# Preparing a protocol for Cochrane intervention reviews including qualitative research

**1. Introduction**

Preparing a protocol for a review including qualitative research is important for several reasons. As well as being a requirement for a Cochrane review, a protocol helps the review team to plan the review and anticipate problems, encourages comment and review amongst peers and facilitates transparency and audit. In the final review, the authors can describe and reflect on the impact of any differences in process and methods that occurred during the work on the review after publication of the protocol.

This chapter aims to help reviewers with pragmatic guidance on how to prepare a protocol in Review Manager 5 for reviews aiming to include qualitative research. It been uses the standard headings provided in the Cochrane Database of Systematic Reviews and Review Manager 5 to lead quickly to the relevant sections of a standard Cochrane protocol. It should be used together with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011) (in particular part 1) and all other chapters in the CQIMG supplemental guidance[[1]](#footnote-1).

Currently, there are two main scenarios for including qualitative research in a Cochrane intervention review. The first is a standalone review of qualitative research linked to an already completed Cochrane intervention review (e.g. Jordan et al., 2012: Glenton, 2012). The second is a review which sets out from the beginning to include qualitative research alongside the other types of research to be included in the review (e.g. Lins et al., 2011; Husk et al., 2013).

**2. Overview of the structure of a protocol**

A Cochrane protocol consists of four sections (see box 2.2a in section 2.2.2 in the Cochrane Handbook): i) title and protocol information such as authors and dates of publication/updates; ii) the main body of the protocol itself; iii) supplementary information such as appendices; and (iv) 'about this article' which covers information such as sources of support for the review.

The handbook gives specific guidance on preparing a title for a review in section 4.2.1. It would be useful if the title could indicate that the review will include qualitative research by using a sub-title such as ‘a qualitative evidence synthesis’ or ‘a mixed methods review’.

# The next section of this chapter has more detailed guidance for the main body of the protocol covering background, objectives and methods. As the latter two sections of the protocol raise no specific issues about including qualitative research in the review, reviewers are referred to the Cochrane handbook for guidance.

The format for the main body of the protocol is relatively flexible and broad. Although at first sight the list of fields in a Cochrane protocol can be daunting and not obviously applicable to a review that includes qualitative research, many of the fields are actually ‘recommended’ rather than ‘mandatory’. Furthermore, most of the mandatory headings and many of the recommended headings on closer inspection also apply to reviews that include qualitative research. Mandatory headings are asterisked\* throughout the rest of this document.

# 3. Background\*

The background section of the protocol has four recommended sub-headings which cover key concepts and mechanisms and the rationale for the review (see section 4.5 'Background' in the Cochrane Handbook). These headings all generally apply in a review which includes qualitative research. The background should also explain why it is important to consider qualitative research.

***3.1 Description of the condition***

This section describes the condition or topic considered in the review and its significance. Key concepts and how these relate to one another need to be described. The SPICE framework can help in identifying key concepts in reviews that include qualitative research (*S*etting, *P*erspective, *I*ntervention/phenomenon of *I*nterest, *C*ontext and *E*valuation). This section is likely to be similar to what would be written in a protocol for a review which does not plan to include qualitative research. Depending on the objectives of the review, the importance of understanding the experiences of patients/the public/ providers or other stakeholders with the condition/issue under consideration could be noted here.

***3.2 Description of the intervention***

As the sub-heading suggests, this section describes the intervention considered. As above, the content of this section is likely to be similar to what would be written in a protocol for a review which does not plan to include qualitative research. It could highlight the importance of understanding how providers and recipients experience the intervention and the context in which the intervention is implemented.

***3.3 How the intervention might work***

As noted in the Cochrane Handbook for Systematic Reviews of Interventions, this section might describe the theoretical and empirical reasoning why the interventions under review may affect potential recipients. Achieving a greater understanding of why and how an intervention might work or not is often a key objective in reviews which include qualitative and implementation research. For example, this type of research could be used to develop or refine a conceptual framework to explain the relationship between intervention, context and outcome. The use of/development of formal programme theory and logic models is relevant here.

***3.4 Why this review matters***

This section should be used to justify why it is important to include and review qualitative research as well as the importance of answering any question(s) posed about the effectiveness of the intervention for dealing with the condition/issue considered. The importance of including qualitative research might be phrased in terms of developing a greater understanding of intervention context, appropriateness, acceptability and implementation and how and why intervention effects might vary across different contexts and sub-groups. For example in their protocol for a review of telephone counseling for informal carers of people with dementia, Lins et al. (2011) argued that qualitative research may help explain previous findings that some people benefit more than others from telephone counseling.

It is also useful to highlight whether the relevant qualitative research has been brought together before in a systematic review and the benefits of doing so.

**4. Objectives\***

Specifying well-formulated questions and objectives for all parts of the review including for the qualitative research is crucial. Many review processes flow from the review questions and objectives including how data are collected and how findings are presented. Often a review team plans to include qualitative research because they have posed questions which are best answered by this type of research. For example, 'How do patients or providers experience intervention X'?; 'Why is intervention Y not always implemented as intended?'; or 'How does context affect the implementation and the outcomes of intervention Z?'. Context might include a range of internal and external factors such as beliefs and behaviours, the social organisation of institutions or wider policy constraints and opportunities.

In a standalone review of qualitative research linked to an existing effectiveness review, objectives will be formulated in relation to the new synthesis of qualitative research and the linked effectiveness review. For example, the overall objective of the review by Jordan et al. (2012) on mechanical ventilation weaning protocols was “To enhance and extend the recent Cochrane effectiveness review of protocolized weaning.....by synthesizing evidence from qualitative research to identify contextual factors that impact on the use of ventilator weaning protocols for critically ill adults and children.” In a review which plans to include qualitative research and effectiveness studies in the same review, separate objectives and questions can be formulated for each part of the review. For example, Leiknes et al. (2011) in their review of electroconvulsive therapy (ECT) for depression had two sets of review questions in their protocol. The first, all related to assessing the short- and long-term benefits and harms of ECT for depression amongst adults, whilst the second was phrased as “What is the lived experience of ECT and how do patients perceive the effect of ECT as a therapy?”.

In either case objectives and review questions should cover how the synthesis of qualitative research will be integrated with the findings of the effectiveness review.

**4.3 Methods\***

***4.3.1 Criteria for selecting studies for this review\****

This section of a protocol has four ‘fixed’, i.e. mandatory sub-headings. The review protocol cannot be submitted unless information is presented under each heading.

*4.3.1.1 Types of studies\**

This section can be used to describe the types of studies to be included in the review. If the review includes a distinct effectiveness component and a separate qualitative synthesis then further sub-headings could be used to describe the types of studies to be included within each component.

When describing the type of qualitative studies to be included it may be valuable to think of different approaches to data collection (e.g. in-depth interviews, focus groups), or overall theoretical approach to design and data analysis (e.g. grounded theory, ethnography, framework analysis). Bear in mind that many mixed methods studies are being published and reports of RCTs and other controlled trials may also report a qualitative component or a process evaluation.

*4.3.1.2 Types of participants\**

This section is likely to be similar to what would be written in a protocol for a review not planned to include qualitative research. If your review plans to integrate an effectiveness component with a qualitative synthesis, highlight whether the same types of participants will be included in both parts. For example, in a qualitative synthesis interested in issues of implementation, types of participants may include health professionals as well as patients or members of the public.

*4.3.1.3 Types of interventions\**

As above the content of this section will be similar to what would be written in a protocol for review which does not plan to include qualitative research.

*4.3.1.4 Types of outcome measure\**

This section is more problematic in terms of a synthesis of qualitative research as it is not usual practice to ‘measure’ outcomes or to specify in advance the important issues or themes that will be important (although often some process measures can be read as though they are outcomes - see below). One option here for reviews which include both an effectiveness synthesis and a synthesis of qualitative research in separate arms is to include information on types of outcome measures for the effectiveness arm only.

Types of outcomes for a synthesis of qualitative research could be expressed in terms of the perspectives and experiences of various groups (e.g. patients, health professionals) on the intervention/condition under consideration in the review. If more appropriate, outcomes could be referred to as contextual outcomes. For example, Jordan et al. (2012, p4) in their review on weaning protocols aimed to include qualitative research that reported on a range of contextual ‘outcomes’ such as the perceptions of health professionals on protocols; the behavior of health professionals in relation to protocols; social organization and professional practice; and wider organizational constraints and opportunities.

The Cochrane Handbook recommends two further sub-headings in this section - ‘primary’ and ‘secondary outcomes’. These may or may not be useful in the context of a review including qualitative research. They are not ‘fixed’ headings so can be ignored if they are not useful for communicating how you intend to conduct your review.

***4.3.2 Search methods for identification of studies\****

Search methods should cover the resources to be used for searching (e.g. electronic resources, reference lists) and the way each resource will be searched (e.g. the keywords to be used and how these will be combined). Search strategies for electronic resources could be included as appendices. Specific guidance for searching for qualitative research can be found in the searching chapter of the supplementary guidance. Reviews which cover a range of research types could consider implementing an electronic database search without a study design filter for either trials or qualitative research.

This section can be structured according to the following recommended sub-headings which may all apply to reviews which include qualitative research:

*Electronic resources*

*Handsearching*

*Reference lists*

*Correspondence*

Other sub-headings can be added as necessary or some could be grouped under the heading ‘*Other resources’*. It may be pertinent to mention whether an exhaustive approach will be taken in the review to trying to identify as much as possible of all qualitative research that exists or whether some form of sampling will be used (see the searching chapter of the supplementary guidance).

***4.3.4 Data collection and analysis\****

# The Cochrane Handbook recommends 12 sub-headings in this part of the protocol but not all are applicable or useful for reporting plans for the systematic review of qualitative research. This section does not therefore discuss in detail the following sub-headings: *Measures of treatment effect; Unit of analysis issues; Dealing with missing data; Assessment of heterogeneity; Assessment of reporting biases; Subgroup analysis and investigation of heterogeneity; Summary of findings table.* Some of these or alternative new sub-headings may become relevant in the future as the science of reviewing qualitative research advances. We do, however, recommend using the following sub-headings.

# *4.3.4.1 Selection of studies*

This part of the protocol is used to describe how studies will be screened for inclusion in the review. The information here is likely to be the same as that reported for a review which does not include qualitative research. If there are plans to use a sampling strategy rather than an exhaustive approach, this strategy should be described here.

### 4.3.4.2 Data extraction and management

Although the types of data to be collected from reports of qualitative studies will differ from those collected from trials or other types of studies, the process of collecting data from reports and managing the data could, in theory, be similar regardless of study type. The process of collecting data could include, for example, the use of a data collection form or the use of two reviewers extracting data independently from the same study report. This section of the protocol should therefore be prepared accordingly using separate sub-headings as necessary. Data extraction forms could be included as supplementary files

Types of data to be collected from qualitative research could include themes, participant quotes, or conceptual models taken from wherever findings and conclusions appear in a study report. Other types of data may include contextual or methodological information such as country, participant characteristics and method of analysis.

Guidance on data extraction for qualitative research is in the data extraction chapter of the supplementary guidance.

### 4.3.4.3 Assessment of risk of bias in included studies

The criteria that will be used to judge the methodological quality of qualitative research will differ from those for trials. What is done as a result of the critical appraisal may also differ (e.g. will studies be graded or weighted according to methodological quality?; will studies judged to be of lower quality be excluded from the review?). As above, the process of critical appraisal may or may not differ according to study type (e.g. the use of two reviewers working independently). This section of the protocol should cover: the criteria to be used to assess methodological quality (and a rationale for why these criteria have been chosen); the process that will be used to apply the criteria and record the results; and what will be done with the resulting quality assessments. Separate sub-headings to distinguish between the methods for qualitative research and other types of research can be used as necessary. Critical appraisal tools could be included as supplementary files.

For full guidance on critical appraisal, please see the relevant chapter in the supplementary guidance.

### 4.3.4.4 Data synthesis

Methods of synthesis for qualitative research differ radically from those used for a statistical meta-analysis. For reviews including a separate qualitative synthesis alongside an effectiveness synthesis, planned methods for synthesis could be reported under separate sub-headings. In most reviews, this section will specify a) how the synthesis of the qualitative research will be conducted; and b) how the findings of this synthesis will be integrated with the findings on effectiveness.

Detailed guidance and signposting of the range of synthesis methods available are provided in the relevant chapter of the supplementary guidance. It is important to note here, that methods for synthesis should be explained in as much detail as possible so that a reader can understand how the review team will move from the findings of individual studies to the final synthesis. Strategies for increasing the robustness of the final synthesis should be described (e.g. the use of more than one reviewer, developing and testing a preliminary synthesis). Generic descriptions of synthesis methods should be avoided. It would be helpful to include any preliminary framework that will be used to guide analysis as a figure within the protocol.

*4.3.4.5 Sensitivity analysis*

This type of analysis is often used within a statistical meta-analysis to assess the impact of the quality or other characteristics of trials on the overall effect size. For example, comparisons are made between the results of the meta-analysis when lower quality trials are removed (or when trials which do not have particular markers of quality such as adequate randomisation are removed).

Some reviewers have begun to explore the value and applicability of sensitivity analysis within reviews that include qualitative research (e.g. Boeije, 2012; Carroll et al., 2012; Thomas and Harden, 2008). Planning a sensitivity analysis might be a useful exercise to consider within your Cochrane review. A sensitivity analysis may help the review team to explore the impact of quality on the findings of the synthesis and inform decisions about whether to exclude or weight studies on the basis of quality. It may also help the review team to explore whether parts of the synthesis findings are based on studies that come only from particular context.

***References***

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1. http://cqim.cochrane.org/supplemental-handbook-guidance [↑](#footnote-ref-1)