THIS GUIDE IS UNDER DEVELOPMENT.

FEEL FREE TO USE IT AND PLEASE SEND US FEEDBACK TO:

KVALMETOD@SBU.SE

Guide to template for qualitative evidence syntheses (QES)

UPDATED 2023-11-01

SBU has developed a template to support the review of qualitative evidence syntheses (QES). The objective of the template is to assess whether the findings of the evidence synthesis may have been affected due to limitations in the design or in the execution of the evidence synthesis. SBU also has a shorter version of this template that can be used, for example by those who are more experienced in assessing qualitative evidence syntheses. You can find that template here.

The template is based on important aspects of the ENTREQ criteria [1] and the publication by Flemming and Noyes [2].

The template begins with an overall assessment of the risk that the findings have been affected by methodological limitations. The overall assessment is made at the very end. Assessment of seven individual domains is made with the support of signal questions. The signal questions highlight significant methodological aspects and the risk that they have affected the findings of the evidence synthesis. This document is a guide to the template. It contains brief descriptions of what the signal questions refer to, as a support for making assessments of methodological limitations.

1

The methodology of qualitative evidence syntheses displays great variety, which can partly be explained by differences between research areas, study types and reporting requirements. In the assessment of a qualitative evidence synthesis, the focus should be on making a balanced overall assessment.

The answer option "unclear" is not described for those signal questions where it is difficult to make a general definition of that option, but also in cases where that option is not essential. If both descriptions of the "yes" and the "no" option do not seem fit, "unclear" is likely to be the most appropriate option. The answer to each signal question is an assessment made by the reviewer.

Comments on domains and signal questions

Overall assessment of methodological limitations in the evidence synthesis

Summarize the assessments made for the seven domains. Assess whether, and if so to what extent, you believe that the identified methodological limitations may have influenced the findings of the evidence synthesis. Note important limitations and pivotal assessments. Observe that the assessment should not be done in such a way that a certain number of domains with methodological concerns automatically leads to a certain overall assessment. The individual domains may have different significance depending on the evidence synthesis. However, a rule of thumb is that major limitations in domain 2 (literature search) have a major impact on overall reliability.

Insignificant or minor limitations: The limitations are insignificant or minor, and the risk of the findings being affected by them is considered to be low.

Moderate limitations: Methodological limitations have been identified and the risk of findings being affected by them is considered to be moderate.

Major limitations: Methodological limitations have been identified, and the risk that the findings have been affected by them is considered high. For example, the assessment is that there is a high risk of central descriptions of the phenomenon being completely different compared to a synthesis where the methodological limitations are minor, or that important variations probably have been missed. SBU usually excludes syntheses with major methodological limitations from their reports.

Domain 1 - Objective and selection criteria

Question 1a) Was the objective of the evidence synthesis clearly described?

Yes

There is a clear description that cannot be misinterpreted, or it is difficult to misinterpret the description.

No

The description can be misinterpreted, even with the help of expertise in the research field, or a description is missing altogether.

Question 1b) Were the selection criteria clearly described?

Yes

Clear selection criteria that cannot be misinterpreted, or the criteria are difficult to misinterpret. Ideally, the criteria are set up with the model SPICE, or similar.

Unclear

There are some ambiguities in the description of the selection criteria, or in the light of the research question, there is a need for more detailed descriptions of the criteria.

No

Selection criteria that may be misinterpreted even with the help of expertise in the relevant field of research, or that the criteria are very poorly described.

Question 1c) Were the selection criteria appropriate for the objective of the evidence synthesis?

Yes

The selection criteria are in line with the question/objective of the evidence synthesis, as described by the context, population, intervention, evaluations, and other selection criteria. Ideally, the selection criteria have been set using SPICE or similar models.

No

The selection criteria are inappropriate for the question/objective of the evidence synthesis. For example, it may be that the criteria are too narrow, too extensive or set in a way that risks skewing the findings of the evidence synthesis in a way that is not appropriate in relation to the objective.

Question 1d) Did the work follow a predetermined research plan?

Yes

There is a pre-published protocol or research plan available, which states that the question/objective has been followed throughout the work process and that deviations are documented, justified (e.g. in an "audit trail") and in line with the original objective. For example, the protocol may be published on www.crd.york.ac.uk/PROSPERO/ or www.thecochranelibrary.com/.

Or that you have good reason to assume that the question/objective has been stated in advance, that the research question/objective has been followed throughout the work process and that deviations are documented, justified and in line with the original objective.

Unclear

There are indications that there are some limitations in the aspects described above, that the objective may have been introduced/adjusted afterwards, or that there are ambiguities in the research plan, or that such a plan is not available.

No

There is support for the fact that several of the aspects described above are missing or that the objective has been introduced/adjusted without explanation afterwards.

Assessment of methodological limitations - domain 1

Insignificant or minor limitations: Efforts, that can be followed through the work process, have been made in formulating the research question and selection criteria that are appropriate, predetermined, justified and sufficiently detailed.

Moderate limitations: There are some ambiguities or question marks about how the research question is stated, how the selection criteria are designed, described, or if they are appropriate for the research question.

Major limitations: Literature that is relevant for the research question has most likely been missed because the research question was unclear, selection criteria were unclear, inappropriate or missing, or due to delimitations that are not suitable for the research question.

Domain 2 - Literature search

It is an advantage if an information specialist, and/or an expert in the field, can be involved in assessing the search strategy.

Question 2a) Was the search approach appropriate for the objective of the evidence synthesis?

Depending on the objective of the evidence synthesis, different search approaches can be used. Some common types of approaches are exhaustive, targeted, or iterative. A structured and exhaustive search is needed if the objective of the evidence synthesis makes it essential to consider all relevant literature in the field. The search strategy must then be established before the search is carried out. If the objective of the evidence synthesis rather is to make an overall interpretation of the phenomenon it would be more appropriate to have a narrow and targeted search (purposive sampling). With an iterative approach, the search is performed stepwise until you consider that data saturation is reached.

Yes

The approach of the search is appropriate for the objective of the evidence synthesis, and it is likely that the approach guarantees that literature of crucial importance for answering the question can be found.

No

The approach of the search is probably not appropriate for the objective of the evidence synthesis. There is a considerable risk that literature essential for answering the question has been missed.

Question 2b) Did the search strategy enable the literature relevant to the evidence synthesis to be captured?

Extensive documentation of the searches needs to be in place, or a description with sufficient detail to replicate the search. It is necessary that the search strategy include appropriate terms in appropriate combinations.

Yes

The search has most likely captured relevant literature to an extent that is sufficient for the objective of the evidence synthesis.

Unclear

Literature relevant to the evidence synthesis may have been missed, for example, because there is a risk that certain key terms are missing, or that they have been combined in an inappropriate way.

No

The search has probably missed literature relevant to the question of the evidence synthesis, for example, because important search terms are missing. Alternatively, there is no information about the search strategy.

Question 2c) Was the literature search conducted in appropriate databases and other types of sources?

It requires expertise from information specialists or similar competencies and sometimes also experts in the field, to assess whether the databases and sources searched are the ones that are most likely to contain the relevant literature.

Yes

There is documentation of the searches which shows that searches have been carried out in relevant databases and other sources in the area. An exhaustive search requires searches in at least two databases.

No

It is not clear which databases and sources have been searched, or that it appears that none of the essential databases or sources in the field have been searched.

Question 2d) Were the delimitations of the search strategy appropriate?

Delimitations in the search strategy may be publication date, language, or publication format. Most often, there is a need to discuss with experts in the field regarding appropriate delimitations.

Yes

No restrictions on date, language, or publication format. Or that the delimitations in the search strategy were well justified and appropriate.

No

The evidence synthesis has used delimitations without justification, and these are most likely inappropriate.

Question 2e) Were appropriate search methods, complementary to the electronic literature search used?

Often, supplementary search methods such as contact with experts, citation search, hand search, and review of reference lists, are needed to increase the likelihood that relevant literature is captured.

Yes

Additional search methods were used that were sufficiently described, and these are assessed as adequate complements to the electronic search.

No

Additional search methods were necessary, but they were not used.

Assessment of methodological limitations – domain 2

Insignificant or minor limitations: An appropriate search approach has been used, and the search strategy was designed in a way that the relevant literature is likely to have been captured.

Moderate limitations: Insufficient reporting makes it difficult to assess whether there are weaknesses in the design of the search, or reporting indicates that the search contains certain weaknesses, e.g., relevant search terms are missing, which makes it unclear whether the search has captured the relevant literature.

Major limitations: Most likely, relevant literature has not been captured, for example, due to an incorrect search approach, or due to major flaws in the design of the search.

Domain 3 - Selection and Assessment of Studies

Question 3a) Was the selection of studies carried out by at least two persons, independently of each other and by consensus?

Yes

At the abstract level it is preferable that independent screening is performed, where at least two people individually read all titles and abstracts and select studies that are potentially relevant. It is sufficient that one person chooses a study for it to be read in full text.

At the full-text level, there are two acceptable options:

- 1. Independent assessment followed by consensus. At least two people read all the full texts separately and select the studies that they judge to be relevant for the evidence synthesis. The findings are compared and discrepancies in the assessments are discussed in a consensus procedure.
- 2. One person reads all the articles in full text and selects relevant studies. Another person verifies (unblinded) both the included and excluded articles. Discrepancies in the assessments are discussed in a consensus procedure.

Unclear

Only parts of the material have been reviewed by at least two persons. However, if the objective of the evidence synthesis for example is to make an overall description of the phenomenon, this method may be adequate. Or that the description of how the selection of studies has been made is unclear.

No

The selection has been made by one person only, without verification of the selection by another person.

Question 3b) Is sufficient information regarding included and excluded studies available?

Yes

There is a list of included studies and enough data about the studies, for example in the form of a table with study characteristics. The data need to be sufficiently comprehensive to provide an understanding of how the included studies have been performed, whether the selection of studies made seems to be appropriate and whether the findings of the evidence synthesis are transferable to the specific context in which the reader is interested. The data may need to include objective, theoretical approach, context, how participants were recruited, brief information about the participants, how data was collected and analyzed, and possibly other relevant information about the studies.

Excluded studies are found in an exclusion list with a clear exclusion reason for each article.

No

The information about the included studies is not available or has serious flaws, or a list of excluded studies is missing.

Question 3c) Were the methodological limitations of relevant studies appropriately assessed, for example by using validated checklists?

Yes

Important aspects of methodological limitations in the included studies were assessed. These can be assessed using a previously developed template/checklist, or that the assessment is sufficiently described so that it is possible to determine if something in the assessment is missing. Identified limitations in each included study shall be summarized and presented in a clear manner.

No

Methodological limitations have not been assessed, or there is good reason to believe that essential aspects of the assessment have not been made.

Question 3d) Was the assessment of methodological limitations carried out by at least two persons, independently of each other and by consensus?

Yes

Independent assessment of the methodological limitations of the studies by at least two people, followed by a consensus procedure.

Unclear

One person assesses the methodological limitations, and another person verifies the assessments (unblinded). Or that the description of how the assessment of the methodological limitations has been made is missing or unclear.

No

Only one person assesses the methodological limitations without validation or verification by another person.

Assessment of methodological limitations - domain 3

Insignificant or minor limitations: The relevance of, and the methodological flaws in, the included studies were systematically assessed with appropriate requirements. The risk of mis-assessment of the studies through independent work was minimized and coordinated. There is sufficient information about the selected studies as well as a list of excluded studies with reasons for their exclusion.

Moderate limitations: An unclear methodological description, results in uncertainty regarding if studies have been selected and assessed appropriately.

Major limitations: There has been no independent selection of abstracts. Or that one person has made assessments of relevance or methodological limitations, or that there are reasons to believe that essential aspects of study assessments are missing. Or that the information about the selected studies is highly inadequate or missing altogether.

Domain 4 - Synthesis

Question 4a) Was the used synthesis method appropriate?

Yes

The synthesis method is sufficiently described, either directly in the article or via reference to a method article, and the assessment is that the used synthesis method is appropriate for the objective of the evidence synthesis. If the synthesis contains an interpretive step, this needs to be in line with the chosen theoretical approach.

No

There is no method reference, and the own description of the synthesis method is inadequate. Or the assessment is that the synthesis method is inappropriate the objective of the evidence synthesis.

Question 4b) Was the synthesis appropriately performed?

Yes

The synthesis process is thoroughly described, and it is possible to assess whether relevant findings from the primary studies have been included and handled further in the synthesis in an appropriate manner. Several people in the research group need to have participated in the work with the synthesis and contributed with different skills. The process should have "gone back and forth" and alternative descriptions/interpretations should have been explored.

No

For example, the work was carried out by one person with no or little participation/supervision of others.

Question 4c) Were the findings of the evidence synthesis clearly grounded in the included studies?

Yes

It is possible to follow how the findings of the evidence synthesis are based on the findings in the primary studies, and that all relevant findings from the studies are essentially described in the overarching themes of the synthesis; that is, the coherence of the synthesis is good. For this assessment, access to meaning units, themes at the lowest level, or the findings of the included studies are presented in more detail in some form. For interpretive steps, it is possible to follow how findings from the studies have been interpreted/how new knowledge has been generated, based on the chosen theoretical approach.

No

The assessment is that the findings of the evidence synthesis are not clearly based on the findings in the included studies, either based on information contained in the evidence synthesis or based on taking part of the findings in the included studies. For example, important variations have been omitted from the descriptions of the themes and categories in the evidence synthesis, some findings are not supported by data from the included studies, or interpretations have been made in an inappropriate or incorrect way based on the stated theoretical approach.

Question 4d) Were the findings appropriately validated?

Validation means that someone who has not participated in the work reviews the synthesis and verifies the findings. There are several methods for validating the synthesis. For example, an external expert or a panel of users can be engaged.

Yes

An appropriate form of validation was used. Any identified limitations in the synthesis have been adequately addressed.

The synthesis has not been validated, or there are reasons to believe that it has been done inappropriately.

Assessment of methodological limitations - domain 4

Insignificant or minor limitations: The chosen synthesis method is clearly described and appropriate with regard to the objective of the evidence synthesis. All steps in the synthesis can be followed and these are performed in an appropriate manner. The findings are clearly grounded in the included studies and a validation of the findings has been carried out in an appropriate manner.

Moderate limitations: There are limitations in the description of the synthesis method or how the synthesis has been performed, there are reasons to believe that the method may not be appropriate, parts of the work with the synthesis are not appropriately carried out, or that there are flaws in the connection with the findings in the included studies. The assessment is that there is a moderate risk that the findings may have been affected by the limitations.

Major limitations: Descriptions of the synthesis method or how the synthesis has been carried out are very rudimentary or missing altogether. Or the assessment is that the method is inappropriate, that the work with the synthesis is inappropriately performed, or that a connection to the findings in the included studies is missing. The assessment is that there is a high risk that the findings may have been affected by the limitations.

Domain 5 – Author reflexivity

Question 5a) Was the collective competence of the authors adequate to handle all steps of the evidence synthesis?

Yes

The evidence synthesis was carried out by several people with different competencies, such as expertise in the field, the experience of qualitative research methods, practical/clinical work in the field, knowledge of literature search for and methodological knowledge of qualitative evidence synthesis. The collective competence within the group ensured that all steps of the evidence synthesis have been managed in an appropriate manner.

Unclear

There are limitations in the description of the author's competence and background and/or in the description of who in the group has carried out which steps in the work.

No

The evidence synthesis was carried out by a few people where key competencies are clearly missing while not describing how the potential lack of skills/experience has been addressed.

Question 5b) Have the authors handled their preunderstanding in an acceptable way?

The preunderstanding includes age, gender, ethnicity, level of education and experience in the field. If there is a clear bias in preunderstanding among the authors, it may be appropriate to involve other people with different preunderstanding in parts of the work. The authors' pre-understanding can affect all steps in the evidence synthesis, not least in the work with the synthesis.

Yes

The authors clearly report their own pre-understanding and have used appropriate methods to deal with the pre-understanding.

Unclear

There are ambiguities in the description of how the authors have handled their preunderstanding, or what person in the group has performed which steps in the work.

No

Descriptions of how the authors have handled their preunderstanding are missing, or the described handling is judged to be inadequate. It is likely that the researchers' preunderstanding has highly affected the findings of the evidence synthesis.

Question 5c) Were the authors independent of conflicts of interest that could affect one or more steps in the work with the evidence synthesis?

Conflicts of interest can often be difficult to identify, why expertise in the field may be needed for identification. For example, controversial topics may contain a risk that results from the research will be skewed to fit a certain position in the debate. Self-interest, such as the evaluation of methods that one or more of the authors have been involved in developing, may have a similar effect. It can also be about relationships with authors of studies that have been handled in the work with the evidence synthesis.

Yes

The researchers do not seem to have any conflicts of interest that have affected them inappropriately during the work with the evidence synthesis. Relationships with authors of studies that have been assessed in the work with the evidence synthesis seem to have been handled in an appropriate manner.

Unclear

There are, or there appear to be, conflicts of interest, but it is difficult to assess whether they have influenced the findings of the evidence synthesis.

The researchers declare conflicts of interest, or knowledge of conflicts of interest have been attained in other ways, and this has probably affected the findings of the evidence synthesis.

Assessment of methodological limitations - domain 5

Insignificant or minor limitations: The authors have sufficient competence, their preunderstanding has been handled appropriately and there appears to be no conflict of interest. The risk of impact on the findings is low.

Moderate limitations: The information on the authors' competence, management of pre-understanding and disclosure of conflicts of interest is not sufficiently well described. The assessment is that there is a moderate risk that these factors have influenced the findings.

Major limitations: There is a lack of important competence among the authors and no description of how this has been handled, or a description of how the authors have handled their preunderstanding is missing altogether, or there are clear conflicts of interest. The assessment is that there is a high risk that these factors have affected the findings.

Domain 6 - Other aspects

Question 6a) Are there other methodological limitations that may have affected the findings in the evidence synthesis?

There may be methodological flaws in the evidence synthesis that are not identified by the signal questions in domains 1–5. Qualitative study methodology covers a great variety, and it is difficult to generally cover all potential limitations in this regard. Consider whether there may be other limitations in the evidence synthesis. If so, note what they are and assess the risk of them having affected the findings of the evidence synthesis.

Assessment of methodological limitations - domain 6

Insignificant or minor limitations: Other methodological flaws have not been found, or these are not considered to have affected the findings to any significant extent.

Moderate limitations: Other methodological weaknesses have been identified, and the assessment is that there is a moderate risk that these factors have influenced the findings.

Major limitations: Other methodological limitations have been identified, and the assessment is that there is a high risk that these factors have influenced the findings.

Domain 7 – Assessing the confidence in the evidence synthesis findings

Question 7a) Has the confidence in the evidence synthesis findings been appropriately assessed?

Can only be adequately answered if assessments of confidence in the evidence synthesis findings have been made. Ideally, the GRADE-CERQual framework is used. If not, important aspects that may affect the confidence in the findings need to be assessed, such as the methodological limitations of included studies, coherence in synthesis, etc. Note that even if the evidence synthesis has used an appropriate methodology, the assessments may need to be redone according to local conditions.

Yes

A thorough description of how the assessments have been made. For example, it is clear whether the authors have decided in advance how deductions in confidence are to be made. Limitations in confidence are clearly described in conjunction with each finding, and the assessments appear to be reasonable.

Unclear

The description of how the assessments have been made is unclear, or there is merely a general discussion of how likely it is that the review finding is a reasonable representation of the phenomenon of interest.

No

The assessments have been made in an inappropriate manner. For example, important aspects of confidence have not been assessed. Or that the assessments appear to be unreasonable, for example findings that have been judged to have high confidence when they in fact are supported by thin data from individual studies with serious methodological limitations.

Assessment of methodological limitations – domain 7

Insignificant or minor limitations: Confidence assessments have been carried out in a structured, transparent and reasonable manner. Or they have not been carried out at all.

Moderate limitations: Unclear descriptions of how the assessments regarding confidence in the findings have been performed, making it difficult to assess whether the assessments have been carried out appropriately.

Major limitations: Assessments regarding confidence in the findings have been carried out inappropriately or appear to be unreasonable.

References

- 1. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. BMC Med Res Methodol 2012;12:181
- 2. Flemming, K. and J. Noyes, Qualitative Evidence Synthesis: Where Are We at? International Journal of Qualitative Methods, 2021;20:1-13