Author's response to reviews

Title: Endorsement of the CONSORT Statement by high impact factor medical journals: a survey of journal editors and journal Instructions to Authors

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Author's response to reviews: see over
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Trials,

Dear Editors,

Re: Publication submission MS: 7551744261784555

Thank you for the detailed comments and suggestions regarding our manuscript entitled “Endorsement of the CONSORT Statement by high impact factor medical journals: a survey of journal editors and journal ‘Instructions to Authors’ ” for consideration in Trials.

We describe below how we have taken into account each of these comments in our revised manuscript and look forward to hearing your response.

Yours sincerely,

Dr Sally Hopewell
Response to reviewer's comments

Major compulsory revisions

1. Page 7 (results): The authors made a calculation error. I would recommend calculating the RR by hand. The RR should be \( \frac{39}{62} / \frac{30}{103} = 2.161 \). Or the authors should change the sentence into Journals that refer to the ICMJE guidelines were much more likely to refer to the CONSORT statement \( \frac{39}{69} \) than those journals that did not refer to the ICMJE guidelines \( \frac{23}{96} \) (RR 2.36).

SH: Thank you for spotting this, we have corrected the error. The RR is 2.16 (95% CI 1.51-3.08)

2. Page 7 (results): The same RR calculation error occurred for the clinical trial register. The RR should be \( \frac{42}{62} / \frac{19}{103} = 3.672 \) and not 3.58.

SH: Thank you for spotting this, we have corrected the error. The RR is 3.67 (95% CI 2.36-5.71)

Minor essential revisions

3. Page 1 (title page): Please, change the title of the paper: To my opinion, not the impact and adherence to the CONSORT Statement is evaluated but the implementation (or use, or endorsement) of the CONSORT statement is evaluated. The word impact refers more to the impact on the quality of reporting of RCTs. This is not evaluated in this paper.

SH: We agree and have amended the title to “Endorsement of the CONSORT Statement.”

4. Page 4 (background): In 2003, Altman conducted a study of journal endorsement of the CONSORT Statement and found that eight years following its initial publication and two after its update, only 22% of 166 high impact factor journals provided any mention of CONSORT in their published Instructions to Authors. Should it be seven instead of eight years? 2003 - 1996 = 7 years?

SH: We have corrected this.

5. Page 4 (background): Four years have elapsed since this journal endorsement survey and we believe it is again timely to assess the impact of the CONSORT statement. Should it be 5 years in stead of 4? 2008 - 2003 = 5 years. Furthermore, what is the main reason to evaluate the endorsement and use of the CONSORT statement? Please, motivate more clearly. Is more attention needed to the CONSORT statement, because the quality of reporting is still poor? Is something changed after the survey of Altman in 2003 (publication 2005)?

SH: The survey was carried out in 2007 and so four years have elapsed since the survey was last conducted.

6. Page 5 (sample): Does this subheading not belong to the methods?

SH: We have changed this.

7. Page 6 (results): Please, report the absolute percentage improvement. The relative increase is misleading. This means, report 16% (38%-22%) and 13% (39%-26%).

SH: We believe that the relative percentage increase is the more appropriate measure to report here and is consistent with the relative risk reported elsewhere in the study.

8. Page 7 (results): Please, report the percentage (ICMJE guidelines 72 of the 166 journals = 43%)

SH: We have added this.

9. Page 7 (results): The sentence Those journals which provided some mention of the CONSORT statement in their instructions for authors were also much more likely to include information about other reporting guidelines. The percentage of the number of journals that reported the other guidelines
(QUORUM, MOOSE, REMARK STROBE, TREND) does not support the first sentence. Please provide evidence for this sentence (i.e. How many journals that mentioned CONSORT also mentioned one of the other guidelines, and how many journals that did not report CONSORT reported one of the other guidelines).

SH: All journals which mentioned the CONSORT Statement also reported other guidelines. No journals, not mentioning CONSORT, mentioned one of the other guidelines.

10. Pages 7 and 8 (results): It is unclear how many editors of journals confirmed that the CONSORT was mentioned in their instructions for authors: 39 of the 64 responders or 47 of the 58 respondents. The numerator is changing on page 8 from 64, to 57, to 56, to 58, to 53. This is confusingly. Please correct or explain.

SH: Not all journals responded to all sections of the survey. This is why the denominator changes for different sections from the survey. A foot note is added to the bottom of Table 2 and 3 to reflect this; however, we have also added a note to the text to hopefully avoid any confusion.

11. Page 9 (discussion): How would you recommend journals to keep their instructions up to date?

SH: We do not feel it is appropriate to stipulate how journals should keep their journal’s “Instructions to Authors” up to date.

Discretionary revisions

12. Page 2 (abstract): first sentence. I doubt whether CONSORT only provides recommendations for reporting the results of RCTs. This sentence should be more correct, including methods etc, or remove the words the results.

SH: We agree and have amended this sentence.

13. Page 2 (abstract): sentence we surveyed the editor-in-chief or editorial office. Is this correct English? Although, I am not a native speaker, I have doubts whether you can survey an editor-in-chief?

SH: We feel this is correct and have not changed the wording here.

14. Page 2 (abstract / methods / results): Does all journals report their instructions for authors online? Some journals only print them in the journal? What did the authors do with these journals? Did all journals have a website?

SH: All journals included in our survey posted their “Instructions to Authors” online or as a PDF download from their journal’s website.

15. Page 5 (sample): Please, remove last sentence One hundred and eighty journals to the results paragraph.

SH: We have changed this.

16. Page 5 (methods): Please specify how editors / the editorial office were contacted (by e-mail or telephone).

SH: Journal editors (or the editorial office) were contacted via email. We have added this.

17. Page 5 (methods): I am wondering whether the sentence in the methods should be written in the present tense. Should it not be “In case editors do not response, a reminder will be send after # weeks and # weeks”. Finally, authors can report the numbers of reminders send.

SH: We feel this is correct and have not changed the wording here.

18. Page 6 (methods): Did the authors asked questions to the editors which can be found in the instructions to authors (i.e. their journals endorsement of the CONSORT Statement, whether CONSORT is included in
their Instructions to authors). If the authors have asked questions to the editors which can be found on the journals website, they might get irritated, explaining the low response. Or do the authors have any (other) explanation Do the authors have any insight whether this was the case?

SH: We asked editors whether they mentioned the CONSORT Statement in their journal’s “Instructions to Authors”. This information could have been found on the journal website. However, this survey also asked specific questions about endorsement of CONSORT in journal editorial and peer review processes (information not commonly available on journal websites). Interestingly we found that despite some journals saying that they included information about CONSORT in their journal’s “Instructions to Authors” this was not always the case when subsequently cross checking; particularly for CONSORT extensions.

19. Page 6 (results): First sentence. Should it be 62 (38%) mentioned the CONSORT Statement instead of some mention of?

SH: We have changed this.

20. Page 7 (results): Please remove the word indeed.

SH: We have changed this.

21. Page 8 (results): Could the authors classify which journal used the CONSORT statement within the editorial process by the reviewer, the author, the editor? This is not clearly described. Furthermore, how many editors of journals checked whether the CONSORT statement was filled in correctly?

SH: We did not extract this level of detail as part of the survey. We asked journals to describe how they incorporated CONSORT into their editorial and peer review processes and have reported some examples of these techniques in our study.

22. Page 9 (discussion): What do the authors mean with a proper endorsement? I have doubts whether this is investigated in the study of A Plint (reference 10).

SH: The citation relates to a comment made by Plint and colleagues, such that only by endorsement by more journals, and greater editorial efforts to ensure that authors comply, can CONSORT begin to yield the full benefits for which it was intended. We have revised the wording of this sentence to reflect this comment more accurately.

23. Pages 9 and 10 (discussion): The authors express their disappointment that the trials should be registered before enrolment of the first patient and that journals should make the same requirements for the CONSORT statement. I would like to remind the authors that CONSORT is not a guideline (checklist) for setting up a RCT, but a guideline to improve reporting of RCTs. Authors could make a statement that CONSORT should not only be used when the data-collection is finished, but that these guidelines could also be used before the start of the patient requirement.

SH: In our study, over a third (37%) of journals required recent clinical trials to be registered as a requirement of submission to that journal. Disappointingly, a number of these journals did not provide the same endorsement of the CONSORT Statement. We are suggesting that, whilst trial registration is important, it by itself, is not the best marker of trial quality and that these journals should also adopt the CONSORT recommendations.

24. Page 9 (discussion): Do the authors have any explanations or ideas why 62% of the journals do not mention CONSORT in their instruction for authors?

SH: It is not clear why the remaining journals do not mention CONSORT in their “Instructions to Authors”. It is hoped that surveys such as the one reported here and empirical studies such as the systematic review undertaken by Plint and colleagues (2006) will help raise awareness of the importance of better trial reporting.

25. Page 15 (table 2): Please, describe the difference between the peer review process and the editorial process in the text or legend.
SH: We think the distinction between the peer review and editorial process are clear, however, we would be willing to add something to the text if the editors think this would be useful to the reader.