

Identifying, documenting, and examining heterogeneity in systematic reviews of complex interventions

Terri Pigott^a, Sasha Shepperd^{b,*}

^a*School of Education, Loyola University Chicago, 820 N. Michigan Ave., #1118, Chicago, IL 60611, USA*

^b*Nuffield Department of Population Health, University of Oxford, Old Road Campus, Headington, Oxford OX3 7LF, United Kingdom*

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Abstract

This article describes approaches for planning, dealing, and analyzing heterogeneity in a systematic review of complex interventions. Approaches aim to generate a priori hypotheses of the mechanism of action of a complex intervention to identify the key variables that might contribute to variation among studies and guide statistical analysis. In addition to characteristics related to the population, intervention, and outcomes, we describe study-related variables, such as the way the interventions have been implemented and the context and conduct of studies. These approaches will guide reviewers planning a meta-analysis and provide a rationale for not meta-analyzing data if there is too much variability. Potential difficulties in applying meta-analytical techniques to examine statistical association among study results and sources of potential heterogeneity are described; these include the selection of a fixed or random-effects model, the risk of multiple testing and confounding when studies include different aspects of a complex intervention or different subsamples of the intended participant pool. © 2013 Elsevier Inc. All rights reserved.

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1. Introduction

Assessing the effectiveness of a complex intervention is more involved than asking whether it works. Instead, understanding the effectiveness of a complex intervention entails assessing the contexts and conditions in which the intervention shows promising results. Thus, the effectiveness of a complex intervention necessarily involves an examination of heterogeneity. Heterogeneity between studies is a different and more difficult type of problem in complex than in simple interventions. Interacting components and potential variation in the way complex interventions are delivered are two major factors that can contribute to the problem [1]. Additional dimensions may include complex behaviors to deliver the intervention, compliance of participants to the complex intervention, adaptation of the intervention to the setting, and interactions between the intervention and context (a problem if studies included in the systematic review are from different health systems).

In this article, we take the view that the interventions under study will result in an outcome in the experimental

group that is in a predictable direction. Although the contexts and components of an intervention may be complex in ways we describe in the following, we assume that the intervention under study is based on evidence-based practice in a given field and is grounded in theory about how a given condition or problem could be alleviated by the treatment. The methods we discuss in this article would not be appropriate for studying an intervention in which patterns of outcomes cannot be anticipated and the intervention comprises of nonlinear interactions between the context and components of the system. In the following sections, we outline our definition of heterogeneity as it might manifest in a complex intervention and discuss methods for studying these forms of heterogeneity.

2. Sources of heterogeneity

One framework useful for characterizing potential sources of heterogeneity can be adapted from the study by Lipsey [2]. Three components of studies that may contribute to variation in study results include (1) substantive features of the complex intervention and how it is implemented in a given study, (2) the particulars of the methods and procedures used to conduct the investigation of the intervention, and (3) characteristics of the researcher and the research

* Corresponding author. Tel.: +44 (0)1865 289237

E-mail address: sasha.shepperd@dph.ox.ac.uk (S. Shepperd).

What is new?

- We focus on systematic reviews of interventions where the outcome in the experimental group is in a predictable direction. We provide guidance for describing, examining and dealing with intervention, methodological, procedural and researcher related factors that may contribute to heterogeneity.

context extrinsic to both the substantive features of the intervention and the research methods. Fig. 1 provides one way to characterize the substantive features of studies of complex interventions that can lead to variation in judgments of the effectiveness of an intervention. Individual studies of a complex intervention will implement the intervention differently, with a range of participants, in diverse settings, and focusing on a variety of outcomes.

In addition to the differences in how the intervention is examined within studies are sources of heterogeneity that are specific to the methodological and procedural aspects of the study and extrinsic to the substantive features of the intervention. For example, the effectiveness of a complex intervention may be related to the overall research design of a study, the year that the study was conducted, the number of participants, the quality of the measures used, and the data analysis strategies. Table 1 provides examples of methodological and procedural characteristics of studies that may contribute to differences in findings across studies of the same intervention.

A third area of potential factors is external to both substantive and methodological features. These include the characteristics of the researcher and the context of the research report itself. For example, published studies more often report statistically significant effects of an intervention than unpublished studies [3]. Table 2 provides examples of research characteristics and the context of the research report that could contribute to variation among study results.

Dealing with these factors in a systematic and transparent way is limited by poor definitions, inadequate reporting, and if these factors feature in some, but not all, of the included studies [4]. Furthermore, the importance of these factors will in part be determined by the review question. For example, for some health service delivery interventions, the impact of different health systems may be a dominant cause of concern [5,6], and for interventions seeking to change behavior [7], the interaction between health-care providers and participants may be the major source of heterogeneity. A systematic reviewer should thus not question if heterogeneity will exist but instead plan for how heterogeneity will be examined in a review of complex interventions. The reviewer has two major tasks in examining heterogeneity in complex interventions; one is to identify prospectively

where heterogeneity may arise and code for these factors in each study and the second is to analyze systematically the potential influences of heterogeneity using graphics and meta-analysis where possible.

3. Identifying and coding sources of heterogeneity due to substantive features of the intervention

Describing the key components of an intervention is a critical step in both planning a systematic review of a complex intervention and anticipating the sources of heterogeneity that might explain the variation in the effectiveness of a treatment. One way to identify these key components is to survey practitioners. Langhorne and Pollack [8] asked a set of trialists to describe the treatment for two hypothetical stroke patients using a combination of surveys and case studies. This strategy informed the development of the review's methods and analytic models.

Creating a logic model is another method for detailing how the intervention might work, including the identification of the components of the intervention, the pathways from interacting components to outcomes, and, if relevant, surrogate outcomes. Process evaluations, including qualitative studies, conducted alongside the trials also have the potential to generate hypotheses regarding the mechanism(s) of effect of the intervention being reviewed; contacting study investigators and obtaining study protocols may also help the reviewer to identify the key components of an intervention.

Anderson et al. [9] provide several examples of logic models and how they inform all stages of the review. In the case of complex interventions, logic models provide a method for elaborating on the chain of events or pathways that comprise the complex intervention's mechanism of action. For example, in a review of housing [10], health outcomes such as increased control over chronic conditions such as asthma is not assumed as a direct outcome of improving housing but instead may evolve from more stability in home life, leading to increased ability to attend work and school and more opportunities to engage with health professionals. Logic models are particularly useful in a systematic review of complex interventions both to help stakeholders understand the nature of the intervention and to inform the plan for examining heterogeneity. For example, in the case of the systematic review of the benefits of programs to improve housing, there are a number of improvements that could be included in an intervention, each with a set of potential benefits on a pathway from more immediate to more distal outcomes. The mechanism of action may determine the sequence of these outcomes. In addition, developing a matrix to tabulate the different components contained within an intervention can assist reviewers to identify the similarities and differences between interventions, thus facilitating an exploration of heterogeneity that is due to differences in the implementation of the intervention.

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