Developing and Evaluating Complex Interventions: New MRC Guidance

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Background: The MRC/NIHR Methodology Research Programme has commissioned two studies, INDEX and GUEST, to respectively develop guidance on (1) the development and (2) the feasibility stages of the MRC Guidance on Developing and Evaluating Complex Interventions (Craig et al 2008). Some further detail on each of these projects is provided in the following summaries:

Identifying and assessing different approaches to developing complex interventions (INDEX study)
A O’Cathain, P Hoddinott, E Croot, K Turner, E Duncan, L Yardley, K Sworn, N Rousseau

Researchers use a range of approaches to developing complex interventions. The field is developing at a rapid rate. The aim of the INDEX study is to produce guidance for researchers on how to develop complex interventions to improve health or health care outcomes. The objectives are to: 1. Identify and describe the different approaches taken to intervention development, the rationales for their use, and any implications for the future utility of the interventions. 2. Compare and contrast different intervention development approaches, the methods of data collection and analysis they used, considering strengths and limitations overall and for different contexts. 3. Understand the history and challenges of intervention development from the perspectives of experienced researchers and wider stakeholders e.g. research funders, public and patient representatives. 4. Measure stakeholder consensus on the key aspects of intervention development and explore the reasons for any lack of consensus. 5. Offer guidance to researchers on good practice, with examples from different approaches.

Guidance for Exploratory Studies of complex public health interventions (GUEST)
L Moore, P.Craig, K Hood, G Moore, S. Murphy, M. Robling, J.Segrott, S.Simpson, R.Turley, D.Wight, J Pugmire, B Hallingberg, S Browne

In this study we aim to develop guidance on exploratory studies of complex public health interventions - those conducted before a full scale effectiveness trial to develop or refine the intervention, and to estimate key trial design parameters. The objectives are to conduct:
1) a systematic review of current guidance and recommendations, to identify what is seen as good or bad practice, and the key gaps and areas of inconsistency;
2) a scoping review of current practice, to identify the aims, terminology and range of methods used in exploratory studies. The reviews use comprehensive database
searches, supplemented by hand searches and citation tracking, double screening using pre-defined eligibility criteria, and narrative synthesis.

3) a web-based Delphi exercise to identify expert consensus on key aspects of the purpose, design and conduct of exploratory studies, and the key areas of disagreement.

4) a horizon scan of novel approaches to exploratory studies in medicine and surgery, to identify innovations that could be applied to complex public health interventions. We shall undertake scoping reviews, key informant interviews and two expert workshops. Outputs will include guidance on the design and conduct of such studies, and a research agenda for innovation in exploratory studies in public health.

Subject and Topicality: This workshop is directly relevant to the health services research and population health research interests of SSM members. MRC Guidance has been a key reference point in the field since 2000, and this workshop is a key opportunity for SSM ASM participants to influence the content of the planned new guidance.

Likelihood of provoking discussion – will there be points for particular discussion? Key issues will be presented to provoke discussion; each small group will be facilitated by one or more members of the project teams. This should ensure a focussed and productive discussion.

What is the rationale for the workshop? In this workshop, members of the teams involved in the two projects will briefly inform the audience about the aims and progress of each project. We will then conduct facilitated small group discussions which will solicit input from the workshop participants on key relevant issues. Workshop participants will also be able to have further engagement with the projects beyond the workshop if they wish to do so.

Aims: What is expected to be achieved overall by the end of the workshop?

Educational objectives: Participants will learn about the key challenges in developing and evaluating complex interventions. Variation and deficiencies in the conduct and reporting of studies to date will be highlighted. The identification of key points to focus on in the development of new guidance will be a key focus of the discussions and a very useful learning point for participants to improve their knowledge and practice.

Structure:
1. Introduction to MRC Guidance and aims & structure of workshop (5 mins)
2. Fifteen minute presentations on (i) INDEX (ii) GUEST (30 mins)
3. Small group discussions (40 mins)
4. Feedback from small groups (10 mins)
5. Closing remarks (5 mins)

Target Group: Up to 35 participants. These should be health services and population health intervention researchers, including those with an interest in intervention theory and content as well as trialists and statisticians. Ideally, some of the participants will be aware of the existing MRC guidance and have experience of its application. However, the workshop will also be accessible to those with an interest to learn about the guidance and its potential value.

Requirements: Will require powerpoint and ideally 2-5 tables which can each sit up to 7 participants (cabaret style). We would have some plenary presentation and then 2-5 facilitated small groups. Up to 5 flip charts would be helpful but each table will have a facilitator/note taker.