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AHRQ Series on Complex Intervention Systematic Reviews-Paper 6: PRISMA-CI Extension Statement and Checklist

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AHRQ series on complex intervention systematic reviews—paper 6: PRISMA-CI extension statement and checklist

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Abstract

Background: Complex interventions are widely used in health systems, public health, education, and communities and are increasingly the subject of systematic reviews. Oversimplification and inconsistencies in reporting about complex interventions can limit the usability of review findings.

Rationale: Although guidance exists to ensure that reports of individual studies and systematic reviews adhere to accepted scientific standards, their design-specific focus leaves important reporting gaps relative to complex interventions in health care. This paper provides a stand-alone extension to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting tool for complex interventions—PRISMA-CI—to help authors, publishers, and readers understand and apply to systematic reviews of complex interventions.

Discussion: PRISMA-CI development followed the Enhancing the QUALity and Transparency Of health Research Network guidance for extensions and focused on adding or modifying only essential items that are truly unique to complex interventions and are not covered by broader interpretation of current PRISMA guidance. PRISMA-CI provides an important structure and guidance for systematic reviews and meta-analyses for the highly prevalent and dynamic field of complex interventions. © 2017 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Keywords: Complex interventions; Publishing standards; Research report standards; Health care interventions; Evidence-based medicine; Systematic review; Research design; Review literature as topic; Guidance as topic

1. Introduction

This is the sixth in a seven-part series of papers presenting tools and approaches for Systematic Reviews for Complex Interventions. This paper represents the collective work in this special series and introduces a checklist for Preferred Reporting Items for Systematic Reviews and Meta-analyses of Complex Interventions (PRISMA-CI).

Systematic reviews have become essential to clinical guideline development, and an important mechanism to help clinicians, educators, community practitioners, and public health workers stay current with practices and advances in

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a field. According to recent analyses, the production of systematic reviews has become big business with almost 29,000 systematic reviews published each year resulting in a “massive production of unnecessary, misleading, and conflicted systematic reviews and meta-analyses” [1]. As with any research, the value of a systematic review depends on the quality and clarity of the product. Reporting guidelines such as Consolidated Standards Of Reporting Trials (CONSORT) [2,3], Strengthening The Reporting of Observational Studies in Epidemiology (STROBE) [4], Meta-analysis Of Observational Studies in Epidemiology (MOOSE) [5], and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [6] have become key tools for authors, journals, policy makers, clinicians, and the public to ensure consistency with accepted standards and transparency among published reports of research and systematic reviews. This guidance has been critical to ensuring scientific rigor and moving the field forward, yet the design-specific focus leaves important gaps relative to complex interventions [6,7]. The purpose of this paper was to increase the quality and usefulness of systematic reviews and meta-analyses of complex interventions by providing minimum required reporting guidelines.

Complex interventions are ubiquitous in health care, education, social services, and community activities. The Agency for Healthcare Research and Quality (AHRQ), a US funder of both health services research and evidence reviews, has seen a rapidly increasing demand for systematic reviews to inform health care decision making about complex interventions. Although guidance exists for primary research on complex interventions, guidance for systematic reviews is missing [8]. A recent AHRQ report on systematic reviews of complex interventions described the challenges of conducting such reviews. The report emphasized a core underlying constraint, that of “inconsistent reporting of informational details among individual studies.” The absence of these informational details may pose problems for primary research and synthesis and potentially limits their usefulness for stakeholders interested in implementing interventions or using information in systematic reviews [8]. For example, a meta-review of heart failure programs found that programs generally worked but flagged concerns about inconsistent and poor descriptions, which could affect the uptake and implementation of programs [9].

Given the rapidly increasing prominence of complex interventions in health care, education, and other fields, authors of systematic reviews increasingly face challenges in reporting complex interventions. Early concerns about reporting requirements for meta-analyses of randomized controlled trials were voiced in the Quality of Reporting of Meta-analyses guidelines in 1999 [10]. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement [6], published in 2009, extends and expands these concerns to all systematic reviews, regardless of design or analysis. The wide use and adoption of these

reporting standards has resulted in improved quality and consistency of reporting of systematic reviews. Extensions of PRISMA relate to analysis methods (e.g., network meta-analysis [11], individual patient data [12]); and topical focus (e.g., equity [13]). PRISMA statements have also been developed for systematic review abstracts [14] and protocols [15]. Systematic review of complex interventions is an important area for which specific guidance is needed [16–19]. Issues specific to systematic reviews of complex interventions include the following:

- Scope formulation may need to be more iterative and involve various inputs to fully explore complexity and determine a review’s focus [16];
- Key questions may be more complex and explanatory in nature—in addition to effectiveness, focusing on how and why an intervention works, for whom an intervention works or does not work, and under what circumstances [16];
- More diverse evidence may be required to inform complex key questions and to explore complexity [16,17];
- Analysis methods may be more diverse [18,19];
- Explicit inclusion of various sources of complexity, including greater detail about the intervention, is needed to understand the review’s conclusions and improve usefulness of the results for people interested in implementing findings of systematic reviews [16,17].

In response, we propose the PRISMA-CI checklist to provide guidance specific to issues for complex interventions and their methods. A companion document, the PRISMA-CI Elaboration and Explanation [20], provides guidance on applying new items in the checklist. These documents together are intended to improve the transparency and consistency of reporting of systematic reviews and meta-analyses in any field that encounters complex interventions.

1.1. Terminology—definition of complex interventions

PRISMA-CI uses the consolidated definition for complex interventions, which was put forward by the Complex Interventions Working Group in the first paper of this series by Guise et al. [21].

Definition of complex interventions [21]

All complex interventions have two common characteristics: they have multiple components (intervention complexity) and complicated/multiple causal pathways, feedback loops, synergies, and/or mediators and moderators of effect (pathway complexity). In addition, they may also have one or more of the following three additional characteristics: target multiple participants, groups, or organizational levels (population complexity); require multifaceted adoption, uptake, or integration strategies (implementation complexity); or work in a dynamic multidimensional environment (contextual complexity).

1.2. How do I know if an intervention is complex?

As previously stated in the introductory paper to this series [21], it is not always readily apparent if an intervention is simple or complex. The primary piece of advice we offer in this regard is to ask “What is the ‘it’ that the review focuses on?” If the focus of the review is the effectiveness of taking aspirin after a myocardial infarction or the effectiveness of one type of eye protection vs. another to prevent blood splashes to the eye in surgery, these would not be complex. Biologic or physiologic complexity alone is not sufficient to be categorized as complex. However, if the review question is rather how to get patients to increase compliance in taking aspirin after a myocardial infarction, or which personal protective equipment is best for a system, these questions are most likely complex. Behavioral interventions such as medication compliance and system change often use multiple approaches, target multiple levels (individual, system, family, provider, etc.), require multifaceted training and/or adoption, and/or require special consideration about the environment/context and available resources. Each of these considerations is a component of the intervention. As a general rule, public and population health, community and system-level interventions, and behavior change are more likely to be complex than simple.

2. Methods

The protocol for this PRISMA-CI extension was registered on the Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network page for reporting guidelines under development [22]. We followed principles for the development of research reporting guidelines and the EQUATOR Network to develop a PRISMA extension for complex interventions: identifying need, obtaining funding, reviewing the relevant literature, conducting a broad survey, and exploring consensus (Fig. 1) [21,23]. Specifically, international multidisciplinary panels of experts in research, reviews, and implementation of complex interventions participated in a multiphased process over a 3-year period to develop guidance and tools for systematic reviewers to use when conducting reviews of complex interventions.

2.1. Literature scan and interviews with national leaders

We began with a literature scan and interviews with international leaders in implementation research, systematic reviews, funders, health system leaders, and stakeholders. This work has been published, and it identified the need for specific guidance for systematic reviews of complex interventions [24,25]. In the interviews, experts

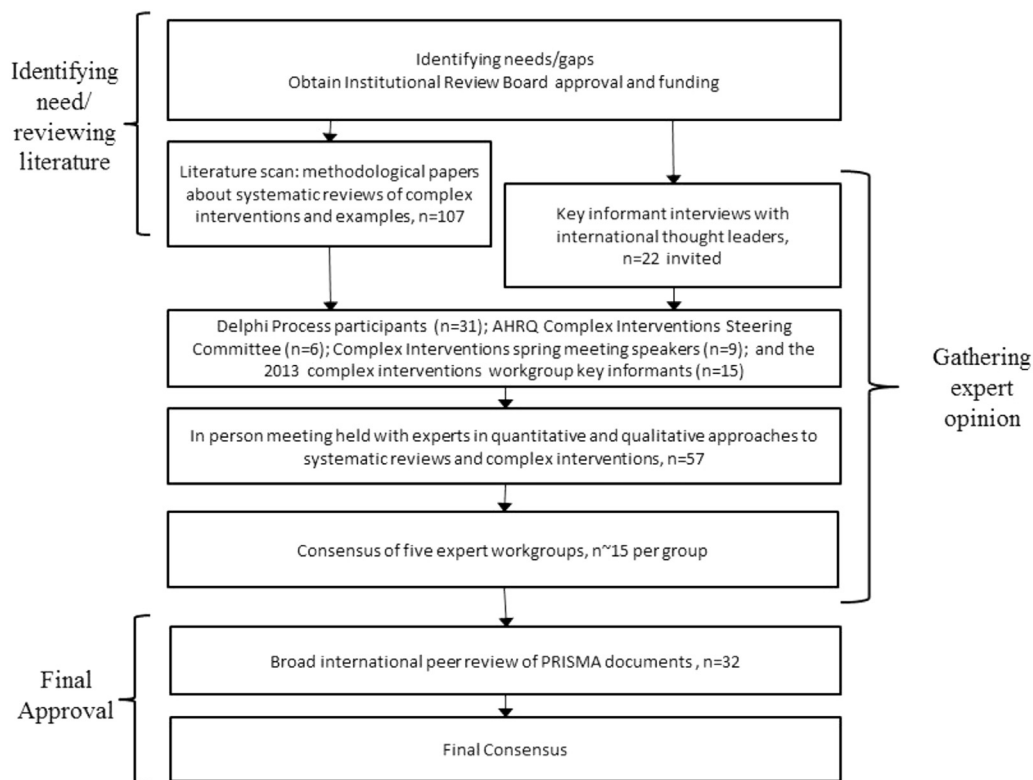


Fig. 1. Development process for PRISMA-CI checklist. PRISMA-CI, Preferred Reporting Items for Systematic Reviews and Meta-analyses of Complex Interventions.

raised concerns about inconsistencies in reporting of publications relating to complex interventions. During the interviews, experts were asked to identify important elements or features to report in primary studies or reviews of complex interventions. These items then informed the first round of the Delphi process.

2.2. Delphi process

A Delphi process was conducted among an international group of experts in the field of complex intervention research, reviews, and/or implementation to achieve consensus ([Appendix A at \[www.jclinepi.com\]\(http://www.jclinepi.com\)](#)). Participants were asked to categorize each item as “Required,” “Suggested,” “Optional,” or “Forget About It.” In addition, participants were asked to provide other items or revisions in unstructured textboxes. Responses were analyzed and summary feedback provided in the following Delphi round. Based on the pattern of responses from round 1, round 2 participants were asked to categorize each item as either “Required” or “Optional” and were asked to assign priority by moving that item up or down on the list. Both Delphi rounds were conducted electronically (e-Delphi), the first round using SurveyMonkey and subsequently by a custom-made electronic program that allowed for easy simultaneous allocation (optional vs. required) and prioritization. All rounds were completed between April 3, 2015 and June 15, 2015. The Delphi process was conducted by a research team at Oregon Health & Science University (OHSU) and approved by the OHSU institutional review board (IRB00011642).

2.3. In-person meeting of experts

A six-person steering committee ([Appendix B at \[www.jclinepi.com\]\(http://www.jclinepi.com\)](#)) comprising representatives from international evidence review groups, methodologists, and funders or publishers of systematic reviews planned an in-person conference to develop guidance and tools for complex intervention systematic review [21]. The group identified five topic areas in need of specific guidance: (1) framing the questions of systematic reviews of complex interventions; (2) frameworks and PICOTS; (3) selecting analytic approaches to systematic reviews of complex interventions; (4) analytic approaches for complex interventions: best practices; and (5) reporting elements for systematic reviews of complex interventions.

Fifty-seven experts in quantitative and qualitative approaches to systematic reviews and complex interventions met in June, 2015, at AHRQ in Rockville, Maryland. The elements prioritized in the Delphi were presented at the meeting for discussion and further refinement. The refined elements were then matched to relevant items of the PRISMA.

2.4. Consensus of expert workgroups

After the in-person meeting, the steering committee and workgroups (collectively the Complex Intervention Workgroup, [Appendix C at \[www.jclinepi.com\]\(http://www.jclinepi.com\)](#)) dedicated to the five content areas participated in twice-monthly workgroup teleconference calls over 5 months to discuss scope, assign and coordinate tasks, collect and analyze data, and discuss and edit draft documents. Each group was asked to provide text for PRISMA items that needed to be modified or tailored specifically to reviews of complex interventions.

A supporting explanation and elaboration document was developed to assist with the application of the PRISMA-CI extension items [20]. This document was developed collaboratively by the Complex Interventions Steering Committee, through biweekly calls.

2.5. Broad input on the PRISMA-CI extension

After completion, the final PRISMA extension checklist and accompanying explanation and elaboration papers were sent to a broad community of international reviewers ([Appendix A at \[www.jclinepi.com\]\(http://www.jclinepi.com\)](#)) for input.

2.6. Final consensus

Suggestions and feedback were assembled and reviewed by the steering committee. The PRISMA-CI Checklist and Explanation and Elaboration documents were revised in response and finalized by the committee.

3. Results

3.1. Delphi results

Delphi participants represented organizations involved in systematic reviews (Cochrane, US Evidence-based Practice Centers, US Centers for Disease Control and Prevention Community Guide, Campbell Collaboration, etc.), policy and guideline development groups (National Institute for Health and Care Excellence, World Health Organization), health care delivery organizations (US Veterans Health Affairs, Intermountain Healthcare), funders (AHRQ, US Veterans Health Affairs, US Centers for Disease Control and Prevention), and individual researchers and research organizations. Twenty-two of 29 invited participants participated in at least one round of the Delphi (22/29 76% round 1, 23/29 79% round 2). They arrived at consensus on 28 required and 10 optional reporting elements ([Appendix D at \[www.jclinepi.com\]\(http://www.jclinepi.com\)](#)).

3.2. Meeting and workgroup input

Meeting participants and workgroups further discussed and refined the 38 Delphi elements, related to PRISMA and grouped similar concepts and consolidated them into only the essential items that are unique to complex

interventions that could not be covered by broader interpretation of current guidance. Our primary focus for PRISMA-CI related to characterizing what was unique about the topic of complex interventions rather than the dimension of analytic approaches and their associated limitations. We refer readers interested in unique quantitative and qualitative approaches to three papers in this series [18,19,26] dedicated to analytic considerations and to Cochrane qualitative and implementation methods guidance [27].

3.3. Broad input and consensus on PRISMA-CI extension

The items in the Table 1 are extensions of PRISMA specific to addressing or analyzing the complexity of interventions included in the review. Of the eight extended items, one (item 2) concerns clearly identifying the review as covering complex interventions, and one (item 4) pertains to providing justification for the specific elements of complexity under consideration in the review. The remaining six items pertain to aspects of the complexity of the intervention or its context (11a–f).

4. Final PRISMA-CI extension

The Table 1 presents the final set of proposed items for the PRISMA-CI extension side-by-side with the standard PRISMA items.

4.1. Applying PRISMA to systematic reviews of complex interventions

Many PRISMA items (e.g., searches, types of data, and analytic approaches) did not require revision because, if interpreted broadly, they would apply to reviews of complex interventions. For example, although papers in this series discuss the broad range of information that might be useful to reviews of complex interventions [16,17] and analytic approaches that can be used [18,19], we did not believe that PRISMA items required revision because the existing elements as written do not prescribe particular approaches.

5. Discussion

We developed PRISMA-CI Extension to provide guidance to promote consistency and improve the reporting and usability of systematic reviews on complex interventions. Although the primary focus is on systematic reviews, we believe this effort nicely complements Template for intervention Description and replication (TiDier) [28] guidance in the design and reporting of primary research. The clear and transparent nature of PRISMA-CI may also be helpful to developers of translational documents such as clinical practice guidelines and registries. Detailed descriptions of the intervention alone have the potential to improve

implementation efforts [29]. Consistent reporting about complexity can further assist people interested in implementing systematic review findings and interventions in understanding whether, how, and where to apply findings given their circumstances. Clinical and public health practitioners, professional societies, and policy makers are increasingly interested in customized or individualized guidelines. Customized and individualized guidelines require systematic reviews that explicitly explore sources of complexity to support applicability to different local populations, resources, and settings. The PRISMA-CI can also increase the utility of registries of complex interventions by specifying details related to sources of complexity to point to important factors to consider when implementing, evaluating, or synthesizing complex interventions. Input from primary researchers and implementers in the early stages of development of the PRISMA-CI checklist anticipated these downstream effects and strengthened it.

Key to the success of this extension is its adoption and use by authors of systematic reviews. Widespread adoption requires a balance between the number of reporting elements and the practicality of reporting. In maintaining this balance, we focus on the main intent of these reporting guidelines—to improve consistency, promote transparency, and improve usefulness to people who will use, be affected by, or have an interest in the topic of the evidence review. Achieving this intent requires including sufficient breadth and depth of reporting in the most critical implementation areas. We acknowledge that every source of complexity may not be relevant for a topic area, nor is it feasible to explore all sources within a single product. For this reason, we ask authors to explicitly note the areas of complexity explored within the review and provide a rationale for this focus.

We anticipate numerous methodological developments and a vast expansion of primary research and systematic reviews on complex interventions. As the needs of implementers, researchers, and society change, so will reporting requirements. We foresee major advances in methodology and look forward to future efforts in updating and further specifying this guidance document.

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Table 1. PRISMA-CI extension

Section	Item	Standard PRISMA item	Extension for complex interventions
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Specifically indicate that the focus of the systematic review includes a “complex intervention”
Abstract			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to PICOS	Include in this statement the sources of complexity of primary interest (see definition of complex intervention)
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	
Search	8	Present full electronic search strategy for at least one database, including any limits, used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate and any processes for obtaining and conforming data from investigators).	
Data items	11	List and define all variables for which data were sought (e.g., PICOTS funding sources) and any assumptions and simplifications made.	
	11a		Pathway complexity: include an analytic framework, causal pathway, or other graphical representation of the chain of evidence to illustrate the complexity of the causal pathway
	11b		Intervention complexity: include sufficient detail for the interventions’ components (including number, sequence, active vs. discretionary, a priori vs. final), frequency, duration, intensity, theoretical foundation, incentives, replicability, and people delivering the intervention.
	11c		Population complexity: include sufficient detail to describe who (or what system level) the intervention targeted and the characteristics of the participants (e.g., age, gender, ethnicity, language, educational or skill level, medical and social risk status, etc.).
	11d		Implementation complexity: clearly define the adoption, uptake, or integration strategies. Strategies can include facilitators (distinct from intervention elements) such as including attestations, financial incentives, periodic reports of findings, reminders, supplemental trainings, or physical environmental changes.

(Continued)

Table 1. Continued

Section	Item	Standard PRISMA item	Extension for complex interventions
	11e		Setting—contextual complexity: include detail about the settings, locations where the data were collected, or other contextual factors (including financial, organizational, and clinical setting). Provide rationale if not relevant.
	11f		Timing: describe the absolute and relative timing of each of the components of PICO. Specifically, describe the time at which eligibility criteria (P) were set, the time at which the interventions or treatment strategies (I, C) were assigned, and the time zero of follow-up when outcome events started to be counted. In addition, describe the timing of the components of interventions I and C during the follow-up. Provide rationale if not relevant.
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies)	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were prespecified.	
Results			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (1) simple summary data for each intervention group; (2) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).	
Discussion			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers)	
Limitations	25	Discuss limitations at study and * outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence and implications for future research.	
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

Abbreviation: PRISMA-CI, Preferred Reporting Items for Systematic Reviews and Meta-analyses of Complex Interventions.

Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.jclinepi.2017.06.016>.

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