Author's response to reviews

Title: Can UK NHS Ethics Committees effectively monitor publication and outcome reporting bias?

Authors:

Rasheda Begum (rasheda.begum@myport.ac.uk)
Simon E Kolstoe (simon.kolstoe@port.ac.uk)

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Author's response to reviews: see over
Dear Editor,

RE: MS: 5584802201604776 - Can UK NHS Ethics Committees effectively monitor publication and outcome reporting bias?

Thank you for the helpful feedback from the reviewers on the above manuscript. I have updated the manuscript addressing all the issues highlighted, and for clarity address the revisions as follows:

Reviewer 143656508164908

All "minor essential revisions" have been done.

Major Compulsory Revisions (comment numbers added for clarity as line numbers refer to original submission):

1. L115, done, new line 113.

2. L120-121 – text clarified to state that publications were monitored from October 2013 until August 2014, and added the sentence "Researchers were not contacted directly as this stage of the project was seeking to determine the level of information that could be gained from the available databases.” New line 125-126.


4. L138 - yes this analysis was conducted and is indicated in figure 1A. We considered adding an additional figure but concluded that it would not add much more than the current figure.

5. L149 – This is the confidence interval range.

6. L150 – done

7. L154 – We have now clarified that we could only get hold of the full REC applications for 28 of the 37 studies. New line 166.

8. Statistics test used now clarified in method (see item 3 above).


Discretionary Revisions:

1. This was the title of the project proposed and agreed by the Health Research Authority so we are reluctant to change it at this stage.

2. We believe we have been consistent as only one odds ratio calculation is reported.
3. We have now added data regarding the number of trials that were registered.

4. (Did you check for reported adverse effects?) No. This would have been interesting but was beyond the scope of this study.

5. Conclusion – yes it would be easier and this is a proposal currently before the HRA.

6. We believe the figures enhance the understanding of the text.

7 & 8, we are hesitant to extend the introduction and discussion too far at this point. There is a lot of interesting work in this area that would merit more extensive discussion in perhaps a follow-up paper. The purpose of this paper is primarily to share our empirical results.

Reviewer 1506949458166540

Major Compulsory Revisions

1. This sentence has since been revised also in accordance with reviewer 1.

2. We have clarified that researchers were not contacted, also in accordance with reviewer 1.

3. As requested a comment regarding study amendments has been added to the discussion.

4. None that we could find.

5. We have now added our data regarding trial registration (also in accordance with reviewer 1).

6. We did not consider a conference abstract alone as a publication due to a lack of information inherent to this type of report. We have now clarified this in the results and provided a reference for this approach.

7. This has now been clarified in the methods, again also in accordance with reviewer 1.

8. We think analysing the mean provides what most people would interpret as “average time to publication”. The next stage of this project will analyse much more data and help to determine this in more detail.

9. 6 primary outcomes were unreported. This has now been added to the results section.

10. We did not examine whether outcomes from specific projects were significant or not. We only mentioned significance here because we thought it relevant that the researchers changed their outcomes.

11. We did not compare anything other than outcomes. This sentence referred to a subgroup analysis reported in the paper that was not a stated outcome in the original REC application. We have tried to clarify this in the text.

12. Yes, only one outcome was upgraded.

13. We have now updated the methods to include this (see point 7 and also point 3 in reply to reviewer 1).

14. Now added – see points 13 and 7 above.
15. We have mentioned (and shown in figure 1C) that in addition to the unreported outcomes we also identified one changed outcome and one new outcome.

16. We agree entirely with the referee that contacting researchers would be beneficial. This stage of the project was just to determine the level of information that could be gained just from a database search, and we are currently applying for funding to include a qualitative aspect to the work by interviewing researchers.

Reviewer 8689108621654291

Major comments:

1. We suggested this project to the Health Research Authority (HRA) in order to gather empirical evidence to inform the discussion on REC action. We have since presented the data at a number of workshops and the discussion regarding REC action is continuing. Once this work is published a follow up paper is planned drawing on the results described here to suggest next steps within the UK HRA context. There are currently many options on the table and discussing each is beyond the scope of this paper.

2. Similar to the point above, whether industry suppresses findings is an interesting area to discuss, but again outside the scope of this paper. The current comment is qualified by referring to a “perception that industry suppresses results” and a reference is provided for this.

3. Part of the purpose of the study was to gather baseline data and then repeat a couple of years from now to see how the requirement to register has changed the situation.

Major limitation

4. Regarding the time allowed for publication, this limitation is acknowledged in the second paragraph of the discussion. We accept that as time goes on the publication rates are likely to increase, but previously have had no indication of the rate for this. The current work suggests that the time period of 4 years may be key, an important observation on its own.

5. This issue of slow publication is again very relevant, but perhaps beyond the scope of this paper.

We have added all the minor points made by this reviewer.

In addition to the reviewers comments there was an editorial request to include a statement regarding whether ethical approval was necessary. This statement is contained within the “competing interests” section.

An editorial request was also made to adhere to PRISMA guidelines and include the checklist and flowchart. These modifications have now been made to the manuscript, however as this study was neither a meta-analysis nor a systematic review, a number of items (including the first one) were not applicable. The PRISMA flow chart is now included as figure 2, but we would caution that it may not be entirely relevant for this study.

We would like to thank the editor and the reviewers for their constructive comments on our work.

Yours Sincerely,
Dr Simon Kolstoe
Senior Fellow and Principal Investigator
University of Portsmouth