Author’s response to reviews

Title: Patients’ and researchers’ experiences with a patient board for a clinical trial on urinary tract infections

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Author’s response to reviews:

Response to reviewers

Dear editors,

Thank you very much for your feedback and the very thoughtful comments of the reviewers. We addressed all of the comments. Please find our responses below each comment.

Kind regards,

Imke Schilling

REVIEWER #1:

Good analysis of this PI experience, very valuable to understand better challenges for an effective involvement of patients in research. I think the article addresses the main barriers for an
appropriate involvement and identifies interesting topics, for instance about their roles and the mode of cooperation. From my point of view, the info showed in this article about operational issues of this board makes the difference of this article compared to similar ones.

This kind of articles are very valuable to raise awareness about the benefits of PI in research.

Reviewer #2:

It's a quality work with few changes to make

I have 2 changes to ask:

First, about goals of the study: Aim of this study isn't real clear, in introduction (L. 98 to 103) you talk about "elucidate the perspectives of patients and researchers..." and after, like if you were talking about a secondary goal "We not only wanted to learn about the challenges faced when conducting effective PPI, but also discussed the patients' and researchers' experiences with the patient board, taking their views on their initial motivation and expectations into consideration"

When reading, it a bit blurry : is the challenges your first goal and experiences your secondary ?

On discussion (L. 359 to 365), it's not the same, there's no distinction between challenges and experiences

It would be better to change both to make it clear.

Response: We agree, that our section on the aim of the study is not precise. We rephrased it and made sure to use the same words consequently (e.g. we now use “experiences” consequently and do not alternate it with “perspectives”) “In addition, so far little is known about how patients and researchers in Germany experience PPI. Building on our previous work in which we investigated patients’ and researchers’ motivating factors and expectations of getting involved with a patient board [12], we therefore aimed to elucidate the experiences of patients and researchers who were members of a patient board that was established for a clinical trial on urinary tract infections (UTI). By doing so, we wanted to learn about the challenges faced when conducting effective PPI, and discussed patients’ and researchers’ experiences with the patient board, taking their views on their initial motivation and expectations into consideration.” (l. 96-103)

Second, about INVOLVE's recommendation: You talk about it (L. 472) like a reference but it's nowere else on the paper and it's not developed, why choose it ? What do you mean by co-production ? They did it on the same time ? You were working with them ?
RESPONSE: We agree with the reviewer that INVOLVE’s recommendations on co-production are not well developed in our paper. As a) we are able to make our point without referencing the guide on co-production, and b) we do not refer to it afterwards, we decided to delete the reference. We rephrased the paragraph accordingly: “These findings underline the need to discuss roles, effort, and ways of collaboration at the beginning of PPI.” (l. 598-600)

REVIEWER #3:

This article presents a qualitative analysis of patients’ and researchers’ experiences with patient involvement in a clinical trial conducted in Germany. The findings have the potential to add to the literature on patient and public involvement (PPI), particularly because little research has been conducted on PPI in Germany, and research about challenges and facilitators of PPI is needed to identify effective practices and inform recommendations. However, a number of issues need to be addressed or acknowledged to improve this manuscript and provide adequate information for readers to be able to judge the strength and relevance of the findings.

1. More information is needed about the way the qualitative analysis was conducted.

   o Could the authors say more about what they mean by "textual work with each case and our focus group guides" and how that informed the development of the primary categories?

RESPONSE: We agree with the reviewer that the line “textual work with each case and our focus group guides” is too general to sufficiently inform potential readers about our procedure. We rephrased the paragraph accordingly: “We started our analysis by thoroughly and repeatedly reading the transcripts of the focus groups, and supplementing them with memos on our research interests, relevant paragraphs and lines of argumentation (step 1). Primary categories for both patients’ and researchers’ experiences were developed based on the transcripts and memos (step 2). All transcripts were coded according to these categories (step 3).” (l. 194ff)

   o The analysis description indicates that analysis of the focus groups was done by two of the authors, but it is unclear if the texts were double-coded and then reconciled, or if the two analysts coded different texts. Please also indicate if/how the two analysts reached adequate intercoder agreement.

RESPONSE: IS conducted the seven steps of qualitative text analysis. HJ checked the accuracy of coding and category development. We elaborated the description of our analysis and added the following paragraph: “The analysis was conducted by two of the authors (IS and HJ). IS conducted the seven steps described above and HJ checked the accuracy of coding and category development. Critical aspects were discussed among all authors until an agreement for each aspect was reached.” (l. 202ff)
On page 7, line 173, the authors state that "Interpersonal perception was reviewed through discussions within the author team." What does interpersonal perception mean? Is this referring to intercoder agreement?

RESPONSE: Yes, indeed - interpersonal perception refers to the intercoder agreements. In the rephrasing of our analysis description we deleted this term (see response to comment above).

In the introduction, the authors mention taking patients' and researchers' views on their motivations and expectations into consideration, seemingly in reference to an earlier study they conducted. It is unclear how the authors took participants' motivations and expectations into consideration, as this is not mentioned in the methods. Please clarify.

RESPONSE: We added an explanation in the methods section of how we used the results of our previous work for the discussion of results in the present paper: “…The discussion section was drafted by all authors together. We used our previous findings on patients’ and researchers’ motivating factors and expectations of getting involved with the patient board [12] to inform our discussion section. We compared the initial motivation and expectations with the actual experiences of the participants.” (l. 211ff)

Better explanations of the overarching qualitative themes and categories are needed, or perhaps reorganization of some of the results to enhance clarity. The overarching themes do not always clearly match up with the categories under them. To give some examples:

RESPONSE: Thank you for these very thoughtful comments, we agree with the feedback and rearranged our results accordingly. Please find our point-by-point responses below.

It's not intuitive to me that "building up a patient board," "atmosphere and communication," and "roles and aims" all group together to reflect "Social issues and culture." "Roles and aims," in particular, seems to be more about facilitation of PPI. I'm not really sure what "Social issues and culture" is intended to mean.

RESPONSE: We agree that the description “social issues and culture” was not well chosen to get an impression of what the category is about. We changed the title to “Basis for cooperation” and added a description for each theme as suggested by the reviewer:

“Theme 1: Basis for cooperation

Patients and researchers discussed issues that relate to the formation of their cooperation. These comprised the composition of the patient board, the atmosphere and the way of communication within the board, as well as the need to clarify roles and aims for cooperation.” (l. 259ff)

“Theme 2: Facilitation of PPI
Three issues that relate to the facilitation of PPI emerged from the patients’ and researchers’ experiences: the training needs for PPI, the need to get familiar with PPI and the trial, and researchers’ difficulties to keep PPI in mind in the context of the clinical trial.” (L. 310ff)

“Theme 3: Organization and conduct

Patients and researchers described their experiences with the organization and conduct of PPI with regard to the timing, the timeframe, the methods, the effort and the allowances.” (L. 343ff)

“Theme 4: Benefits

Benefits of the involvement were described for the people involved, the trial itself as well as for future research.“ (L. 399ff)

The "Benefits" theme includes results about researchers benefiting more from attending meetings than from reading minutes. This finding seems to be more about methods of PPI (under the "Organization and conduct" theme) than about how PPI benefited or affected the researchers.

RESPONSE: We agree with the reviewer that these findings would be of better use in the results section on methods. We deleted these findings in the section on benefits and added the following paragraph to the section on methods: “Researchers described that they benefited more from actually attending meetings than from just reading the minutes of each meeting. Furthermore, having attended at least one meeting helped them to better understand the minutes of the meetings they had not attended. The minutes were described as valuable documents, which can also be used as a reference in the future. Patients did not discuss the value of having minutes.” (L. 384ff)

It is unclear why the "Benefits" theme has no subtopics under it, unlike the other 3 themes. The results that are presented within this theme could be organized in a number of ways, such as:

- benefits to the research; benefits to the people involved
- experienced benefits; uncertainty about benefits

RESPONSE: We followed the reviewer’s suggestion and organized the results on benefits in “Benefits to the people involved” and “Benefits to the research”:

“Benefits of the involvement were described for the patients and researchers involved, the trial itself as well as for future research.

Benefits to the people involved: Patients appreciated getting the opportunity to develop a deeper understanding of UTIs, and to learn about different projects, research results, and research in general. Researchers learnt about using language that is better understandable and less discriminatory for the patients. For example, patients preferred the term “to gain patients for a clinical trial” rather than “recruitment”, as, from their perspective, the latter seemed to objectify
human beings. Participating in a patient board meeting was reported to have been an intense experience, “that was not a doctor-patient-relationship, but an entirely new situation, different from the ones I know” (R3:26). After their experience with the patient board, researchers reported that they were now “[…] richer in experience and knowledge about what it [PPI] can do to oneself and the trial” (R3:273).

Benefits to the research: While patients described benefits for themselves, they wondered about the actual impact of their input and the discussions in the patient board on research, “because for me it is not clear, what could be used at all” (P6:15). Some thought they were able to give stimuli for the researchers or generate ideas, e.g. for the recruitment of patients.

Researchers found that the PPI was of use for a range of aspects. They felt reassured that patients considered the aim of the research project to be of relevance. The patients made suggestions to the researchers regarding better ways to reach out to patients, and also gave them new ideas for the dissemination of results. Further, from the discussion of trial questionnaires, researchers learnt how question should be phrased for them to be easily understood while still being explicit. Researchers were also informed that patients would prefer questionnaires that also ask for positive changes, instead of focusing on negative experiences and symptoms only. Researchers summarized the benefits for the trial stating that “there were many details […] on which […] I certainly would not have come up with” (R3:19). In addition, researchers thought that the work with patients would be of use for the conception of future trials.” (L. 400ff)

At a minimum, the authors should add brief descriptions of each overarching theme to explain what it's about. That would make it easier for the reader to understand the authors' views about how each theme relates to the categories under it and how the categories hang together. The authors may also want to consider regrouping some of the categories or specific findings.

RESPONSE: We agree with the reviewer and adjusted the text accordingly (please see responses above).

3. The authors need to acknowledge the limited attendance/experience of some of the board members, especially the researchers. This study's findings are based on transcripts and notes from board meetings and from focus groups about patients' and researchers' experiences on the board. It is therefore very important to note that only 3 researchers participated in the focus group, and 2 of those researchers had only attended one board meeting. Thus, this study's findings about researchers' experiences come from a small number of people, most of whom had limited experience with the board, and the findings may overrepresent the experience of the one researcher who attended all board meetings. The authors do note this limited attendance in the Results section, but they do not discuss it as a limitation or how this may have affected the themes that were identified and the generalizability of the results.

RESPONSE: We agree that the limited experiences of researchers are an important limitation of our results. Thank you for your thoughtful and detailed reflections on this aspect. We added this issue to the section on limitations: “Only three researchers participated in the focus group on experiences, and two of them had attended only one meeting of the patient board. Therefore, our
findings about researchers’ experiences come from a small number of people, most of whom had limited experience with the board, and the findings may overrepresent the experience of the one researcher who attended all board meetings. This may affect the generalizability of the results.” (L. 674ff)

4. Also related to generalizability, the authors should provide more information about the activities of the patient board as important context for understanding this study’s findings. Since the patient board was created after the study had been designed, what types of activities did the board members engage in? What was their intended role? How was their input asked for and incorporated into the study? Were they involved in decision-making? More information about the activities and level of involvement of the patient board would be helpful context because it likely influenced patients’ and researchers’ experiences with PPI and the challenges they perceived. A research team using a different approach to PPI may experience different challenges.

* The authors may want to consider using a framework from prior literature to describe their patient board along a continuum of engagement. See Carman et al., 2012 (doi: 10.1377/hlthaff.2012.1133) and Forsythe et al., 2019 (https://doi.org/10.1377/hlthaff.2018.05067) in Health Affairs. Using such a framework could help the authors speculate in their discussion about how their approach to PPI may have influenced patients’ and researchers’ experiences and how PPI could be approached or structured differently to avoid or lessen some of the challenges they experienced.

RESPONSE: We followed the reviewer’s advice and added further information on the PPI in the patient board to our section in the methods “general set-up of the patient board” to provide potential readers with more context information. We used Forsythe et al. (2019) to classify our PPI approach as consultation.

“2.3 General set-up of the patient board

The patient board met regularly every five to seven months. Next to the patients, one researcher of the trial team participated in all meetings of the patient board. The other researchers were invited to join the board meetings as they wished as they lived in a different city (approximately 200 km away). Independent of the patient board, the researchers also held regular trial team meetings every month or two (in person or via telephone).

The form of cooperation within the patient board was discussed and agreed upon during the first patient board meeting. Both patients and researchers could have defined the agenda setting, but in fact, only the researchers and the moderator added issues to the agenda. Issues discussed were for example the relevance of the research question, patients’ experiences with UTIs and their resulting research interests, the usability of information material for test persons, the planned recruiting strategy and patients’ ideas for a wider recruitment, the dissemination of results and how the relevant findings can reach the patients. Most frequently, the researchers or the moderator prepared a short introduction for the discussion and invited the patients to share their
perspectives and discuss the issues at hand. As the discussions were allowed to merge in new issues for further exchange the patients were able to influence the agenda indirectly. The results of the patient board meetings were shared via written minutes and could then be incorporated into the trial by the research team. Patients were not involved in final decision-making. Applying the continuum of involvement practices as suggested by Forsythe et al. [22] our PPI would qualify as consultation (which would be different from “input and collaboration” or “shared leadership”).

The meetings took place at a venue centrally located in the town of Bremen and were moderated by a researcher (IS), who was not a member of the trial team. Each meeting lasted 120-150 minutes, including a 15 minutes break. For every patient board meeting they participated in, patients received an allowance of 50 Euros to cover time and travel expenses. Researchers did not receive any allowances.” (L. 132ff)

5. The authors' conclusions not always clearly tied to results. For example, the authors conclude that adequate structures and resources are needed to facilitate effective PPI. While I agree with this statement, it's not clear which part of the results gave rise to that conclusion. Perhaps the authors can more clearly articulate the implications of particular findings and the conclusions drawn from them.

RESPONSE: We agree that this conclusion is not very precise. We draw it from the findings on the effort of involvement, the mode of cooperation and the discussion on training needs. We added some information to help enhance clarity: “To facilitate the conduct of effective PPI, resources in terms of staff, time and finances, adequate working and communication structures, and training for patients and researchers are needed.” (L. 692ff)

We feel that the other conclusions are plausibly linked to our findings, but if the reviewer thinks that there is further need for explanation, we are more than willing to add to it.

6. Similar to the previous point, the authors could sharpen their discussion section to more clearly emphasize key take-aways. The discussion section is quite long, and it's hard to keep it all in mind and come away with a clear sense of the overall findings and their implications for engagement strategies. A table summarizing the key findings from each theme, perhaps broken down into engagement challenges and strategies that worked well, would help the reader digest all of the findings and would make the article more impactful.

RESPONSE: In accordance with the reviewer’s suggestion we emphasized key messages by adding a summarising paragraph at the end of each theme (instead of tables), and highlighted them by using the same introduction for each summary:

“In summary, we found that for a successful cooperation, enough time should be scheduled to discuss roles, aims, hopes and fears during all phases of the project. A well-reflected composition of the people involved and a pleasant atmosphere are crucial to enable cooperation.” (l. 538ff)
“In summary, to facilitate effective PPI, both patients and researchers need to be trained. Supporting patients in a way that enhances their confidence, knowledge and skills empowers them to actively shape the conduct and agenda of PPI. Researchers need to learn about PPI. Being involved in the organization of PPI might help them to incorporate PPI in their research routines.” (L. 573ff)

“In summary, it might be a common challenge for the organization and conduct of PPI that PPI is only installed after a trial has been approved for funding. Patients and researchers should discuss and agree on possible approaches in order to avoid unnecessary conflicts due to differences in perception of the intensity and effort of PPI.” (l. 624ff)

“In summary, making sure that all parties involved are aware of the benefits of PPI is essential to maintain their motivation. This might be challenging if all individuals involved are unfamiliar with PPI and still need to develop their awareness on the impact of PPI.” (L. 656ff)

7. I appreciate that the authors define what they mean by the terms 'PPI' and 'patients' and acknowledge related terms in this field. I wish more articles did this! Thank you.