Author’s response to reviews

Title: "Developing a patient decision aid for the treatment of women with early stage breast cancer: the struggle between simplicity and complexity"

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Version: 3 Date: 18 May 2017

Author’s response to reviews:

Thank you again for reviewing our paper. We are grateful for the constructive comments which made us improve the paper. Hopefully this revised version meets your expectations.

Editor Comments:

Both reviewers have re-reviewed your manuscript and have additional comments which should be addressed. Reviewer 1 felt that some of their concerns were not addressed fully in the last round of revisions and so we would be grateful if you could address the following points further or indicate where these revisions were already made:

1. “please explain why this was an extensive process as well” in reference to the first sentence of the conclusions section.

You can find this adjustment in the abstract page 2 line 54

The development was an extensive process, because the professionals rejected the simplifications as proposed by the research group This resulted in the development of a complete new drafted PtDA, which took double the expected time and resources.

2. Page 9, line 230: so, did different people in each round see different versions of the DA and interview questions? Or do you mean alterations were made between rounds? And why did you choose this?
Analysis took place in an iterative process: interviews and analyses were alternated if modifications and improvements to the successive drafts of the PtDA between each round made it necessary to collect additional information.

3. Line 297: when you use the word patient, perhaps you can somehow “remind” the reader that these were different patients from round 1 (new patients).

You can find this adjustment on page 13 line 343

The new patients participating in this round indicated that the PtDA was attractive, easily readable, with clear language, and simple to use.

4. Line 478: perhaps better to state that an option grid was not the solution here, instead of questioning whether this would have been better. It undermines your result a bit.. – we are not sure you have addressed this point since you say that “Given the complexity of the options for primary treatment of early-stage breast cancer, we realized that a one-page option grid would have been appropriate and sufficient.”

See adjustment on page 21 line 539

The research group had opted for simplicity (brief and compact) which could be used during consultation to facilitate implementation, while the clinicians objected to such a short version as it ignored the complexity of the decision. The implication of this was that we had to extend our first draft with about 20 slides which made the power point format much too complicated to use. The research group finally decided to develop a web-based PtDA instead of the intended short format inspired by ‘option grid’.

5. Line 501: are women of 50+ representative for early stage BC? Then it is no problem. But otherwise, explain more about why young women are not in your study now? Also, I do not understand why you mention the hereditary aspect here. Do you mean they have no choice? Please take the reader by the hand so that no confusion exists.

You can find this adjustment on page 22 line 572

It could be a limitation that the majority of the participants was above 50 years of age. The occurrence of breast cancer in young patients is relatively low, so access to this age group is limited. In addition, in young women diagnosed with breast cancer heredity causes are more frequent resulting in strong indications for mastectomy instead of breast conserving treatment. This means that there is no preference-sensitive choice at stake and no indication to use this PtDA.

6. 218: what are “some national experts”? Professionals working for the Dutch breast cancer association.
In the fourth round, professionals of dedicated breast cancer teams, as well as professionals working for the Dutch Breast Cancer Association, received a login name and a password.

7. Line 260: they were “critical”, hence negative?

You can find this adjustment on page 12 line 302

The professionals’ general opinion towards the PtDA was that they were cautious about the feasibility and usefulness of the PtDA.

8. Line 285: Was the first prototype ever really intended to stay a powerpoint?

Comment for the reviewer: yes, we, the research group thought that a simple power point presentation could support the clinicians during the consultation. We wanted to keep it simple and easy to use in the consultation room. We were inspired by simple power point like Da’s that are being used by clinicians in another Dutch hospital, the academic medical center in Amsterdam. As described, during the development process, it became clear that the PP was not an option for the clinicians.

9. Line 288: how does this values clarification exercise look? It is a comparable of the pros and cons per treatment option, or does it compare different treatment options at the same time?

You can find an additional explanation on page 15 line 384

We identified attributes of the treatment options which affects the patient’s preference through interviewing patients and we asked professionals about frequently asked questions during consultation. Based on both sources, we developed crucial questions to elicit values in choosing between options.

10. Line 405: you could refer them to patient associations for more emotional support and information? Did you explain something about this in the DA? It is obviously important to discuss

Comment for the reviewer: Patients receive a comprehensive information packet together with the prescription pad and login code of the PtDA. This packet includes information about the patient association and about social support programs in the Oncology center. We know that in other hospitals in the Netherlands similar information is given to patients.

11. I do not recall reading “when” the DA should be used. I imagine before or after the consultation (at home) since it is a website, but then I do not understand why it is compared to OPTION grids that are used during the consultation. Also, from some of the suggestions of professionals (e.g. 1 in round 1) it seems that they think it should be used “during” consultation? If this is better clarified in the methods or introduction, perhaps you can skip it from the discussion? Or wasn’t it sure when to use the tool? (was it an intended result of the alpha testing
procedure to reach consensus on when to use it? In that case, could you mention this somewhere?)

I added this in the introduction, page 5 line 134

For sake of implementation we opted for simplicity and developed a prototype PtDA with brief, easy to read and compact information, inspired by the one-page option grids to be used by clinicians during clinical encounters.

12. 480: prolonged engagement is about engaging the same people for a longer period of time. You did not engage people for a longer period but invited new participants for each round, so this is not really met. Although we tested with different participant, we worked in a research team together with clinicians from different hospitals during a long period of time.

Comment for the reviewer: You are right, we used different patients and professionals to test the PtDA. I skipped the term from the text.

12. 490: what is the difference between your focus group discussions and the group discussions? Comment for the reviewer: The focus group discussion we held was structured by an interview guide, the group discussion we held with professionals was more consultation like, not structured, but with the intention to discuss the progress in the PtDA in which participants were invited to address their own issues.

Reviewer 2 has also raised a number of additional concerns and so we would also be grateful if you could address these (please see below for their report). In addition, please make the following editorial revisions:

1. Please proof read the manuscript for spelling and grammar errors: e.g. Methods section of the abstract, “Our qualitative descriptive study applied methods include face-to-face think-aloud interviews, a focus group and semi-structured telephone interviews” should be “Our qualitative descriptive study applied various methods including face-to-face think-aloud interviews, a focus group and semi-structured telephone interviews”. I adjusted this error on page 2 line 44. Furthermore, we have read the entire manuscript several times with two of the senior researchers removed typing errors, rephrased unclear sections ore replaced expressions.

2. Please include the abstract in the main manuscript file. Done

3. Please change the title of the 'Introduction' to 'Background'. Done

4. Please include a description of the contributions of author Wilma Savelberg as they do not appear to be mentioned in the Authors’ contributions section currently. Done, see page page 23 line 634

5. Please include the tables in the main manuscript file at the end of the main text (after the references). Done. You will find them from page 29
6. We note that table 1 includes the patient ages again, please remove this information as these data could be identifiable. Done

7. Please remove the figure legends from the figure files and instead include a list of the legends at the end of the manuscript file (after the tables). Done page 32

8. After this please include a description of the appendix which should include the following:

File name (e.g. Additional file 1) Done page 33

File format including the correct file extension for example .pdf, .xls, .txt, .pptx (including name and a URL of an appropriate viewer if format is unusual) Title of data Description of data

BMC Medical Informatics and Decision Making operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Mirjam Marjolein Garvelink (Reviewer 1): I would like to thank the author for revising the paper. In general, the author responded well to my queries. However, in some cases I would have preferred to see the answers to my questions in the paper, instead of in the response to me only (especially when it concerned a limitation to the study). As my previous review was quite thorough I do not have new things to add. The paper reads a lot better now, I like the addition of table 4.

I still see both ptDA and decision aid in the text, but perhaps this is on purpose? (also in abstract) I replaced decision aid and used PtDA.

Elina Farmanova (Reviewer 2): 1. The introduction needs to be improved: the authors need to explain early on and clearly why they undertake the development of a new PtDA when 11 similar DAs already exist but have not been alpha-tested.

I added some extra explanations (see below) on why we developed a new PtDA page 4 line 105

Among the 11 existing PtDAs there was only one Dutch version. This PtDA was out dated and not used by Dutch professionals. The other PtDAs could not be easily adapted because of the differences in guidelines and care processes between countries. We wanted to ensure that we developed a PtDA that professionals want to use, and patients appreciate, and that helps them to fully understand the options to make a decision.

Moreover, I would recommend that the authors try to convey the complexity of the decision-making surrounding BCT (what is problematic? why? who is affected?) and sharpen the message
around how this new alpha-tested PtDA could resolve the issues related to SDM, available options, potential impacts, etc.

Comment for the reviewer: In the original project proposal, we focused on the surgical dilemma of the early stage breast cancer treatment. But along the way, the professionals that were engaged in our study disapproved to limit the decision to be made to the surgical dilemma only without taking reconstruction and neo-adjuvant therapy into account. Moreover, the professionals did not approve to focus only on the two basic options. To make things a bit more clear, I added some extra explanation (see below) which you can also find on page 3 line 73.

In addition, patients are increasingly faced with the option for reconstructive surgery of the breast after a breast removal or even a breast-conserving surgery. The outcome of these treatments are comparable with regard to life expectancy but not with regard to cosmetic results, long term side effects or treatment burden.

2. If authors decided to follow a systematic development process recommended by Coulter et al. (2013), they need to clearly state it. Please also explain your motivation (is it because the development process is difficult as you say?)

One of the authors of this paper is also one of the co-authors of Coulter’s paper. Therefore, it was obvious that we used this model. I also added one sentence explaining why we used Coulter’s model see page 4 line 96.

Coulter et al. [4] described, on behalf of the IPDAS group, quality criteria for the development of PtDAs, one of which is alpha testing, that is, co-creating a draft in an iterative process among experienced patients and professionals.[9] (figure 1) It involves patients who have faced the decision in question in the past, and clinicians working for the target population.[10]

3. If you are only developing a PtDA, you really need to focus on aspects of usability and acceptability from that perspective. I think you are mixing a lot of concepts in your introduction that might confuse the reader. Please state clearly what exactly you are pursuing, for what reason, how you propose to do it and who your potential users are (women with the diagnosis of breast cancer? Professionals providing therapy for these women? Both?).

Although this article only focuses on the development of the PtDA, our aim is to implement SDM. One ingredient of our implementation strategy is the PtDA. On page 3 line 83 you will find an addition, to clarify our intentions.

Our aim is to implement SDM behaviour and for that purpose we designed a multifaceted implementation strategy.[3] In this paper we will focus on one of the ingredients of the implementation strategy, the Patient Decision Aid (PtDA).

4. Please state clearly how many professionals were invited to take part in the testing and how many responded. If that is not possible, then please explain how many hospitals were targeted and why those hospitals were chosen (e.i. do they all have a breast health clinic?)
I gave some extra details on the recruitment of professionals (see below). You can find this on page 7, line 191.

Twenty-six health care professionals were invited and they all took part in the alpha test. They were recruited by members of the development team, using purposive sampling to achieve diversity in terms of disciplines and hospitals (Table 2). The professionals participating in the alpha testing included oncologic surgeons, radiation oncologists, medical oncologists, and nurses from eight different hospitals with dedicated breast cancer teams, a radiotherapy clinic and professionals from the Dutch Breast Cancer Association. Professionals involved in the process of developing the first draft PtDA were excluded from the other rounds in the alpha test.

5. In Methods, Design you might want to describe the PtDA that you developed. What did it include? (see comment 10 below)

10. You need to tell your reader much earlier in the paper what format of DA was chosen first to help us understand how it developed and figure out why. It is a little too late to talk about it at the end of your discussion.

I added a box you will find it on page 6 line 159
Box 1

The first draft PtDA was built in the format of a PowerPoint-like presentation. It included two surgical treatment options, survival rates, side-effects, all pros and cons of the treatments, pictures of surgical results, and value elicitation statements.

The second draft was built as a website. We used the same content, same amount of pictures and graphs to present risks. At the end of the PtDA it showed a summary of the patient’s response to the value clarification statements.

The final structure of the PtDA was established in the third draft. It is a website including interactive elements to provide tailored information to individual patients. Patients gain access into the website with a personal login code. The homepage enabled them to personalize the PtDA by using a prescription pad they received from their clinician. The content consisted of the treatment options, including neo-adjuvant therapy and breast reconstruction, pros and cons, side effects and value elicitation statements.

6. Did you recruit new participants for each round? If not, please explain why and also address that in your limitations.

We recruited new participants for each round. I added “new” to patients in the recruitment section page 7 line 182

Comment for the reviewer: We used Jacob Nielsens models for our test: To test usability and, you must have at least 15 users testing the digital tool. The best way to test, with maximum results and minimal costs, is to test in multiple rounds with no more than five users per round. After the first round with five participants, 85% of the usability problems will be found. Then,
these problems must be solved in a subsequent prototype and then re-tested to assess whether the improvements have been implemented successfully. There is always a risk that the improvements will lead to a new problem. According to Nielsens (2000) calculations, 2% of usability problems remain for the final round.

7. It is quite interesting how you developed the prototype, it appears that the format and content has changed drastically from round 1 to 4. Can you comment on that in more detail as for how format was first chosen and how you ended up developing the web site, etc.

You can find the addition in bold below on page 21 line 538

During the development process it became clear that the clinicians who had to adopt the PtDA opposed the short pilot format that the research group initially developed. The research group had opted for simplicity (brief and compact) which could be used during consultation to facilitate implementation, while the clinicians objected that the complexity of the decision could not be ignored. The implication of this was that we had to extend our first PtDA with, about 20 slides which made the power point format much too complicated to use.

8. Why could you not comply with (you might want to say "consider") all the recommendations? Were they not reasonable? Please explain. It is an interesting and important discussion topic in a participatory research, how do we find the balance between researchers-driven and user-participatory design of DAs, who owns it in the end?

I adjusted the first sentence . Page 19, line 483

We could not consider all of the sometimes conflicting recommendations of the participants.

I added this in the section conclusion page 23 line 590

We spent much time in trying to get achieving consensus between the patients and professionals on the content and format of the PtDA. This resulted in a kind of balance between the input of different stakeholders with professionals being more dominant in defining the final content on risk communication and pros and cons of treatments while patients were more dominant in defining the value elicitation statements.

9. You say it was difficult to reach consensus among the professionals. Please summarize and explain in one sentence or two why it was so difficult. Differences of visions and academic backgrounds among different professionals? different perception of their roles as providers? What was the obstacle exactly and how you dealt with it exactly? (i.e. one on one basis, group session, what exactly did you employ as a tactic to reach consensus?)

I added one sentence. Page 19 line 494

It was challenging to reach consensus among the professionals with regard to data on risks and outcomes. Data collection on risks like complication rates are given less attention in trials so we lack robust details. Professionals quite often disagreed with the numeric data on probabilities,
arguing for instance that complication rates at their hospital differed from the average data reported in the PtDA.

It is a very interesting project and it is important to communicate as many details as possible to support other DA developers. However, I continue to struggle with the organization of this paper, lack of important details not reported and the quality of writing. Please consider engaging an editor to proof-read and revise the text.

We have read the entire manuscript several times with two of the senior researchers, removed typing errors, rephrased unclear sections or replaced expressions/words. As you can see above, we added some more details, which hopefully makes the manuscript much clearer.