Reviewer’s report

Title: Professional medical writing support and the quality, ethics and timeliness of clinical trial reporting: a systematic review

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Reviewer: Holger Langhof

Reviewer's report:

In their article, Evuarherhe et al. present the findings of a systematic review of the quality, ethics and timeliness of publications of clinical trials that had been prepared with professional medical writing support (PMWS). Results reporting of clinical trials is a critical point and indeed an ethical imperative. Several studies in the last years highlighted the often biased, incomplete or opaque publication of results. In their article, the authors review existing studies that examined effects of professional medical writing support on trials results reporting. The research question is interesting and the findings overall contribute to ongoing discussions on the improvement of result reporting rates. I think the article deserves publication in Research Integrity and Peer Review, subject to some minor revisions.

More specifically, I have the following comments to the authors:

Abstract: The conclusion given in the abstract conclusion sounds a little too straightforward, given the results presented in the review. The statement that the "overall quality" increases would certainly benefit from a bit more empirical evidence. Maybe you could choose a wording that is more careful, as you do for instance by stating that PMWS "may improve the timeliness of publication". The wording on Page 7 lines 151-53 also sounds more appropriate.

Background: I think the background could benefit from some few more words on why the timely publication of trial results is an ethical imperative. I would therefore suggest to link this study in the broader context of the "Value and waste"-debate (see for instance Macleod MR, Michie S, Roberts I, et al.: Biomedical research: increasing value, reducing waste. Lancet. 2014; 383(9912). There are currently many initiatives and research groups working on improvement of trials results reporting, some of them are already cited. It would underline the importance of this systematic review.

Methods: Is there a reason why you limited the supplementary searches from 2014-17?

Overall, it is not entirely clear how you define quality, ethics and timeliness. How did you extract information from the included studies on e.g. ethics? What would have been ethical aspects? As your results suggest, the only issue in "ethics of publication" is the reporting of non-
pre-specified outcomes. How is this distinct from quality (e.g. the CONSORT items)? If you were not able to pre-define what you have been looking for when you searched for "ethics of publication", I would suggest to omit "ethics" as an individual result, but instead subsume the of non-pre-specified outcomes to "quality". To me, even adherence to CONSORT is part of an "ethics of publication". Later in the conclusions section, however, you list some more ethical issues (e.g. transparency on conflict of interest etc.) and you cite two studies. Why have these studies not been included in your review?

Page 4, line 93: I would suggest to say "effect" instead of "influence", as the latter is too causal.

Results: The results are presented in a nice and readable manner. Only point is the unclear operationalisation of "ethics of publication". However, I wonder if in any of the reviewed studies the authors also investigated how quality of reporting with or without PMWS differs in relation to study characteristics (e.g. phase I/II versus phase III trials). Is there any evidence on this?

Conclusions: To me the conclusions drawn from the systematic review seem appropriate.

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Quality of written English
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