Author's response to reviews

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

Authors:

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Version: 4 Date: 22 June 2015

Author’s response to reviews: see over
22nd June 2015

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 and for the further clarification I have received from the editors. I have updated the manuscript addressing all the issues highlighted:

Reviewer Mario Malicki:

Major Compulsory Revisions

1. Please define acronyms before u use them firs time, e.g. CTIMPs, isrctn, EudraCT Hpss, NHS....

This has now been done.

2. Data Analysis - Please add MedCalc version number used

This has now been done – see line 147

3. Line 178- why the need to mention subgroup analysis. ? If the outcome was the same? Subgroup analysis explains the results, should not be considered an outcome.
4. Line 178- why the need to mention subgroup analysis. ? If the outcome was the same? Subgroup analysis explains the results, should not be considered an outcome. This makes me question the outcomes you measured. An additional table with these could perhaps be provided as supplementary materials.

We think 3 and 4 are duplicate requests. We have now edited the text (new line 201) to sound less accusatory “One tissue study had a new subgroup analysis in the publication that was not mentioned in the REC form.” We still believe it is significant that a new subgroup analysis was performed, although agree with the referee that this is perhaps not as significant as including a new outcome. We are unable to provide supplementary material listing all outcomes from all studies as this data is confidential due to the terms of the UK research ethics database.

5. Lines 214-218 should be in results first.

This has been added to the results, new line 174/175

6. Line183 proportion of unreported outcomes per study was 38%. Please provide 95% CI for the Median

This has been done in line 206
7. There was no correlation between the number of papers a study produced and the percentage of reported outcomes. (please list the range of p values for correlations or provide them in supplementary tables)

This has been added to the text in line 207.

8. correlation between the number of outcomes and the percentage of reported outcomes. As above

This has been added to the text in lines 209.

9. Line 222 -223 Add here a range as in line 197

In this work studies were either defined as “published” or “not-published”. As such the sentence “The only significant difference was with studies sponsored by industry that only showed a 12% publication rate, compared to around 30% for other types of sponsors.” Is just a statement of the percentage of studies in both groups that were in the “published” category. The statistical ranges etc. for the significance are stated in the results, line 173.

10. In my previous review I have listed as discretionary recommendations the need for expanding the intro and discussion sections, including newest version of Declaration of Helsinki and sys reviews of publication bias. There however I feel are mandatory to compare your results with the current knowledge of the field.

The reviewer has changed their mind regarding a previously discretionary recommendation. We would tend to agree with the second reviewer (Elizabeth Wager) who stated:

“They have chosen to keep the Discussion quite short and focused rather than broaden it to discuss causes for phenomena such as slow publication, but this is legitimate, since this study did not attempt to examine these factors, it simply provided a snapshot and focused on selective reporting.”

Nevertheless we have now added a reference to the Declaration of Helsinki (line 214).

11. Please add limitations about the generalisability of the results based upon the small sample size and the fact you did not contact the authors.

This has now been added to the discussion (new lines 239-243).

Discretionary Revisions

1. Abstract - Suggest removing from the conclusions:
The data gathered by this project, as well as the method described here and rephrasing the sentences that contain them

This has been done, see new line 77.

2. Intro - suggest deleting:
In this paper we report our findings and argue that as a national body, the HRA is well placed to monitor reporting bias. Just state the hypothesis, the argument can be left in the discussion.

This has now been removed from the introduction and expanded in the discussion (lines 222-226)

Reviewer Elizabeth Wager:
I am not sure the PRISMA diagram adds much useful information and it is, perhaps, even a bit confusing as it includes both the number of studies and the number of publications. Unlike the other reviewer, I’m not convinced it is a very useful addition and would agree with the authors that, as this wasn’t a systematic review, such a diagram isn’t really relevant for this study.

We agree with the reviewer and wish to remove this diagram.

**Editorial Revisions (communicated by email from the executive editor):**

Please provide a statement regarding ethical exemption and data access within the Methods section. This is currently included within the Acknowledgements.

A section in the methods entitled "Ethics and data-access" has now been added (line 149).

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

Yours Sincerely,

Dr Simon Kolstoe  
Senior Fellow and Principal Investigator  
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