Reviewer’s report

Title: Developing a checklist for research proposals to help describe health service interventions in UK research programme: a mixed methods study

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Reviewer: Bryony Soper

Reviewer’s report:

Major Compulsory Revisions

1. Background

Given its provenance and its subject this is clearly an important study that could begin to address an important gap. The authors acknowledge (p.16) that the work described should be considered as a first step, but even so this paper is disappointingly sketchy.

While it is clear they could only get so far in a small study, it would help if the authors could provide more detail about the background to this work, and, in particular, the practical and intellectual contexts within which this work was undertaken. In doing so they might usefully seek to answer more fully the questions any lay person might ask, i.e.: “Why is this checklist needed, what do the authors expect it to achieve, and can it achieve these objectives on its own?”.

1.1 The practical context:

The declared aim of the checklist is to enhance the quality of the research proposals submitted to NIHR HS&DR (p.5). But this raises the further issues of what type of research the programme is seeking to fund, and why. An abbreviated version of the NIHR HS&DR remit is given at the start of the paper, and this notes the groups for whom HS&DR research funded (though it doesn’t mention patients) and what, in broad terms, this research covers.

However, the fuller version of the NIHR HS&DR remit that is available on the NIHR HS&DR web site also stresses (as the paper notes on p. 4) that much of this research is about (complex) service developments that need evaluation. Additionally the HS&DR programme aims to support research that is likely to lead to changes in practice that will have a significant impact, is likely to generate new knowledge of direct relevance to the NHS, and has the potential for findings to be applied to other conditions or situations outside the immediate area of research. Practical applicability, relevance and generalisability are therefore recognised as important hallmarks of HS&DR research. They are also hallmarks of research on complex service interventions generally, as the MRC guidance cited on p. 4 of the paper notes: “A key question in evaluating a complex intervention is about practical effectiveness – whether the intervention works in everyday practice.” (MRC Guidance 2008) Developing successful research on these interventions requires understanding all the stages of the research and its implementation:
“Developing, piloting, evaluating, reporting and implementing a complex intervention can be a lengthy process. All of the stages are important, and too strong a focus on the main evaluation, to the neglect of adequate development and piloting work, or proper consideration of the practical issues of implementation, will result in weaker interventions, that are harder to evaluate, less likely to be implemented and less likely to be worth implementing.” (MRC Guidance 2008) And in the new world of the ASHNs and the second-round CLAHRCs, developing useful research on complex interventions also requires an understanding of the potential of any successful service development to be scaled-up (generalised) and sustained.

In seeking to enhance the quality of HS&DR research proposals the checklist therefore has to address a complicated set of requirements. It would help if these important requirements were more clearly identified in the paper.

1.2 The intellectual context:

There are two issues here: (a) what can the literature tell us about why there is lack of clarity in research applications about the complex interventions and their contexts?, and (b) what has been done already to address this (and in what contexts, with what aims, on the basis of what theoretical considerations, and with what results)?

On (a) the paper lists three challenges: the difficulties of describing the active ingredient in healthcare interventions; the blurring between intervention and context; and the existing inadequate understanding of the complex nature of contexts. The paper also cites some of the important discussions of these different but related issues. What would enhance the paper here would some attempt to provide more detail and, perhaps (difficult though that might be), to link the discussions in the literature more closely to the six constructs described in the Results section, even if this is only one worked example. Thus Taylor’s work on complex contexts is cited (ref 4 in the paper) but it would be of interest to see how this had contributed to the final development of the sixth (rather catch-all) construct of “Other Important Contextual Information”. Similarly, Stevens and Shojana’s important point about the difficulties of distinguishing context from intervention is also noted (ref 3 in the paper). The authors also say that their final six constructs “have a blurring between intervention and context” (p.15), and again cite Stevens and Shojana. But they provide no discussion about what this blurring might mean in practical terms for researchers seeking to apply the constructs in the checklist, and it is unclear whether the authors think this blurring is helpful or not.

On (b) the paper cites several previous pieces of work on checklists, which is helpful. But many of these lists concerned trials. It would be helpful if this section could be expanded to answer more clearly the points raised above about the contexts, aims, theoretical bases, and outcomes of these previous checklists, and their relevance to the checklist developed here.

It would also be helpful if the rather throw-away comment that checklists on their own are not sufficient (the second sentence of the main paragraph on page 5 of
the paper) could be expanded. This is an important point that could be read as undermining the project reported in this paper. The authors therefore need to explain why they have joined others in producing yet another checklist and what (given the comments made by Stevens and Shoja, and by Bosk) they might reasonably expect their checklist (on its own?) to achieve.

2. The methods
A review of existing checklists and “some relevant literature” is mentioned. It would help to have more detail about how the checklists were identified, and about what the review covered and how it was managed.

3. Results
3.1 The final sentence on p. 9 says: “The content of the checklist appeared to be clearly understood; therefore it should be straightforward for researchers to interpret the checklist in the way it was intended.” But this appears to be at odds with a sentence on page 10 which reads: “For instance a couple of the researchers interpreted the meaning of particular parts of the checklist differently to what had been intended, therefore the wording was changed to improve clarity [sic].” The confusion of a couple of researchers is not negligible if only 8 researchers gave feedback. The authors may wish to reconsider the wording here, and also in the final sentence of the same paragraph which reads: “However other recommendations were made, but they were not applicable to meet the aims of the project” – something of a non-sequitur as it stands.

3.2 On p. 11 the authors note that: “Most checklists which are used to report research emphasise the importance of having a good description of the participants. This is not entirely applicable to this current checklist; however it is still important to know about the patient group.” I may have missed something but am unclear why this is not applicable. Is this because the programme is focused on organisational developments, or is there some other reason? Could this be clarified please?

3.3 On pages 12/13 the authors note the importance of leadership and culture as part of context but also the difficulties of describing them. Both these constructs were finally included in a sixth construct entitled “other important contextual information”. This construct is intended to “cover all other aspects which would be missed by the other constructs... [and] ...ensure the researchers have considered all aspects of contextual information in their proposal, particularly those that affect the generalisability to other sites.” A lot therefore rests on this final construct if it is to support HS&DR applicants to propose projects that can adequately explore whether interventions will work in everyday practice and can be scaled up and sustained. However at present the final checklist in Table 2 offers only four examples of ‘other contextual aspects’. While appreciating the difficulties, would it be possible for the authors to construct a more detailed list of what HS&DR proposals should consider under this construct, as has been provided for the other constructs?

4. Discussion
In the first paragraph on p. 15 the discussion returns to the point about a blurring between intervention and context, and it would be helpful if the authors could address the points made above (at 1.2).

Minor Essential Revisions

Methods

By and large this section is clear, though it would help if the numbers of research applications reviewed and researchers who were involved at various stages were described more clearly, I had to hunt around a bit to find these figures.

Results

The first paragraph on page 9 mentions nine key constructs in Fig. 1, but this figure only portrays eight constructs.

Discussion

The paper by Chalmers and Glasziou on “Avoidable Waste in the production and reporting of research evidence” is cited as ref 1 on p. 15, but it is not ref 1 (which refers to the MRC guidance) nor is it elsewhere in the list of references.

Discretionary Revisions

The limitations described on p. 15 make it clear that this was an initial, small study, and the authors return to this point at the end of this section when they say (on p.16) that further research is needed to strengthen the checklist. Might it be better therefore to describe the work done to date as a pilot, or scoping study?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

To the extent that I have been a recipient of NIHR HS&DR grants, I have in the past five years, received reimbursement from an organisation that may in some way gain or lose financially from the publication of this manuscript, either now or in the future, but only to the extent that this paper is part of an attempt by that organisation to use its budgets more wisely.

Otherwise I declare that I have no competing interests.