Reviewer’s report

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

Version: 0 Date: 31 Jul 2017

Reviewer: Anne-Kirstine Dyrvig

Reviewer’s report:

The manuscript concerns an aspect of utmost importance and relevance. I find that there is sufficient coherence between the themes given in the title, abstract, manuscript, and conclusions.

My main concerns and the reason that I selected the option "major revisions" is that the statistical analyses need to be reconsidered and that some central aspects in terms of organising the paper and restating the aims is necessary. Otherwise I truly enjoyed reading the paper and find that the Work is valuable and a great contribution to the field of external validity.

My comments are structured in chronological order with reference to the manuscript section below.

Introduction:

- The aim is clearly stated, although it would be valuable with a definition of "sufficient information" or perhaps choosing another term. I would recommend that a section is added with clear specified objectives of the paper, as the aim does not cover all the topics/objectives that are addressed in the manuscript.

- Also, please consider if your ambitions with the manuscript are too extensive for one article, or if it could be better presented in two manuscripts. For instance, the "case study" that is used partly for illustrative purposes could perhaps provide sufficient information for a separate article.

Methods:

- Study cohort is clearly described. It is not clear, however, why the different cut-offs were made (period 1998-2007 and papers with publication years 200-2015). It would be nice to know why these periods were selected and why the delimitation was made on period rather than publication or on whether studies were finished or any other characteristic.

- Data extraction: Why were only half of the trials assessed by two authors. And how were they selected (it is mentioned in the discussion that the selection was random)

- Data extraction: You mention that data are extracted on setting, patient selection, primary outcome, and eligibility criteria. While those are reasonable choices, they are not
properly introduced and thus it seems they were not actively chosen. If they were selected, please mention if they were selected on the basis of availability, relevance, or...

- Data extraction: Here the case-study is mentioned. It should be introduced earlier. And if the current amount of attention spent on the case-study is to be maintained, the case study deserves an earlier introduction, and a mentioning in the aims/objectives.

- statistical analyses: The section is fine, although it is unclear why the choice was made to test for before/after 2007. I think these tests that were conducted for a number of the variables are arbitrary. Either the variables should be tested for trends over time, or analyses should be kept to descriptive statistics. Chi-squared tests for arbitrary 2X2-tables seem like an attempt to introduce statistics, where statistics may be redundant as the trends can be spotted through the very nice Graphs presented in the appendix.

Results

- Reporting of trial setting: Much attention is given to the presence or absence of statistical significant differences. But as it was not mentioned as an aim to investigate the Development over time (or, more precisely, the difference between before and after 2007), it seems quite surprising and not necessary.

- I would suggest to simply report the items that were investigated and drop the focus on before/after 2007.

- Reporting of patient selection: You state in the final sentence: "The proportion reporting eligibility criteria improved over time", but is that supported with an analysis or is it mainly based on visual interpretation of the figure?

Discussion

- The section is generally difficult to understand, as it is not clear when authors are discussing their own results or when they are referring to the results of others. Revision of the language is recommended, as the points made in the section are valid and relevant.

Conclusions

- The sentence "we here observed improved reporting over time". I don't think this is true on the basis of the analyses. You observed an improvement after as compared to before 2017. Not necessarily a trend over time.

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

No

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

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