Reviewer’s report

Title: Selection Bias and Subject Refusal in a Cluster-Randomized Controlled Trial

Version: 0 Date: 07 Feb 2017

Reviewer: Roberta Scherer

Reviewer’s report:

The authors of this manuscript have looked for evidence of bias in a cluster randomized trial of pharmacists-led versus usual care for individuals at risk of decreased cardiovascular health. The trial was conducted in 12 clusters, 6 in each arm of the trials. To identify selection bias, they compared the proportion of eligible individuals with health indicators (uncontrolled diabetes, hypertension, or hyperlipidemia and mean HB1AC, LDL, systolic and diastolic pressure, and smoking status) in four groups: intervention arm consenting, intervention arm refusals, control arm consenting, and control arm refusals. Overall the methods are clearly presented and straightforward. Most of my comments are related to clarification of the methods.

1. There is an underlying assumption that the clusters have similar populations. There is no mention in this or the protocol on how the sites were chosen and whether any measures were taken to ensure comparability (i.e., if they were matched at all). The small difference in the total number of eligible persons with uncontrolled diabetes in the two groups (65% (154/236) versus 58% (130/225) suggests either that the sites were not be completely matched or this could be just a chance finding. Similarly, given the number of comparisons (over 20), the significant finding of a difference in the proportion in the declined intervention group could also simply be a chance finding; the authors should suggest that is a possibility in the discussion.

2. Three different methods of recruitment were mentioned in the paper (mailed letter, telephone contact or face-to-face during an office visit). Is there a difference in how participants were recruited in each of the 12 sites? For example, if most of the intervention sites recruited during face-to-face meetings rather than by mail. If so, could the method of recruitment have made a difference leading to the difference in the proportion of persons with uncontrolled diabetes in the declined versus the consented groups?

3. Lastly, the findings of this paper were generated from the ICARE trial. Because the scope of the journal is on methods, it would be appropriate to comment on the application of this method for assessing bias in other cluster randomized trials. What are the strengths and limitations of this method in general, rather than specifically for this trial? What are the lessons learned? For example, could this study have been strengthened if the reasons for refusal were collected?

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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