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Cochrane Qualitative and Implementation Methods Group guidance paper 3: methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings

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Abstract

The Cochrane Qualitative and Implementation Methods Group develops and publishes guidance on the synthesis of qualitative and mixed-method implementation evidence. Choice of appropriate methodologies, methods, and tools is essential when developing a rigorous protocol and conducting the synthesis. Cochrane authors who conduct qualitative evidence syntheses have thus far used a small number of relatively simple methods to address similarly written questions. Cochrane has invested in methodological work to develop new tools and to encourage the production of exemplar reviews to show the value of more innovative methods that address a wider range of questions. In this paper, in the series, we report updated guidance on the selection of tools to assess methodological limitations in qualitative studies and methods to extract and synthesize qualitative evidence. We recommend application of Grades of Recommendation, Assessment, Development, and Evaluation—Confidence in the Evidence from Qualitative Reviews to assess confidence in qualitative synthesized findings. This guidance aims to support review authors to undertake a qualitative evidence synthesis that is intended to be integrated subsequently with the findings of one or more Cochrane reviews of the effects of similar interventions. The review of intervention effects may be undertaken concurrently with or separate to the qualitative evidence synthesis. We encourage further development through reflection and formal testing. © 2017 Elsevier Inc. All rights reserved.

Keywords: Systematic review; Qualitative research; Qualitative evidence synthesis; Methodological limitations; GRADE CERQual; Cochrane

1. Introduction

This paper in the Cochrane Qualitative and Implementation Methods Group (CQIMG) series provides updated guidance on methods for assessing methodological strengths and limitations of included studies; data

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* Corresponding author. Tel.: +44(0) 1248 388519. E-mail address: Jane.noyes@bangor.ac.uk (J. Noyes). extraction; synthesis of qualitative evidence; expressing the synthesis; reporting review author reflexivity; and assessing confidence in synthesized qualitative findings.

This third paper follows on from Paper 2 [1], which outlines guidance on question formulation, searching for evidence and protocol development for qualitative evidence syntheses. Paper 2 also provides good examples of questions that are best answered by synthesizing findings from primary qualitative studies, building on the idea that an in-depth analysis and synthesis of qualitative findings across studies

What is new?

• The paper outlines new guidance and novel method developments in the assessment of the methodological limitations of qualitative studies, methods for data extraction, and qualitative evidence synthesis, expressing the synthesis and reporting review author reflexivity and recommends the use of Grades of Recommendation, Assessment, Development, and Evaluation—Confidence in the Evidence from Qualitative Reviews (GRADE-CERQual) to assess the confidence in qualitative synthesized findings.

Key findings

• The paper provides new guidance on the selection of tools to assess the methodological strengths and limitations of qualitative studies and how to use this information in decision-making as the review progresses. Four approaches to qualitative data extraction are highlighted, and new guidance is signposted on the selection of qualitative evidence synthesis methods from the spectrum of available methods. Application of GRADE-CERQual to assess confidence in synthesized qualitative findings will be of benefit to decision-makers. The reflexive processes of review authors need to be made more transparent.

What this adds to what was known?

The paper highlights that significant methodological work and progress has been made in the last 5 years in developing and applying qualitative evidence synthesis methods. The paper emphasizes the benefits of undertaking and publishing further methodological exemplars that explore key methodological issues.

What is the implication and what should change now?

 We recommend that review authors adopt and use this updated guidance to further improve the quality and utility of qualitative evidence syntheses for key stakeholders.

creates potential to develop a better understanding, or more comprehensive models or theories, of the phenomena of interest. A better understanding of these issues can inform the design of interventions, strategies, and health systems and their implementation to develop more personalized approaches that benefit patients and improve outcomes. Paper 5 [2] provides guidance on integrating the qualitative evidence synthesis with evidence of intervention effectiveness,

and paper 6 [3] outlines guidance on the selection and application of relevant reporting guidelines. Finally, paper 4 provides guidance on designing a synthesis using a broader range of mixed-method evidence derived from process evaluations and other types of studies that can be used to address implementation questions [4].

2. Assessment of study methodological strengths and limitations

The issue of why and how to judge the quality and more specifically the methodological strengths and limitations of qualitative studies and what to do with the assessments has long been debated among qualitative researchers with a range of, sometimes conflicting, proposals being made [5]. Opinion remains divided as to the value of quality appraisal of qualitative evidence, and a wider exploration of these issues can be found elsewhere [6–8].

Qualitative researchers generally make an assessment of study quality by identifying methodological strengths and limitations (i.e., "rigor"). Although different criteria are used to establish qualitative "rigor" compared with "risk of bias" in quantitative studies, the information is used in a similar way to make judgments about the impact of methodological limitations of studies that contribute to synthesized findings. An example of the criteria used to assess study quality/methodological rigor using the Critical Appraisal Skills Programme (CASP) tool for qualitative studies is shown in Box 1. This CASP tool is currently the most commonly used tool in qualitative evidence syntheses in Cochrane and World Health Organization (WHO) guideline processes.

Assessment of methodological strengths and limitations of included studies are considered essential to the Cochrane review process. In our initial guidance to review authors in

Box 1 CASP[©] qualitative research checklist

- 1. Was there a clear statement of the aims of the research?
 - Yes Cannot tell No
- 2. Is a qualitative methodology appropriate?
- 3. Was the research design appropriate to address the aims of the research?
- 4. Was the recruitment strategy appropriate to the aims of the research?
- 5. Was the data collected in a way that addressed the research issue?
- 6. Has the relationship between researcher and participants been adequately considered?
- 7. Have ethical issues been taken into consideration?
- 8. Was the data analysis sufficiently rigorous?
- 9. Is there a clear statement of findings?
- 10. How valuable is the research?

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