Author's response to reviews

Title: Development and initial testing of a computer-based patient decision aid to promote colorectal cancer screening for primary care practice

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Author's response to reviews: see over
To the Editors:

Thank you for encouraging us to submit a revised version of our manuscript, ID 1521137416700581, “Development and Initial Testing of a Computer-Based Decision Aid to Promote Colorectal Cancer Screening for Primary Care Practice.” Attached to this letter is the following:

-A revised manuscript with formatting changes as requested

Thank you for your consideration. I look forward to hearing from you soon.

Sincerely,

Jane Kim, MD, MPH
1. **Methods, ethical approval** - Any experimental research that is reported in the manuscript should have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration <http://www.wma.net/e/policy/b3.htm>, and any experimental research on animals should follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

**Reviewer: Paul Taylor**

**Discretionary Revisions:**

1. *Some more detail on the nature of the information provided in the decision aid would be of value.* Please see additional text in Section 2.2, Decision aid content and format. We included more description about what information was included and how it was presented.

2. *I think that the most interesting finding is that many patients who said, having consulted the tool, that they did not intend to be screened, actually were screened. What can your data tell us about this? Did these patients say that they were content with the information they obtained from the tool? I think you need to take seriously the possibility that patients did not make their minds up about screening until after the questionnaire was completed.*

The fact that 40% who said they were not ready actually underwent screening may indicate that they were not ready for screening at the time of the exit questionnaire but for some reason were screened. There are a number of possible reasons for this finding, one of which is that individuals decided on screening after completing the questionnaire because of a discussion with their provider. Most of these individuals said that the aid increased their knowledge about colon cancer and thought the aid helpful in deciding on screening. We did not investigate reasons for this relatively high rate of screening among those who were not ready at the time of the exit questionnaire, but as we indicate in our discussion, this is an interesting area for future investigation.

**Reviewer: Mary-Ann O’Brien**

**Major Compulsory Revisions:**

1. *A major issue in the design is the inclusion of patients (18%) who were up-to-date with their screening. This appears to have been handled in a secondary analysis by comparing the proportion of patients with completed tests among patients who had previously been screened, were up-to-date with screening, or had previous conversations about screening versus those who had not (page 11). On page 13, the authors state that “screening test completion rates did not differ significantly between those who were already up-to-date with screening and those who were not in compliance”. It is not clear whether the authors had sufficient power to detect an important difference between these two groups.*
As the authors state, patients who are up-to-date may be less likely to have test ordered or completed. Conversely, these patients may be more interested in screening in general as evidenced by the fact that they have completed screening appropriately. Therefore, these patients could be quite different from those who would be the actual target of the intervention that was developed. The main analysis should be clearly reported for both main outcomes (intent and interest) with and without patients who were up-to-date. Further, all data (Tables 1–3, Figure 4) should be presented separately for those who were up-to-date with screening and those who were not. We agree with these points. In this pilot trial, we did not plan our study to have sufficient power to detect significant differences in effect between those who were up-to-date and those who were not, as this was not one of the aims of our study. Because there were only 14 patients who were up-to-date with screening, this small number makes estimates for comparison to the rest of the patients who were up-to-date (n=66) less reliable and should be interpreted with caution. This point was added to the Discussion.

We have, however, included an additional table (Table 4) that stratifies intent and interest as well as screening tests ordered and completed by up-to-date status. Calculating the percentage of screening tests ordered and completed by up-to-date status and by readiness to be screened produced too few numbers in some of the cells to be reliable enough to be reported or interpreted. We did, however, include patients’ readiness to be screened in Table 4 stratified by up-to-date status. The demographics of those who were up to date and those who were not were similar, which we have now noted in section 3.1, Patient characteristics, but we did not include this information in table form.

2. The second issue relates to the low response rate (31%) and selection bias... It is unclear why patients were not asked to come in early for their visit so that more patients could be enrolled..... Was there another eligibility criterion, “interest in learning”? The low response rate reflects the difficulties of performing research within a busy primary care practice. Interest in learning was not a specific inclusion criterion. We have deleted this sentence from section 2.5 as it did appear from the wording that we selected patients based on interest in learning, which was not the case.

Minor essential revisions:

3. More detail is needed about how readability was assessed. The authors should also indicate whether or not there was attempt to balance the information on risks and benefits for each option. The decision aid had an accompanying audio track providing narration for all the figures and much of the decision aid content was delivered through patient vignettes and physician narration, which made the decision aid context accessible to patients with a variety of reading levels. We attempted to provide a balanced overview of the risks and benefits for each screening option. We included this information in section 2.2, Decision aid content and format.

4. Section 2.8 Outcome measures: The use of the word “change” in this section is somewhat confusing. The suggested revisions were made.
5. I suggest that ‘standard deviation’ rather than ‘standard distrubtion’ be used. This change was made.

6. Could the authors comment on the clinical importance of a difference of 0.3 in patient interest in being screened and a difference of 0.4 in intent to ask for screening? This represents an increase and interest and intent to be screened, but whether this led to increased screening cannot be determined from this pilot study. In our previous RCT, a 0.6 point difference in intent led to a 14% difference in test completion. We have added this limitation to the discussion, noting that a larger, randomized trial would be better able to define the clinical significance of this increase.

Section 3.4 It would be clearer if the authors indicated the percentage of patients who received both tests. This information was added to Section 3.4.

7. The authors should report which IRB approved the study. The study was approved by the UNC-Chapel Hill IRB. This information was already present in section 2.9, statistical analysis.

8. How was the study funded? The study was funded by Dr. Pignone’s American Cancer Society Career development award. This information was included on the title page.

9. Abstract. The conclusion could be more consistent with the aims of the study. The suggested changes were made.

Regarding the usability testing, more detail should be reported about how these patients were selected. These patients were a convenience sample recruited from the academic general internal medicine practice, 50-75 years old. We tried to identify a wide range of users in terms of previous computer experience and education levels. This information was included in section 2.3, Usability testing.

Reviewer: Vivek Goel

Minor Essential Revisions:

1. This is a pilot study and is appropriately referred to in the paper. The conclusions in the abstract and the main paper are much more conclusive and should be appropriately tempered. The conclusions in the abstract and main paper were modified to reflect the pilot nature of the study.

2. If possible provide a link to the decision aid so it can be viewed by the reader. Figure 1 does not show the main menu of choices but is instead the introduction to the aid. The decision aid was located on a local computer; an internet link to the aid is in development. Figure 1 was changed to a graphic of the main menu of choices.

3. It would be useful to describe the speed of the computer and bandwidth requirements for use of the aid and the type of system on which usability testing was conducted. The computer used for the usability testing and the pilot study was an IBM PC with a Pentium processor and Windows operating system. The intervention was delivered on a local computer, not over the Internet, so
bandwidth was not an issue. This information was included in the Methods section 2.3, Usability testing.

4. For future work the investigators should consider using an objective measure of knowledge rather than subjective measures. We did not include an objective measure of knowledge in this pilot study due to limitations in questionnaire length, although we recognize this as a potentially important measure to include as we design larger trials. This limitation is included in the Discussion section.

The last sentence of the Statistical Methods section now reads, “Prior approval for the study was obtained from the University of North Carolina-Chapel Hill Institutional Review Board, and the research was carried out in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm).”