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Qualitative and Implementation

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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)

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Conflict of Interest Statement

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

Andrew Booth & Jane Noyes

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Overview of whole program

1-2 pm 28th October, 2021
Introduction to qualitative research and qualitative evider
Jane Noyes, Professor in Health and Social Services Researc
Kate Flemming, Professor of Hospice Practice and Evidence

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

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

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

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Study Selection

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)

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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.

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Cochrane Handbook Chapter 21.9 Selecting studies to synthesize

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.

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Similar…?

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)

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But Different!

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)

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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

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

Figure 3: Theoretical or purposeful screening

Theoretical or Purposeful Sampling

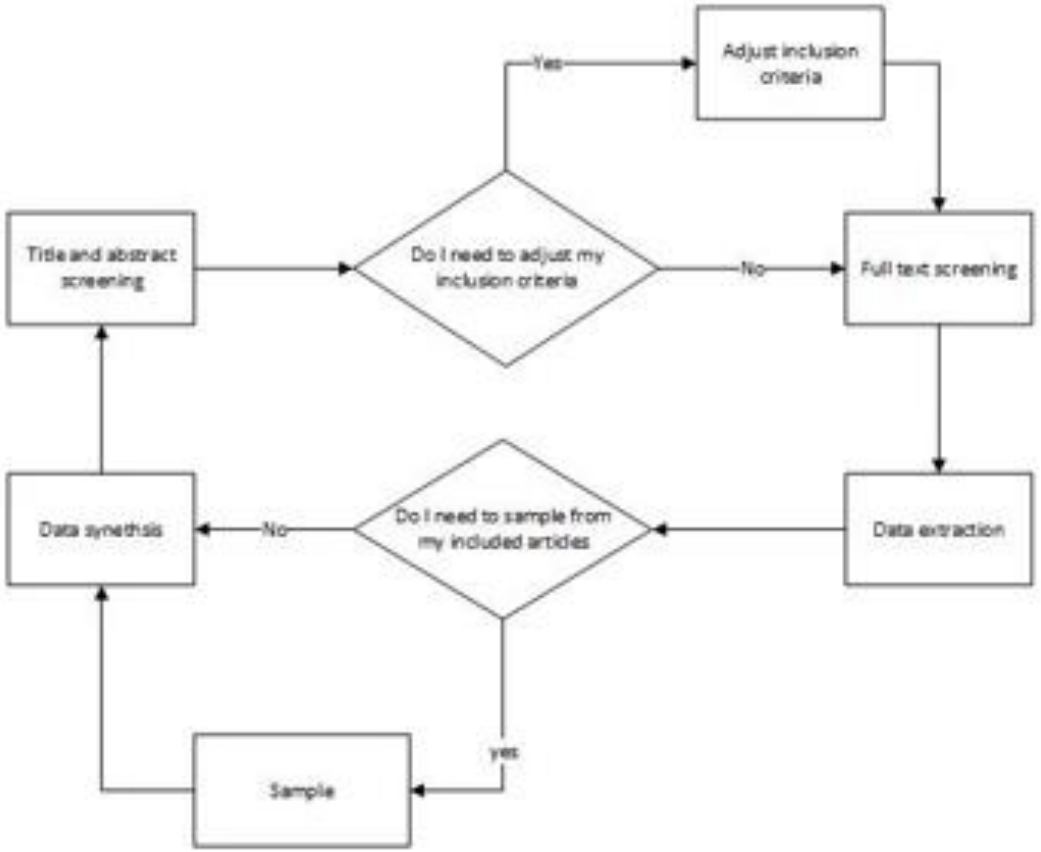
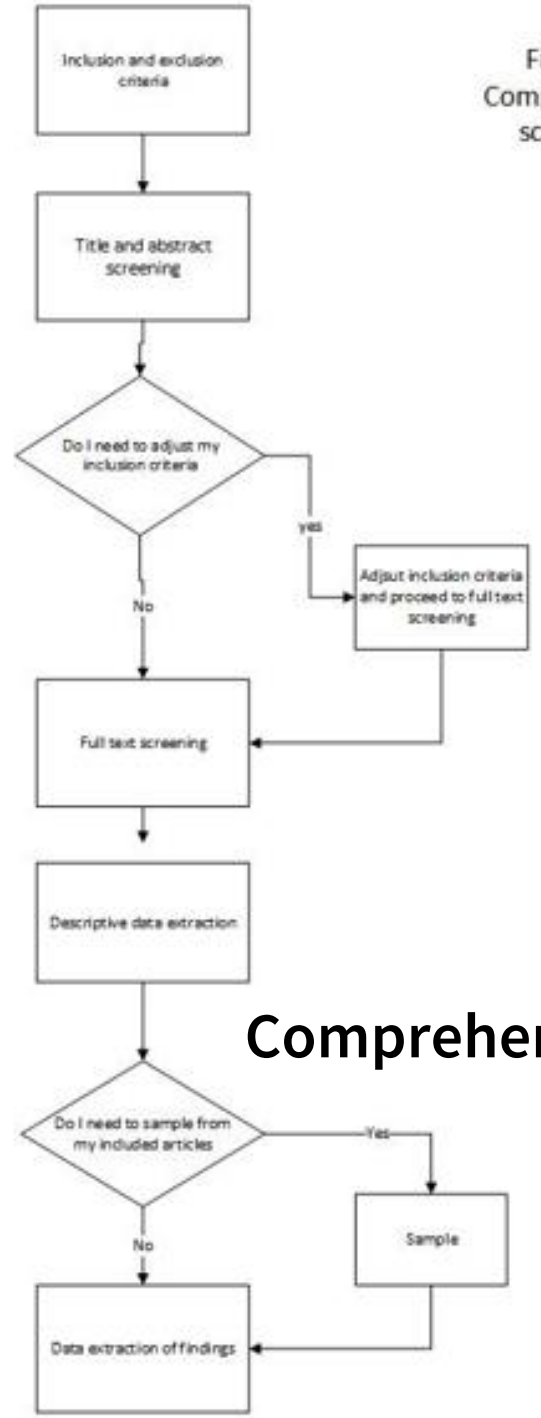


Figure 2: Comprehensive screening



Comprehensive

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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?

Evaluation: Qualitative studies? Qualitative data? *Verbatim Extracts? Author Observations? Richness?* [Sampling?]

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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)?

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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

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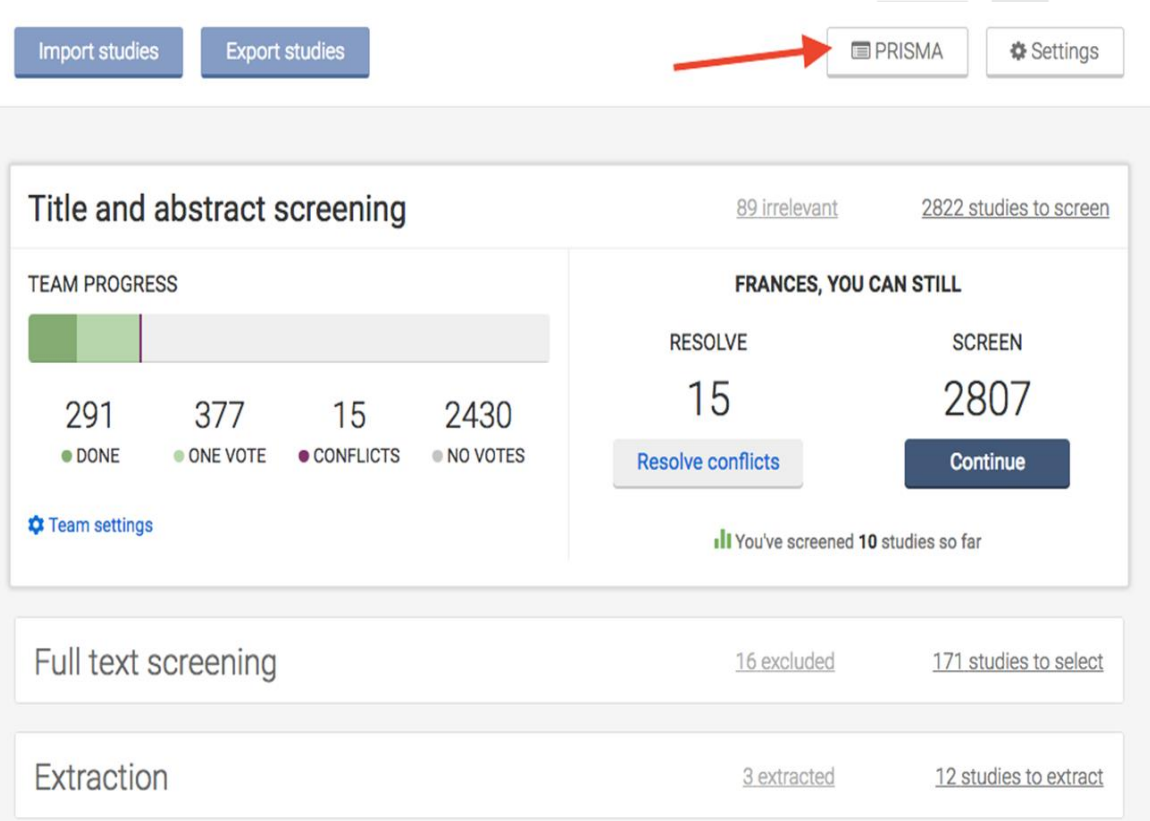
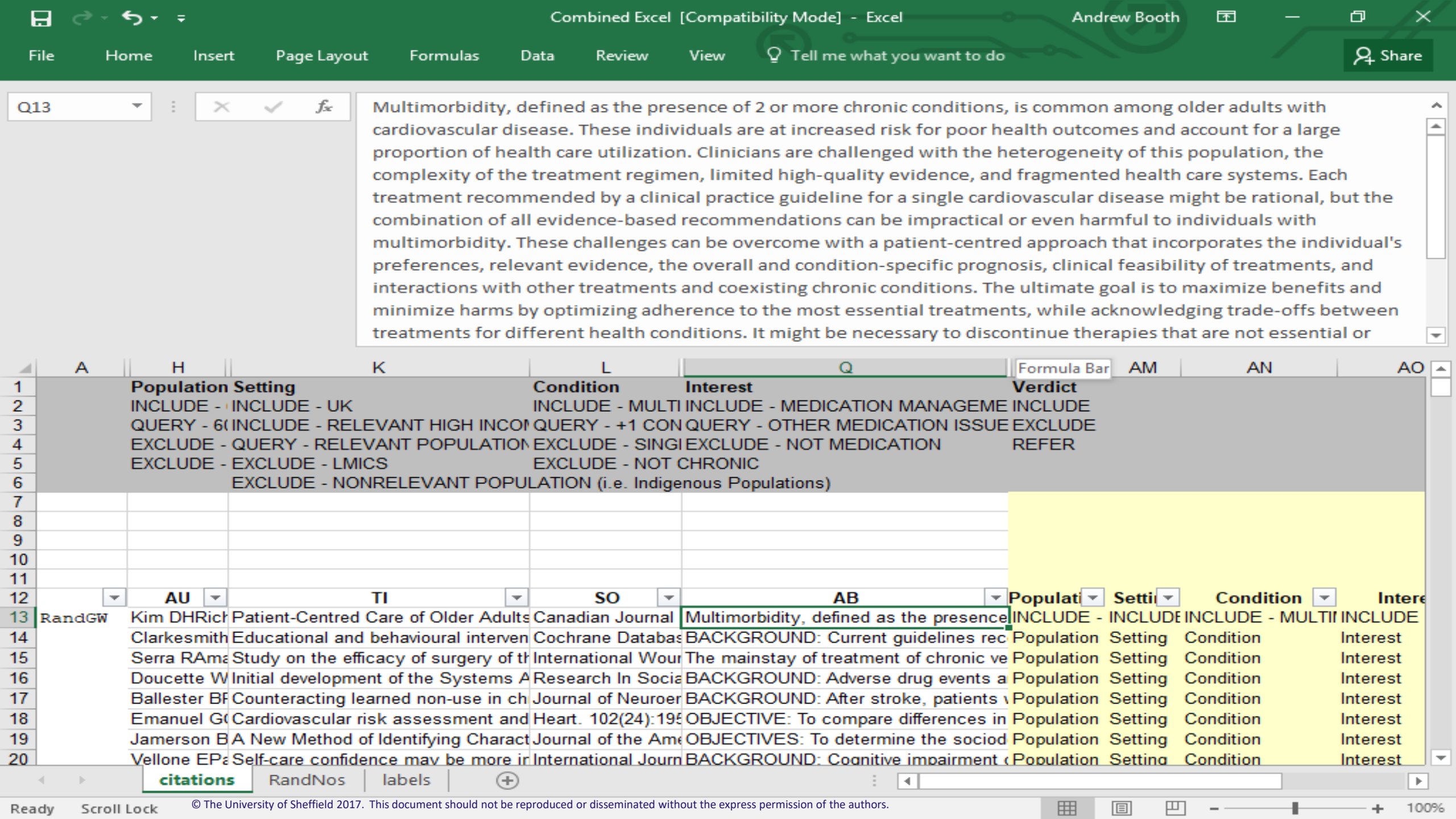
Covidence – Screening Tool used by Cochrane




Combined Excel [Compatibility Mode] - Excel
Andrew Booth
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Q13
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 with 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 acknowledging trade-offs between treatments for different health conditions. It might be necessary to discontinue therapies that are not essential or
Population Setting Condition Interest Verdict
INCLUDE - INCLUDE - UK INCLUDE - MULTI INCLUDE - MEDICATION MANAGEME INCLUDE
QUERY - 6(INCLUDE - RELEVANT HIGH INCOI QUERY - +1 CON QUERY - OTHER MEDICATION ISSUE EXCLUDE
EXCLUDE - QUERY - RELEVANT POPULATION EXCLUDE - SINGI EXCLUDE - NOT MEDICATION REFER
EXCLUDE - EXCLUDE - LMICS EXCLUDE - NOT CHRONIC
EXCLUDE - NONRELEVANT POPULATION (i.e. Indigenous Populations)
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RandGW Kim DHRich Patient-Centred Care of Older Adults Canadian Journal Multimorbidity, defined as the presence INCLUDE - INCLUDE INCLUDE - MULTI INCLUDE
Clarkesmith Educational and behavioural interven Cochrane Databas BACKGROUND: Current guidelines rec Population Setting Condition Interest
Serra RAma Study on the efficacy of surgery of th International Wour The mainstay of treatment of chronic ve Population Setting Condition Interest
Doucette W Initial development of the Systems A Research In Socia BACKGROUND: Adverse drug events a Population Setting Condition Interest
Ballester BR Counteracting learned non-use in ch Journal of Neuroer BACKGROUND: After stroke, patients v Population Setting Condition Interest
Emanuel G(Cardiovascular risk assessment and Heart. 102(24):195 OBJECTIVE: To compare differences in Population Setting Condition Interest
Jamerson B A New Method of Identifying Charact Journal of the Ame OBJECTIVES: To determine the sociod Population Setting Condition Interest
Vellone EPa Self-care confidence may be more ir International Journ BACKGROUND: Cognitive impairment (Population Setting Condition Interest
citations RandNos labels
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100%

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Poll

Which software is your preferred option for study selection?

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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)

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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

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Patton's 16 Sampling Strategies

Typical cases

Random

Criterion

Snowball or Chain

Random purposeful

Politically important cases

Extreme or deviant cases

Homogenous

Theory based

Confirming and disconfirming cases

Opportunistic or emergent

Intensity

Stratified purposeful

Maximum variation

Convenience

Critical Case

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Problems with sampling the literature

"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".**

Atkins et al (2008)

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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

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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)

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How much of this can we interpret?

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The missing piece could be critical – depends upon sampling!

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A priori versus iterative sampling frames

"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)

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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*

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Matching Sampling to Synthesis

A 'Dual Heritage' for QES

Table 2 - Synthesis Methods with Appropriate Sampling Methods

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

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

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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.

Ames et al (2019)

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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

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Reporting Sampling

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)

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Pause for questions

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Qualitative Evidence Synthesis: Assessing methodological limitations in primary studies

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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

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Critical appraisal is not a perfect process

"…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)

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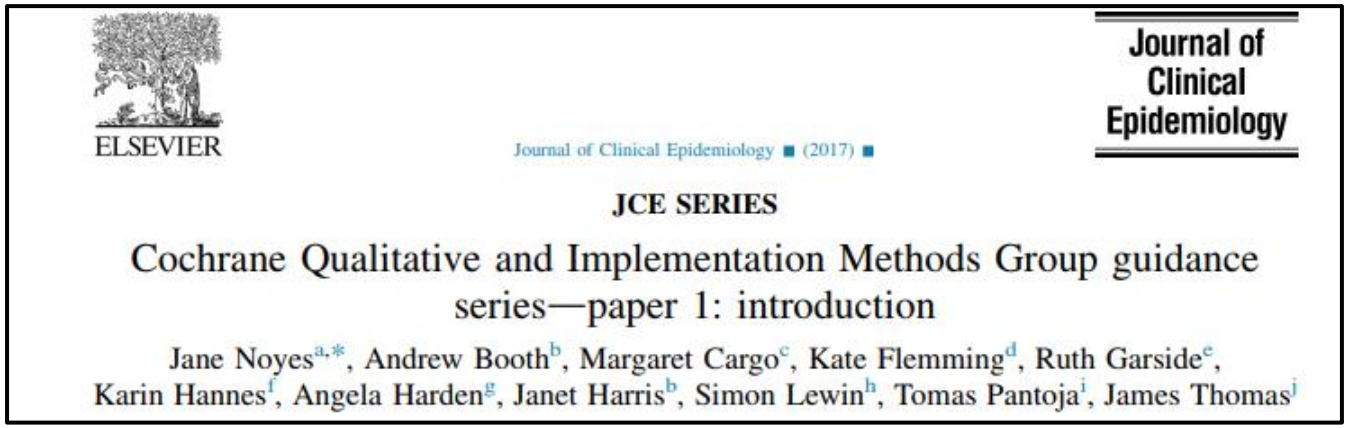

Updated Methodological guidance
May 2018 print version JCE

- Noyes J, Booth A, Flemming K, Garside R, Harden A, Lewin S, Pantoja T, Hannes K, Cargo M, Thomas J, Cochrane Qualitative and Implementation Methods Group Guidance Paper 2: **Methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings.** *Journal of Clinical Epidemiology* (2018), doi: 10.1016/j.jclinepi.2017.06.020.
- Cargo M, Harris J, Pantoja T, Booth A, Harden A, Hannes K, Thomas J, Flemming K, Garside R, Noyes J. Cochrane Qualitative and Implementation Methods Group Guidance **Paper 3: Methods for Assessing Evidence on Intervention Implementation.** *Journal of Clinical Epidemiology*. 2017 Dec 6. pii: S0895-4356(17)31334-3. doi: 10.1016/j.jclinepi.2017.11.028.
- Harden A, Thomas J, Cargo M, Harris J, Pantoja T, Flemming K, Booth A, Garside R, Hannes K, Noyes J, Cochrane Qualitative and Implementation Methods Group Guidance Paper 4: **Methods for integrating qualitative and implementation evidence within intervention effectiveness reviews,** *Journal of Clinical Epidemiology* (2018), doi: 10.1016/j.jclinepi.2017.11.029.
- Flemming K, Booth A, Hannes K, Cargo M, Noyes J. Cochrane Qualitative and Implementation Methods Group Guidance **Paper 5: Reporting guidelines for qualitative, implementation and process evaluation evidence syntheses.** *Journal of Clinical Epidemiology.* 2017 Dec 5. pii: S0895-4356(17)31327-6. doi: 10.1016/j.jclinepi.2017.10.022.
- Harris JL, Booth A, Cargo M, Hannes K, Harden A, Flemming K, Garside R, Pantoja T, Thomas J, Noyes J, Cochrane Qualitative and Implementation Methods Group Guidance series - paper 6: **Methods for question formulation, searching and protocol development for qualitative evidence synthesis,** *Journal of Clinical Epidemiology* (2018), doi: 10.1016/j.jclinepi.2017.10.023.

Supplements current and forthcoming new edition of **the Cochrane Handbook**

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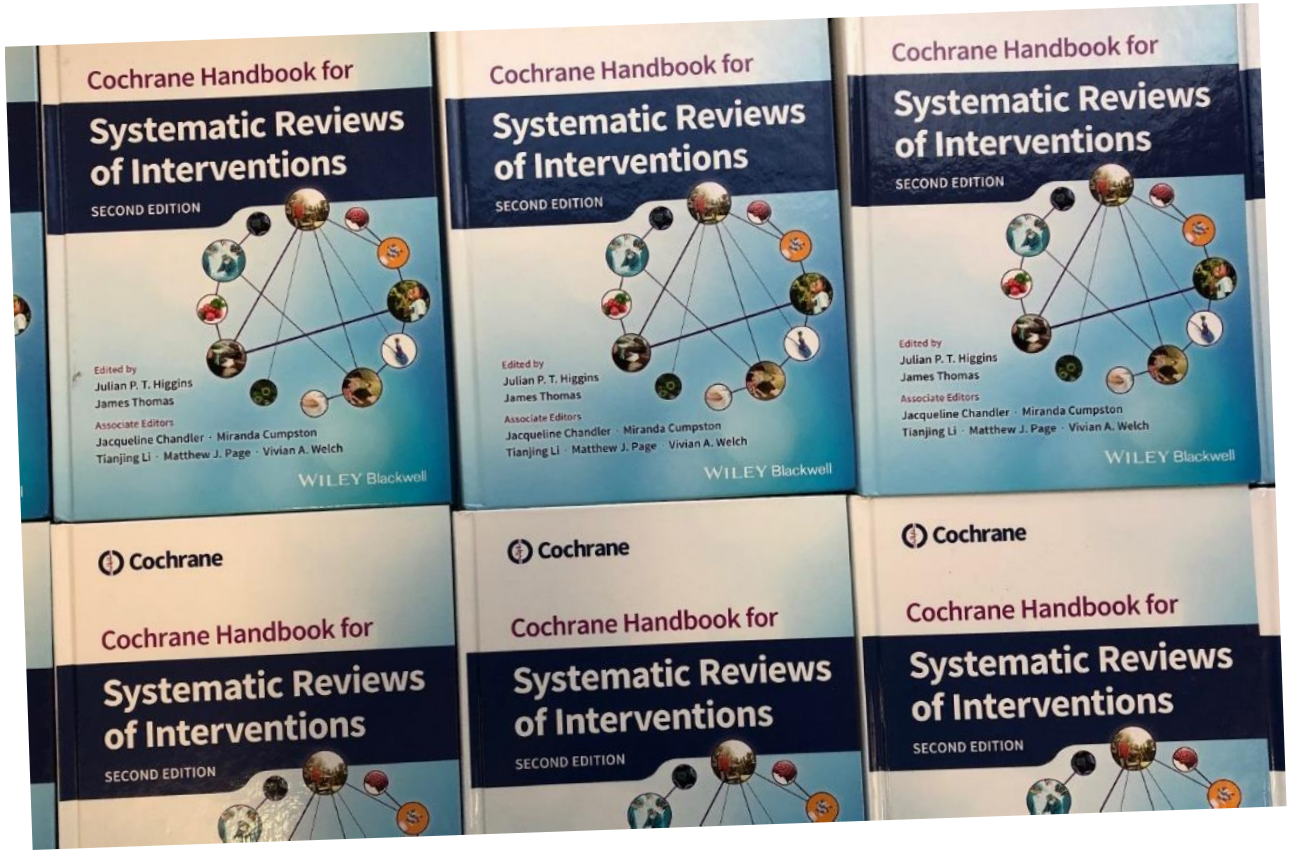
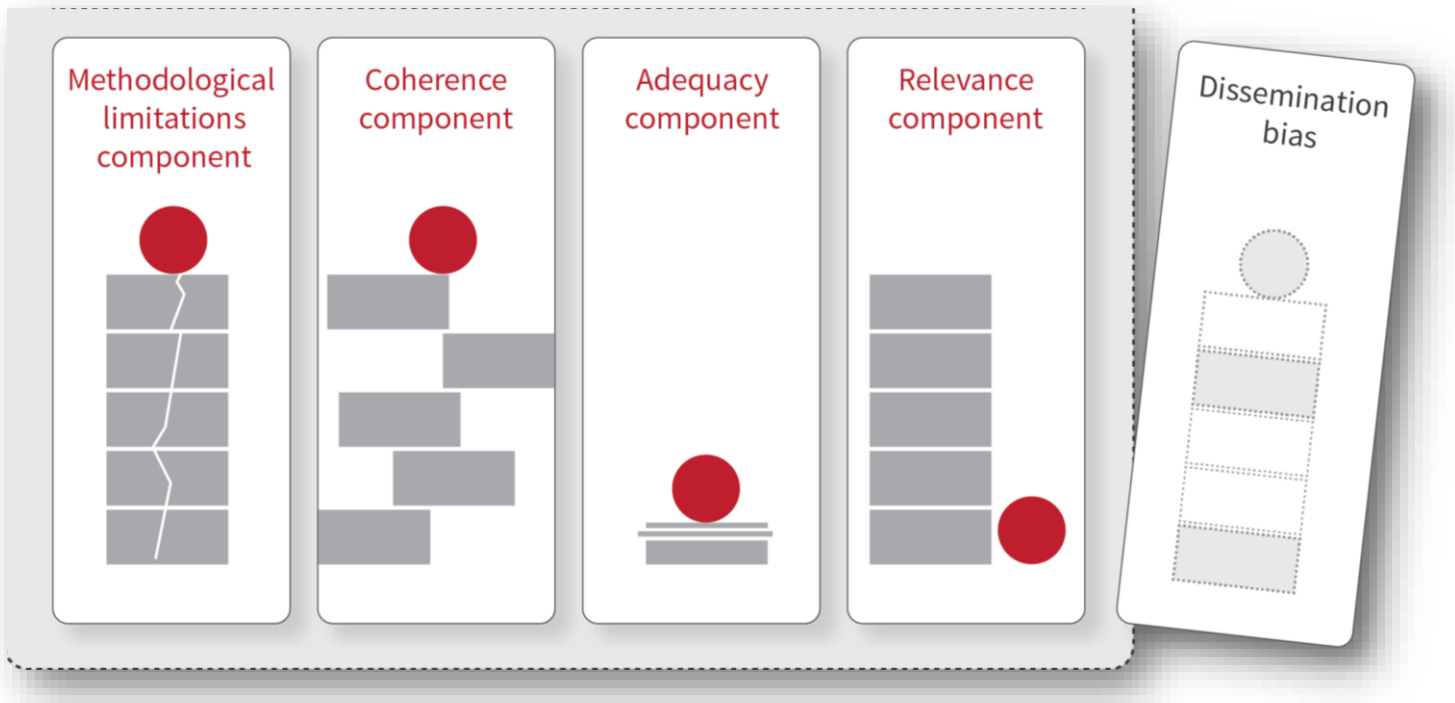


Chapter 21 Qualitative Evidence Synthesis

GRADE CERQual For assessing confidence in synthesised qualitative findings



CERQual components

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Assessing methodological limitations as a GRADE CERQual component

Munthe-Kaas *et al. Implementation Science* 2018, **13**(Suppl 1):9
DOI 10.1186/s13012-017-0690-9

Implementation Science

METHOD Open Access

Applying GRADE-CERQual to qualitative evidence synthesis findings—paper 3: how to assess methodological limitations

Heather Munthe-Kaas[1*], Meghan A. Bohren[2], Claire Glenton[1], Simon Lewin[1,3], Jane Noyes[4], Özge Tunçalp[2], Andrew Booth[5], Ruth Garside[6], Christopher J. Colvin[7], Megan Wainwright[7], Arash Rashidian[8,9], Signe Flottorp[1] and Benedicte Carlsen[10]

Quality appraisal: Basic criteria

Risk of Bias (quantitative) Risk to Rigour (qualitative)

Aspect	Qualitative term	Quantitative term
Truth value	Credibility	Internal validity
Applicability	Transferability	Generalisability
Consistency	Dependability	Reliability
Neutrality	Confirmability	Objectivity

Qualitative term	Techniques
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

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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'

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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

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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

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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.

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In the absence of an officially endorsed and/or validated checklist for quality assessment of qualitative research the following are proposed as good principles when using any checklist: Survival guide for Quality assessment of Qualitative Research (SuQQuaR)

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 of study quality and should be assessed by the reviewer during synthesis.

CASP Checklist for qualitative studies

CASP question	HINT: Consider
1. Was there a clear statement of the aims of the research? HINT: Consider	• What was the goal of the research? • Why it was thought important? • Its relevance
2. Is a qualitative methodology appropriate?	• If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants • Is qualitative research the right methodology for addressing the research goal?
3. Was the research design appropriate to address the aims of the research?	• If the researcher has justified the research design (e.g. have they discussed how they decided which method to use)?
4. Was the recruitment strategy appropriate to the aims of the research?	• If the researcher has explained how the participants were selected • If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study • If there are any discussions around recruitment (e.g. why some people chose not to take part)

CASP question	HINT: Consider
5. Was the data collected in a way that addressed the research issue?	• If the setting for data collection was justified • If it is clear how data were collected (e.g. focus group, semi-structured interview etc.) • If the researcher has justified the methods chosen • 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)? • If methods were modified during the study. If so, has the researcher explained how and why? • If the form of data is clear (e.g. tape recordings, video material, notes etc) • If the researcher has discussed saturation of data
6. Has the relationship between researcher and participants been adequately considered?	• 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 • How the researcher responded to events during the study and whether they considered the implications of any changes in the research design
7. **Have ethical issues been taken into consideration?**	• If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained • 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) • If approval has been sought from the ethics committee
8. Was the data analysis sufficiently rigorous?	• If there is an in-depth description of the analysis process • If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data? • Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process • If sufficient data are presented to support the findings • To what extent contradictory data are taken into account • Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

CASP question	HINT: Consider
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

Cochrane Methods
Qualitative and Implementation

Undertaking a Theoretical appraisal

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

Assessment guidance	Examples of data of different richness	Data richness score
Very little qualitative data presented that relate to the synthesis objective. Those findings that are presented are fairly descriptive.	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	1
Some qualitative data presented that relate to the synthesis objective	A limited number of qualitative findings from a mixed methods or qualitative study	2
A **reasonable** amount of qualitative data that relate to the synthesis objective	A typical qualitative research article in a journal with a smaller word limit and often using simple thematic analysis	3
A **good amount and depth** of qualitative data that relate to the synthesis objective	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	4
A **large amount and depth** of qualitative data that relate in depth to the synthesis objective.	A detailed ethnography or a published qualitative article with the same objectives as the synthesis	5

Ames H, Glenton C, Lewin S. Purposive sampling in a qualitative evidence synthesis: a worked example from a synthesis on parental perceptions of vaccination communication. BMC Medical Research Methodology. 2019;19(1):26.

Cochrane Methods
Qualitative and Implementation

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

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Qualitative and Implementation

Common methodological issues picked up by the appraisal process

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

Cochrane Methods
Qualitative and Implementation

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

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

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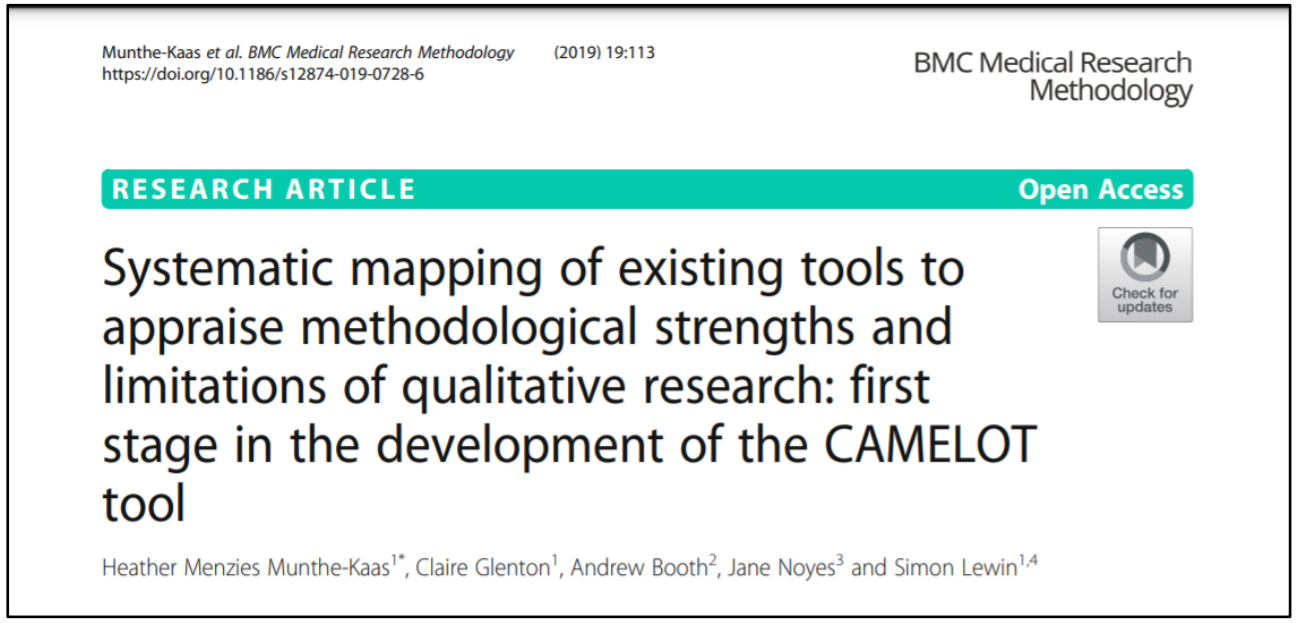
Qualitative and Implementation

Using Assessments

- Engaging with the paper and it's 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

Cochrane Methods
Qualitative and Implementation

Ongoing methodological work to develop a tool that is fit for purpose



Munthe-Kaas *et al. BMC Medical Research Methodology* (2019) 19:113
https://doi.org/10.1186/s12874-019-0728-6

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Systematic mapping of existing tools to appraise methodological strengths and limitations of qualitative research: first stage in the development of the CAMELOT tool

Heather Menzies Munthe-Kaas[1*], Claire Glenton[1], Andrew Booth[2], Jane Noyes[3] and Simon Lewin[1,4]

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Pause for questions

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Overview of whole program

1-2 pm 28th October, 2021
Introduction to qualitative research and qualitative evider
Jane Noyes, Professor in Health and Social Services Researc
Kate Flemming, Professor of Hospice Practice and Evidence

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

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

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