Reviewer’s report

Title: Clinical drug trials in general practice: How well are external validity issues reported?

Version: 0 Date: 02 Jul 2017

Reviewer: Merrick Zwarenstein

Reviewer’s report:

Dear Authors,

I think this is a well conducted review of a large number of relevant trials, and would be immediately publishable if you somewhat improve your literature review and include other existing works on this same topic in your background and discussion.

Specifically, your assertion that there is no existing standard for reporting trials with reference to their external validity or generalizability is not correct. I think the introduction and discussion sections of your paper should be rewritten to take critical account of the already published standards for this question, and your empirical results can be used to argue for or against the comprehensiveness of the existing published standards for external validity.

On the Consort website you will find a Consort reporting standards paper specifically aimed at reporting pragmatic trials, that is, trials aiming at wide applicability and real world use of results.

The published reference is:


On the same note: you reference another paper in which I was involved, but don't really grapple with its main point, which is explicitly about designing trials for external validity. This paper, your reference number 50, itself contains a series of 9 recommendations for items that should be considered during design of a randomized trial; these items could well be used as a basis for your discussion on what should be reported for trials with an intention to focus on real world usefulness and external validity.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

No competing financial interests, but my view of the paper is obviously influenced by my authorship of several papers on trials intending to maximize external validity, the same problem on which the authors are writing this paper.

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