

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

Kathryn Skivington,<sup>1\*</sup> Lynsay Matthews,<sup>1</sup>  
Sharon Anne Simpson,<sup>1</sup> Peter Craig,<sup>1</sup> Janis Baird,<sup>2</sup>  
Jane M Blazeby,<sup>3</sup> Kathleen Anne Boyd,<sup>4</sup>  
Neil Craig,<sup>5</sup> David P French,<sup>6</sup> Emma McIntosh,<sup>4</sup>  
Mark Petticrew,<sup>7</sup> Jo Rycroft-Malone,<sup>8</sup>  
Martin White<sup>9</sup> and Laurence Moore<sup>1\*</sup>

<sup>1</sup>Medical Research Council/Chief Scientist Office Social and Public Health Sciences Unit, Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

<sup>2</sup>Medical Research Council Lifecourse Epidemiology Unit, University of Southampton, Southampton, UK

<sup>3</sup>Medical Research Council ConDuCT-II Hub for Trials Methodology Research and Bristol Biomedical Research Centre, University of Bristol, Bristol, UK

<sup>4</sup>Health Economics and Health Technology Assessment Unit, Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

<sup>5</sup>Public Health Scotland, Glasgow, UK

<sup>6</sup>Manchester Centre for Health Psychology, University of Manchester, Manchester, UK

<sup>7</sup>London School of Hygiene and Tropical Medicine, London, UK

<sup>8</sup>Faculty of Health and Medicine, Lancaster University, Lancaster, UK

<sup>9</sup>Medical Research Council Epidemiology Unit, University of Cambridge, Cambridge, UK

\*Corresponding authors [Kathryn.skivington@glasgow.ac.uk](mailto:Kathryn.skivington@glasgow.ac.uk) and [Laurence.moore@glasgow.ac.uk](mailto:Laurence.moore@glasgow.ac.uk)

**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

## Plain English 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](http://www.journalslibrary.nihr.ac.uk)

## Plain English summary

**I**nterventions are actions taken to make a change, for example heart surgery, an exercise programme or a smoking ban in public. Interventions are described as complex if they comprise several stages or parts or if the context in which they are delivered is complex.

A framework on how to develop and evaluate complex interventions was last published by the Medical Research Council in 2006 (Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and Evaluating Complex Interventions*. London: Medical Research Council; 2006). This document describes how the framework has been updated to include advances in research methods and thinking and presents the new framework document.

The updating process had four stages: (1) review of the literature to identify areas requiring update; (2) workshop of experts to discuss topics to update; (3) open consultation on a draft of the framework; and (4) writing the framework.

The updated framework divides the research process into four phases: development, feasibility, evaluation and implementation. Key updates include:

1. the definition of a complex intervention was changed to include both the content of the intervention and the context in which it is conducted
2. addition of systems thinking methods: an approach that considers the broader system an intervention sits within
3. more emphasis on interventions that are not developed by researchers (e.g. policy changes and health services delivery)
4. emphasis on the usefulness of evidence as the key goal of complex intervention research
5. identification of six elements to be addressed throughout the research process: context; theory refinement and testing; stakeholder involvement; identification of key uncertainties; intervention refinement; and economic considerations.

The updated framework is intended to help those involved in funding and designing research to consider a range of approaches, questions and methods and to choose the most appropriate. It also aims to help researchers conduct and report research that is as useful as possible to users of research.



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.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) ([www.publicationethics.org/](http://www.publicationethics.org/)).

Editorial contact: [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)

The full HTA archive is freely available to view online at [www.journalslibrary.nihr.ac.uk/hta](http://www.journalslibrary.nihr.ac.uk/hta). Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: [www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)

## Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme or, commissioned/managed through the Methodology research programme (MRP), and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

## HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

## 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.

This report presents independent research. The views and opinions expressed in this publication are those of the authors and do not necessarily reflect those of the MRC, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the MRC, NETSCC, the HTA programme or the Department of Health and Social Care.

**Copyright © 2021 Skivington *et al.* This work was produced by Skivington *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaption in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.**

Published by the NIHR Journals Library ([www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)), produced by Prepress Projects Ltd, Perth, Scotland ([www.prepress-projects.co.uk](http://www.prepress-projects.co.uk)).

## NIHR Journals Library Editor-in-Chief

---

**Professor Ken Stein** Professor of Public Health, University of Exeter Medical School, UK

## NIHR Journals Library Editors

---

**Professor John Powell** Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

**Professor Andrée Le May** Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

**Professor Matthias Beck** Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

**Dr Tessa Crilly** Director, Crystal Blue Consulting Ltd, UK

**Dr Eugenia Cronin** Senior Scientific Advisor, Wessex Institute, UK

**Dr Peter Davidson** Consultant Advisor, Wessex Institute, University of Southampton, UK

**Ms Tara Lamont** Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, UK

**Dr Catriona McDaid** Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

**Professor William McGuire** Professor of Child Health, Hull York Medical School, University of York, UK

**Professor Geoffrey Meads** Emeritus Professor of Wellbeing Research, University of Winchester, UK

**Professor James Raftery** Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

**Dr Rob Riemsma** Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

**Professor Helen Roberts** Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

**Professor Jonathan Ross** Professor of Sexual Health and HIV, University Hospital Birmingham, UK

**Professor Helen Snooks** Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

**Professor Ken Stein** Professor of Public Health, University of Exeter Medical School, UK

**Professor Jim Thornton** Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Please visit the website for a list of editors: [www.journalslibrary.nihr.ac.uk/about/editors](http://www.journalslibrary.nihr.ac.uk/about/editors)

**Editorial contact:** [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)