

Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update

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Declared competing interests of authors: Additional time on the study was funded by grants from the Medical Research Council (MRC) for Kathryn Skivington (MC_UU_12017/11, MC_UU_00022/3), Lynsay Matthews, Sharon Anne Simpson, Laurence Moore (MC_UU_12017/14, MC_UU_00022/1), and Peter Craig (MC_UU_12017/15, MC_UU_00022/2). Additional time on the study was also funded by grants from the Chief Scientist Office of the Scottish Government Health Directorates for Kathryn Skivington (SPHSU11), Lynsay Matthews, Sharon Anne Simpson and Laurence Moore (SPHSU14), and Peter Craig (SPHSU13 and SPHSU15). Kathryn Skivington and Sharon Anne Simpson were also supported by a MRC Strategic Award (MC_PC_13027). Sharon Anne Simpson was a member of the National Institute for Health Research (NIHR) Clinical Evaluation and Trials Programme Panel (November 2016 to November 2020) and the Chief Scientist Office Health Improvement, Protection and Services Committee (2018 to present) at the time of commissioning and during the project, and was a member of the NIHR Policy Research Programme during the latter parts of the project (November 2019 to present). Janis Baird is a member of the NIHR Public Health Research (PHR) Programme Funding Committee (May 2019 to present). She is also a core member (since 2016) and vice chairperson (since 2018) of the National Institute for Health and Care Excellence (NICE) Public Health Advisory Committee C. Jane M Blazeby is a former member of the NIHR Clinical Trials Unit Standing Advisory Committee (2015–19). Jane M Blazeby is funded in part by the NIHR Biomedical

Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. David P French is a former member of the NIHR PHR programme research funding board (2015–19) and a former member of the MRC–NIHR Methodology Research Panel (2014–18). David P French is funded in part by the NIHR Manchester Biomedical Research Centre (IS-BRC-1215-20007) and NIHR Applied Research Collaboration – Greater Manchester (NIHR200174). Emma McIntosh is a member of the NIHR PHR funding board panel. Jo Rycroft-Malone is programme director and chairperson of the NIHR’s Health Services Delivery Research programme (2014 to present) and is a member of the NIHR Strategy Board (2014 to present). Mark Petticrew is funded in part as director of the NIHR’s Public Health Policy Research Unit, and has funding as part of the MRC-funded TRIPLE C project (grant reference MR/S014632/1) and the NIHR School for Public Health Research at London School of Hygiene & Tropical Medicine. Martin White was funded in part as director of NIHR’s PHR programme (July 2014 to June 2020), which contributed funding to the project via the NIHR/MRC Methodology Research Programme. He is a member of the MRC’s Population Health Sciences Strategic Committee (July 2014 to June 2020). Laurence Moore was a member of the MRC–NIHR Methodology Research Programme Panel (2015–19) and MRC Population Health Sciences Group (2015–20) at the time of commissioning and early stages of the project.

Published September 2021

DOI: 10.3310/hta25570

Scientific summary

Framework for complex interventions

Health Technology Assessment 2021; Vol. 25: No. 57

DOI: 10.3310/hta25570

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background and rationale

In 2006, the Medical Research Council published guidance for developing and evaluating complex interventions (Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and Evaluating Complex Interventions*. London: Medical Research Council; 2006), building on a framework that was published in 2000 (Medical Research Council. *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. London: Medical Research Council; 2000). The aim was to help researchers and research funders recognise and adopt appropriate methods to improve the quality of research to develop and evaluate complex interventions and, thereby, maximise its impact.

Since the 2006 edition of the guidance was published, there have been considerable developments in the field of complex intervention research. In some areas, the accumulation of experience and knowledge in the application of approaches and methods has led to the publication of detailed, focused guidance on the conduct and/or reporting of research. In other areas, new challenges in complex intervention research have been identified and the reliance on traditional approaches and methods promoted in previous guidance has been challenged.

There was, therefore, a need to update the 2006 guidance and, given the greater amount of detailed guidance now available and the need for inclusion of a wider range of approaches, the aim was to provide a less prescriptive and more flexible guide. The new framework aims to improve the design and conduct of complex intervention research to increase its utility, efficiency and impact. Consistent with the principles of increasing the value of research and minimising research waste, the framework (1) emphasises the use of diverse research perspectives and the inclusion of research users, clinicians, patients and the public in research teams, and (2) aims to help research teams prioritise research questions and choose and implement appropriate methods.

Methods

The framework was developed in four stages.

Stage 1

The 'gap analysis' aimed to identify and summarise aspects of the previous guidance that required updating. An initial list of topics to explore further was developed by the project team and the Scientific Advisory Group. A brief scoping review of existing literature was undertaken for each topic. This was then used to develop questions to explore in more detail with experts in stage 2. This initial stage set the agenda for the update.

Stage 2

The expert workshop was facilitated to obtain views and record discussions on topics that should be newly covered or updated. Participants were identified by the project team and Scientific Advisory Group, and we aimed to have at least two experts for each of the topics identified in the gap analysis. These topics were then the starting point for the facilitated breakout discussions. Thirty-six experts from many disciplines relevant to complex intervention development and evaluation, such as public health, health services research, clinical research and health economics, participated in the workshop. Discussions were audio-recorded and these recordings were reviewed and thematically organised and used to make decisions on the content of the first draft of the updated framework.

Stage 3

The open consultation (April 2019) aimed to collect views on the first full draft of the framework document. Consultees were targeted via e-mail, but also through public social media channels. Consultation responses ($n = 52$) were organised thematically and the project team, along with the Scientific Advisory Group, decided how to revise the framework.

Stage 4

The project team, in discussion with the Scientific Advisory Group and with the support of all authors, drafted the final document. We then sought further review from the Medical Research Council and National Institute for Health Research (NIHR) Methodology Research Programme Advisory Group and Population Health Sciences Group, plus another eight experts in May/June 2020, and made final edits accordingly.

Results

The findings from each stage of the process described above supported decisions taken on the content of the new framework.

Key changes from the previous guidance:

1. We have extended the definition of a complex intervention to include complexity that arises from the interaction between an intervention and the context in which it is implemented, as well as complexity arising from the structure of the intervention.
2. We draw on recent developments in thinking and methods to suggest ways in which researchers can take account of complexity, and we encourage consideration and use of diverse research perspectives and the pragmatic and pluralist choice of research questions and methods. We define four overlapping research perspectives that can be drawn on to answer different types of research questions:
 - i. Efficacy perspective – to what extent does the intervention produce the intended outcome(s) in experimental or ideal settings?
 - ii. Effectiveness perspective – to what extent does the intervention produce the intended outcome(s) in real-world settings?
 - iii. Theory-based perspective – what works in which circumstances and how?
 - iv. Systems perspective – how do the system and intervention adapt to one another?

We encourage consideration of the different research perspectives, particularly how they could be used to conceptualise and evaluate the intervention, the intervention's place in the wider systems in which it is implemented and the interdependence between the two over time. The aim of this is to encourage appropriate consideration of the potential sources of complexity.

3. We identify six core elements that should be addressed throughout the research process:
 - i. Context – we have introduced a new emphasis on the importance of context and the value of understanding interventions as 'events in systems' that produce effects through interactions with features of the contexts in which they are implemented.
 - ii. Refinement and testing of programme theory – programme theory describes how an intervention is expected to lead to its effects and under what conditions. The programme theory should be tested and refined at all stages and used to guide the identification of uncertainties, research questions and evaluation outcomes. The development of programme theory is a collaborative and iterative process.
 - iii. Stakeholders – genuine engagement of appropriate stakeholders throughout the research process and working with them as partners to jointly develop, identify or prioritise interventions for research and agree programme theories, research perspectives, key uncertainties and research questions.

- iv. Uncertainties – identifying the key uncertainties that exist given what is already known and what the programme theory, research team and stakeholders identify as being the most important. These judgements inform the framing and prioritisation of research questions and should yield more useful evidence for decision-making.
- v. Intervention refinement – the process of ‘fine tuning’ or making changes to the intervention once a preliminary version (prototype) has been developed. We suggest that ongoing refinement of an intervention, consistent with the programme theory, can improve the potential implementability of the intervention.
- vi. Economic considerations – the comparative resource and outcome consequences of the interventions for those people and organisations affected. More emphasis is placed on these than in the previous guidance because we see them as a key element at all phases of a research project, rather than simply a set of methods for assessing cost-effectiveness.

We divide the research process into four phases: development, feasibility, evaluation and implementation. For each, we provide a concise summary of recent developments, key points to address and signposts to further reading.

1. Development

- i. Developing an intervention: we draw heavily on the comprehensive guidance provided by the INDEX study (O’Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, *et al.* Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* 2019;9:e029954). The steps are adequate planning; involving stakeholders; bringing together an intervention development team with relevant expertise; review related existing literature and theories; develop, test and refine programme theory; draw on primary data; take efforts to understand the context of the intervention; consider future implementation; refine the intervention as appropriate; and end the development phase, including writing up the process. In addition to these steps, we have added four sets of issues that may be useful in the development of an intervention: adaptation of interventions to new contexts, consideration of wider system factors, modelling or simulation of the intervention and consideration of economic factors.
- ii. Identifying an intervention: researchers are not always involved in the design phase of intervention development, for example where interventions are designed and driven in policy settings. This presents slightly different challenges for this phase of research. For example, it may not be entirely clear what the theoretical basis for the intervention is, or there may not be explicit programme theory. At this phase of research, the key step is to develop programme theory, which will be an important basis for considerations around the evaluation design.

2. Feasibility

This phase is designed to explore the uncertainties that have been identified at the development phase. ‘Progression criteria’, ideally developed with input from multiple relevant stakeholders, should be used to guide the decision on whether or not to proceed to the next stage of evaluation, conduct more feasibility work, return to intervention development or terminate the research. Criteria for progression could relate to the evaluation design, for which key aspects are feasibility of recruitment and retention of participants; capacity to achieve appropriate sample size; feasibility of the outcomes of the evaluation (e.g. data collection tools and follow-up duration); the capacity and time to collect and analyse the data; and consideration of the unintended outcomes. Criteria for progression could also relate to uncertainties around the intervention itself, for example optimal and acceptable intervention content and delivery; adherence to the intervention; likelihood of cost-effectiveness; and capacity of those providing the intervention to deliver as planned. This is important even if the intervention has been shown to be efficacious, particularly where contextual or implementation factors may influence the intervention’s effectiveness. A key point here is that further work may be required to refine the intervention before embarking on full-scale evaluation, and the programme theory itself should be refined in an ongoing manner. Economic modelling can

be used to assess whether or not expected benefits from an intervention justify its costs and, thus, is useful for decisions on whether or not it is worth proceeding to full-scale evaluation. Evaluability assessment is a complementary approach to a feasibility study. This is a collaborative approach to support the development and evaluation of interventions, aiming to determine whether or not an intervention can usefully be evaluated, and the most appropriate methods for doing so.

3. Evaluation

At this phase it is important to consider how to maximise the 'usefulness' of information for decision-making. To do this, there needs to be an understanding of the key uncertainties surrounding the intervention, and research questions should be developed that are relevant to resolving these uncertainties. As noted above, there are a range of research perspectives that should be considered, rather than necessarily focusing on effectiveness alone. There are numerous study designs and the decision on which to use should be made based on the research questions posed, which should be defined based on the uncertainties that have been identified. There is no 'best' study design: the approach needs to be tailored. A crucial aspect is the choice of outcome measures or evidence of change. Again, these should be chosen based on which outcomes or change are important for stakeholders and on a good theoretical understanding of the intervention. Outcome measures do not need to be reserved to capturing changes in individuals, but can also assess changes in the system, for example changes to policy or to social norms, or by exploring how changing the dynamics in one part of the system alters behaviour in other parts, for example the displacement of smoking into the home after a public smoking ban.

4. Implementation

This phase is about taking deliberate effort to increase the impact of interventions. Even where interventions are shown to be effective, they are seldom implemented successfully. Implementation science is a developing research field, with one focus being on maximising the effective implementation of interventions that have already demonstrated effectiveness in a study. In implementation studies, the main outcomes of interest are measures of the effectiveness of implementation, for example reach, policy impact and uptake of a service. Implementation should be considered in all phases of complex intervention research. Early consideration of implementation increases the potential of developing interventions that can be adopted and maintained in real-world settings.

We present case studies, which are referred to in relevant parts of the text, to illustrate a variety of approaches and demonstrate particular points.

Throughout the phases of complex intervention research, we encourage a regular return to 'check in' with the core elements mentioned above. We provide a checklist to support and document use of this framework, in particular the attention to the core elements and the key considerations for each research phase, in the preparation of funding applications and journal articles.

Complex intervention research is an interdisciplinary, rapidly developing field in which key terms are used in varying ways. The glossary sets out our working definitions of these terms. The framework document provides brief guidance on how complexity should be approached in evidence synthesis.

Conclusions

The framework adopts a pluralist approach and encourages consideration and use of diverse research perspectives. We acknowledge that to generate the most useful evidence for decision-making will often require a trade-off between precise, unbiased answers to narrowly defined questions and more uncertain answers to broader, more complex questions. Earlier editions of this framework were underpinned by an assumption that unbiased estimates of effectiveness are the cardinal goal of evaluation. We have emphasised that improving theories and understanding how and in what circumstances interventions contribute to change are also an important goal for complex intervention research.

For many complex intervention research problems an efficacy or effectiveness perspective will be the optimal approach, for which a randomised controlled trial will probably provide the best design to achieve an unbiased estimate. For other problems, this will not be the case and alternative perspectives and designs will be more likely to generate useful new knowledge to help reduce decision-maker uncertainty. What is important for the future is that the scope of intervention research commissioned by funders and undertaken by researchers is not constrained to a limited set of perspectives and approaches that may be less risky to commission and more likely to produce a clear and unbiased answer to a specific question. In many cases, what is needed is a bolder approach, including some methods and perspectives for which experience is still quite limited, but for which there is an urgent need to make progress by mainstreaming new methods that are not yet widely used, as well as undertaking methodological innovation.

It is recommended that future updates of this framework continue to adopt a broad, pluralist perspective, which means that given the widening scope of the framework and the rich, diverse and constantly evolving body of detailed methods guidance that is now available on specific methods and topics, it will most usefully be in the form of a high-level framework with signposting, published in a fluid, web-based format, which will ideally be frequently updated to incorporate new material, through both updating of text and the addition of new links to updated and emerging key resources.

Funding

This project was jointly funded by the Medical Research Council (MRC) and NIHR (Department of Health and Social Care 73514).

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

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This report

This issue of the Health Technology Assessment journal series contains a project commissioned by the Medical Research Council's (MRC) Population Health Sciences Group (PHSG). Jointly funded by the MRC and NIHR, the work refreshed the previous version of the Medical Research Council framework for development and evaluation of complex interventions: A comprehensive guidance (2006).

PHSG is responsible for developing the MRC's strategy for research to improve population health. NIHR's mission is to improve the health and wealth of the nation through research. As population level interventions in community and clinical settings become more important, and as science advances and innovates, both funding partners agreed that updating the existing framework was timely and needed.

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. This report has been published following a shortened production process and, therefore, did not undergo the usual number of proof stages and opportunities for correction. The Health Technology Assessment (HTA) programme editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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