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Can We Systematically Review Studies That Evaluate Complex Interventions?

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Background

Complex Interventions

Analytical Challenges in Synthesising Studies of...Fitzpatrick: We Must Address the Conceptual and...Sharon Straus, Mike Clark, Martin P. Eccles, and Ray Fitzpatrick

...review; and (4) synthesising data. In this Viewpoint, we describe...the implications of these limitations and suggest some approaches...help systematic reviewers reflect on the conceptual and...posed by these types of review.

1. Defining the Complex Intervention

To varying degrees, complex interventions can be standardised and defined in individual prospective studies. However, the lack of an agreed definition of complex interventions that have the same aim but are described differently, or inadequately, across studies poses inherent difficulties for systematic reviewers and users of these reviews [7]. Case management illustrates this well. Despite there being no agreed typology, case management has become a generic concept across different specialities to improve inter-professional collaboration and co-ordination of care for individual...
patents. Case management comes in many forms, including a brokerage model, an integrated care pathway, a liaison service, and self-managed care [2]. All these variations can occur alone or in combination.

Defining the intervention is made difficult when the core purpose of an intervention, such as behavioural counselling [8], varies according to the characteristics of the participants or the trial setting, or if the intervention aims to promote an abstract concept, such as promoting trust or continuity of care [4,5]. In the field of service delivery, interventions become complex and difficult to define if, as is often the case, (1) they are delivered across the primary-secondary care interface; (2) they are delivered in new settings; or (3) there is an added behavioural dimension and staff perform new behaviours or current behaviours in a new context [9].

Solutions to improve the description and conceptual understanding of the content of a complex intervention include (1) typologies to guide the classification of interventions and (2) supplementary evidence, such as qualitative or descriptive data [10,11] (see Table 1).

A. Typologies. Typologies can guide the classification of common elements of interventions into homogeneous groups. The Cochrane Effective Practice and Organisation of Care Review Group (EPOC) has developed a typology for interventions aimed at professional practice, organisational, financial, and regulatory systems (see http://www.epoc.cochrane.org/). The Cochrane Consumers and Communication Review Group has developed a typology for consumers’ interactions with health care professionals, services, and researchers (see http://www.latrobe.edu.au/chcp/assets/downloads/TopicList.pdf). As an example of how such typologies are used, the EPOC typology was used to classify quality improvement strategies designed for the care of people with type 2 diabetes [12]. Subsequent correspondence highlighted the risk of misclassifying interventions due to inadequate detail [13]. In another example, a typology for heart failure disease management guided the grouping of clinical service interventions (multi-disciplinary, case management, and clinic models) [14,15].

An alternative is to develop a typology of interventions by consensus. For example, in a systematic review of occupational therapy interventions for rheumatoid arthritis, four occupational therapists identified seven types of intervention (comprehensive therapy, training of motor function, skills training, joint protection, education, support, and assistive devices, counselling, and provision of splints) [16].

Table 1. Identifying the key components of a complex intervention for a systematic review.

<table>
<thead>
<tr>
<th>Solutions</th>
<th>Examples of Where These Techniques Have Been Used</th>
<th>Is This Prospective or Retrospective?</th>
<th>Additional Data Required</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Typologies of the structural characteristics of a complex intervention</td>
<td>Application of the EPOC taxonomy of professional, organisational, and financial interventions to classify quality improvement strategies designed to improve the care of those with type 2 diabetes [12]. In another example, the interpretation by pre-review consensus identified seven categories of occupational therapy intervention for rheumatoid arthritis [16].</td>
<td>Prospective at the review stage.</td>
<td>No</td>
<td>Few typologies exist as this is an evolving field and existing typologies are relatively untested; misclassification can occur [13]; and the mechanism of action for many interventions remains poorly understood [34]. Employing the expertise of those working in the field provides face validity to the categorisation; this is a method that could be applied relatively easily, but problems could occur if consensus is not reached; the results may not be comprehensive.</td>
</tr>
<tr>
<td>2. Trial-related data (trial protocols, supplementary studies)</td>
<td>A survey of trialists contributing to a systematic review of stroke units to identify the key attributes of the intervention [18]. In another example, trialists were contacted for their definition of peer support in a review of peer support telephone calls for improving health [35].</td>
<td>Can be prospective [17,36] or retrospective [18].</td>
<td>Yes</td>
<td>Few examples of supplementary studies to develop intervention typologies [19]; may be problems in generalising the results of these studies across the review.</td>
</tr>
<tr>
<td>3. Policy documents</td>
<td>Policy supporting the adoption of a complex intervention can explain subtle differences in the way interventions have been designed and implemented.</td>
<td>Prospective while drafting the protocol for the review.</td>
<td>Yes</td>
<td>Can be difficult to identify the policy documents that correspond to the development of an intervention, particularly as systematic reviews are of the world literature; interventions may not have been developed in response to a particular policy change.</td>
</tr>
<tr>
<td>4. Alternative sources of data (qualitative, descriptive) to guide the categorisation of interventions</td>
<td>A qualitative synthesis guided the categorisation of interventions aimed at promoting healthy eating among children and the exploration of heterogeneity [21].</td>
<td>Carried out in parallel with the systematic review of quantitative data.</td>
<td>Yes</td>
<td>A major limitation is the lack of related data [19]; the process is resource intensive and adds another layer of complexity to an already labour-intensive process.</td>
</tr>
<tr>
<td>5. Theoretical basis of an intervention</td>
<td>Interventions designed to implement change in practice were categorised according to their theoretical construct [27].</td>
<td>Prospective at the review stage.</td>
<td>No</td>
<td>Theory has seldom been used explicitly to guide intervention development. There are a large number of theories and the empirical basis for many of the behaviour theories remains limited [34].</td>
</tr>
</tbody>
</table>
define interventions. A qualitative study, conducted alongside a trial of intensive case management for people with severe mental illness, investigated the active ingredients of the intervention in terms of staff roles and organisational features [17]. Team management, comprehensive assessment, and needs-led service were regarded as the key mechanisms of this intervention. In another example, trialists contributing to a systematic review of stroke units were surveyed to build a description of the active components of stroke unit care. These included comprehensive assessment, active physiological management, early mobilisation, skilled nursing care, early rehabilitation, and discharge planning involving carers [18].

B. Supplementary evidence: (ii) Qualitative data, descriptive data, and policy documents. When trial-related evidence is inadequate [19], other sources of information may be relevant [20]. A systematic review of barriers and facilitators to healthy eating among children used qualitative evidence, unrelated to the trial data, to gain a better understanding of children’s perspectives [21]. The qualitative synthesis guided the categorisation of interventions, according to the degree to which they combined health advice with the promotion of eating fruit and vegetables. A synthesis of qualitative studies aided a fuller understanding of the interventions included in a systematic review of directly observed therapy (DOT) for tuberculosis, by identifying factors that improved adherence [22]. Factors included flexible delivery systems, involving patients in decisions, and social and family support systems [23]. Policy documents can be particularly informative in understanding the development of service interventions across settings, for example, interventions designed to reduce reliance on hospital beds and interventions involving school feeding programmes [24,25].

B. Supplementary evidence: (iii) Theory. Theory may help to explain how an intervention is related to similar interventions in a particular field [26]. However, many reviews fail to locate interventions within a theoretical model. Realist synthesis, which attempts to provide an explanatory analysis of how and why complex social interventions work (or not) in particular contexts, can aid this process. For example, a realist review of school feeding programmes identified the theory and components of an intervention during data extraction; and (4) being explicit in the review about where disagreement occurred.

3. Selecting Studies for Inclusion in a Review
A major threat to validity from an imprecise definition of an intervention is the non-standardised and potentially non-reproducible selection of studies for inclusion in a review. Based on the available information, considerable judgement may be required when assessing how similar any given intervention is to the intervention of interest, particularly for multi-faceted interventions and those at the boundary of the content area. For example, reaching a common understanding of patient-centred interventions was not easily achieved in a review of interventions intended to promote patient-centred care [32].

Solutions to this problem of definition include: (1) refining the definition of an intervention through an iterative process to accommodate previously unseen configurations; (2) contacting study authors for further information; (3) recording the components of an intervention during data extraction; and (4) being explicit in the review about where disagreement occurred.

4. Synthesis of Data
Complex interventions with a large number of ill-defined elements may result in a high degree of heterogeneity. Conversely, applying a narrow definition limits generalisability by losing the potential relevance gained from examining an intervention being implemented across a range of settings. A meta-analysis of DOT for tuberculosis provided in clinics, by lay health workers, or in the home provides an example of the usefulness of exploring sources of heterogeneity [22]. The authors found no important difference between DOT and self-administered treatment (risk ratio 1.02, 95% confidence interval 0.86 to 1.21; F 64%). However, when the trials were grouped by the location of DOT there was a small beneficial effect for delivering DOT in a home setting compared with self administration (risk ratio 1.10, 95% confidence interval 1.02 to 1.18; F 53%). This beneficial effect allows for several possible interpretations; for example, the burden upon patients of travelling to a clinic five days a week is minimised by having their therapy supervised at home by a lay health worker or a community or family member.

Solutions to the problem of data synthesis include categorising interventions by key variables and retaining these in the analysis. For example, a meta-analysis of discharge planning and post-discharge support categorised interventions by intensity, which varied from a single home visit, to increased clinic follow-up with telephone contact through to extended home care services [3]. If meta-analyses cannot be performed, similar processes can be conducted whilst performing narrative synthesis. The quality of narrative analysis and applicability of review findings have recently received more attention [33] (see Box 1).

Conclusion
Despite the range of supplementary methods available to improve the synthesis of complex interventions, most of these
methods are infrequently used. There are several reasons for this lack of use. In some cases the theory underpinning a specific complex intervention has not been assembled. However, there are usually few data reporting the characteristics of complex interventions, and what data there are tend to be of poor quality. Although simple in concept, providing an adequate description of complex interventions can be technically difficult. The need to address this is becoming urgent as interventions with multiple components evolve in response to the complex health problems faced by health services. Current criteria to improve the reporting of health research are primarily concerned with the internal validity of studies [6], and while these include criteria related to the intervention, these guidelines can still be followed without providing adequate details of the intervention (see Table 2). It is essential that methods to improve the descriptions of complex interventions are further developed and tested with the expectation that they will complement existing systematic review methodology.

Geoff Wong’s Viewpoint: We Must View Complex Health Interventions in a New Way

I believe that complex health interventions (CHIs) can be systematically reviewed, but only if a paradigm shift occurs in the way that these interventions are conceptualised. In this Viewpoint, I discuss an alternative way of viewing CHIs that focuses on the interactions between components of a CHI and the impact of human behaviour on the outcome of the intervention. I then discuss how this different way of viewing CHIs has given rise to a different method, called “realist review”, to systematically review CHIs.

CHIs Are Non-Linear and Produce “Irregular” Outcomes

CHIs are more than just a complicated “jumble” of components that interact in a regularly predictable but linear fashion (i.e., deterministically) to produce health outcomes. Interactions between the components are not as deterministic as might be expected because CHIs are highly dependent on human behaviour [1,40]. The “components” in CHIs are invariably made up of people (e.g., researchers) trying to get other people (e.g., study participants) to “do” or “not do” something (e.g., to stop smoking in a CHI of smoking cessation). The actions taken by the “human components” of CHIs are influenced by the context in which the intervention takes place. Taking the example of smoking cessation, the actions that smokers can take will depend on their personal circumstances, including their health status, while the actions the clinic staff can take will be guided by factors such as the trial protocol and the clinical setting.

Thus the context in which CHIs take place is a key variable, because context influences and limits the range of people’s choices and actions. Such context explains why the interactions between the components of CHIs are not deterministic and why the outcomes of CHIs can vary when the CHI is repeated. There will be a myriad of different contexts, each having a slightly different influence on those components that interact in a regularly predictable but linear fashion (i.e., deterministically) to produce health outcomes.

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Box 1. Presentation of Review Findings: Information To Support Assessment of the Applicability of Evidence of Effectiveness

**Intervention Content** [1]

- Describe the content (the active ingredients) of the interventions
- Describe any interventions received by the control group, including the content of “usual care”
- Describe how the interventions were delivered and any differences in delivery across the included trials
- Describe the contextual similarities and differences between the trials

**Intervention Fidelity**

- Include details describing whether the interventions included in a review do what is intended or if they deviate from the intended shape or form during the course of implementation
- Include an assessment of whether an intervention failed because it was poorly implemented or it was not effective

**Intervention Sustainability**

- Include details on the sustainability of intervention effects over time

**Roll Out/Scaling Up of the Intervention** [7]

- Report data on accessibility, the risk of adverse events, cost-effectiveness, or budget impact of interventions
- Address the following questions regarding the applicability of the evidence to individual patients (where applicable) [37]:
  - Have biological results (e.g., sex, co-morbidities, age) that might modify the treatment response been excluded?
  - Can consumers comply with the treatment requirements?
  - Can health care providers comply with the treatment requirements?
  - Are the likely benefits worth the potential risks and costs?
- Address the following questions regarding the applicability of the evidence in other health systems (where applicable) [38]:
  - Are there important differences or similarities in the structural elements of health systems or of health services between where the research was done and where it will be applied that might mean that an intervention could not work in the same way?
  - Are there important differences in on-the-ground realities and constraints (i.e., governance, financial, and delivery arrangements) between where the research was done and where it could be applied that might substantially alter the potential benefits of the intervention?
  - Are there likely to be important differences in the baseline conditions between where the research was done and other settings? If so, would this mean that the intervention could have different absolute effects, even if the relative effectiveness was the same?
  - Are there important differences in perspectives and influences of health system stakeholders between where the research was done and where it could be applied that might mean an intervention will not be accepted or taken up in the same way?
Realist Review

Realist review is a systematic review method that focuses more on trying to explain as opposed to judge CHIs. As such, it seeks not so much to answer the question of “If” a CHI works, but “How”, “Why”, “In what circumstances”, “For whom”, and “To what extent” it works. The underlying premise of realist review is that the semi-regular patterns of interactions between the components (so-called “demi-regularities”) that make up CHIs with similar goals can be explained by middle-range theory [Box 2] [42]. For any similar group of CHIs (e.g., smoking cessation interventions), the myriad of contexts influencing behaviour so as to generate outcomes are not impediments to realist review, but act as the “raw materials” from which demi-regularities can be identified. Middle-range theory (or theories) are then sought to explain why these demi-regularities occur. As the review progresses iteratively, theories that “work” (i.e., best explain sets of demi-regularities) are repeatedly “tested” against the observations reported in each CHI included in the realist review [41,43,44].

In exploring the feasibility of systematically reviewing studies that evaluate CHIs, I believe we have come to a crossroads. Currently, the dominant systematic review methodology and paradigm is based on the Cochrane review. Without doubt, its dominance has been well earned as its usefulness in the systematic review and meta-analysis of pharmaceutcal and other “simpler” medical interventions has advanced the evidence-based practice of medicine. However, efficacy studies of pharmaceutical studies are less reliant on the human agency that we see in CHIs. In other words, a well-characterised “drug” does things to people to cause outcomes in a deterministic way, and context is much less relevant. Once human agency comes into play (as can be seen in the differences in outcomes reported between pharmaceutical efficacity and effectiveness trials), then context starts to play a bigger role. By the time we come to CHIs (where outcomes are highly dependent

Shepperd and colleagues rightly point out that the systematic review of CHIs remains challenging. From the range of solutions they have proposed, the greatest progress is likely to be made by focusing on theories [Box 2] that can explain and “predict” how certain contexts influence individuals to act in certain ways to produce certain outcomes. Pawson and colleagues have already made some progress towards such explanation and “prediction” using the “realist review” method of systematic review [41].

### Box 2: Definitions of Theory

**Theory:**

There are multiple definitions for theory, and in this Viewpoint article: “A theory is an attempt to organize the facts—some ‘proven’, some more conjectural—within a domain of inquiry into a structurally coherent system” [45].

**Middle-Range Theory:**

This is a theory that lies “…between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behavior, social organization and social change…”

“It is intermediate to general theories of social systems which are too remote from particular classes of social behavior, organization and change to account for what is observed and to those detailed orderly descriptions of particulars that are not generalized at all. Middle-range theory involves abstractions, of course, but they are close enough to observed data to be incorporated in propositions that permit empirical testing.” [42].

### Table 2. Current guidance for reporting complex interventions and where further research is needed.

|--------------------|-------------------------------------------------------------|------|-----------------------------------------------------------------------------------------------------------|
| CONSORT for non-pharmacologic treatments such as surgery, technical interventions, rehabilitation, psychotherapy, behavioural interventions, implantable and non-implantable devices, and complementary medicine (extension of the CONSORT statement for reporting randomised controlled trials) | Details of the intervention and the experience of the care provider for therapist-dependent interventions | Does not address fidelity or external validity; can be applied in a non-systematic fashion | Individual Studies  
- Systematise the description of complex interventions in trial reports as well as in the reports of studies using other evaluation designs  
- Ensure that more attention is given in reporting to issues of intervention fidelity and external validity, such as the characteristics of interventions, the health care system, and the setting and implementation  
- Increase the use of qualitative and quantitative process evaluations alongside trials  
- Ensure that the development of interventions for new trials is better informed by the findings of existing systematic reviews and by existing typologies and frameworks |
| QUOROM (Quality of Reports of Meta-Analysis of Randomised Controlled Trials) | Details of the intervention | Does not provide detailed guidance | |
| Transparent Reporting of Evaluations with Non-Randomized Designs (TREND) [39] (developed for reporting behavioural and public health interventions) | Details of how and when interventions were delivered, the context, the delivery, location, and setting, number of sessions, time span, and external validity | Provides the most detailed guidance, to be empirically tested | Research Synthesis  
- Formalise methods to identify and disaggregate the key elements and effects of a complex intervention within a systematic review to complement existing systematic review methodology  
- Refine methods to identify relevant qualitative data linked to trials  
- Systematise the description of complex interventions in systematic reviews  
- Develop empirically based typologies of interventions, linked to their hypothesised mechanisms of actions and effect, and test how well these work |

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on human agency), then the appropriateness of the current
dominant systematic review method needs to be questioned.

Conclusion
In CHIs, the action of individuals under specific contexts results
in outcomes. The way these outcomes result is neither determin-
istic nor regular, but can be explained and “predicted” by middle-
range theory. Systematically reviewing CHIs is only feasible when
the review method takes into account these properties, and theory-
driven reviews are our best bet.

Aziz Sheikh’s Viewpoint: Undertaking Meaningful
Systematic Reviews of Complex Interventions Is
Inherently Complex

The evaluation of complex interventions is increasingly
commonplace within health services research. It is therefore
important and timely that attention is given to reflecting critically
on how these studies can best be identified and appraised, and
their findings then synthesised and interpreted. The answer to the
somewhat rhetorical question of whether it is feasible to
systematically review studies of complex interventions is, at one
level at least, obvious. Many of the general principles of systematic
review methods can and indeed should be used when undertaking
systematic reviews of complex intervention studies in health care.
Sasha Shepperd and colleagues offer a number of useful
suggestions in this respect, including: (1) the need to use broad
search techniques in an attempt to identify and include studies that
may have been poorly indexed; (2) carefully defining and
describing the interventions being studied; and (3) a willingness
to consider narrative synthesis if studies are found to be too
heterogeneous to be synthesised quantitatively.

There are, however, a number of important conceptual and
practical challenges in undertaking such reviews. One key
consideration that is usefully highlighted by Geoff Wong is the
importance of studying contextual considerations, both in relation
to understanding the broader picture in which individual studies
have been conducted, and in order to make sense of how the
landscape has (often irrevocably) changed as a result of the
intervention being applied. Wong also helpfully discusses the
central importance of considering not only what was achieved in
relation to standard parameters of interest, such as effect size, but
also why this may have been achieved, i.e., a clear description of
the processes that the intervention has operated through in order
to achieve this effect [46]. This latter consideration is particularly
important in that it is these processes that are far more likely to
change and, more fundamentally, expanded its list of core
deliverables [48]. Such changes are often mirrored, albeit on a
smaller scale, in the health interventions that we more routinely
consider as complex interventions. The key issue here is that such
modifications should not be seen as compromising the fidelity of
the intervention. Instead, these modifications should be recorded
and described as fully as possible in order to allow readers to make
sense of what modifications were considered necessary and why,
and through so doing allowing readers to appreciate what was
actually delivered [1].

A second important consideration relates to what is and what is
not considered a complex intervention. Most interventions do
have a degree of complexity—even a “simple” aspirin effectiveness
trial has some complexity—because the processes through which
the delivery of the intervention leads to actual patient compliance
with the treatment is inevitably made up of “several interacting
components” [1]. Some argue that this in effect means that the
term “complex intervention” is somewhat meaningless. I would
take a somewhat different view, stressing that what we must not do
is take the other extreme of excluding from our frame of reference
interventions that are judged so complex that they are not
amenable to study through randomised controlled trial designs.
Many health policy initiatives, particularly those that are national
or supra-national, are inherently multi-faceted, such as national
legislation prohibiting smoking in public places and the National
Programme for Information Technology. Such programme-level
interventions are often not easily amenable to study using quasi-
experimental designs, but their evaluation remains important and
such interventions should also be studied through systematic
reviews.

My third point relates to the importance of elucidating the likely
mechanisms through which the effects of the intervention are
mediated [49]. Carefully theorised studies/interventions can help
greatly in this respect, as can accompanying embedded qualitative
work, particularly if it has a longitudinal dimension [50,51]. One
way forward is to assign greater weight to studies that have
described mechanisms, but a more general point is the importance
of searching for and including relevant theoretical and qualitative
work into complex intervention systematic reviews.

Considering then the question of meta-analysis, whilst this may
be appropriate in some systematic reviews of complex interven-
tions [52], meta-analysis may also often be somewhat inappropri-
ate. Instead, we should really be more interested in understanding
the ways in which local contextual considerations may have acted
as co-factors in helping shape delivery of the intervention, rather
than focusing on finding any overall summary effect of the
intervention. Such summary effects may tend to obscure rather than
enlighten [25]. Consider, for example, our phase III and IV
studies of the accessibility, acceptability, and effectiveness of a
telephone-based review service for hard-to-reach people with
asthma [53,54]. These studies could only have been possible in a
climate that has a well-developed information technology
infrastructure, including routine use of electronic health records,
values regular review of those with long-term conditions, and
rewards practitioners accordingly. Paying careful attention to such
crucial contextual influences allows readers to begin to assess the
role of co-factors in shaping delivery of the intervention and also in
assessing its likely generalisability.

The upshot of all of this is that systematic reviews of complex
health interventions can and should be done, but if they are to
shed more light than darkness, the systematic reviewers need
explicitly to consider doing two things. First, they should search for
and include relevant theoretical and qualitative work. Second,
where relevant, they should include data from a broader range of
Spearheading and supporting these developments, this would necessitate development of better search strategies to locate this non-trial literature and also the availability of techniques for the experimental study designs than is currently normally the case in hospital admission through provision of hospital care at home: A systematic review and meta-analysis of individual patient data. CMAJ 180: 175–182. doi:10.1503/cmaj.081491.