Chapter 7. Assessing methodological strengths and limitations of qualitative studies

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Key points

- The confidence in and usefulness of synthesised findings for decision making is in part dependent on the quality of included studies.
- Methodological limitations in the design or conduct of a primary study may pose a threat to study trustworthiness.
- Assessment of methodological strengths and limitations in primary qualitative studies is considered essential for qualitative evidence syntheses (QESs) published in Cochrane and Campbell libraries and this assessment is also required for a GRADE-CERQual assessment of confidence in synthesised qualitative findings.
- Rigorously conducted qualitative studies are those that have been assessed as having no, minimal or minor methodological limitations.
- Selection of an appropriate tool to support assessment of methodological limitations is challenging; of the many tools available the majority are neither evidence-based nor designed for use in a QES.
- The Cochrane Qualitative Methodological Limitations Tool (CAMELOT) has been developed for use in a QES and with GRADE-CERQual. CAMELOT is evidence-based and is designed to facilitate a consistent, systematic and transparent process to identify methodological limitations in primary studies.

- Review authors should focus on how specific methodological limitations in included studies may weaken their overall assessment of confidence in the findings synthesised from these studies.
- Guidance on assessing methodological strengths and limitations of process evaluations and intervention implementation evidence remains underdeveloped.

7.1 Introduction

Qualitative evidence syntheses (QESs) and mixed-methods reviews with a qualitative component are increasingly used to support decision making (Carroll, 2017; Langlois et al., 2018). The degree to which QES findings are useful depends in part on the quality of the primary studies included in the synthesis. Variations in study quality may explain variations in findings from primary studies. The degree to which primary study findings can be trusted to accurately represent the phenomenon of interest depends on: the design and conduct of the study, how all the selected methods and processes fit together, how the protocol was realised and the study operationalised, the conflicts of interest and biases of the researchers and stakeholders involved, and how well the study is reported.

This chapter is important because assessing the methodological strengths and limitations of studies often poses significant challenges for QES authors (Munthe-Kaas et al, 2019). The process has lacked standardisation with many tools to select from, few of which are fit for purpose. Review authors have been inconsistent in how they have applied tools and in how they have interpreted and reported the resulting assessments. Irrespective of the tool selected, individual assessments are typically based on judgements that may vary among review authors (Dixon-Woods et al., 2007). Review authors who are familiar with assessing *'risk of bias'* in trials of interventions may inappropriately apply 'risk of bias' terminology and assessment criteria when assessing qualitative studies. The approach for assessing qualitative studies involves establishing risks to study rigour or trustworthiness. For simplicity, this chapter generally refers to 'study trustworthiness' as encompassing study rigour.

To address the lack of standardisation, the Cochrane Methodological Innovation Fund invested in the development of the **C**ochrane qu**a**litative **Me**thodological **L**imitati**o**ns **T**ool (CAMELOT) for use with GRADE-CERQual. This chapter introduces CAMELOT for use in Cochrane and Campbell reviews (Munthe-Kaas et al., 2024). The use of the predefined and

evidence-based CAMELOT criteria to make assessments of methodological strengths and limitations should enable review authors to standardise their evaluations and be explicit and transparent about their judgments (Munthe-Kaas et al., 2018). Standards and tools, which can be supplemented by informed expert judgement, are highly useful for those less familiar with qualitative research (Torrance, 2012). Judgements derived from using tools are generally superior to ad hoc, unclear judgments of quality in that they provide review authors with a systematic and transparent approach. Tool-based judgements are further enhanced where the review authors have extensive experience of the specific tool or where they possess considerable knowledge/experience of primary qualitative research and the topic. When review authors undertake an assessment of methodological strengths and limitations of included studies in a QES well, using an evidence-based tool, they are promoting overall review quality and usability by decision makers.

An assessment of methodological strengths and limitations is considered essential for any review with a qualitative component for publication in the Cochrane and Campbell libraries. When preparing a QES intended for the Cochrane Library, review authors apply GRADE-CERQual to assess the confidence in synthesised findings. One of the four components of GRADE-CERQual is an assessment of methodological limitations of the primary studies contributing to a review finding. This process entails conducting an assessment of each primary study, as described in this chapter. Chapter 13 provides guidance on the GRADE-CERQual approach and illustrates why and how to undertake and report an assessment of methodological limitations in primary qualitative studies as one component within an overall assessment of confidence in synthesised qualitative findings.

Primary qualitative research studies vary substantially in terms of their design, conduct and reporting. Researchers select from a choice of methodologies (e.g. ethnography, phenomenology, grounded theory), methods of data collection (e.g. interviews, focus groups and observations) and methods of analysis (e.g. framework analysis, thematic analysis, content analysis, constant comparative analysis). As exemplified by the CAMELOT tool, the mapping of a study's 'fit' of methodology and methods against its research question and phenomena of interest helps to determine the extent to which the study was designed and/or conducted in an appropriate and rigorous manner.

This chapter describes why and how to assess methodological strengths and limitations of the qualitative studies included in a QES and provides review authors with guidance and considerations to further improve the quality of these assessments and their reporting. Box 1 provides an explanation for why study reporting quality is not covered in this chapter (signposting to tools that support an assessment of reporting quality is done in Chapter 20), and cross references additional tools to assess study conceptual richness and contextual thickness located in Chapter 6.

Box 1. Note on reporting quality and tools for assessing study conceptual richness and contextual thickness.

- This chapter does not include assessment of reporting quality. Chapter 20 signposts reporting checklists for primary qualitative studies. However, while a well reported study is easier to assess for methodological quality, it can still contain methodological limitations. Some QES authors also incorrectly select reporting guidelines to assess methodological limitations.
- Chapter 6 provides definitions, further tools and guidance on the assessment of study conceptual richness and contextual thickness within a QES sampling strategy. Although studies that report conceptually rich and contextually thick findings tend to be also rigorously conducted, they still need to undergo an assessment of their methodological strengths and limitations.

This chapter first defines the interrelated concepts and criteria most closely related to study quality in primary qualitative studies and introduces the new CAMELOT tool. The next section focuses on general processes: how and when to assess methodological strengths and limitations in a QES and how to choose a tool that will be appropriate for given synthesis methods. Practical considerations and procedures for undertaking, presenting and using assessments are explained, with reference to specific study designs (e.g. interview, questionnaire-based and mixed-method) and review purposes (e.g. the evaluation of intervention processes and implementation). Brief details on how to apply the CAMELOT tool is supported by reference to additional guidance and resources. Finally, the chapter discusses equity, diversity and inclusion, stakeholder engagement and involvement and reflexivity in relation to the assessment of methodological strengths and limitations.

7.2 Quality concepts and criteria in qualitative research

Lincoln and Guba identified *trustworthiness* (also referred to as *rigour*) as the prime conceptual marker of overall study quality comprising four criteria (Lincoln et al., 1985). These are presented below together with simplified explanatory notes derived from Lincoln and Guba's work and the later work of Koch and Harrington (1998):

- *Credibility*: use of a rigorous and transparent research process whereby it should be possible to recognize similar findings across various data sources;
- *Transferability*: presentation of reasoning or evidence that enable judgements as to whether or not the findings could be transferred to another setting;
- *Dependability*: evidence of consensus between two or more people regarding the accuracy, relevance and meaning of the data;
- *Confirmability*: presentation of clear links between data, analytic processes and findings (when credibility, transferability and dependability issues have been addressed).

Lincoln and Guba's conceptualisation of *trustworthiness* and the four associated criteria outlined above are also closely tied to concepts generally associated with study quality, such as truth value, applicability, consistency and neutrality (Lincoln et al., 1985). Others (e.g. Koch and Harrington, 1998) have placed additional emphasis on the importance of reflexivity (Koch et al., 1998). These concepts and their application in the assessment of studies within a QES are outlined in Table 7.1.

Table 7.1 – Conceptualisations of study quality and their application for assessing methodological strengths and limitations of qualitative studies included in a QES.

Concepts used across research types (qualitative and quantitative) for various dimensions of quality	**Term(s) used for this concept in qualitative research studies[1]**	**Included in assessment of methodological limitations of primary studies using CAMELOT**
A. For an overall assessment (see below for contributing criteria and processes)		
Overall methodological (study) quality Includes assessment of methodological quality: the appropriateness of the fit between the design, conduct, methodology and research question. Includes considerations of the concepts of Credibility (truth value), Transferability (applicability), Dependability (consistency), Confirmability (neutrality), and study author reflexivity. See rows below for definitions.	**Trustworthiness / Rigour**	**YES** - except Transferability (see below)
B. Criteria and process (which support an overall assessment of methodological quality – see above)		
Truth value Degree of confidence in the "truth" of primary study research findings. Whether the study has answered the research question using appropriate methods. Encompasses the degree to which researchers are able to represent the phenomenon of interest with available data.	**Credibility**	**YES**
Applicability Degree of transferability of the findings to another context. Considers theoretical quality, degree of data conceptual richness and contextual thickness. (See also Chapter 6)	**Transferability**	**YES** – in terms of conceptual richness/thickness. Use of CAMELOT can also be supplemented with use a data richness/thickness assessment tool (Chapter 6). **NO –** in terms of transferability (applicability) to other contexts and settings. This is considered throughout the QES process using TRANSFER (Munthe-Kaas et al., 2020).
Consistency	**Dependability**	**YES**

[1] Lincoln and Guba (1985) describe "internal validity", "external validity", "reliability" and "objectivity" as serving comparable purposes for quantitative studies. "Risk of Bias" is often used to identify an overall assessment of quantitative studies. "Risk to Rigour" or "Threats to Trustworthiness" are the appropriate terms for use within an overall assessment of qualitative research.

Concepts used across research types (qualitative and quantitative) for various dimensions of quality	Term(s) used for this concept in qualitative research studies[1]	Included in assessment of methodological limitations of primary studies using CAMELOT
The degree to which the data are conceptually rich and contextually thick enough to sustain the researchers' interpretations.		
Neutrality The degree to which the researchers looked for similarities and differences in data patterns and meanings to explain differences in findings.	**Confirmability**	**YES**
Study author reflexivity A process of ongoing self-critique and self-appraisal by the researcher, in response to their necessarily bringing their own social 'positioning' into the processes of research conceptualisation, design, conduct and writing (Koch et al., 1998, p. 887).	**Reflexivity**	**YES**

7.3 Introducing CAMELOT as a tool for assessing methodological limitations

An assessment of *methodological strengths and limitations* can be used to discern how well a qualitative study has been designed and conducted. The Cochrane and Campbell approach to assessing study trustworthiness is based on such an assessment. CAMELOT is an evidence-based tool that is based on qualitative research principles to support review authors in assessing the methodological strengths and limitations of primary qualitative research studies in a QES (Munthe-Kaas et al., 2024). These qualitative research principles include the:

- Appropriateness of the study design for the research question and study context;
- Appropriateness of the selected methodology and methods, including accepted method-specific principles and practices and study author reflexivity, and how they were applied;
- Relevant quality criteria that are specific to qualitative research, including those related to credibility, dependability and confirmability, as well as aspects of transferability that relate to the conceptual richness and contextual thickness of the study (i.e. aspects unrelated to the context to which findings might be transferred).

CAMELOT should be cited as follows when used in reviews: Munthe-Kaas, H., Booth, A., Sommer, I., Cooper, S., Garside, R., Hannes, K., & Noyes, J. (2024). Developing CAMELOT for assessing methodological limitations of qualitative research for

inclusion in qualitative evidence syntheses. *Cochrane Evidence Synthesis and Methods*.

An overview of the CAMELOT tool is provided in Figure 7.1 and Table 7.2 describes the 12 CAMELOT domains. These include: four *Meta domains* that encourage review authors to consider characteristics of the primary study beyond how the study was carried out, but which inform the conduct and design of the primary study (Research aim & question(s), Researchers, Stakeholders, Context). These *Meta domains* are supplemented by eight *Method domains* divided into four Research design domains (Research strategy, Ethical considerations, Equity, diversity / inclusion considerations, and Theory) and four Research conduct domains (Participant recruitment & selection, Data collection, Analysis and interpretation, Presentation of findings). The Method domains encourage review authors to consider how the study was designed, planned and/or conducted, and how study conduct fits with the information provided in the four Meta domains. Review authors extract or code data from included studies while noting concerns with each domain. They assess the appropriateness or fit between *Meta domains* and *Method domains* (Munthe-Kaas et al., 2024).

CAMELOT has been developed using extensive and prolonged engagement with relevant methodological experts and stakeholders. The approach was specifically developed for use in the context of QES and GRADE-CERQual. The tool is new and subject to further evolution over time. The Cochrane Qualitative and Implementation Methods Group and the Campbell Qualitative Methods Group encourage review authors to use CAMELOT in their Cochrane and Campbell reviews when using GRADE CERQual and to provide feedback on their experience. Living guidance on how to apply the tool is available at www.camelotapproach.com, and a brief overview on how to use CAMELOT is found in section 7.5.3.

Figure 7.1 Overview of CAMELOT

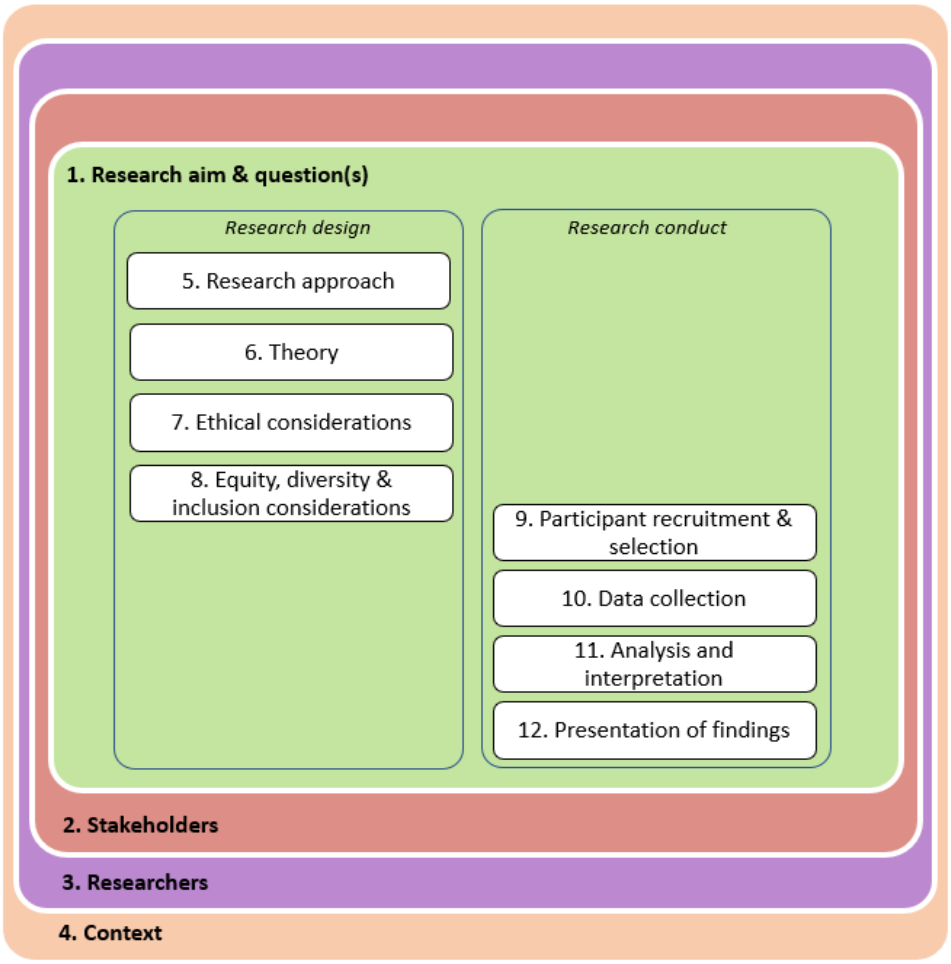

Table 7.2 Definitions of CAMELOT domains

Domain	Definition
META domains	
Research aim & question(s)	The purpose of the study and/or what questions the researchers aim to explore.
Stakeholders	Anyone with an interest (financial or otherwise) in the findings of the research study. Stakeholders are not the same as research participants in this context. Stakeholders may include, among others, funders, patient and public participants.
Researchers	The investigators who have designed, planned and conducted the study and their relationship to the study question, context and/or participants.
Context	The local, national or international setting in which the study was conducted.
METHOD domains	
Research design domains	
Research strategy	The overall intended plan, proposal or strategy for the study. This domain refers to the overarching roadmap for carrying out the research project (also referred to as research approach, study design, or type of study). This domain does not include issues related to participant recruitment and selection, data collection and analysis and interpretation. These are separate domains.

Domain	Definition
Ethical considerations	How the researchers considered and incorporated ethical principles and standards into decisions related to the design, planning and conduct of the study.
Equity, diversity & inclusion considerations	Whether and how the researchers considered: (1) equity – including distribution of power within the research context, whether there was equitable representation and participation in the research process, particularly for underrepresented groups, the possible differential experiences or perspectives of a phenomenon of interest for different populations and whether there was and whether unnecessary or discriminating differences in how people participate in a study (2) diversity – including seeking out diverse experiences, perspectives and backgrounds, inclusion of participants with diverse backgrounds and considering how diversity can influence research findings (3) inclusion – including the degree to which the research environment was such that all participants felt welcome and valued, whether culturally sensitive and inclusive research methods and communication strategies were employed and whether research materials, locations and processes were accessible for all participants.
Theory	Organization of concepts, ideas, literature or principles into systems or frameworks that attempt to describe, explore, explain, understand or predict a phenomenon.
Research conduct domains	
Participant recruitment & selection	How participants were identified, recruited and selected for the research study.
Data collection	The process of gathering qualitative information (data) in the form of perspectives, experiences or opinions from participants, and/or observations, prolonged engagement in the field by researchers in order to explore or answer the research questions and address the research aim.
Analysis and interpretation	The process of systematically examining, exploring and interrogating data gathered during the study in order to identify themes, patterns, lines of argument and, if appropriate, theories and gain a greater understanding of the phenomenon of interest.
Presentation of findings	How the findings from the study are organized and communicated and how well they appear to represent the underpinning data.

Other tools described in section 7.5.2 below can be used to assess methodological strengths and limitations of primary qualitative studies, but these lack the robust design and development process of CAMELOT. Over time and with increasing experience, CAMELOT is intended to become the tool of choice for Cochrane and Campbell QESs.

Assessments of methodological strengths and limitations, using tools such as CAMELOT and/or expert judgement, can be done at multiple stages in the QES process. When and how to assess methodological strengths and limitations will vary between QESs according to which approach best fits an individual review. Common to all Cochrane and Campbell QESs, however, is a specific stage dedicated to assessing the methodological strengths and limitations of included studies with a tool (whether or not these assessments are also used

in other stages of the QES). The following sections provide practical information related to choosing a tool to assess methodological strengths and limitations (7.4) and guidance on how to apply a tool including specific guidance on how to apply CAMELOT (7.5)

7.4. Choosing a tool to assess methodological strengths and limitations

Review authors are encouraged to use the CAMELOT tool and undertake user testing and methodological research within the QES processes (e.g. by comparing CAMELOT assessments and judgements with those from other tools and by evaluating the overall utility of CAMELOT in a decision-making context). CAMELOT has been designed for use with GRADE-CERQual to minimise concerns about how it fits with other GRADE-CERQual components. If opting not to use CAMELOT, review authors need to reflect on whether any criteria from their selected tool overlap with GRADE-CERQual components. For example, if a criterion in the selected tool addresses number of participants and adequacy of the data, review authors should note that this information is used subsequently to inform the GRADE-CERQual assessment of adequacy of data contributing to a synthesised finding (see chapter 13).

Although there are more than 100 other tools available to assess the quality of qualitative research, few have been specifically designed for use in a QES (Munthe-Kaas et al., 2019). The large majority of available tools also fall short of the criteria required of an evidence-based and tested tool (Whiting et al., 2017). This has informed the recommendation to start using CAMELOT going forward and to support its further development over time. Most available tools were designed for critical appraisal of a single primary qualitative study for its suitability to inform practice. The overall process of critical appraisal therefore differs from an assessment of methodological strengths and limitations, in that it generally combines an assessment of study quality with the assessment of the value and relevance of the evidence for a particular context, for example the healthcare centre where the person making the assessment works. Some tools also incorporate an assessment of study reporting alongside study quality and predate reporting guidelines for qualitative research; these tools should no longer be used.

Tools are also available for specific types of qualitative research studies. Examples include tools for focus groups (Vermeire et al., 2002) or for questionnaire surveys that contribute qualitative data (Davids et al., 2014) (See also section 7.7).

The Cochrane Qualitative and Implementation Methods Group suggest six questions to consider when selecting a tool for assessing methodological strengths and limitations and determining its purpose (see Table 7.3). Tools cited in Table 7.3 enable a review author to engage with and interrogate a study by asking questions that reveal specific information about study design and conduct that could lead to an assessment of methodological strengths and limitations and the subsequent identification of concerns (Crombie, 2022). If using one of these tools, review authors will still need to adhere with the guidance for applying and reporting the assessments outlined in this chapter, as most available tools were not designed to be used within a QES.

Table 7.3 Questions to ask to select an appropriate tool for assessing methodological strengths and limitations in primary studies included in a QES

Questions to ask
1. Who is involved in the review? a. If the review team possesses considerable knowledge of qualitative research principles, they may feel comfortable using a more complex tool (CAMELOT or (Popay et al., 1998)) and consider comparing assessments across the two tools b. If the review team comprises novice review authors or review authors who are less experienced with qualitative research, they should choose an accessible tool (e.g. CASP) and consider undertaking additional training to use CAMELOT and compare assessments across the two tools
2. What is the purpose of the QES? a. All review teams should assess the methodological strengths and limitations of included studies. b. The choice of tool(s) and types of assessments should accommodate the purpose of the synthesis e.g. syntheses which aim to build theory may require an assessment of conceptual richness, contextual thickness and methodological strengths and limitations (CAMELOT, Popay et al, 1998, and also the data richness/thickness tool in Chapter 6).
3. Will the review team sample from the body of eligible studies? a. Where a review team plans to exclude studies against a specific threshold of methodological limitations within a planned sampling strategy (Chapter 6), they may undertake an assessment of methodological strengths and limitations using a tool such as CAMELOT at this stage. Alternatively, they may opt to only assess data richness and contextual thickness using the tools described in Chapter 6. They may also want to undertake a preliminary assessment of the consequences (e.g. consider how many and which studies will be excluded and the richness or thickness of the data they would contribute to the review) during the inclusion/exclusion stage. Review authors may need to trade off the relevance of included studies to the phenomenon of interest against the methodological quality of studies. Subsequent GRADE-CERQual assessments of the confidence in synthesised findings can be

Questions to ask
used to examine the consequences of sampling decisions, and to decide on potential remedial actions.
4. What methodological approaches are represented in the included studies? a. With the exception of questionnaire surveys that contribute qualitative data, review teams can select a generic tool such as CAMELOT or CASP to assess all study designs and methodologies and use their expert judgement about how these best apply to different methodologies. b. The review team could also consider using additional tools for different types of studies included in the QES (e.g. for ethnographic studies (Hammersley, 1991) or focus groups (Vermeire et al, 2002) or for questionnaire surveys that contribute qualitative data (Davids & Roman, 2014 to assess surveys when combined with an assessment of the qualitative analysis using a method-specific tool). Review authors should clearly justify why and how they chose tools to assess the different study designs and methods within the QES.
5. What synthesis approach will the review team use for the qualitative evidence synthesis? a. For Meta-aggregation using Joanna Briggs Institute (JBI) methods (see chapter 18) the JBI QARi instrument is the tool of choice. b. For Meta-ethnography (see chapter 11) assessment of conceptual richness and contextual thickness for sampling (see Chapter 6), and assessment of methodological strengths and limitations using CAMELOT, Popay et al or CASP.
6. How will the review team and decision-makers use the assessments? a. When using GRADE-CERQual review teams should record methodological limitations as levels of concern (see section7.5.2). These assessments inform the methodological limitations assessment of GRADE-CERQual for each review finding. Decision-makers value a summary of findings table with accompanying GRADE-CERQual assessments. CAMELOT is designed for use with GRADE CERQual. b. If not using GRADE-CERQual it is helpful to consider narratively whether themes are supported by studies with specific methodological strengths and limitations.

7.5. General considerations for assessing methodological strengths and limitations of studies using tools

This section outlines general considerations when thinking about the purpose and timing of assessments and applying assessment tools. It then focuses specifically on how to use the CAMELOT tool.

7.5.1 The purpose and timing of assessments

Assessment of methodological strengths and limitations can take place at multiple stages in the QES process. Each review team must decide which approach best fits their individual review and how to make their decisions transparent.

An assessment of methodological strengths and limitations (with or without a tool) can be used to exclude studies early on in the QES process (see chapter 6). Explicit inclusion and exclusion criteria focused on methodological characteristics and use of expert judgement enable a review team to rule a study 'In or Out'. A QES protocol stipulates the types of studies

and the types of methods that are eligible for inclusion, typically requiring that studies use a qualitative method of data collection and analysis. The protocol may also outline minimum methodological criteria when considering studies that are not qualitative or solely qualitative. For example, for mixed-methods studies with a qualitative component, it is common to stipulate that the qualitative component is sufficiently 'stand-alone' to facilitate a full assessment of the qualitative component. Sometimes, where few primary qualitative studies exist or primary studies report conceptually poor and contextually thin data, review authors may decide to also include studies with findings derived from analysis of qualitative data collected via open-ended questions in a questionnaire survey. The QES protocol should stipulate whether these types of studies should be included and specify minimum methodological requirements for their inclusion (e.g. no identified concerns related to data collection and analysis methods).

A QES conducted by the Cochrane and Campbell Collaborations includes a specific stage dedicated to using a tool for assessing the methodological strengths and limitations of included studies to feed into GRADE-CERQual assessments. The right-hand column in Table 7.1 above shows the different aspects that are commonly considered at this stage and explicitly covered by the CAMELOT tool.

7.5.2 Identifying and recording methodological concerns

Whatever tool is selected, the focus should be on identifying and recording methodological concerns. CAMELOT is specifically designed to assess methodological strengths and limitations in primary qualitative studies in order to identify methodological concerns, and covers the key quality concepts that contribute to Lincoln and Guba's overall conceptualisation of study trustworthiness (as shown in Table 7.1)(Lincoln et al., 1985). Most other tools fall short of this and review authors need to use expert judgement to fill in any gaps when making their assessments. This fits with Morse's assertion that tools should not be used as a tick box checklist for assessing study quality (Morse, 2021). Tools have most utility as a framework for engaging with the content when reading and re-reading the study as a start towards identifying methodological strengths and limitations and aspects for concern. It is important to note that, within the context of conducting a QES, review authors are not looking for a "rigorous" study per se, but rather interrogating each study to identify

concerns about trustworthiness. The perfect study or gold standard for qualitative research does not, and indeed cannot, exist. Rather than focusing on how "good" a study is, it is prudent to focus on concerns that lead the assessor to pause and consider how a feature of the study design or conduct may influence trust in the study findings. Table 7.4 provides common examples of methodological limitations in primary studies (adapted from Oplatka (2021)) and Box 7.2 provides questions to enable review authors to think critically to identify concerns.

Table 7.4. Common examples of methodological limitations and associated concerns in primary studies (adapted from Oplatka, 2021)

Common sources of methodological limitations	**Examples**
Lack of engagement with field or topic	Lack of clarity about how the research fits in with prior research
Inappropriate participant recruitment and selection	Poor choice of participants to represent the target population (e.g, asking only men/employers about barriers and facilitators to returning to work after maternity leave, and failing to include women's perspectives.) Interviewing only a subset of respondents (e.g., only participants with negative views on a topic, and not those with positive views)
Inappropriate data collection methods	Use of focus groups (instead of interviews) to explore sensitive or taboo topics/themes (such as trauma or abuse) with participants Use of narrow/leading questions to explore participant experiences with or perspectives on a topic
Inappropriate data analysis methods	Unsystematic analysis methods (only jotting down insights and observations without systematically recording digitally, transcribing, coding and analysing data) Quantifying of participant responses (counting answers instead of exploring themes emerging from responses) Superficial analysis (e.g., not exploring why/how participants feel a certain way about a topic)
Lack of reflexivity	Absence of reflection on how author relationships to the research topic/participants have influenced the research.

Box 7.2 Questions that review authors should consider irrespective of the tool that they have selected (adapted from (Noyes et al., 2019).

When undertaking an assessment of methodological limitations, regardless of specific tools used, review teams should consider the following questions to identify concerns:

Setting – Do I have concerns that the choice of setting for data collection might influence the study methods or findings?

Participants – Do I have concerns that the selected participants might influence study methods or findings?

Research team – Do I have concerns that the position of the research team, relative to the research question, the phenomenon of interest and the participants might influence study methods or findings?

Appropriateness of methodology – Do I have concerns that the choice of methodology might influence the choice of setting, choice of participants, choice of the phenomenon being investigated?

Data – Do I have concerns about how the data collection, data analysis or interpretation was planned and/or conducted?

Phenomenon – Do I have concerns that the design or conduct of the study related to the phenomenon of interest might impact on cultural or other sensitivities/controversies?

Use of theory within the qualitative study – Do I have concerns about how theory was selected and used? Is the theory speculative or well-substantiated by data?

Overall study design - Do I have concerns about how the study methods and processes fit together to address the research aims and question?

Identification and recording of methodological concerns requires a thoughtful and holistic approach, that extends beyond simply answering “yes” or “no” to a question within a tool. For example, a study using adult interviewers to understand teenagers’ relationships to alcohol and drugs is not inherently “good” or “bad”. However, if the review team believes that participants might view the interviewer as an authority figure then they may express concerns about findings related to illegal behaviours. Thus, the review team does not make a judgment on the quality of the study, but rather notes potential methodological limitations in design or conduct with consequences for the trustworthiness of a potential review finding to which that study contributes data. Box 7.2 outlines considerations for review authors regardless of the tool that they have selected.

Review authors should be systematic and transparent when collecting information from individual studies for the purposes of assessing strengths and methodological limitations. At least two authors should be involved in collecting information (to ensure no relevant information is overlooked or left out). A review team may use a simple proforma or

spreadsheet, or software intended for managing and analysing qualitative data or data for a systematic review to map and/or extract relevant information for each criterion from any chosen tool (e.g. NVivo QSR Software (2020)(Lumivero, 2023); EPPI Reviewer (Thomas et al., 2022)).

Review authors should consider all sections of a primary study report when assessing methodological strengths and limitations. Unlike quantitative study reports, where all relevant information for conducting a risk of bias assessment is more likely to be found only in the methods section, a qualitative study report may contain relevant information within the Abstract, Introduction or Discussion and Conclusion, or even its footnotes. Online supplementary information and appendices may also contain relevant detail.

As previously mentioned, an important challenge when collecting information is the reporting quality of primary studies. A poorly reported study that lacks key details is difficult to assess. Review authors should record as much information as possible. Where information is unavailable, this limitation should be explicitly recorded and not simply left blank. Review authors can contact the corresponding author of the primary study for additional clarification, although this is time consuming and not always fruitful.

7.5.3 Other issues to consider in identifying methodological concerns

Researchers and review authors recognise that assessing quality in qualitative research includes considering elements of coherence and fit that transcend itemizable methodological features but can still have considerable impact on the rigour with which studies are designed and conducted (Sandelowski et al., 2006). Various procedures and verification strategies can contribute to building rigour within a primary qualitative study (Morse et al., 2002; Patterson et al., 2022). Review authors should look for these strategies when seeking to establish trustworthiness. Examples include publication of a high quality peer reviewed a priori protocol, having appropriate qualitative research skills and experience amongst the research team, engagement with appropriate stakeholders and patient and public representatives (see section 7.9), appropriately applying the methodology and methods, the quality of the data collection and analysis and reporting. Also important are checks and balances within research processes that help the authors of

qualitative studies to avoid creating methodological concern and uncertainty, such as double independent coding of interview data, reaching agreement by consensus, and frequent reviewing and discussion by the research team of processes, analysis and researcher reflexivity (see section 7.7). Patterson's systematic review presents an overview of factors that contribute to the enhancement of rigour during the conduct of a qualitative research study and provides useful additional guidance (Patterson et al., 2022).

7.5.4 Reporting and interpreting methodological concerns at individual study level.

Review authors also need to consider how to report and interpret their assessments (Munthe-Kaas et al., 2019). Assessments of methodological strengths and limitations should be clearly presented in the QES review report showing how each included study performed against each methodological criterion. This information is usually presented in a detailed table published as an appendix of a QES report. See the handbook website for examples of these summary tables. Review teams should neither apply scores to tool domains nor calculate a total quality score as these are considered meaningless given that not all domains of quality are considered equal (Noyes et al., 2018). Scores also give a spurious precision to the assessment. It is far more important that review teams identify specific methodological limitations that may impact on the confidence in, and interpretation of, synthesised findings. Likewise, it is insufficient to merely assign a colour (or other visual marker), to indicate whether information for each domain is simply present or absent, or to use a categorical label (e.g. "moderate concerns") without providing sufficient detail of how each identified methodological limitation could influence individual review findings.

Review authors should make an overall assessment of the level of concern for each individual study included in the QES and indicate that level of concern with clear accompanying explanations (e.g. inappropriate data collection to address the research question). Table 7.5 illustrates how to translate tool domains into a proforma for recording and evidencing assessments and reporting an overall level of concern. The example in Table 7.5 shows how a review team used a modified CASP tool to make an assessment of methodological limitations .

Table 7.5. Example of a proforma for collecting and reporting information for assessing methodological limitations

Criteria	Information	Page number
Is there a statement of research aims?	Yes - The aim of this study is to explore women's experiences with birth companions.	3
Is a qualitative approach justified?	Yes. The qualitative approach is appropriate to answer the review question and well justified.	1
Was the research design appropriate to address the aims?	Partial - Focus group discussions and in-depth interviews with women took place in the hospital shortly after birth. Focus group discussions at the hospital were considered less appropriate for women as they may not have felt comfortable sharing their personal experiences, especially if they or the birth companion were known to others.	4
Was the recruitment strategy appropriate to address the aims?	Unclear how participants were recruited.	4
Was the role of the researcher/ reflexivity described?	Partial - researchers described as maternity nurse researchers but no discussion on how this might influence data collection or analysis or whether they were known to the women or had any other responsibility for the women's care.	8
Have ethical issues been considered?	Yes - Partial - mentions consent but not review board approval. No discussion of the ethical considerations associated with interviewing women after birth.	8
Was the data analysis sufficiently clear and rigorous?	Partial - researchers described the data collectors but no discussion on how this might influence data collection or analysis. The overall analysis appeared to be well done.	5 and 8
Were the findings supported by the evidence?	Partial - stated that researcher viewpoints were taken into consideration, but not what the viewpoints were, therefore it was not clear if the findings consistently privileged the experiences and meanings of the women or what the researcher interpretations added.	6-8
Overall assessment	**Moderate concerns**	

The review team should then communicate the overall assessment of the level of concern for an individual study. Levels of concern should be attributed as follows:

- No or minimal concerns regarding methodological limitations
- Minor concerns regarding methodological limitations
- Moderate concerns regarding methodological limitations
- Serious concerns regarding methodological limitations

Tables 7.6 provides examples of things to consider when assigning an overall assessment of study quality. See also Table 7.5 and Box 7.2 which outline common concerns and sources of methodological limitations. Assigning a level of concern is always a value judgement. That said, a study that is assessed to have either no or minimal or only minor concerns regarding methodological limitations is generally considered to have been designed and conducted with methodological rigour and therefore trustworthy. Summary displays can be reported in tables within the final QES report with full assessments being available as an Appendix.

Table 7.6. Examples of issues to consider when assigning levels of concern regarding methodological limitations in a primary qualitative study.

No, minimal, minor concerns → **Serious concerns**	
A methodologically rigorous and trustworthy study	Any one or a combination of the issues below would strongly suggest a study that lacks rigour
Research question well written with no or minor issues about the context, scope and inclusion/exclusion criteria	Poorly written research question, contextual information lacking, inappropriate or unclear research scope/ inclusion/exclusion criteria
Appropriate choice of research method but some aspect may cause concern such as whether minor deviations from the protocol were not entirely justified or explained.	Inappropriate choice of research method to address the research question
Appropriate recruitment as specified in the protocol, but some aspect may cause concern such as the sample almost but not quite meeting the pre-specified theoretical characteristics	Inappropriate recruitment or participant selection (e.g. asking the wrong people…)
Appropriate data collection methods were used but some aspect may cause concern such as a participant not wishing to be recorded.	Inappropriate data collection methods (e.g. focus groups where interviews would have been more suitable)
Appropriate data analysis methods but some aspect may cause concern such as not being able to verify transcripts with a small number of participants	Inappropriate data analysis methods (e.g. counting responses, unsystematic analysis)
Researchers are reflexive and make transparent any biases/conflicts of interest	Lack of reflexivity of researchers and/or potential conflicts of interest
Others – examples are not exhaustive	Others – examples are not exhaustive

7.5.5. Using CAMELOT

When using CAMELOT, review authors should take account of the considerations previously outlined in this chapter as well as the specific guidance presented in this section. Box 7.3 provides an overview of how to make a CAMELOT assessment. Further instructions are provided in Munthe-Kaas et al. (2024) (see https://zenodo.org/records/10973143) and in a living guidance document at www.camelotapproach.com.

The key difference between CAMELOT and other tools is that review authors are required to make explicit judgements of the appropriateness of fit between *Method* and *Meta domains* to arrive at an overall assessment of level of concerns regarding methodological limitations, expressed as no or minimal concerns, minor concerns, moderate concerns or serious concerns. As described previously, a study with no or minimal, or minor methodological concerns equates to a rigorously conducted and trustworthy study. It is challenging to follow this process using tools other than CAMELOT because review authors must rely on common sense and expert judgement to apply tools in a specific way and for this specific purpose, which may not be as originally intended.

Box 7.3 Making an assessment of methodological limitations using CAMELOT

Step 1. Extract/code data

Extract or code data from the primary study related to the following domains (some of these domains will not be relevant for some studies):

Meta domains

1. Research aim & question(s)
2. Stakeholders
3. Researchers
4. Context

Method domains

Research design

5. Research strategy
6. Theory
7. Ethical considerations
8. Equity, diversity & inclusion consideration

Research conduct

9. Participant recruitment & selection
10. Data collection
11. Analysis and interpretation
12. Presentation of findings

See below for definitions of the CAMELOT domains

Step 2. Note any comments regarding each domain. This may include problems or missing information. This step is optional but will act as an audit trail and help to inform the subsequent steps.

Step 3. Describe concerns regarding, and make assessment of, fit between domains

- Describe concerns regarding appropriateness of fit between the Research design domains and each of the Meta domains and the Research conduct domains (as a whole). Make an assessment using the following categories to describe the fit: Excellent, Good, Fair, Poor, Unclear
- Describe concerns regarding appropriateness of fit between the Research conduct domains fit with each of the Meta domains. Make an assessment using the following categories to describe the fit: Excellent, Good, Fair, Poor, Unclear.

Step 4. Describe level of concern regarding methodological limitations

Combine these assessments to make an overall assessment of methodological limitations by indicating level of concern using the following categories and provide an explanation for your assessment:

- *No or minimal concerns, minor concerns, moderate concerns, serious concerns*

Step 5. Combine assessments across studies

Combine assessments of fit across studies contributing to a review finding and indicate level of concern regarding methodological limitations using the following categories:

- *No or minimal concerns, minor concerns, moderate concerns, serious concerns*

7.6. Using assessments of methodological limitations in sensitivity analyses to test the robustness of findings

Review authors can explore the robustness of review findings by removing data flagged from studies with many and/or serious methodological limitations to see whether the review finding changes as a result (Carroll et al., 2015). Review authors could conduct a post hoc sensitivity analysis to assess the impact of excluding studies below a certain quality threshold to see if the findings still hold true (as Feys and colleagues did for reporting criteria (Feys et al., 2017)). However, QES authors are generally less interested in individual study quality. The focus is on how identified methodological limitations, expressed as concerns, influence trust in the study findings. Review authors could agree on "critical" methodological limitations for each review finding (e.g., lack of researcher reflexivity, use of focus groups instead of interview methods, or unclear analysis methods) and conduct a sensitivity analysis using presence or absence of identified limitations as their "quality threshold".

Sensitivity analysis can be conducted alone, or in conjunction with an ongoing sampling strategy (Chapter 5), or during the process of making an assessment of the GRADE-CERQual methodological limitations component (Chapter 13).

7.7. Additional guidance for different study designs

- Questionnaire surveys that contribute to a QES

Tools designed for assessing a primary qualitative study are not appropriate for assessing the methodological strengths and limitations of the methods used to collect and analyse qualitative data from open-ended questions within a questionnaire survey. Review teams that include questionnaire surveys may consider selecting tools to assess the conduct of the survey (Davids et al., 2014) in addition to selecting the relevant aspects of the method specific tool to assess the analysis of qualitative data from open ended questions. Due to the inherent methodological limitations associated with the analysis of qualitative data from questionnaire surveys (i.e. conceptually poor and contextually thin data), some teams automatically moderate the influence of these types of findings from surveys by using them to verify but not to generate themes.

- Qualitative component of mixed-methods studies

Findings from mixed-methods studies may be included in a QES where the qualitative component is distinct enough to be extracted and analysed. Where this occurs a tool designed for a primary qualitative study can be used. Additionally there is a mixed-methods tool (MMAT) (Hong et al, 2018) which is available for use for primary studies within a genuinely mixed-methods review. However, it appears to offer little advantage over a stand-alone qualitative tool when conducting a QES or synthesising only the qualitative components of a mixed methods study, particularly as it includes fewer criteria for assessment.

- Qualitative process evaluation and intervention implementation evidence

Guidance for appraising methodological strengths and limitations for process evaluations and implementation evidence remains relatively immature. This section reiterates guidance from Chapter 21 of the Cochrane Handbook (Noyes et al., 2019). Few assessment tools explicitly address rigour in process evaluations or implementation evidence. For qualitative primary studies, the 8-item process evaluation tool developed and used in reviews by the EPPI-Centre (Rees et al., 2009; Shepherd et al., 2010) supplements tools previously described in this chapter. One of these items, a question on usefulness (framed as *'how well the intervention processes were described and whether or not the process data could illuminate why or how the interventions worked or did not work'*) offers a mechanism for exploring rigour in process evaluations (Cargo et al., 2018).

7.8. Moving from single studies to synthesised findings and applying GRADE-CERQUal

Once review authors have identified the methodological limitations and concerns at individual study level and have established which studies contribute to specific synthesised findings, they will be able to move on to making assessments of methodological limitations for *each* review finding. Given that each review finding is typically supported by multiple studies, this process entails examining the body of evidence (studies) contributing to a review finding and assessing whether identified methodological limitations may impact on the confidence in a review finding. See Chapter 13 for more information.

7.9. Review author reflexivity

Reflexivity acknowledges that the influence of the review team's epistemological, professional, methodological opinions and perspectives on the findings is unavoidable. Reflexivity statements are important when developing the protocol and reporting the QES and should consider the *Methods* (prospective reflexivity) and *Results* (retrospective reflexivity) (Glenton et al., 2023). In both statements review authors should consider their potential personal influence on the assessment of methodological strengths and limitations of included studies. Review authors should take a reflexive approach to considering how individual stances within their team could have influenced their choice of tool and individual and collective assessments (Downe et al., 2019). Review authors should also be aware of the "relativity trap" whereby authors are more or less critical in their assessments relative to the body of available studies. Ideally, review authors should assess studies based on their individual merit against pre-agreed thresholds for their review and not in comparison with other studies included in the review or studies that contribute data to a specific review finding.

Involvement of multiple review authors (simultaneously or via checks for consensus) offers opportunities for reflexive discussions related to methodological limitations. Review authors whose primary studies are included in the synthesis should recuse themselves from undertaking any assessments of their own studies.

7.10. Equity, diversity and inclusion

Reviews undertaken in a Cochrane and Campbell context typically address questions that require consideration of equity, diversity and inclusion in the design and analysis and include evidence from lower and middle countries. Studies may be reported in journals that do not require adherence to qualitative reporting guidelines, contain poor conceptual data and thin contextual details and often raise methodological concerns when assessed. Nonetheless, these studies frequently provide unique evidence from specific contexts and perspective of interest, so a review team often privilege relevance over methodological limitations when making decisions about including studies. Furthermore, diverse perspectives can be viewed as a methodological strength while lack thereof may be a concern (see CAMELOT Equity, diversity and inclusion considerations domain above).

7.11. Stakeholder engagement and involvement

Involvement of stakeholders may appear challenging because of the need for expertise in qualitative research methods when undertaking assessments. However, the benefits of stakeholder engagement may be that stakeholders are able to identify concerns that the review team can miss (e.g., related to Equity, diversity and inclusion considerations). Few accounts document how to involve, or describe experiences of involving stakeholders in undertaking assessments of methodological strengths and limitations. Stakeholders, such as patients and members of the public, may however provide valuable insights that could help review authors interpret assessments and make decisions on which studies to include. Patients and public stakeholders who have extensive experience of being involved in research could be trained to undertake assessments that could feed into the process of agreement by consensus.

7.12. Chapter information

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Declarations of interest

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