Author's response to reviews

Title: The electronic self report assessment and intervention for cancer: Promoting patient verbal reporting of symptom and quality of life issues in a randomized controlled trial

Authors:

Donna L Berry (donnalb@uw.edu)
Fangxin Hong (fxhong@jimmy.harvard.edu)
Barbara Halpenny (barbara_halpenny@dfci.harvard.edu)
Anne Partridge (ann_partridge@dfci.harvard.edu)
Erica Fox (erica_fox@dfci.harvard.edu)
Jesse R Fann (fann@uw.edu)
Seth Wolpin (swolpin@uw.edu)
William B Lober (lober@uw.edu)
Nigel Bush (nigel.e.bush.civ@mail.mil)
Upendra Parvathaneni (upendra@uw.edu)
Dagmar Amtmann (dagmara@uw.edu)
Rosemary Ford (rford@seattlecca.org)

Version: 2 Date: 18 March 2014

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Erica Fox: erica_fox@dfci.harvard.edu
Jesse R Fann: fann@uw.edu
Seth Wolpin: swolpin@uw.edu
William B Lober: lober@uw.edu
Nigel Bush: nigel.e.bush.civ@mail.mil
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Author's response to reviews: begins next page
Reviewer: Laura Ashley

Reviewer's report:

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. It would be helpful to include in the Introduction a description and explanation of the underpinning theoretical framework – in terms of the hypothesised mediators / ‘mediational chain’. For example, if patients communicate more SxQoL issues / communicate these issues ‘better’ in consultations, how is it hypothesised that this then leads to reduced distress? Through clinicians responding with help? Through this initial behaviour being a trigger for the patients to then do something else? Through several mechanisms?

   The suggested description and explanation have been added to the beginning of the methods (p.5), as well as a Figure illustrating the variables tested in these analyses.

2. The quantitative and qualitative differences between the 2 trial arms, in the reporting of SxQoL issues, needs to be made clearer. In the Results: there was no difference between the 2 arms in the number of problematic SxQoL issues addressed during clinic visits (p=.41). In the Discussion: intervention patients more frequently reported problematic SxQoL than controls. It is not completely clear if/when findings refer to reported more often / reported more often as coached. Has the intervention promoted verbal report of more problematic SxQoL issues and/or promoted use of particular language (coached statements) for reporting SxQoL issues?

   The intervention promoted verbal report of specific aspects (coached statements) of problematic SxQoL issues. When the number of discussed "at all" SxQoL issues was calculated for both clinician-initiated and patient-initiated problematic SxQOL issues, there was no difference between groups. The difference is apparent in the patients' specific reports, as coached. We have revised the language in the abstract and clarified the approach on pages throughout the manuscript (7, 9, 10-13).

3. In the Introduction it is noted that barriers to communication in consultations include clinicians interrupting patients’ reports and changing the subject. The inclusion of some analysis of the clinicians’ behaviours/responses in the clinic visits would greatly enhance the paper and make it more ‘complete’. Clinician responses to patients’ reports is of key importance and presumably one hypothesised mechanism via which patients raising issues in visits could result in reduced distress.
Clinicians responses have been calculated and added to the paper in the appropriate sections (pp. 2-3, 5, 11-12).

4. The paper would also be enriched by including some analysis of and comment on the proportion of reports made by patients versus caregivers.

This proportion has been added to p. 9.

5. Statistically it may not be feasible, but if it is, it would benefit the analysis to undertake some form of explicit test of mediation. In a previous paper the authors showed that the 2 trial arms differed in distress and in this paper they show that they also differ in terms of patients’ verbal reporting of SxQoL issues. Although suggestive, these two findings do not indicate that the reduction in distress in the enhanced intervention arm is (to whatever degree) mediated by the increase in patients’ increased SxQoL reporting.

We were able to execute a mediation analysis as suggested by the reviewer. The method has been added to pp. 8-9 and results on p. 10.

6. The trial arms differed in age with the intervention arm being significantly younger. As younger patients may well be more vocal in consultations I was surprised that this group difference was not considered in the Discussion.

This baseline group difference has been clarified in the analytic methods on p. 8 and had been addressed in the first paragraph of p.10 and Table 3 in the results. The interaction between study group and age was not significant and the age covariate was not significant in the multivariable analysis. The discussion has been edited for clarification (p. 12).

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. It would be helpful to be clearer in the abstract about how the control and enhanced intervention arms differ.

Edits have been made for clarification

2. The final sentence of the introduction could be more comprehensive and clearer. It’s slightly confusing if compared with the abstract due to the use of different terms: intensity/severity and duration/pattern, and the fact that requests for help are missing. Also, are ‘individual’ issues ones not on the list of 26 covered by ESRA-C?
Edits made to abstract and final sentence of introduction for consistency and clarification.

3. It would be helpful to have a small diagram/table summarising the similarities and differences between the two interventions (standard and enhanced), including home/clinic, delivered via the internet etc.

   This has been published elsewhere and was referenced in this paper: PMIDs 21282548 and 24344222.

4. The regression analysis needs to be more clearly explained in the analysis section of the Methods.

   Edits have been made for clarification.

5. The Results say 517 clinic visits were audio-recorded and coded, but the abstract says 515.

   This typographical error has been corrected.

6. It’s quite difficult to get a handle on what the report index represents – patients in the intervention group had an average 0.036 higher report index than those in the control group – it would be helpful to illustrate / explain what this means.

   An example has been added on p.8

7. The first sentence of the last paragraph of the Discussion states that “while our findings from the present analysis clearly suggest that communication between patients and clinicians with regard to SxQoL may be improved with our intervention…”. I think this could be misleading as the analysis doesn’t look at communication BETWEEN patients AND clinicians.

   Edits made

8. Table 2 should present the interquartile range alongside the median values.

   These have been added.
Reviewer: Roxanne Jensen

Reviewer's report:
This manuscript presents findings from a patient-focused web-based intervention to promote patient identification of symptoms during active cancer treatment. Current capabilities of electronic patient-reported outcomes systems are increasing quickly, and this paper highlights some of the exciting future opportunities in the field to promote symptom identification and discussion in a clinical care setting.

Overall the study and findings presented here are noteworthy in an understudied area. Further elaboration on the intervention details and delineation among the many domains (symptoms, function, quality of life, and supporting patient constructs) reported would make this work clearer and interpretable. Also, incorporating information about measured symptom severity would complement and enrich the findings presented here.

- Major Compulsory Revisions
(1) Intro: More elaboration on barriers to discussion are needed on both the provider and patient side. On the provider-side, other studies have suggested for broader QOL issues providers may consider these issues for other providers (e.g., PCP) or aren’t sure what to do or address them. On the patient side, please include citations for “time-limitations” and clarify what is meant by “forgotten experiences from inter-visit periods”. (pg. 4)

Edits made and references added on p.4 as requested

(2) Intro: Lead-in to previous work (second paragraph) should be condensed and incorporate a more general discussion of the literature on the limited or mixed impact of symptom reports on clinician behavior and patient outcomes in the literature

The more general discussion of symptom reports impact is provided in the Discussion section (pp. 11-12).

(3) Methods: Further clarity about the intervention is necessary. What happened when people identified multiple symptoms in the screening—did they receive interventions in every area? Was there any verification that web-participants logged on and viewed the content, if so what percent? What was the agreement between intervention symptom-tailored content and symptoms discussed with their doctor after viewing?

- Yes, coaching was provided tailored to each problematic SxQOL. Clarified on p. 6.
- The analysis of remote use if not yet completed.
- The agreement between problematic SxQOL and discussion analysis is not yet completed.
(4) Results. Since participants complete PRO assessments, further elaboration on how identified issues reflect measured severity, especially between the two groups would be helpful. Were the symptoms reported (outcome) reflected by the participant’s PRO scores? What percent of identified symptoms reflected content providers were alerted to in the PRO reports?

The match between on-line PRO reports and discussions of issues is being analyzed for another paper. This submission has focused solely on the audio-recorded data.

(5) Results. Unprompted symptom reporting is mentioned (Top of pg. 9), however identifying prompted vs. unprompted symptoms reporting was not stated previously as a goal. (it is unclear if unprompted symptoms are the outcome of interest in the tables)

Edits throughout have clarified the topic of this comment.

(6) Results. Given the overall similarity of the number of issues discussed between treatment arms (pg. 8), is here anything else about these unprompted symptoms that would be especially interesting to the reader (i.e., more function/QOL related than treatment symptoms).

Yes, most specifically described issues were about symptoms rather than quality of life domains. One sentence added to page 10.

(7) Results/Discussion: The interpretability of the results are a limited because it incorporates so many different symptom, function and HRQOL domains. An exploration of sub-groupings (e.g., symptoms, function, QOL) would be helpful.

This was a omnibus analysis– the intervention approach was the same for each type of issue. We agree that subset analyses would be interesting, but the purpose of this study was examining across all for the effect of the intervention.

- Minor Essential Revisions
(8) Intro: Second paragraph leads with a run-on sentence. (pg. 4)

Minor edit made

(9) Intro: It isn’t clear how the two aims of this study are different are the two aims: any discussion vs. the “quality” of discussion? (pg. 5)

Edits made to clarify
(10) Methods: what was the “pre-defined threshold for symptom severity (pg. 6) and was this used in the analysis?

The threshold was used with the patient on line questionnaire responses to generate the clinician summary report. This threshold was not used in this analysis.

(11) Methods: Was there any mode difference between rates of symptom reporting for those that received a report immediately prior to their visit?

All clinicians received report immediately prior to the clinic visit. Patients in the intervention group received the coaching intervention within 24 hrs before visit. Therefore, we have not created a more granular variable. Minor edits on p. 6.

(12) Methods: Were the symptoms included in the counts here limited to the items where the patient selected and viewed related educational content?

No

(13) Methods: What is a SDS-15 score (pg. 8)? Abbreviation is not seen elsewhere in the manuscript. Text says it was a covariate in the analysis, but not listed in the tables.

Description and references added to p. 8.

(14) Results: Are the main findings unprompted symptoms? Or overall reported symptoms? Please clarify in the text and tables. (see revision #5)

Clarified throughout the manuscript

(15) Table 1: please provide more information about the demographics of your patient group. Including cancer type, advanced/non-advanced cancer stage, and more information about the age of the sample than just above/below 50. Average symptom scores would also be informative for each group.

Added

- Discretionary Revisions

(16) Header on the graph “favor vs. do not favor ESRA-CII” was a bit confusing. At first, I thought it was a measure of patient satisfaction for the intervention. May want to consider a re-naming for clarity

The figure legend has been edited however the axis label has remained