Reviewer’s report

Title: When are clinical trials registered?: an analysis of prospective versus retrospective registration

Version: 0 Date: 28 Sep 2015

Reviewer: Daniel Strech

Reviewer's report:

I do not feel competent enough to judge whether the study provides sufficient new insight on the topic of publication of retrospectively registered clinical trials. The authors mentioned some other studies but at first glance all seem to be rather explorative. However, my focus will be on another point which I mention in the following paragraph.

The issue of retrospective registration itself is of interest for those that study issues around registration as one cornerstone in the overarching "increasing value, reducing waste" discussion. The fact that the majority of published trials in the BMC series were not registered prospectively is certainly an interesting finding, helps raising awareness of the work to do and supports ongoing efforts such as the All-Trials initiative. The fact that the authors build part of BMC is welcomed.

Before I come to my major comment I would like to highlight some minor comments:

Page 4, line 7: the authors stated that clinical trial registries address the problem of selective reporting. Maybe it is better to state that registries "aim" to address this problem and then the authors could mention some recent reviews that assessed the completeness of registries and how often summary results are published in registries, etc.

Page 4, line 20 and 24: the authors should cite references for their empirical claims.

Page 9, line 7: the authors mentioned that "Journals are not well placed to enforce prospective registration". Some more discussion on this topic would strengthen the claim. Although it is true that other stakeholders could be more involved in promoting prospective trial registration, editorial policies are in a strong position to influence registration efforts and contribute their part
to increase value and reduce waste in research. I am fine with the argument of the authors that some journals should also publish trials that have not been registered so as to avoid the loss of trial information, but this does not mean that journals could not play an important role in enforcing prospective registration at the same time.

Major comment:

The discussion on the ethics of publishing retrospectively registered trials is important for this paper and should be expanded; especially, but not only, because the authors build part of BMC. The argument in favor of publication of retrospectively registered studies to prevent the potential loss of information is sound. However, it is only one argument that needs to be analyzed and balanced with regards to other equally sound arguments against publication. The authors should mention these arguments in a neutral way as well. Otherwise, the discussion section is too biased. After neutral presentation of arguments for and against publishing non registered or retrospectively registered clinical trials, the authors can then state that the BMC series decided, of all things considered, for an editorial policy that allows this type of publication.

However, the ethical analysis should not stop at this point but should elaborate more on "what conditions should be fulfilled to make the publication of retrospectively registered trials as ethical as possible". For example, journals such as the BMC series might require authors to explicitly state in the main text that the study was registered retrospectively. This is necessary information for the reader. Otherwise, the reader might put more trust in the paper than they should. Simply because the higher credibility of results that might come with prospective registration (such as transparency about protocol deviations) do not apply for this paper. If papers only state that the study was registered without adding the relevant information that it was retrospective registered, journals consciously misinform the reader.

Unfortunately, this important point does not appear in the discussion and even more important the authors do not present any data on how many of the retrospectively registered studies reported that fact explicitly (and not only the registration number or date). This empirical information should be added to paper. It is only in the last sentence of the conclusion where this point shows up (but again without data about the current status quo). Additionally, I also miss any remark on whether BMC or any other journals have this explicit policy that requires (and not only recommends) an explicit statement on the date of registration or even better an explicit statement that the registration was retrospective. The latter is better because most readers will probably not check whether the data of registration was for or after enrollment of participants.
In summary, I vote for a major revision decision with regard to my major comment. If the authors present the mentioned data and comprehensively discuss their findings with an outlook on the potential changes for editorial policies, the paper would contribute highly to the field of clinical research reporting and suit well for a publication in Trials.

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