

# Systematic reviews of complex interventions: framing the review question

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Accepted 20 May 2013; Published online 14 August 2013

## Abstract

The first and most important decision in preparing any systematic review is to clearly frame the question the review team seeks to answer. However, this is not always straightforward, particularly if synthesis teams are interested in the effects of complex interventions. In this article, we discuss how to formulate good systematic review questions of complex interventions. We describe the rationale for developing well-formulated review questions and review the existing guidance on formulating review questions. We discuss that complex interventions can contain a mix of effective and ineffective (or even harmful) actions, which may interact synergistically or dysynergistically or be interdependent, and how these interactions and interdependencies need to be considered when formulating systematic review questions. We discuss complexity specifically in terms of how it relates to the type of question, the scope of the review (i.e., lumping vs. splitting debate), and specification of the intervention. We offer several recommendations to assist review authors in developing a definition for their complex intervention of interest, which is an essential first step in formulating the review question. We end by identifying areas in which future methodological research aimed at improving question formulation, especially as it relates to complex interventions, is needed. © 2013 Elsevier Inc. All rights reserved.

**Keywords:** Complexity; Systematic review; Question; Complex interventions

## 1. Introduction

The first and most important decision in preparing a systematic review is to determine its focus. This is best done by clearly framing the questions the reviewer seeks to answer. Well-formulated questions will guide many aspects of the review process, including determining eligibility criteria, searching for studies, collecting data from the included studies, and presenting the findings [1–3]. In Cochrane reviews, questions are traditionally stated broadly as review “Objectives.” As well as focusing the conduct of the review, the contents of the objectives/questions are used by stakeholders in their initial assessments of whether the review is likely to be directly relevant to the issues they face. In this article, we discuss how to formulate good systematic review questions of complex interventions. Specifically, we (1) describe the rationale for developing well-formulated review questions, (2) review the existing guidance on formulating review questions, (3) discuss complexity in terms of how it relates to formulating review questions, and (4) offer recommendations to assist review

authors in formulating a review question for a systematic review of complex interventions.

## 2. What makes a good systematic review question?: state of the existing guidance

Current guidance states that a clear and concise statement of a review’s objectives (or questions) is critical and should begin with a precise statement of the primary objective, including the interventions reviewed and the targeted problem; ideally, this would be presented in a single sentence [4,5]. Where possible the style should be of the form “To assess the effects of [intervention or comparison] for [health problem] in [types of people, disease or problem, and setting if specified].” This might then be followed by one or more secondary objectives, for example, relating to different participant groups, different comparisons of interventions, or different outcome measures [4].

Good review questions come from many sources: practice experience, results of prior research, and critical appraisal of the literature are but a few origins [6]. Cummings et al. [7] proposed the FINER criteria for writing “good” research questions. The FINER criteria state that

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**What is new?**

- Describes the rationale for developing well-formulated systematic review questions.
- Describes how complexity relates to framing a systematic review question.
- Offers guidance for formulating systematic review questions of complex interventions.
- Offers suggestions for future methodological research related to framing systematic review questions of complex interventions.

research questions should be *Feasible* (specific and answerable), *Interesting*, *Novel*, *Ethical*, and *Relevant* (although clearly some of these criteria, e.g., novel, may be less relevant when framing systematic review questions). Detailed specification of a research question requires consideration of several key components [8,9]. The question “should specify the types of population (participants), types of interventions (and comparisons), and the types of outcomes that are of interest. The acronym PICO (*Participants, Interventions, Comparisons, and Outcomes*) helps to serve as a reminder of these” (sometimes *Context* or *Study design* is added as a fifth consideration) [10]. Equal emphasis in addressing each PICO component is not necessary. For example, a review might concentrate on competing interventions for a particular stage of breast cancer, with stage and severity of the disease being defined very precisely; or alternately focus on a particular drug for any stage of breast cancer, with the treatment formulation being defined very precisely. This challenges synthesis teams to carefully identify the key components of their research question. “These components of the question, with the additional specification of types of study that will be included, form the basis of the pre-specified eligibility criteria for the review” and comprise current recommendations in the Cochrane handbook for formulating review questions [4].

The scope of the review question can also depend on the target users of the review. Therefore, in addition to a detailed specification of the PICO components, it is helpful to discuss the review question widely to ensure that the question is *relevant* to and *addresses the needs* of the different potential stakeholder audiences. We recommend that a preliminary search be undertaken to ensure that a high-quality and up-to-date systematic review of the question of interest does not already exist and to gauge the likely number of studies that will be included in carrying out the review. This gauging is important for pragmatic reasons to determine the amount of work that the review will require and can also be used to help refine the review question (for manageability purposes).

**3. Why is additional guidance on formulating review questions necessary?**

PICO, although a very useful tool, is not always straightforward to apply, particularly if synthesis teams are interested in the effects of complex interventions. No guidance currently exists on how to formulate review questions of complex interventions. If an intervention is complex, often the synthesis team will need to undertake considerable background work to specify the intervention of interest in detail. For example, typically in reviews of drug interventions, the definition of the intervention is relatively straightforward and simple (although the review authors still need to make decisions about which classes of drugs to consider and whether to include different chemical formulations and different dosages). There is often international consensus on the terms used to describe drugs (or at least, an understanding of synonyms for the same drug classes). Finally, the mechanisms of action of many drug interventions are clearly established in basic science research. However, when considering complex or multifaceted interventions, none of these criteria may apply. Consider the following examples of complex interventions:

- *Therapist-dependent interventions* (where the intervention is a combination of the therapist effect and the therapy or procedure and the effectiveness is dependent on both).
- *Complex health care interventions* (where the intervention is a combination of several actions, e.g., multidisciplinary health care in stroke units).
- *Multilevel public health interventions* (where the intervention is a combination of several activities directed at different levels and samples, e.g., informational material disseminated at community forums to community members, training programs delivered to pharmacists, and counseling or outreach programs for patients across multiple populations).
- *Professional or patient education interventions* (e.g., introduction of clinical guidelines).

Such complexity (as illustrated above) makes the task of formulating a good review question both more important and more difficult. Furthermore, given the expected heterogeneity, systematic review questions should go beyond simple effectiveness questions (e.g., “does X work?”) to consider under what circumstances X works. This complexity necessitates additional guidance beyond what currently exists in the Cochrane handbook and other sources.

**4. Complexity**

Complexity can come in many forms: it may be related to characteristics of the intervention, the study population, the outcomes measured, or other methodological issues relating to the conduct of primary studies. In this series on

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