Reviewer’s report

Title: Learning as an outcome of involvement in research: What are the implications for practice, reporting and evaluation?

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Reviewer: Theresa Bengough

Reviewer’s report:

Thank you for this interesting contribution.

I am personally convinced that we need frameworks for meaningful patient engagement in the entire lifecycle of medicines, collaborating with the industry, the regulators, the HTA community and healthcare professionals, patients and so on. When reading through your article I found myself constantly wondering which phase of lifecycle of medicine you are prioritizing in your reflections e.g. medicines research, clinical trial design or (early) dialogue between industries, regulators, the HTA community and patients on looking at the evidence requirements for specific product technologies? My apologies if this is defined in your article, but it was unclear to me until the end. I would personally feel that the most important stage of research where patients/the public can be involved is to discuss whether "We ask the right questions?" Patients need to be involved in this discussion because they are the ultimate recipients of healthcare services and what the healthcare system stands for. The right approach is therefore to involve them in the dialogue. They should be involved in the discussion around what endpoints researchers are looking at and what matters for them as patients in terms of outcomes. There is an OECD project on this: http://www.oecd.org/health/PaRIS.htm

In the beginning the authors seem to define public involvement as involvement of clinicians, researchers and funders, but in the following they do not stick with those terms. Sometimes they only mention researchers and public, at other points they do mention patients as well. To me it would be helpful to (a) stick to the same group of involved individuals throughout the article and (b) to clearly define who is included in each of them (e.g. funders seemed never to be defined clearly and I guess the definition of the term funder differs a lot within European countries.

I think that adding a conceptual model would help readers to understand/visualise the different stages that different actors could be involved in and it would make up some redundancies within the text.

General challenges that I faced when reading through the article:

- the many headers respectively sections got me confused some times. i would consider it helpful to add an additional explanatory section that runs the reader quickly through the structure of the article as some sort of narrative table of content.
- what kind of paper is this? conceptual paper?

- I am missing some of the important information e.g. (research) question of the paper, objectives, etc.

- does the concept of involvement equals the concept of engagement? In my work/ research field I am only confronted with the term patient/ public engagement. A term that is also widely used by European associations as the European Patients Forum (EPF). Also, the European Medicines Agency (EMA) has a patient engagement strategy. So I was wondering, whether this is the same idea and if not, how do they differ from each other?

- Reading through the paper I was wondering if there is any evidence on what researchers think about the concept of involvement?

- The different sections show a lot of repetitions

- I think the article would benefit from more references

- I miss concrete examples when reading through the article. E.g. in the abstract, line 10 ....have applied the same thinking to involvement." an example of how this involvement would concretely look like would have helped me understand the context better.

- I am uncertain of who's involvement we speak. The authors sometimes mention public or patient involvement, sometimes also funders. Define and use consistently.

Concrete suggestions:

- page 3 line 19 header "Plain english summary" is this header a requirement from the journal or did the authors choose it? It the latter is the case, I think that this paragraph would better be turned into some sort of "Rationale" or "Problem".

- page 5 line 14: is this historical context UK related or can it be applied to the European context? How did the concept of involvement evolve in the EU?

- generally I do miss concrete examples or references that underline an argument throughout the whole article. On page 5 line 26 e.g. the authors describe a "tendency for professionals to conceptualise.." is this argument based on the author's experience or is this evidence-based? line 41 then tells the reader that the authors draw on their experiences as "people who support and promote involvement in research", but no information is offered on how exactly they are doing so or in what position. This is a crucial information to add in my opinion.

- page 6 line 3 "the people involved" is not concrete enough. please define.

- page 6 line 18 I would add "specific" to "a health condition". Again, you introduce a new group of individuals of involvement that haven't been adressed before: carers.
- page 6 line 20: please add a definition of experiential knowledge with reference.

- page 6 line 40 to 45: this seems to be the working definition of involvement. Is this the definition of the authors or is this definition used by other researchers/academics? Also I think that the definition of involvement must be presented to the reader in the very beginning together with a conceptual background that addresses commonly used concepts of involvement and/or engagement.

- on page 6 you address what do patients ... learn from involvement and on page 7 what do researchers learn from involvement. Why do the authors no longer address funders or carers at this point?

- page 7 line 12: does reference number 10 address to all bullet points or only the last one?

- page 7 line 22: it would help the reader to elaborate on the references that are indicated e.g. Staley et al demonstrated in their study that...

- page 7 line 41: I understand the location of the references in a way that all bullet points come from this references, but what bullet point is based on what reference?

- page 8 line 12: again I would prefer if the authors elaborate more in depth on the indicated references.

- page 8 line 22: the very last sentence is it based on the author’s ideas or on a reference?

- page 8 line 32: so this paragraph tells us more about what perspective the authors focus on. I think this part of the article should be moved to the background section.

- page 9 line 19: what or whom do the authors base their arguments on? If this is based on the authors experience, it should be mentioned.

- page 11 line 5: the research questions that are used here as an example do not represent typical research questions to me. Rather these are questions that clinicians do address. But again, maybe if there would be a more concrete information on what kind of researchers or clinicians we are looking at here, these questions would be more comprehensive.

- page 11 line 14: here the authors introduce the term "proposal" which made me wonder whether we are focussing on the proposal stage of research only when discussing involvement?

- page 11 line 52: rather than asking whether there is a best method, I would be curious whether there are any methods for involvement at all?

- page 12 line 23: is the last argument the authors make evidence-based?

- page 12 line 41: in my opinion the way that researchers talk with residents of care homes IS different from the way the talk to teenage boys.
- page 12 line 56: the authors mention a range of approaches. I would like to have an overview of these, but again, rather in the background section with some information on what is working well or not.

- page 13 line 7: what is the experience of the authors based on? are they researchers themselves? If yes, I think that they should add some reflective views on their standpoint to the topic. Also, do researchers currently develop involvement plans? How do they look like? Is there any guidance on how to develop these?

- page 13 line 29: the last sentence is not clear.

- page 13 line 34: may help? I don't think I have got the impression from what I have read that this has been tested.

- page 14 after reading the first paragraph it is not clear to me whether there is any standards/guidance of whether the authors claim this call? Elaborate on the references would solve that question I assume.

- page 14 line 12: I guess that these standards are supposed to help researchers....

- page 15 line 7: I suggest the authors formulate this rather as a proposal e.g. we propose the solution is....

- page 15 line 22 to 27: this is a recommendation for research and should go in another section.

- page 15 line 27 to 29: are people involved supposed to identify missing perspectives (of additional individuals) or dimensions of a research proposals? Clarify please.

- page 15 line 41 to 46: first sentence needs references in my opinion.

- page 15 line 56 to 59: what practice? clinical practice?

- page 16 line 2: again, please elaborate on the mentioned observed examples, describe them.

- page 16 line 5: new concept of involvement lead. Please define this, what a lead does in this particular context. The authors mention a gold-standard so I would expect a reference.

- page 17 line 0-1: please delete "in the room" as this is not clear.

- page 17 line 16: so here the authors seem to define involvement lead. this needs to come when this term is first introduced to the reader.

- page 17 line 44: the authors mention current conceptualisations but never have discussed these.
- Page 19 line 17 Table 1: I do appreciate a table in a rather text-based article. I would prefer if the authors changed the last row from "mostly quantitative statistics" to "quantitative or qualitative data" and "mostly descriptive stories" to "descriptive or narrative information".

- Page 22 line 19-20: it would be interesting to elaborate on potential impact measures here.

- Page 22 line 44: it would be helpful to the reader if the cited references are described in the text.

- Page 23 line 14-15: elaborate more on the different forms of involvement.

- Page 23 line 19-20: perhaps far more problematic... sounds judgmental, please try to find other words.

- Page 23 line 22: "projects in need of help with recruitment" --> is that a reference?

- Page 24 line 5: what does contextual factors mean in this context? There are various dimensions of contextual factors that could play a role here e.g. socio-cultural background of the researcher and/or patient, perception of research in a particular society; culture of a research organisation etc. define or suggest them.

- Page 24 line 29: aid understanding of what exactly?

- Page 25 line 56 to 58: this information should have been included much earlier in my opinion.

- Page 26 line 39: what is an echo chamber?

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Please indicate how interesting you found the manuscript:

An article of importance in its field

**Quality of written English**

Please indicate the quality of language in the manuscript:

Acceptable

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