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ORIGINAL ARTICLE

Cochrane Qualitative and Implementation Methods Group guidance paper: reporting guidelines for qualitative, implementation, and process evaluation evidence syntheses

Kate Flemming^{a,*}, Andrew Booth^b, Karin Hannes^c, Margaret Cargo^d, Jane Noyes^e

^aDepartment of Health Sciences, Faculty of Science, University of York, Seabrook Rowntree Building, Heslington, York YO10 5DD, UK

^bSchool of Health and Related Research (ScHARR), Regent Court, 30 Regent Street, Sheffield S1 4DA, UK

^cSocial Research Methodology Group, Centre for Sociological Research, Faculty of Social Sciences, KU Leuven, Leuven, Belgium

^dSpatial Epidemiology & Evaluation Research Group/Centre for Population Health Research, University of South Australia, 8th Floor Office 310, South Australia Health & Medical Research Institute, North Terrace, Adelaide SA 510, Australia

^eSchool of Social Sciences, 2 Bangor University, Bangor, Gwynedd, LL57 2DG, UK

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Abstract

Objectives: To outline contemporary and novel developments for the presentation and reporting of syntheses of qualitative, implementation, and process evaluation evidence and provide recommendations for the use of reporting guidelines.

Study Design and Setting: An overview of reporting guidelines for qualitative, implementation, and process evaluation evidence syntheses drawing on current international literature and the collective expert knowledge of the Cochrane Qualitative and Implementation Methods Group.

Results: Several reporting guidelines exist that can be used or adapted to report syntheses of qualitative, implementation, and process evaluation evidence. Methods to develop individual guidance varied. The use of a relevant reporting guideline can enhance the transparency, consistency, and quality of reporting. Guidelines that exist are generic, method specific, and for particular aspects of the reviewing process, searching.

Conclusion: Caution is expressed over the potential for reporting guidelines to produce a mechanistic approach moving the focus away from the content and toward the procedural aspects of the review. The use of a reporting guideline is recommended and a five-step decision flowchart to guide the choice of reporting guideline is provided. Gaps remain in method-specific reporting guidelines such as mixed-study, implementation, and process evaluation evidence syntheses. © 2017 Elsevier Inc. All rights reserved.

Keywords: Qualitative evidence synthesis; Reporting guidelines; Implementation; Systematic reviews; Methods

1. Introduction

It is now almost 20 years since the appearance of the first formally developed guideline to improve the presentation, quality, and reliability of published research. What began with the publication of the Consolidated Standards of Reporting Trials (CONSORT) statement to enhance the reporting of randomized controlled trials (RCTs) and its subsequent updates, led to a sustained growth in development of other guidelines to enhance the reporting of other research methods [1–3]. This expansive response acknowledged the problems that arise through inadequate reporting

including, lack of transparency, clarity, and completeness associated with the research itself along with the subsequent ethical and moral consequences of inadequately reported research [3].

Such prodigious growth required focused and collaborative co-ordination of the development of reporting guidelines, particularly to reduce the then-wide variation in the methods being used to develop guidelines. From this realization grew the development of the Enhancing the Quality and Transparency of Health Research (EQUATOR) network (<http://www.equatornetwork.org/>), which was funded initially by the National Knowledge Service of the United Kingdom's National Health Service [4]. The aim of the international EQUATOR network is to improve the quality of scientific publications by assisting in the development, dissemination, and implementation of robust reporting guidelines through the provision of resources and

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* Corresponding author. Tel.: +44-1904-321345.

E-mail address: kate.flemming@york.ac.uk (K. Flemming).

What is new?**Key findings**

- This paper outlines contemporary developments around the presentation and reporting syntheses of qualitative, implementation, and process evaluation evidence.
- Existing guidelines can be used or adapted for reporting syntheses of qualitative, implementation, and process evaluation evidence. The use of a guideline can enhance the transparency, consistency, and quality of reporting. Gaps remain in method-specific reporting guidelines such as mixed-study, implementation, and process evaluation evidence syntheses.

What this adds to what was known?

- This paper highlights that much work has been undertaken to raise the standards of reporting, and projects in progress will further enhance this work. It also emphasizes the benefits of standardization and the possible unintended consequences that may result.

What is the implication and what should change now?

- In the context of the current development and debate surrounding the reporting of evidence syntheses, a 5-point “decision flowchart” has been provided to help support review authors in their choice of reporting guideline.

training [5]. The EQUATOR network offers a focus for the development of reporting guidelines and provides an invaluable repository of reporting guidelines for all research methods. It also provides a facility to register intent to develop a new reporting guideline or an extension to an existing guideline.

From these early days, development of reporting guidelines sought to improve the utility of primary research to be included within systematic reviews, which at the time were predominantly quantitative in nature. Within a decade, however, qualitative researchers also began to engage with the development of consolidated guidance for reporting qualitative methods. This effort resulted in the publication of the consolidated criteria for reporting qualitative research guidance (COREQ) [6]. This guidance focused on the reporting of key elements of qualitative research such as study methods, context of the study, findings, analysis, and interpretations as well as the research team. More recently, a standards for reporting qualitative research tool has been developed, consisting of 21 items aiming to improve the

transparency of all aspects of qualitative research [7]. A scoping review of emerging, qualitative, and mixed-methods evidence synthesis approaches highlighted both poor operationalization of the steps of such syntheses and the need for further empirical work to enhance this [8,9].

The development of reporting guidance for systematic reviews was contemporaneous to, and mirrors the efforts channeled into, primary research. The initial focus was the quality of reporting of meta-analyses (QUOROM) statement and subsequently followed by the guidance for the reporting of systematic reviews of effectiveness through the publication of the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement [10]. Subsequent work has led to extensions to the original PRISMA statement, so that the reporting of systematic reviews of other research methods and foci meet the same standards as those for reviews of RCTs. These are detailed on the EQUATOR network website (<http://www.equatornetwork.org/>).

Alongside the advancements in the reporting of systematic reviews, researchers have developed methodological guidance for systematic reviews of qualitative, implementation, and process evaluation evidence. The purpose and methodology of such reviews are detailed in earlier papers in this series. The aim of this final paper is to outline both contemporary and novel developments for the presentation and reporting of syntheses of qualitative, implementation, and process evaluation evidence. This includes a brief outline of the methodology for developing reporting guidelines and a description of current guidelines and reporting tools available. Finally, the paper outlines new developments in presentation and reporting and their associated challenges and provides recommendations for the use of reporting guidelines.

2. Methodologies for the development of a reporting guideline

Increasing recognition of the importance of reporting guidelines has been accompanied by the evolution of more rigorous methods for their development. Well-established approaches now exist for the development of new reporting guidelines. These approaches are documented, both through the EQUATOR network and elsewhere; although, it is agreed that these must accommodate a plurality of valid approaches [11]. We will not replicate the excellent advice available elsewhere, other than to highlight the importance of the use of accepted advice in the development of guidelines.

3. What guidelines are available for reporting syntheses of qualitative, implementation, and process evaluation evidence?

3.1. Reporting of aspects of synthesis methodology, for example, STARLITE

Given the challenges of co-ordinating a robust guideline for the entire qualitative, implementation, or process

evaluation synthesis product, some authors have focused on reporting the individual aspects of the synthesis. In 2007, Dixon-Woods et al [12] reviewed 42 published syntheses of qualitative research in health and health care. Many of these syntheses lacked explicitness about methods associated with systematic reviewing, including lack of transparency about searching with little evidence of emerging consensus on many issues. Specifically, in connection with searching methods, they observed that many papers “offered no defense of their lack of explicitness in describing their techniques of searching; nearly 40% did not describe how the studies were identified at all”. One of the authors used essentially the same data set to further investigate specific characteristics of reporting of search strategies. The fulfillment, or otherwise, of many search criteria were documented, and from this, the mnemonic STARLITE (Standards for Reporting Literature Searches (Sampling strategy, Type of study, Approaches, Range of years, Limits, Inclusion and exclusions, Terms used, Electronic sources) was devised as a prompt for those aspects to be reported: sampling strategy, type of study, approaches (e.g., handsearching and citation tracking), range of years, limits, inclusion and exclusions, terms used, and electronic sources [13].

Although STARLITE, as an unfunded initiative, remains deficient in not having progressed to the consensual methods that constitute good practice for the development of reporting standards, it continues to be cited in support of transparency of reporting and can be recommended for use with both qualitative and implementation syntheses.

An update of the Dixon-Woods review for the period 2005–2008 determined that not only had the number of qualitative evidence syntheses doubled but also the reporting of both searching and critical appraisal methods have become more transparent. There continues to be, however, a lack of clarity between what authors claim to use as a method of synthesis and what they actually do in practice [14]. Adoption of an appropriate reporting guideline should help mitigate against this.

3.2. Reporting a complete review

One of the first guidelines written specifically for reporting qualitative evidence syntheses is the enhancing transparency in the reporting of syntheses of qualitative research (ENTREQ) tool [15]. Its development occurred at a point when qualitative evidence syntheses were being regularly published in mainstream journals, albeit mostly by researchers with an interest in methodological development. As other researchers adopted the methods associated with qualitative evidence syntheses, it was recognized that issues regarding the reporting of qualitative evidence syntheses were becoming more apparent.

The development of ENTREQ involved initial identification of criteria from published texts on the conduct of qualitative evidence syntheses, guides to synthesis, key methodological papers and works, and the authors’

collective experience of conducting qualitative syntheses. The items were compiled and grouped into five categories: introduction; methods and methodology; literature search and selection; appraisal; and synthesis of findings [15]. Forty published qualitative evidence syntheses were identified, and the initial framework was pilot tested against 32 syntheses by members of the research team. Through discussion during the pilot testing, duplicate items were removed, and items were rephrased to remove ambiguity. The revised guideline was then tested against the eight remaining reviews without further changes. The final ENTREQ statement consists of 21 items within the five overarching categories [15]. As a generic tool, the ENTREQ tool documents the most frequently used methods for qualitative evidence synthesis to which it might apply, acknowledging that the approaches and methodology for synthesis are usually driven by the posed research questions.

Although ENTREQ currently occupies a position as the only reporting guideline written for qualitative evidence synthesis, its development fulfilled only the first criterion for guideline development [5]. Consequently, ENTREQ still requires validation through a Delphi exercise. It should, therefore, be used with this limitation in mind. ENTREQ is, however, listed by the EQUATOR network and is well cited. ENTREQ can, therefore, be recommended for the reporting of qualitative evidence synthesis except when a method-specific guideline is more appropriate.

3.3. Methodologically specific reviews

An exemplification of reporting for a particular type of systematic review is demonstrated by the realist and meta-narrative evidence syntheses: evolving standards guidance (RAMESES) project. As the title suggests, this constitutes paired guidance for the reporting of realist syntheses [16] and meta-narrative reviews [17]. They are included here as methods of both illuminating a heterogeneous topic area by the inclusion of both qualitative and quantitative research in a review [17] and as an application for implementation research [18]. Both sets of guidelines were developed through a Delphi method with an interdisciplinary panel of evidence synthesis experts. The aim was to produce and iteratively refine a draft set of methodological steps and publication standards, collated from existing literature on principles of good practice and the use of these principles in published reviews [19]. A multifaceted approach to development led to consensus on 20 key items for reporting for meta-narrative reviews [17]. A parallel process for realist syntheses [16] drew upon experience from 35 published realist syntheses and nine on-going syntheses, leading to consensus for 19 key publication standards. The two guidance documents were published simultaneously and are supported by training materials and can be recommended for the reporting of meta-narrative and realist reviews.

The RAMESES guidance is perhaps untypical in the fact that the team developed both sets of guidance, whereas the

methodologies themselves were still undergoing development. It is anticipated that as the experience of using the methodology evolves, the guidance will be adapted to reflect these developments [16,17]. As each guideline focuses on a particular type of review, RAMESES includes specific items on the rationale for choosing that type of review and why it was considered appropriate to the subject under investigation. This augments the reporting of the step-by-step processes involved in the conduct of the review typically included in most guidelines [16,17].

3.4. Reporting of synthesized evidence to explain intervention implementation

Assessing implementation is a crucial component in the systematic review of health and social care interventions. Lack of information on implementation weakens internal validity and inhibits the translation and uptake of evidence by decision makers. Core aspects of implementation such as intervention dose, fidelity, and reach can be quantitatively assessed in the following: (1) efficacy studies, whose purpose is to determine whether interventions demonstrate benefit or harm to the population they are intended for when tested in very controlled or “ideal” conditions; (2) effectiveness studies, whose purpose is to determine whether interventions provide benefit or harm to the population they are intended for in “real-world” conditions; (3) dissemination studies, which evaluate how to successfully implement health information interventions with a specific audience to enhance the impact of and knowledge about an evidence-based intervention; (4) implementation studies, which evaluate how a specific set of activities and designed strategies are used within targeted settings to enable the successful integration of an evidence-based intervention; and (5) scale-up studies, whose purpose is to evaluate the effectiveness of approaches to increase the impact of an evidence-based intervention to benefit more people and to foster policy and program development on a lasting basis [20].

In addition, it is increasingly common that some studies include qualitative research alongside a trial, which can be synthesized to better understand implementation. A synthesis of qualitative studies that are unrelated to trials can also be helpful in understanding the factors that affect intervention implementation [21].

There is no standard guidance for reporting on implementation in systematic reviews. In some circumstances, review authors will need to consult more than one reporting standard and supplement with an implementation checklist or index, preferably as early as the protocol design stage.

Table 1 and Fig. 1 guide selection of reporting guidelines supplemented by relevant checklists. Although PRISMA is the principal guideline used to report systematic reviews of quantitative studies, none of its items report on the nature of the interventions or their implementation. An extension developed to the PRISMA statement for complex interventions (PRISMA-CI), similarly does not particularly address

qualitative methods. Consequently, we recommend that review authors consider using existing implementation checklists and indexes to identify relevant implementation constructs to extract, synthesize, and report in their review.

“Process evaluation” or “implementation assessment” subheadings in systematic reviews may be useful for highlighting the procedures and/or measures used to extract and synthesize evidence on implementation. Use of such headings may facilitate data interpretation and knowledge translation by end users.

4. What is currently in development?

4.1. eMERGe meta-ethnography reporting guideline

One approach to qualitative evidence synthesis is meta-ethnography, which is consistently the most commonly applied and complex qualitative evidence synthesis approach; however, the methodology is frequently poorly reported [28]. A group led by researchers at Stirling University, has obtained funding to develop a meta-ethnography reporting guideline with a specific focus on the complex synthesis process (<http://www.stir.ac.uk/emerger/>). A review of 32 reports of meta-ethnography published between 2012 and 2013 found that the analytical and synthesis processes were poorly reported overall with little reference to standard methodological texts [28]. Cochrane Qualitative and Implementation Methods Group (CQIMG) convenors are contributing to its development.

The aims of the eMERGe project [27] are to:

- Undertake a methodological systematic review to identify current guidance on conducting and reporting meta-ethnography (International prospective register of systematic reviews (PROSPERO) registration: CRD42015024709);
- Undertake a review and audit of published meta-ethnographies to identify good practice principles and develop standards in conduct and reporting; and
- Facilitate an online workshop and Delphi study to agree guideline content.

The guideline and reporting template is due to be published in 2017.

5. Discussion

Producing consolidated guidance across qualitative evidence synthesis approaches is challenging; largely because of the broad variety of paradigms, schools of thought, designs, and techniques that are currently promoted within the qualitative research community. Such richness offers good grounds for methodological debate and, consequently, methodological progress. Review authors continue to differ in opinions about when reporting guidelines are appropriate in the context of qualitative and implementation syntheses, for which particular stages of a synthesis guidance is most useful, what should be included, the potential advantages and

Table 1. Reporting guidelines and supplementary resources of relevance to the assessment of implementation in systematic reviews

Study type or approach	Primary study	Systematic review
Efficacy	CONSORT [1], SPIRIT [22], TIDieR [23]	PRISMA [10]
Effectiveness	TREND [24], TIDieR [23]	PRISMA [10]
Dissemination	StaRI [25], Hales et al. [26] ^a	PRISMA [10]
Implementation	StaRI [25], Hales et al. [26] ^a	PRISMA [10]
Scale-up	StaRI [25], Hales et al. [26] ^a	PRISMA [10]
Qualitative	COREQ [6]	ENTREQ [15], SRQR [7]
Meta-ethnography		eMERGe [27] – under development
Realist review	Under development	RAMESES (Realist Review) [16] ^a
Meta-narrative Review	-	RAMESES (Meta-Narrative review) [16] ^a

Abbreviations COREQ, consolidated criteria for reporting qualitative research; SRQR, standards for reporting qualitative research; PRISMA, preferred reporting items for systematic reviews and meta-analyses; ENTREQ, enhancing transparency in the reporting of syntheses of qualitative research; RAMESES, realist and meta-narrative evidence syntheses: evolving standards; SPIRIT, Standard Protocol Items; Recommendations for Interventional Trials; TIDieR, Template for Intervention Description and Replication; StaRI, Standards for Reporting Implementation Studies; eMERGe, Meta-ethnography reporting guidelines; TREND, Transparent Reporting of Evaluations with Non-randomised Designs.

^a Reporting guidelines encompasses mixed methods.

disadvantages of reporting standards, and the level of consensus required to identify reporting guidance as “consolidated”.

The methodological richness surrounding both primary qualitative research and syntheses complicates the search for common ground in developing standards for reporting many aspects of qualitative inquiry. Reports of qualitative evidence syntheses do, however, reveal substantive agreement on how to extract descriptive data from a set of primary research articles.

Developers have produced guidance on how to conduct several different types of qualitative evidence synthesis, or how to apply a best-fit framework to qualitative findings, at least at a technical level. New guidelines on the design and conduct of process evaluations are available [29], but guidelines at the synthesis level are still awaited. Nevertheless, many authors choose to deviate from or to adapt guidelines [14]. This wish to deviate suggests that review authors either “require” some methodological flexibility in approaching their review topic or “request” a certain

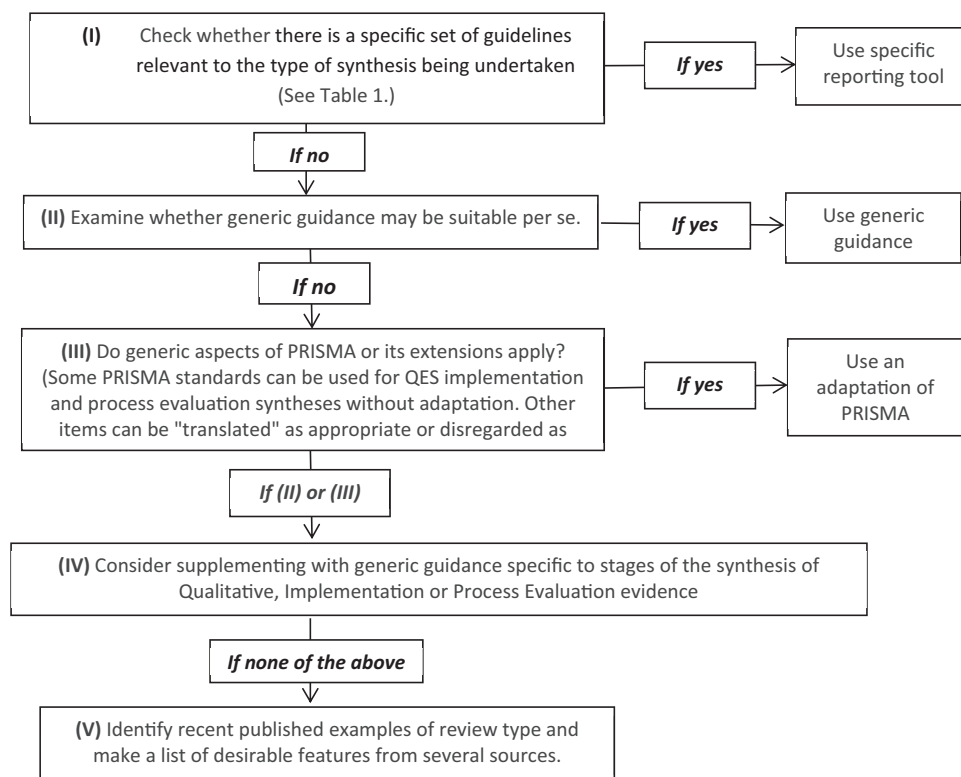


Fig. 1. Decision flowchart for choice of reporting approach for syntheses of qualitative, implementation, or process evaluation evidence. PRISMA, preferred reporting items for systematic reviews and meta-analyses; QES, qualitative evidence synthesis.

degree of freedom to adapt methods to better fit their purpose. Review authors may “require” methodological flexibility because it allows them to bring together different perspectives and strategies. The act of “requesting” the freedom to develop a style of reporting that fits the review project is probably linked to the idea that reporting guidelines risk becoming too rigid or too narrow restricts creativity and prevents review authors from borrowing emerging or innovative approaches when analyzing or disseminating their findings [30].

Although CQIMG recommends that reporting guidelines should be embraced for increasing the level of transparency and clarity in reporting styles, it is worth remembering that perversely they may introduce insufficient reporting. In novice reviewers, in particular, adherence to reporting guidelines may initiate a rather mechanistic approach to synthesizing evidence, moving the focus away from the content and toward the procedural aspects of the review. This may create a false sense of security in reviewers. Simply “ticking boxes” on a checklist in either a quantitative or qualitative systematic review does not contribute to a standard of reporting that facilitates understanding of a review topic. Using a set of criteria to assist in reporting without appropriate training in qualitative methods is to be avoided. There is no guarantee that reporting guidelines improve the quality of qualitative reasoning in review authors or produce a more thoughtful and reflective written account of the inferences drawn from the analytical and interpretation process.

The development of reporting guidelines may be construed as an attempt to standardize practice. Standardization contributes to the establishment of a language that facilitates communication between different stakeholders, offering a basis for comparison of reviews and review proposals. Such comparison is particularly useful for peer reviewers, funders, and end users. However, it is worth bearing in mind that the idea that reporting guidelines are useful in stimulating debates on what constitutes “good” practice is opposed by many stakeholders in the qualitative research community [30]. In amongst the development and debate surrounding the reporting of syntheses of qualitative, implementation, and process evaluation evidence, we considered it would be helpful to provide a 5-point “decision flowchart” to help support review authors in their approach to reporting (Fig. 1). The flowchart outlines a 5-point approach to decision-making and reporting dependent on whether a specific set of reporting guidance is available; whether generic guidance might be more suitable; whether to use a reporting tool, additional checklists, or tools for a specific aspect of the review; or develop a list of desirable reporting features from exemplar sources.

6. Conclusion

This paper draws together contemporary thinking on existing and new methodological developments in reporting guidelines for syntheses of qualitative, implementation,

and process evaluation evidence. It highlights that while meaningful work has been undertaken to raise the standards of reporting, projects in progress offer much needed enhancement of this work. There are also some obvious gaps, such as reporting standards for mixed-study reviews and reviews of implementation and process evaluation evidence. It highlights the benefits of standardization, transparency, and the possible unintended consequences that may result. In particular, standardization may shift attention from the quality of the review itself to a more mechanistic compliance with a checklist. Furthermore, standards have been found to liberate those with the experience and confidence to apply them flexibly but to enslave those who feel forced to adhere rigidly to their detail. Most positively, the increased rigor of methodologies for the development of reporting standards, with its focus on evidence-based review and researcher consensus, offers a flexible way forward in ensuring that standards continue to meet the needs of their stakeholders.

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