>
<td>Maximal Divergent Sampling (Corbin-Staton, 2009)</td>
</tr>
<tr>
<td>Meta-Narrative Synthesis</td>
<td>Purposive Sampling of key papers within different research 'traditions' (Barnett-Page &amp; Thomas (2009))</td>
</tr>
<tr>
<td>Qualitative meta-synthesis</td>
<td>Comprehensive (representative) Sampling (Paterson et al, 2001)</td>
</tr>
<tr>
<td>Realist Synthesis</td>
<td>Comprehensive Sampling (Brunton et al, 2010); Purposive Sampling (Pawson, 2006c); Snowball Sampling (Pawson et al, 2004)</td>
</tr>
<tr>
<td>Scoping Review</td>
<td>Random Sampling (Brunton et al, 2010)</td>
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</tbody>
</table>

Ideas to be expanded in new “Cochrane QES Handbook” – Chapter on Sampling by Ames, Booth & Noyes, 2022
Studies on Purposive Sampling

“Demands considerable.. flexibility, and is labour-intensive, which goes against the argument …that using purposeful sampling provides a pragmatic solution or a short cut for researchers, compared with exhaustive sampling.

Opportunities… were possible inclusion of new perspectives to the line-of-argument and enhancement of the theoretical diversity of the papers being included, which could make the results more conceptually aligned with the synthesis purpose.”

Benoot et al (2016)

Assessed 79 studies, sampled 38. Sampled:

(i) 9 studies from LMICs;
(ii) 24 studies scoring high for data richness;
(iii) 5 studies most closely matching synthesis objectives.

“Helped ensure that included studies represent[ed] a wide geographic spread, rich data and a focus that closely resembled our synthesis objective”.

May have overlooked primary studies that did not meet sampling criteria but would have contributed to synthesis. (e.g. two studies on migration/access to health services did not meet sampling criteria but might have strengthened at least one finding). Need methods to cross-check for under-represented themes.

When can I stop sampling?

Consider: is it worthwhile extending my sample further?

- “theoretical saturation” (when you are confident you will only find more of the same interpretations) – but sample for dissonance and diversity
- “bibliographic sufficiency” (when the same references keep coming up) – but sample for dissonance and diversity
- when you have no more questions to answer
Where approaches other than comprehensive sampling are used, reviewers must **justify** their sampling strategy, **match** it to their synthesis method and **describe** fully how it was implemented.

“I hope the users and producers of research synthesis will use this...as a departure point to think creatively and critically about purposes and amenable sampling strategies for a research synthesis” Suri (2011)
Pause for questions
Qualitative Evidence Synthesis: Assessing methodological limitations in primary studies

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University of Sheffield
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Trusted evidence.
Informed decisions.
Better health.
Quality/critical appraisal /assessing methodological limitations

What purpose does it have?

- Considered an essential step in the systematic review process
- Identification of methodological limitations that could impact on the interpretation of findings
- Further engagement with the study to better understand its conduct and reporting
- Process provides more understanding of study relevance, conceptual richness and data thickness
- Assessments can contribute to deciding whether to include or exclude

**BUT** Quality appraisal/assessing methodological limitations in primary studies is controversial
- No current tool is entirely fit for purpose
“...critical appraisal is a flawed ‘technology’ with limitations surrounding the paper itself, the appraisal instrument and the appraisers, either collectively or individually.

To the danger, reported by Sackett, of ‘critical appraisal nihilism’—the perception that no paper is ever good enough—we add two further dimensions—no instrument is good enough and no appraiser is good enough!”

(Booth, 2007 p. 75)
Cochrane Qualitative and Implementation Methods Group guidance series—paper 1: introduction


Chapter 21 Qualitative Evidence Synthesis
CERQual components

For assessing confidence in synthesised qualitative findings
Assessing methodological limitations as a GRADE CERQual component
# Quality appraisal: Basic criteria

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Qualitative term</th>
<th>Quantitative term</th>
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<tbody>
<tr>
<td>Truth value</td>
<td>Credibility</td>
<td>Internal validity</td>
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<tr>
<td>Applicability</td>
<td>Transferability</td>
<td>Generalisability</td>
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<tr>
<td>Consistency</td>
<td>Dependability</td>
<td>Reliability</td>
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<tr>
<td>Neutrality</td>
<td>Confirmability</td>
<td>Objectivity</td>
</tr>
<tr>
<td>Qualitative term</td>
<td>Techniques</td>
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</table>
| **Credibility**: the representation of data fits the views of the participants studied, the findings hold true | • outside auditors or participants validate findings (member checks)  
• peer debriefing,  
• attention to negative cases,  
• independent analysis of data by more than one researcher  
• verbatim quotes  
• persistent observation (stay in the field long enough) |
| **Transferability**: research findings are transferable to other specific settings | • providing details of the study participants to enable readers to evaluate for which target groups the findings potentially hold true  
• providing contextual background information, demographics  
• providing thick description about both the sending and the receiving context |
| **Dependability**: process of research is logical, traceable and clearly documented, particularly on the methods chosen and the decisions made by the researchers | • peer review, debriefing, audit trails  
• triangulation, the use of different methodological approaches to look at the topic of research  
• reflexivity to keep a self-critical account of the research process  
• calculation of inter-rater agreements |
| **Confirmability**: findings are qualitatively confirmable through the analysis being grounded in the data, through examination of the audit trail | • assessing the potential effects/impact of the researcher during all steps of the research process  
• Reflexivity toward personal influences, bias  
• providing background information on the researcher’s background, education, perspective, school of thought |
Different stages of appraisal

- Quality/critical appraisal/assessing methodological limitations involves
  
  (i) filtering against minimum criteria, involving adequacy of reporting detail
  - Limit the type of qualitative studies to be included to empirical studies with a description of the sample strategy, data collection procedures and the type of data-analysis considered.
  - Exclude: descriptive papers, editorials, opinion papers
  
  (ii) technical appraisal of technical rigour of study elements indicating methodological soundness
  
  (iii) theoretical appraisal of paradigmatic sufficiency, referring to researchers’ responsiveness to data and theoretical consistency’
Technical appraisal stage

Use an appraisal instrument to look for indications in a study that add to the level of methodological soundness of the study to determine the degree of confidence in the researcher’s competence to conduct research following established norms.

Needs a general understanding of qualitative criteria

THE CHECKLIST APPROACH
Theoretical appraisal stage

Use a subsequent paradigmatic approach to judgement, which refers to an evaluation of methodological coherence between theory and methodology/methods, to evaluate the quality and rationale of the decisions made.

Needs a more in-depth understanding of qualitative research

THE OVERALL JUDGEMENT APPROACH
Selecting an appraisal tool

There is currently no tool that is entirely fit for purpose

Selection of appraisal instruments:

- Used in recently published QES
- Online available and ready to use
- Broadly applicable to different qualitative research designs
- Developed and supported by an organisation/institute/consortium
- Meets the criteria outlined in chapter 21 of the Cochrane Handbook

Also note the difference between assessing reporting quality and assessing methodological limitations - there are reporting guidelines and checklists to assess how well a study is reported.
GENERAL PRINCIPLES
1. Unless reviewing only a single type of qualitative research, generic approaches to quality assessment should not include any items that privilege one type of qualitative method/methodology over another.
2. The importance of individual items should be determined by the review team within the context of their specific review.
3. As far as possible, it should be clear from each question (or at least from the response of the review team when completing) whether the question is addressing study quality or study reporting.
4. While study reports that justify methodological choices may be considered particularly helpful the absence of such a justification should not be considered a study weakness.

OVERALL APPROACHES
5. Compound questions (i.e. questions asking for fulfilment of multiple items) should be avoided as far as possible.
6. While assessment of study quality and/or study reporting are legitimate approaches these should, as far as possible, be separated in different items.
7. Scoring of items should be avoided at all costs.
8. Formal weighting of individual items should be avoided.

INDIVIDUAL ITEMS
9. Items relating to whether a study is qualitative research or whether the research question can be addressed by qualitative research should be managed at study selection, not quality assessment.
10. A checklist should include assessments of both data collection and data analysis.
11. A checklist should include one or more items relating to the positionality of the researcher in relation to their research.
12. Consideration of ethical issues, and more specifically, the confirmation of ethical approval, should not be considered a marker of study quality.
13. Items on how well the researcher relates their study to previous research are not necessarily markers of study quality and should be assessed by the reviewer during synthesis.
14. Items on the importance or significance of the research are not markers of study quality and should be assessed by the reviewer during synthesis.
<table>
<thead>
<tr>
<th>CASP question</th>
<th>HINT: Consider</th>
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<tbody>
<tr>
<td>1. Was there a clear statement of the aims of the research? HINT: Consider</td>
<td>• What was the goal of the research?</td>
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<td></td>
<td>• Why it was thought important?</td>
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<td></td>
<td>• Its relevance</td>
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<tr>
<td>2. Is a qualitative methodology appropriate?</td>
<td>• If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants</td>
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<tr>
<td></td>
<td>• Is qualitative research the right methodology for addressing the research goal?</td>
</tr>
<tr>
<td>3. Was the research design appropriate to address the aims of the research?</td>
<td>• If the researcher has justified the research design (e.g. have they discussed how they decided which method to use)?</td>
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<tr>
<td>4. Was the recruitment strategy appropriate to the aims of the research?</td>
<td>• If the researcher has explained how the participants were selected</td>
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<td></td>
<td>• If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study</td>
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<td>• If there are any discussions around recruitment (e.g. why some people chose not to take part)</td>
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<td>CASP question</td>
<td>HINT: Consider</td>
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<tr>
<td>5. Was the data collected in a way that addressed the research issue?</td>
<td>• If the setting for data collection was justified</td>
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<td>• If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)</td>
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<td>• If the researcher has justified the methods chosen</td>
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<td>• If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, or did they use a topic guide)?</td>
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<td>• If methods were modified during the study. If so, has the researcher explained how and why?</td>
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<td>• If the form of data is clear (e.g. tape recordings, video material, notes etc)</td>
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<td>• If the researcher has discussed saturation of data</td>
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<tr>
<td>6. Has the relationship between researcher and participants been adequately considered?</td>
<td>• If the researcher critically examined their own role, potential bias and influence during (a) Formulation of the research questions (b) Data collection, including sample recruitment and choice of location</td>
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<td>• How the researcher responded to events during the study and whether they considered the implications of any changes in the research design</td>
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<tr>
<td>7. Have ethical issues been taken into consideration?</td>
<td>• If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained</td>
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<td>• If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)</td>
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<td>• If approval has been sought from the ethics committee</td>
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<tr>
<td>8. Was the data analysis sufficiently rigorous?</td>
<td>• If there is an in-depth description of the analysis process</td>
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<td>• If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data?</td>
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<td>• Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process</td>
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<td></td>
<td>• If sufficient data are presented to support the findings</td>
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<td>• To what extent contradictory data are taken into account</td>
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<td>• Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation</td>
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<tr>
<td>CASP question</td>
<td>HINT: Consider</td>
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</table>
| 9. Is there a clear statement of findings? | HINT: Consider  
• If the findings are explicit  
• If there is adequate discussion of the evidence both for and against the researchers arguments  
• If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)  
• If the findings are discussed in relation to the original research question |
| 10. How valuable is the research? | HINT: Consider  
• If the researcher discusses the contribution the study makes to existing knowledge or understanding e.g. do they consider the findings in relation to current practice or policy?, or relevant research-based literature?  
• If they identify new areas where research is necessary  
• If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be use |
Undertaking a Theoretical appraisal

- Methodological choice and coherence
- Development of theory and/or new theoretical insights
- Conceptual richness, data thickness

<table>
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<tr>
<th>Assessment guidance</th>
<th>Examples of data of different richness</th>
<th>Data richness score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very little qualitative data presented that relate to the synthesis objective. Those findings that are presented are fairly descriptive.</td>
<td>A mixed methods study using open ended survey questions or a more detailed qualitative study where only part of the data relates to the synthesis objective</td>
<td>1</td>
</tr>
<tr>
<td>Some qualitative data presented that relate to the synthesis objective</td>
<td>A limited number of qualitative findings from a mixed methods or qualitative study</td>
<td>2</td>
</tr>
<tr>
<td>A reasonable amount of qualitative data that relate to the synthesis objective</td>
<td>A typical qualitative research article in a journal with a smaller word limit and often using simple thematic analysis</td>
<td>3</td>
</tr>
<tr>
<td>A good amount and depth of qualitative data that relate to the synthesis objective</td>
<td>A qualitative research article in a journal with a larger word count that includes more context and setting descriptions and a more in-depth presentation of the findings</td>
<td>4</td>
</tr>
<tr>
<td>A large amount and depth of qualitative data that relate in depth to the synthesis objective</td>
<td>A detailed ethnography or a published qualitative article with the same objectives as the synthesis</td>
<td>5</td>
</tr>
</tbody>
</table>

Undertaking Assessments

- Requires considerable skill and experience of primary qualitative research
- Is a consensus process
- Not an exact science as individual judgements vary
- Undertaken by more than one person who resolve disagreements by consensus
- A third person can arbitrate if two people cannot resolve differences

- The overall assessment should bring together the technical and theoretical appraisal within the context of how well the study is reported.
- If there is time – review authors can contact the primary study authors to clarify information not reported or is insufficiently clear in the paper
### Common methodological issues picked up by the appraisal process

<table>
<thead>
<tr>
<th>Section of the review</th>
<th>Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question</strong></td>
<td>Not clear – or no question</td>
</tr>
<tr>
<td></td>
<td>Not a good ‘fit’ for the question</td>
</tr>
<tr>
<td></td>
<td>No method articulated or a reporting guideline is inappropriately cited as the method</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>Named method not used or applied as originally intended without sufficient justification or sometimes without any justification</td>
</tr>
<tr>
<td></td>
<td>No or little evidence that the selected method was actually used in reality</td>
</tr>
<tr>
<td></td>
<td>Participants do not consistently represent the population of interest</td>
</tr>
<tr>
<td></td>
<td>Inappropriate choice of theory/conceptual framework or not applied</td>
</tr>
<tr>
<td><strong>Data processing and analysis</strong></td>
<td>Does not align with the stated method</td>
</tr>
<tr>
<td></td>
<td>Not reported how data were processed and analysed and by whom or how internal validity was maintained</td>
</tr>
<tr>
<td><strong>Findings</strong></td>
<td>Do not appear to be underpinned by data</td>
</tr>
<tr>
<td><strong>Theory development</strong></td>
<td>Does not seem to be supported by the findings</td>
</tr>
<tr>
<td><strong>Reporting</strong></td>
<td>The relevant reporting guideline has not been followed</td>
</tr>
<tr>
<td><strong>Reflexivity</strong></td>
<td>Concerns about threats to rigour and conflicts of interest not made transparent</td>
</tr>
</tbody>
</table>
Reporting Assessments

- Do not score domains and report a total score as this is considered meaningless.
- Do not create scales of ‘quality’ (high, medium, low) based on counting the domains as not all domains are equal.
- What is more important is to identify CONCERNS about methodological limitations and how they may impact on findings of the primary study and the synthesis.
- Transparent reporting is key.

### Appendix 3. Critical appraisal of included studies

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Is there a statement of research aims?</th>
<th>Is a qualitative approach justified?</th>
<th>Was the recruitment strategy appropriate to address the aims?</th>
<th>Was the role of the researcher/reflexivity described?</th>
<th>Have ethical issues been considered?</th>
<th>Was the data analysis sufficient to reach clear and rigorous findings?</th>
<th>Were the findings supported by the evidence?</th>
<th>Overall assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abushaikha 2012</td>
<td>Yes</td>
<td>Yes</td>
<td>Partial - FGIs and IDIs with women took place in the hospital shortly after birth</td>
<td>Partial researchers described as maternity nurse researchers but no discussion on how this might influence data collection or analysis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Moderate concerns</td>
</tr>
<tr>
<td>Abushaikha 2013</td>
<td>Yes</td>
<td>Yes</td>
<td>Partial - FGIs and IDIs with women took place in the hospital shortly after birth</td>
<td>Unclear how participants were recruited</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Moderate concerns</td>
</tr>
</tbody>
</table>
Using Assessments

• Engaging with the paper and its findings (familiarisation)

• Deciding on inclusion/exclusion and purposively sampling

• Aspects of the process involve data extraction

• Feeds into GRADE-CERQual – methodological limitations component

• Methodological limitations in included studies can impact on the development and interpretation of synthesised findings
Ongoing methodological work to develop a tool that is fit for purpose
Pause for questions
Overview of whole program

1-2 pm 28th October, 2021
Introduction to qualitative research and qualitative evidence synthesis
Jane Noyes, Professor in Health and Social Services Research

15th November, 2021
Question formulation and searching for qualitative evidence
Dr Andrew Booth, Reader in Evidence Based Information Practice

13th December, 2021, 14:00 UTC [Check the time in your timezone]
Selecting studies and assessing methodological limitations
Jane Noyes, Professor in Health and Social Services Research

20th January, 2022
Making Sense of Framework and Best Fit Framework Synthesis
Dr Andrew Booth, Reader in Evidence Based Information Practice & Director of Information, University of Sheffield, UK.

Thematic Synthesis – Thursday 24th February 2022 at 09:00 am - Angela Harden and James Thomas

Meta-ethnography – Thursday 17th March 2022 at 14:00 pm - Kate Flemming

GRADE CERQual – Monday 25th April 2022 at 14:00 pm - Megan Wainwright

Integrating qualitative and quantitative syntheses – Monday 16th May 2022 at 14:00 pm - Angela Harden and James Thomas