

Complex interventions: some definitions, examples and challenges

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What is a complex intervention?

- *What do you think?*

PICO

Does PICO cover everything you want to know about a complex intervention? If not, what else do you want to know?

What is “context”?

- Complex interventions are often said to be context-dependent – but what is “context”?
- *The “interrelated conditions in which something occurs” (Webster)*
- *“the social, economic, political, & organisational characteristics of the setting in which interventions take place” (Penny Hawe)*
- *“An ecological perspective encompasses ...physical, social, cultural, and historical aspects of context (including trends at the local and global level such as globalisation, urbanisation, and large scale environmental change) as well as attributes and behaviours of persons within”. (McLaren & Hawe, 2005) – but what is “context”?*

Implications for systematic reviews of complex interventions: going beyond PICO

- Getting the review question right is *even more important* than for other types of review.
- **Population:** (Individuals, families, communities?)
- **Intervention:** What is the intervention? Delivered at what level? Do we **lump** or **split**?
- **Comparison:** Are there likely to be any RCTs? What if there are not even any controlled trials? (RCTs of area-based interventions, or changes in organisations/systems are few and far between...)
- **Outcomes:** What outcomes? At what levels?

Beyond PICO

- **Context:** How do we assess the mediating effect of context?
- **Processes:** Where do we find, and how do we integrate this information?
- **Theory:** Describing the causal pathways linking the intervention and the health outcomes

Defining complex interventions: Top down and bottom up

- We will look at (1) a few **definitions** to work out what complex interventions are, and (2) a few **examples**

Key features of complex interventions

(Craig et al. Br Med J 2008;337:a1655.; the MRC guidance on complex interventions)

- Number of interacting components
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted (Non-standardisation/reproducibility; Hawe, JECH 2004)

Characteristics of complex interventions

- Non-pharmacological (MRC)
- Behavioural (MRC)

Also:

- Lack of linear, well-evidenced causal pathways linking the intervention and the health outcomes, and
- Feedback loops, synergies, phase changes

Alliance for Health Policy & Systems Research (2009)

- “Complexity” arises from a system’s interconnected parts, and “**adaptivity**” from its ability to communicate and change based on experience.”...
- ...The high degree of connectivity means that a change in one subsystem affects the others....
- They are governed by feedback (a positive negative response that may alter the intervention or expected effects), and non-linear (relationships within a system cannot be arranged along a simple input-output line).”

Hawe et al. (2004) Complex interventions: how “out of control” can a randomised controlled trial be? *JECH* 2004

- Complexity is defined as “a scientific theory which asserts that some systems display behavioural phenomena that are completely inexplicable by any conventional analysis of the systems’ constituent parts” and

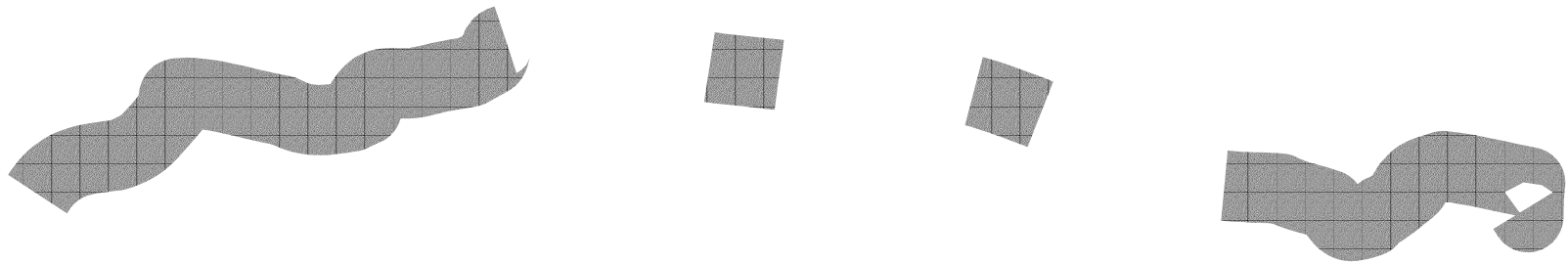
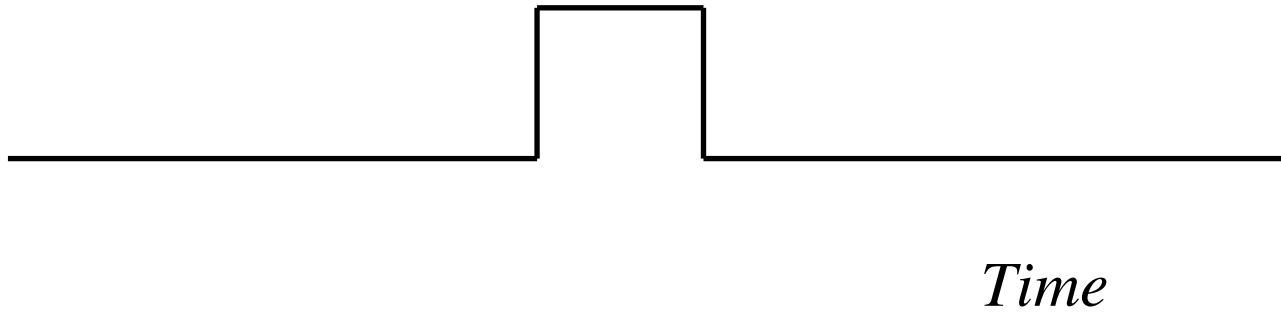
Intervention integrity

- “In school health... non-standard interventions that “cannot be compartmentalised into a predetermined number and sequence of activities... Characterised by activities like capacity building and organisational change, these interventions have specific, theory-driven principles that ensure that non-standard interventions (different forms in different contexts) conform to standard processes”.

Hawe et al. (2004) Complex interventions: how “out of control” can a randomised controlled trial be? JECH 2004

- Many interventions are not discrete, rapidly-introduced, “on/off” interventions – but more gradual perturbations over long periods in a complex system (Hawe, Shiell & Riley, 2009)

Some outcome or other...



e.g. Evaluations of natural experiments...such as policies

2. Examples from the literature

- P4P – a pay- for-performance intervention to improve health service quality
- A heart integrated care programme involving trials of primary care interventions for risk reduction in cardiovascular disease
- Community based health promotion
- Stroke Units
- Strategies for implementing clinical guidelines;
- Community based screening for genital *Chlamydia trachomatis* infection
- Adolescent sexual health intervention in rural Zimbabwe
- *Etc etc*

Based on these and other examples, complex interventions involve...

- Changes in complex inter-related systems, where it is important to understand how parts of the system interact to produce individual (or higher-level) outcomes

Evaluations of complex social interventions (including public policies) can use ...

- Randomised Controlled Trials; other trial designs
- Quasi-experimental study designs, using control/comparison groups/areas where appropriate
- Uncontrolled studies (e.g. time series analysis, before-and-after studies) – what we know about the effects of smoking bans comes from ITS and uncontrolled B/A studies

Some things it might be helpful to know about (when doing SRs of complex interventions)

- Mechanisms and pathways by which the intervention brings about the desired intermediate and final outcomes
- Mediators (causal mechanisms) and moderators (characteristics of studies, populations, settings etc)
- Aspects of context and setting
- Feedback loops, synergies, phase effects (Maybe)
- Theory underlying the intervention

Developing and evaluating complex studies

(Craig et al. Br Med J 2008;337:a1655.)

- A good theoretical understanding is needed of how the intervention causes change, so that weak links in the causal chain can be identified and strengthened

The key steps in systematic reviews of complex interventions...

- Spend time getting the review question(s) right
- Work out what question(s) do you - or your user – really want the review to answer? Is it a question about outcomes? Processes? Causal pathways? Differential effects in subgroups? All of these?
- Ask: What sort of evidence (studies) do need to answer each of those questions?
- Locate it, appraise it, synthesise it
- Systematic review methods are flexible and can cope with complexity

Things I haven't discussed...

- Searching for studies of complex interventions – how might this differ?
- Critical appraisal - – how might this differ?
- Incorporating an equity perspective, and the use of subgroup analysis
- Heterogeneity
- Meta-analysis vs narrative review methods
- The role of theory and logic models to clarify the question and mechanisms



Not that simple...

- Misunderstanding of right-of-way rules, especially at crossings where pedestrian and traffic signals appear to give contradictory messages (Hatfield et al., 2007)
- Context: Many drivers maintain the same speed (or accelerate) depending on the pedestrian behaviour at the kerb [Várhelyi A,](#) 1998)

A matter of perspective?

- So, it's a simple structural intervention which in most cases slows or stops traffic, and helps prevent injury
- It's also a complex intervention involving unspoken behavioural communication between driver and pedestrian, and driver and other road users, other signals
- You can evaluate it either way (as if simple, or complex)
- It depends on the question and whether you want a simple or complex answer