Reviewer’s report

Title: Reporting of Clinical Trials: a review of guidelines

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Reviewer: Roberta Scherer

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Review for Reporting of Clinical Trials: a review of guidelines by Dwan, Gamble, Williamson, and Altman

Selective outcome reporting is a relatively recently described form of publication bias. The authors seek to determine if guidelines provided by funding organizations and charities incorporate recommendations regarding reporting of all outcomes described in the initial RCT protocol of studies for which they provide funding. In addition, the authors wish to describe recommendations provided in guidelines regarding publication bias (mainly reporting of negative or null results), and trial registration.

The first question, which the authors implicitly ask, is whether funding agencies provide guidelines at all. This is an important question and to my knowledge has not been previously addressed. The second aspect of the question, then, is if guidelines are provided, what recommendations are included in the guidelines. Again, the research question is pertinent. The general approach seems reasonable and the study conduct appears appropriate. The main difficulty I had with the manuscript is in the presentation. The writing is not focused and definitions are generally not present, making it difficult to understand and interpret exactly what the authors have found. On the other hand, the discussion was a reasonable attempt to interpret the findings and bring other areas into the interpretation (e.g., possible revisions to the CONSORT statement).

Major Compulsory Revisions

1. The abstract conclusions do not follow from the results; there is no mention of outcome reporting bias in either the methods or results, yet the main conclusion is that “there is a need to provide more detailed guidance ...to help prevent the selective reporting of outcomes.”

2. The introduction lacks focus. For example, it starts off describing RCTs, but then goes into a description of systematic reviews without describing any connection between funding organization recommendations for RCT reporting and systematic reviews. The authors then describe reporting bias and outcome reporting bias, but fail to mention trial registration.

The description of generally recognized guidelines in the next section requires more focus. Why not start out with a definition of “guidelines” including a brief description of the types of domains that should be included, with a particular
focus on those related to the research question. For example, while participant safety can certainly be considered an important aspect of any guideline developed for conduct of an RCT, the research question the authors ask is about publication biases and registration; there is no question related to participant safety in the questionnaire (Appendices 2 and 3). Similarly, “high quality” research and reporting as described by CONSORT, while laudable for guideline development, are not pertinent to the research questions posed by the authors, as currently written. There is more than a page of text describing these domains of guidelines, even though these are related to the research question in being a domain which should be included in a guideline. I would suggest that these areas need only a few sentences or a brief description, followed by a more detailed description of the domains of interest identified in the research question.

3. How were funding organizations and charities identified? Does the sample include all the organizations which fund UK research? Is it a representative sample? While you describe searching the AMRC site for charities, it is not clear how the other organizations were identified. Also, you mention 7 newly added charities when you last visited the AMRC site in September 2007 and that 2 charities had been excluded from the site. Could you clarify exactly how these were counted in the “140” contacted?

4. It was not clear when the shortened version of the questionnaire (Appendix 2) was used and when the longer questionnaire was used (Appendix 3). Was the questionnaire in Appendix 3 always used with the questionnaire in Appendix 2 only used as a means of contacting the funding agency and requesting a copy of their guideline?

5. Including information from the guidelines from the four organizations that do not fund RCTs simply muddies the water. The inclusion criteria for this study was that only organizations that fund RCTs were to be included; this protocol should be adhered to (just as one would expect in a trial).

6. Given that you mention having difficulty in finding guidelines on the websites, indicate how many were identified and for how many you were required to request that information from the organization contact. In this context, it would be useful to know how the guidelines were issued to the researcher (question on Appendices 2 and 3) - if guidelines are difficult to find on the website, are they sent to the researcher or is s/he expected to find them?

7. Table 1: Some definitions are needed here to understand the table.

What is meant by “limited contact?” Does this mean that no guidelines were received?

Please use full names, not acronyms for “other guidelines.” Also, what is meant by “Department of Health,” “Institution,” “Charity specific,” “National regulations and guidelines,” and “Legal?”

Please address the following:
1. How was it decided if a guideline domain was mentioned “explicitly” versus “implicitly?”

2. What do you mean by “Protocol adherence/amendment” (one assumes you mean by this that there are guidelines related to what the researcher should do if there is a protocol change - but please be explicit)

3. Trial publication - do you mean any statement about publication or a statement about publishing negative results, or the timing of publication?

4. By “monitoring against guidelines,” do you mean monitoring for adherence to the published guidelines?

8. Please add the additional domains investigated (related to outcomes, outcome reporting bias, and publication bias (i.e, the information in Table 2) to Table 1. While Table 2 is useful in seeing exactly how the guidelines are stated, it is important to see which of these areas are covered by how many guidelines.

9. There looked to be some differences in guidelines (yes/no or content) between “organizations” and “charities.” Please comment of these differences. How do you interpret these findings?

Discretionary Revisions

1. The original studies examining publication bias were conducted by Dickersin and Easterbrook and should be cited rather than an “in press” publication. In addition, there is a published Cochrane protocol on this topic, as well as one on time to publication, both with Hopewell as lead author that should be acknowledged.

2. Exactly what are the differences and similarities between “terms and conditions of a grant” and guidelines. My perception was that the terms and conditions would include areas dealing with the legalities of passing monies between the funding organization and the researcher rather than research guidelines describing safety, research quality, publication, etc., yet you use them interchangeably. Confidentiality issues might prevent an agency from sending you a copy of terms and conditions, but I find it difficult to understand why confidentiality was a issue for research guidelines.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

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