

**COCHRANE QUALITATIVE AND IMPLEMENTATION METHODS
GROUP GUIDANCE SERIES****Cochrane Qualitative and Implementation Methods Group guidance
series—paper 3: methods for assessing methodological limitations, data
extraction and synthesis, and confidence in synthesized qualitative findings**

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Abstract

The Cochrane Qualitative and Implementation Methods Group develops and publishes 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 synthesize qualitative evidence. We recommend application of Grades of Recommendation, Assessment, Development, and Evaluation—Confidence in the Evidence from Qualitative Reviews to assess confidence in qualitative synthesized 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. © 2017 Elsevier Inc. All rights reserved.

Keywords: Systematic review; Qualitative research; Qualitative evidence synthesis; Methodological limitations; GRADE CERQual; Cochrane

1. 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 synthesized qualitative findings.

This third paper follows on from Paper 2 [1], which outlines guidance on question formulation, searching for evidence and protocol development for qualitative evidence syntheses. Paper 2 also provides good examples of questions that are best answered by synthesizing findings from primary

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What is new?

- The paper outlines new guidance and novel method 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 the use of Grades of Recommendation, Assessment, Development, and Evaluation—Confidence in the Evidence from Qualitative Reviews (GRADE-CERQual) to assess the confidence in qualitative synthesized 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 synthesized 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 5 years in developing and applying qualitative evidence synthesis methods. The paper emphasizes 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.

qualitative studies, building on the idea that an in-depth analysis and synthesis 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 personalized approaches that benefit patients and improve outcomes. Paper

5 [2] provides guidance on integrating the qualitative evidence synthesis with evidence of intervention effectiveness, and paper 6 [3] outlines guidance on the selection and application of relevant reporting guidelines. Finally, paper 4 provides guidance on designing a synthesis using a broader range of mixed-method evidence derived from process evaluations and other types of studies that can be used to address implementation questions [4].

2. 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 [5]. Opinion remains divided as to the value of quality appraisal of qualitative evidence, and a wider exploration of these issues can be found elsewhere [6–8].

Qualitative researchers generally make an assessment of study quality by identifying methodological strengths and limitations (i.e., “rigor”). Although different criteria are used to establish qualitative “rigor” compared with “risk of bias” in quantitative studies, the information is used in a similar way to make judgments about the impact of methodological limitations of studies that contribute to synthesized 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 Organization (WHO) guideline processes.

Assessment of methodological strengths and limitations of included studies are considered essential to the Cochrane

Box 1 CASP[®] qualitative research checklist

1. Was there a clear statement of the aims of the research?
Yes Cannot tell No
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?

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 have 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 [9]. 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).

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 rigor. Readers should also refer to Section 4, 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 organizations commonly publish their research outputs as reports and make these available via websites. This type of report is classified as gray 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 gray literature.

Tools that would not meet the criteria of focusing 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 6 [3]) recommended for assessing methodological strengths and limitations because 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 [10,11]), whereas 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 [12,13].

Specific tools have also been developed to assess both quantitative and qualitative research within a single instrument [14]. 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 [15]. 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.

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);
- Rigor 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.

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.

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

Box 3 Considerations when choosing an approach to assess 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 gray 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 learned from this? Could it be used in a similar way in your qualitative evidence synthesis?

primary studies. In line with contemporary thinking, applying scores to domains and calculating total quality scores should not be used because 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 cutoff point to determine inclusion or exclusion of studies; we do not advocate or support this practice because these cutoffs 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 recognize 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 analyze data as a complementary step to improve 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 with reviews of trials that aim to include all relevant studies within a given time frame. 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.

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 synthesized qualitative studies on the perspectives of children on healthy eating, all identified studies meeting the inclusion criteria for the review were included [17]. 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 rigor and conceptual depth. Sensitivity analysis 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 programs globally [18]. The qualitative evidence synthesis [18] was then integrated with the Cochrane intervention effect review [19] looking at

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 synthesized findings [16]? Do multiple qualitative studies with methodological concerns report similar consistent findings?
- Need to report deviant/disconfirming cases or alternative lines of argument and reputational analyses. Consider if excluding qualitative studies will reduce the 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

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 because both reviews informed development of a WHO global guideline on the optimization of health worker roles to deliver care in maternal, neonatal, and child health settings [20].

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 [21]. Focusing on conceptual robustness of data instead of generalization of the findings, the team was more sensitive to “deviant data”, that is, 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. 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 because the findings of the primary studies may be

Table 1. Contextual and methodological information for insertion in an included study table

Data extraction field	Information extracted
Context and participants	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) and so forth.
Study design and methods used	Methodological design and approach taken by the study; methods for identifying the sample recruitment; the specific data collection and analysis methods used; and any theoretical models used to interpret or contextualize the findings.

Table 2. Recommended methods for undertaking a qualitative evidence synthesis for subsequent integration with an intervention effect review and use in decision-making

Likely to be most suitable		Requires some caution in its use		Requires more caution in its use	
Methodology	Explanation	Methodology	Explanation	Methodology	Explanation
Thematic Synthesis (Thomas & Harden) [23]	<p>Pros: Most accessible form of synthesis. Clear approach, can be used with ‘thin’ data to produce descriptive themes and with ‘thicker’ data to develop descriptive themes in to more in-depth analytic themes. Themes are then completely integrated within any quantitative synthesis</p> <p>Cons: May be limited in interpretive ‘power’ and risks over- simplistic use and thus not truly informing guideline development</p> <p>Complex synthesis process that requires an experienced team. Theoretical findings may combine empirical evidence, expert opinion and conjecture to form hypotheses. More work is needed on how CERQual can be applied to theoretical findings. May lack clarity on how higher level findings translate into actionable points.</p>	Framework Synthesis Best-fit Framework Synthesis (Carroll et al) [24,25]	<p>Pros: Works well within reviews of complex interventions by accommodating complexity within the framework, including representation of theory. The framework allows a clear mechanism for integration of qualitative and quantitative evidence in an aggregative way.</p> <p>Works well where there is broad agreement about the nature of interventions and their desired impacts.</p> <p>Cons: Requires identification, selection and justification of framework.</p> <p>A framework may only be revealed as inappropriate once extraction/synthesis is underway</p> <p>Risk of simplistically forcing data into a framework for expedience</p>	Meta-Ethnography (Campbell et al.) [26]	<p>Pros: Primarily interpretive synthesis method leading to creation of descriptive as well as new high order constructs. Descriptive and theoretical findings can help inform guideline development. Explicit reporting standards have been developed.</p> <p>Cons: Complex methodology and synthesis process that requires highly experienced team. Can take more time and resources than other methodologies. Theoretical findings may combine empirical evidence, expert opinion and conjecture to form hypotheses. May not satisfy requirements for an audit trail (although new reporting guidelines will help overcome this. More work is needed to determine how CERQual can be applied to theoretical findings. May be unclear how higher level findings translate into actionable points.</p>

Reproduced from Flemming et al [22], from an original source developed by convenors.

misinterpreted. To avoid this, review authors may want to refer back to the original papers during the analysis and synthesis process.

3.2. Extracting, analyzing, and synthesizing 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 because such guidance is provided in a number of other texts. Although some methods are more suited to a Cochrane context (such as thematic synthesis see Table 2, 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 [27].

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-aggregation [11]). Others hold the capacity to develop new theory (e.g., meta-ethnography [26] and theory-building approaches to thematic synthesis [23]). 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 continuum [28]. We recommend this paper [28] as an essential contextual reading when selecting methods.

The CQIMG endorses the INTEGRATE-Health Technology Assessment guidance [29] 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 Research question, Epistemology, Time/Timeframe, Resources, Expertise, Audience & Purpose, Type of Data framework, for review authors to consider when selecting a methodology/method [29]. Review authors are advised to consider these selection criteria when deciding which methodologies and methods are appropriate for their review. Flemming et al. [22] further elaborate on previous advice and cautions to facilitate selection of a method that is particularly suited to a Cochrane and decision-making context, where a qualitative evidence synthesis may be added to explore issues of complexity (Table 2). 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.

Cochrane is open to considering new exemplars to demonstrate the value of other methods not listed in Table 2. Review authors are advised to contact the Qualitative and Implementation Methods Group Convenors before proceeding.

For completeness, we add a note of clarification in Box 5 concerning the four stage “narrative synthesis” approach [30].

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 [31]. In a qualitative evidence synthesis context, participant quotes have been classified as first order constructs; themes, author explanations and recommendations as second order interpretations; and new insights derived from a synthesis of studies as third order interpretations [26].

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 summarized 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 labeled “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”, whereas 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 backward and forward 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, standardized, 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

Box 5 Clarification concerning the four stage narrative synthesis approach [30]

The four stage “narrative synthesis” approach [30] 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 four stage methodology and incorrectly identifying the narrative synthesis approach as primarily a method for synthesizing 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.

study type (such as the template developed by the National Institute for Health and Care Excellence [NICE]) [32]. 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 to better understand the phenomena of interest [24,25]. 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 [33]. For example, Glenton et al. [18] extracted data against a modified Supporting the Use of Research Evidence framework [34] to develop a thematic synthesis of factors affecting the implementation of lay health worker interventions. The Supporting the Use of Research Evidence framework provides a comprehensive list of possible factors that may influence the implementation of health system interventions [34]. 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 [35].

3.4.3. Using a software program to inductively code original studies

A wide range of software products have now been developed by systematic review organizations, 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 program 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 fruits and vegetables from included primary studies [23].

3.4.4. Using a logic model of the program 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 [36–38].

For example, all Cochrane reviews of intervention effects are supposed to describe how the intervention is intended to work, and realist syntheses [39] begin with the development of initial program theories or theory areas. Logic models can

then be developed and used to search for, extract, and map evidence of interest to achieve a better understanding of specific phenomena of interest and mechanisms of action that lead to impacts and outcomes [37]. 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 [38].

4. Assessing confidence in syntheses findings

We recommended the use of the Grades of Recommendation, Assessment, Development, and Evaluation—Confidence in the Evidence from Qualitative Reviews (CERQual) approach [16] to assess confidence in synthesized 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 be seen at the website (www.cerqual.org) and in a forthcoming series in Implementation Science. The Cochrane Qualitative Methodological Limitations Tool for use with CERQual is currently in development (<http://methods.cochrane.org/methods-innovation-fund-2>).

5. 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 synthesis [39,40] and reporting of processes and findings [26,41]. More recently, summary of qualitative findings tables have been introduced in various formats from simple to detailed [16]. Some reviews present complex logic models and theories as the end point of the synthesis [18].

6. 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. Similarly, review authors should make transparent their conflicts of interests, prior beliefs, and potential/actual prejudices with potential to impact on data interpretation.

7. Conclusion

This paper offers new guidance to support the assessment of methodological strengths and limitations and 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.

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