Developing and Evaluating Complex Interventions: New Guidance

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Outline

- What is a complex intervention?
- A phased approach
  - Development
  - Feasibility and piloting
  - Evaluation
  - Implementation
- Recent developments
- Forthcoming events

The UK Medical Research Council guidance

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Developing and evaluating complex interventions:
new guidance

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www.mrc.ac.uk/complexinterventionsguidance

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RESEARCH METHODS & REPORTING

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

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New MRC guidance on evaluating complex interventions

Clarifying what interventions work by researching how and why they are effective

It is eight years since the publication of the Medical Research Council's original report on methods for developing and evaluating randomised controlled trials for complex interventions.[1] Although presented as a "discussion document," the MRC framework and its companion paper have often been cited as authoritative guidance on methods. Other people, however, have found the definition of the complexity of interventions narrow and misconceived,[2] and the suggested phases for developing and evaluating complex interventions as unhelpfully similar to commercial drug evaluation. However, the report can probably be credited with stimulating much of the ongoing debate about appropriate methods and concepts in healthcare evaluation—particularly when the intervention of interest is hard to define, hard to evaluate (using conventional experimental methods), or just hard to explain.

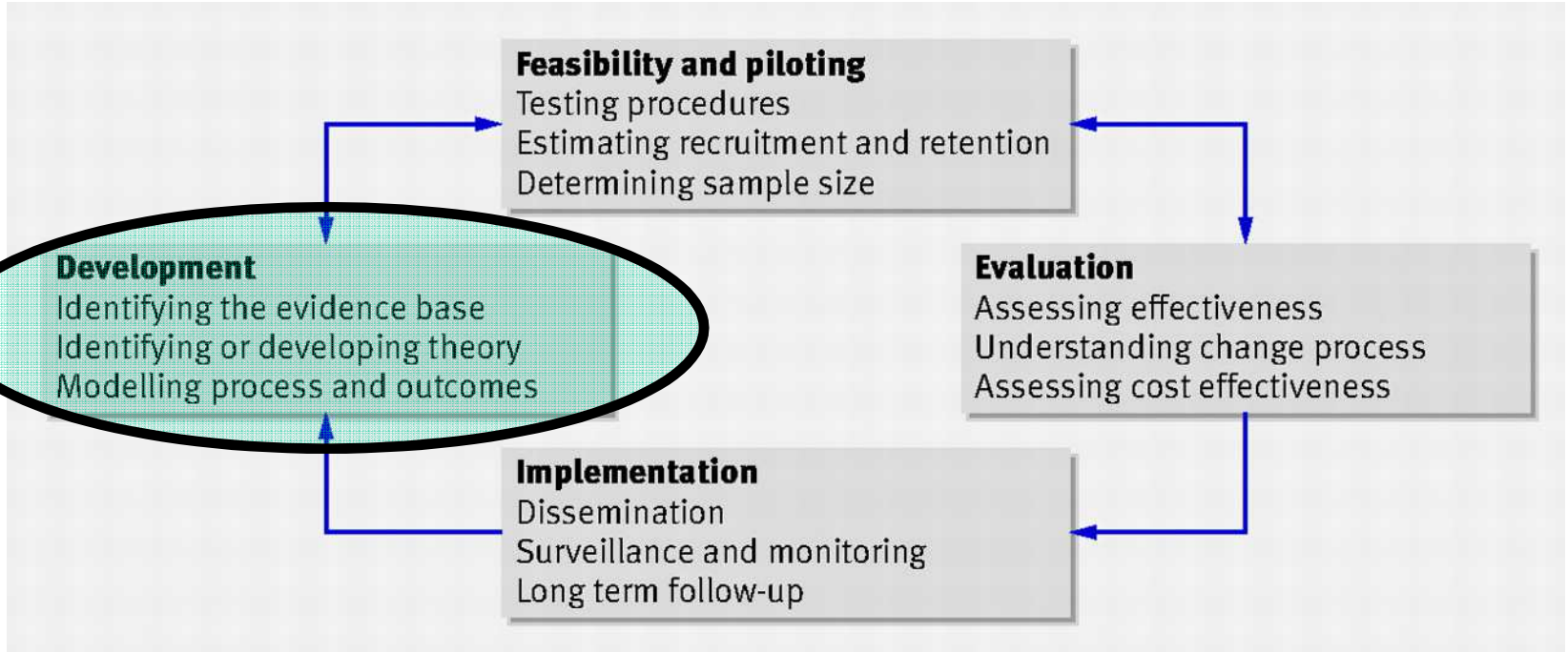
The MRC has now updated its original report (www.mrc.ac.uk/complexinterventionsguidance) to reflect recent developments in methods and lessons learnt in applying them. The guidance is summarised in the linked article by Craig and colleagues (doi:10.1136/bmj.a1655).[3] It has a broader scope than the original version—it covers observational methods as well as randomised controlled trials and implementation as well as the development and evaluation of interventions; it also has a broader definition of complex interventions beyond the core dimension of having multiple components.

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



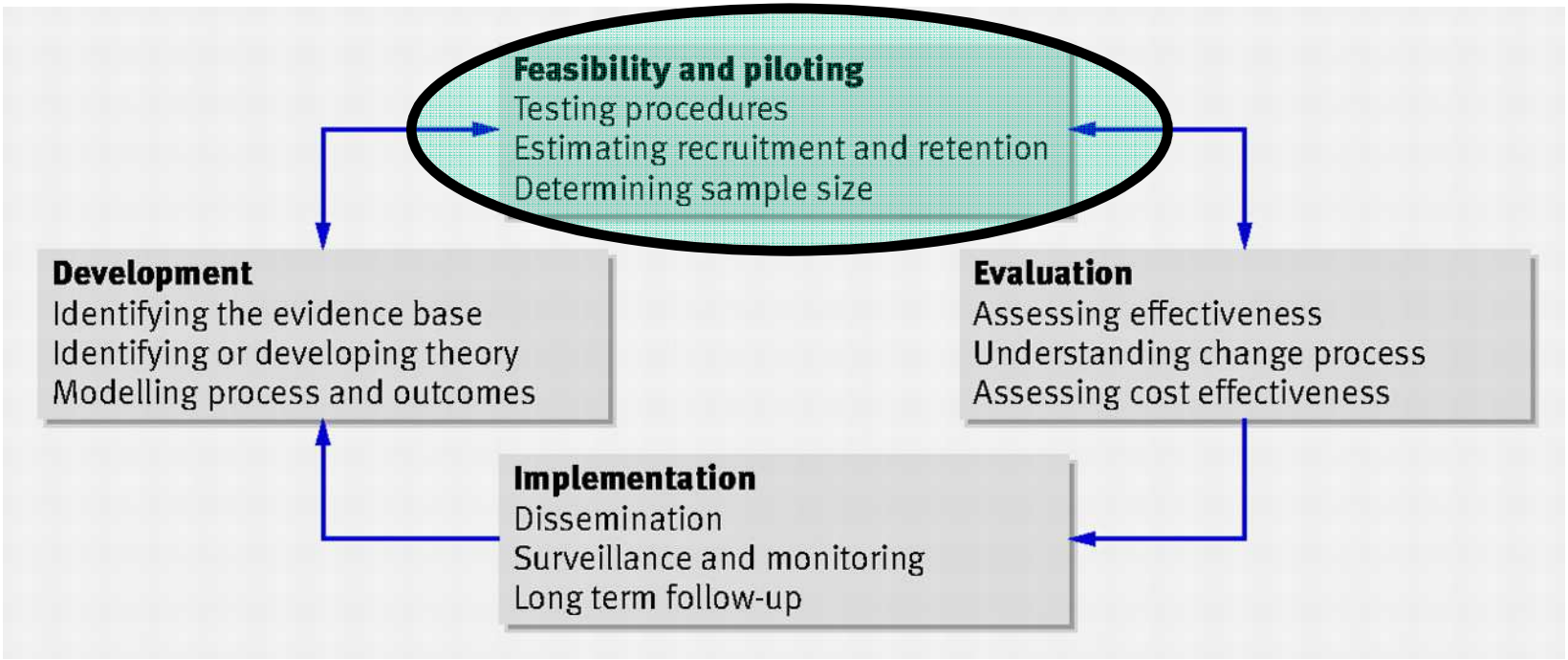
Developing an intervention

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

- An iterative, not necessarily linear process
  - May go “back” to an earlier phase at any point

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

Feasibility and piloting



Feasibility 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.

- standard deviation of the outcome measure, which may be needed to estimate sample size;
- willingness of participants to be randomised/willingness of clinicians to recruit participants;
- number of eligible patients, carers or other appropriate participants;
- characteristics of the proposed outcome measure
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs for cluster trials, etc.

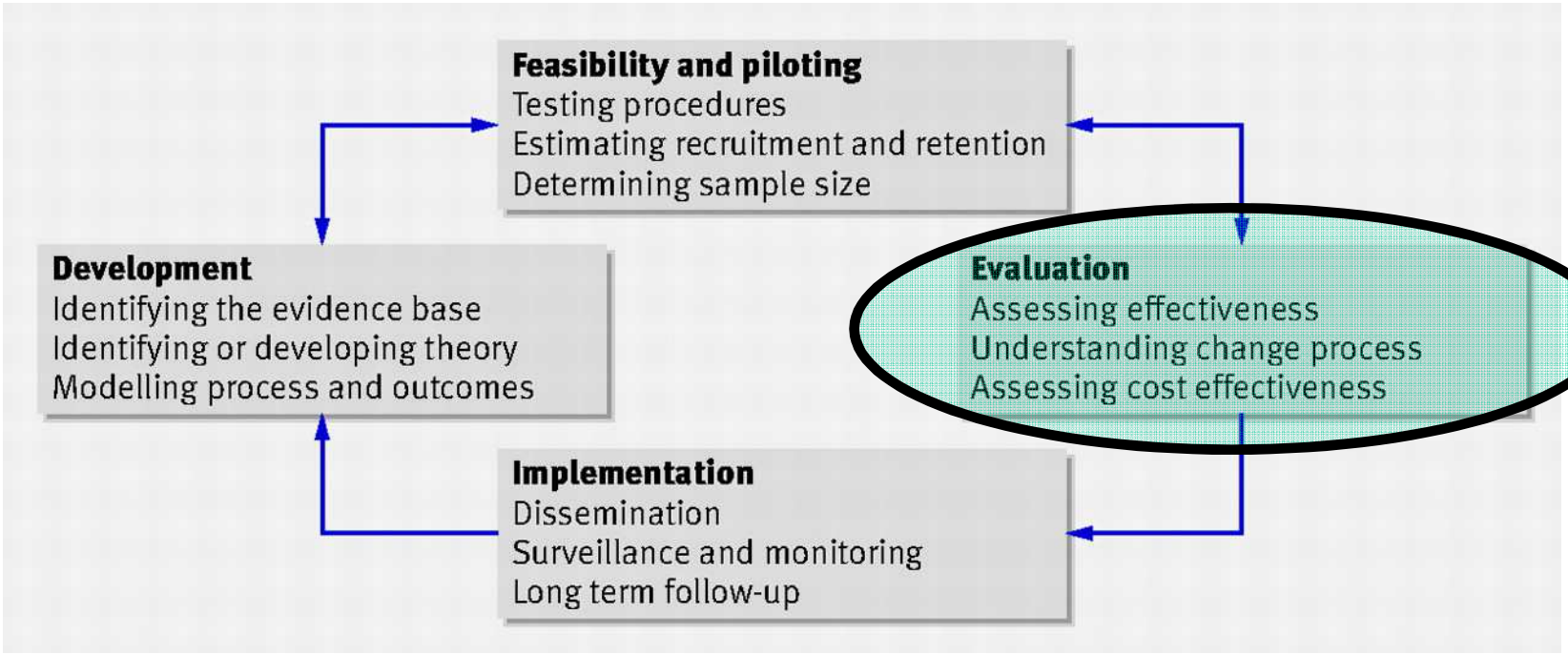
Pilot studies

A version of the main study that is run in miniature to test whether the components of the main study can all work together

Focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly

A pilot will resemble the main study in many respects, including an assessment of the primary outcome.

Evaluation


Feasibility and piloting
Testing procedures
Estimating recruitment and retention
Determining sample size
Development
Identifying the evidence base
Identifying or developing theory
Modelling process and outcomes
Evaluation
Assessing effectiveness
Understanding change process
Assessing cost effectiveness
Implementation
Dissemination
Surveillance and monitoring
Long term follow-up

Assessing effectiveness

Choosing an appropriate evaluation design

- Trials are the gold standard, but there ARE alternatives to the classical RCT, e.g:
  - Cluster randomisation
  - Stepped wedge designs
  - Preference designs
  - Randomised consent
  - Non-randomised designs

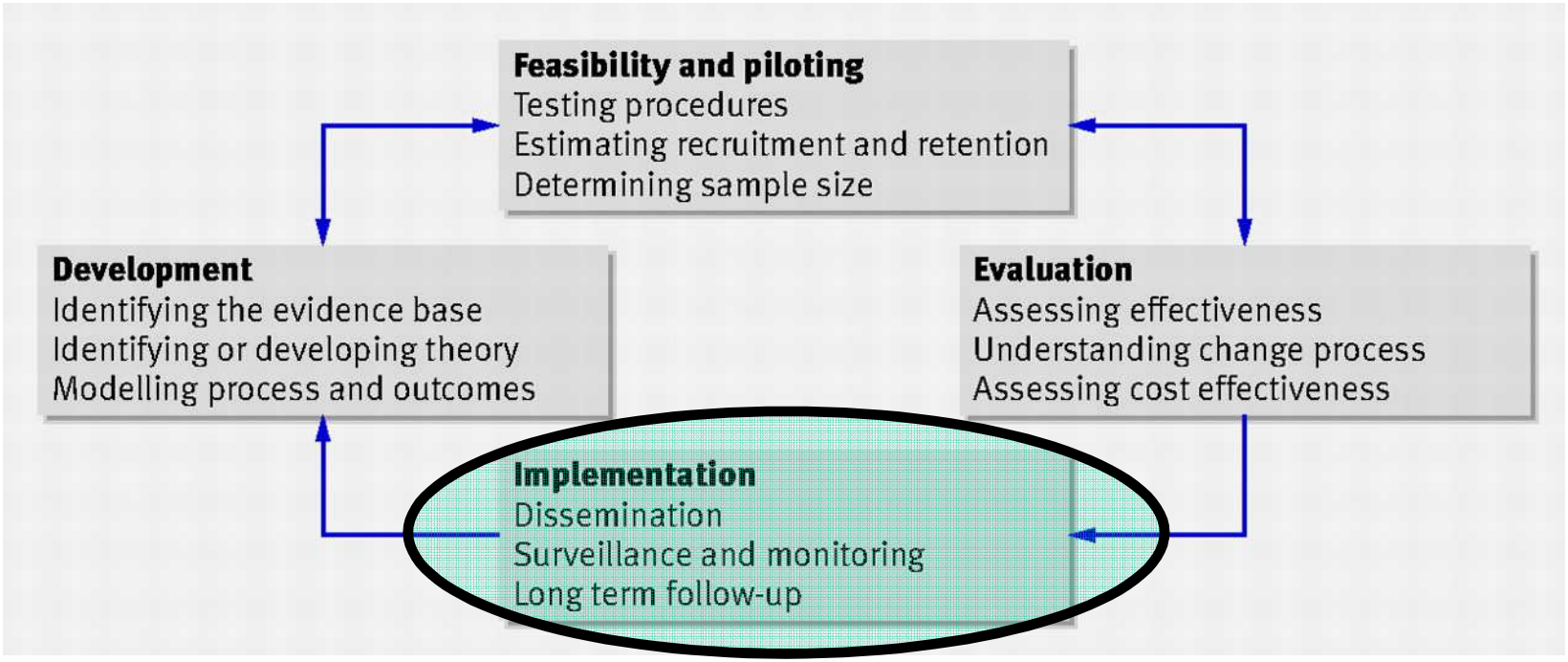
- With the exception of cluster RCTs these are rare, but stepped wedge designs allow randomisation to be built into large scale implementation and deserve to be more widely used.

Understanding the change process

- Failure or unanticipated outcomes are common with complex interventions
- Intervention failure or implementation failure?

- Process evaluation can help to distinguish such outcomes, and to understand how interventions achieve their effects

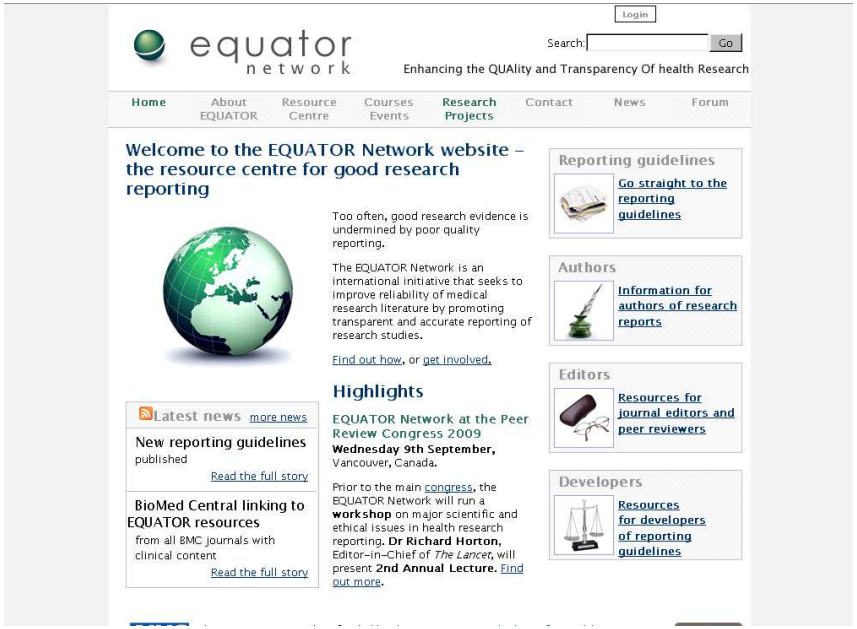
Implementation



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.'



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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 made after a careful consideration of the whole range of options.

Recent developments

- MRC guidance on
  - Process evaluation
    - http://decipher.uk.net/wp-content/uploads/2014/11/MRC-PHSRN-Process-evaluation-guidance.pdf
  - Natural experiments
    - www.mrc.ac.uk/naturalexperimentsguidance
    - Craig P et al., Using natural experiments to evaluate population health interventions: new Medical Research Council Guidance. *Journal of Epidemiology and Community Health*. 2012;66:1182–1186.
- Reporting guidelines for
  - Pilot and feasibility studies
    - http://www.equator-network.org/wp-content/uploads/2009/02/Nature-Medicine.pdf
  - Social and psychological interventions
    - http://www.spi.ox.ac.uk/research/site/consort-spi/home.html
  - Implementation studies
    - http://www.equator-network.org/wp-content/uploads/2013/09/Proposal-for-reporting-guidelines-of-Implementation-Research-StaRI.pdf

Forthcoming …

http://store.exeter.ac.uk/browse/extra_info.asp?compid=1&modid=2&catid=51&prodid=987