Chapter 13. Assessing confidence in the evidence using the GRADE-CERQual approach

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Key points

- GRADE-CERQual is an approach for assessing how much confidence to place in findings from qualitative evidence syntheses.
- GRADE-CERQual requires assessment of four components: methodological limitations in studies contributing to a finding, coherence of the finding, adequacy of data and relevance of data contributing to a finding, followed by an overall assessment of confidence.
- The GRADE-CERQual Summary of Qualitative Findings (SoQF) table is a key product of a qualitative evidence synthesis that uses the GRADE-CERQual approach.
- A SoQF table includes a summary of each review finding, the GRADE-CERQual assessment of each finding, an explanation of this assessment and references for contributing studies.
- GRADE-CERQual Evidence Profile tables complement SoQF tables by also providing the detailed assessments of each GRADE-CERQual component for each review finding.
- Review authors applying the GRADE-CERQual approach can use the free, online interactive Summary of Qualitative Findings (iSoQ) tool.

13.1 Introduction

Decisions about health, social care, and other interventions, programmes, and policies need to be based on the best available evidence, and a broad range of evidence is typically needed to inform decision-making (Oxman, Lavis et al. 2009). Findings from qualitative evidence syntheses (QES) are used increasingly in decision-making processes, including within decision-support tools such as the GRADE Evidence-to-Decision and WHO-INTEGRATE frameworks (Alonso-Coello, Oxman et al. 2016, Moberg, Oxman et al. 2018, Rehfuess, Stratil et al. 2019), to complement evidence on the effects of interventions and resource use. The 'Confidence in the Evidence from Reviews of Qualitative research' (GRADE-CERQual) approach was developed to support people to use QES findings in decision-making processes by providing guidance on how much confidence they can place in these findings. The GRADE-CERQual approach complements other 'Grading of Recommendations Assessment, Development, and Evaluation' (GRADE) tools for assessing how much certainty to place in evidence on the effectiveness and harms of interventions, on resource use, and on diagnostic tests (Guyatt, Oxman et al. 2011, Hsu, Brożek et al. 2011, Lewin, Booth et al. 2018). GRADE-CERQual shares a similar objective to GRADE but was designed specifically to be applied in QES and is based on principles and concepts grounded in qualitative research.

The chapter is important as a recent evaluation identified several fidelity issues in the appropriate application and reporting of GRADE-CERQual (Wainwright, Zahroh et al. 2023). Review authors who apply GRADE-CERQual can take advantage of the online interactive Summary of Qualitative Findings (iSoQ) tool (isoq.epistemonikos.org). The iSoQ tool is free to use and is designed to assist review authors with applying the GRADE-CERQual approach. The iSoQ tool can be used as soon as review authors have a final list of included studies and are able to upload the references for these to the platform. The iSoQ tool is not intended to teach review authors how to apply GRADE-CERQual; rather review authors need to familiarise themselves with the available methodological guidance (such as this chapter), and the most up-to-date guidance on applying the approach (Colvin, Garside et al. 2018, Glenton, Carlsen et al. 2018, Lewin, Bohren et al. 2018, Lewin, Booth et al. 2018, Munthe-Kaas, Bohren et al. 2018, Noyes, Booth et al. 2018). Review authors can also access training

videos and live webinars on the approach via the GRADE-CERQual website (https://www.cerqual.org) (2024). For more information about GRADE-CERQual and to stay updated on methodological developments, see the GRADE-CERQual website.

In this chapter, the GRADE-CERQual approach, the steps to apply it and how to use the assessments are described. The chapter highlights specific issues relating to stakeholder engagement and involvement, equity, diversity and inclusion and reflexivity in the context of conducting GRADE-CERQual assessments. Examples of the use of GRADE-CERQual and tips for using iSoQ are integrated throughout the chapter.

13.2 What is confidence in the evidence in relation to findings from a QES?

Confidence in the evidence is "an assessment of the extent to which a review finding (e.g., an analytic output from a QES - see section 13.3.1) is a reasonable representation of the phenomenon of interest" (Lewin, Booth et al. 2018). The confidence assessment communicates the extent to which the review finding is likely to be substantially different from the phenomenon or topic of interest. 'Substantially different' means different enough that it might change how the finding influences a decision about health, social care, or other interventions (Lewin, Glenton et al. 2015). The GRADE-CERQual assessment of 'confidence' in a review finding thereby communicates a similar message as a GRADE assessment of 'certainty' in a finding from a review of intervention effectiveness. However, the term 'confidence' rather than 'certainty' is used to reflect differences in the nature of the underlying data and in how these assessments are made.

For example, a review with a global focus may describe a finding on how pregnant women highly value being able to carry their own medical records. High confidence in this finding means that the finding is likely to be a reasonable representation of what is valued by pregnant women in general. However very low confidence in the review finding means that it is not clear from the available evidence whether pregnant women value being able to carry their medical records. This type of information about confidence can help guide decision-makers when they make decisions about patient-held medical records.

13.3. The GRADE-CERQual approach

The GRADE-CERQual approach involves assessing confidence in **each individual review finding** developed as part of a QES**.** See section 13.4.1 for more information on types of QES findings.

GRADE-CERQual assessments are based on four components:

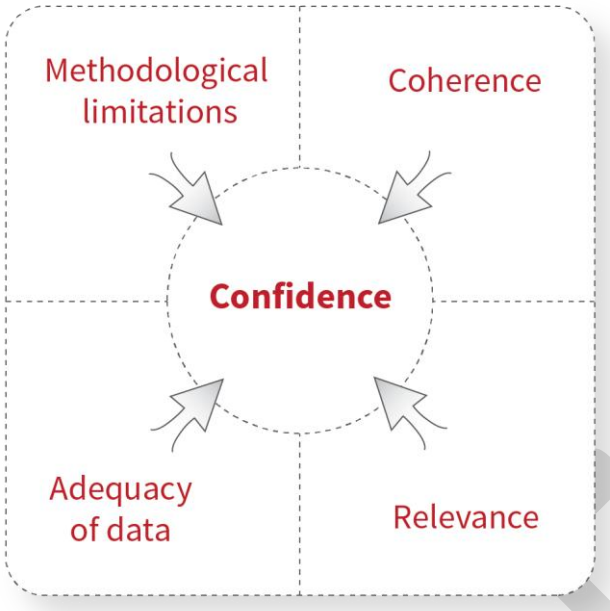
1. Methodological limitations (Munthe-Kaas, Bohren et al. 2018)
2. Coherence (Colvin, Garside et al. 2018)
3. Adequacy of data (Glenton, Carlsen et al. 2018)
4. Relevance (Noyes, Booth et al. 2018)

Current definitions of the four GRADE-CERQual components are summarised in Table 13.1. Figure 13.1 illustrates how the four GRADE-CERQual components contribute to an overall assessment of confidence.

Table 13.1. Current definitions of the GRADE-CERQual components.

GRADE-CERQual component	Definition
Methodological limitations	The extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to a review finding.
Coherence	How clear the fit is between the data from the primary studies and the review finding.
Adequacy of data	The degree of richness and quantity of data supporting a review finding.
Relevance	The extent to which the body of data from the primary studies supporting a review finding is applicable to the context specified in the review question. By “context” we refer to a range of factors that may interact and could include, but are not restricted to, the perspective or population, the phenomenon of interest, and the setting.

Figure 13.1. Each of the four GRADE-CERQual components contribute collectively to an overall assessment of confidence (Lewin, Booth et al. 2018). Image credit: Sarah Rosenbaum.



Review authors first assess whether they have any concerns for each of the components and then bring these assessments together to make an overall judgement on the level of confidence to place in the finding (Figure 13.1).

The GRADE-CERQual approach and components share several similarities with criteria in the GRADE tool used to assess certainty in findings from reviews of intervention effectiveness (risk of bias, directness, inconsistency, imprecision) (Guyatt, Oxman et al. 2011). However, the GRADE-CERQual components have been developed in line with qualitative research traditions, and the definition and application of each component reflects this. The GRADE tool for intervention effectiveness also includes a component that assesses publication or 'dissemination' bias. Work is underway to explore how the concept might impact within qualitative research (Toews, Glenton et al. 2016, Toews, Booth et al. 2017, Booth, Lewin et al. 2018, Toews, Nyirenda et al. 2021), but it is not yet included in the GRADE-CERQual approach.

13.3.1 Purpose of GRADE-CERQual

QES authors can use the GRADE-CERQual approach to make transparent assessments for each review finding about how much confidence should be placed in these findings by users

(such as decision-makers or researchers) (Lewin, Booth et al. 2018). People involved in using review findings from a QES may already make confidence assessments intuitively or informally, based on their own experiences and beliefs (Lewin, Booth et al. 2018). However, such assessments may not be transparently described or reported, and different people may use different criteria to assess confidence (Oxman, Lavis et al. 2009). Using the GRADE-CERQual approach addresses these concerns by providing clear criteria for assessing and reporting confidence assessments for review findings.

13.4. Applying GRADE-CERQual

Review authors applying GRADE-CERQual should also refer to the recent evaluation of fidelity and reporting in order to avoid common pitfalls when applying the approach to review findings (Wainwright, Zahroh et al. 2023).

13.4.1 What is a review finding?

A review finding is a theme, category, thematic framework, theory or contribution to theory, or another similar output from a qualitative evidence synthesis, and that is based on data from primary studies.

13.4.2 Reporting full review findings of the synthesis

Review authors should first report their full review findings from the synthesis using the Cochrane RevMan template for QES and the accompanying guidance that draws on existing published reporting guidance. See Chapter 20 for additional guidance on how to report full review findings from the synthesis. In addition, if reporting a meta-ethnography, the eMERGe reporting guideline has an extension for reporting GRADE-CERQual (Chapter 11).

The nature of a review finding is also shaped by the type of QES methodology chosen (see also method-specific reporting guidance in other handbook chapters). All review findings in a QES are to varying degrees 'transformations' of the underlying data into descriptions, interpretations, and/or explanations of the phenomenon of interest (Colvin, Garside et al. 2018). More descriptive findings (e.g., findings that summarise patterns in the data) are generally less transformed than interpretive or explanatory findings (e.g., those that provide theoretical interpretations or explanations for patterns in the data) (Colvin, Garside

et al. 2018). In practice, QESs typically include a mix of both descriptive and interpretive/explanatory findings. There are currently more examples of applying GRADE-CERQual to descriptive level findings. See (Cooper, Schmidt et al. 2021) for an example of the application of GRADE-CERQual to interpretive/transformed findings using a meta-ethnographic approach (Chapter 11).

13.4.3 Producing summaries of findings

Alongside formulating and reporting full review findings from the synthesis, review authors draft short statements or "**summaries of findings**" that provide a short and clear description of each review finding (Lewin, Bohren et al. 2018). The summarised findings statements establish a starting point for applying GRADE-CERQual and for reporting findings and GRADE-CERQual assessments in Summary of Qualitative Findings tables and Evidence Profile tables.

These summaries of findings have several additional benefits, including (Lewin, Bohren et al. 2018):

1. Providing end users with a summary of the full review findings, making review findings more accessible,
2. Helping the review authors to identify the central idea of each finding and key explanatory aspects, and
3. Promoting an iterative and reflexive discussion among the review authors about the key content of the review finding before it is finalised.

The summaries of review findings should be written with the stakeholders who are the end users of the review in mind. This is because the summarised review findings and corresponding Summary of Qualitative Findings table« and Evidence Profile table are commonly used in decision-making. Tips for writing summaries of review findings are provided in the most recent GRADE-CERQual guidance (see (Lewin, Bohren et al. 2018) Table 2).

13.4.4 Assessing methodological limitations

Methodological limitations in the design or conduct of the primary studies that contributed evidence to a review finding, can reduce review authors' confidence that a review finding reflects the phenomenon of interest (Munthe-Kaas, Bohren et al. 2018). Review authors need to apply a tool to assess methodological limitations of each included study. Approaches to assessing the methodological limitations in primary studies included in QES are outlined in Chapter 7. Of particular note, CAMELOT (CochrAne qualitative MEthodological LimitatiOns Tool) has been developed for use with GRADE-CERQual (Munthe-Kaas et al 2024) and is described in Chapter 7. A more detailed discussion on the process of assessing methodological limitations within GRADE-CERQual that predates development of the CAMELOT tool can be found in the paper by Munthe-Kaas and colleagues (Munthe-Kaas, Bohren et al. 2018).

Table 13.2 describes, in order, the steps that review authors should take to assess methodological limitations as part of a GRADE-CERQual assessment (Munthe-Kaas, Bohren et al. 2018). The assessment is based on the studies contributing to each individual review finding (Munthe-Kaas, Bohren et al. 2018). This is because each finding may be supported by a different combination of primary studies, each with its own strengths and limitations.

Table 13.2. How to assess methodological limitations as part of a GRADE-CERQual assessment. Adapted from (Munthe-Kaas, Bohren et al. 2018).

#	Step	Tips and issues to consider
1	Collect and consider the information related to methodological limitations	• Select an appropriate tool to assess methodological limitations for primary qualitative studies, considering the specific study design/s of the studies and the review question. Review authors are encouraged to use CAMELOT and to follow the guidance in Chapter 7 and Munthe-Kaas et al 2024. • Assess all included primary studies. • Record in detail the assessments for each domain for each primary study, for example in a table. • For the GRADE-CERQual assessment, review authors will need a detailed explanation for each domain of the tool to assess methodological limitations, rather than ticking 'yes' or 'no' on a checklist. • Make an overall assessment of methodological concerns for each primary study. Categorise any concerns for each primary study as: no or very minor concerns, minor concerns, moderate concerns, or serious concerns. • If the assessment of methodological limitations is affected by limited reporting in the primary study, consider contacting the authors of the primary study for more information.

2	Assess the body of data contributing to each review finding and decide whether there are concerns about methodological limitations	• For each individual review finding, consider the assessments of methodological limitations for each contributing primary study. • Consider whether a review finding is particularly affected by any methodological limitations in the contributing studies, recognising that not all limitations raise the same level of concern. Some methodological strengths and weaknesses may be more important for some findings but not others (e.g., using focus groups may be an inappropriate method for collecting data on sensitive topics, but may be appropriate for less sensitive topics).
3	Make a judgement about the seriousness of the concerns and justify this judgement	• Start with the assumption of "no/very minor concerns regarding methodological limitations" and then consider rating down if the review authors have greater concerns. • Categorise the concerns as: no or very minor concerns, minor concerns, moderate concerns, or serious concerns. • Minor concerns will probably not lower the confidence in the review finding, while moderate concerns may lower confidence and serious concerns probably will lower confidence. • To ensure transparency, describe in the Evidence Profile the methodological limitations that are driving the level of concern (required for minor, moderate and serious concerns).
4	iSoQ tips	• Create or import a methodological assessments table in the 'My Data' section of iSoQ. • Once this is done, assessments for contributing studies will appear in the 'GRADE-CERQual assessment worksheets' alongside the review finding and the extracted data. The review authors can then consider the methodological limitations of the body of evidence in relation to the review finding and to the data each primary study contributes to the review finding. • Use the 'Notes' box to record concerns, select the level of concern and complete the explanation.

13.4.5 Assessing coherence

The coherence of a review finding is an assessment of how clear the fit is between the data from the primary studies and the review finding (Colvin, Garside et al. 2018). Where the fit is not clear, review authors may have less confidence in the review finding. Assessing the fit between the data and the review finding involves the review authors actively looking for data that complicate or challenge their review findings, and this iterative approach is typical for QES (Hsu, Brożek et al. 2011, Booth, Carroll et al. 2013).

Table 13.3 describes, in order, the steps that review authors should take to assess coherence as part of a GRADE-CERQual assessment (Colvin, Garside et al. 2018). **Assessing coherence is an iterative process**, particularly when there are serious concerns about the coherence of a review finding. A more detailed discussion on the process of assessing

coherence and guidance on dealing with the degree of data transformation and how this may impact coherence assessments see: (Colvin, Garside et al. 2018)).

Table 13.3. How to assess coherence as part of a GRADE-CERQual assessment. Adapted from (Colvin, Garside et al. 2018)

#	Step	Tips and issues to consider

1	Collect and consider the information related to coherence	• Ensure review authors have access to the underlying data contributing to the review finding, such as the data extraction tables or coded data in a qualitative data analysis software.
		• Review authors may need to return to the primary studies if:
		  ○ They do not have all data relevant to the focus of the review finding.
		  ○ Details necessary for assessing how well the data from primary studies support a particular review finding are missing from the data extraction process.

2	Assess the body of data that contributes to each finding and decide whether there are concerns about coherence	• Where there is clear support for a review finding across the underlying data, review authors should not have concerns about coherence.
		• Assess coherence for each review finding individually (not for the QES as a whole).
		• Review authors may have concerns about coherence when the patterns in the underlying data are not well explored or explained (either by the review authors or the primary study authors).
		• There are three main threats to coherence:
		  ○ Some of the data from included studies **contradict** the review finding, and these contradictory data (e.g., 'outliers' or 'disconfirming cases') are omitted in the review finding.
		  ○ It is **not clear** if some of the underlying data support the review finding – for example if the underlying data are vaguely defined or described. Or, for more explanatory review findings, if there are insufficient data for certain aspects of the review finding.
		  ○ **Plausible alternative explanations** could be used to synthesise the underlying data and these have not been explored or assessed by the review authors.

3	Make a judgement about the seriousness of the concerns and justify this judgement	• Start with the assumption of "no/very minor concerns regarding coherence" and rate down if the review authors identify concerns. • Categorise the concerns as: no or very minor concerns, minor concerns, moderate concerns, or serious concerns. • Minor concerns will probably not lower confidence in the review finding, while moderate concerns may lower confidence and serious concerns probably will lower confidence. • To ensure transparency, review authors should describe in the Evidence Profile any concerns about coherence (required for minor, moderate, and serious concerns).
4	iSoQ tips	• Insert extracted data that contributed to the review finding into the 'Extracted data' table in the 'GRADE-CERQual Assessment Worksheet'. • Extracted data will appear alongside the review finding for easy comparison. • Use the 'Notes' box to record the concerns, select the level of concern and complete the explanation.

13.4.6 Assessing adequacy of data

The adequacy of data refers to an overall determination of the degree of richness and quantity of data supporting a review finding (Glenton, Carlsen et al. 2018). **Richness of data** means the extent to which the information provided in individual included studies is detailed enough to allow the review author to interpret the meaning and context of the phenomenon of interest (Glenton, Carlsen et al. 2018), see also Chapter 6. **Quantity of data** refers to the number of studies supporting a review finding, as well as the number of participants or observations (e.g., a study may include very few participants but may interview these participants multiple times) (Glenton, Carlsen et al. 2018).

When assessing data adequacy, the aim is to **judge whether there are grounds for concern that are serious enough to lower confidence in the review finding** (Glenton, Carlsen et al. 2018). Review authors are likely to have concerns about the richness of data if it does not provide sufficient detail to gain an understanding of the phenomenon described in the review finding (Glenton, Carlsen et al. 2018).

Table 13.4 describes, in order, the steps that review authors should take to assess adequacy of data as part of a GRADE-CERQual assessment (Glenton, Carlsen et al. 2018). A more detailed discussion on the process of assessing adequacy within GRADE-CERQual can be found in the paper by Glenton and colleagues (Glenton, Carlsen et al. 2018).

Table 13.4. How to assess adequacy of data as part of a GRADE-CERQual assessment. Adapted from (Glenton, Carlsen et al. 2018).

#	Step	Tips and issues to consider
1	Collect and consider the information related to adequacy of data	To assess adequacy of data, review authors need the following information for each review finding (for example, in a table or matrix): • Underlying data contributing to the review finding, such as the data extraction tables or coded data in a qualitative data analysis software. • Overview of the number of studies contributing to each review finding. • Information about the number of participants or observations (in each included study, or – where possible – contributing to each review finding. It may be difficult to assess how many participants contribute to each theme in a primary qualitative study; in this case, base the assessment of adequacy on the information available).
2	Assess the body of data that contributes to each finding and decide whether there are concerns about adequacy of data	• Assess adequacy for each review finding individually (not for the QES as a whole). Assessing data richness: Review authors may have concerns about data richness (see Chapter 6) if the available data are not sufficiently rich to allow understanding of the phenomenon of interest – this is a judgment made in relation to the individual review finding. • Review findings that are more descriptive can usually be developed from less rich data while review findings that are more explanatory generally require richer data that allow review authors to sufficiently explore the phenomenon of interest. Assessing data quantity: • Consider the number of studies, and the number of participants or observations contributing to a review finding. • There is no fixed rule about what constitutes a sufficient number or studies, participants, or observations. Instead, this assessment is made in relation to the individual review finding. • Review authors may have less confidence when a review finding is supported by data from only one or very few studies, participants, or observations. This is because review authors may be less sure that studies undertaken in other settings or groups would report similar findings. • QES authors are often aiming for diversity of perspectives in the included studies. Review authors may therefore not necessarily seek to include all studies on a topic but rather use a sampling approach to select studies for inclusion (see Chapter 6). • Qualitative researchers look for both common attitudes and experiences, as well as outliers or 'disconfirming cases.' Review findings that make claims about relatively unexplored topics may require more data, compared to review findings that represent more widely researched experiences.
3	Make a judgement about the seriousness of the concerns and justify this judgement	• Start with the assumption of "no/very minor concerns regarding adequacy of data" and rate down if concerns are identified. • Categorise the concerns as: no or very minor concerns, minor concerns, moderate concerns, or serious concerns. • Minor concerns will probably not lower confidence in the review finding, while moderate concerns may lower confidence and serious concerns probably will lower confidence. • To ensure transparency, review authors should describe any concerns about adequacy of data in the Evidence Profile (required for minor, moderate and serious concerns).

4	iSoQ tips	• Create or import a 'Characteristics of Studies' table into the 'My Data' section of iSoQ and ensure this table includes information that is pertinent to assessing the adequacy component. • Insert extracted data that contributed to the review finding into the 'Extracted data' table of the 'GRADE-CERQual Assessment Worksheet'. • Consider the number of studies, number of participants and observations (characteristics of studies table) and the richness of the data (extracted data table) • Use the 'Notes' box to record the concerns, select the level of concern, and complete the explanation.

13.4.7 Assessing relevance

Relevance of the data is defined as the extent to which the body of data from the primary studies supporting a review finding is applicable to the context specified in the review question (Noyes, Booth et al. 2018). This means that relevance assessments are tied to the context specified in the QES review question. "Context" refers to perspective or population, the phenomenon of interest or intervention, the setting or the timeframe (Noyes, Booth et al. 2018). Evidence-informed policy-making encourages the use of 'relevant research' that relates to the review question (Lavis, Oxman et al. 2009), which can be considered a type of internal validity (Bambra 2011, Noyes, Booth et al. 2018).

When assessing relevance in a GRADE-CERQual assessment, the aim is to judge whether there are grounds for concern regarding relevance that are serious enough to lower confidence in the review finding (Noyes, Booth et al. 2018). Examples of concerns about relevance include:

- (Some of) the underlying data are of *indirect relevance*: this assessment is made where the review finding is supported by studies that correspond with some factors from the context of the review question but not with others. This is likely to occur in reviews where the review team is unable to identify studies that fully represent the context specified in the review question. In other words, one or more aspects of context are substituted with another in these studies. For example**,** Carroll et al 2020 conducted a QES of the implications of congential zika syndrome for infant feeding. The review and synthesis identified only a small number of relevant congential zika syndrome qualitative studies (n = 6), all from Brazil ('direct' evidence). As a result,

the review was expanded to include qualitative studies of the lived experience of women and others regarding infant feeding in the presence of similar physical problems, e.g. Cerebral Palsy ('indirect' evidence, n = 8). The phenomenon of interest (infant feeding) was the same, though the underlying conditions (congential zika syndrome or other similar physical problems) were different. Review authors therefore need to be cautious when interpreting indirect evidence where some contextual factors are similar and others are not in order to ensure that the use of indirect evidence is not misleading.

- It is unclear whether the underlying data is relevant (*unclear relevance*), meaning that review authors are unsure whether the studies underlying the review finding reflect the review question. Poor reporting of primary studies can make it challenging to assess the relevance of the evidence. Review authors can contact the primary study authors to obtain more information. In some QES, review authors may identify factors that may influence interpretation or transferability of the review findings (typically before starting the GRADE-CERQual assessments), for example using the TRANSFER approach (Munthe-Kaas, Nøkleby et al. 2020). If these important factors cannot be identified in the included studies, then the review authors may determine that it is unclear whether the underlying data are relevant.
- Some or all of the underlying data are partially relevant (*partial relevance*), meaning that the studies underlying the review finding only represent a subset of the review question. For instance, the evidence only covers some of the population, setting or time frame that the review authors are interested in. It is, however, very common that individual studies do not cover all aspects of the review question, especially when the review question refers to a global context. Most QESs commonly include a mixture of relevant and partially relevant studies and the inclusion of partially relevant studies may not raise concerns. Review findings that *specifically state* that they only cover specific sub-populations or aspects of the context may shift assessments of relevance from 'partially relevant' to 'directly relevant'. However, when deciding whether to narrow the scope of a review finding, review authors need to consider what will be meaningful to users.

Table 13.5 describes, in order, the steps that review authors should take to assess relevance of the data as part of a GRADE-CERQual assessment (Noyes, Booth et al. 2018).

Table 13.5. How to consider relevance as part of a GRADE-CERQual assessment. Adapted from (Noyes, Booth et al. 2018).

#	Step	Tips and issues to consider
1	Clarify the review question and context	• Consider what contextual factors are important for the review question (e.g., perspective, population, phenomenon of interest, and setting). • Using a QES question framework can help to articulate the important contextual factors (e.g., SPICE or PerSPEcTiF (Booth, Noyes et al. 2019), see Chapter 2 • Including insights from external frameworks, theories, or complementary reviews at the design stage can help with assessing relevance. This might include using a specific 'theoretical perspective' (e.g., behavioural theory), or 'lens' (e.g., an equity lens. • Review authors can use different strategies to select studies for inclusion. Some QES may include 'all studies' meeting the inclusion criteria. Other QES may use a sampling approach, for example if a large number of studies have been identified (see Chapter 6). • It is helpful to categorise the relevance of each eligible study (direct, partial, indirect, unclear). • If sampling approaches are used, if feasible aim to include directly and partially relevant studies first (see Chapter 6).
2	Collect and consider the information related to relevance of the data	• Gather information from the included studies to identify similarities between the primary study context and context specified in the review question. It can be helpful to include this information in a table or matrix. This stage also helps further clarify the category of relevance (direct, partial, indirect, unclear) for each study. • This step is a "search, find, extract" step and can be integrated with data extraction.
3	Assess the body of data that contributes to each finding and decide whether there are concerns about relevance of the data	• Assessments of relevance are best facilitated by access to subject-specific knowledge either within your review team or from an expert advisory group that may include patient and public representatives. • Assess relevance for each review finding individually (not for the QES as a whole). • Factors that may affect relevance assessments include characteristics of the population, setting/place, time period, or intervention, as well as policy or political issues, the social climate, or legislation. • There are two main threats to relevance of the data: indirect relevance and unclear relevance. Partially relevant studies may or may not cause concern. • Consider whether any contextual characteristics identified as important in the review question and inclusion criteria and reported in the primary studies contributing to a review finding are **directly relevant, partially relevant, indirectly relevant, or of unclear relevance**. • Clarify and agree the category of relevance (direct, partial, indirect, unclear) for each study contributing to a review finding • Where review findings are written in relation to specific sub-populations or aspects of the context, this may shift assessments of relevance from 'partially relevant' to 'directly relevant'. However, review findings should be written in a way that remains meaningful to users.
4	Make a judgement about the	• Start with the assumption of "no/very minor concerns regarding relevance of the data" and rate down if concerns are identified.

	seriousness of the concerns and justify this judgement	• Categorise the concerns as: no or very minor concerns, minor concerns, moderate concerns, or serious concerns. • Minor concerns will probably not lower confidence in the review finding, while moderate concerns may lower confidence, and serious concerns probably will lower confidence. • To ensure transparency, review authors should describe any concerns about relevance of data in the Evidence Profile (required for minor, moderate and serious concerns).
5	iSoQ tips	• Create or import a 'Characteristics of Studies' table into the 'My Data' section of iSoQ and ensure this table includes information that is pertinent to assessing the relevance component (e.g., this may include information about the setting, population or perspective, time, and phenomenon of interest). • Enter the review question and the review inclusion and exclusion criteria in the 'My Data' section of iSoQ. • The 'GRADE-CERQual assessment worksheet' will display this information so that context(s) of the review question can be compared to the context(s) specified in the primary studies. • Use the 'Notes box' to record concerns, select the level of concern, and complete the explanation.

13.4.8 Making an overall GRADE-CERQual assessment of confidence

After assessing each of the four GRADE-CERQual components individually, an overall assessment of confidence in the review finding is made to determine the extent to which the review finding is a reasonable representation of the phenomenon of interest (**confidence**) (Lewin, Bohren et al. 2018). While the methodological limitations, coherence, adequacy and relevance components are assessed in terms of "level of concern", the overall assessment is made in terms of "level of confidence" (Guyatt, Oxman et al. 2011). An assessment of confidence is made for each individual review finding, not the QES as a whole (Lewin, Bohren et al. 2018). Table 6 depicts the four levels of confidence and their corresponding definitions.

In assessing overall confidence, review authors should look for **important concerns** that may threaten confidence in the findings. Minor concerns will probably not lower confidence in the review finding, while moderate concerns may lower confidence, and serious concerns probably will lower confidence.

It is **not recommended** to attempt to numerically score or quantify assessments for each component, as this may introduce a false sense of precision (Lewin, Bohren et al. 2018). GRADE-CERQual assessments are judgements, and the aim is to make these judgments

explicit and transparent through standardised assessment, reporting, and explanations of concerns.

All review findings start as “high confidence” and are then downgraded by one or more levels if there are concerns regarding any of the GRADE-CERQual components (Lewin, Bohren et al. 2018). Decide whether the review authors will ‘rate down’ (lower the level of confidence in the finding) for the concerns identified, and if so, whether the finding will be rated down by one or two levels. For GRADE-CERQual components where review authors identify ‘serious concerns’, the overall assessment of confidence is typically rated down by at least one level (e.g., from high confidence to moderate confidence). Where the concerns regarding the GRADE-CERQual component are minor or moderate, it may not be necessary to rate down. However, if there are a number of concerns across GRADE-CERQual components, it may be appropriate to rate down by one level to represent these (e.g., if there are moderate concerns regarding adequacy of data, and minor concerns regarding methodological limitations, review authors may decide to rate down once for the overall assessment from ‘high confidence’ to ‘moderate confidence,’ due to the moderate concerns regarding adequacy of data).

The process of developing review findings and making GRADE-CERQual assessments may also help to promote an iterative and reflexive discussion amongst the review authors (i.e., reflexivity, see Section 13.8) (Lewin, Bohren et al. 2018). A reflexive approach means considering how the review authors’ positionality influenced the interpretation of data, development of review findings, and GRADE-CERQual assessments (Glenton, Lewin et al. 2022). A more detailed discussion on the process of making an overall GRADE-CERQual assessment of confidence can be found in the paper by Lewin and colleagues (Lewin, Bohren et al. 2018).

Table 13.6. Descriptions of level of confidence in a review finding using the GRADE-CERQual approach (Lewin, Booth et al. 2018)

Level of confidence	Definition
High confidence	It is highly likely that the review finding is a reasonable representation of the phenomenon of interest
Moderate confidence	It is likely that the review finding is a reasonable representation of the phenomenon of interest
Low confidence	It is possible that the review finding is a reasonable representation of the phenomenon of interest
Very low confidence	It is not clear whether the review finding is a reasonable representation of the phenomenon of interest

13.4.9 Who should undertake an overall assessment?

GRADE-CERQual assessments should ideally be undertaken by the review authors to their own review findings because familiarity with the evidence is needed to make reasonable judgments about each GRADE-CERQual component. Typically, GRADE-CERQual assessments are made through discussion between at least two of the review authors. This allows the opportunity to debate the judgments and is a helpful step in the iterative and reflexive process of developing review findings. There may also be a role for patients and the public in helping to make or interpret the overall assessments, for example if these representatives are part of the review team or advisory group (see Section 13.6).

13.4.10 Practical considerations when making a GRADE-CERQual assessment

The following are some practical considerations that review authors should consider when making a GRADE-CERQual assessment (Lewin, Bohren et al. 2018):

- Each overall GRADE-CERQual assessment of confidence should ideally be agreed by consensus and involve at least two members of the review team.
- There is no established order to assess GRADE-CERQual components, and the assessment is an iterative process.
- When making judgments on whether to rate down, consider whether there are any potential interactions and overlaps between GRADE-CERQual components to avoid rating down for the same concern across components (Lewin, Glenton et al. 2015). For example, when assessing methodological limitations, the review team may have

concerns about the methods used for selecting participants as this may have favoured only certain types of participants, but this may overlap with the review team's relevance and/or adequacy assessment depending on how the finding is written.

- If review authors use a sampling approach, this may have implications for the GRADE-CERQual assessments (see Chapter 6).
- When making GRADE-CERQual assessments, review authors are assessing the body of evidence contributing the summarised review findings, regardless of the totality of the evidence potentially available (e.g., studies that met the inclusion criteria but not sampled). Overall GRADE-CERQual assessments for each review finding should be explained transparently in a Summary of Qualitative Findings table that includes a narrative explanation of the GRADE-CERQual assessment.
- Use the recommended standard phrases for describing the assessment of each GRADE-CERQual component and overall assessments (See Section 13.4.8 Making an overall GRADE-CERQual assessment of confidence).
- When the review team has finished making GRADE-CERQual assessments for all review findings, they should review all assessments to ensure that that each component and overall assessment have been conducted consistently, and that the explanations are clearly communicated for the end user.

13.4.11 Creating GRADE-CERQual Evidence Profile and Summary of Qualitative Findings Tables

The GRADE-CERQual Evidence Profile and Summary of Qualitative Findings tables both provide structured summaries of the review findings and information contributing to the GRADE-CERQual assessment (Lewin, Bohren et al. 2018). Producing these two tables helps the review authors to (Lewin, Bohren et al. 2018):

- Carefully consider what constitutes a review finding,
- Express each review finding clearly, and
- Ensure that judgments underlying GRADE-CERQual assessments are transparent.

An **Evidence Profile** is a table that includes the summaries of the review findings, level of concerns and explanations for each GRADE-CERQual component, the GRADE-CERQual overall assessment of confidence and explanation, and references to the studies contributing to each review finding.

The **Summary of Qualitative Findings table** is a shorter version of the Evidence Profile and includes the summaries of the review findings, overall GRADE-CERQual assessments, explanation of the overall GRADE-CERQual assessment, and references to the studies contributing to each review finding. Examples of an Evidence Profile and corresponding Summary of Qualitative Findings table are available in Tables 13.7 and 13.8.

The Summary of Qualitative Findings table is typically the version most useful to end users of the review (e.g., guideline panels). The Summary of Qualitative Findings table is also a version of the review findings that can be shared and discussed with patient or consumer groups for feedback on understandability and transferability (Munthe-Kaas, Nøkleby et al. 2020). How to consider and assess transferability of a QES is discussed in detail elsewhere (Munthe-Kaas, Nøkleby et al. 2020).

The iSoQ tool is designed to help review authors produce an Evidence Profile table and a Summary of Qualitative Findings table. Once review authors enter their summarised review findings into the iSoQ table and assign the findings their supporting references, a 'GRADE-CERQual assessment worksheet' becomes available for each individual finding. This worksheet includes the Evidence Profile table which review authors work their way through completing – starting with assessing the four components and then the overall assessment. The worksheet displays the information about the contributing studies (e.g., study characteristics, extracted data, methodological assessments) that the authors need to consider when making their assessments. iSoQ also helps to ensure that consistent and correct language is used in GRADE-CERQual assessments, and that all of the essential elements are present in Summary of Qualitative Findings and Evidence Profile tables. This includes an explanation of the overall assessment of confidence which, as a minimum, states the level of concern for each component, but ideally also includes in brackets the

concerns that are driving down the level of confidence (moderate and serious concerns). Summary of Qualitative Findings tables and Evidence Profile tables can be printed and exported to Word or PDF and can be copied and pasted into other systematic review programmes such as RevMan for QES, GRADEpro GDT, or MAGICapp. The iSoQ table can also be published to the iSoQ database, providing the users of qualitative evidence with easy access to review findings and respective confidence assessments. By making iSoQ tables fully public on the iSoQ database, users can access the 'GRADE-CERQual Assessment Worksheets' and interact with the Evidence Profile to understand how confidence assessments were reached.

Table 13.7. Example of a GRADE-CERQual Evidence Profile. Adapted from (Cooper, Schmidt et al. 2021). Please note that Tables 13.7 and 13.8 have been adapted from the original for training purposes only.

Summarised review finding	Methodological limitations	Coherence	Adequacy	Relevance	GRADE-CERQual assessment of confidence	References
Claiming parental expertise. Many parents from high income countries held a view of themselves as experts of their child, possessing the best understanding of their child's health strengths and vulnerabilities. They in turn considered themselves best placed to judge their child's vaccination needs and risks.	Minor concerns: limited evidence of sensitivity to ethical concerns and reflexivity in many studies	Moderate concerns: although generally the case, data were a bit more varied; for example, in some studies, parents did not consider themselves to be experts of their child, and other studies showed that some parents considered others (such as doctors, peers) to be experts of their children and also well-positioned to judge their children's needs (contradictory data)	No/very minor concerns: 10 studies contributing a large amount of rich data	Minor concerns: 4 studies focused only on MMR vaccination, 3 studies only included parents who were hesitant towards or nonaccepting of vaccination, and 4 studies only included parents from higher socioeconomic groups (partial relevance)	**Moderate confidence**: Moderate concerns about coherence (contradictory data). Minor concerns about relevance and methodological limitations	Petts 2004; Poltorak 2005; Casiday 2007; Brunson 2013; Johnson 2014; Reich 2016; Sobo 2016; Ward 2017; Carrion 2018; Peretti-Watel 2019
Religious beliefs. Some parents were less accepting of childhood vaccination due to the religious beliefs they held, and the view that illness, including in children, can only be prevented by divine providence. These parents	Minor concerns: limited evidence of sensitivity to ethical concerns	No/very minor concerns	Serious concerns: there were only two relatively small studies	Moderate concerns: one of the two studies looked at nurses' views and experiences of parent's beliefs about childhood vaccination, rather than the views of the	**Low confidence:** Minor concerns about methodological limitations Serious concerns about adequacy (only two small studies), Moderate concerns about relevance as	Renne 2010; Reich 2016

expressed religious objections to vaccination.				parents themselves (indirect relevance)	one of the two studies looked at nurses' views and experiences of parent's beliefs about childhood vaccination, rather than the views of the parents themselves (indirect relevance)	

Table 13.8. Example of a GRADE-CERQual Summary of Qualitative Findings table. Adapted from (Cooper, Schmidt et al. 2021).

Summarised review finding	GRADE-CERQual assessment of confidence	Explanation of GRADE-CERQual assessment	References
Claiming parental expertise. Many parents from higher income countries held a view of themselves as experts of their child, possessing the best understanding of their child's health strengths and vulnerabilities. They in turn considered themselves best placed to judge their child's vaccination needs and risks.	Moderate confidence	Finding downgraded because of moderate concerns about coherence (contradictory data), and minor concerns about relevance (partial relevance) and methodological limitations	Petts 2004; Poltorak 2005; Casiday 2007; Brunson 2013; Johnson 2014; Reich 2016; Sobo 2016; Ward 2017; Carrion 2018; Peretti-Watel 2019
Religious beliefs. Some parents were less accepting of childhood vaccination due to the religious beliefs they held, and the view that illness, including in children, can only be prevented by divine providence. These parents expressed religious objections to vaccination.	Low confidence	Finding downgraded because of minor concerns regarding methodological limitations, serious concerns about adequacy (only two small studies), and moderate concerns about relevance as one of the two studies looked at nurses' views and experiences of parent's beliefs about childhood vaccination, rather than the views of the parents themselves (indirect relevance)	Renne 2010; Reich 2016

13.5 Using GRADE-CERQual assessments to inform the 'Implications for research' section of a QES

Review authors can use the GRADE-CERQual assessments to develop the 'Implications for research' section of their QES. Review authors can do so by assessing whether their confidence was often downgraded for the same reasons across multiple findings. For example, review authors can consider the following:

- Was there often a lack of data in relation to the review findings?
- Were certain relevant perspectives (such as those of younger people or those with particular gender identities) often missing that may have implications for equity (see Section 13.7)?
- Were studies mostly conducted in very specific settings or with particular population groups?
- Were studies often poorly designed or conducted? (e.g., did most of the included studies display poor reporting of study author reflexivity?).

Review authors can use this information to suggest the range of evidence gaps and challenges that future researchers should be addressing. Further detailed information on how to use GRADE-CERQual assessments to inform the 'Implications for research' section can be found elsewhere (Glenton, Lewin et al. 2022).

13.6 Stakeholder involvement and engagement

Collaboration with stakeholders such as policy makers, decision-makers, patient and public representatives can help ensure the relevance and accessibility of the review. For instance, stakeholders can be involved when determining the review question, defining key concepts, and developing implications for practice. Review authors may also engage stakeholders early in the review process to explore factors influencing the transferability of the review findings, for example using the TRANSFER approach (Munthe-Kaas, Nøkleby et al. 2020). Where this has been done, these factors can inform judgments regarding the relevance component of GRADE-CERQual. Stakeholders can also provide feedback regarding the understandability and readability of key sections in the review, such as the

plain language summary, the Summary of Qualitative Findings table, and the implications for practice section.

The iSoQ tool can facilitate stakeholder involvement in providing feedback on the Summary of Qualitative Findings and Evidence Profile tables specifically. The tool enables the lead review author to activate a temporary link to the interactive Summary of Qualitative Findings which can then be shared with stakeholders such as guideline panelists, committee members, or service users. They can thus view the most up-to-date version of the Summary of Qualitative Findings and Evidence Profile tables any time they use the link and can access all the underlying data and component assessments on which the GRADE-CERQual overall assessment of confidence is based.

13.7 Equity, diversity, and inclusion

It is important to consider how decisions made at various stages of the review may influence the GRADE-CERQual assessments. One of the aims of a QES is to explore a broad range of perspectives as specified in the protocol. Review authors should therefore consider which perspectives they have searched for and which have been identified in the included studies; whether specific groups are underrepresented; and the implications this may have for equality, diversity and inclusion. For instance, minority and marginalised populations may not be well represented in the available studies addressing a particular review question.

Review authors often engage and involve stakeholders. The choice and selection of stakeholders ideally needs to reflect the review topic, question and population of interest in order to accommodate equity, diversity and inclusion considerations in the development of findings and GRADE-CERQual assessments. In addition, review authors should consider equity, diversity and inclusion if a study sampling approach is used (see Chapter 6) and when decisions are made regarding which publication languages the review will include. Engaging with diverse languages when conducting a QES is discussed in detail elsewhere (Glenton, Lewin et al. 2022).

It is important that review authors do not disregard review findings judged to be low confidence, as it might be that the GRADE-CERQual assessment draws important attention to the limited evidence regarding a particular issue affecting a particular population or sub-population of interest.

13.8 Reflexivity

When developing review findings and conducting GRADE-CERQual assessments, review authors should carefully consider their own positionality concerning how the review findings are developed, which review findings are presented in the Summary of Qualitative Findings and Evidence Profile, and judgments made when conducting the GRADE-CERQual assessments. For example, where review authors have a clinical background and are working on review findings that explore patients' experiences of care, attention should be paid to ensure that the review authors' clinical perspectives do not overshadow the patient's perspectives, including any negative experiences of care. Having a review team with diverse backgrounds and training and engaging in reflexive discussions and debriefing throughout the conduct of a QES, including during GRADE-CERQual assessments, can help to identify personal or group beliefs that may influence the QES findings and GRADE-CERQual assessments, and to challenge assumptions. Involving relevant stakeholders may also help to draw attention during GRADE-CERQual assessments to a wide range of perspectives.

13.9 Chapter information

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Declarations of interest

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