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Cochrane Qualitative and Implementation Methods Group Guidance paper 2:
Methods for assessing methodological limitations, data extraction and synthesis, and
confidence in synthesized qualitative findings

Jane Noyes, Andrew Booth, Kate Flemming, Ruth Garside, Angela Harden, Simon
Lewin, Tomas Pantoja, Karin Hannes, Margaret Cargo, James Thomas

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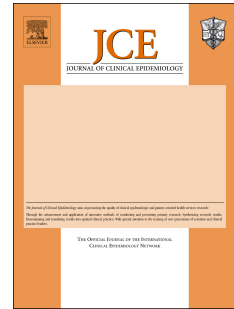
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Cochrane Qualitative and Implementation Methods Group Guidance paper 2: Methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings

Author name and Affiliations

Jane Noyes¹ (**Corresponding author**); Andrew Booth²; Kate Flemming³; Ruth Garside⁴; Angela Harden⁵; Simon Lewin⁶; Tomas Pantoja⁷; Karin Hannes⁸; Margaret Cargo⁹; James Thomas¹⁰

Corresponding author:

¹School of Social Sciences,
Bangor University,
Bangor,
Gwynedd, LL57 2DG, UK
UK

Email: Jane.noyes@bangor.ac.uk

² School of Health and Related Research (SchARR)
Regent Court, 30 Regent Street
Sheffield S1 4DA
UK

Email: A.Booth@sheffield.ac.uk

³Department of Health Sciences,
Faculty of Science
University of York
Seebohm Rowntree Building
Heslington
York YO10 5DD
UK

Email: Kate.flemming@york.ac.uk

⁴European Centre for Environment & Human Health
University of Exeter Medical School
Knowledge Spa, Royal Cornwall Hospital
Truro, Cornwall, UK

Email: r.garside@exeter.ac.uk

⁵The University of East London

Stratford Campus

Water Lane

London, UK

Email: a.harden@uel.ac.uk

⁶Global Health Unit | Norwegian Knowledge Centre for the Health Services at the Norwegian

Institute of Public Health, and

Health Systems Research Unit, South African Medical Research Council, Cape Town, South Africa

Email: Simon.Lewin@fhi.no

⁷Department of Family Medicine, Faculty of Medicine

Pontificia Universidad Católica de Chile

Lira 44. Edificio Decanato, Primer Piso

Santiago, Chile

Email: tpantoja@med.puc.cl

⁸Social Research Methodology Group,

Centre for Sociological Research,

Faculty of Social Sciences,

KU Leuven,

Leuven,

Belgium.

Email: karin.hannes@kuleuven.be

⁹Spatial Epidemiology & Evaluation Research Group/Centre for Population Health Research

University of South Australia

8th Floor Office 310,

South Australia Health & Medical Research Institute

North Terrace

Adelaide SA 510

Australia

Email: Margaret.cargo@unisa.edu.au

¹⁰UCL Institute of Education

University College London
20 Bedford Way
London, UK
Email: james.thomas@ucl.ac.uk

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Cochrane Qualitative and Implementation Methods Group Guidance paper 2: Methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings

Abstract

The Cochrane Qualitative and Implementation Methods Group develop and publish guidance on the synthesis of qualitative and mixed-method implementation evidence. Choice of appropriate methodologies, methods and tools is essential when developing a rigorous protocol and conducting the synthesis. Cochrane authors who conduct qualitative evidence syntheses have thus far used a small number of relatively simple methods to address similarly written questions. Cochrane has invested in methodological work to develop new tools and to encourage the production of exemplar reviews to show the value of more innovative methods that address a wider range of questions. In this paper in the series we report updated guidance on the selection of tools to assess methodological limitations in qualitative studies, and methods to extract and synthesise qualitative evidence. We recommend application of GRADE-CERQual to assess confidence in qualitative synthesised findings. This guidance aims to support review authors to undertake a qualitative evidence synthesis that is intended to be integrated subsequently with the findings of one or more Cochrane reviews of the effects of similar interventions. The review of intervention effects may be undertaken concurrently with or separate to the qualitative evidence synthesis. We encourage further development through reflection and formal testing.

Keywords: Systematic review, qualitative research, qualitative evidence synthesis, methodological limitations, GRADE CERQual, Cochrane.

What is new?

The paper outlines new guidance and novel methods developments in the assessment of the methodological limitations of qualitative studies, methods for data extraction and qualitative evidence synthesis, expressing the synthesis and reporting review author reflexivity, and recommends use of GRADE-CERQual to assess the confidence in qualitative synthesised findings.

Key findings

The paper provides new guidance on the selection of tools to assess the methodological strengths and limitations of qualitative studies and how to use this information in decision making as the review progresses. Four approaches to qualitative data extraction are highlighted and new guidance is signposted on the selection of qualitative evidence synthesis methods from the spectrum of available methods. Application of GRADE-CERQual to assess confidence in synthesised qualitative findings will be of benefit to decision-makers. The reflexive processes of review authors need to be made more transparent.

What this adds to what was known?

The paper highlights that significant methodological work and progress has been made in the last five years in developing and applying qualitative evidence synthesis methods. The paper emphasises the benefits of undertaking and publishing further methodological exemplars that explore key methodological issues.

What is the implication and what should change now?

We recommend that review authors adopt and use this updated guidance to further improve the quality and utility of qualitative evidence syntheses for key stakeholders.

1.0 Introduction

This paper in the Cochrane Qualitative and Implementation Methods Group (CQIMG) series provides updated guidance on methods for assessing methodological strengths and limitations of included studies; data extraction; synthesis of qualitative evidence; expressing the synthesis; reporting review author reflexivity; and assessing confidence in synthesised qualitative findings.

This second paper follows on from Paper 1₁, which outlines guidance on question formulation, searching for evidence and protocol development for qualitative evidence syntheses. Paper 1 also provides good examples of questions that are best answered by synthesising findings from primary qualitative studies, building on the idea that an in-depth analysis of qualitative findings across studies creates potential to develop a better understanding, or more comprehensive models or theories, of the phenomena of interest. A better understanding of these issues can inform the design of interventions, strategies and health systems and their implementation to develop more personalised approaches that benefit patients and improve outcomes. Paper 4₂ provides guidance on integrating the qualitative evidence synthesis with evidence of intervention effectiveness, and paper 5₃ outlines guidance on the selection and application of relevant reporting guidelines. Finally, paper 3 provides guidance on designing a synthesis using a broader range of mixed-method evidence derived from process evaluations other types of studies that can be used to address implementation questions.

2.0 Assessment of study methodological strengths and limitations

The issue of why and how to judge the quality and more specifically the methodological strengths and limitations of qualitative studies and what to do with the assessments has long been debated among qualitative researchers with a range of, sometimes conflicting, proposals being made.⁴ Opinion remains divided as to the value of quality appraisal of qualitative evidence and a wider exploration of these issues can be found elsewhere.⁵⁻⁷

Qualitative researchers generally make an assessment of study quality by identifying methodological strengths and limitations (ie '*rigour*'). Although different criteria are used to establish qualitative '*rigour*' compared with '*risk of bias*' in quantitative studies, the information is used in a similar way to make judgements about the impact of methodological limitations of studies that contribute to synthesised findings. An example of the criteria used to assess study quality/methodological rigor using the Critical Appraisal Skills Programme (CASP) tool for qualitative studies is shown in Box 1. This CASP tool is currently the most commonly used tool in qualitative evidence syntheses in Cochrane and World Health Organisation (WHO) guideline processes.

Box 1. ©Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist

- | | Yes | Can't tell | No |
|---|-----|------------|----|
| 1. Was there a clear statement of the aims of the research? | | | |
| 2. Is a qualitative methodology appropriate? | | | |
| 3. Was the research design appropriate to address the aims of the research? | | | |
| 4. Was the recruitment strategy appropriate to the aims of the research? | | | |
| 5. Was the data collected in a way that addressed the research issue? | | | |
| 6. Has the relationship between researcher and participants been adequately considered? | | | |
| 7. Have ethical issues been taken into consideration? | | | |
| 8. Was the data analysis sufficiently rigorous? | | | |
| 9. Is there a clear statement of findings? | | | |
| 10. How valuable is the research? | | | |

Assessment of methodological strengths and limitations of included studies is considered essential to the Cochrane review process. In our initial guidance to review authors in 2008 and 2011, we used the term 'quality appraisal' and suggested that any 'verified' quality appraisal tool (of which there are hundreds) could be used to assess the quality of qualitative studies that met the review inclusion criteria. We have subsequently observed that quality appraisal practice, the choice and

application of tools, and the use of appraisal information has varied widely in both Cochrane and non-Cochrane reviews.

We are now able to provide guidance on the selection of a more narrowly defined set of tools that focus on assessing methodological strengths and limitations, and provide additional guidance on how to interpret and use information gained from assessments when developing review findings. A contemporary analysis of currently available tools to appraise the quality of qualitative studies is available, and this should be referred to in conjunction with the following updated guidance.⁸ We now recommend selection of published and commonly used tools that privilege and focus on the assessment of the methodological strengths and limitations of qualitative studies (Box 2).

Box 2. The domains that provide an assessment of methodological strengths and limitations should include, for example:

Clear aims and research question;

Congruence between the research aims/question and research design/method(s);

Rigour of case and or participant identification, sampling and data collection to address the question;

Appropriate application of the method; richness/conceptual depth of findings, exploration of deviant cases and alternative explanations, and reflexivity of the researchers.

The CASP tool in Box 1 maps onto the above domains.

It is important to clarify that these domains are not based on any empirical evidence, but have evolved from practice and are commonly accepted as reasonable considerations when assessing rigour. Readers should also refer to 4.0, where brief mention is made of methodological research into currently available tools that is being undertaken funded by Cochrane. Once this work is complete, we may issue a further update to this guidance.

Another important consideration is fully assessing methodological strengths and limitations will involve looking in all sections of the study report and not just the methods section. Not-for-profit organisations commonly publish their research outputs as reports and make these available via websites. This type of report is classified as grey literature. Our recommendation is to apply a method-specific quality appraisal tool regardless of whether a piece of research is reported in a peer-reviewed journal or the grey literature.

Tools that would not meet the criteria of focussing on assessment of methodological strengths and limitations include those that integrate assessment of the quality of reporting (such as scoring of the title and abstract etc) into an overall assessment of methodological strengths and limitations. Nor are reporting guidelines (see paper 5₃) recommended for assessing methodological strengths and limitations as their primary purpose is to ensure that critical information is included in the study report. A good research report featuring a transparent methodological audit trail is considered a marker of best reporting practice, but it tells us little about the rationale of authors for making particular methodological choices and how these influence development of findings.

Some tools that focus on assessing methodological strengths and limitations are generic for any qualitative research methodology (e.g., CASP, Qualitative Assessment and Review Instrument - QARI^{9,10}) whilst others are method specific, and the criteria used to judge the strengths and limitations of research studies may vary substantially across designs and methods. For justice-oriented, Arts-based or participatory action research studies, it is important to assess the involvement of stakeholders, equal access to the process and benefits of the research and enhancement of understanding among stakeholders.^{11,12}

Specific tools have also been developed to assess both quantitative and qualitative research within a single instrument.¹³ However, these may meet requirements for consistency at the expense of sensitivity to each of the components. The Mixed Method Appraisal Tool (MMAT) has been used widely in systematic reviews.¹⁴ The MMAT contains a unique set of quality indicators that allows review authors to assess the interdependent qualitative and quantitative components of a primary mixed method research study. The instrument further outlines a set of criteria that need to be taken into account when dealing with a primary mixed method study, such as whether or not there is a justification for mixing evidence and whether the way the quantitative and qualitative data are integrated is appropriate and meaningful.

2.1 Selecting a tool to assess study methodological strengths and limitations

Considerations when choosing a tool for assessment of primary qualitative studies are outlined in Box 3.

Box 3 - Considerations when choosing an approach to assessing the methodological strengths and limitations of qualitative studies.

1. What types of qualitative study designs/methods have been selected to address the synthesis question? What study designs/methods and types of qualitative evidence have been included and do the studies contain rich or thin descriptions? Will any type of study be particularly disadvantaged if methodological strengths and limitations are assessed using a specific tool? Would using more than one tool be optimal?
2. Will qualitative components from mixed-methods studies be included? Can the selected tool(s) be applied to assess the methodological strengths and limitations of this kind of evidence?
3. Will qualitative evidence from the grey literature be included? Consider using an appropriate tool for the study design.
4. Does the proposed tool(s) privilege assessment of methodological strengths and limitations and exclude domains on quality of reporting? Select the tool only if the answer is 'yes'.
5. What qualitative expertise and experience is available within the review team?
6. How familiar are the review authors with applying the proposed tool(s)?
7. If selecting a single tool - how complex is the tool, and how easy will it be to apply it to multiple primary study designs/methods?
8. Has the proposed tool already been used in the context of a qualitative evidence synthesis and, if so, how was it used and what can be learnt from this? Could it be used in a similar way in your qualitative evidence synthesis?

2.2 Undertaking assessments of study methodological strengths and limitations

Whichever tool is selected for whatever qualitative study design or method, an important guiding principle is that it should be used as a way of engaging with and better understanding the methodological strengths and limitations of primary studies. In line with contemporary thinking, applying scores to domains and calculating total quality scores should not be used, as not all domains of quality are equal, and therefore scores are not useful and may give a false sense of precision. Many review teams also use total quality scores as a cut-off point to determine inclusion or exclusion of studies; we do not advocate or support this practice as these cut offs are arbitrary and therefore not methodologically defensible. The preferred convention is for review authors to discuss the studies and the assessment outcome for each paper and determine how study methodological limitations play out at the level of review findings.

In completing the quality assessment process, it is considered best practice for more than one person to assess study quality and to agree concerns about study strengths and limitations by consensus. For transparency, it is helpful to report the assessment of methodological strengths and limitations for each study and each domain of quality in the appendices or additional online file of the qualitative evidence synthesis report. In making these recommendations we recognise the challenge of assessing methodological strengths and limitations of studies across different reporting standards and expectations across disciplinary and theoretical fields. We encourage parallel improvement of methods development and application, together with clear reporting of what has been undertaken to collect and analyse data as a complementary step to improving quality of conduct and reporting of qualitative evidence syntheses.

2.3 Using information on study methodological strengths and limitations to include or exclude studies

Decisions about inclusion or exclusion of studies can be more complex in qualitative evidence syntheses compared to reviews of trials that aim to include all relevant studies within a given timeframe. Methodological limitations of included studies may only be one consideration of many. Decisions on whether to include all studies or to include a sample of studies depend on a range of

general and review specific criteria (see Box 4). The guiding principle is transparency in the reporting of all decisions and their rationale. This should include a clear audit trail of evidence included or excluded from the review. Clarifying these considerations to the reader is an important step in producing methodological transparent qualitative and mixed-method syntheses.

Box 4. Examples of criteria to consider when deciding whether to include or exclude qualitative studies from a synthesis

- Size of the pool of relevant qualitative studies published within the specified time frame of the synthesis. Consider the adequacy of the review sample: is it likely that studies are sufficiently plentiful to develop a coherent finding with adequate and relevant data of sufficient methodological quality? Will any particular subgroups be poorly represented through application of an arbitrary methodological quality threshold?
- Need for inclusion of specific elements of context as specified in the qualitative evidence synthesis question. Consider whether all contextual elements are adequately represented in the included qualitative studies. Consider if it is desirable to include all relevant perspectives on the phenomena of interest and whether to do so would entail including studies with some methodological limitations.
- Need for the context of trials in the linked Cochrane intervention effect review(s) to map onto the context of studies in the qualitative evidence synthesis so that they can 'speak' to each other to facilitate the later integration of findings. Consider the contexts of the included trials and whether the contexts in the qualitative studies are sufficiently similar?
- Maturity of the topic (new or well established area). Consider where on the spectrum the specific topic lies and whether it is important to include all evidence if the topic is critically under researched or new? Could identifying gaps be an important function of the synthesis?
- Individual study methodological strengths and limitations. Consider any methodological concerns of individual studies and their contribution to the development and interpretation

of findings. What is the likelihood of excluding valuable insights on the basis of quality?

Consider if excluding a study will affect assessments of adequacy or coherence of qualitative synthesised findings¹⁵? Do multiple qualitative studies with methodological concerns report similar consistent findings?

- Need to report deviant/disconfirming cases or alternative lines of argument and refutational analyses. Consider if excluding qualitative studies will reduce ability to report alternative explanations and hypotheses?
- Ability of the selected method of synthesis to accommodate all or a sample of qualitative studies
- The tipping point at which adding another qualitative study is not likely to alter the review finding
- Expertise of the review authors
- Time available to complete the review

2.3.1 Example of a qualitative evidence synthesis that included all identified studies and suggested additional methods to determine impact of studies on findings

In a review which synthesised qualitative studies on the perspectives of children on healthy eating, all identified studies meeting the inclusion criteria for the review were included.¹⁶ The review authors examined the impact of excluding studies judged to be of lower methodological quality on the review findings. They found that the findings of the synthesis did not change regardless of whether the lower quality studies were included or excluded suggesting there may be little value in including studies which lack methodological rigour and conceptual depth. Sensitivity analyses is a recommended way to understand the contribution of different levels of quality of evidence in a review and should be reported in full.

2.3.2 Examples of qualitative evidence synthesis that included a sample of qualitative studies

A Cochrane qualitative evidence synthesis was undertaken to determine the barriers and facilitators to the implementation of lay health worker programmes globally.¹⁷ The qualitative evidence synthesis¹⁷ was then integrated with the Cochrane intervention effect review¹⁸ looking at similar interventions globally. The qualitative evidence synthesis privileged geographical context and relevance of evidence to the review question by purposively sampling qualitative studies to ensure a global representation from high, middle and low income countries. Achieving global representation was considered important as both reviews informed development of a WHO global guideline on the optimisation of health worker roles to deliver care in maternal, neonatal and child health settings.¹⁹

Review authors have also used a combination of three purposeful sampling techniques – intensity sampling, maximum variation sampling and confirming/disconfirming case sampling – in their review on sexual adjustment of cancer patients and their partners.²⁰ Focusing on conceptual robustness of data instead of generalization of the findings, the team was more sensitive to “deviant data”, i.e. information that may not have been picked up when synthesizing information from an exhaustive sample of the literature, because review authors are generally more focused on detecting commonalities between articles rather than differences.

3.0 Data extraction and synthesis

3.1 Extracting contextual and methodological information from the included studies

Irrespective of the review type and selection of synthesis method, it is considered best practice to extract contextual and methodological information on each study and to report this information in an included studies table (Table 1). The length and type of detail varies according to the report type. A Cochrane report requires a detailed summary of every study, whereas a journal report typically includes a distilled summary with only essential contextual and methodological information.

Thereafter, it is vitally important that the context of the primary study data is not lost during the synthesis process as the findings of the primary studies may be misinterpreted. To avoid this, review authors may want to refer back to the original papers during the analysis and synthesis process.

Data extraction field	Information extracted
<i>Context and participants</i>	Important elements of study context that are relevant to addressing the review question and locating the context of the primary study, such as: the study setting, population, participant characteristics and the intervention delivered (if appropriate) etc.
<i>Study design and methods used</i>	Methodological design and approach taken by the study; methods for identifying the sample recruitment; the specific data collection and analysis methods utilized; and any theoretical models used to interpret or contextualize the findings.

3.2 Extracting, analysing and synthesising findings from primary qualitative studies

The purpose of this guidance is to highlight methodological issues to consider when selecting methods and to signpost to more detailed external guidance to inform decision-making. We do not intend to provide detailed guidance on the application of particular extraction and synthesis methods as such guidance is provided in a number of other texts. Although some methods are more suited to a Cochrane context (such as thematic synthesis), Cochrane is receptive to registering exemplar reviews to demonstrate the value of other methods, particularly more complex or methods in development. For example, A Cochrane review included a realist synthesis as one component of an exemplar review protocol that incorporated several different review designs and methods to demonstrate different approaches, and an overarching synthesis to better understand what works for whom in which contexts to reduce repeat teenage conceptions.²¹

Methods for qualitative data extraction vary according to the synthesis method selected. Some methodologies are designed primarily to develop descriptive level findings feeding directly into lines of action for policy and practice (e.g meta-aggregation¹⁰). Others hold the capacity to develop new theory (e.g meta-ethnography²² and theory building approaches to thematic synthesis²³). Each qualitative evidence synthesis methodology is underpinned by epistemological assumptions and a set of specific principles, methods and processes. Qualitative evidence synthesis methods for addressing different question-types can be located on a 'realist to idealist' epistemological continuum²⁴. We recommend this paper²⁴ as essential contextual reading when selecting methods.

The CQIMG endorses the INTEGRATE-HTA guidance ²⁵ on selecting methodology and methods for qualitative evidence synthesis in a health technology assessment context as the starting point for selecting an appropriate methodology, and methods such as data extraction. A plethora of different approaches to synthesizing qualitative evidence have evolved that vary in complexity and in their methods of sampling, data extraction and synthesis. Choice of methodology and methods depend on multiple factors, incorporated in the RETREAT (Research question, Epistemology, Time/Timeframe, Resources, Expertise, Audience & Purpose, Type of Data) framework, for review authors to consider when selecting a methodology/method.²⁵ Review authors are advised to consider these selection criteria when deciding which methodologies and methods are appropriate for their review. Subsequent reference should then be made to more detailed methods manuals, guidance and published examples of the selected approach. Review authors may not be able to select an appropriate design and method until the pool of available qualitative evidence becomes known.

For completeness, we add a note of clarification in Box 5 concerning the 4 stage 'Narrative Synthesis' approach²⁶.

Box 5. Clarification concerning the 4 stage Narrative Synthesis approach. ²⁶

The 4 stage 'Narrative Synthesis' approach ²⁶ is designed to facilitate the integration of quantitative and qualitative evidence of intervention effect and implementation factors. Many review authors are selecting specific tools from the tool box of this 4 stage methodology and incorrectly identifying the Narrative Synthesis approach as primarily a method for synthesising qualitative evidence. We advise that review authors obtain and read the entire methods manual to determine the appropriate application of this integrative approach to the synthesis of qualitative and quantitative evidence.

3.3 Locating qualitative findings in qualitative study reports

Methods such as meta-ethnography have been applied in conjunction with an adaption of Schultz' typology of findings, which can be used when extracting data from primary studies.²⁷ In a qualitative evidence synthesis context, participant quotes have been classified as 1st order constructs; themes, author explanations and recommendations as 2nd order interpretations; and new insights derived from a synthesis of studies as 3rd order interpretations.²²

Qualitative findings may be in the form of quotes from participants, sub themes and themes, explanations, hypotheses or new theory, or observational excerpts and author interpretations of these data. Findings may be presented as a narrative, or summarised and displayed in various ways in tables, infographics and logic models.

It should be noted that useful findings in qualitative studies may be found outside of the section labelled "results or findings". For example, a discussion of the theoretical framework used to interpret data may be discussed in the background or methods section. In addition, some journals prefer the authors' interpretations of their data to be in the discussion section, not in the results, and it is not uncommon to find more interpretative theoretical findings discussed here.

Increasingly findings and additional explanations can be located in supplemental online only files. Again, whether or not review authors opt for the inclusion of interpretive parts in findings or

discussion sections depends on what they consider appropriate as 'findings' to be used as building blocks for a synthesis, and how they define the role of the reviewer in a review project. Reviewers taking an idealist stance are more likely to include 'interpretations of primary authors' as a 'finding', while realist reviewers are more likely to remain close to the 'original findings' reported in result sections.

3.4 Spectrum of method-specific approaches to data extraction

There are several method-specific approaches to the identification, extraction, analysis and synthesis of qualitative evidence. Regardless of method, a key principle of qualitative data extraction, analysis and synthesis is that the process is not sequential and linear. It typically involves moving backwards and forwards between these review stages. Completing the iterative review stages will benefit from regular team meetings to discuss and further interrogate the evidence to achieve a shared understanding, and it may be helpful to draw on a key stakeholder group to support interpretation of evidence and formulation of key findings. Additional approaches (such as subgroup analyses) can be used within the synthesis to further explore the evidence pertaining to specific contexts.

3.4.1 Using a bespoke universal, standardised or adapted data extraction template

Review authors can develop their own review-specific data extraction template, or select a bespoke data extraction template that can be used in a Cochrane context for any study type (such as the template developed by the National Institute for Health and Care Excellence (NICE)).²⁸ The NICE template also provides a good guide for review authors wishing to develop a review-specific extraction template.

3.4.2 Using an a priori extraction conceptual framework to extract data

Framework synthesis and the 'Best Fit' Framework approach both involve extracting data from primary studies against an a priori framework or conceptual/theoretical framework in order to better understand phenomena of interest.^{29,30} Cochrane have recently published guidance for review authors on the selection and application of social theories in systematic reviews that can be used to aid the extraction, analysis and synthesis of evidence.³¹ For example, Glenton¹⁷ extracted

data against a modified SURE Framework³² to develop a thematic synthesis of factors affecting the implementation of lay health worker interventions. The SURE framework provides a comprehensive list of possible factors that may influence the implementation of health system interventions.³² Equity criteria, expressed as the acronym 'PROGRESS' (referring to place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status, and social capital), may help to ensure that data extraction has an explicit equity focus.³³

3.4.3 Using a software programme to inductively code original studies

A wide range of software products have now been developed by systematic review organisations and most software for the analysis of primary qualitative data can be used for coding studies in a systematic review. For example, one specific method of data extraction, analysis and thematic synthesis involves coding the original studies using a software programme to build inductive themes and a theoretical explanation of phenomena of interest.²³ A detailed worked example is provided as to how they coded and developed a new understanding of children's choices and motivations to eating fruit and vegetables from included primary studies.²³

3.4.4 Using a logic model of the programme theory to inform data extraction, analysis and synthesis

Review authors are increasingly developing logic models to show how an intervention is intended to work. Logic models can also be developed to show causal mechanisms leading to impacts and outcomes, and factors that lead to implementation success and failure, including human factors such as patient preferences and experiences.³⁴⁻³⁶

For example, all Cochrane reviews of intervention effects are supposed to describe how the intervention is intended to work and Realist syntheses³⁷ begin with development of initial programme theories or theory areas. Logic models can then be developed and used to search for, extract and map evidence of interest in order to achieve a better understanding of specific phenomena of interest and mechanisms of action that lead to impacts and outcomes.³⁵ A clearer understanding of mechanisms of action can in turn be used to further develop the logic model, which can then be

used to look for additional evidence that will help with more complex and nuanced explanations and hypotheses.³⁶

4.0 Assessing confidence in syntheses findings

We recommended use of the GRADE-CERQual approach¹⁵ (Grades of Recommendation, Assessment, Development and Evaluation - Confidence in the Evidence from Qualitative Reviews, henceforth referred to as CERQual) to assessing confidence in synthesised qualitative findings. The approach was developed with part-funding from the Cochrane Methods Innovation Fund. The CERQual approach includes four components for assessing how much confidence to place in findings: the methodological limitations of the individual qualitative studies contributing to a review finding; the relevance to the review question of the individual studies contributing to a review finding; the coherence of the review finding; and the adequacy of data supporting a review finding. Additional guidance on applying the CERQual approach can at the website (www.cerqual.org). The Cochrane qualitative Methodological Limitations Tool (CAMELOT) for use with CERQual is currently in development (<http://methods.cochrane.org/methods-innovation-fund-2>).

5.0 Expressing the synthesis

Methods for expressing the synthesis have evolved considerably since our previous guidance. There are now good examples of visual and narrative presentations that use tables, conceptual diagrams, models and infographics to display findings and the contribution of studies to findings. See for example reporting a line of argument synthesis³⁷ and reporting of processes and findings.^{22,39} More recently, summary of qualitative findings tables have been introduced in various formats from simple to detailed.¹⁵ Some reviews present complex logic models and theories as the end point of the synthesis.¹⁷

6.0 Review author reflexivity

We previously highlighted that a key marker of methodological quality in primary qualitative studies is the reflexivity of the researchers, including how they make transparent their potential and actual impacts on the research context, participants and interpretation of findings. Likewise, review authors should make transparent their conflicts of interests, prior beliefs and potential/actual prejudices with potential to impact on data interpretation.

7.0 Conclusion

This paper offers new guidance to support the assessment of methodological strengths and limitations, data extraction and synthesis, particularly in the context of systematic reviews produced within Cochrane. This guidance is intended to raise awareness of the methodological advances and evaluation of qualitative evidence synthesis methods, and areas of future methodological development. We hope that updated guidance will further stimulate a change in reviewing practices towards the judicious use of systematic methods and tools, and to encourage further development through reflection and formal testing.

The methods and tools that we have highlighted have all been tested in qualitative evidence syntheses. Methods and tools are still emerging, however, and it is important to generate more worked examples of methods and application of methods in exemplar reviews to understand the key analytic and methodological choices made and the challenges experienced.

References

1. Paper 1: Methods for question formulation, searching and protocol development for qualitative evidence synthesis.
2. Paper 4: Methods for integrating findings from syntheses of qualitative and process evaluation evidence with intervention effectiveness reviews.
3. Paper 5: Reporting guidelines for qualitative, implementation and process evaluation evidence syntheses.
4. Sparks AC. Myth 94: Qualitative health researchers agree about validity. *Qual Health Res.* 2001;11(4):538-552
5. Garside, R. (2014). Should we appraise the quality of qualitative research reports for systematic reviews, and if so, how?. *Innovation: The European Journal of Social Science Research*, 27(1), 67-79.

6. Sandelowski, M. (2015). A matter of taste: evaluating the quality of qualitative research. *Nursing inquiry*, 22(2), 86-94.
7. Carroll, C., and Booth, A. (2015) Quality assessment of qualitative evidence for systematic review and synthesis: Is it meaningful, and if so, how should it be performed?. *Res. Syn. Meth.*, 6: 149–154.
8. Santiago-Delefosse, M, Gavin A, Bruchez, C, Roux, P, Stephen SL, Quality of qualitative research in the health sciences: Analysis of the common criteria present in 58 assessment guidelines by expert users, *Social Science & Medicine*, Volume 148, January 2016, Pages 142-151.
9. CASP – Critical Appraisal Skills Programme. (2013 version) Making sense of evidence: 10 questions to help you make sense of qualitative research. Public Health Resource Unit, England http://media.wix.com/ugd/dded87_29c5b002d99342f788c6ac670e49f274.pdf. Accessed 4.4.16
10. Hannes, K., Lockwood, C. (2011). Pragmatism as the philosophical underpinning of the Joanna Briggs meta-aggregative approach to qualitative evidence synthesis. *Journal of Advanced Nursing*, 67 (7), 1632-1642.
11. Saini, M. & Shlonsky, A. 2012 (pp 133-135). *Systematic synthesis of Qualitative Research*. Oxford: Oxford University Press.
12. Barone, T. & Eisner, E. (2012). *Arts based Research*. Thousand Oaks: Sage
13. Heyvaert, M., Hannes, K., Maes, B., & Onghena, P. (2013). Critical appraisal of mixed methods studies. *Journal of Mixed Methods Research*, 7, 302-327. doi:10.1177/1558689813479449
14. Pluye P, Gagnon M-P, Griffiths F and Johnson-Lafleur J. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in mixed studies reviews. *International Journal of Nursing Studies* 2009;46(4):529–46. <http://dx.doi.org/10.1016/j.ijnurstu.2009.01.009>.
15. Thomas J, Harden A, Oakley A, Oliver S, Sutcliffe K, Rees R, Brunton G, Kavanagh F. (2004) Integrating Qualitative Research with trials in systematic reviews: an example review from public health shows how integration is possible and some potential benefits. *BMJ* 328: 1010-12
16. Lewin S, Glenton C, Munthe-Kaas H, et al. Using qualitative evidence in decision making for health and social interventions: an approach to assess confidence in findings from qualitative evidence syntheses (GRADE-CERQual). *PLoS Med* 2015;**12**(10):e1001895.
17. Glenton C., Colvin C.J., Carlsen B., Swartz A., Lewin S., Noyes J. & Rashidian A. (2013) Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis. *Cochrane Database Systematic Review* 10, CD010414.
18. Lewin S, Munabi-Babigumira S, Glenton C, Daniels K, Bosch-Capblanch X, van Wyk BE, Odgaard-Jensen J, Johansen M, Aja GN, Zwarenstein M, Scheel IB. Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Database of Systematic Reviews* 2010, *Issue 3*. Art. No.: CD004015.
19. WHO. Optimizing health worker roles for maternal and neonatal health. www.optimizemnh.org Accessed 16.03.16
20. Benoot, C., Hannes, K., Bilsen, J. (2016). The use of purposeful sampling in a QES: A worked example on sexual adjustment to a cancer trajectory. *BMC Medical Research Methodology*, 16 (21), 1-12.

21. Whitaker, R., Hendry, M., Booth, A., Carter, B., Charles, J., Craine, N., ... & Rycroft-Malone, J. (2014). Intervention Now To Eliminate Repeat Unintended Pregnancy in Teenagers (INTERUPT): a systematic review of intervention effectiveness and cost-effectiveness, qualitative and realist synthesis of implementation factors and user engagement. *BMJ open*, 4(4), e004733.
22. Campbell R, et al. Evaluating meta-ethnography: systematic analysis and synthesis of qualitative research. *Health Technol Assess* 2011;15(43):1-164.
23. Thomas, J., & Harden, A. (2008). Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC medical research methodology*, 8(1), 1.
24. Barnett-Page, E., & Thomas, J. (2009). Methods for the synthesis of qualitative research: a critical review. *BMC medical research methodology*, 9(1), 1.
25. BOOTH, A., NOYES J, FLEMMING K, GERHARDUS, A., WAHLSTER, P., VAN DER WILT, G.J., MOZYGEMBA, K., REFOLO, P., SACCHINI, D., TUMMERS, M., REHFUESS, E. (2016) Guidance on choosing QES methods for use in health technology assessments of complex interventions [Online]. Available from: <http://www.integrate-hta.eu/downloads/>
26. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, Britten N Guidance on the conduct of narrative synthesis in systematic reviews. <http://www.lancs.ac.uk/fass/projects/nssr/2007>.
27. Schutz A. 1962 Collected papers, vol 1. The Hague: Martinus Nijhoff.
28. NICE (2006) Methods for development of NICE public health guidance, NICE UK. Available at: <http://www.nice.org.uk/phmethods> Accessed 18th March 2016
29. Carroll, C., Booth, A., & Cooper, K. (2010). A worked example of "best fit" framework synthesis: a systematic review of views concerning the taking of some potential chemopreventive agents. *BMC medical research methodology*, 11, 29-29.
30. Carroll, C., Booth, A., Leaviss, J., & Rick, J. (2013). "Best fit" framework synthesis: refining the method. *BMC medical research methodology*, 13(1), 1.
31. Noyes J, Hendry M, Booth A, Chandler J, Lewin S, Glenton C, Garside R. Current use was established and Cochrane guidance on selection of social theories for systematic reviews of complex interventions was developed. *J Clin Epidemiol*. 2016 Jan 6. pii: S0895-4356(16)00005-6.
32. SURE Framework (2011) The SURE (Supporting the Use of Research Evidence) Collaboration. *SURE Guides for Preparing and Using Evidence-based Policy Briefs: 5. Identifying and Addressing Barriers to Implementing the Policy Options*. Version 2.1, updated November 2011. The SURE Collaboration; 2011. URL: <http://global.evipnet.org/SURE-Guides/> (accessed 13 March 2016).
33. Tugwell P, Petticrew M, Kristjansson E, Welch V, Ueffing E, Waters E, Bonnefoy J, Morgan A, Doohan E, Kelly MP. Assessing equity in systematic reviews: realising the recommendations of the Commission on Social Determinants of Health. *BMJ*. 2010 Sep 13;341:c4739. doi: 10.1136/bmj.c4739.
34. Anderson, L. M., Petticrew, M., Rehfuss, E., Armstrong, R., Ueffing, E., Baker, P., Francis, D. and Tugwell, P. (2011), Using logic models to capture complexity in systematic reviews. *Res. Synth. Method*, 2: 33–42. doi: 10.1002/jrsm.32
35. Kneale, D., Thomas, J., & Harris, K. (2015). Developing and optimising the use of logic models in systematic reviews: Exploring practice and good practice in the use of programme theory in reviews. *PLoS ONE*, 10 (11). doi:10.1371/journal.pone.0142187

36. Turley R, Saith R, Bhan N, Doyle J, Jones K, Waters E. Slum upgrading review: methodological challenges that arise in systematic reviews of complex interventions. *J Public Health (Oxf)*. 2013 Mar;35(1):171-5. doi: 10.1093/pubmed/fdt008.
37. Pawson R, Tilley N: *Realistic Evaluation*. London: Sage; 1997.
38. Garside R, Britten N, Stein K. (2008) The experience of heavy menstrual bleeding: a systematic review and meta-ethnography of qualitative studies. *J Adv Nurs*. 63(6):550-62. doi: 10.1111/j.1365-2648.2008.04750.x.
39. Malpass A, Shaw A, Sharp D, Walter F, Feder G, Ridd M, Kessler D. "Medication career" or "moral career"? The two sides of managing antidepressants: a meta-ethnography of patients' experience of antidepressants. *Soc Sci Med*. 2009 Jan;68(1):154-68.