Chapter 2 Defining the scope and formulating review questions

Andrew Booth, Jane Noyes, Kate Flemming and James Thomas

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Key Points:

- Qualitative evidence syntheses (QESs) seek to address answerable questions and to generate findings based on primary qualitative research.
- Primary qualitative research and QESs seek understanding grounded in people's perspectives, experiences and actions while paying particular attention to meaning in context.
- Developing good review questions takes time, expertise, and input from stakeholders, including patients and the public.
- QES questions may target specific interventions or conditions or specific phenomena or situations of interest.
- The question sets the pattern for subsequent stages of the QES.
- Conceptual frameworks – including logic models and other formats for expressing theories - may help a review team to identify and refine the scope of a review and the question(s) that it will address.
- Review authors and stakeholders need to make transparent their individual and collective biases when formulating questions and refining the scope of the review

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2.1 Introduction

Defining the scope of the review and developing a well-formulated question are the first and most important decisions in the review process (Squires, Valentine, and Grimshaw 2013). A well-formulated question makes clear the topic of interest and what the review seeks to understand, explain or describe. A well-formulated 'scope' will define the main concepts in the review – for example, populations, conditions, interventions, contexts, and theories – and how they relate to one another. A review team conducting a QES without a clear scope and focussed question will find it difficult to decide which studies to include/exclude (Harris et al. 2018). The review question and scope are developed alongside one another, defining the issues to be addressed, and the boundaries of the review; this in turn helps to define eligibility criteria for studies to be included.

Formulating the review question and specifying the scope of a review involve a process of problem framing, often involving the construction of a preliminary conceptual framework or logic model (Chapters 3 and 4) to illustrate relationships and develop an understanding of context (Harris et al 2018). Questions and scope are then refined and focused which then drives protocol development including specifying inclusion and exclusion criteria and searching to identify available evidence (Chapter 5).

Early steps of the QES associated with defining the scope and formulating review questions often include:

1. Turning the topic that the QES will address into a clear and specific question that reflects the overall purpose of the QES (Section 2.2 and Chapters 3 and 4).
2. Identifying and defining relevant concepts that are central to the QES question including what is being studied, who is being affected, what is the context and what data is being collected (Section 2.2 and Chapters 3 and 4)
3. Developing inclusion and exclusion criteria for including and excluding studies (Section 2.5).
4. Conducting a preliminary scoping search (Section 2.5).
5. Refining the review question to ensure that it is feasible and addresses a gap in the literature (Section

This chapter begins by outlining key issues to consider when developing the review question and scope for a QES including criteria for developing a good review question and

the types of questions that might be addressed by a QES. It then considers issues of relevance; focusing first on the important role of stakeholders in helping to ensure the scope of a QES is relevant before extending to different interpretations of what relevance means. Having described how to define the scope of a review question, different question frameworks are described and alternative frameworks and models explored. Issues relating to stakeholder engagement and involvement and equity, diversity and inclusion are then discussed. The chapter concludes by outlining important considerations regarding reflexivity in relation to question formulation and defining the review scope.

2.2 Moving from a review topic to a review question

Novices commonly confuse a topic with a review question. They claim that "a review already exists on my topic" or "there are too many studies on my topic to synthesise them". A topic is less precise than a question. . According to the Cochrane intervention handbook consideration of scope is where a review team explores whether their question will be broad or narrow and whether they will "lump" similar conditions or interventions together or whether conditions or interventions are sufficiently different to be "split" across different reviews (Thomas et al, 2021). Consideration of scope is also a chance for a review team to discuss the essential nature of the topic, the likely characteristics of included studies and the quantity and quality of the available evidence.

A Cochrane intervention review typically states questions as review 'Objectives'. A statement of the review's objectives should be precise, stating the main objective(s), preferably in a single concise sentence. For example, an objective might read: To identify factors that influence the organisation and delivery of X for population Y[1].

While expressing the question as objectives seems reasonable in intervention reviews given their shared purpose in determining an effect, such an approach feels less appropriate in a QES with its variation in question formulations and its diversity of phenomena of interest. Further clarity is achieved by following publishing practice in reporting a well formulated

[1]The team "factors" is preferred to "barriers and facilitators" as it offers a more nuanced (non-binary) way of conceiving variation across populations or interventions.

review question that is then followed by a set of objectives that outlines how the review question was addressed.

Some syntheses may include secondary objectives and seek to explore:

- whether the data show differences across different population subgroups (e.g. younger versus older adults) or contexts (e.g. rural versus urban environments) (see section 2.9 on equity, diversity and inclusion)
- how the QES helps explain aspects of a corresponding intervention review.

Subsequently, the components of a question are operationalized, in choosing the studies eligible to answer those questions, as 'Criteria for considering studies for this review'" (McKenzie et al, 2019).

2.3 What makes a good review question?

A good review question is likely to meet most (if not all) of the criteria summarised in the FINER mnemonic: **F**easible, **I**nteresting, **N**ovel, **E**thical, and **R**elevant (Cummings, Browner, and Hulley 2013).

Most importantly, reviews must be **F**easible. If a question is framed too broadly (see section 2.5 on 'scope' below), then it may result in unmanageable quantities of literature being retrieved, and the review failing simply because the team does not have the resource to complete the work. Overly broad reviews are not only a data management challenge however, as they may contain so much diverse literature that in-depth and nuanced analysis becomes impossible, resulting in rather vague and abstract findings, which are difficult to apply and use.

Possibly surprisingly on first glance, it is also important for review questions to be **I**nteresting. Many systematic review projects are conducted without specific funding, and many fail if the team is not sufficiently invested in the value of their work; they need to be interested enough in the question to want to see it answered. As well as the review team itself, people in the wider environment – including stakeholders, and potential funders – will only pay attention to a review if it addresses a question of interest to them.

A **N**ovel review question is one that will contribute new knowledge to the field. While replication has its place in science, most QESs will not seek to reproduce existing evidence syntheses but will address gaps in understanding. For this reason, it is important that

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review authors are aware of potentially overlapping QESs by undertaking scoping searches (see Chapter 5 and Section 2.5) and checking the PROSPERO database (https://www.crd.york.ac.uk/prospero/). This helps to minimise research waste and positions the intended review within the wider research context.

All research should adhere to high **E**thical standards, and reviews are no different. Given their proximity to decision-making, and the fact that a QES is often one of the ways that more marginalised voices can be heard when decisions are made, ethical considerations should be central when framing the question of a QES. For example, when developing a QES which is intended to inform hospital discharge policy, which study population should be included? Hospital staff, carers, and / or patients? Choices about where to draw the boundaries of a review directly affect which perspectives are included or excluded; in this sense, review questions are not value-neutral or 'objective': they represent the values and priorities of the review team (and wider stakeholders). More prosaically, significant resources are often devoted to undertaking a review, and time spent addressing one question cannot be spent on another. It is important then, that scarce and valuable review author time is devoted to questions that matter – and will make a difference – rather than those that will not.

Finally, reviews should address **R**elevant questions, clearly articulated, and a decision maker should be able to compare the review question to what they need to know to establish that the QES is relevant to their issue of interest. Involving all relevant stakeholders in framing the review question is critical to ensuring its relevance, and this is addressed in section 2.4.1. In addition, it may be helpful to bear in mind that Cochrane and Campbell reviews are undertaken to support global decision making. This creates challenges for review authors in being specific about relevance as QES questions are often situated within a specific context; for example, a QES may be undertaken to address specific questions for a national or regional funder and then be published in the Cochrane library for a global audience (Booth, Moore, et al. 2019; Booth, Mshelia, et al. 2019). Consideration will need to be given to how relevance is considered in both situations. (See also section 2.9 on equity, diversity and inclusion.)

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2.3 Types of Questions addressed by a QES

QESs are flexible in the type of questions that they can address – mirroring the questions answered by primary qualitative studies (Harris et al. 2018). In the context of Cochrane and Campbell reviews, QES questions often fall into two broad areas: 1) those that are concerned with people's experiences and understandings about a particular condition or situation; and 2) those that are focused on people's experiences of interventions. The first type of question covers numerous diverse foci, ranging from, for example, understanding the factors that affect participation in randomized trials (Houghton et al, 2020 to how children and young people with chronic non-cancer pain and their families experience and understand their condition, pain services and treatments (France et al, 2022). France et al. (2022) formulated their overall question as "How do children (with chronic non-cancer pain) and their families conceptualise chronic pain?" and listed several sub-questions as follows:

- How do children and their families live with chronic pain?
- What do children and their families think of how health and social care services respond to and manage their own/their child's chronic pain?
- What do children and their families conceptualise as 'good' chronic pain management, and what do they want to achieve from chronic pain management interventions and services?"

Many reviews address questions concerned with interventions, to understand the acceptability and appropriateness of interventions to inform intervention development or to explore issues relating to an intervention or programme's implementation in practice (Noyes, Booth, Cargo, et al. 2018). So, for example, a mixed-methods review on reducing anxiety in pregnant woman aimed to answer the following questions (Evans et al, 2020):

- How acceptable for pregnant women are non-pharmacological interventions for reducing the symptoms of mild to moderate anxiety?
- How beneficial do pregnant women consider non-pharmacological interventions to be in reducing the symptoms of mild to moderate anxiety in pregnancy?

A mixed-methods review specifically addressing appropriateness aimed to:

- identify factors affecting administration and duration of exposure of four interventions for preterm birth management

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- explore whether the factors affecting appropriate use differ across types of health facilities;

but, notably, interpreted appropriate use in terms of a who, when, were and how question framework.

Finally, a separately-reported QES sought to address one specific implementation question within a set of six review questions (O'Neill et al, 2021):

- why Health Care Professionals may fail to escalate as per the early warning system protocols and to identify barriers and facilitators to escalation? (review question 6 only)"

Initial QES questions that can be further developed are given in Box 1.

Box 1 – Initial qualitative synthesis questions

- what is it like to experience this condition/this situation?
- how do people behave when receiving the intervention/experiencing a situation?
- what do people believe makes the intervention work?
- why do people believe it works for some and not for others?
- what do people think needs to be in place for the intervention to work and why do they feel this is important?
- how does the reality of how an intervention works in practice differ from how it was expected to work – by planners? by professionals? by patients? by carers?

Of note here is that the research question developed will, to some extent, determine the types of study included in the review, and the way studies are analysed and synthesised. The first of seven criteria to be used when selecting an appropriate method of qualitative synthesis (known as the 'RETREAT' criteria (Booth et al. 2018) is to consider the 'Research Question'. While the review question alone is not sufficient to govern which synthesis method to choose (see **Chapter 8** for further information on the selection of synthesis method), a QES team should try to establish whether their question type means that their review will only include qualitative data, whether it will mainly include qualitative studies (e.g. the review might also be open to including findings generated from open-ended questions in surveys)) or whether the review could also potentially include quantitative

studies. A review team may also need to decide whether findings from a mixed-methods study are to be included either in part (will the qualitative component of a mixed methods study be included in a review which intends to only include qualitative research?) or in full (if a review aims to include qualitative studies alongside quantitative studies will mixed-methods studies also be included?).

Questions for a QES may need to be aligned to those for an intervention review so that they collectively address the diverse questions that a decision-maker may face. Examples of how QES question and intervention review questions may be connected and addressed include

- Through **separate but complementary questions, separate reviews.** This model is seen when an intervention review addresses effectiveness questions and a QES tackles feasibility and acceptability.
- Through **separate sub-questions, combined review.** This model acknowledges that decision-makers often need to address multiple considerations within a single review product. Health technology assessment agencies for example have found this a helpful model. In this model the review might be entitled "The Effectiveness and Acceptability of….. " and the reviews may be presented as separate cross-referenced sections of the report.
- Through a **combined question, combined review**. This requires use of words in the question that may be interpreted both quantitatively and qualitatively. Some have suggested questions such as "what is the impact of…." or "what is the effect of…" For example, one review describes itself as the first mixed methods review of the evidence on the *impact* of occupational therapy in the self-management of rheumatoid arthritis (providing a holistic overview of outcomes *and* patient experience) (Gavin. 2024).

2.4 Addressing appropriate scope and relevant questions

It is important to ensure that a QES sets appropriate boundaries for the scope of the review and then addresses relevant questions. Consideration of stakeholder perspectives; equity, diversity and inclusion; situational relevance; and conceptual relevance can support this. These are considered in turn below.

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2.4.1 Stakeholder perspectives

Stakeholders bring multiple perspectives to defining the scope of a review and its question(s) (Merner et al. 2021). Those involved in a review should encompass the range of relevant perspectives available. This may involve including members of the public such as patients, carers or residents, professionals of different backgrounds, policy makers and others (Chapter 1). Perspectives may be complementary, synergistic or even antagonistic across different types of stakeholders such as those representing patients and those with a professional role in delivering services and policy makers and managers. Stakeholder perspectives in developing the scope and questions for a QES is explored further in the context of equity, diversity and inclusion (2.4.2), situational relevance (2.4.3) and conceptual relevance (2.4.4) below.

2.4.2 Equity, diversity and inclusion

Determining who is affected by a particular issue depends on the question, the complexity of the system within which the issue of interest exerts its effect and, where relevant, who is expected to implement the intervention (if any). Priority setting exercises are often used to elicit thoughts and opinions in a timely manner. However, their strength – of seeking consensus across different perspectives – may be a corresponding weakness when it comes to the views of minoritised groups or the disenfranchised. A review team should seek to capture diversity of opinion (Booth et al. 2013) and, if it is not possible to include a particular perspective within a particular review question and scope, the review team can seek to ensure that the review highlights this absence and prioritises it for future investigation.

Intervention reviews emphasise the complete reporting of outcomes so that they can be complete, unbiased, and precise in estimating intervention effects. Authors of QESs should be similarly preoccupied with completeness of perspectives; seeking to ensure that relevant stakeholders' views are not omitted, either unintentionally (error) or through study identification, or selection, or analytical procedures (bias). Just as an intervention review team might consult study protocols to identify a comprehensive set of outcomes, a QES review team might brainstorm pertinent perspectives with stakeholders. If perspectives from a specific subgroup are omitted from currently identified studies or study samples then additional purposive searching could be devised in case the original search

strategies failed to identify studies with these missing perspectives (see Chapter 5). Equity, diversity and inclusion in developing the scope and questions for a QES is explored further in the context of situational relevance (2.4.3) and conceptual relevance (2.4.4) below.

2.4.2 Situational Relevance

The importance of the setting (in which interventions are delivered) and the environment (the wider social, political and economic context) is well-recognised within QES methods (see Chapter 13). Before embarking on any QES, a review team should surface the extent to which findings from one setting or environment are likely to extend to another (Munthe-Kaas et al. 2020). The review team must decide whether to encompass different settings within a single review question ("lumping"), from the beginning and throughout the synthesis, or whether to focus more narrowly ("splitting") and then explore transferability of findings at the conclusion of the QES.

Situational relevance may need to be interpreted broadly. Interventions, situations or conditions may be underpinned by a common theory (e.g. attitudes to legislation) or may share a common mechanism (e.g. building up trust) (Noyes, Booth, Lewin, et al. 2018). An empty review (a review with no studies that meet the exact eligibility criteria) is relatively uncommon in qualitative evidence synthesis. In some cases, only one or two studies directly address a review question but several studies contain relevant data alongside their particular area of focus. So, for example, a QES examining attitudes to specialist versus generalist medical care in epilepsy found only one study directly addressing this issue but over a dozen more containing isolated observations within general explorations of epilepsy medical care. In other instances, a QES team that starts by looking for directly relevant data that answer a precise focused question may need to settle for studies examining analogous situations or contexts. Useful insights from something similar e.g. swine flu for bird flu, may be more useful than having no data at all (Noyes et al, 2018). (See also **Chapter 13** on GRADE CERQual.)

Similarly, a QES team that is seeking qualitative data about receiving a specific, possibly novel, intervention may gain useful understanding from accounts about experiences of the condition being targeted by that intervention (Lorenc et al. 2012). For example, in the early days of Post-Covid recovery few studies specifically addressed return to work. Broadening

the scope might involve including occasional specific mentions on return to work from within general qualitative studies on Post-Covid recovery. Alternatively, a QES team might broaden their scope to comparable conditions; for example, asking whether post-Covid recovery is sufficiently similar to post viral fatigue syndrome to make inclusion of studies on this latter condition insightful for the final QES.

2.4.4 Conceptual Relevance

Early in the review process, a team will find it helpful to spend time developing definitions for key concepts to ensure a shared understanding of assumptions on which the QES depends. This requires identifying which concepts they consider to be similar (or relevant) and which they consider different (non-relevant). It is unusual for all concepts to be clear and unambiguous – the phenomenon of interest may require an agreed definition to allow the team to operationalise the QES. Alternatively, review authors may be seeking to clarify concepts by means of the QES itself. A compound concept such as "inter-professional communication" requires definition of both "interprofessional" and of "communication". It may also require differentiation from related concepts such as "interdisciplinary", "cross-professional" and "trans-professional". Review teams may find it helpful to gather together diverse definitions of the population, intervention or condition and setting and then allocate time for choosing between them (Thomas et al. 2019).

Specifically, a review team might ask questions based on the following prompts for reviewers:

1. **Does a preferred single definition reflect the views of the review team and of relevant stakeholders?** Or alternatively, perhaps, does a consolidated definition from multiple sources best capture the complexity of the review?
2. **Will the review team only admit interventions that use a preferred term or phrase? or will the review team accommodate a variety of intervention components captured within multiple diverse phrases?**
3. **Which phrase(s) best represent the *population* focus of the review?** E.g. "adolescent girls" (developmentally) or "teenage mothers" (chronologically)?
4. **What is included or not included within the phenomenon of interest as used in its community?** (e.g. Does the *phenomenon* of "knowledge translation" only refer

to interactive processes involving both researcher and the research user or does it also include conventional dissemination?

5. **What terms best reflect the setting?** E.g. Is the *setting* best represented by "primary health care", "community care" or "general practice"?

Such are the detailed and often protracted discussions in which a review team should engage.

Intervention reviews sometimesmake arbitrary judgements on which interventions are or are not relevant, often informed by clinical or organisational considerations (Weir et al. 2012). Decisions on whether to "lump" together particular populations or interventions within a single review or to split interventions or subgroups between separate reviews are determined by subjective judgements of homogeneity or heterogeneity (Squires, Valentine, and Grimshaw 2013). Authors of intervention authors often have well-theorised reasons for determining whether things are too similar / dissimilar, and there are also statistical tests that can be used to determine heterogeneity. For QES, decisions relating to "similarness" or "differentness" may not relate simply to what can be observed. Similarities may operate at the level of mechanisms – how interventions or conditions activate a response in either the one delivering or the one receiving an intervention or in the one experiencing a condition (Bonell et al. 2021) (See also Chapter 4 and Chapter 15). For example, 'Do headteachers respond to school performance league tables in the same way that hospital administrators respond to hospital league tables?' 'Why do surgeons respond differently to surgeon league tables than to hospital league tables?' Even interventions, settings or populations that look very different could share a mechanism. Conversely, interventions that are superficially similar (e.g. interventions for low back pain in working age adults) could be "split" if they activate different mechanisms (Petticrew and Roberts 2008). Moreover, as well as conceptual considerations, the way that the review findings will inform decisions need also to be addressed. The degree of 'lumping' and 'splitting' that is appropriate will also be driven by the context of use: in some situations, lumped results will be most useful, whereas in others, the most actionable findings will be those that make finer conceptual distinctions.

The scoping process (See 2.5 below) may be the first opportunity for a review team to identify useful theories that are useful throughout the QES. Theory may be used from the

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beginning of a QES to justify decisions on what is considered "similar". Alternatively, it may be invoked at the end of the review when seeking to explain similarities in findings (**See Chapter 3**). As the Cochrane intervention handbook reiterates, each element of the review's PICO (or equivalent) raises its own definitional challenges (McKenzie et al. 2019).

2.5 Defining the scope of a review question

An essential part of the early phases of a QES is defining its scope; this is necessary to develop its protocol. It involves the careful consideration of the question(s) of interest in conjunction with stakeholder input (Section 2.4.1 and Section 2.9) and, often, 'scoping searches' which are non-systematic and non-exhaustive searches of the literature to enable authors to get a feel for the extent and nature of the research that may be relevant (Chapter 5).

Defining the scope of a QES serves multiple important purposes (Booth 2021). Conceptually, it helps to define what to include and what to exclude from the QES. It therefore directly informs the eligibility criteria. Logistically, when combined with scoping searches, it enables the review team to conduct a preliminary exploration of the size and quality of the literature in order to agree what can be delivered within the given timeframe and resources (McKenzie et al. 2019). Practically, it enables identification of potential studies for inclusion to inform decisions on search strategies, data extraction, and quality assessment and synthesis methods. Within a QES, articles identified from the scoping search may help when describing the topic of interest and what this review seeks to understand, explain or describe. Literature from scoping may help in explaining:

- How the intervention might work / How the topic of interest might affect individuals or have an impact upon a population
- Why it is important to do this review, and
- How this review might inform or supplement what is already known in this area

A Cochrane/Campbell QES often focuses on descriptions of the perspectives, values, preferences and experiences of the intended recipients of services, or of those making decisions during the delivery or management of policies, interventions or services. Equally, a QES could observe the behaviours of those receiving or delivering an intervention through ethnographic study or capture their perceptions via photovoice (e.g. Rohwer et al, 2021).

Finally, scoping may reveal how researchers and others have undertaken theorising in connection with the topic of interest. While not a substitute for a systematic search for relevant theory (**See Chapter 3**) briefly surveying relevant theory helps the review team to sensitise themselves to the topic under consideration. Mapping search terms or identified studies to the individual components of a review question (such as SPICE) greatly facilitates the scoping process.

Qualitative studies that explore experiences of a specific intervention may not exist. For example, an intervention may only recently have gained regulatory approval and therefore not be associated with any qualitative research (Lorenc et al. 2012). Alternatively, a programme or complex intervention may have been adapted to a new context, with the addition or omission of one or more components. In order to avoid an empty review under these circumstances a review team has three main options (i) by exploring experience of a condition they can hypothesise how a population might react to the new intervention; (ii) by examining existing interventions that may identify how a population has responded in the past to diverse intervention components; (iii) by shifting their focus from interventions to mechanisms they can explore the responses that may be activated by the new intervention. Understanding the mechanisms by which an intervention works (or is intended to work) can help decision makers when they are assessing whether review findings apply to their situation (Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG) 2006; Bonell et al. 2021). (See also **Chapter 4** and **Chapter 15**). Before expanding the review scope a review team should explore thoroughly the availability of unpublished findings for example, from process evaluations conducted alongside an intervention study (Noyes et al. 2019).

2.6 Refining the question(s)

Questions associated with a QES may be more open to change throughout the review process and may demonstrate a greater need for refinement of questions when compared with their intervention counterparts. While the risk of bias may be less instrumental in a QES, several reasons explain why a QES review team needs to guard against unjustified modification of questions. Adding each additional perspective places greater demands on the timeframe and the resources of the QES. Conversely, omitting a perspective may pose

a threat to equity or transparency. Changes to the protocol that result from revising the question for the QES should be documented in a section 'Differences between the protocol and the review'. Where either stakeholders or the QES team themselves raise concerns regarding variations to the protocol, the team could conduct qualitative methods of sensitivity analysis (Noyes et al. 2019) to see how the changes made may have an impact on the overall shape of the findings or the prominence of individual observations. The Cochrane intervention handbook provides a list of questions that a review team could usefully ask when modifying their questions or scope (Thomas et al, 2021)(Box 2).

Box 2 - Questions to ask when refining review questions

- What is the motivation for the refinement?
- Could the refinement have been influenced by findings from any of the included studies (for example by "cherry-picking" subgroups with particularly extreme experiences)?
- Does the refined question require a modification to the search strategy and/or reassessment of any decisions regarding study eligibility?
- Are data collection methods appropriate to the refined question?
- Does the refined question still meet the FINER criteria discussed in Section 2.2.1?

2.7 Frameworks for question formulation

Conventionally, a review team specifies their review question(s) for an intervention effects review using the 'PICO' mnemonic (Richardson et al. 1995; Counsell 1997), an acronym for Population, Intervention, Comparison(s) and Outcome. Several factors explain why these four epidemiological elements are less suitable for a QES. Intervention questions typically target a single population. In contrast, the phenomenon (or issue) of interest of a qualitative review may impact on the perceptions and attitudes of multiple affected parties. These perspectives may include the one directly experiencing a condition or treatment, their partner who is experiencing it "indirectly" or "second-hand" or a third person who is experiencing it vicariously (for example when experience is related to family members or neighbours). The concept of "perspective" is therefore more flexible. The issue (or phenomenon) of interest may not involve an intervention (e.g. it could relate to experience of a condition or situation e.g. substandard housing). For this reason, an explicit

Comparison is not always present. Finally, the quantitative precision of "Outcome(s)" may be inappropriate when compared to the many ways that the impact of phenomena may be documented. For this reason, alternatives to PICO have been proposed: at least 38 different frameworks for formulating questions were identified in a recent rapid review (Booth, Noyes, et al. 2019). The rapid review authors specified that a QES question framework should (i) recognise context (as setting, environment or context); (ii) acknowledge different stakeholder perspectives; (iii) accommodate elements of time/timing and place; (iv) be sensitive to qualitative research. None of the 38 frameworks satisfied all four criteria. Those most relevant to a QES are discussed briefly below. However, the take home point is that no particular framework is right or wrong: review authors only need to choose one that works for them and their particular question.

2.7.1 PICo

PICo (**P**opulation, phenomenon of **I**nterest and **Co**ntext) is a formulation popularised by the Joanna Briggs Institute (Lockwood 2020). It harnesses the familiarity of the PICO formulation familiar to users of intervention reviews. However, PICo's three elements are best considered prompts rather than a complete structure. At a meta-study level the simultaneous use of the similar looking PICO and PICo question formulations, for example in mixed methods reviews, may be wrongly interpreted as meaning that the quantitative and qualitative review questions share the same scope. As mentioned above, this is not always the case.

Table 1 - Worked Example of PICo Question Formulation

Review Question: What are the experiences of children, teachers and parents of class size issues in special education contexts? [Campbell Review] (Bondebjerg et al. 2021).		
Population	**Interest, phenomenon of**	**Context**
Children, teachers and parents	Experiences of class size issues	Special education contexts

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2.7.2 SPICE

SPICE is an indirect variant of the PICO formulation (Booth, Noyes, et al. 2019). Population is differentiated as both Setting and Perspective, Intervention becomes Interest (phenomenon of) while the precision of 'Outcome' becomes the more inclusive Evaluation. SPICE seems to be memorable and recognises the importance to qualitative research of both context (in the form of Setting) and perspective. Comparison has always been optional, given that qualitative studies are not typically comparative, and this occasionally presents challenges, particularly to less experienced reviewers. Others find difficulties in interpreting "Evaluation" given that it may variously represent "Themes", "Findings", "Experiences", "Attitudes" etcetera.

Table 2 - Worked Example of SPICE Question Formulation

Review Question: What are the factors influencing how healthcare professionals use protocols to wean adults and children from mechanical ventilation? (Jordan et al. 2016)				
Setting	**Perspective**	**Interest, phenomenon of**	**Comparison (optional)**	**Evaluation**
Intensive Care Unit (ICU)	Health professionals	Weaning adults or children from mechanical ventilation	Not explicit (but may be different for adults and children)	Factors (enablers, barriers, influences etc)

2.7.3 PerSPE(C)TiF

The seven element PerSPE(C)TiF (Perspective, Setting, Phenomenon of interest/Problem, Environment, Comparison (optional; as indicated by the bracketed lower case "c"), Time/Timing and Findings) is the most comprehensive, current and flexible question structure (Booth, Noyes, et al. 2019). As a product from a WHO Expert Working group on Complex Interventions, PerSPE(C)TiF was designed for complex interventions. Consequently, it is intended to accommodate quantitative, qualitative and mixed methods

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questions. It seeks to capitalise on features of other structures (for example, in acquiring the optional Comparison used in SPICE). It seeks to distinguish the broader socio-politico-environmental-economic elements of context as signified by “Environment” from the physical/virtual location where interventions are delivered (“Setting”). Similarly, just as geographical context is a key source of variation for both these concepts, so too Time/Timing recognises temporal variation, whether that be era, stage of development or position on a disease or care pathway. The label, “PerSPE(C)TiF”, emphasises the subjectivity of qualitative questions.

In moving helpfully away from strict question formulation, towards offering a review team a useful framework for ensuring that they surface key factors that relate to the scope of the review, PerSPE(C)TiF imposes additional coherence on the inter-connection between scope and review question. Within the seven-element structure of PerSPE(C)TiF it is possible to formulate multiple questions or sub-questions; each requiring separate eligibility criteria and search procedures.

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Table 3 - Worked Example of PerSPE(c)TiF Question Formulation

Review Question: What are the values and preferences of pregnant women, partners, carers and significant others, care providers, and policy makers concerning feeding (breastfeeding, breast milk feeding or alternative infant feeding) when an infant has difficulties as a result of congenital Zika syndrome (CZS) in low- and middle-Income countries (LMICs) where Zika Virus is prevalent?						
Perspective(s)	Setting	Phenomenon of interest	Environment	(Comparison - Optional)	Timing/ Time	Findings
Women, partners, carers and significant others, care providers, policy makers	Any setting (primarily community settings)	Infant feeding in the context of congenital Zika syndrome (CZS)	International, particularly Low- and Middle-Income countries (LMICs) where Zika Virus is prevalent	(Implicitly compared with other parents with infants experiencing feeding difficulties)	When contemplating, carrying out or supporting breastfeeding, breast milk feeding or alternative infant feeding	Fears, perceptions, experiences, beliefs values and preferences regarding phenomenon of interest

2.7.4 Summary of question frameworks

Little empirical data exists to support choices in question formulation framework (Methley et al. 2014; Cooke, Smith, and Booth 2012). That said, the process of considering a review's question or its scope against an explicit question formulation framework may prove valuable as a team process and consultation exercise, irrespective of the chosen framework. Additional guidance, focusing on PICOC (PICO with the addition of Context), SPICE and other frameworks, is available (Booth, Noyes, et al. 2019; Harris et al. 2018). The guidance acknowledges the challenges of representing complex interventions within such

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frameworks while concluding that simple question frameworks nevertheless prove useful when scoping the review question.

2.8 Taxonomies, Frameworks and Logic Models

Specific tools to help review teams when defining review questions and planning their review include (Thomas et al. 2019):

1. **Taxonomies:** hierarchical structures used to categorize (or group) related interventions, populations, perspectives or concepts.
2. **Generic frameworks:** for structuring intervention characteristics (Hoffmann et al. 2014) or describing aspects of context (Pfadenhauer et al. 2017) or complexity in systematic reviews (Lewin et al. 2017). Diverse tools exist to help in incorporating context (Booth, Moore, et al. 2019). Frameworks that incorporate implicit or explicit approaches to incorporating theory can be identified in a systematic manner (Booth and Carroll 2015).

Frameworks (see Section 2.7 above) such as PICO or its qualitative equivalents may be conceptualised as "static" frameworks. Each question is designed to "anchor" its component concepts and thus ensure that the subsequent synthesis focuses on these concepts at all stages of the QES (Booth 2016).

One alternative to static uni-dimensional frameworks is a logic model that seeks to demonstrate complexity and interrelationships between review elements (Chapter 3) (Kneale, Thomas, and Harris 2015). A logic model (closely related to "conceptual framework" or "theory of change" – see Chapter 3 and 4) is a graphical representations of theories about how interventions work (sometimes called "programme theories"). They depict intervention components, mechanisms (pathways of action), outputs, and outcomes as sequential (although not necessarily linear) chains of events. Logic models fulfil multiple functions within a systematic review (Thomas et al, 2021) (Anderson et al. 2011) (Chapter 4). In the context of question formulation, a logic model may encompass multiple static qualitative question frameworks. This multi-pronged approach can be particularly helpful when a QES is being used to support the production of guidelines, for international organisations such as the World Health Organization (Downe et al. 2019) or national bodies such as CADTH in Canada or NICE in the UK (Carroll 2017). For example, a

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logic model for risk of infectious disease transmission when breastfeeding (Figure 2.1) includes the values and preferences of

1. health or community workers,
2. of women who may or may not be contemplating breastfeeding (pre-exposure),
3. of the family and community supporting the women, and
4. a subset of those who decide to breastfeed (post-exposure) – in effect four questions within a single logic model (Carroll et al. 2020).

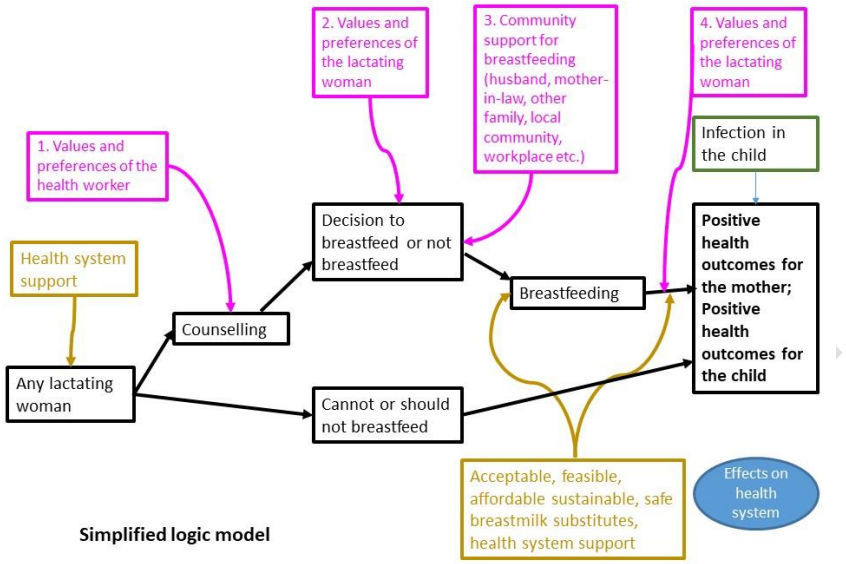

Figure 2.1 – Simplified Logic Model

Logic models (see also chapter 4) offer a way to communicate the scope of a QES visually and thus aid development of a shared understanding between different stakeholders of the scope of the review (Thomas et al. 2019). They are very versatile tools and so can be used as part of the scoping process or as an interim product from scoping, or to structure the review after having formulated the question. A review team may specify logic models *a priori* as part of the question formulation process that remain unchanged until the end of the review (Kneale, Thomas, and Harris 2015). In other cases, reviews take a staged approach, pre-specifying points in the review process for the model to be revised (Rehfuess et al. 2018). Methodological papers on logic models can help review authors to develop and use logic models – see also chapter 4 (Anderson et al. 2011; Allmark et al. 2013; Baxter et al. 2010; Baxter et al. 2014; Kneale, Thomas, and Harris 2015; Rohwer et al. 2017).

2.9 Reporting the Review Question

ENTREQ (Enhancing Transparency in Reporting the Synthesis of Qualitative Research) (Tong et al, 2012), eMERGe (Meta-ethnography Reporting Guidance) (France et al, 2019), and STARLITE (Standards for Reporting Literature searches on Evidence) (Booth et al, 2016) each provide valuable yet complementary guidance for reporting the review question for a QES. ENTREQ (Item 1 – Aim) emphasizes the need to state the research question in relation to qualitative evidence, requiring explicit articulation of how the question aligns with qualitative approaches. eMERGe (Items 2 – Aim(s) and 3 - Focus) specifically requires a reviewer first to describe the meta-ethnography aim(s) and then to consolidate this by describing the meta-ethnography review question(s) (or objectives), emphasizing the interpretive nature of the synthesis and how the question should facilitate conceptual innovation. STARLITE, while focused primarily on search reporting, highlights how the review question should be operationalized into searchable components, ensuring alignment between the question formulation and the subsequent search strategy. Noticeably, the PRISMA-S search extension does not specifically address the review question (Rethlefsen et al, 2021). Instead, the search extension is designed to supplement Item 4 of the main PRISMA 2020 document which requires reviewers to provide “an explicit statement of all objective(s) or question(s) the review addresses, expressed in terms of a relevant question formulation framework” (Page et al, 2021). Together, these standards ensure that review questions in QES are not only clearly stated but also appropriately aligned with qualitative methodologies, interpretive approaches, and practical search considerations.

2.10 Stakeholder engagement and involvement

As explored in section 2.4.1 above, it is important to engage and involve stakeholders in setting the scope and finalising the review question. Review teams should seek to engage and hear diverse perspectives from diverse stakeholders including members of the public. Relevant members of the public could be those who are actual or potential recipients of services, any patients, carers and family members, or people who are seeking information about their situation or condition or potential interventions from which they might benefit; members of representative organisations for those who use services (Ellis, Kitchin, and Vis-Dunbar 2021). Stakeholders also include practitioners of different backgrounds, policy

makers and commissioners. Specific functions of stakeholder involvement at the scoping and question formulation stage include defining terminologies and explaining overlapping concepts, ensuring that the final question is important and meaningful to all stakeholder groups and protecting against potential research waste.

Specific instances of stakeholder input into the scoping and question formulation process are infrequently reported. A rapid QES (Shaw et al. 2020) describes a framework synthesis approach "where the initial framework was based directly upon the research objectives identified through consultation with the commissioners of our research". In another example, at the protocol and grant development stage, France et al 2022, developed their meta-ethnography question and refined the scope of their QES through engagement with three children and young people with chronic pain and four parents, 2 adult patient representatives from the not-for profit sector, and 2 adult members one with chronic pain and one with a chronic illness from a university Patient and Public Involvement Group. The review authors sent these patient and public stakeholders materials via email about the review topic, the rationale for the focus and scope of the review and draft review questions. Late, a designated patient and public involvement group directly influenced the scope of the review by advising the review authors to include a wider group of international studies which resulted in changes to the protocol.

Multiple perspectives from different stakeholders can bring rigour to the process of defining the scope of a review and its question(s) and can challenge blind spots of the review team (Merner et al. 2021). In the specific context of QES it is particularly important not to assume that stakeholder interests will be adequately represented by qualitative findings from the review itself (Klaprat et al. 2019). The review team will only extract and interpret data that matches the final agreed review question and participants' views from research studies are shaped by the interests of the researchers, the questions they ask and factors relating to the time and place of data collection.

2.11 Equity, diversity and inclusion

A QES should try to capture the views of the majority but should equally harness procedures to elicit the dissenting, lone or often-silent voice (Booth et al. 2013). This fundamental principle applies both to the identification of perspectives in the literature and to

complementary processes of stakeholder engagement. Effective engagement with affected parties ("any person who would be a knowledge user of research but whose primary role is not directly in research"(Pollock et al. 2018)) is not an optional extra but deserves sustained effort.

For example, from an equity diversity and inclusion standpoint, review teams frequently assert that experiences of health or care systems in low and middle income countries (LMICs) are substantively different from those in high income countries (Noyes, Booth, Lewin, et al. 2018). This may be equally true of education systems, legal systems, government administrations etcetera. Other contexts may relate to the social, cultural and ethnic characteristics of particular populations; in fact, variation may follow a schema such as PROGRESS-Plus (Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socio-economic status, Social capital, and other characteristics ('Plus') such as sexual orientation, age, and disability) (O'Neill et al. 2014). In practical terms, this variation can either be handled by splitting the original review into multiple reviews or by conducting a single review where the review question is divided into multiple questions. If a major change is to be undertaken, such as splitting a broad review into a series of narrow focused reviews, the review team must document a new protocol for the component reviews each with individual eligibility criteria (Thomas et al. 2019).

It is important to recognise that the target population ("I want to apply this evidence to Uganda") rarely proves an exact match to the review population ("I am looking for studies from Sub-Saharan Africa") which, in turn, may not match the study populations ("I have only found studies from Ghana, Kenya, Nigeria and Tanzania"). The review team and potential users of the review need to agree which review population(s) is (are) most meaningful, how to determine review priorities and whether to broaden or narrow the eventual scope.

Such equity, diversity and inclusion decisions are not simply made in a standard or uniform way (Booth, Moore, et al. 2019). For example, closed systems (such as a surgical operating theatre) may exhibit little variation across settings. Semi-closed systems such as a hospital, community centre or school may share some commonalities (e.g. in the types of activities that take place, but may serve a very diverse population). Open systems such as public health systems, social care systems or local government administrations may demonstrate

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considerable variation and so may be best suited for separate review questions and/or separate QES that each consider equality, diversity and inclusion.

A review team can use priority setting exercises to determine where review resources should be concentrated. They should ensure that issues such as equity are considered so that priorities reflect genuine need and not simply the interests of those best able to vocalise or mobilise their concerns. Inequity may be experienced across the characteristics defined by PROGRESS-Plus (O'Neill et al. 2014) (Chapter 1). Issues relating to equity should be considered when review questions are developed. The review team should also be reflexive about decisions that have an impact on scope and inclusion. The use of priority setting for reviews is explored in the Cochrane intervention handbook (Thomas et al, 2021). Many of these issues clearly translate across review types.

2.12 Reflexivity

Review authors and stakeholders exert considerable influence over the question formulation process and refining the scope of the review. Individually and collectively, they may contribute specific conscious and unconscious biases that have an impact on the decisions made and these influences, discussions and decisions need to be made transparent. Equally, the funder may have specific motivations and biases towards certain questions or aspects of questions that also need to be made transparent. The potential impact of such biases on the QES needs to be articulated in the protocol and review report. While little has been written on measures to mitigate potential biases, standard procedures might include seeking inclusion of diverse perspectives from the literature and stakeholders, ensuring editorial independence and inclusion of reflexivity statements that extend beyond commencement of the QES to include the question setting process.

2.13 Chapter information

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