Author's response to reviews

Title: The Development of a Web- and a Print-Based Decision Aid for Prostate Cancer Screening

Authors:

Caroline S Dorfman (csd9@georgetown.edu)
Randi M. Williams (rmw27@georgetown.edu)
Elisabeth C Kassan (eck33@georgetown.edu)
Sara N Red (snr5@georgetown.edu)
David L Dawson (dlid27@georgetown.edu)
William Tuong (wt45@georgetown.edu)
Elizabeth R Parker (erp3@georgetown.edu)
Janet Ohene-Frempong (jofrempong@comcast.net)
Kimberly M Davis (kmd54@georgetown.edu)
Alexander H Krist (ahkrist@mail1.vcu.edu)
Steven Woolf (swoolf@vcu.edu)
Marc D Schwartz (schwartm@georgetown.edu)
Mary B Fishman (mbf3@gunet.georgetown.edu)
Carmella A Cole (Carmella.a.cole@medstar.net)
Kathryn L Taylor (taylorkl@georgetown.edu)

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Author's response to reviews: see over
Dear Dr. Norton:

Thank you very much for the reviews of our manuscript entitled, “The Development of a Web- and a Print-Based Decision Aid for Prostate Cancer Screening.” Our responses to the reviewers’ and editor’s comments are detailed below and highlighted in the manuscript on the pages indicated.

Reviewer 1

The authors have utilized focus groups, to gather qualitative data and feedback, on the development and implementation of the decision aids. However, no qualitative framework has been discussed on which the focus groups were based. Qualitative data should be housed within an appropriate theory (e.g. grounded theory etc.), with the specific method of analysis explicitly stated. This manuscript would be strengthened with the following:

1. What qualitative framework was used when conducting the focus groups and analyzing the qualitative data? (e.g. grounded theory, thematic analysis, content analysis.)

We believe that several of Reviewer 1’s comments may stem from our lack of clarity regarding our use of the term ‘focus group.’ In Study 1, we conducted 8 traditional focus groups to aid us in the development of our first version of our educational materials. The development process and thematic analysis conducted for this study are described in detail in a prior publication (Taylor et al., 2001). We have added a sentence describing the development of the Study 1 materials on page 8. The educational materials that we developed in Study 2 and Study 3 were updated versions of the original material. Because we already had the majority of the content for the booklets and the website, the subsequent formative work done for Study 2 and 3 was for usability testing as opposed to qualitative focus groups.

The purpose of the usability testing was to obtain feedback on the presentation of the materials (e.g., color, format, layout, ease in navigating, response to figures and tables, etc.) rather than to have in-depth discussions regarding the content. While we did obtain quantitative data on participants’ impressions of the presentation of the content (e.g., whether there was a balance of pro and con messages), our primary goal during the usability sessions was not to assess participants’ ideas about or prior experiences with prostate cancer screening. Thus, we were not looking for content oriented themes, but rather whether participants had a positive or negative response to various aspects of the materials. As a result of this goal, we were not guided by qualitative theory for the design of this work nor did we tape record participants’ comments. Instead, we took...
detailed notes during the sessions and relied on men’s responses to our quantitative questionnaires regarding their impressions of our materials.

In the sections describing Study 2 and Study 3 (pages 8-13) and throughout the manuscript, we have changed the term ‘focus group’ to ‘usability testing’ to clarify this issue.

2. **Further description on how the focus groups were conducted – for example, were focus groups conducted with the same facilitator, how many authors independently analyzed the transcripts, how was the qualitative data interpreted?**

Additional information about the structure of the usability testing has been added to the methods section on pages 12 and 13, including the number of moderators used, the moderators’ roles, and the setting. Information was also added to clarify that the goal of the usability testing was to assess men’s impressions of the design aspects of the materials, ability to navigate the website, and understanding of the overall message of materials. This was accomplished predominantly through the use of a questionnaire administered to participants at the end of the session and by observing participants as they were using the website and booklet.

3. **Qualitative data should be reported in the results section according to the themes that were derived from the transcripts. This approach would further illustrate how each of the focus groups added to the development of the decision aids.**

The majority of the data from the usability testing were quantitative as opposed to qualitative. We administered a questionnaire to participants at the end of the sessions. As described above, we did not undertake a formal qualitative analysis during the formative stages of Studies 2 and 3.

4. **The manuscript would be further strengthened by commenting on the potential limitations associated with the focus groups. For example, is it possible to reach a point of ‘saturation’ when focus groups are conducted with 14 participants (booklet focus groups)? Is conducting two focus groups with clinicians sufficient to gather information rich data on their attitudes and perspectives on the decision aids (study 1)?**

As mentioned above, we have clarified our goal of conducting usability testing in Studies 2 and 3, as opposed to conducting traditional qualitative focus groups. As a result, our sample size was not as much of a limitation as it would have been if we were conducting traditional focus groups (HHS, 2006; Stoddard et al. 2006). Further, in Study 2, we included 29 men to assess an earlier version of the current booklet, and in Study 3, we included 14 to assess the next version of the booklet, for a total of 43 subjects. However, as we acknowledge that the sample size for usability testing could have been larger, particularly for the website, we have included the small sample size as a limitation in the results (p. 21).

5. **A brief outline on how the information in the decision aids was framed, e.g. in a positive...**
or negative framework, and what implication this might have on participants’ decision making.

While this is an interesting point, we did not use the concept of framing in the development of these materials. The overarching messages of the booklet and website are that there is not a right or wrong answer about prostate cancer screening, that men need to understand the issues, and they need to make the decision with which they are most comfortable. As a result, prostate cancer screening education does not lend itself to the utilization of framing effects, as we are not attempting to impact screening behavior in one direction or the other (i.e., we are not attempting to increase it or decrease it). The materials include statements about the potential benefits and harms of screening and about the potential benefits and harms of not screening. Thus, framing did not play a role in the development of our materials.

Reviewer 2

1. I recommend that the authors include more detail on how they carried out their focus groups and how they analysed data derived from their focus groups. Did they, for example, use standard qualitative research methods and if so, which ones.

Please see responses to Reviewer 1 above, items 1-3.

2. The authors indicate that there are 18 RCTs evaluating decision aids for prostate cancer screening. Is this number based on a systematic review? The authors should indicate how they arrived at this number. Was a systematic review undertaken? If so, I would include the search strategy with Appendix 1.

As noted on page 6, our search criteria were informed by criteria used in a review paper by Volk et al., 2007. While we did not intend to undertake a systematic review of all prostate cancer screening decision tools, we did use the same Medline search criteria as Volk et al. from January 2007 to June 2009 (‘prostate cancer’ and ‘decision making’). To our knowledge, we have found all of the additional trials that met our eligibility criteria (i.e., randomized controlled trials, evaluated prostate cancer screening decision tools that do not intend to increase screening, assessed informed decision making or active participation regarding prostate cancer screening, and were published between January 2007-June 2009; see Additional File 1).

3. I question the false negative rate of 2 out of 87 (Figure 3). This seems a little high. It may be important to provide references for these figures when presenting them in the decision aid.

We appreciate the reviewer’s concern and acknowledge that the false negative rate could also have been 1 out of 87. However, 2 out of 87 is within the boundaries of several published studies, particularly given the continuing concern about underestimating false negatives. We have added the following references to Figures 3 and 4.


Editor Comments

1. Please could you also include a copy of the questionnaire that you used and a link to the website if possible.

We were not clear about which questionnaire you were referring, as we used several different questionnaires over the three studies presented in the manuscript. We would be glad to send you whatever you would like to see, but thought we should first see if we can narrow down your request so we can send the most appropriate file.

Because our randomized trial is still underway, we do not want to publish our website address in the manuscript. However, we are glad for just you and the reviewers to have access to it. The website address is: www.prostatedecision.org; the username is guest; and the password is guest1235.

2. Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. 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.

Please see page 8 for the inclusion of the following statement: All studies were approved by the Georgetown University/Medstar Oncology Institutional Review Board.

Please let us know if further clarification of these points is needed. We look forward to your reply.

Sincerely,
Kathryn L. Taylor, Ph.D.
Associate Professor

References

