

Chapter QQ:Qualitative and Implementation Evidence and Cochrane Reviews

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Key points

- Evidence from qualitative studies can play an important role in adding value to systematic reviews for policy, practice and consumer decision-making.
- Cochrane Intervention reviews now include qualitative and implementation research embedded within, or associated with, the trials.
- There are five primary roles for qualitative evidence syntheses within the context of Cochrane Intervention reviews:
 - Scoping review: Qualitative research, either as individual studies or within a synthesis, may be used to inform Cochrane intervention reviews by helping define and refine the question, and to address all important outcomes;
 - Integrated review: Integration of both quantitative and qualitative evidence within a single coherent Cochrane review product;
 - Qualitative review of trial sibling studies: Conduct of a qualitative evidence synthesis alongside a Cochrane intervention review using qualitative studies informing the intervention that are directly related to included trials and thus share a common context;
 - Qualitative review of unrelated qualitative evidence: Conduct of a qualitative evidence synthesis that includes qualitative studies of the intervention but not necessarily related to included trials; and
 - Qualitative review of wider relevant issues: Conduct of a qualitative evidence synthesis that includes qualitative data beyond that relating to the intervention e.g. attitudes of patients, staff members or carers to the experience of a disease or health condition.
- Many methods of qualitative evidence synthesis are appropriate to the aims and scope of Cochrane Intervention reviews.
- The synthesis of qualitative research is an area of debate and evolution. The Cochrane Qualitative and Implementation Methods Group provides a forum for discussion and further development of methodology in this area.

QQ.1Introduction

The purpose of this chapter is to outline ways in which Qualitative Evidence Synthesis (QES - an umbrella term for all types of qualitative systematic review) might be used to complement Cochrane Intervention reviews. Qualitative evidence is not intended to contribute to the measures of effect of interventions, although it may help to explain issues relating to adherence, for example. Instead it

seeks to help explain, interpret and apply the results of a Cochrane intervention review. In this way, evidence derived from qualitative studies complements systematic reviews of quantitative studies.

This chapter aims to enable authors to:

1. Consider the types of reviews and review questions for which a synthesis of qualitative evidence could complement a Cochrane review;
2. Consider the resource and methodological issues when deciding to synthesize qualitative evidence to complement a Cochrane review;
3. Signpost some of the approaches and methods available for the synthesis of qualitative evidence; and
4. Access further information, advice and resources if required.

The chapter is divided into two parts. The first part (Section [QQ.2](#)) provides considerations and guidance for the incorporation of evidence from qualitative research in Cochrane reviews, including resource implications. The second part (Section [QQ.3](#)) provides a general discussion of methodological issues, key reading and the role and details for the Cochrane Qualitative and Implementation Methods Group (see Section [QQ 3.2.5](#)). We provide an exemplar showing how a synthesis of qualitative evidence has been used to complement an existing Cochrane review of effects.

QQ.2 Incorporating evidence from qualitative research in Cochrane Intervention reviews: concepts and issues

QQ.2.1 Definition of qualitative research

Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them (Denzin 1994). Qualitative research is intended to penetrate to the deeper significance that the subject of the research ascribes to the topic being researched. It involves an interpretive, naturalistic approach to its subject matter and gives priority to what the data contribute to important research questions or existing information.

Within health care any consideration of the contribution of evidence from qualitative research to systematic reviews should acknowledge the varied and diffuse nature of evidence (Pearson 2005; Popay 1998). Qualitative research encompasses a range of philosophies, research designs and specific techniques including in-depth qualitative interviews; participant and non-participant observation; focus groups; document analyses; and a number of other methods of data collection (Pope 2006). Given this range of data types, there are also diverse methodological and theoretical approaches to study design and data analysis such as phenomenology; ethnography; grounded theory; action research; case studies; and a number of others. Theory and the researchers' perspective also play a key role in qualitative data analysis and in the bases on which generalizations to other contexts may be made.

Within the empirical sciences, the standing of a given theory or hypothesis is entirely dependent upon the quantity and character of the evidence in its favour. The relative weight of supporting evidence allows us to choose between competing theories. Within the natural sciences, knowledge generation involves testing a hypothesis or a set of hypotheses by deriving consequences from it and then testing whether those consequences hold true by experiment and observation.

Health professionals seek evidence to substantiate the worth of a very wide range of activities and interventions. Thus the type of evidence needed depends on the nature of each activity and its

purpose. For many research questions, for example, those about parental beliefs and childhood vaccination (Mills 2005a; Mills 2005b), qualitative research offers an appropriate and desirable methodology.

QQ.2.2 Using evidence from qualitative research in Cochrane reviews

Cochrane Intervention reviews aim primarily to determine whether an intervention is effective compared with a control and, if so, to estimate the size of the effect. High quality randomized trials are central to the endeavours of The Cochrane Collaboration. While qualitative research could conceivably make a contribution to almost every Cochrane intervention review, it is neither appropriate nor possible to conduct a qualitative evidence synthesis within or alongside all Cochrane reviews.

It is increasingly recognized that evidence from qualitative studies that explore the experience of those involved in providing and receiving interventions, and studies evaluating factors that shape the implementation of interventions, have an important role in ensuring that systematic reviews are of maximum value to policy, practice and consumer decision-making (Arai 2005; Mays . 2005; Popay 2005).

The relevance of qualitative evidence to the assessment of interventions has only recently received recognition in the health field, but it is now more common for qualitative components to be built into the evaluation of health interventions (Pope 2006) and for the evaluation of complex interventions such as differing models of health service delivery to use a ‘mixed methods’ approach. Increasingly outcome studies included in Cochrane Intervention reviews will have qualitative research embedded within, or associated with, them. Authors of Cochrane reviews are therefore increasingly asking how to utilize evidence from qualitative research to enhance the relevance and utility of their review to potential users.

A synthesis of evidence from qualitative research can explore questions such as how do people experience illness, why does an intervention work (or not), for whom and in what circumstances? In reviews addressing healthcare delivery, it may be desirable to draw on qualitative evidence to address questions such as what are the barriers and facilitators to accessing healthcare, or what impact do specific barriers and facilitators have on people, their experiences and behaviours? Findings of QES may be generated, for example, through ethnographies and interview studies of help-seeking behaviour. Evidence from qualitative research can help with interpretation of systematic review results in understanding how an intervention is experienced by all of those involved in developing, delivering or receiving it; what aspects of the intervention they value, or not; and why this is so. Qualitative evidence can provide insight into factors that are external to an intervention including, for example, the impact of other policy developments, factors which facilitate or hinder successful implementation of a programme, service or treatment and how a particular intervention may need to be adapted for large-scale roll-out (Roen 2006).

Qualitative syntheses, accompanying intervention reviews, take either a multi-level or a parallel synthesis approach, as discussed in Section [QQ.3.2.5](#) .

The Cochrane Public Health and Health Promotion field have produced additional guidance on the types of reviews and questions where qualitative research can add value (see [Chapter 21](#)). Such reviews are designed to answer the following questions: 1) does the intervention work (effectiveness), 2) why does it work or not work – including how does it work (feasibility, appropriateness and meaningfulness), and 3) how do participants experience the intervention?

Where qualitative research is used to complement a Cochrane Intervention review, methods for the specification, identification, critical appraisal and synthesis of qualitative research should be described under a separate heading under ‘Data collection and analysis’ in the Methods of the review.

QQ.2.3 Considering qualitative studies that are identified within, or alongside, randomized controlled trials.

As ‘mixed methods’ evolve to evaluate the effects of complex interventions such as health service delivery strategies, it is increasingly likely that studies included in Cochrane Intervention reviews will have qualitative research embedded within or associated with them. The evidence resulting from the qualitative studies may not however be reported within the same publication as the trial. For example, in an exemplar review we summarize in [Box QQ.3.a](#), five out of six trials included in the Cochrane Intervention review included a qualitative component or associated study, although not all qualitative data had been analysed or published. Importantly, this qualitative component was not always referenced in the trial report. Indeed some studies only came to light after the review team made contact with the trial principal investigator. Methods of “cluster” searching (Booth 2013a) may be required to identify directly related outputs, so-called “sibling studies”, that originate from a common study.

When considering qualitative research identified within or alongside randomized trials, the following issues need to be considered:

1. Identification of qualitative evidence: Qualitative evidence retrieved using a topic-based search strategy designed with the primary purpose of identifying trials cannot be viewed as being either comprehensive or representative. Such a search strategy is not designed for the purpose of identifying qualitative studies and indeed achieves a measure of specificity by purposefully excluding many qualitative research types.
2. Qualitative evidence synthesis to explore the experience of having the disease: If the experience of the disease is the focus of interest then qualitative sources identified from the trial search strategy will not necessarily provide a holistic or comprehensive view. In these cases a multilevel or parallel synthesis should be considered or facilitated (see [Section QQ.3.2.5](#)). Ideally an author would work with a qualitative researcher and information specialist to develop a qualitative search strategy to identify other relevant studies. Lorenc (2012) reports that qualitative studies are less likely to focus on the experience of specific interventions, especially when these represent new technologies, being more likely to examine the experience of a particular disease or condition.
3. Qualitative synthesis to explore issues of implementation of the intervention: If issues surrounding implementation are the focus of interest then qualitative evidence embedded within or associated with the trials would be most relevant. Such implementation evidence is most likely to be generated by mixed methods research and to include both qualitative and quantitative evidence (see [Section QQ.3.2.5](#)). Steps need to be taken to identify all qualitative sources associated with the trials, such as undertaking additional targeted searching and contacting the trial principal investigator (Booth 2013a).
4. Considering qualitative evidence within studies excluded from Cochrane Intervention reviews: There may be occasions when a trial does not meet the eligibility criteria for a Cochrane Intervention review (for example due to unacceptable risk of bias) but the qualitative research embedded within or accompanying the trial is considered high quality. The guiding principle follows that if the qualitative evidence appears robust, this evidence can be incorporated into the review.

QQ.2.4 Resource considerations

The prospect of incorporating evidence from qualitative research in a Cochrane intervention review or the development of a complementary qualitative evidence synthesis inevitably has many

consequences for authors and Cochrane Review Groups (CRGs). Resource limitations may dictate the extent to which qualitative syntheses can be undertaken to accompany or complement quantitative reviews. Authors will need to consider the following:

- Is the qualitative evidence likely to address the review question(s), either uniquely or in terms of complementary insights?
- Does the team have the appropriate expertise or access to advice from researchers experienced in primary qualitative research and/or qualitative syntheses?
- Will additional training be required?
- Will the budget cover the additional time and resources needed?
- Does the team have access to appropriate databases and journals?
- Does the team have access to an information specialist who is familiar with the particular challenges of retrieving qualitative research?
- Does the CRG responsible for the review support the incorporation of qualitative evidence and have the resources to support the review through the editorial process?

QQ.3 Qualitative evidence synthesis

QQ.3.1 First published Exemplar of synthesizing qualitative evidence to complement a Cochrane Intervention review: directly observed therapy and tuberculosis (TB)

Before considering methodology for qualitative evidence synthesis, we provide an exemplar, summarized in [Box QQ.3.a](#). The full review is published in the *Journal of Advanced Nursing* (Noyes 2007). This parallel qualitative evidence synthesis extends and supplements a Cochrane review of directly observed therapy (supervised swallowing of medication) as an intervention to improve peoples' adherence to TB regimens, which included six randomized trials. The Cochrane intervention review found no statistically significant effect of directly observed therapy (DOT) when compared with people treating themselves at home. The accompanying synthesis of qualitative evidence focuses on lay experiences and perceptions of TB treatment to consider whether evidence from these studies could help explain the results of the randomized trials and contribute to the development of policy for the treatment of TB. In doing so the qualitative evidence synthesis addressed questions beyond those of the Cochrane Intervention review such as the appropriateness of DOT and the way it was facilitated in practice.

Box QQ.3.a: Directly observed therapy and tuberculosis: a synthesis of qualitative evidence summary

Background: DOT is part of a World Health Organization (WHO)-branded package of interventions to improve the management of TB and adherence with treatment (Maher 1999). DOT involves asking people with TB to visit a health worker, or other appointed person, to receive and be observed taking a dose of medication. A Cochrane Intervention review of trials of DOT showed conflicting evidence as to the effects of DOT when compared with self-administration of therapy. To complement this review, we conducted a synthesis of qualitative evidence concerning people with, or at risk of, TB, service providers and policy makers, to explore their experience and perceptions of TB and treatment. Findings were used to help explain and interpret the Cochrane Intervention review and to consider implications for research, policy and practice.

Review questions: Two broad research questions were addressed:

1. What are the facilitators and barriers to accessing and complying with tuberculosis treatment?
2. Can exploration of qualitative studies and/ or qualitative components of the studies included in the intervention review explain the heterogeneity of findings?

Method:

Search methods: A systematic search of the wider English-language literature was undertaken: The following terms were used: DOT; DOTS; Directly observed therapy; Directly observed treatment; supervised swallowing; self-supervis*; in combination with TB and tuberculosis. We experimented with using methodological filters by including terms such as 'qualitative', but found this approach unhelpful as the Medical Subject Heading (MeSH) 'Qualitative Research' was only introduced in 2003, and even after 2003 many papers were not identified appropriately as qualitative. We searched MEDLINE, CINAHL, HMIC, Embase, British Nursing Index, International Bibliography of the Social Sciences, Sociological Abstracts, SIGLE, ASSIA, PsycINFO, Econ lit, Ovid, Pubmed, the London School of Hygiene and Tropical Medicine database of TB studies (courtesy of Dr Simon Lewin), and Google Scholar. Reference lists contained within published papers were also scrutinized. A network of personal contacts was also used to identify papers. All principal researchers involved in the six randomized trials included in the Cochrane Intervention review were contacted and relevant qualitative studies obtained.

Selection and appraisal of studies: The following definition was used to select studies: 'papers whose primary focus was the experiences and/or perceptions of TB and its treatment amongst people with, or at risk of, TB and service providers'. For inclusion in the review a study had to use qualitative methods of data collection and analysis, as either a stand-alone study or a discrete part of a larger mixed-method study. To appraise methodological and theoretical dimensions of study quality, two contrasting frameworks were used independently by JN and JP (Critical Appraisal Skills Programme 2006; Popay . 1998a). Studies were not excluded on quality grounds, but lower quality studies were reviewed to see if they altered the outcome of the synthesis – which they did not.

Analysis: Thematic analysis techniques were used to synthesize data from 1990-2002, and an update of literature to December 2005. Themes were identified by bringing together components of ideas, experiences and views embedded in the data – themes were constructed to form a comprehensive picture of participants' collective experiences. A narrative summary technique was used to aid interpretation of trial results.

Findings: Fifty-eight papers derived from 53 studies were included. Five themes emerged from the 1990-2002 synthesis, including: socio-economic circumstances, material resources and individual agency; explanatory models and knowledge systems in relation to tuberculosis and its treatment; the experience of stigma and public discourses around tuberculosis; sanctions, incentives and support, and the social organization and social relationships of care. Two additional themes emerged from the 2005 update: the barriers created by programme implementation, and the challenge to the model that culturally determined factors are the central cause of treatment failure.

Conclusions: The Cochrane Intervention review did not show statistically significant differences between DOT and self-supervision, thereby suggesting that it was not DOT *per se* that led to an improvement in treatment outcomes. The six randomized trials tested eight variations of DOT compared with self-supervision and varied enormously in the degree to which they were tailored around the needs of people with TB. The variants of DOT differed in important ways in terms of who was being observed, where the observation took place and how often observation occurred. The synthesis of qualitative research suggests that these elements of DOT will be crucial in determining how effective a particular type of DOT will be in terms of increased cure rates. The qualitative review also highlighted the key role of social and economic factors and physical side effects of medication in shaping behaviour in relation to seeking diagnosis and adhering to treatment. More specifically, a predominantly inspectorial approach to observation is not likely to increase uptake of service or

adherence with medication. Inspectorial elements may be needed in treatment packages, but when the primary focus of direct observation was inspectorial rather than supportive in nature, observation was least effective. Direct observation of an inspectorial nature had the most negative impact on those who had the most to fear from disclosure, such as disadvantaged women who experienced gender-related discrimination. In contrast, treatment packages in which the emphasis is on person-centred support are more likely to increase uptake and adherence. Qualitative evidence also provided some insights into the type of support that people with TB find most helpful. Primarily, the ability of the observer to add value depended on the observer and the service being able to adapt to the widely-varying individual circumstances of the person being observed (age, gender, agency, location, income, etc.). Given the heterogeneity amongst those with TB, findings support the need for locally tailored, patient-centred programmes rather than a single world wide intervention.

QQ.3.2 Methodological issues

The main methodological challenges for qualitative evidence syntheses relate to the design and conduct of search strategies, the appraisal of study quality and the appropriate methods for synthesis. The reader is referred to the Supplementary Guidance (See Table 1) on the Website of the Cochrane Qualitative Research and Implementation Methods Group which includes chapters on all of these processes together with other important issues.

Table 1 - Supplementary guidance for Qualitative Evidence Synthesis processes

Developing a protocol in REVMAN: In Development

Question Formulation: Harris J. Chapter 2: Using qualitative research to develop robust effectiveness questions and protocols for Cochrane systematic reviews.

Searching: Booth A. Chapter 3: Searching for Studies

Critical Appraisal: Hannes K. Chapter 4: Critical appraisal of qualitative research.

Data Extraction: Noyes J & Lewin S. Chapter 5: Extracting qualitative evidence.

Synthesis: Noyes J & Lewin S. Chapter 6: Supplemental Guidance on Selecting a Method of Qualitative Evidence Synthesis, and Integrating Qualitative Evidence with Cochrane Intervention Reviews.

All Chapters In: Noyes J, Booth A, Hannes K, Harden A, Harris J, Lewin S, Lockwood C (editors), *Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions*. Version 1 (updated August 2011). Cochrane Collaboration Qualitative Methods Group, 2011. All guidance is available from: <http://cqim.cochrane.org/supplemental-handbook-guidance>:

QQ.3.2.1 Search strategies

The Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards (Chandler, 2013) state (C26) that it is mandatory to undertake appropriate searches if the review has specific eligibility criteria to address qualitative research questions. Significant progress has been made in analysing indexing systems of databases for qualitative studies. The Hedges Project at McMaster University has expanded its coverage of empirically-tested methodological filters to include qualitative research filters for MEDLINE (Wong . 2004), CINAHL (Wilczynski . 2007), PsycINFO (McKibbin . 2006) and EMBASE (Walters . 2006). Nevertheless evidence from qualitative studies collected and reported within randomized trials or as part of linked studies is difficult to retrieve (Evans 2002). MEDLINE introduced the MeSH term 'qualitative research' only in 2003. CINAHL

introduced 'Qualitative Studies' in 1988, reflecting particular interest in qualitative studies for nursing researchers, with a corresponding focus on 'quality of life' issues (see Chapter 17, Section 17.3). However, locating qualitative studies remains problematic because of the varied use of the term 'qualitative' (Grant 2004).

In addition, current strategies for indexing terms related to qualitative study designs and protocol-driven search strategies are only of limited value (Barroso 2003; Evans 2002; Greenhalgh 2005). Review authors must be aware that limiting a search to well-known databases may result in missing much useful information. An audit of sources for a review of complex interventions (including qualitative evidence) found that only 30% were identified from databases and hand searches. About half of studies were identified by 'snowballing' and another 24% by personal knowledge or personal contact (Greenhalgh 2005). Search strategies to identify qualitative studies using a range of different qualitative methods need to be further developed. Recent examples include studies by Gorecki (2010), Papaioannou (2010) and Finfgeld-Connett (2013).

While there is general agreement on the need for search strategies aiming to identify qualitative research to be systematic and explicit, recent debate centres on whether qualitative evidence syntheses share the need for comprehensive, exhaustive searches. It is argued that a more purposive sampling approach, aiming to provide a holistic interpretation of a phenomenon, where the extent of searching is driven by the need to reach theoretical saturation and the identification of the 'disconfirming case' may be more appropriate (Dixon-Woods 2006; Booth 2013b). Nevertheless this places an even greater imperative to improve quality of reporting standards of search methods (Booth 2006).

QQ.3.2.2 Critical appraisal

Assessment of study quality (critical appraisal) is a particularly contested issue in relation to qualitative evidence synthesis. At present, opinion on the value of formal quality assessment is divided and there is insufficient evidence to inform a judgement on the rigour or added value of various approaches. However, a growing trend may be observed amongst authors of qualitative evidence synthesis to consider quality assessment as an obligatory step in the review process together with an emerging consensus on making judgments on inclusion of evidence more transparent and explicit (Hannes 2012a).

Over one hundred tools and frameworks are available to aid the appraisal of qualitative research, mirroring those available for the appraisal of methodological quality in randomized trials and other forms of quantitative research (Vermeire 2002, Cote 2005). However, it is important to recognize that questions about 'quality' are very different in the context of qualitative research. Formal appraisal processes and standards of evidence presented as rigid checklists informing an 'in or out' decision can be argued to be inappropriate for qualitative research. Rather, such tools are perhaps best utilized as part of a process of exploration and interpretation. Studies rated as low methodological quality on the basis of a rigid formulaic method can generate new insights, grounded in the data, while methodologically sound studies may suffer from poor interpretation, leading to insufficient insight into the phenomenon under study. Dixon-Woods (2007) compared three structured appraisal approaches and concluded that structured approaches may not produce greater consistency of judgements about whether to include qualitative papers in a systematic review.

A further issue relates to the timing of quality assessment and when outcomes from the process should be taken into account – should critical appraisal be viewed as a hurdle for establishing a quality threshold or as a filter for mediating the differing strength of the resultant messages from included research?

If authors decide to incorporate quality appraisal as part of the systematic review process then they may use the framework that is integral to the particular method (such as the Evidence for Policy and Practice Information (EPPI) approach or Joanna Briggs Institute (JBI) approach), or select any

published qualitative appraisal tool, framework or checklist. Spencer (2003) and Harden (2012) have reviewed many current appraisal frameworks and checklists, which authors may find helpful in deciding which approach to apply. In addition, Hannes (2010) compared three online critical appraisal instruments' ability to facilitate an assessment of validity and concluded that some instruments are less sensitive to some aspects of validity than others, suggesting that authors of reviews should carefully consider their choice of instrument and quality criteria. There is common consensus amongst qualitative researchers that expert judgement is also an important factor when appraising the quality of studies. Garside (2014) and Carroll (2014) provide brief synopses of current thinking in quality assessment, including a consideration of the role of sensitivity analysis (Carroll 2012) in testing the robustness of qualitative findings.

Key references reflecting this debate are included in Section [QQ.6.6: Further Reading](#).

QQ.3.2.3 Synthesizing evidence from qualitative research

Qualitative evidence synthesis is a process of combining evidence from individual qualitative studies to create new understanding by comparing and analysing concepts and findings from different sources of evidence with a focus on the same topic of interest. Therefore, qualitative evidence synthesis can be considered comparable to a meta-analysis within a systematic review on effects of interventions or diagnostic tests. Synthesis can be aggregative or interpretive but requires transparency of process. A QES requires authors to identify and extract evidence from studies included in the review; to categorize the evidence; and to combine these categories to develop synthesized findings. In undertaking this methodological work, however, it is important to recognize that the real added value from the synthesis of qualitative evidence is not just a description of how people feel about an issue or treatment but an understanding of 'why' they feel and behave the way they do.

Just as primary qualitative research might present people's accounts of the onset of chronic illness, yet moves beyond description to seek to explain the social purpose of these accounts – showing how through these narratives people 'reconstruct' a sense of worth in a social context in which all illness has moral overtones, so too, a meta-ethnography of medicine taking ((Campbell 2003, Pound 2005) moves beyond providing a summary of recurring 'themes' across studies to build an explanation of why people use medication (or not) in the way they do.

QQ.3.2.4 Choosing an appropriate method

The choice of method for inclusion of qualitative evidence in a qualitative evidence synthesis will depend on several factors, including the:

- type and scope of the review and review question(s);
- pool of available evidence;
- expertise of the team; and
- available resources.

Several evolving methods exist for the synthesis of qualitative and mixed-method evidence. Along with other interested individuals and systematic review organizations, Cochrane Qualitative Research Methods Group members are actively involved in developing and, more recently, beginning to evaluate the range of methods available. Members have contributed to core texts on synthesizing qualitative and quantitative health evidence, which provide more detailed information and guidance on methods and processes.

We recommend that any high quality method of qualitative evidence synthesis may be used that is best suited to the type of review.

It is beyond the scope of the chapter to include a detailed description of the range of methods available for qualitative and mixed-method evidence synthesis. A variety of methods have been used

in published reviews. Examples include: Bayesian meta-analysis, critical interpretive synthesis, the mixed methods approach from the Evidence for Policy and Practice Information Coordinating (EPPI) Centre, meta-aggregation, meta-ethnography, meta-synthesis, meta-study, meta-summary, narrative synthesis, qualitative evidence synthesis drawing on grounded theory, realist synthesis, thematic synthesis, framework synthesis and secondary thematic analysis.

Most methods have associated detailed guidance (see for example Noblit (1988) on meta-ethnography, Popay (2006b) on narrative synthesis and Pearson (2011) on meta-aggregation). Dixon-Woods (2005, 2006) and Barnett-Page (2009a, 2009b) provide a detailed overview of the potential of several methods and associated challenges (Dixon-Woods 2005; Dixon-Woods 2006). As yet, little evaluation has been undertaken to determine the robustness of different methods. One such recent example is *Evaluating Meta-ethnography* (Campbell, 2011) Further reading is found in Section [QQ.6](#).

QQ.3.2.5 Approaches to integrating qualitative and quantitative evidence syntheses

Two broad approaches can be used to integrate qualitative and quantitative findings:

1. Multilevel syntheses: Qualitative evidence (synthesis 1) and quantitative evidence (synthesis 2) can be conducted as separate streams or separate, but linking, reviews and the product of each synthesis is then combined (synthesis 3) (see, for example, Thomas 2004; Harden 2009).
2. Parallel syntheses: Qualitative evidence (synthesis 1) and quantitative evidence (synthesis 2) can be conducted as separate streams or separate but linked reviews. The qualitative synthesis (1) can then be used in parallel and juxtaposed alongside to aid the interpretation of synthesized trials (synthesis 2) (see, for example, Noyes 2007).

Multilevel and parallel syntheses both require a separate systematic review of qualitative evidence, which at a later stage is synthesized with, or juxtaposed alongside, the synthesis of trials. Guidance on the conduct of narrative synthesis (Popay 2006b) contains a toolkit for bringing together findings from different study designs within different methods and approaches. Further methodological work is required on the processes by which studies using different qualitative methods and generating a range of types of evidence can be synthesized and combined with quantitative findings on effect without compromising the need to minimize bias.

The MECIR standards acknowledge the potential for incorporating qualitative research evidence and the importance of and reporting appropriately how this was undertaken, (see standards R7, R26, R37).

QQ.3.2.6 Adding implementation research to the Qualitative Research Methods Group

Implementation research was added to the expanded and re-named Qualitative and Implementation Methods Group (QIMG) as an extension of the Group's previous remit to develop methodological guidance for qualitative evidence synthesis and integration of qualitative evidence with Cochrane intervention reviews. Qualitative research has traditionally been used in health care and public health to increase understanding of a phenomenon, identifying associations between the broader environment, individual characteristics, and attitudes toward health conditions. Findings from qualitative research help to describe the relationships between the intervention context, sender, message and receiver, provide insight into the mechanisms of action, and can explain equivocal effects for interventions presumed to be straightforward and linear. When qualitative research is added to experimental research either through process evaluations alongside clinical trials or as part of a mixed methods evaluation of health systems, it can help to define the components of a complex intervention in relation to individual patients, organizational pathway, and health systems (Bradley 1999; Vanhaecht 2012). It may also serve to explain the connections that either promote or hinder implementation of evidence and service improvement (Cresswell 2012).

The Group aims to develop systematic review methods to assess implementation in efficacy, effectiveness and implementation studies. Implementation research has been defined as ‘the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care (Eccles 2009). Implementation research places an emphasis on assessing and understanding the actions of providers/ clinicians and the characteristics of the health system in hindering or facilitating intervention adoption and delivery. The unit of analysis is the clinician, clinical unit or site. Clinical outcome data is less important (or is a secondary consideration) since intervention effectiveness has been established through efficacy and effectiveness trials. As such, the primary outcome measures of interest are process measures like, for example, rates of adoption, adherence/ fidelity and service utilisation indicators. Process evaluation is the core business of implementation research studies and it often involves the use of multiple qualitative methods (e.g., stakeholder interviews, logs, field notes) to understand the multi-level causal drivers of successful adoption, implementation and institutionalisation.

Implementation research is a growing field in health care, which has been developed in response to the need to provide cost effective health services based on best quality evidence. The WHO, UNICEF, the World Bank and UNDP have noted that rather than developing new interventions via research, we need to optimise the use of existing research by exploring how findings can be translated into effective health care delivery across different cultures and contexts (WHO, 2008). One of the ways to progress transfer of research to practice is via reviews of implementation. Implementation reviews aim to synthesize high quality implementation research, that assesses the effectiveness of strategies for promoting the uptake of clinical research findings and other evidence-based practices by practitioners, the public and the broader community that span the “bench to bedside” and “benchside to community” research spectrum, also known as Type 1 and Type 2 translational research. Although process evaluation is used to assess implementation in both types of translational research, the study focus, primary outcomes, units of analysis and relative emphasis placed on implementation in these types of research differ (Woolf, 2008). Below, we outline how implementation is featured across the different types of studies.

Clinical efficacy studies assess whether a treatment improves clinical outcomes under controlled conditions whereas effectiveness studies test whether an intervention is effective in less controlled conditions and in more diverse samples. Process evaluations integrated alongside clinical research efficacy and effectiveness trials (Type 1 translational research) can provide insight into variations in participant responsiveness to an intervention and the individual, interpersonal, organisational or broader contextual factors that impact provider capacity to deliver a clinical intervention as originally intended. Most often, the patient is the unit of analysis and randomisation in these studies and the patient’s clinical symptoms, side effects, hospitalisations or health are the primary health outcomes. Process evaluations in clinical efficacy and effectiveness trials can strengthen internal validity by accounting for variations in implementation and participant and provider experiences and thus rule out a Type III error. Given the emphasis of clinical efficacy trials on clinical outcomes, process evaluation has tended to be a secondary consideration. Process evaluation has been featured more prominently in clinical effectiveness trials, which favour external validity in determining whether efficacy trial results are robust in more pragmatic real world settings.

QIMG will be developing implementation review guidance for future versions of this *Handbook*.

QQ.3.2.7 Conclusion

Interest in systematically reviewing broader forms of evidence and in particular evidence from qualitative research is being driven by a growing recognition that qualitative research can improve the relevance and utility of a review (Petticrew 2015). However, research evidence that is rigorously generated, regardless of design, demands due consideration of its quality before it can be applied in

decision-making. To be considered as a Cochrane review, qualitative evidence synthesis must be subjected to equally rigorous methods of review. Methods for appraising and analysing evidence from qualitative research have been established and will continue to evolve over time. Further evidence is required to establish the rigour and added value of the various approaches to quality appraisal and analysis in the systematic review process.

QQ.4 Chapter information

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Box QQ.4.a: The Cochrane Qualitative and Implementation Methods Group

The Cochrane Qualitative and Implementation Methods Group (QIMG) develops and supports methodological work on the inclusion in systematic reviews of evidence from research using qualitative methods and disseminates this work within and beyond the Collaboration's CRGs.

The QIMG is attempting to fulfil its role by:

- Identifying appropriate roles for evidence from qualitative research within the context of Cochrane systematic reviews.
- Collating, developing and disseminating appropriate methodological standards for:
 - searching for qualitative research relevant to Cochrane reviews;
 - critically appraising qualitative studies;
 - combining evidence from qualitative research with other data within the context of a systematic review; and
 - dissemination of these methodological standards through various routes including contributing to the guidance for authors in the *Handbook*.
- Providing a forum for discussion and debate about the role of qualitative evidence within the systematic review process and the development of rigorous and systematic methods to promote this role to:
 - encourage transparency of, and learning about, method developments; and
 - encourage and facilitate liaison and sharing with other methods groups.
- Providing links for Cochrane Review Groups to people with expertise and experience of qualitative research to:
 - provide advice and support for people aiming to incorporate qualitative research into a review; and
 - provide a mechanism for evaluating and developing review protocols.
- Providing training for members of Cochrane and Campbell Review Groups.
- Maintaining a register/database of relevant methodological papers.
- Maintaining a Cochrane register/database of systematic review protocols that include qualitative evidence synthesis or are solely focused on the systematic review of qualitative evidence.
- Maintaining a register/database of completed systematic reviews that include qualitative

evidence synthesis; and of reviews that are solely focused on the systematic review of qualitative evidence.

- Surveying members on an annual basis to identify developing interests and ongoing contributions.

Members of the Group have contributed to the guidance on the commissioning and conduct of systematic reviews produced by the Centre for Reviews and Dissemination at the University of York and have supported the development of guidance produced by the Cochrane Health Promotion and Public Health Field.

Web site: cqim.cochrane.org

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QQ.6.8 Web sites

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Campbell Collaboration

A Campbell Review can include evidence from studies of the implementation of an intervention.

- www.campbellcollaboration.org

Centre for Reviews and Dissemination (CRD), University of York, UK

In addition to a handbook, CRD has an online resource centre.

- www.york.ac.uk/inst/crd

Evidence for Policy and Practice Information and Coordinating (EPPI) Centre

The EPPI Centre provides links to methods, tools and databases.

- eppi.ioe.ac.uk/cms

Joanna Briggs Institute (JBI)

JBI offers a variety of evidence-based healthcare resources concerning the synthesis of evidence.

- joannabriggs.org/

National Institute for Health and Clinical Excellence (NICE)

NICE has produced guidance on methods for development of NICE public health guidance which incorporate diverse study designs.

- www.nice.org.uk

Social Care Institute for Excellence (SCIE)

SCIE has produced guidance on the conduct of knowledge reviews which incorporate diverse study designs.

- www.scie.org.uk