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AHRQ Series on Complex Intervention Systematic Reviews-Paper 7: PRISMA-CI Elaboration and Explanation

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AHRQ series on complex intervention systematic reviews—paper 7: PRISMA-CI elaboration and explanation

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Abstract

Background: Complex interventions are widely used in health care, public health, education, criminology, social work, business, and welfare. They have increasingly become the subject of systematic reviews and are challenging to effectively report. The Complex Interventions Methods Workgroup developed an extension to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Complex Interventions (PRISMA-CI).

Rationale: Following the EQUATOR Network guidance for Preferred Reporting Items for Systematic Reviews and Meta-Analysis extensions, this Explanation and Elaboration (EE) document accompanies the PRISMA-CI checklist to promote consistency in reporting of systematic reviews of complex interventions.

Discussions: The EE document explains the meaning and rationale for each unique PRISMA-CI checklist item and provides examples to assist systematic review authors in operationalizing PRISMA-CI guidance. The Complex Interventions Workgroup developed PRISMA-CI as an important start toward increased consistency in reporting of systematic reviews of complex interventions. Because the field is rapidly expanding, the Complex Interventions Methods Workgroup plans to re-evaluate periodically for the need to add increasing specificity and examples as the field matures. © 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

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0895-4356/© 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/>).

1. Introduction

This is the final paper in the seven-part series of papers presenting tools and approaches for Systematic Reviews for Complex Interventions. This paper is intended to be a companion to the prior paper in the series [1] and describes examples and elaboration on how to apply the checklist for Preferred Reporting Items for Systematic Reviews and Meta-Analyses of Complex Interventions (PRISMA-CI).

Complex interventions in health care are challenging to report effectively in a manner that supports intervention replication. This reporting challenge in primary studies

permeates systematic reviews of complex interventions. In addition to the difficulties of distilling information on individual studies that may be poorly reported, systematic reviews need to account for multiple sources of complexity and selective reporting presented within and across included studies. Five members of the Complex Interventions Steering Committee (J.-M.G., M.B., C.C., M.V., and P.T.) established a consolidated definition of complex interventions (described in Guise et al. [2] and in Table 1) that guided the development of a PRISMA-CI. The purpose of this paper was to provide guidance and examples of how to implement the PRISMA-CI checklist for systematic reviews of complex interventions.

2. Methods

The PRISMA-CI statement itself provides details regarding its background and development [1]. To briefly recap, to develop PRISMA-CI extension guidance for reviews of complex interventions, we followed principles for the development of health research reporting guidelines: identifying need, obtaining funding, reviewing the relevant literature, conducting a broad survey, and exploring consensus [3,4]. International multidisciplinary panels of experts in research, systematic 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. Five members of the Complex Interventions Steering Committee (J.-M.G., C.C., M.B., M.V., and P.T.) drafted specific items for this document and discussed items regularly on conference calls to further refine the document, which was circulated and ultimately approved by the larger Complex Interventions Workgroup and international leaders in systematic reviews and in complex interventions.

3. PRISMA-CI: explanation and elaboration

This accompanying Explanation and Elaboration (EE) document explains the meaning and rationale for additions to PRISMA that are specific to complex interventions. Examples and elaboration are provided for each PRISMA-CI checklist item [1] to clarify their use in reviews of complex interventions. Original PRISMA items remain in the PRISMA-CI checklist as they provide the traditional foundation for reporting elements of systematic reviews. The reader should refer to prior published EE for standard PRISMA items [5]. The PRISMA-CI extension provides additional or revised reporting items that are specific to the dimensions of complexity (see definition of complex intervention, mentioned previously). There are many dimensions of complexity, and a given systematic review may not intend to address all sources. All reviews of complex interventions are expected to report their specific objectives, pathway complexity, and intervention

complexity, in addition to traditional PRISMA items. In addition, the review should report details according to PRISMA-CI for the remaining dimensions of complexity addressed by the review. This document provides a rationale and examples for the additional dimensions of complexity. These are drawn from a limited set and are not the only way to meet the PRISMA-CI goals.

3.1. PRISMA-CI additions/changes

3.1.1. Item 2, title

Specifically indicate that the focus of the systematic review includes a complex intervention.

To identify systematic reviews of complex intervention topics, it is critical to indicate in the title that the review involves a complex intervention.

3.1.2. Item 4, objectives

Include in this statement the sources of (Table 1 definition of complex intervention) complexity of primary interest

A first step in the process of clarifying reporting standards for systematic reviews of complex interventions is to clarify what constitutes complexity. Include in this statement which sources of complexity are of primary interest (see definition of complex intervention, mentioned previously).

3.1.2.1. Example. “The purpose of this report was to review the comparative clinical utility and diagnostic accuracy of risk assessment instruments for evaluating risk of pressure ulcers and to evaluate the benefits and harms of preventive interventions for pressure ulcers. People at risk for pressure ulcers are cared for in diverse settings, including acute care hospitals, long-term care facilities, and the community at large. This report therefore also reviews how effectiveness varies in specific patient subgroups and in different settings.” [6].

3.1.2.2. Elaboration. A critical step in reporting is to clearly state and communicate the questions and important elements of the scope of the review. Reviews of complex interventions should explicitly include relevant complexity elements. Individual systematic reviews may emphasize one or more sources of complexity, such as population or intervention delivery complexity, or may focus on elements of complexity within a particular complexity source, such as one treatment setting rather than another. The sources of complexity that a review examines should arise in the course of scope development. A review may be commissioned and scoped to inform specific decisions, including clinical decision making, policy, coverage, identification

Table 1. Definition of complex interventions [2]

All complex interventions have two common characteristics: they have multiple components (intervention complexity) and they have complicated/multiple causal pathways, feedback loops, synergies, 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).

of research gaps, or other purposes. Explicitly including the information about the type of decision and the role of the review provides insight into the timing, scoping, and focus of the review, which in turn provide insight into why certain areas of complexity were or were not included in the scope.

3.2. Review methods

It is important for readers to know what information review authors sought, even if some of the information was not available [7]. Reporting this level of detail informs the reader about limitations in the knowledge base and also informs potential avenues for future research. Consistency in this level of reporting has been cited as a major

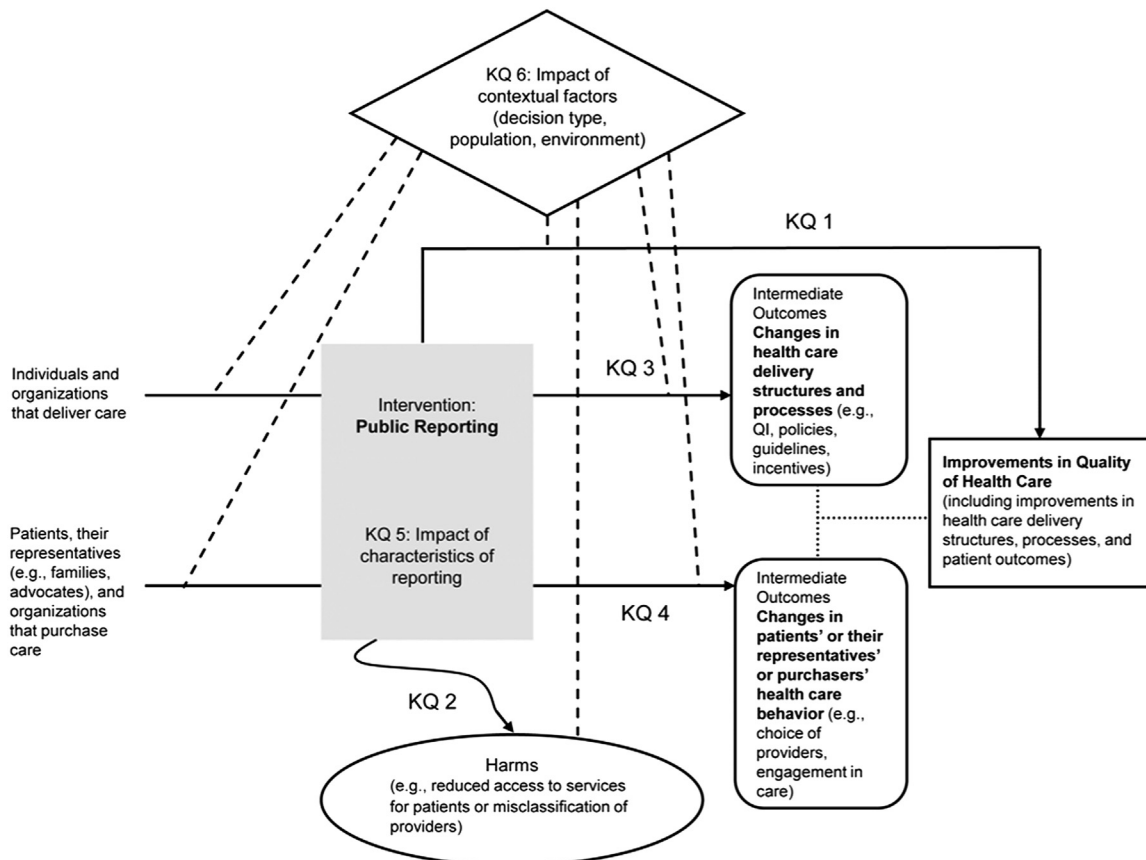
limitation in the field of complex interventions. Audiences of the review, including implementers and researchers, report that this limitation creates inefficiencies when searching for absent or inconsistent information and limits their ability to use and apply review findings [8,9]. Items 11a–f provide guidance, examples, and details for each of the definitional components of complex interventions.

3.2.1. Item 11a, data items: 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.

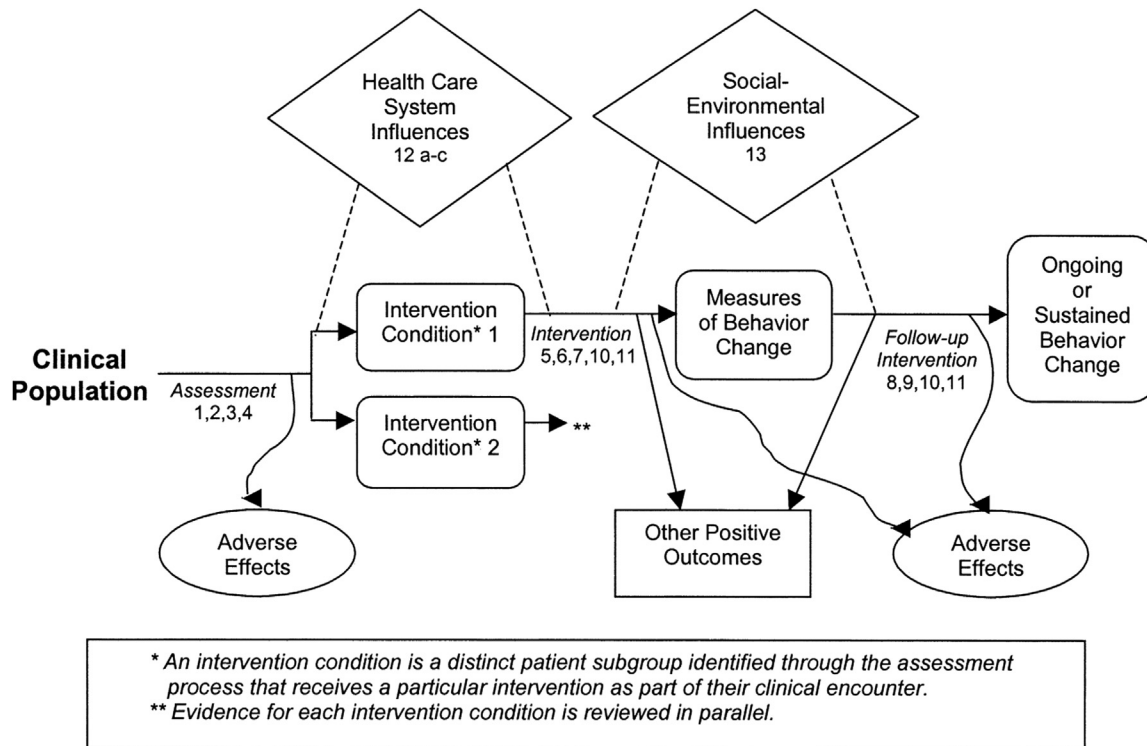
Because complex interventions can include many dimensions of complexity in topics, a graphical representation of the PICOTS relating to that topic and delineating which are within the scope of the systematic review can be very useful. It can help to specify which dimensions are the primary focus of the review.

3.2.1.1. Example. Public reporting analytic framework illustrating contextual factors and varying population and organizational levels targeted by the complex intervention [10].



Note: Dotted lines indicate relationships between intermediate outcomes and ultimate improvement in the quality of care. KQ = Key Question; QI = quality improvement.

3.2.1.2. *Example.* Behavior change analytic framework illustrating contextual factors, multiple approaches to intervention component bundles, and both planned (Measures of Behavior Change, Ongoing or Sustained Behavior Change) and unplanned outcomes (Other Positive Outcomes, Adverse Events) [11].



3.2.1.3. *Elaboration.* Complex interventions—because they can involve multiple components, multiple targets, multiple levels of a system, and number and variability in planned and unplanned beneficial and harmful outcomes—require special effort to assure the research questions, scope, general analytic approach, and the pathway complexity are adequately reported. An analytic framework provides a graphical representation of the intervention, its target, the scope of the review, and the relationships among variables. We advise the authors to report analytic frameworks that link the critical actions that lead from population identification to desired outcomes (most commonly patient-important health outcomes for clinical interventions) to clarify the focus and guide the systematic review. The review research questions should be visually integrated within the analytic framework, and the PICOTS elements should be identifiable and map to those listed in the body of the report.

No standard graphic will serve for all possible review topics. Authors often create variations of a form used by the Agency for Healthcare Research and

Quality (AHRQ) Evidence-based Practice Center program, which has conventions to assist in its communication and reproducibility [12–14]. Two examples are provided for this AHRQ form; Anderson and colleagues provide other approaches to logic models [15].

We realize that journals often limit the number of figures and tables for a publication, and the PRISMA flowchart, forest plots, or other results graphics compete for journal space. Given the communication power of a visual depiction of the review questions, scope, and pathway complexity, if insufficient space in the main article, we encourage including the analytic framework in Web-based supplemental materials if provided by the journal.

3.2.2. Item 11b, data items: intervention complexity

Include sufficient detail for the interventions' components (including number, sequence, necessary vs. discretionary, a priori vs. final), frequency, duration, intensity, theoretical foundation, incentives, replicability, and people delivering the intervention.

3.2.2.1. *Example.* “This review examines the impact of slum-upgrading programs on health and social well-being. A

broad range of slum-upgrading approaches and their interlinkages with health and socioeconomic outcomes have been depicted in the logic model. These have been grouped into proximal interventions within the living environment (physical environment, social environment, service access, health promotion, and behavioral interventions) and distal strategies that enable structures and systems to implement these proximal environment interventions (policies, laws and regulations, financial investment, community action, or a combination of these factors). The logic model also demonstrates that strategies may be delivered by governments (global, national, state, or local), the private sector, civil society, or by a combination of these actors and stakeholders.” [16].

“The number, breadth, and diversity of slum-upgrading interventions outlined in the logic model are too broad to be assessed in a single systematic review. This review, therefore, has focused on upgrading interventions involving physical environment and infrastructure improvements, with or without the integration of wider slum-upgrading approaches (e.g., policy, legal, financial, community action, social, or service interventions). Where such studies deliver multicomponent strategies, the nature of the full package of interventions was examined.” [16].

3.2.2.2. Elaboration. Intervention complexity can arise from many possible sources. Essential items to report may include the following:

- The number and description of all components
- Necessary vs. optional or discretionary components
- Intervention intensity
- Intervention frequency
- Replicability of intervention—provide sufficient detail so the intervention can be replicated
- Note the stated theoretical foundation for the intervention, that is, how the intervention is thought to work
- Intervention incentives
- A priori vs. final components—distinguishing which were added or removed after the protocol was established

Other optional items may include the following:

- The degree to which components are independent vs. interactive/effect modifiers
- The theoretical basis for studies demonstrating replicability of the intervention
- Cost of intervention

3.2.3. Item 11c, data items: 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 & social risk status, etc.).

Include sufficient detail to describe who the intervention targeted and the characteristics of the participants, including skills or educational level required for and behaviors targeted by the intervention.

3.2.3.1. Example. “This review focuses on adults with medical illness and complex care needs in the outpatient setting. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs were defined broadly, and we included studies with case definitions based on health care resource utilization, patient health outcomes, and/or multifactor assessments that include measures such as socioeconomic status or patient self-efficacy ... The population of interest included all adults with medical illness and complex care needs. To identify the broadest sample of literature relevant to [case management] (CM) for such patients, we did not want to limit the results of the literature search to any particular disease condition or conditions. Our search was designed to include all subpopulations with any medical illness and complex care needs for whom CM had been studied. However, we excluded studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder.” [17].

3.2.3.2. Elaboration. The complexity contributed by the populations can come in many forms. Complex interventions commonly require active participation from the study participants more comprehensive than pharmacologic or surgical interventions. Alternatively, the patients targeted by the interventions may be more complicated medical cases. Items that are generally essential to understand population complexity include the following:

- Who or what the intervention targets (e.g., individual, population, health system, etc.).
- The skill and educational level required to participate in the intervention.
- The medical and social risk status of the participants.
- The behaviors of the population that are targeted for change.
- Participant demographics: age, gender, ethnicity, language.

Other optional items might include other important cultural factors that characterize the population.

3.2.4. Item 11d, data items: 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.

3.2.4.1. Example. “Implementation strategies are methods used by the practices to implement the changes needed to be more consistent with the Patient-Centered Medical Home (PCMH) [model of care], as well as the methods used to measure the impact of the PCMH transformation on clinical care processes or outcomes. The categories of implementation strategies initially used for data abstraction for this review include the following:

- a. Audit and feedback to providers, teams, and/or clinics
- b. Quality improvement measures
- c. Academic detailing
- d. Lectures/classes for staff (i.e., didactic education)
- e. Designated clinical champion (facility/practice level)
- f. Designated project manager (facility/practice level)
- g. Plan-Do-Study-Act cycles/rapid cycle improvement mechanisms
- h. Flow mapping of care system
- i. Total quality improvement/continuous quality improvement
- j. Strengths-weakness-opportunities-threats analysis
- k. External benchmarking at the organizational level
- l. Other

Through the data abstraction process, we found that we often had to draw some inferences regarding the implementation strategy from the description of the process of change to categorize them.” [18].

3.2.4.2. Elaboration. Complexity can arise in the short term, when specific strategies may be required to establish the intervention. These strategies are not required once the intervention is established and therefore should be considered part of implementation complexity, rather than intervention complexity. Clearly define implementation strategies or implementation facilitators such as including attestations, financial incentives, periodic reports of findings, reminders, supplemental trainings, physical environmental changes. Distinguish these strategies or facilitators from the intervention. Reporting on strategies or facilitators of implementation complexity separately from intervention complexity enables readers to understand techniques that facilitate adoption of the intervention. Consistent reporting across reviews on these factors allows crosscutting reports on the effectiveness of implementation strategies overall.

3.2.5. Item 11e, data items: contextual complexity

Include details about the settings, locations where the data were collected, or other contextual factors (including financial, organizational, and clinical setting). Provide rationale if not relevant.

3.2.5.1. Example. “The context of an intervention, for example, the type of health care setting, the leadership

structure, the safety culture, the openness to innovation, can have an important impact on whether preventive interventions are adopted. Furthermore, the ability to transfer a successful quality improvement strategy from one setting to another may depend in part on whether the contexts differ [...these include:]

- Theory or logic model behind the patient safety practice
- Structural organizational characteristics (such as size, location, financial status, existing quality, and safety infrastructure)
- External factors (such as regulatory requirements or incentive systems)
- Patient safety culture, teamwork, and leadership at the level of the unit
- Availability of implementation and management tools (such as staff education and training, use of internal audit and feedback, presence of internal or external individuals responsible for implementation)
- Description of interveners, intervenees, and their roles in the implementation process” [19].

3.2.5.2. Elaboration. Complex interventions typically involve many actors and moving parts. As a result, contextual factors can influence complex interventions and should be described in detail to clarify the wider “system” within which the intervention is located. Intervention, implementation, and contextual complexity can be closely related and need to be distinguished in the context of specific review. Review teams will need to rely on content experts, extensive reading, or engagement with stakeholders (people who will use, be affected by, or have an interest in the topic of the evidence review) to ensure adequate subject-matter expertise. An implementation factor for one complex intervention or one systematic review approach may be a contextual factor for another. A guiding principle for distinguishing contextual complexity from intervention or implementation complexity is to consider whether geographic, organizational, or other setting characteristics influence the effectiveness of the intervention. These settings are not an explicit component of the interventions or strategies to implement interventions but may incidentally influence outcomes. Frameworks, such as Consolidated Framework for Implementation Research, comprehensively include contextual factors that may be pertinent to complex interventions. Some essential items to report may include the following:

- Organizational features—leadership at organizational level
- Geographic location
- Financial setting (e.g., fee for service, capitation, Medicare/Medicaid, uninsured)
- Clinical setting (e.g., solo or group private practice, public health, integrated health plan)

Optional items:

- Rival activities

3.2.6. Item 11f, data items: 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. Also describe the timing of the components of interventions I and C during the follow-up. Provide rationale if not relevant.

3.2.6.1. Example. “Data fields included author; year of publication; setting, subject inclusion and exclusion criteria; and study design characteristics. For KQ1, we also abstracted intervention and control characteristics (intervention components, timing, frequency, duration); follow-up duration; participant baseline demographics; type of CIS [clinically isolated syndrome] or MS [multiple sclerosis], MS severity; descriptions and results of outcomes and adverse effects; reasons for discontinuation; and study funding source.” [20].

3.2.6.2. Elaboration. The timing of intervention components and the relation to outcome ascertainment may be important to note when it is related to other types of complexity, such as pathway complexity and outcome complexity. Provide sufficient timing detail so each of the treatment strategies of interest could be replicated. At a minimum, explain whether the treatment strategy consists of a once-only intervention (e.g., surgery) or whether the intervention is sustained over time (e.g., daily aspirin for 5 years). If the strategy is sustained over time, specify the timing of the component interventions and whether it is a static or dynamic strategy, that is, whether the intervention changes over time. If the review will follow a formal analytic approach that treats the analysis as equivalent to an observational study designed to mimic an ideal trial—that is, a trial optimally designed to address the research question—detail at the level of eligibility criteria (population), treatment strategies and possibly specific components, and follow-up for outcomes is critical. [21].

4. Conclusion

We present a limited number of examples and recognize that reviewers may need to present shorter or more succinct versions than those presented here. The examples used in this document were by necessity drawn from a period before this guidance. We offer these examples as a source of guidance and inspiration to better describe systematic reviews of complex interventions. As more systematic reviews of complex interventions are published, authors and journal editors will

need to continue to work on creative solutions to provide transparency without sacrificing readability. New developments will enhance the portfolio of examples for systematic reviews of complex interventions. We note the important role of subject-matter and methods expertise, as exemplified by the need for judgment in laying out objectives; depicting pathway complexity; and distinguishing between intervention, implementation, and contextual complexity.

Researchers bear responsibility to their participants, funders, and the public for extracting as much meaning as possible from their research. The PRISMA-CI tool can help achieve this goal by taking advantage of changing trends in scientific publishing. As journals shift reliance from paper-based to electronic dissemination, the use of supplements and other enhanced electronic content such as “mouseover” or pop-up text and graphics can increase richness and detail to the narrative. A clear articulation of reporting elements necessary to build a cumulative body of evidence can enhance efficiency in research without sacrificing readability.

We plan several activities to encourage broad dissemination and immediate implementation of PRISMA-CI: we will write to PRISMA-endorsing journals and ask them to consider endorsing PRISMA-CI, we will contact funding agencies and professional organizations that commission systematic reviews to consider recommending the use of PRISMA-CI, and we will submit abstracts for major international conferences such as the Guidelines International Network, Cochrane, and other professional meetings to encourage PRISMA-CI use in the field.

We developed PRISMA-CI to establish a shared language around the sources of complexity and to improve transparency and completeness of reporting. We followed processes considered best practice in guideline development. [2] Our development process has a number of strengths including use of an independent process among a broad array of experts for item selection and prioritization (minimizing bias), an in-person meeting promoting rich discussion, intensive bimonthly expert calls for thoughtful consideration of items, and broad international peer review of both the PRISMA-CI checklist [1] and EE documents. Follow-on efforts are planned to promote use and application. We expect that this effort will improve transparency and accountability in reporting and better inform investments in the use of evidence and research investments. Future revisions to this extension may be needed as the field matures.

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