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Cochrane Qualitative and Implementation Methods Group guidance series—paper 1: introduction

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1. Introduction

Cochrane reviews are systematic reviews of primary research in human health care and health policy and are internationally recognized health care resources for use in a decision-making process [1]. Cochrane works collaboratively with contributors around the world to produce authoritative, relevant, and reliable reviews. Cochrane reviews are commonly used in a guideline development process to determine recommendations for practice. The Cochrane Qualitative and Implementation Methods Group provide methodological advice and guidance to Cochrane as well as leading methodological development to benefit the wider qualitative evidence synthesis community. In this introductory paper 1, we briefly outline the evolution of qualitative and mixed-method synthesis methods, the role of qualitative and mixed-method syntheses in a decision-making process, and the contribution of qualitative and mixed-method syntheses to understand the complexity in complex intervention reviews. We then introduce a series of papers that provide Cochrane guidance on conducting qualitative and mixed-method evidence syntheses for a decision-making context.

1.1. The evolution of qualitative and mixed-method synthesis methods

Methods for qualitative and mixed-method evidence synthesis have evolved substantially since the Cochrane Qualitative and Implementation Methods Group was formed in the late 1990s [2]. There are now over 30 methods for conducting a qualitative evidence synthesis, although not all methods are suitable for a decision-making process whereby a clear statement of qualitative findings is required to feed into an evidence-to-decision framework [3]. There are also around 10 evolving methods that are commonly used for integrating qualitative evidence or a qualitative synthesis with quantitative evidence of intervention effects in a mixed-method synthesis [3]. Although qualitative evidence synthesis methods have evolved substantially over the last decade, some methods have been subject to more development and testing than others, and thus choice of an appropriate method is critical. A new guide on the choice of qualitative evidence synthesis methods and methods for integrating quantitative and qualitative evidence has recently been published that makes clear the factors to consider when selecting a method [3].

The recent development of the Grading of Recommendations Assessment, Development and Evaluation Confidence in the Evidence from Reviews of Qualitative Research (GRADE CERQual) [4] approach for assessing how much confidence to place in findings from qualitative evidence syntheses is also changing the way qualitative evidence syntheses are conducted and reported to more clearly align with a decision-making process.

Methods for mixed-method synthesis have not evolved at the same pace, and further development and testing is required. We anticipate that publication of the UK Medical Research Council Guidance [5] on designing complex

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intervention process evaluations will increase the need to synthesize process evaluation evidence, and this will lead to further methodological innovation in methods of synthesis and assessing the confidence in synthesized findings.

2. The role of qualitative and mixed-method evidence synthesis in a decision-making process

A synthesis of qualitative and mixed-method evidence has a clear role to help establish how an intervention works, for whom and in what contexts, and to shed light on how best to implement it [2]. From the beginning, Cochrane guidance on qualitative evidence synthesis has been based on the tenet that qualitative evidence can inform understanding of effectiveness, by increasing understanding of a phenomenon, identifying associations between the broader environment within which people live and interventions are implemented, and unpacking the influence of individual characteristics and attitudes toward health conditions and interventions [2].

2.1. Complex intervention reviews and complexity

Over time, the importance of qualitative and mixed-method synthesis for gaining a more detailed understanding of the complexity of interventions and their impacts and effects on different subgroups of people within different contexts has gained ascendency. Given the extra time, effort and resources required to conduct a qualitative evidence synthesis and to then integrate the findings with quantitative evidence of intervention effect in a decision-making process, application of these additional syntheses is more commonly associated with complex interventions.

The first qualitative evidence synthesis that looked at implementation complexity linked with a corresponding review of effectiveness was published in the Cochrane Library in 2012 [6,7]. This milestone coincided with the World Health Organization (a Cochrane partner) commissioning and using qualitative evidence syntheses to inform development of a guideline on optimizing health worker roles to improve access to maternal and newborn health interventions through task shifting [8]. The World Health Organization has subsequently commissioned further guidelines to be developed with input from qualitative evidence syntheses [9].

The role of and methods for qualitative and mixed-method evidence synthesis in achieving a better understanding of complexity was outlined in a seminal series on considering complexity in systematic reviews of interventions published in 2013 [10–16]. The first series was part-funded by Cochrane and took a methodological lens that largely drew on Cochrane guidance on quantitative and qualitative evidence synthesis methods. It has been highly influential in getting guideline developers, reviewers, and other key stakeholders to consider how to make best use of diverse sources of evidence to address questions about the complexity of complex interventions. A second series funded by the Agency for Healthcare Research and Quality Evidence-based Practice Center Program and published in 2017 takes a broader lens that incorporates more stakeholder perspectives in the methods to produce systematic reviews of complex interventions for a decision-making context [17–22]. A third series (forthcoming in BMJ Global Health and funded by WHO), applies a more global and health systems lens to outline the methods that are most suitable for conducting systematic reviews of complex interventions that inform a guideline process to produce recommendations.

2.2. Cochrane Qualitative and Implementation Methods Group: series approach

Cochrane reviews are produced to inform decision-making and to feed into decision-making processes such as guidelines and this distinctive lens provides the unique focus of this series. Cochrane has developed an evidence-based strategy for methods development and application. Methodological research is undertaken in parallel with production of worked examples of methods and their application, and exemplar reviews of new or evolving methods. Collectively the convenors and members of the group have produced a substantive body of methodological outputs in the field of qualitative and mixed-method evidence synthesis.

Each year, there are Cochrane methods symposium and methods training workshops. Cochrane Qualitative and Implementation Methods Group convenors also actively facilitate additional methods training opportunities and maintain a Methodology Register of over 8,000 records. More details can be found on our website [23]. These various activities provide opportunities for feedback and gaining consensus on methods development and application.

Cochrane Qualitative and Implementation Methods Group Convenors are responsible for maintaining a chapter in the Cochrane Handbook for Systematic Reviews of Interventions [2] and for developing more detailed supplemental methods guidance for review authors, which are used as a global resource beyond Cochrane. Our first chapter on conducting a qualitative evidence synthesis was published in the 2008 version of the Cochrane Handbook [2]. More detailed guidance (now archived) that further supplemented the qualitative evidence synthesis handbook chapter was published on our website in 2011 [3].

Cochrane has invested in methods development for qualitative evidence synthesis by for example funding development of the GRADE CERQual [4] approach for assessing how much confidence to place in findings from qualitative evidence syntheses, the Cochrane qualitative Methodological Limitations Tool for use with CERQual, and a GRADE CERQual methods training workshop.

The current series of five peer-reviewed papers published in the Journal of Clinical Epidemiology updates previous 2011 guidance on question formulation, protocol development, searching, data extraction and synthesis, which has now been archived on the Cochrane Qualitative and Implementation Methods Group website [23]. Four

new methodological topics have been incorporated including, synthesis of implementation and process evaluation evidence, integration of qualitative and quantitative evidence, application of GRADE CERQual [4], and reporting guidelines. The five papers provide additional insight into the key issues for consideration and signposting to further resources for more detailed guidance.

The five papers are as follows:

- Cochrane Qualitative and Implementation Methods Group guidance paper 2: *Methods for question formulation, searching and protocol development for qualitative evidence synthesis* [24]- describes updated approaches to frame questions, search for evidence and construct protocols for reviews that use qualitative evidence, including qualitative evidence on implementation of interventions.
- Cochrane Qualitative and Implementation Methods Group guidance paper 3: *Methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings* [25]- outlines new guidance on the selection of tools to assess methodological strengths and limitations in primary qualitative studies and methods to extract and synthesize qualitative evidence in a Cochrane context. Use of GRADE CERQual [4] is recommended as an approach to assess the confidence in qualitative synthesized findings.
- Cochrane Qualitative and Implementation Methods Group guidance paper 4: *Methods for question formulation, identifying and processing evidence on intervention implementation* [26]- provides new guidance on methods for identifying and processing evidence to understand intervention implementation.
- Cochrane Qualitative and Implementation Methods Group guidance paper 5: *Methods for integrating findings from syntheses of qualitative and process evaluation evidence with intervention effectiveness reviews* [27]- outlines updated guidance on approaches, methods, and tools which can be used to integrate the findings from trials with those from qualitative and implementation research.
- Cochrane Qualitative and Implementation Methods Group guidance paper 6: *Reporting guidelines for qualitative, implementation and process evaluation evidence syntheses* [28]- outlines contemporary and novel developments for presentation and reporting of syntheses of qualitative, implementation, and process evaluation evidence and provide recommendations for use of reporting guidelines.

2.3. The fit of the series with existing and forthcoming series on complex intervention reviews

The five papers in this series should be read in combination with the three aforementioned series on methods for synthesizing complex interventions, and the INTEGRATE [3] guidance on choice of qualitative and mixed-method integration methods. The unique focus on methods for qualitative and mixed-method syntheses in this series complements and adds to the foci of the other series.

2.4. Application of the guidance in a Cochrane context

Cochrane has taken a careful approach to the introduction of qualitative and mixed-method evidence synthesis approaches. Cochrane is committed to publish qualitative and mixed-method evidence syntheses as exemplar reviews and has developed a flexible version of RevMan to accommodate reporting of diverse review designs [29].

A recent audit in 2015 revealed 18 relevant qualitative synthesis (six reviews and 12 protocols) titles registered across 11 Cochrane Review Groups with the Effective Practice and Organization of Care Group (five titles), Consumers and Communication (three), and Public Health (two) recording more than one title.

At present an additional qualitative evidence syntheses can be undertaken within a Cochrane context if the phenomenon of interest is likely to be best addressed by qualitative evidence and (1) the questions broadly align with one or more effect reviews of the same or a linked intervention, (2) the Cochrane Review Group agrees to register the title, and (3) the Cochrane Qualitative and Implementation Methods Group is able to provide methodological guidance and support as required. Reviewers undertaking a qualitative evidence synthesis may conduct a stand-alone synthesis to integrate with an already completed, or published, Cochrane intervention effect review. Alternatively, reviewers may undertake the synthesis and subsequent integration in parallel with conducting a Cochrane intervention effect review.

We hope that the updated methods guidance contained in these five papers will further strengthen the conduct and reporting of Cochrane reviews and beyond. We plan to expand this guidance over time by publishing additional method-specific articles and working to produce more detailed Cochrane guidance. These papers will also inform development of the new chapter on qualitative evidence synthesis methods in the forthcoming major update of the Cochrane Handbook for Systematic Reviews of Interventions. Finally, we would like to express our sincere thanks to Peter Tugwell, Andrea Tricco, and Jessie McGowan for facilitating the rigorous peer review process that served to further strengthen the papers and for their help in making this series a reality.

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