Author’s response to reviews

Title: Abstracts in high profile journals often fail to report harm.

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Author’s response to reviews: see over
Reviewer #1
Sheena Derry

“There are a number places in the text where dashes and hyphens are used inconsistently to separate phrases or clauses”

Reply: Accepted and changed.

Reviewer #2
Sally Hopewell

Page 4; para 1: the authors state that a random number table was used to get a sample of RCTs published in 2003. I think it would be helpful to still be more explicit here.

Reply: We appreciate the comment. We hope the new text is more specific.

Those RCTs fulfilling inclusion criteria were sorted by their PMID number. A consecutive id number from 1 to 363 was assigned. Then, a random numbers table was used to recover the sample of 2003 RCTs to be studied.

Page 6; para 1: the authors report that only 34% of abstracts reported any kind of numerical data. Again I think it would be helpful to report what sort of numerical data was reported and more importantly what was reported for the remaining 76% of abstracts reporting harms.

Reply: We have added a new text giving additional information about how numerical information in the abstracts is given.

Harm was reported or quantified in 135 abstracts [37.2% (CI95%:32.2% to 42.38%)], 40% of them (54 out of 135) used some kind of numerical data: 33 abstracts reported either “p values” (27 articles) or confident intervals (6 articles). The remaining 21 abstracts referred to harm in terms of percentage (or mean) of events in each arm, though no statistical information was offered. When no numerical data was reported (81 articles) unspecific expressions like “there were no differences in adverse events” were used.
Page 9; para 2: reviewer 4 recommended that the authors take into account the publication of a very recent extension to the CONSORT Statement for reporting abstracts of randomized trials. This has not been addressed by the authors and could be mentioned here as many of the issues brought forth by the authors are covered in these publications.

Reply: We fully agree with the reviewer in quoting both articles. Furthermore, some additional comments have been added, in both the introduction and the discussion to better fit the quote.

Reviewer #3
David Moher

1. Some important literature on the topic is missing and needs to be cited

Reply: I would like to thank Dr Moher for his suggestions. Suggested quoted have been cited both in the introduction and in the discussion sections. His main suggestion (CONSORT extension for abstracts, 2008 PLOS Medicine) was not quoted in our last reply because it was not available the time we uploaded the 1st revision of our manuscript.

2. Page 3, 3rd paragraph. Most RCTs are not phase IV. Such studies are typically post marketing surveillance ones. Without clarification as to how the authors have included what appears to be randomized phase IV trials readers will find this classification confusing and possibly troubling.

Reply: We admit that some expressions may be troubling for readers. However, in our study we only accepted RCTs, no post-marketing surveillance studies as expressed in box 1 (search strategy).

3. The authors need to explain why they chose a sample of 2003 reports almost 5 years old.

Reply: The decision was driven by the fact that the first extension of CONSORT which included some comment on the way harm must be reported in RCTs was published in 2004. Although the recommendations were no specific for abstracts, we decided to avoid the possibility of contamination choosing articles from the previous year.
4. It appears that the authors did not use standard search filters to identify the RCT reports. For example a widely acknowledged and acceptable filter the HSSS one. The authors did to explain why this was not used.

**Reply:** We would have agreed with the reviewer’s comment if our aim had been to carry out a systematic review or meta-analysis but we simply wanted to develop a structured revision of a sample of RCTs. We also would agree with Dr Moher if any kind of inference over the universe of RCTs had been made in the text, which we did not.

5. The authors do not report whether the two junior researchers (page 4) received any training and/or participated in a pilot study. This is important as it appears they did the majority of data extraction (upon which the results are based).

**Reply:** We fully agree with Dr Moher. In fact we developed a pilot study and the research period started when concordance between observers was high. We have added a paragraph to better understand the method we used.

New text: Secondly, two trained junior researchers, blinded to the hypothesis of the study received an electronic copy of each article –any single reference to the authors and to the journal was masked– and retrieved all the remaining information using the developed tool. In order to control inter-observer reliability, accuracy between observers was evaluated before (pilot study) and during the research period. Accuracy ranked from 73% to 82% in main variables. Disagreement was resolved by a third blinded observer using consensus when necessary.

6. Are the included studies in the research available complete reference list) to interested readers.

**Reply:** A file with the articles used has been uploaded for the reader’s additional information if needed.