Process Evaluation: Understanding Theory, Context and Implementation

Dr Rhiannon Evans
DECIPHer, Cardiff University
Email: EvansRE8@cf.ac.uk
Session Outline

- Map evolution of Medical Research Council’s Guidance on Developing and Evaluating Complex Interventions.

- Consider critiques of:
  - Critical realism
  - Systems thinking

- Present Medical Research Council’s Process Evaluation Guidance
Limitations:

1. **The role of context is largely omitted.**

2. **Implementation is not fully addressed until the point of replication and scale-up.**

3. **Intervention conceived as immutable and unified entities.**

4. **Outcomes not sufficiently viewed as spatially and temporally contingent.**
Perspective One: (Critical) Realism

- **Clinical Trials**: Pathogens are consistently and uniformly responsive to treatment.
  - Allows for successionist view of causality (If we do a then b will occur)

- **Social Interventions**: Participants (and practitioners) are volitional across open systems.
  - Encourages a generative view of causality (If we do a then b,c,d,e may occur with the context of f,g,h,i,j)

- Shift from thinking “what works” to “what works in which circumstances and for whom” (Pawson and Tilly, 1997).
  - Understanding interventions as CMO (Context, mechanism, outcome) configurations
The VICTORIE Mnemonic (Pawson, 2013)

Social intervention outcomes are highly contingent on time and place due to:

- **Volition**: Reliant on people to make choices
- **Implementation**: Implementation chains are prone to inconsistency and reinterpretation, blockages, and delays
- **Context**: Outcomes change under different circumstances
- **Time**: Previous activities will shape the next
- **Outcomes**: Planned, unplanned and contested
- **Rivalry**: Interventions compete with one another in the real world
- **Emergence**: Interventions beget change which causes more change
Realism and MRC Guidance

• **Intervention Development:**
  
  *Pragmatic Formative Process Evaluation (Evans et al., 2014):* Retrospective development and evaluation of complex interventions already in routine practice as implementation and context already transpired.

• **Piloting and Feasibility:**
  
  *Realist Pilot and Feasibility Trials:* Purposive sampling of contextually diverse participants; rich qualitative evidence; multi-arm trials.

• **Full Scale RCT:**
  
  *Realist RCT:* Comprehensive mixed methods process evaluation; mediational and moderation analysis; ‘dark logic’ models.
Perspective Two: Systems Thinking

- Systems thinking underpinned by complexity theories – a far from unified field of thought (Chandler et al. 2016);
  - Emerged separately from critical realism, though increasing focus on compatibilities (Byrne, 2015; Fletcher et al. 2016)
  - Role of system characteristics in shaping actions and their effects
  - Emphasis on holism rather than reductionism – the whole cannot be reduced to component parts
Challenging the Conceptualisation of Complex Interventions:

MRC Definition:

“The greater the difficulty in defining precisely what, exactly, are the “active ingredients” of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention.” (Campbell et al. 2000)

- Complexity purely conceived as an intrinsic property of the new intervention.
- Systems perspectives suggest that context is the primary source of complexity; the most simple interventions are rendered complex when inserted into context.
Is any social intervention simple?

- Smoke free legislation – one intervention component
  - Implementation possible as system at a tipping point (Holliday et al. 2009)
  - Effects patterned by SES, interacted across different contexts (Moore et al. 2012)

- Hence, even a mono-component intervention is complex in terms of its interaction with the system
  - Is “complex intervention” even a useful term, given that there are no non-complex interventions in population health?
Systems based definitions of intervention (Hawe et al. 2009)

- Much influential work focused on articulating detail of intervention components.
- But intervention is a process, not a set of discrete actions
  - it is a process of displacing or disrupting current structures, process and actions.
  - Any “effect” as much to do with what is taken away, as what is added;
- Complex systems (e.g. schools, hospitals, communities):
  - Functioning shaped by dynamic interplay among (ever-changing) agents;
  - Ceaseless adaptation to ensure system survival;
  - Tendency toward self-organisation; order emerging spontaneously;
  - Emergent and unpredictable patterns of system behaviour in response to introduction of change – feedback loops, reinforcement or discontinuation
## Logic Models: Integration System Influences

### Antecedent System Influences:
Determine how the problem is conceived, how we might intervene, and the parameters of intervention implementation.

<table>
<thead>
<tr>
<th>Resources</th>
<th>Activities</th>
<th>Outputs</th>
<th>Short and Long term outcomes</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>In order to accomplish our set of activities we will need the following</td>
<td>In order to address our problem we will conduct the following activities</td>
<td>We expect that once completed or underway these activities will produce the following evidence of service delivery</td>
<td>We expect that if completed or on-going these activities will lead to the following changes in 1-3 then 4-6 years</td>
<td>We expect that if completed these activities will lead to the following changes in 7-10 years</td>
</tr>
</tbody>
</table>

Systems are dynamic and the influence exerted on the intervention mechanisms (and implementation practices) will likely evolve and change.
Process evaluation of complex interventions: Medical Research Council guidance

Graham F Moore,1 Suzanne Audrey,2 Mary Barker,2 Lyndal Bond,2 Chris Bonell,3 Wendy Hardeman,4 Laurence Moore,5 Alicia O’Cathain,6 Tannaze Tinati,4 Danny Wight,4 Janis Baird2

Process evaluation is an essential part of designing and testing complex interventions. New MRC guidance provides a framework for conducting and reporting process evaluation studies.

Attempts to tackle problems such as smoking and obesity increasingly use complex interventions. These are commonly defined as interventions that comprise multiple interacting components, although additional dimensions of complexity include the difficulty of their implementation and the number of organisational levels they target. Randomised controlled trials are regarded as the gold standard for establishing the effectiveness of interventions, when randomisation is feasible. However, these designs do not provide detailed information on how an intervention might be replicated in their specific context, or whether real outcomes were reproduced. Therefore, guidance for evaluating complex interventions focused on randomised trials, making no mention of process evaluation. Updated guidance recognised the value of process evaluation within trials, urging that it ‘can be used to assess the quality of implementation, clarify causal mechanisms and identify contextual factors associated with variations in outcomes’. However, it did not provide guidance for carrying out process evaluation.

Developing guidance for process evaluation

In 2010, a workshop funded by the MRC Population Health Sciences Research Board discussed the need for guidance on process evaluation. There was consensus that researchers, funders, and evaluators would benefit from guidance. A group of researchers with experience and expertise in evaluating complex interventions was assembled to produce the guidance. In line with the principles followed in developing earlier MRC guidance documents, initial guidance was produced during a literature review, process evaluation case studies, workshops, and discussions at conferences and seminars. It was then circulated to academic, policy, and practice stakeholders for comment. Around 100 stakeholders provided written comments on the draft structure, while others commented during conference workshops run throughout the development process. A final draft was circulated for further review, before being reviewed and approved by key MRC funding panels.

Although the aim was to provide guidance on process evaluation of public health interventions, the guidance is highly relevant to complex intervention research in other domains, such as health services and education. The full guidance (www.pophealthsci.org/Process-Evaluation-Guidance.pdf) begins by setting out the need for process evaluation. It then presents a review of theoretical theories and frameworks which informed its development, before offering practical recommendations, and detailed case examples. In this article, we provide an overview of the new framework and summarise our practical recommendations using one of the case studies as an example.

MRC process evaluation framework

The new framework builds on the process evaluation themes described in the 2008 MRC complex interventions guidance.4,5 Although the role of theory within evaluation is connected, we caution with the position set out in the 2008 guidance, which argued that an understanding of the causal assumptions underlying the interventions and use of evaluation to understand how interventions work in practice was in building an evidence base that informs policy and practice. Causal assumptions may be drawn from social science theory, although complex interventions will often also be informed by other theories such as pain experience or community norms. An intervention as simple as a health information leaflet, for example, may not necessarily have increased knowledge of health consequences but trigger behavioural change. Effectively testing causal assumptions about how the intervention will work can allow causal scrutiny of its plausibility and help evaluators decide which aspects of the intervention are to be focused on for investigation. Our framework also emphasises the role of theory between implementation, mechanisms, and outcome. For example, implementation of a new intervention will be
1. Implementation

- How are interventions delivered in practice?
  - Without assessment of implementation we risk Type 3 error. Risk of dismissing good ideas because of poor implementation
  - Risk of attributing success to bad ideas which are locally reinvented during implementation
  - Risk understanding level of contextual variation that can be permitted whilst...
2. Mechanisms

- What are the active mechanisms underpinning the process of change?
  - Avoid risk of serendipitous successes.
  - Consider if there are redundant components (allow consideration of traffic light systems etc.)
  - Build middle range theory - what mechanisms might future interventions target (perhaps through different intervention methods) to produce change?
3. Context

- What is the interaction of the intervention with system dynamics?
  - Can the intervention interrupt causal mechanisms which give rise to and sustain a “problem” in a given context?
  - Intervention effects arise from introduction of mechanisms sufficiently suited to context (Pawson and Tilley 1997)?
  - How the system support or inhibit implementation practices?

---

Without context, a piece of information is just a dot. It floats in your brain with a lot of other dots and doesn't mean a damn thing. Knowledge is information-in-context ... connecting the dots.

- Michael Ventura
Planned intervention

Implementation

Mechanisms of impact

Outcomes

Context
Opportunities for Further Development

- Context still the area of greatest uncertainty in evaluation research
  - Drive for “theory-driven” evaluation has often led to decontextualized theory, rather than engagement with how a problem is sustained in context.
  
  - Mainstream moves toward more realist thinking (Pawson and Tilley 1997; Bonell et al. 2012; Fletcher et al. 2016).
    - Less work on implications of systems perspectives
  
  - Focus on context-specificity can risk becoming quite nihilistic:
    - How can we make systematic judgments about the applicability (or otherwise) of evidence from one context to another?
Summary

- The complexity of interventions is derived from the system as much as from intervention components.

- Interventions cannot be disentangled from context. This impacts upon the underpinning mechanisms of change and implementation.

- Process evaluations aim to understand context, mechanisms and implementation. This data can contextualise and explain outcome data.
DECIPHer Short Courses

Course 1: Process Evaluation of Complex Interventions

September 28th 2016

To book: www.decipher.uk.get/decipher-short-courses

DECIPHer SHORT COURSES - SEPTEMBER 2016

COURSE 1: PROCESS EVALUATION OF COMPLEX INTERVENTIONS

The aim of this one-day course is to provide participants with a working knowledge of the theory and practice of process evaluation of complex interventions.

The course is led by Dr Graham Moore (Senior Lecturer and programme lead for complex intervention methods in DECIPHer). The teaching team (Dr Suzanne Audrey, Dr (Renato) Elena, and Dr Jeremy Sigsworth) includes authors of numerous empirical and methodological works related to process evaluation, including recent MRC guidance.

Course will cover:
- The role of process evaluation in understanding complex interventions;
- The importance of intervention theory and logic models;
- Fidelity and implementation of complex interventions;
- Relationships and resources issues;
- Identifying questions and combining methods;
- Analysis and dissemination of process data.

COURSE 2: INVOLVING CHILDREN AND YOUNG PEOPLE IN THE DESIGN AND CONDUCT OF RESEARCH

The aim of this one-day course is to provide participants with an understanding of how to involve children and young people in the design and conduct of research, with a particular focus on the development and evaluation of complex interventions. The course includes practical sessions where delegates can apply learning to develop a plan for involving children and young people in their own projects or research ideas.

The course is led by Hayley Read (the Involving Young People Research Officer at DECIPHer) and Dr Jeremy Sigsworth, and draws on their extensive experience of public involvement, including leading DECIPHer’s young people’s research advisory group – ALPHA.

Course will cover:
- The principles underpinning the involvement of children and young people in the conduct and design of research studies;
- Key approaches to, and methods for, involving children and young people;
- Facilitating, and overcoming barriers to, involvement activities;
- The potential impacts of involving children and young people on research processes and outcomes.

KEY INFORMATION

COURSE 1: PROCESS EVALUATION OF COMPLEX INTERVENTIONS
DURATION: 1 DAY
DATE: 28 SEPTEMBER 2016
PRICE: £295
VENUE: GLAMORGAN BUILDING, CARDIFF UNIVERSITY

COURSE 2: INVOLVING CHILDREN AND YOUNG PEOPLE IN THE DESIGN AND CONDUCT OF RESEARCH
DURATION: 1 DAY
DATE: 29 SEPTEMBER 2016
PRICE: £295
VENUE: GLAMORGAN BUILDING, CARDIFF UNIVERSITY

To book a place, visit: www.decipher.uk.net/decipher-short-courses