

Complex interventions and their implications for systematic reviews: a pragmatic approach

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Abstract

Complex interventions present unique challenges for systematic reviews. Current debates tend to center around describing complexity, rather than providing guidance on what to do about it. At a series of meetings during 2009–2012, we met to review the challenges and practical steps reviewer could take to incorporate a complexity perspective into systematic reviews. Based on this, we outline a pragmatic approach to dealing with complexity, beginning, as for any review, with clearly defining the research question(s). We argue that reviews of complex interventions can themselves be simple or complex, depending on the question to be answered. In systematic reviews and evaluations of complex interventions, it will be helpful to start by identifying the sources of complexity, then mapping aspects of complexity in the intervention onto the appropriate sources of evidence (such as specific types of quantitative or qualitative study). Although we focus on systematic reviews, the general approach is also applicable to primary research that is aimed at evaluating complex interventions. Although the examples are drawn from health care, the approach may also be applied to other sectors (e.g., social policy or international development). We end by concluding that systematic reviews should follow the principle of Occam's razor: explanations should be as complex as they need to be and no more. © 2013 Elsevier Inc. All rights reserved.

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1. Introduction

There is considerable interest among practitioners, policymakers, and researchers in how evidence of the effects of complex interventions can be produced and synthesized. This interest is not new; the first workshop on systematic reviews of complex interventions was organized at the 1994 Cochrane Colloquium, with a report the next year [1]; and the first detailed guidance on the design and evaluation of complex interventions to improve health was issued in 2000 [2,3]. This interest stems partly from the

need to develop further the evidence base of the effectiveness of health care and public health interventions, along with an awareness that synthesizing this evidence becomes more challenging as one moves along the spectrum from simpler toward more complex interventions. Another driver is debates about the most appropriate methods of evaluating health systems, and the recognition that it is important to know not only just whether health system interventions work but also about when, why, how, and in what circumstances such interventions work well [4,5].

Evaluations of interventions in health care and other systems therefore tend to involve collecting a range of qualitative and other evidence to explain processes and help understand how the intervention interacts with its context. Not all these data may be scientific: Shepperd et al. [6] noted the role of nonacademic evidence such as policy documents. The challenge for systematic reviewers is therefore

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What is new?

Key findings

- Where complexity is a focus of a review, the most important first steps are to clarify the review question and whether it is really about complexity; to identify the sources of complexity in the intervention; and to identify what type of study should be sought as evidence of those aspects of complexity.

What this adds to what was known?

- It is a challenge for systematic reviewers to produce reviews that incorporate a “complexity perspective,” where the review question and methods take account of complexity in the intervention. This article sets out an approach to thinking about sources of complexity in interventions, and how this can be mapped onto specific types of study.

What is the implication and what should change now?

- Much academic discussion is focused on describing aspects of complexity, rather than identifying its practical implications. Although it may be useful to identify sources of complexity in an intervention’s implementation and effects, it does not always follow that it is essential to adopt correspondingly complex review methods.

to produce reviews that incorporate a “complexity perspective,” where the review question and methods take account of complexity in the intervention and then identify, analyze, and integrate heterogeneous evidence to help understand its processes and outcomes. The further challenge is to do this in a way that it results in a review that is meaningful and useful to decision-makers.

However, although it is easy to describe aspects of complexity, it is less clear methodologically what one might do about it in a systematic review. The risk here is that complexity simply becomes a descriptor—we are keen to describe our interventions as complex as that attract funding and publication but are less clear on the practical implications.

This article describes a pragmatic approach to dealing with complexity in systematic reviews that focus on the research question and on research users’ needs. It proposes that, where complexity is a focus of a review, the essential first steps are to clarify the review question and whether it is really about complexity; to identify the sources of complexity in the intervention; and to identify what type of study should be sought as evidence of those aspects of complexity. It also notes that although it may be useful to

identify sources of complexity in an intervention’s implementation and effects, it does not always follow that it is essential to adopt correspondingly complex review methods. In describing this approach, we focus on the degree of complexity of our models of reality, rather than that of reality itself, as this is beyond the scope of the article.

2. Aspects of complexity, and what to do about them

There are many sources of complexity in systematic reviews. Grimshaw et al. [1] noted complexity because of the characteristics of the intervention, contextual factors, multiple outcomes, and research factors, in which, for example, the data collection methods act as an effect modifier (or moderator). The research question itself may also be complex (e.g., it may not be confined to a single intervention but may relate to a package of interventions), and the evidence to answer that question may be difficult to locate, appraise, and synthesize. Many articles describing complex interventions draw on the UK Medical Research Council guidance and the articles by Rychetnik et al. [7], Hawe et al. [8], and Shiell et al. [9]. Table 1 lists aspects of complexity as identified in these articles and other health literature. These aspects fall into two broad categories: characteristics of the intervention itself and characteristics of the hypothesized causal pathway from the intervention to the outcomes.

If these sources of complexity are indeed important to understanding an intervention and how it works, then it is important to consider how these would be identified and synthesized in a systematic review. The starting point for this process, as for any piece of research, is to define the question clearly.

2.1. Clarifying the review question

A good systematic review—regardless of the complexity or simplicity of the intervention—needs to start with a clear focused question. This applies whether the question is about outcomes, processes, mechanisms, or something else (e.g., the theory underpinning the intervention). For reviews of complex interventions, this stage is probably even more important than usual. However, even if the intervention is complex, this does not automatically mean that in all cases the review question needs to be focused on complexity. Consider a hypothetical complex intervention, which involves many of the elements from Table 1. It may have numerous interacting components, directed at various groups or organizational levels, which may be implemented flexibly or adaptively depending on the context. Such interventions will almost certainly have complex causal pathways because of complex relationships both between their components and with the myriad contextual factors in which the intervention is embedded. It should be noted that even apparently simple interventions may also have such complex causal effects when contextual factors are considered.

Table 1. Examples of complexity described in the health literature

Examples of characteristics of complexity	Reference (examples)
1. Characteristics of the intervention itself	
Multiple components (made up of various interconnecting parts)	Various including Campbell et al. [2]
Number of groups or organizational levels targeted by the intervention	Craig et al. [3]
Degree of flexibility or tailoring of the intervention permitted	Craig et al. [3] and Hawe et al. [10]
Self-organization, adaptivity, and evolution over time	Alliance for Health Policy and Systems Research [11] and Hawe et al. [10]
2. Characteristics of the intervention's causal pathway	
Nonlinear relationships (cannot be arranged along a simple input–output line); phase changes	Alliance for Health Policy and Systems Research [11] and Hawe et al. [10]
Multiple mediators and moderators of effect such as the background characteristics and environment of the patient	Emsley et al. [12]
Feedback loops, (e.g., where changes in behavior create the conditions for behavior to change further and where uptake in cycling results in more cyclists, which means that cycling becomes the norm, encouraging more people to take up cycling)	Galea et al. [13]
Synergy between components, and does the program have symbolic value over and above its operational components?	Hawe et al. [10]
Number and variability of outcomes; emergent novel outcomes	Craig et al. [3] as well as Plsek and Greenhalgh [14]
Connectivity, where individual components of an intervention are linked together in a system, so they influence each other	Alliance for Health Policy and Systems Research [11]
Interaction with context and the capability created from this interaction; very susceptible to effect of different contexts (e.g., policy timing, organizational culture and leadership, resource allocation, staffing levels and capabilities, interpersonal relationships)	Hawe et al. [8] and Mills et al. [5]

One approach to evaluating this intervention might be to develop a complex understanding of the working of the system as a whole. This will make for a complex research question, and an answer to this would undoubtedly be useful. However, it is not the only approach to this task. In many cases, it may still be useful to answer a simple question such as, “What is the average effect (or range of effects) of the complex intervention on the outcome(s) of interest?”. Although this question leaves many potentially important questions unanswered, it may provide a clear answer to a valid question that could provide valuable information to research users (such as clinicians or policymakers).

The key issue is that the identification of aspects of complexity in an intervention does not automatically mean that a systematic review needs to *start* with those complex processes. Undoubtedly, the moment one starts dealing with complexity, the review questions proliferate and there is no longer a single question. However, the starting point should be to identify the set of research questions that need to be answered. These may be about effectiveness and other aspects of the intervention, such as the causal mechanisms. Table 2 identifies some of the possible questions beyond issues of effectiveness. Developing a logic model at the start of the review will also help clarify and prioritize these question(s) [18]. In short, it is generally useful to start with a simple analysis before proceeding to the more complex analysis.

Simple questions can therefore legitimately be asked about complex interventions. These simpler and more complex analyses reflect different but equally legitimate research questions. The intervention is the same, of course, but analyzed from different perspectives. This is illustrated using the example of day care in Box 1.

In this example—as in many complex interventions—we are interested in outcomes at different levels. Refining the review question therefore requires deciding which level to focus on and whether to consider one or more subcomponents of the intervention as opposed to the whole package. These choices may be dictated by the principle of lumping and splitting; “lumpers” tend to group concepts into broad categories, whereas “splitters” usually try to avoid grouping together categories unless they are obviously conceptually very similar [1]. In systematic reviews of complex interventions, these lumps might include variations in types of intervention and/or types of outcome, as well as different study designs or populations. The size and nature of the lumps as well as the size and position of the splits depends on the underlying theoretical model of the intervention, and how it works in different groups, and the extent to which the data from different studies in different populations are generalizable [21]. This decision may also be dictated by available resources and by consideration of whether interactions between the components are key to how the intervention works. Shiell et al. [9] differentiate between complicated and complex interventions; the former made up of individual noninteracting elements and the latter made up of interacting components. If such interactions are key to an intervention's success, then splitting the review into individual components may mask this.

2.1.1. The spectrum of simple and complex interventions

Evaluators and systematic reviewers frequently decide to treat complex interventions as simple and conduct appropriately simple reviews. Arguably, all systematic reviews address a simplified (if not simplistic) set of questions

Table 2. Mapping complexity onto study design inclusion criteria

Source of complexity	Study design or source of data for this type of complexity
Multiple components Synergies/interactions (between components of an intervention)	Evidence of the independent effects of components of the intervention and interactions between those components. This evidence may be available in the form of either quantitative data or qualitative data. Studies with factorial designs may also explore these effects. Individual studies with different configurations of components may be included in a review allowing indirect comparisons between studies [15]. Metaregression may also be of value.
Flexibility or tailoring or nonstandardization of implementation	Process evaluations; studies describing implementation; policy documents, and other sources [6].
Feedback loops	Qualitative studies carried out alongside trials; or may be described in qualitative or quantitative research (e.g., structural equation modeling). Longitudinal studies carried out as part of process evaluations may be of value.
Phase transitions	Longitudinal data, for example, changes in direction or size of effects over time may be observed in studies with multiple data points (e.g., interrupted time series studies). Qualitative data may also be available to describe phase changes.
Multiple outcomes [9]	Data on multiple health and nonhealth outcomes may come from any type of evaluative study—qualitative studies may also show the range and nature (direction) of effects.
Effects at different levels	Any type of evaluative study; for example, cluster randomized controlled trials may provide outcome data at both cluster and individual level; studies may collect data from individuals about effects not just on themselves but on their families, communities, and so on. External data sources (e.g., routine data) may show effects at these levels. Qualitative studies have also been used to explore effects of interventions at multiple levels, for example, housing interventions [16].
Moderating effects of context	First, agreement on what aspects of context are of interest to the review is needed. Evidence of contextual effects may then be sought from quantitative data (e.g., subgroup and sensitivity analyses in primary studies). It may also be described in qualitative research carried out as one component of a mixed-methods study and policy documents [6]. Mediators and moderators may also be explored through meta-analysis [17].

A more detailed version of this *n* appears in Paper 5 in this series, “Synthesizing evidence on complex interventions: the contribution of meta-analytic, qualitative, and mixed-method approaches.”

relative to a reality that is inevitably complex. All interventions are in fact likely to be complex when one considers all the contextual factors that they interact with when they are implemented in the real world. Take, for example “medical interventions,” such as the administration of drugs, which are often presented as prototypical simple interventions. A systematic review of the effects of aspirin on coronary

heart disease may legitimately focus solely on clinical end-points for a representative group of patients to show its general effectiveness in primary and secondary preventions [22]. A more complex perspective, however, may see the administration of drugs as involving an interplay between the patient and the clinician as well as invoke issues of compliance and concordance to explain the issues of use

Box 1 Simple and complex approaches to reviewing complex interventions: day care for people with severe mental disorders

This is a complex intervention for a complex population [19]. There are multiple health, social, and other outcomes, which extend beyond the patients to their family and wider society [20]. However, it is also legitimate to ask a more narrowly focused question about the effectiveness of day care compared with other models of care (e.g., inpatient care or outpatient care), in relation to a smaller set of outcomes (e.g., mental health and functioning as well as readmission rates).

A simple perspective

To answer this simple question, one could identify and synthesize the relevant outcome evaluations (e.g., randomized and nonrandomized trials). Even with such a simple approach, providing descriptive information regarding the most important characteristics of the interventions reviewed is still desirable. Reviewers should not ignore important aspects of complexity, even if they end up answering simpler questions. It is this descriptive information that allows the end user to distinguish between simple evidence syntheses and simplistic ones.

A complex perspective

Alternatively (or even in parallel), a more complex perspective could be adopted. In this more complex analysis, the reviewer might start by identifying the components of day care; perhaps create typologies of day care, analyzing the barriers and facilitators of effective care, and how different elements in the system interact. They might also explore how the processes of care differ in various contexts and how these relate to intermediate and final outcomes. They might also consider the effects of day care at multiple levels, that is, its impacts on the individuals, their family, their carers, wider society, and the health system.

and differential effectiveness in different groups or circumstances; a wider perspective still might see this interaction within a broader health systems perspective. All these are valid, but different, research questions. It is unlikely that there really are any simple interventions. If anything, complexity lies on a spectrum, from simpler to more complex interventions as well as simpler and more complex explanations. Both the simpler and more complex explanations may be of value to users.

2.2. Sources of complexity in an intervention and implications for inclusion criteria

Refining the research question also has resource implications. Focusing on relatively simple aspects of complexity, such as the presence of multiple components, makes for a manageable review. However, a more complex perspective might incorporate the processes in Table 1. To do this, the reviewer needs to develop appropriate inclusion criteria for the types of study in which evidence of these complex processes will be found. Table 2 therefore maps some aspects of complexity onto relevant study designs.

Take, for example, phase changes, described by Shiell et al. [9] as nonlinear transitions, in which a complex system jumps from one position to another. They give the example of the impact of public health advocacy on gun control, in which “multiple advocacy episodes” have no discernible impact on policy until a tipping point is reached, and new laws are introduced [9]. Evidence of such phase transitions may derive from studies with a temporal element, in which the effects of an intervention are tracked over time prospectively or retrospectively. In theory, for example, this would be possible in interrupted time series studies. Qualitative studies may also identify such transitions.

Not all useful sources of information about complexity are scientific studies. Policy documents may provide information on the political or other context [6]. Historical documents may also show how the intervention context has changed over time. Although there is likely merit in incorporating descriptive information from policy and historical documents, there are relatively few examples of this approach being reported in practice. One such example is a review of school feeding programs where information about the history and context of each program were collated. The information was used on a study-by-study basis to understand interactions between context, mechanism, and outcome and also across studies to detect patterns [23]. The full potential of integrating policy and historical documents in the context of systematic reviews of complex interventions has yet to be explored.

3. Multiplicity of outcomes

As noted previously, multiple outcomes may be a feature of complex interventions, but they are not specific to them. Shiell et al. [9] make the important point that simpler

interventions, such as vaccination, also have externalities but we often choose to ignore them. Whether to incorporate a single outcome or a multiplicity of outcomes in a systematic review of a complex intervention represents a choice (on the part of the reviewer, stakeholders, or funders) and may be a consequence of adopting a simple or complex perspective.

If a systematic review adopts a more complex perspective, the reviewer is left with the difficult question of how to integrate all this complex evidence from Table 2 into a final synthesis. Several options are available. A narrative synthesis can help integrate findings from different strands of the review. Simple approaches such as tables can also be a helpful first step in organizing and analyzing complex review data [21]. Meta-analysis or metaregression of the quantitative impact data may be conducted alongside the narrative review, statistical, and other forms of heterogeneity permitting. Network meta-analysis may be used for more complex reviews, and Bayesian meta-analysis has also been demonstrated as an approach to this task [24]. The Evidence for Policy and Practice Information and Co-ordinating Centre has also described an approach to integrating qualitative and quantitative data, which may be of value [25]. Other nonsystematic review approaches may also be considered, such as realist synthesis, in which the theories underlying the interventions are described and justified (or not) by empirical evidence [26]. (See also the articles in this series on the spectrum of approaches and the article on approaches to synthesis.) Finally, as for any systematic review, a key further stage will be the critical appraisal of the primary studies, although this may itself be complex, given the range of study designs and evidence sources involved.

4. Conclusions

This is not a recommendation that systematic reviewers confine themselves to taking a simple approach to complex interventions but instead to recognize that although most interventions involve elements of complexity, decisions regarding whether and how to address that complexity reflect choices on the part of the researcher. In systematic reviews, the reality we deal with is inherently complex, and only our models of it can be simple. In some cases, it may be most appropriate to set aside this simple perspective in favor of a more complex analysis, but the reverse also holds true. Where complexity is indeed relevant to the review, it may be helpful to start by formulating the issues of complexity as specific research questions and then move on toward identifying what type of evidence of complexity will be sought to answer them.

Although we have focused in this article on systematic reviews, the approach we outline is also applicable to primary research, which is aimed at evaluating the effects of interventions, and although the examples come from health

care and public health, the same approach may equally be applied to interventions in other sectors (e.g., social policy or international development).

In summary, systematic reviews of complex interventions need to consider not only just complexity but also logic and the use of Occam's razor, the (possibly mythical [27]) 14th Century philosophical principle, which states that explanations should be as complex as they need to be and no more. Similarly, systematic reviews should be as complex as they need to be and no more.

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