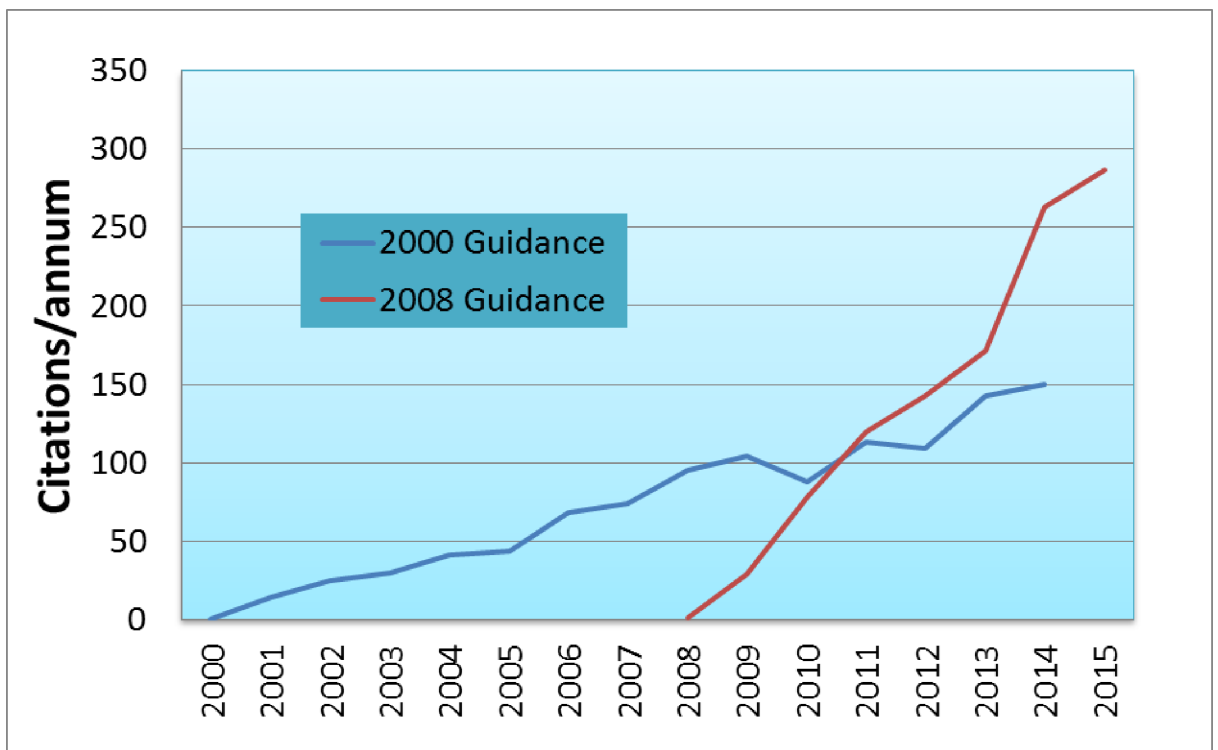


1. **Background: the need for updating and integrating the MRC guidance**

The MRC guidance on evaluating complex interventions (CIs) was first published in 2000, and updated in 2008. Over this period, interest in complex interventions has grown rapidly, and more specialised guidance has been published or is being developed in several related areas, including intervention development, intervention description, process evaluation, natural experimental approaches, dealing with intervention context, group-delivered interventions, realist trials, surgical trials, exploratory trials, trial management, disability research and knowledge translation [see **References** for examples]. A number of other areas that were identified as gaps in the 2008 guidance, such as research priority-setting and the application of complex systems science to health interventions, have also attracted interest, but are not yet covered by accessible guidance for producers or users of evidence. Both the 2000 and 2008 core guidance documents continue to be highly cited (figure), but given the pace and extent of methodological development, there is a strong case for updating the core guidance, linking it with related developments, and also addressing some of the remaining weaknesses and gaps in the existing guidance.

Aim & objective: To identify and summarise aspects of the 2006 MRC complex intervention guidance that require updating, with the aim of using this gap analysis as a starting point for discussion (through workshops and authorship group) to achieve consensus on focus points and resulting updates for the new guidance.



Source: Web of Science. The '2000 Guidance' refers to Campbell *et al.* (2000) and the '2008 Guidance' refers to Craig *et al.* (2008).

2. Proposed outputs

The 2000 and 2008 guidance each comprised a long version, published online by the MRC, and a short version published by the BMJ. The MRC's process evaluation and natural experiments guidance followed a similar model. Citations of the short versions greatly outnumber citations of the long versions, although the longer versions have important additional detail and have a very high number of downloads. For the updated guidance we recommend two products to disseminate the updated core guidance:

- a) A **downloadable pdf** version of the core guidance.
- b) A **journal article** (ideally published simultaneously in a number of journals, as the CONSORT statements are) which would describe the importance and need for the guidance as well as outlining its content, also referring potential users to the detailed online pdf version and signposting resource.

In addition, we will continue discussions about creating an online resource comprising the updated core guidance with links to signpost other related source documents (e.g. the MRC's process or natural experiments guidance) or to brief summary statements prepared specifically, with links to other useful published resources already available online.

3. Proposed stages of development

- *Gap analysis*: based on scoping reviews to find publications that identify gaps and weaknesses in the existing guidance, or that provide more detailed guidance on specific topics. This will take the form of *horizon scanning and further literature review*: a brief scoping review will be followed by discussion at the Scientific Advisory Group (SAG) meeting (24/11/17). Our initial search (google scholar, forward/backward citations) will focus on: (a) New approaches/progress since previous guidance; (b) Criticisms of existing guidance; (c) Other gaps. Prior to the SAG meeting we will develop a brief list of topics to address in the updated guidance. We will present these topics to the SAG (by sending a summary in advance and by presentation of an overview at the meeting). Following discussion at the SAG meeting we will finalise a list of topics that we will explore in more depth.
- *Expert workshop*: The findings from the gap analysis will inform the agenda for an expert workshop to be held in early 2018. Each of the 'topics/themes' identified for update should be represented (by an expert) at the workshop i.e. we will invite experts based on these themes. The aim of the expert workshop is to achieve consensus on topics that should be newly covered or updated by the new guidance and as a basis for the project team, along with the rest of the authorship group, to produce the updates and additions. Follow-up consultation (email and a consensus meeting) will be used to achieve consensus on the details of the updated guidance.
- *Identify relevant case studies*: Worked examples of the development, implementation, or evaluation of a complex intervention. This will be started at the workshop and finalised through consultation afterwards.
- Convening a steering group to oversee the work, review and approve drafts, and ensure stakeholder commitment; and a writing group to draft the update and linked summaries
- Drafting the update and summaries
- Drafting the journal article and managing the publication process

4. Representation

- (a) **Steering group**: The steering group will meet on an infrequent basis (e.g. two or three times over timeline of activity). The steering group members are: (chair) Martin White (NIHR Public Health Research Programme), David French (MRC–NIHR Methodology Research Programme), Jo Rycroft-Malone (NIHR Health Services Delivery Research Programme), Mark Petticrew (Co-author of previous guidance), Martin Ashton-Key (NIHR HTA Programme & Consultant Adviser, NETSCC), Janis Baird (Co-author of previous process evaluation guidance), Jane Blazeby (MRC Hubs for Trial Methodology Research), Samuel Rowley (Observer), Gavin Malloch (Observer). All will be offered authorship (alongside formal authorship criteria).
- (b) **Writing group**: The writing group will meet on a more regular basis (tbc), be engaged in the progress of the guidance and contribute to the writing process. Members of the writing group will be acknowledged as authors on the final guidance. The project team will be members of the writing group, with additional authors identified as appropriate, e.g. to fill gaps in expertise.
- (c) **Project team**: Employed researchers Kathryn Skivington & Lynsay Matthews; senior staff from the host institution Sharon Simpson, Peter Craig, Laurence Moore.

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