CECAN Webinar:

An update of the Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions

Wednesday 15th June 2022, 13:00 – 14:00 BST

Presenters: Kathryn Skivington & Laurence Moore, MRC/CSO Social and Public Health Sciences Unit, University of Glasgow (hosted by Corinna Elsenbroich)

Welcome to our **CECAN Webinar.**

All participants are muted. Only the Presenters & CECAN Host can speak. The webinar will start at **13:00 BST.**

Kathryn and Laurence will speak for around 45 minutes and will answer questions at the end.

Please submit your questions at any point during the webinar via the Q&A box in the Zoom webinar control panel.

Today's webinar will be recorded and made available on the CECAN website.

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MRC/CSO Social and Public Health Sciences Unit

Developing and Evaluating Complex Interventions – A Framework

15/06/22

Kathryn Skivington & Laurence Moore

NIHR | National Institute for Health and Care Research

Education And Debate

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BMJ 2000 ; 3

Cite this as: BM

Article

Michelle Campb

Ray Fitzpatrick,

Andrew Haines,

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BMJ 2008;337:a1655 doi: 10.1136/bmj.a1655 (Published 29 September 2008)

RESEARCH METHODS & REPORTING

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professor[4], Irwin Nazareth *dire*

Check for updates

A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

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The UK Medical Research Council's widely used guidance for developing and evaluating complex interventions has been replaced by a new framework, commissioned jointly by the Medical Research Council and the National Institute for Health Research, which

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of social and economic policy that have consequences for health. Such interventions are delivered and evaluated at different levels, from individual to societal levels. Examples include a new surgical procedure, the redesign of a healthcare programme, and a change in welfare policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on

Intervention

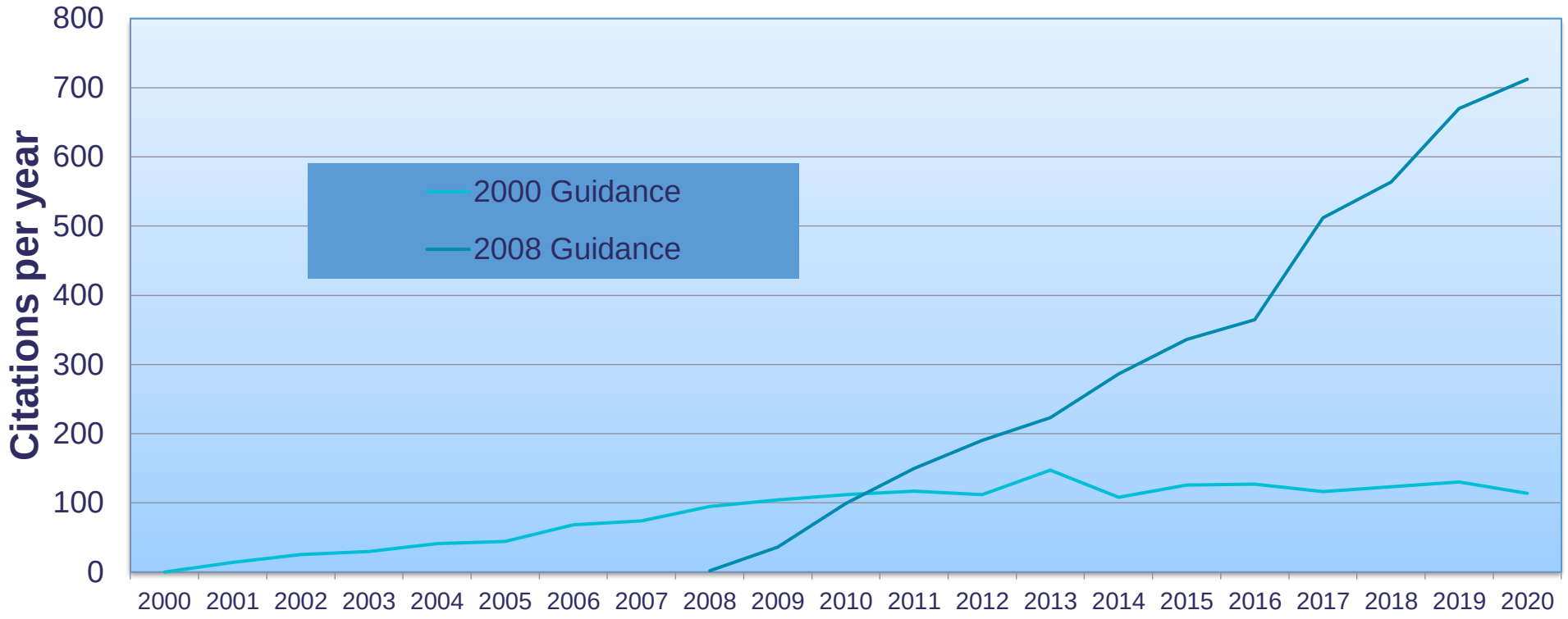
- An “action or programme that aims to bring about identifiable outcomes”
  - (Rychetnik L et al. http://dx.doi.org/10.1136/jech.2003.011585)

- This term is used for everything from medical treatment to changes in policy; it could be something developed and implemented by the research team, or something beyond the researchers’ control.

Why did we update the MRC complex intervention framework?

1. To update the definition of complex interventions, highlighting the relationship between the intervention and its context
2. To shift focus to the usefulness of evidence as the basis for determining research perspective and questions
3. To emphasise the use(fulness) of diverse research perspectives
4. To give due attention to intervention adaptation and to interventions developed outside of research teams
5. To highlight various important aspects of complex intervention research that are not always necessarily given due focus

Why did we update the MRC complex intervention framework?



Based on data from Web of Science (accessed 28/09/2021)

How did we go about the update?

- Gap analysis
- Expert workshop
- Open consultation
- Rounds of peer review
- Scientific Advisory Group

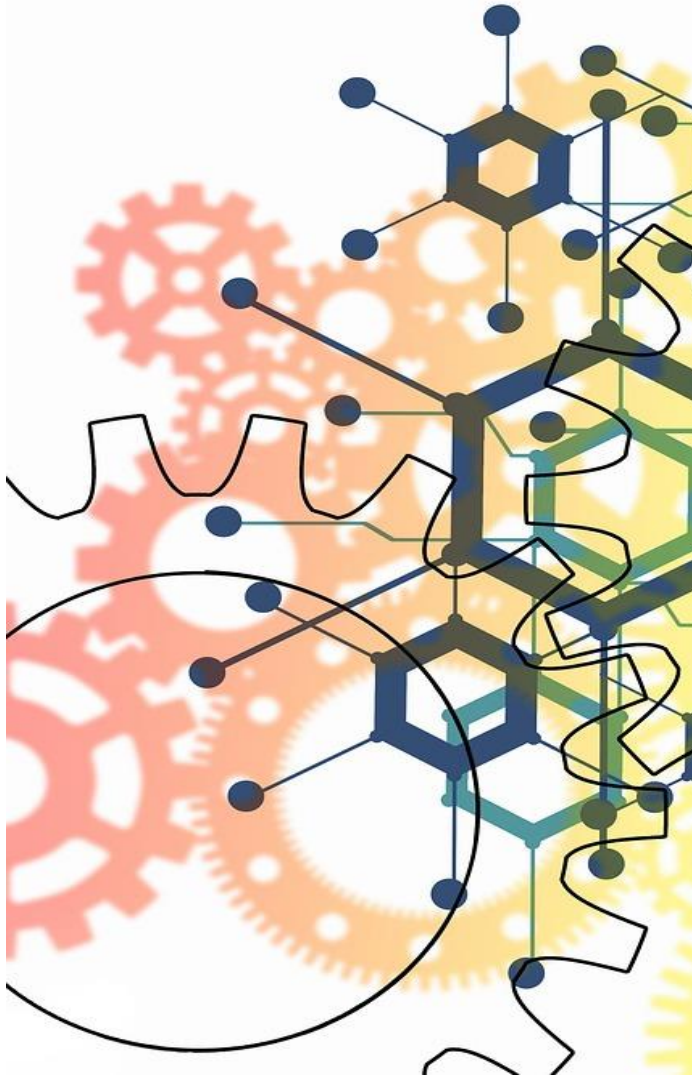
1. To update the definition of complex interventions, highlighting the relationship between the intervention and its context

Definition of ‘complex intervention’

- Some dimensions of complexity (Craig 2006):
  - Number of and interactions between components within the experimental and control interventions.
  - 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.

What makes an intervention complex?

- The updated framework states that complexity arises through:
  - characteristics of the intervention itself; and/or
  - interactions between the intervention and its context



Context

- *A*ny feature of the circumstances in which an intervention is conceived, developed, evaluated, and implemented.
- Effects of an intervention may be highly context dependent
- Context is dynamic and multi-dimensional

Source: Dflock, CC BY-SA 4.0 <https://creativecommons.org/licenses/by-sa/4.0>, via Wikimedia Commons, https://commons.wikimedia.org/wiki/File:Lucky_Iron_Fish_package.jpg

Made locally, low tech

Lasts 5 years

Cause of anaemia

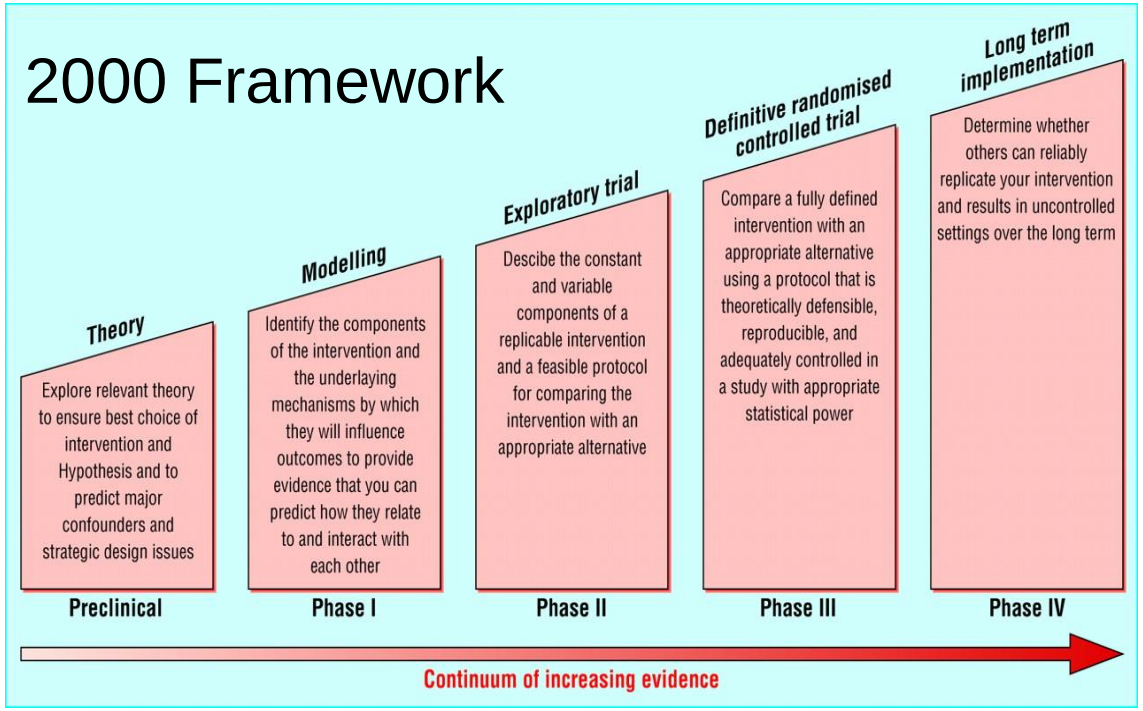
Endemic iron deficiency → Iron fish → Increased iron intake → Anaemia reduced

Cultural symbol

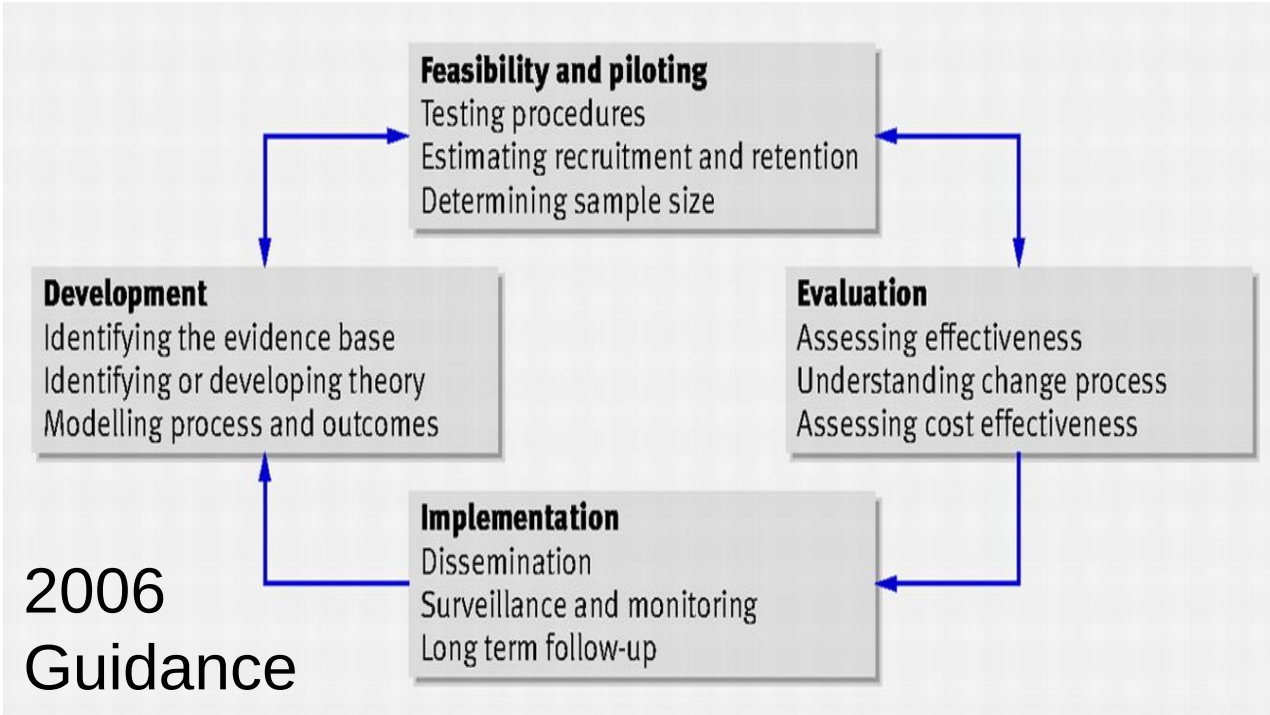
High acceptability & reach

2. To shift focus to the usefulness of evidence as the basis for determining research perspective and questions

2000 Framework



Michelle Campbell et al. BMJ 2000;321:694-696



2006 Guidance

Peter Craig et al. BMJ 2008;337:bmj.a1655

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But…

- Many of the most promising interventions don’t get / can’t be evaluated in this way
  - Service and policy innovation
  - Population level policies

- Even if effective in a controlled trial this is not always replicated
  - Not implementable or encounters implementation failure
  - Not transferable across contexts
  - Wider system effects emerge

Research Waste

- Production line of researcher-led ‘effective interventions’ that are limited in terms of implementation requirements and stakeholder insight, so generally don’t work!

- We need: “less research, better research, and research done for the right reasons” (Doug Altman)

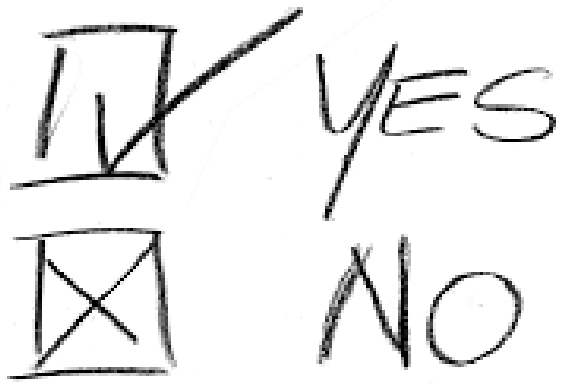
3. To emphasise the use of diverse research perspectives

Perspective	Questions
Efficacy	Does the intervention work, in a tightly controlled experimental setting?
Effectiveness	Does the intervention work, in the kind of setting(s) where it is expected to be implemented in practice?
Theory based	How does the intervention achieve impact, given its interactions with the context in which it is implemented?
Systems	How do system and intervention adapt to one another? Does the intervention change the system in which it is implemented and vice versa?

Efficacy perspective

- An explanatory approach to test causal hypotheses about the outcome(s) generated by the intervention
- Aims for high internal validity
- Control for contextual variation
- Idealised/controlled conditions

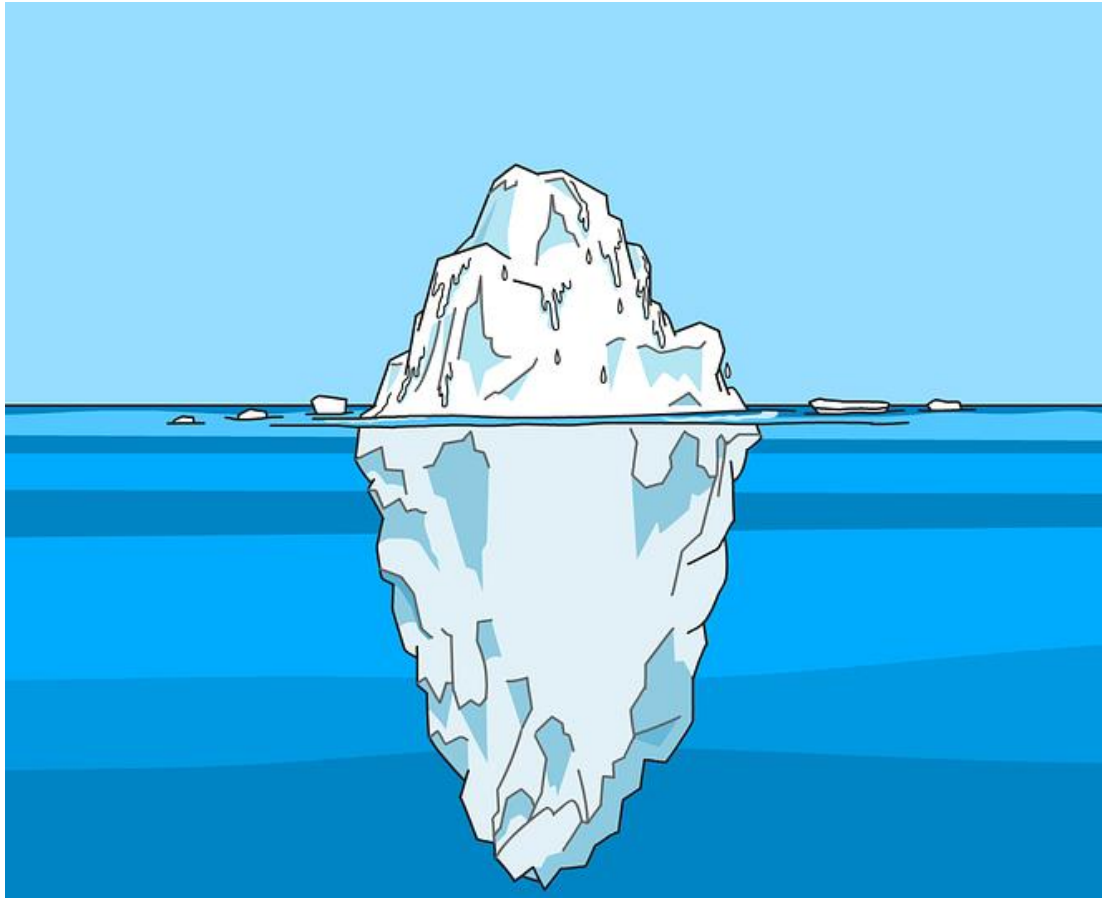
Effectiveness perspective



- Aim to test an intervention in samples and settings representative of those in which the intervention would be implemented in everyday practice
- Average estimates of effect
- Some intervention flexibility

Theory-based perspective

- Various theory-based evaluation approaches
- Theory-driven approaches to explore complexity
- Underpinned by causation
- Developing, testing, updating programme theory



Programme theory

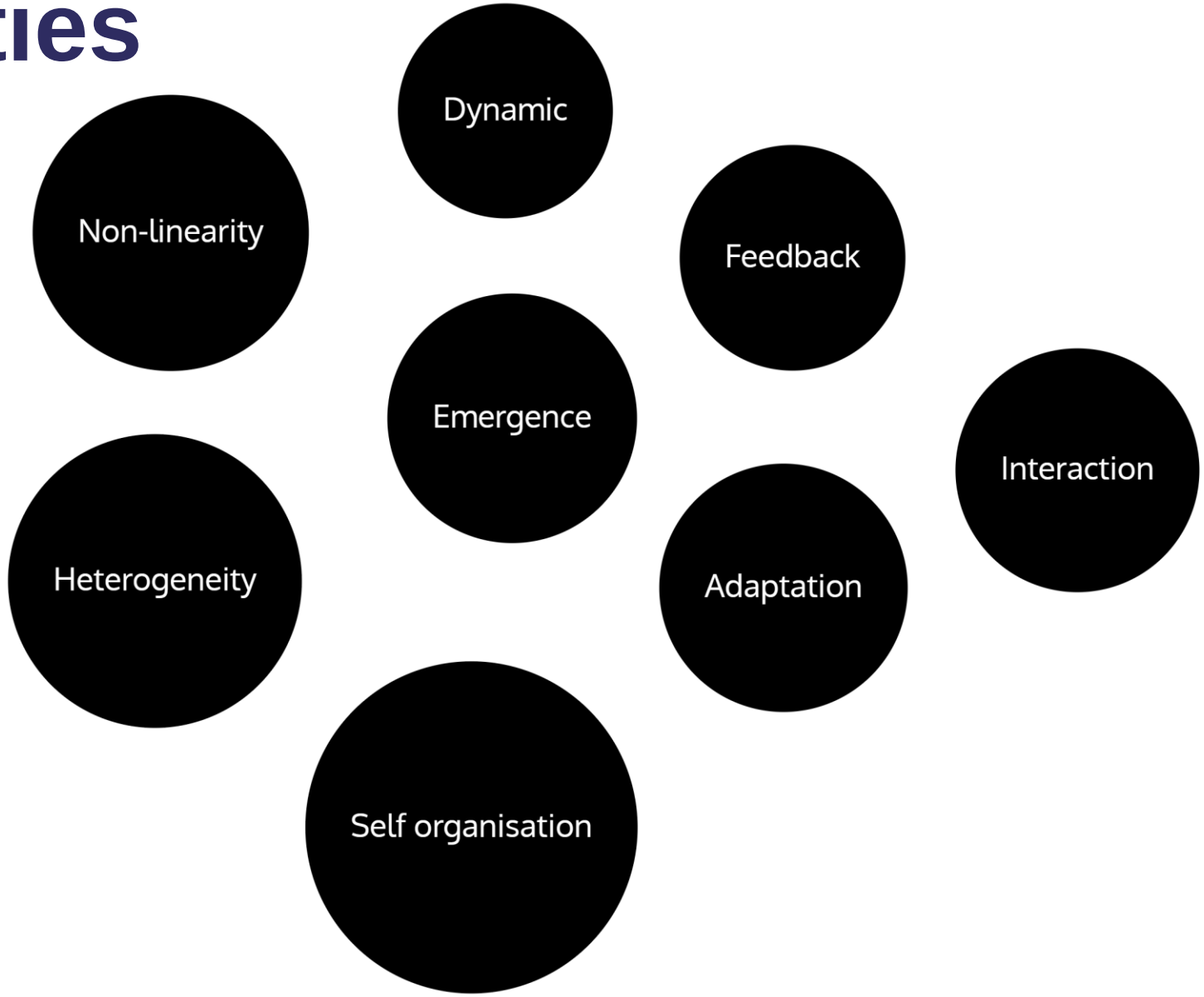
- Describes how an intervention is expected to lead to its effects and under what conditions. It articulates:
  - (1) the key components of the intervention and how they interact;
  - (2) the mechanisms of the intervention;
  - (3) the features of the context that are expected to influence those mechanisms; and
  - (4) how those mechanisms may influence the context

(Funnell SC, Rogers PJ. Purposeful Program Theory. Effective Use of Theories of Change and Logic Models. San Francisco, CA: Jossey-Bass; 2011).

Systems perspective

- A system is a set of things (e.g. cells, people, organisations…) that are interconnected in such a way that they produce their own pattern of behaviour over time (Meadows 2008)
- Systems thinking can help us to understand the interaction between an intervention and the context in which it is implemented in a dynamic way
- It encourages us to think more about the 'bigger picture', e.g. how interventions can impact on different parts of the system, sometimes in unexpected ways, through system properties
- Outcomes emerge from the interaction of the parts of a system in ways that cannot be predicted from the properties of the individual parts; a system cannot be understood by breaking it down to its individual entities and studying each part separately.

System properties

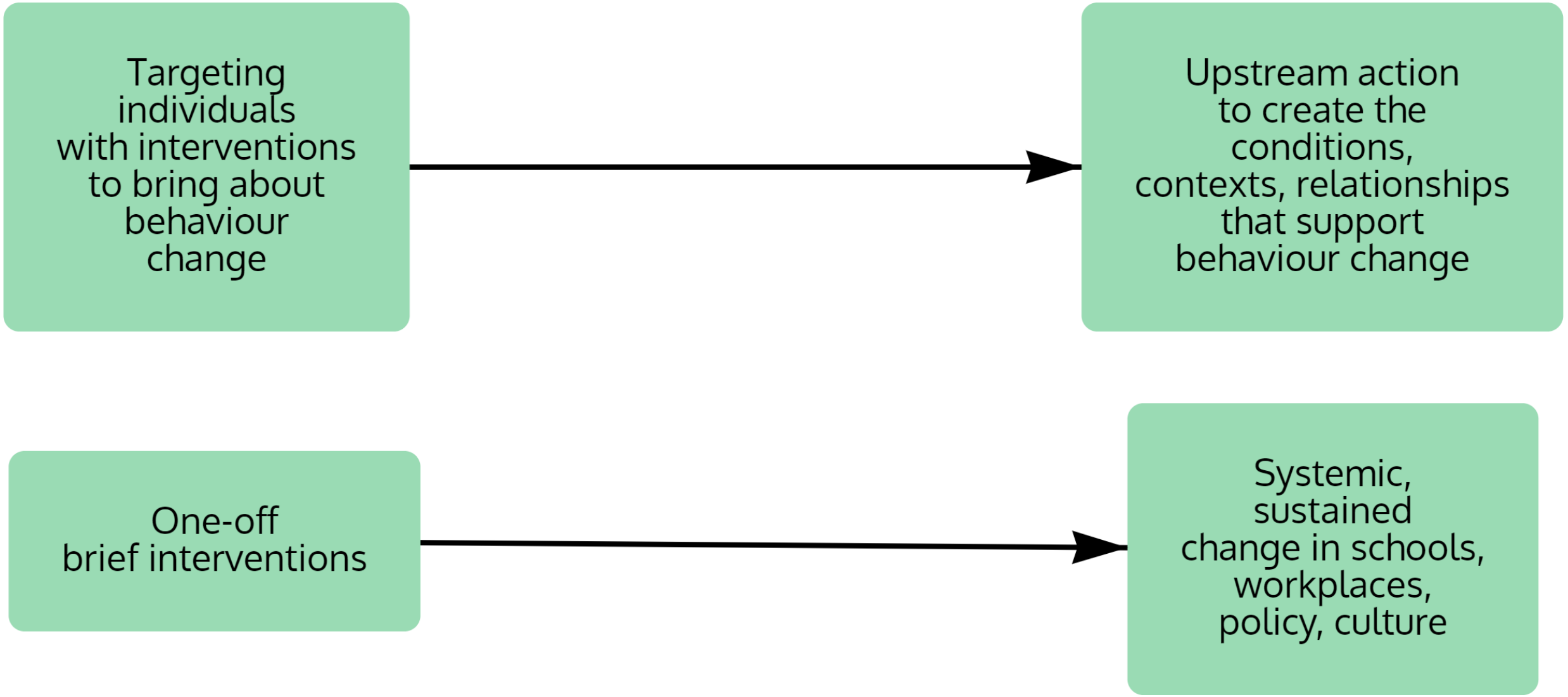


Taking a systems perspective

'Rhetoric urging complex systems approaches is only rarely operationalised in ways that generate relevant evidence or effective policies.' (Rutter et al, 2017)

- Approaching interventions with a systems perspective can encourage:
  - Researchers to develop research questions which take into account the wider contextual factors that influence an intervention.
  - Encourage researchers, funders, practitioners and policy makers to develop, evaluate and implement (whole) systems interventions.

… changes the focus of interventions



… changes the focus of evaluation

Is it effective?

Does it contribute?

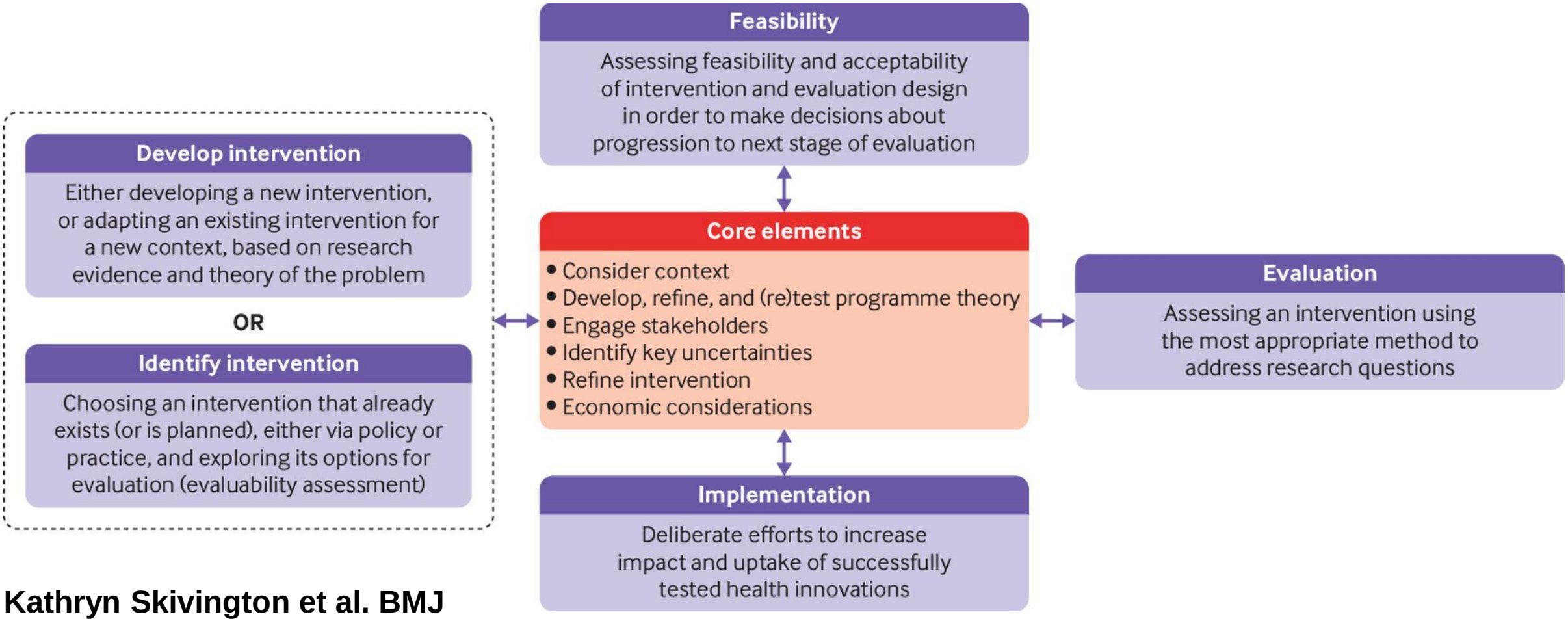
Research Perspectives: Conclusion

- Efficacy; Effectiveness; Theory-based; Systems
- Provide appropriate consideration to all sources of complexity before deciding on a research perspective
- What is already known?
- What is the most important thing to find out?
- Overlapping research perspectives

4. To give due attention to intervention adaptation and to interventions developed outside of research teams

5. To highlight various important aspects of complex intervention research that are not always necessarily given due focus

Framework for developing and evaluating complex interventions



Kathryn Skivington et al. BMJ 2021;374:bmj.n2061

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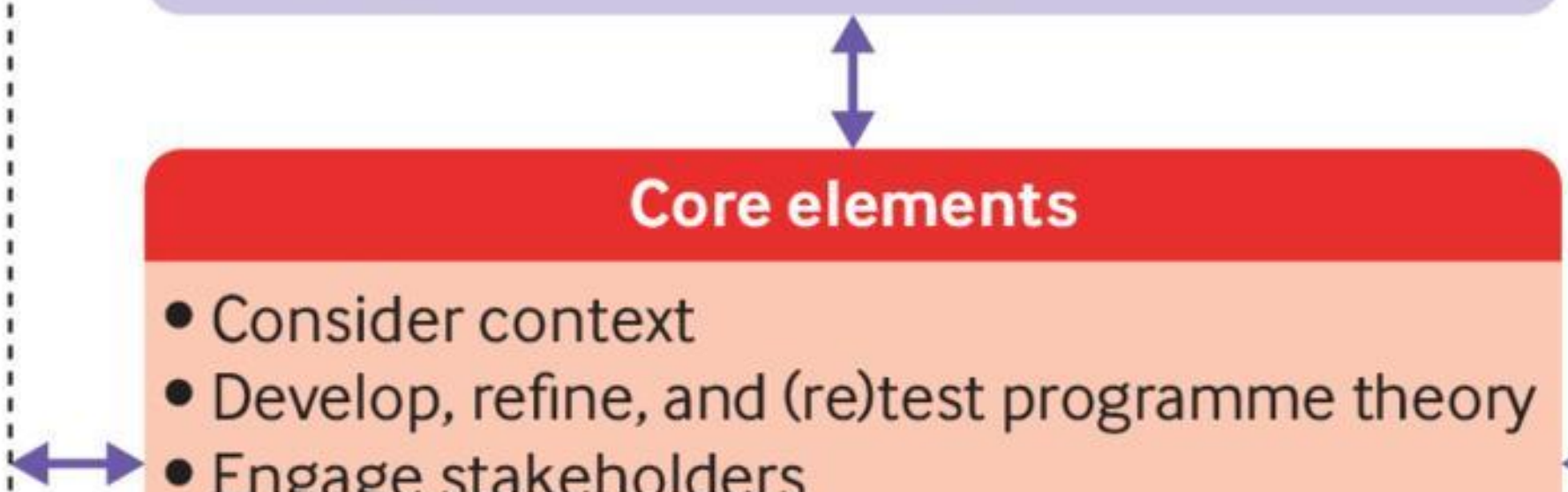
Source: Zero Wait State

in order to make decisions about progression to next stage of evaluation



Core elements

- Consider context
- Develop, refine, and (re)test programme theory
- Engage stakeholders
- Identify key uncertainties
- Refine intervention
- Economic considerations

Implementation

Deliberate efforts to increase

Appendix 6 Checklist for developing and evaluating complex interventions

This checklist is intended as a tool to help researchers prepare funding applications, research protocols and journal publications. It may also help reviewers to assess whether or not the recommendations have been followed.

Item	If NO, please justify. If YES, briefly describe how this has been addressed	Reported on page number(s)
Addressing uncertainties		
1. Have you determined the aim(s)/purpose(s) of the intervention?		
2. Have you identified the key uncertainties given existing evidence about the intervention and the context in which it will be tested or implemented?		
3. Do the research questions and methods address the key uncertainties?		
4. Does the choice of research perspective (efficacy, effectiveness, theory-based, systems) reflect the key uncertainties that have been identified?		

Checklist for developing and evaluating complex interventions

- Why have this?

- For researchers to help with use of framework
- For funders and peer reviewers to assess whether planned research is consistent with framework's best practice
- For publishers and reviewers to assess research quality
- For evidence users to understand and use research

MRC ASSIST Trial: Study phases & timetable

1993/4: Phase 0: Seminar, discussion, networking

1995: Phase 1: Development, piloting, feasibility testing

1998/99: Phase 2: Publication, planning and fund-seeking

2001: Phase 3: Full-scale randomised trial (£1.5M)

2001	Further piloting
	School recruitment
2002	Baseline measures, intervention
2003	1-year follow-up
2004	2-year follow-up

2006-: Phase 4: Implementation, *Lancet* paper, Roll-out

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University of BRISTOL

Addressing uncertainties (1)

1. Have you determined the aim(s)/purpose(s) of the intervention?
   - Clear focus on adolescent smoking prevention
   - Particularly among high risk youth
   - An intervention that can be effective in widescale implementation

2. Have you identified the key uncertainties given existing evidence about the intervention and the context in which it will be tested or implemented?
   - These changed as the study proceeded through phases
   - Proof of concept – acceptability/feasibility of intervention and trial methods – does it work? - how to scale up/disseminate

Addressing uncertainties (2)

3. Do the research questions and methods address the key uncertainties?

- Wide range of mixed methods used at different stages and at same time

4. Does the choice of research perspective (efficacy, effectiveness, theory-based, systems) reflect the key uncertainties that have been identified?

- Efficacy never really a focus as this had been demonstrated by Kelly
- Effectiveness and Theory-based perspectives used in combination – 'a realist trial'
- Systems perspective adopted in later work on spillover, longer term roles of peer supporters, changing policy and behavioural context

Engaging stakeholders

1. Have you engaged stakeholders in the design/identification of the intervention and the development of the research protocol?
   - Initial idea came from Health Authority Seminar
   - Intervention Development with teachers, health education advisory teachers, public health professionals

2. Have you engaged stakeholders in the conduct of the research and the dissemination of findings?
   - Welsh Govt and Health Authority staff were co-investigators
   - Intervention team included youth workers, health education advisor, teacher trainer

3. Have all stakeholders declared any potential conflicts of interest?
   - Not formally in research phase
   - Yes in implementation phase

Considering context

1. Have you identified all the dimensions of context that may influence how the intervention achieves its effects?
   - baseline level of risk, school climate and connectedness of pupils, pupils trust contact teacher, school supports intervention, absence of opposition to messages from parents and teachers

2. Have you considered how context may affect the scaling up or scaling out of the intervention?
   - Not relying on untrained teachers in crowded PSHE lessons was a key consideration from outset.
   - At implementation phase, focus on commissioning and staffing, and business model for support of roll out with quality assurance and training
   - And evaluation in Scotland as policy and epidemiological context changed

Developing and refining programme theory

1. Have you developed a programme theory for your intervention that describes the key components and mechanisms of the intervention and how it interacts with the context in which it will be implemented?
   - We did not explicitly draw a logic model or programme theory at the time
   - But there was relentless consideration of how to preserve the key components of diffusion of innovation theory and a sensitivity to understanding and measuring context and mechanisms

2. Have you updated the programme theory to incorporate the new evidence gathered by the study?
   - Not done at the time, but programme theory now drawn (post hoc)
   - At implementation phase, critical components identified and specified
   - Adaptations have further developed the programme theory

Refining the intervention

1. Have you refined the intervention so that it is optimised for the context in which it will be implemented?
    - Refinements throughout development phase; further refinement at end of feasibility study (e.g. gender bias); and again during implementation (vouchers dropped), as well as further adaptations to other behaviours and contexts

2. Have you specified how far and in what ways the intervention can be refined during implementation without undermining the programme theory?
    - In implementation, based on programme theory and process evaluation data, the core components were identified and specified; the intervention manual included a traffic light system to signal which specific activities could easily, could possibly, or definitely must not, be omitted if a training session was squeezed for time

Economic considerations

1. Have you considered whether or not the value of the evidence, in terms of informing future decision-making, justifies the cost of the research?
   - We did not do a value-of-information analysis. Smoking in adolescence was the top health priority and there was no known effective intervention. Existing evidence base was weak in quality of both interventions and evidence.

2. Have you identified an economic evaluation framework that is appropriate to the expected outcomes of the intervention?
   - Cost-consequences analysis was included in the planned trial. Subsequent to the trial, cost effectiveness analysis was undertaken and then further cost-benefit modelling undertaken by NICE. This evidence was necessary to achieve support in NICE guidance and was a huge influence on wider uptake beyond the initial collaborating areas (Wales and SW England).

Phase-specific considerations

- Developing (or adapting) interventions – have you used a formal framework (such as INDEX) to guide development of the intervention?
- Identifying interventions – for policy and practice interventions, have you performed an evaluability assessment to determine whether or not and how an evaluation should be undertaken?
- Feasibility – have you defined and used clear progression criteria to guide decisions about whether to proceed to an evaluation study?
- Evaluation – have you chosen an appropriate study design to answer the research questions and provide robust evidence to inform decision-making about further intervention refinement, evaluation or implementation?
- Implementation – have constraints and enablers of implementation been considered at all phases, from intervention development, through feasibility and effectiveness testing, to large-scale roll-out?

Acknowledgements

- Co-authors on the framework: Lynsay Matthews, Sharon Anne Simpson, Peter Craig, Janis Baird, Jane M Blazeby, Kathleen Anne Boyd, Neil Craig, David P French, Emma McIntosh, Mark Petticrew, Jo Rycroft-Malone, Martin White
- SPHSU colleagues - Olga Utkina-Macaskill, Enni Miller
- Participants in expert workshop, conference workshops, consultation, final feedback, specific sessions on intervention development and systems methods.

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Q&A

- Do you have accessible examples of where taking a systems perspective has been usefully used in evaluation?
- We would be grateful to hear from you if so.
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- Laurence.moore@glasgow.ac.uk