Developing and Evaluating Complex Interventions

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Developing and evaluating complex interventions: new guidance

Developing and evaluating complex interventions: the new Medical Research Council guidance

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Outline

- What is a complex intervention?
- A phased approach
  - Development, feasibility and piloting
  - Evaluating outcomes
  - Understanding processes
- Reporting and implementation
What is a complex intervention?

- Number of interacting components
- Number and difficulty of behaviours involved
- Number of groups or organisational levels targeted
- Number and variability of outcomes
- Degree of flexibility or tailoring permitted

- Good theoretical grasp of the change process
- Implementation vs. intervention failure
- Individual variation may reflect higher level processes
- A range of outcome measures
- Interventions may work better if adaptation to local context is permitted
Evaluating complex interventions

Development
- Identifying the evidence base
- Identifying or developing theory
- Modelling process and outcomes

Feasibility and piloting
- Testing procedures
- Estimating recruitment and retention
- Determining sample size

Implementation
- Dissemination
- Surveillance and monitoring
- Long term follow-up

Evaluation
- Assessing effectiveness
- Understanding change process
- Assessing cost effectiveness
Developing an intervention

- Develop interventions systematically
  - Use best available evidence, ideally from systematic review(s)
  - Develop theoretical understanding of process of change
  - Model process and outcomes

- Implementation considerations should guide all phases
  - “Would it be possible to use this?”

- An iterative not a linear process

- May be useful to follow a formal framework
An example: 6SQuID

- Breaks the development process into 6 steps:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Define and understand the problem and its causes</td>
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<tr>
<td>2</td>
<td>Clarify which causal factors have greatest scope for change</td>
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<tr>
<td>3</td>
<td>Identify how to bring about change: what is the change mechanism?</td>
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<td>4</td>
<td>Identify how to deliver change mechanism</td>
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<td>5</td>
<td>Test and refine the intervention on a small scale</td>
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<tr>
<td>6</td>
<td>Collect sufficient evidence of effectiveness to justify rigorous evaluation/implementation</td>
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</tbody>
</table>

Wight D et al. Six steps in quality intervention development (6SQuID), In press: *Journal of Epidemiology and Community Health*
Feasibility and piloting

Feasibility and piloting
- Testing procedures
- Estimating recruitment and retention
- Determining sample size

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Feasibility and pilot studies

Research done before a main study to answer the question “Can this study be done?”. They are used to

- estimate important parameters that are needed to design the main study, e.g.
  - variability of the outcome measure, which may be needed to estimate sample size;
  - willingness of participants to be randomised/willingness of clinicians to recruit participants;
  - Feasibility of implementing the intervention in the study settings;
  - number of eligible patients, carers or other appropriate participants with target population;
  - follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs for cluster trials, etc.

- Test whether the procedures for the main study (recruitment, randomisation, treatment, follow-up, etc) all work together
Evaluating outcomes

Feasibility and piloting
Testing procedures
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Assessing effectiveness

Choosing an appropriate evaluation design

- Randomised trials are often needed, but there are alternatives to the classical parallel group RCT, e.g:
  - Cluster randomisation
  - Stepped wedge designs
  - Preference (complete cohort) designs
  - Randomised consent
- With the exception of cluster RCTs these are rare, but stepped wedge designs may allow randomisation to be built into large scale implementation and deserve to be more widely used.
- What if randomisation is not possible?
Alternatives to randomised trials

• Using ‘natural’ rather than planned variation in exposure
  • How large is the change?
  • Is it abrupt or gradual?
  • How large is the population affected?
  • Does it affect the whole population or a subset?
  • How readily can individuals manipulate their own exposure?

• Size and nature of effects
  • How large are they?
  • How rapidly do they follow change in exposure?

➤ Rapid large effects are more readily detectable, but natural experiments can be used to detect more subtle effects so long as there is a suitable source of variation in exposure
Methods for natural experiment-based studies

- For large and/or rapid effects, simple approaches may be adequate

Fig 1 Suicide rates in Sri Lanka 1880-2005

- All class I pesticides banned 1995
- Parathion / methyl parathion banned 1984
- Endosulfan banned 1998
- First case of pesticide poisoning reported, 1954

Methods for natural experiment-based studies

- If the effects are smaller or more gradual, more complicated designs will usually be needed to deal with selection and other biases
  - By design
    - Multiple pre-post measures
    - Multiple exposed/unexposed groups
  - In analysis
    - Selection on ‘observables’
      - Matching
      - Multivariate adjustment
      - Propensity scores
    - Selection on ‘unobservables’
      - Difference in differences
      - Instrumental variables
      - Regression discontinuity
  - Testing
    - Mediators of change
    - Non-equivalent dependent variables
    - Sensitivity analysis
    - Combining methods and comparing results
Understanding the change process

• Why is process evaluation important?
  ➢ Failure or unanticipated outcomes are common with complex interventions
  ➢ Intervention failure or implementation failure?
  ➢ It is valuable to distinguish such outcomes, and to understand how interventions achieve their effects

• Process evaluation can
  ➢ Identify relevant features of context, and how they interact with the intervention
  ➢ Provide insights into mechanisms of impact
  ➢ Explore intervention delivery: was it delivered as intended?
Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation).

Source: Graham F Moore et al. BMJ 2015;350:bmj.h1258
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MRC/CSO Social and Public Health Sciences Unit, University of Glasgow.
Implementation

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Reporting

- Full reporting is essential
- Important to include a detailed description of the intervention and the context
- Wide-ranging set of guidelines now available

‘Much healthcare research is wasted because its findings are unusable.’

www.equator-network.org
Influencing decision-makers

- Implementation is a behaviour change problem!
- Ask research questions that matter to patients, practitioners and policy-makers
- Involve stakeholders in planning and conducting the research
- Provide evidence in an integrated and graded way
- Identify the elements relevant to decision-making
- Make recommendations as specific as possible
- Take a multifaceted approach
- Exploit opportunities for long-term follow-up
Summary

Adequate, rigorous assessment of complex interventions requires careful development work, appropriate choice of evaluation design, incorporation of process measures, and a concern for implementation throughout the whole process.

There are alternatives to the classical RCT – but all methods have drawbacks, and the choice should be made after a careful consideration of the whole range of options.
References

• MRC guidance on Complex interventions
  [http://www.bmj.com/content/337/bmj.a1655?ijkey=9c59ba1e6df770cfdd868ed58f1580ba7662318b&keytype2=tf_ipsecsha](http://www.bmj.com/content/337/bmj.a1655?ijkey=9c59ba1e6df770cfdd868ed58f1580ba7662318b&keytype2=tf_ipsecsha)

Process evaluation
  [http://www.bmj.com/content/350/bmj.h1258.full.pdf+html](http://www.bmj.com/content/350/bmj.h1258.full.pdf+html)

Natural experiments
  [www.mrc.ac.uk/naturalexperimentsguidance](http://www.mrc.ac.uk/naturalexperimentsguidance)
  [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3796763/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3796763/)