Reviewer's report

**Title:** The effect of a decision aid intervention on decision making about coronary heart disease risk reduction: a randomized trial

**Version:** 2  **Date:** 30 May 2013

**Reviewer:** Kensaku Kawamoto

**Reviewer's report:**

Major Compulsory Revisions

1. Title does not reflect that this is a secondary analysis of a RCT. Please revise.

2. The authors use a 2003 review (Ref. 30) to justify that this study is needed. Also, they simply state that “few decision aids have been studied in this context.” This implies that other decision aids have been studied in the same space. Without the authors reviewing the literature for similar studies, and moreover outlining them and explicitly specifying what this study adds that was not addressed in these prior studies, it is hard to draw a conclusion on the need for this study. Therefore, please add in the introduction a review of what has been done previously on this topic, and what questions remain that were addressed by this study. For example, doing a quick PubMed search on the terms “decision aid” medication, and adherence, I found several studies that seemed to have significant overlap with this manuscript:

   http://www.ncbi.nlm.nih.gov/pubmed/21605732,
   http://www.ncbi.nlm.nih.gov/pubmed/21533288,
   http://www.ncbi.nlm.nih.gov/pubmed/20519453,
   http://www.ncbi.nlm.nih.gov/pubmed/20473211,
   http://www.ncbi.nlm.nih.gov/pubmed/19959322,
   http://www.ncbi.nlm.nih.gov/pubmed/19786674. Of note, these manuscripts were all published after 2003.

3. In reporting decision support tools such as the one described here, it is essential that it is described in sufficient detail to enable replication and detailed understanding. Please include information to that level of detail, e.g., as an Appendix or supplement that shows screenshots from the system that would allow for replication and detailed understanding.

4. I would recommend using a term such as “individualized risk assessment and education” as a better term than just “education” to characterize an intervention that includes giving patients their 10 year CHD risk information. Prior to getting to the methods, I assumed education referred just to educating patients about CHD risk and risk reduction in general. Please use a more descriptive term such as the one suggested here.

5. There seems to be conceptual overlap between the “education” component and the “coaching tool” component. It seems that a number of items in the “coaching tool” component are in fact education. Also, the “coaching tool”
includes a summary sheet for the providers – which does not seem to me to be a coaching tool. Please clarify terms and make them match the contents of the intervention more closely. E.g., perhaps this part of the intervention can be called something like “provider interaction coaching and provider summary”.

6. In table 4, please add 95% confidence intervals for all relevant columns (post-education, post-values clarification, post-coaching tool, post-visit). Please describe in the results, and discuss, why intent sometimes went down (sometimes significantly) after post-values clarification and the post-coaching tool. E.g., why was BP med intent 11% at baseline, 65% after the first two intervention components, down to 37% after the coaching, and down to 26% after the visit? There seems to be indications that the coaching and, in fact, interaction with the provider reduced intent. I think this is a really interesting finding that should be explicitly brought up and discussed.

7. Please describe in more detail and try to explain the difference in time required by participants – this is an important consideration for practical, non-study-setting use. Please include a standard deviation. Please also comment further on what did or did not correlate with the time required. Was the 45 minute outlier, for example, among the 2% of intervention patients who did not have a college education? Would it have gone longer if the study visit was designed to go beyond 45 minutes?

8. The study design does not allow for the conclusion that component 1 (“education”) resulted in the change, and not components 2 and 3. This is because component 1 was never tested against components 2 and 3 – it was always tested against 1 + 2 and 1 + 2 + 3. It’s possible that if component 2 or 3 was given first, that the result would have been the same – e.g., component 2, when given first, produces the change, and adding in component 1 doesn’t make a difference. To overcome this, the tool could potentially have been designed to randomize the order in which the different components were provided. This probably wasn’t feasible in this context, but it’s important to explicitly consider this issue and to describe the results in a way that acknowledges this. A simple reading of this study could be that the “education” component is the most important, and that we shouldn’t bother with the other two. This may be true if the first component was the easiest to implement in practice, but it may also be the case that perhaps some of the other component are easier to carry out because they don’t require the calculate of a 10-year risk score. Please make sure this issue is considered and explicitly reflected in the description of the results and the discussion.

9. Was a question asked about whether the time required was excessive or appropriate? Did anybody comment on this? Please provide some insights on this, as this is of practical importance.

10. There is no information on patient feelings about the decision aid in the abstract. At attempt should be made to add this.

Minor Essential Revisions

11. Please provide a reference when defining a decision aid.
12. Under Participants, “risk” should be after “(> 10%)”.
14. Under Measures, please specify more clearly how a composite “best evidence” variable of intent was produced.
15. Make the Healthcare Climate Questionnaire a provided appendix. The link provided is already broken.
16. Please specify more clearly how a composite “best evidence” variable for intent to take aspirin, blood pressure, or cholesterol medication and/or to stop smoking was developed. Also, please clarify why you are calling this and the other measure a “best evidence” variable. A more descriptive term seems to be something like “risk reduction intention composite score.”
17. “We electronically tracked” should have something like “the following” before the colon. Otherwise, the colon should be taken out.
18. Analyses section – use “did not” rather than “didn’t.” “Dichotomous variable” should be plural. Should have apostrophe after “We compared control and intervention groups”.
19. Were free text patient comments captured? If so, please briefly summarize what patients commented on in those free text comments.
20. Remove extraneous comma space in second paragraph, first sentence, section “Effect of decision aid on patient-provider discussions…”
21. Missing an opening parentheses in the next section. Please make sure to proof-read the manuscript and correct these types of grammatical errors prior to the next submission.
22. The acronym DA is added late in the manuscript and without prior definition. Please either use it throughout or spell out throughout.
23. In first paragraph of Discussion, it alternates between “patients’” and “patient’s”. I think it should be the former for both. Please correct.
24. In the methods, it should be clarified what was optional and what was required (e.g., the coaching resources). The results should include information on the use rate of all optional elements, including the coaching resources.
25. If possible, please add line numbers with the manuscript for the next submission.

Discretionary Revisions

26. I believe “data” are considered plural, rather than singular. Data are currently treated as singular. Please revise (or not) based on the editorial policy of the journal.

**Level of interest:** An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interest.