

Author's response to reviews

Title: Ethical issues in implementation research: The problem of informed consent

Authors:

Jane L Hutton (J.L.Hutton@warwick.ac.uk)
Martin P Eccles (martin.eccles@ncl.ac.uk)
Jeremy M Grimshaw (jgrimshaw@ohri.ca)

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Author's response to reviews: see over

Dear Editor,

Re MS: 1165877578113987 Ethical issues in Implementation Research. Jane L Hutton, Martin P Eccles and Jeremy M Grimshaw

Thank you for your and Dr Wensings' comments. We have addressed these as detailed overleaf. We hope the manuscript is now acceptable for publication.

Yours faithfully,

Jane Hutton on behalf of all authors

Response to comments

Dr Wensings' comments

Comment. The paper is written in a philosophical style, which makes it basically a reflective or discussion paper.

Response. We agree that this is a discussion piece and have structured it as a Debate article according to the Journal's instructions to authors.

Comment. It is therefore somewhat confusing that section 2 is labelled Methods for implementation research. I am not sure whether this section is really needed in this paper, certainly for readers of Implementation Science.

Response. With the re-structuring of the manuscript as a Debate article the sub-heading "Methods of Implementation Research" has now gone. We use the three trials described as examples of the various points that we raise in the ensuing Discussion and so see them as an important part of the material in the manuscript. We have therefore retained them and have moved the text describing the three cluster randomised controlled trials into three Tables.

Comment. Section 3 is fine to me, although it should be argued better why the focus is on consent and not on other aspects of ethical issues (as listed in table 1).

Response. This is a very helpful observation. As a consequence of this we have changed the title to "Ethical issues in Implementation Research; the problem of informed consent" and, at the end of the Background we finish with the sentence "In this paper we discuss the ethical challenges relating to consent in cluster trials in implementation research." The Discussion then addresses a number of issues relating to informed consent and concludes with a discussion on the choice of ethical code for implementation research (see our response to the comment below).

Comment. Section 4 is a bit strange in the logic of this paper. It offers an alternative viewpoint, that could be a solution for the problems. It is probably insufficient (or too short) in its analysis of different ethical theories. The whole point of section 4 could be expressed in one or two paragraphs in a discussion section of this paper, after section 3. Alternatively, it is a separate paper.

Response. We have taken Dr Wensing's advice and have both re-ordered and shortened this section. Though it is still slightly longer than the suggested "one or two paragraphs" it is well under half of its former length. Within the content we have chosen to focus on the broader issues and have removed some of the more detailed content. Hopefully this makes it an easier read for the general reader.

Comment. So, I partly agree with the comment that the paper is not well structured. I would recommend to ask the authors to restructure their paper, but suggest that publication of a revised paper would be possible.

Response. We hope that our response detailed above has achieved this and allows the paper to be accepted for publication.

Editor comments

Comment. Taking into account the full set of comments (four in total), I see the comments on Section 4 as most important in terms of the magnitude of recommended revisions. Revisions to Section 2 appear next in importance, to simplify and clarify the specific message or contribution of this text to the manuscript.

Response. We hope that our response above, particularly around the former sections 2 and 4 are acceptable and allow the paper to be published.