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Developing and Evaluating Complex Interventions

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The UK Medical Research Council guidance



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.a1653).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.

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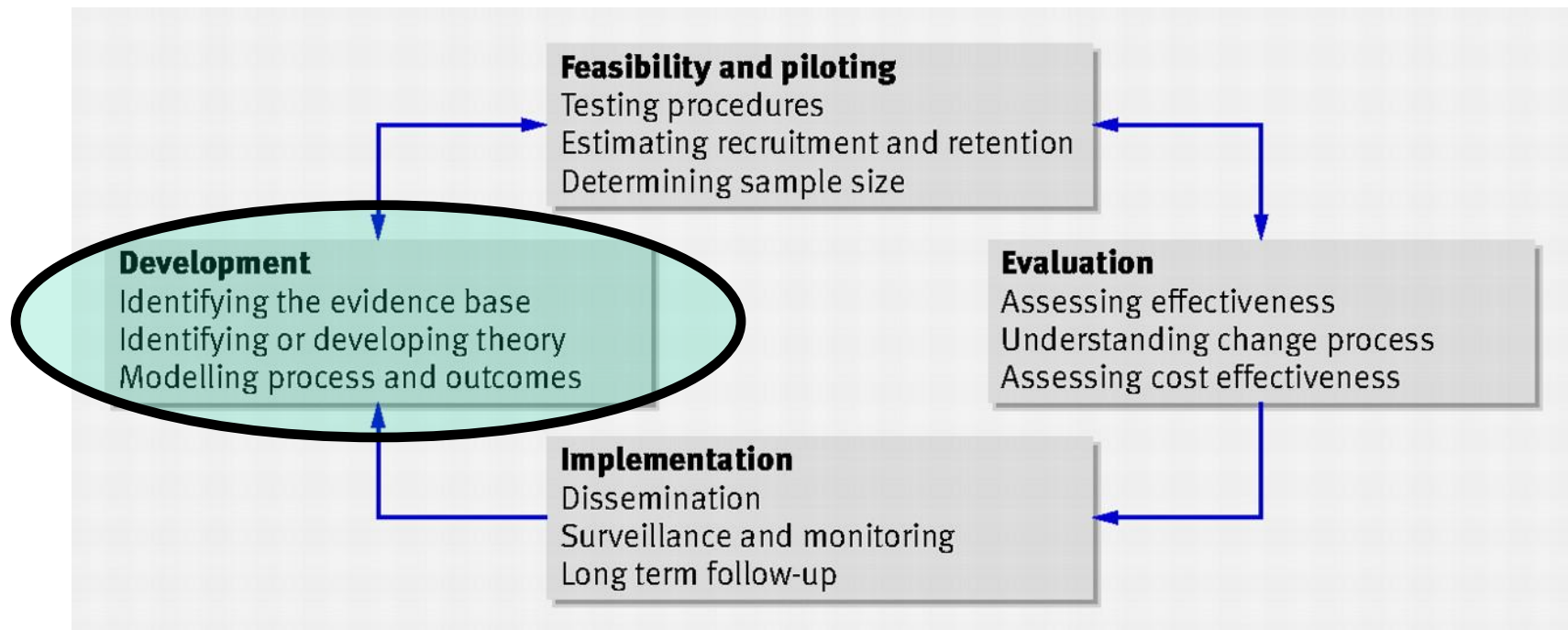
Outline

- 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

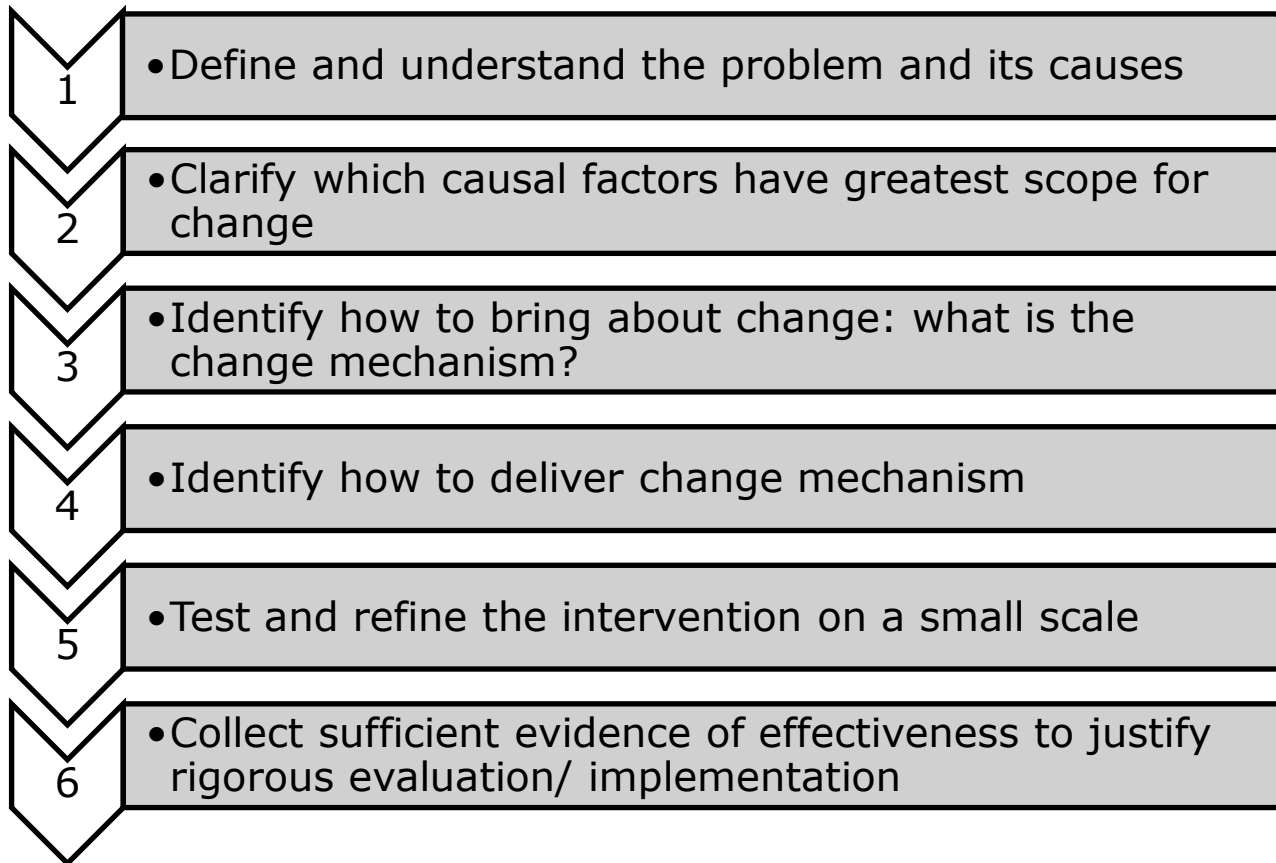


Developing an intervention

- 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

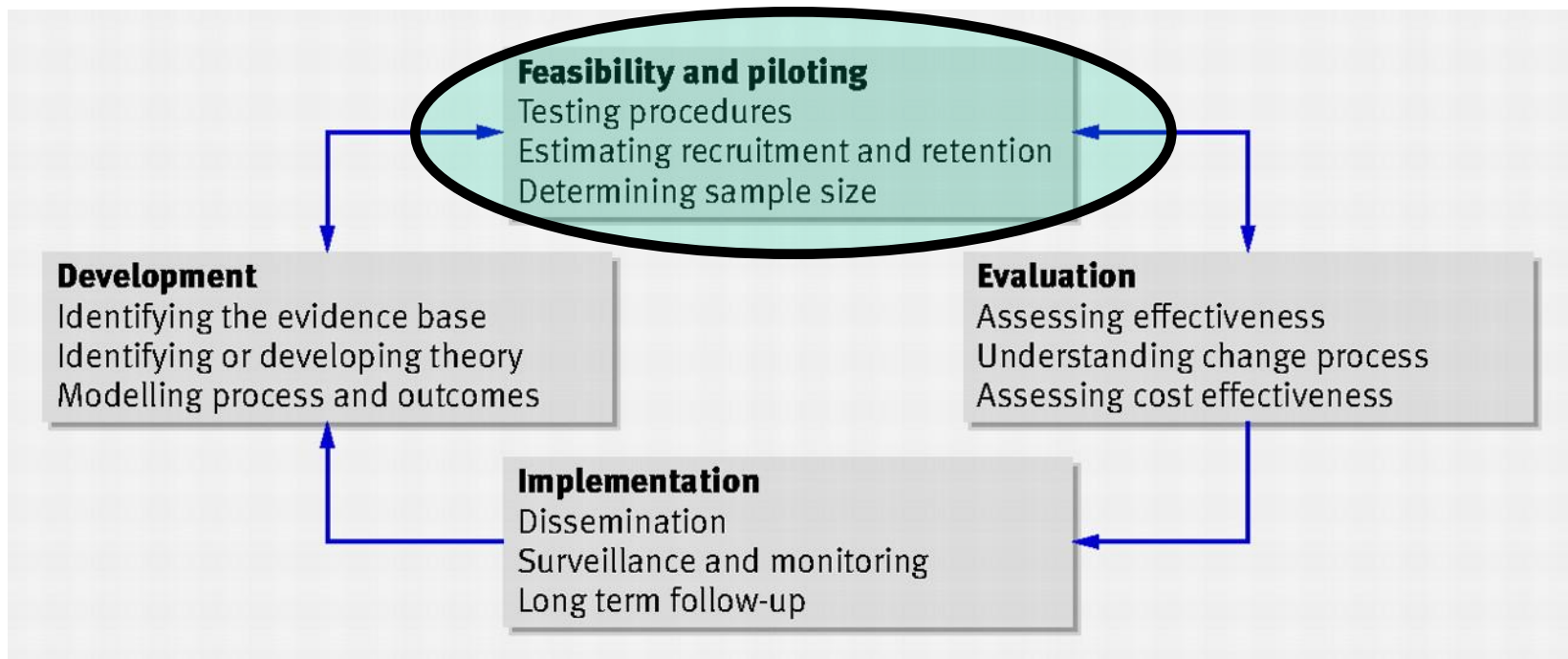
An example: 6SQuID

- Breaks the development process into 6 steps:



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

Feasibility and piloting

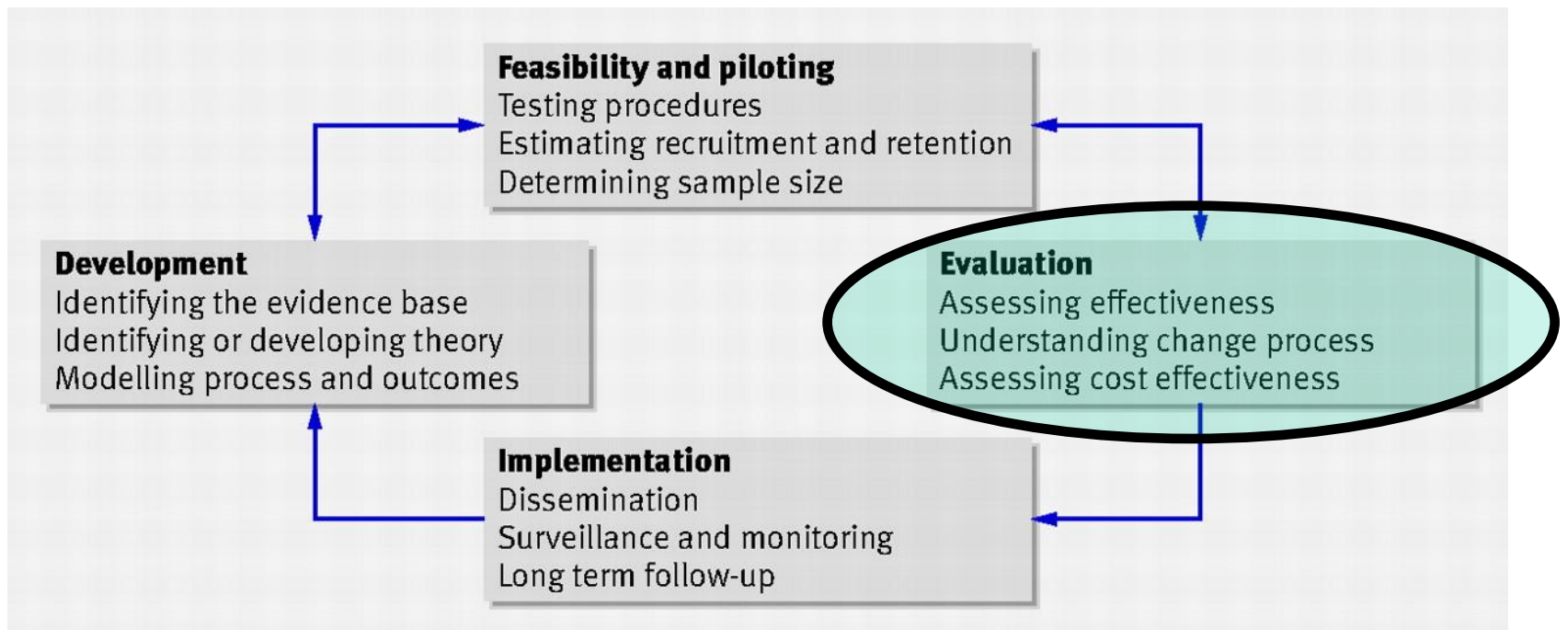


Feasibility and pilot studies

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



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?

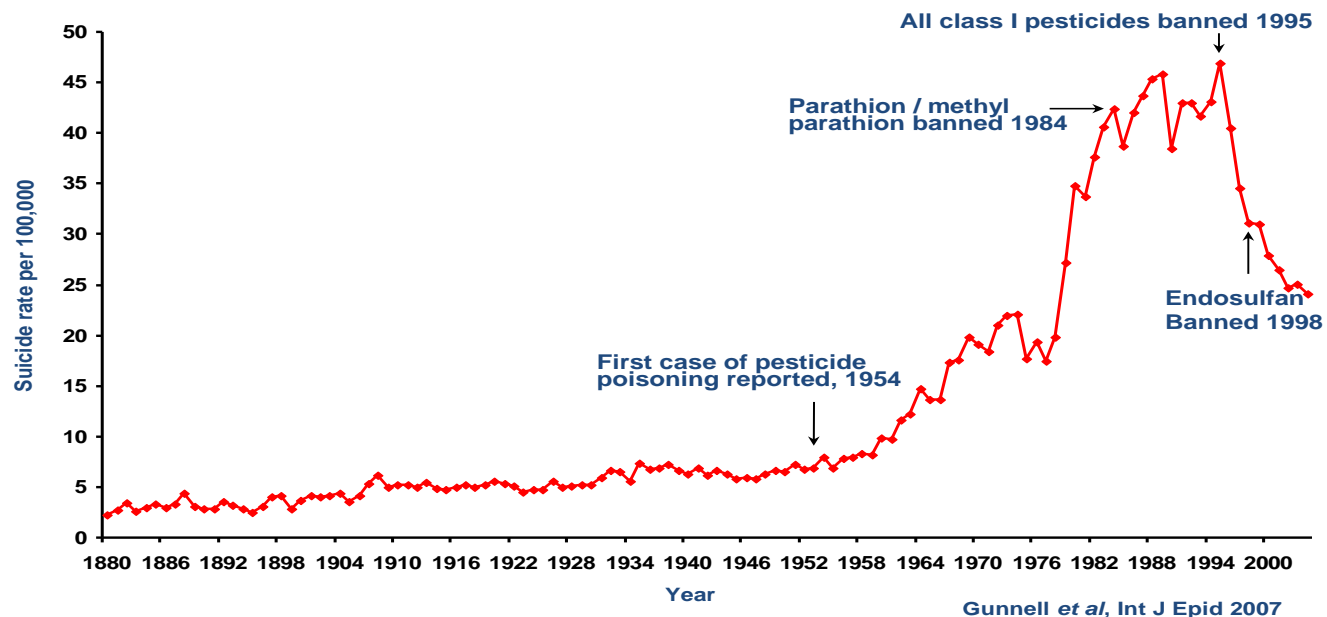
Alternatives to randomised trials

- 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



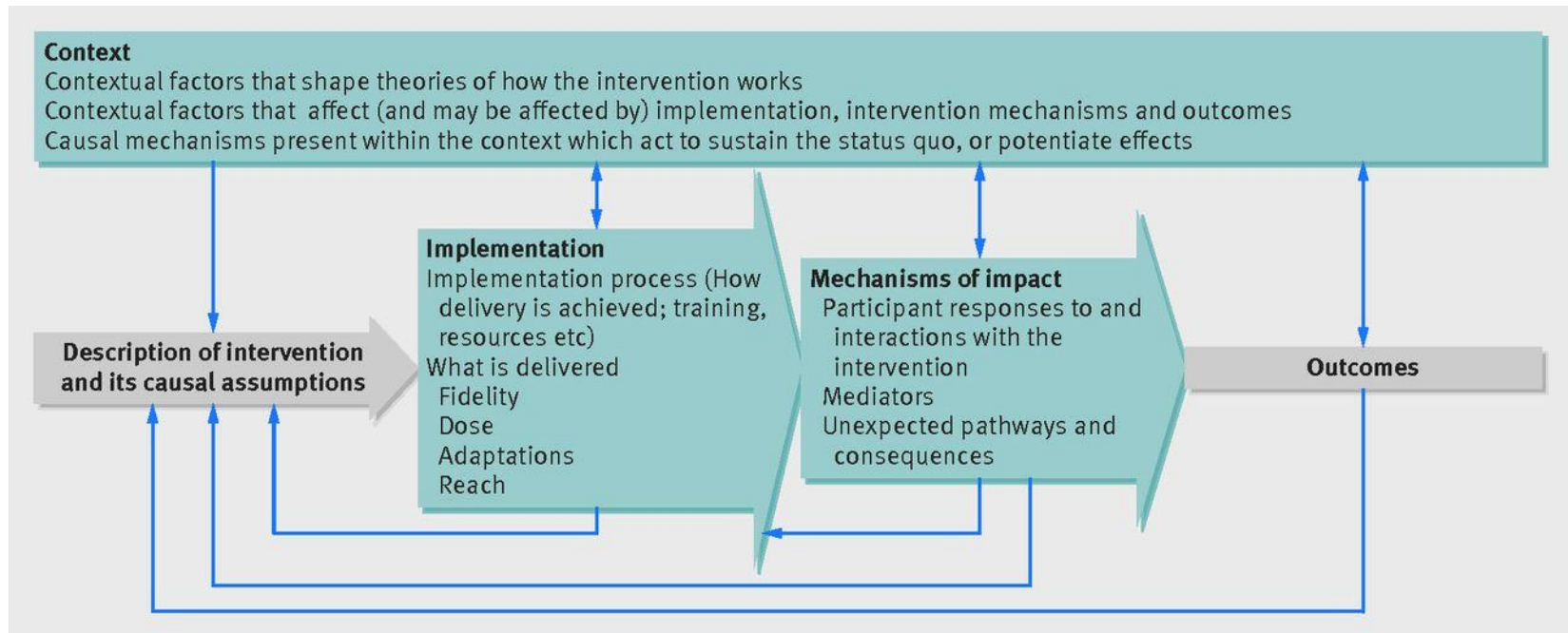
Methods for natural experiment-based studies

- 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?

MRC guidance on process evaluation

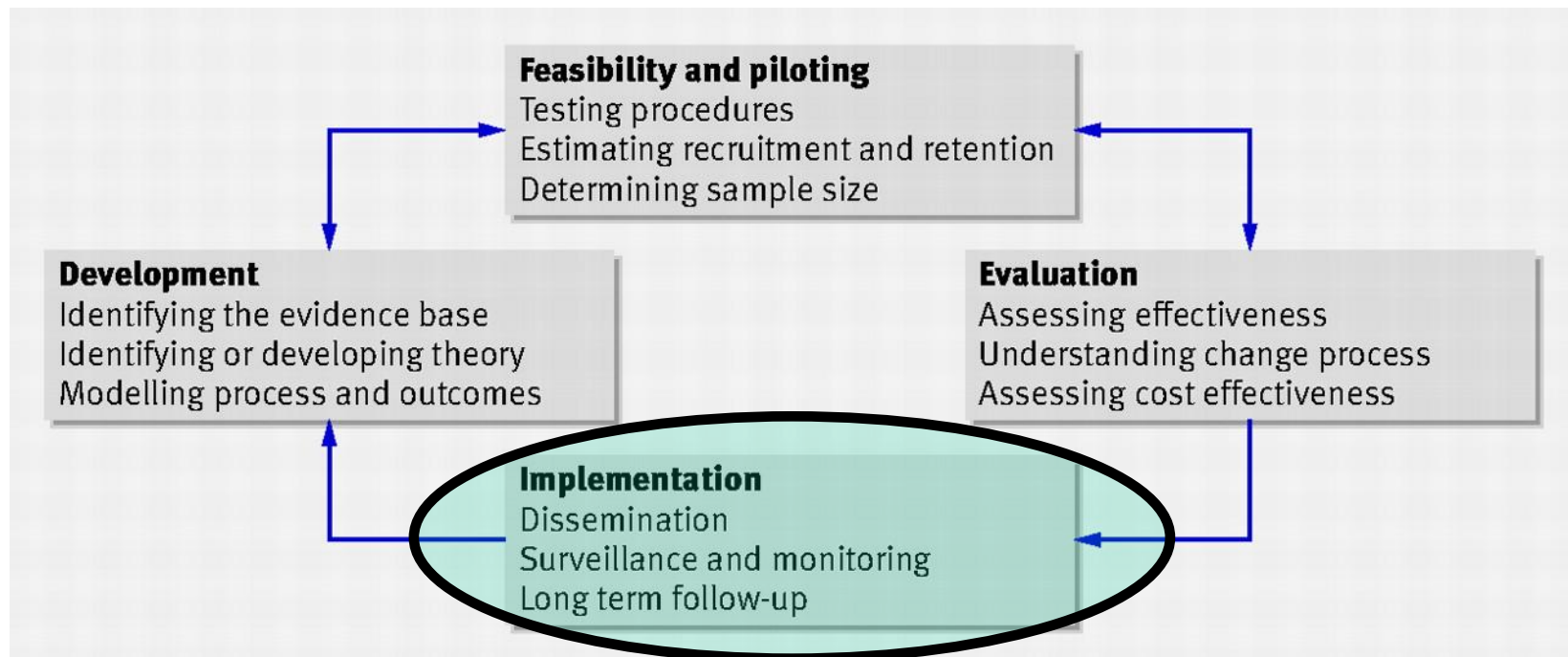


Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation).

Source: Graham F Moore et al. *BMJ* 2015;350:bmj.h1258
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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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EQUATOR Network at the Peer Review Congress 2009
Wednesday 9th September, Vancouver, Canada.

Prior to the main congress, the EQUATOR Network will run a **workshop** on major scientific and ethical issues in health research reporting. **Dr Richard Horton**, Editor-in-Chief of *The Lancet*, will present **2nd Annual Lecture**. [Find out more.](#)

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.mrc.ac.uk/documents/pdf/complex-interventions-guidance/>

http://www.bmj.com/content/337/bmj.a1655?ijkey=9c59ba1e6df770cfdd868ed58f1580ba7662318b&keytype=tf_ipsecsha

Process evaluation

<http://www.populationhealthsciences.org/Process-Evaluation-Guidance.html>

<http://www.bmj.com/content/350/bmj.h1258.full.pdf+html>

Natural experiments

www.mrc.ac.uk/naturalexperimentsguidance

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3796763/>