Author's response to reviews

Title: 'Is it worth doing?' Measuring the impact of patient and public involvement on research.

Authors:

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Version: 2 Date: 2 July 2015

Author's response to reviews: see over
Dear Dr Staniszewska,

Many thanks to the reviewers for their helpful comments. I address their concerns below also explaining where I have made changes to the manuscript where required.

I am not surprised to find the reviewers have raised very important and complex issues in relation to evaluating the impact of involvement. These are all questions I have grappled with and continue to grapple with. I find I am unable to address their concerns adequately within the confines of a single article. I could write several more and plan to do so!

In this article, I am focusing on only one of the many issues around impact, which is the current quest for empirical approaches to evaluation. I am hoping to challenge the assumption that this will enhance our understanding of how involvement works. I question whether such approaches will generate new knowledge and remain uncertain as to who wants this ‘robust evidence’ or why they want it.

I think there is much more discussion to be had with a wider range of people to address the broader questions. My hope is that this article will challenge some of the existing assumptions and encourage greater clarity on what we still need to find out about involvement and for what purpose.

Reviewer 1:

1. In the plain English summary p3: They do not tell us whether the same impact will occur in the same way in other projects, and therefore have limited value

This may read as having no value. Is it worth adding a link sentence ...however there may be value in the researcher having undertaken the study by enhancing their knowledge in context/insight.

As I explain in the main text, I’m not sure whether carrying out an empirical study to explore impact on individual research projects would make a difference to the researchers involved. In the example I describe, the researcher already had complete confidence in the service users’ recommendations. Their experience of recruitment to their study was enough to give them the insight that involvement had made a difference. It was the first time that researcher had involved service users and the first time she had no problem with recruitment. I’m suggesting that this type of experience is valid and useful learning for researchers and that this is sufficient for them to see the value of involvement and to change their practice. Sharing this experiential knowledge may be a more effective way of learning about involvement than generating quantitative evidence. I’m not sure that an empirical study would add anything new to their knowledge or be useful to them.

I have not therefore made this change to the manuscript.
2. In the plain English summary p3:

because at the start of any project researchers ‘don’t know what they don’t know’ – they don’t know what problems they might anticipate, until the patients/public tell them.

This might read as researchers being empty vessels as opposed to individuals able to draw upon previous personal and professional experience to make reasonable assertions about what may happen.

I do not intend to suggest that researchers don’t know anything! I’m suggesting that they lack specific knowledge about life with a health condition. Often this causes them to make the wrong assumptions about what’s important to patients, what’s acceptable to participants in research and what patients want to hear about the findings. This is where involvement really adds value – it fills a gap in researchers’ knowledge, corrects their assumptions and identifies problems they might not otherwise anticipate. In many researchers’ accounts they report that involvement reveals the ‘unexpected’. This is all in the context of individual research projects where researchers collaborate with patients/the public.

I have another manuscript in preparation that describes this in more detail.

To address the reviewer’s concerns, I’ve added the word ‘precisely’ to this sentence on p3.

3. on p6 (see Table 1) Does this refer to Box 1?

I am referring to Table 1 and the general view of what constitutes evidence.

4. p7 2nd para Consider revision in last sentence:

A weakness of the current evidence is that the detail of the of ‘why’, ‘when’ and ‘how’ is often missing, which limits our understanding of the context and therefore its impact.

With this sentence I’ve tried to summarise the issues in plain English – the ‘why’, ‘when’ and ‘how’ is: ‘purpose’, ‘context’ and ‘mechanism’ and the ‘difference made’ is the ‘impact’. The addition therefore seems repetitive and I think would need to say, ‘which limits our understanding of the purpose, context and mechanism and therefore its impact’.

I have not therefore made this change to avoid repetition.

5. p10 Patient and public involvement would have had no impact on recruitment where there was no pre-existing problem. Can we say this? Even where there is considered to be no pre-existing problem there may still be the
potential to enhance recruitment. It may depend on who defines recruitment as a problem in the first instance?

I think we can say this. If a researcher knows where to find potential participants, has written a really clear patient information sheet and has trained all their recruiters in good practice in obtaining consent, has designed their study in such a way as to meet all the participants’ needs and minimises distress, and is addressing a topic that is relevant and important to patients, and has made plans to keep everyone informed of the results - then I’d suggest that they wouldn’t have a problem with recruitment. If there’s none of these ‘problems’ to fix, then involvement won’t make a difference.

This phenomenon has been reported in the context of involvement in writing participant information sheets. In a study where the researchers wrote clearly about a simple trial, for a population that was well-informed about their condition, patient involvement in developing the participant information sheet didn’t make any measurable difference to the readability of the information or recruitment. See: Guarino P, Elbourne D, Carpenter J, Peduzzi P. Consumer involvement in consent document development: a multicenter cluster randomized trial to assess study participants’ understanding. Clin Trials. 2006;3(1):19-30.

6. p6 same as point 3.

I am referring to Table 1 and the general view of what constitutes evidence.

Reviewer 2:

a) A brief reference to the concept that proving PPI impact is seen by some as irrelevant (user involvement as a democratic right rather than as something that improves research)

It’s really difficult to be brief on this topic – this would merit another paper in itself.

I have added a paragraph to the introduction – but these are my views alone. I’m not sure if this paragraph works in this article or if I’ve given the topic sufficient attention. I’d prefer to do this in another article with other people’s input. However, if the reviewer and editor are happy with this change, I am happy to keep it in.

b) Some discussion is needed of what happens when the lines become blurred between “researcher” and “service user” – if a service-user works in partnership with a researcher, and it is only the service-user’s contribution that it is being scrutinised for value and impact, that becomes uncomfortable and even humiliating. This article makes the assumption that service users will always be in a subordinate position (which is increasingly not the case). The authors mention the importance of looking at when and how involvement takes place, but don’t go far enough in imagining how impact could ever be measured in gold-standard PPI (where the researcher and service users are
genuinely equal and reach decisions through discussion rather than taking particular sides).

This is a really important point.

I have been thinking about the issue of service user researchers, and this is a very different context. The reviewer is right - the arguments I have made in this article apply to studies where service users are consulted or collaborate with researchers. I have made additions to the text to make this clear.

I agree that it is important that the contribution of the service users should not be evaluated alone. I believe that it is the effectiveness of the partnership that should be evaluated when researchers and service users work together. I have written about this on my blog in a post titled, ‘Where is your other half?’ I think this is another important topic that needs proper discussion and consideration. I do not feel I can do this topic justice in this article. I would prefer to address this in another article with input from others.

I will shortly be attending a symposium where I hope these exact questions will be discussed by a multi-stakeholder group and I expect a publication that will address them more comprehensively will emerge from this event.

I therefore have not attempted to address them in the main text.

(c) In an ideal world I’d like to see some acknowledgement of the fact that there has been considerable work outside healthcare on how to get the most impact from user involvement (not just in social services but also in design, market research etc) as well as how to maximise the impact of communication, response rates, recruitment, take-up of a particular intervention etc – some of which is extremely generalisable. However I appreciate that to go into this in depth would be a whole new article, so this is just a suggestion for a discretionary revision. (And a suggestion to the editors perhaps to commission such an article so that healthcare can learn from disciplines outside its ‘silos’).

I agree – sometimes I think certain aspects of involvement, for example, getting the target audience to review written materials is just good comms and a very basic aspect of marketing. Do we really need an RCT to tell us that’s worth doing? It has been done! See: Knapp, P., Raynor, D.K., Silcock, J. & Parkinson, B. (2011) Can user testing of a clinical trial patient information sheet make it fit-for-purpose? – a randomised controlled trial. BioMed Central Medicine, 9, 89.

However, I do think involvement contributes much more than market research and it is important to understand the difference between involvement and comms. Again, as the reviewer suggests another article would be needed to cover this.
Reviewer 3

No changes to the manuscript required.

Reviewer 4

It was unclear as to whether the lay summary had been proof read by a lay person.

I had not asked a lay person to review the lay summary prior to submission. However, as some of the reviewers appear to be service users and have not commented on the lay summary, I conclude it has met their requirements.

Title: the term ‘worth’ in the title is a little misleading so suggest delete the question in the title or have a clear definition of ‘worth’ and use this consistently throughout.

I have used the title ‘Is it worth doing?’ almost as a pun! It’s a question researchers ask about involvement and I’m saying it’s a question we should ask about empirical approaches to evaluating the impact of involvement. I’d like to have a plain English catchy short title to prompt interest – so I would really like to keep this in if possible.

In the main text, what I hope I’ve communicated is that measuring impact is possible to do, but because of the highly-context dependent nature of involvement, the evidence that emerges from it has little explanatory or predictive value. This is distinct from using empirical studies to test treatments, where it is possible to control for confounding contextual factors through randomisation, where it is possible to standardise and objectify the intervention and also possible to standardise and measure outcomes. I think these things become difficult with involvement because of its complexity and dependence on context. So I’m concluding that measuring impact isn’t ‘worth’ doing in the same way that it is ‘worth’ doing for medical interventions.

There seems to be an expectation that empirical evidence will support researchers in making decisions about what involvement to do and to know how it will help them. I think this is a misconception and am concerned that we will invest considerable time and resources in trying to develop these elusive metrics and at the end will be none the wiser. I don’t think it helps individual researchers in the context of their projects, and I don’t think it helps the wider community to understand involvement. So therefore I’m questioning whether these empirical studies are worth doing. What new knowledge will they contribute?

I’m not sure how I can define ‘worth’ any further than this. I’m using it as a lay-term rather than one used by social scientists. I would welcome further input from the reviewer as to what more I need to say.

‘Context’ is key to the manuscript so this needs explaining more fully. For example what theoretical frameworks that describe context would be helpful to us? What are the different levels at which context might impact e.g. policy (e.g. INVOLVE, NIHR, Senior Investigators); organisation (e.g. Clinical Trials Units;
Research Centres/Institutes; local PPI structures; Research Design Service; regional leadership); professional level (e.g. do interdisciplinary teams fare better than uni-disciplinary teams?); individual level (researchers and PPI members); and the overall fit with the intervention. Only certain components of context are illustrated. Consider disentangling the different levels to highlight gaps in evidence and our understanding.

I’ve expanded the description of context in the main text to take on board this important point. I think what the reviewer is identifying are the very issues that need to be researched. I don’t know if the contextual factors the reviewer identifies are the ones that are relevant. I don’t think anyone knows, as we haven’t tried to answer this question. I have made additions to the text to be clear that I am talking about involvement at the level of individual research projects.

My response to the questions about involvement in different levels and different structures, would be to suggest that the impact of the involvement still comes down to one thing – the conversation between patients/carers/the public and researchers/policymakers/health professionals and the mutual learning that takes place. So I’d argue that in order to understand the impact in other levels of involvement, we’d still need to look at where those people started, what was said, what was learnt and what was acted upon. I think this would require further research before I could draw any stronger conclusions.

I have anecdotal evidence to support this argument. In 2007, TwoCan evaluated the impact of a user advisory group on the work of the National Diabetes Support Team while they were implementing the National Service Framework. One of the senior members of Department of Health explained that talking to the service users hadn’t told her anything she didn’t already know as she had extensive experience of user involvement. However, it did remind her to prioritise an issue in the next conversation with one of her managers, to make sure that when he went to his next committee meeting that that topic would be on their agenda. I think that nicely illustrates the way that involvement often works – it impacts on peoples’ priorities, values, ideas and knowledge and then changes what they think and do.

The manuscript illustrates the multidimensionality of PPI. It is possible that unidimensional strategies are as effective as multidimensional approaches e.g. PPI in an advisory group or steering group may be as effective as having both. Do such questions need to be tested? Is ‘How it works’ vs ‘what it achieves’ an either/or? Are these simply different questions and given the paucity of evidence are both not equally important?

Given the conclusions I have drawn in the text, I would argue that the aspects of involvement discussed here – advisory group versus steering group versus both – is less significant to impact than what gets said, what gets learnt and what gets done differently as a result of the involvement (as described above). I think taking the approach I have suggested in the discussion would help answer the questions the reviewer has posed.
I would challenge the assertion that there is a paucity of ‘evidence’. I have read over 200 reports of the impact of involvement on research for INVOLVE’s evidence library and personally written over 100 case studies of impact. I know other people have written more case studies. I think there is a paucity of quantitative data, but a wealth of experiential knowledge in the literature. I’m arguing we can learn more from the insights gained through this experience, than from trying to find ways to quantify the impact.

Existing evidence is hampered by retrospective PPI data collection and data on PPI are poorly recorded. Standard recording of PPI in research would give a more accurate account of PPI for example using agreed quality indicators. Such PPI-and-researcher generated indicators could ‘measure components of PPI practice to assess the quality, and therefore any change in quality, of any research evidence generated.’ Percentage achievement could then be audited.

I agree this could all be done – but my question is why would you want to do it and how would it help? It would require considerable investment of resources and time, so I would want to be sure it will contribute useful learning. My conclusion is that it doesn’t help individual researchers know about what involvement is useful to them, nor does it help the wider community understand how involvement works or when it works best. What questions would this approach address?

On the one hand the author suggests that elements of PPI impact e.g. refining recruitment strategies, could easily be undertaken and measured in real time, but on the other hand lists reasons why we don’t design complex multi-layered studies to do this. Could this be addressed together as one paragraph?

I think there are a series of arguments to be made on this point and would prefer to keep them as separate paragraphs.

Consider using the MRC complex interventions framework as a signpost for researchers.

Internal vs external validity of quantitative studies was confusing. The study has to be internally valid before external validity and generalisability of the findings can be considered. Here is where a theoretical framework might be useful. Suggest add a statement on this.

I think this opens up another big area of debate, which I am intending to address in another article. What I’m concluding in this current article is that the impact of involvement is often subjectively experienced by researchers. I’m advocating a process of ‘learning from experience’ - gaining insight from researchers’ accounts of their experiences. I think researchers can understand involvement in a different way than having to research it themselves or consider quantitative ‘evidence’ of impact. There are many ways to understand the world other than through systematic, objective, empirical research.

I’m suggesting researchers doing involvement will gain insights from hearing about other researchers’ experiences in the same way that researchers gain insights from...
Hearing about patients’ experience. Capturing these insights might be better achieved through evaluation processes – which I do not think are the same as research. They are much more value-driven i.e. subjective rather than objective. They are not underpinned by theories or hypotheses, but by stakeholder views about ‘what success looks like’.

The following table summarises how the differences between evaluation and research might be understood – but I realise this is contested (from: http://betterevaluation.org/blog/framing_the_difference_between_research_and_evaluation)

<table>
<thead>
<tr>
<th>Research</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose is testing theory and producing generalizable findings.</td>
<td>Purpose is to determine the effectiveness of a specific program or model.</td>
</tr>
<tr>
<td>Questions originate with scholars in a discipline.</td>
<td>Questions originate with key stakeholders and primary intended users of evaluation findings.</td>
</tr>
<tr>
<td>Quality and importance judged by peer review in a discipline.</td>
<td>Quality and importance judged by those who will use the findings to take action and make decisions.</td>
</tr>
<tr>
<td>Ultimate test of value is contribution to knowledge.</td>
<td>Ultimate test of value is usefulness to improve effectiveness.</td>
</tr>
</tbody>
</table>

My understanding is that conceptual/theoretical frameworks are analytical tools. So they will support the researchers who want to research involvement, rather than the researchers doing the involvement. I don’t think researchers need a conceptual or theoretical framework to do involvement, they just need to be clear about why they are doing it. I also believe that the purpose of evaluation is to support the ‘doing’ and that theory and conceptual frameworks are not required for this purpose.

These are complex arguments and I certainly haven’t done justice to them here and I need to expand on them. I don’t feel I can adequately address them in one article.

I had been careful to refer to evaluating the impact of involvement rather than researching it. However, given the potential for confusion, I have also revised some of the wording in the text to define what I mean by evaluation, and to remove some of the shared terminology that might suggest I am talking about researching involvement.
Reviewer 5

Can this sentence be made clearer - for example, example, defining ‘scientific approaches’ “However, if scientific approaches are designed in such a way as to take these factors into account, the findings may not be generalisable.”

I have made this change.

Keywords - consider adding more if allowed - ‘consumer’ may bring this up in Australian searches and ‘citizen’ in Canadian. Perhaps adding ‘measure’ to impact and the word ‘evidence’?

I have made these changes.

Insert ‘if’ to be more balanced “It is expected that evidence gained through empirical methods will provide a definitive answer to the question ‘Is public involvement in research worth doing?’ and identify IF, when, where and how involvement brings benefits.” I have made these changes.

I have added the second ‘if’ to this sentence. However, I believe it is expected that empirical evidence will provide definitive answers, and I think that’s a problem and that’s what I want to challenge with this article. So I have not included the first ‘if’.

Change to ‘Participant information sheet’ “For example, if involvement is restricted to asking the public to comment on a Participant information sheet”.

I have made these changes.

Perhaps add a comment on the support they are given to be involved? “Therefore the involvement process is not simply about the ‘method’ used to seek people’s views, but also precisely what patients/ the public are asked to contribute, what specific recommendations they make and what action is taken in response to their input.”

I would suggest that the ‘method’ used to consult people is the way it’s done which for me includes the training and support offered to patients. I’m suggesting this is important only as far as it facilitates the mutual learning between researchers and patients/ the public, rather than being the actual mechanism by which involvement makes a difference. I conclude it’s what gets said, what gets heard and what gets done that influences outcomes, rather than the ‘method’ used.

Suggested insertion in block capitals “In practice, it is therefore often the researcher who DIRECTLY experiences the impact of involvement, WITH THE WIDER IMPACT POTENTIALLY FELT BY THE PUBLIC” e.g. better research.

I have added ‘directly’ as requested. I have not added the second phrase for two reasons. Firstly, I think this is downstream to the impact on researchers and I am wanting to focus on this more immediate effect of involvement. Secondly, I think the wider impacts or downstream impacts are felt by lots of stakeholders, not just the public.
Reviewer 6

Firstly, there are potentially different ways of measuring impact, each with their strengths and weaknesses. Consequently, it could be argued that another approach would be to advocate that purpose, methodology and limitations should be adequately explained whenever impact of PPI is being measured rather than trying to come up with a perfect solution to measuring PPI impact.

Yes I think this reviewer has highlighted an important point – what is the purpose of measuring impact? I have yet to find a clear answer to this. My sense is that people think this it will provide the evidence to inform researchers’ decisions about whether and how to involve patients and the public and I am not convinced it will do this. This is another debate that merits further exploration.

Secondly, the argument against quantitative research is in danger of being overstated in this article as quantitative research is itself moving in the direction suggested by the author. It is becoming increasingly recognised that RCT evidence only applies to the population studied. For example in RCTs of new drug interventions, the elderly and those with comorbidities are often excluded and hence the growing importance of the post marketing surveillance of new drugs especially in these (unstudied) populations. Use of the PICO principles is increasing in quantitative research and quantitative research based Guidelines and Recommendations. There is also a "grudging" recognition that there can be unconscious subjectivity in RCTs. For example, several systematic reviews have demonstrated a higher number of positive studies for a drug where the study is funded by the makers of that drug than when the study is carried out independent of the company that manufactures the drug.

I do not intend to suggest that we should never measure the impact of involvement. I’m concluding that if we want to understand when and how involvement works then measuring impact does not help. Nor am I convinced it is evidence that changes behaviour i.e. I’m not convinced that more ‘robust evidence’ is what will convince researchers to do involvement (see my blog post ‘It’s a trip’). I would welcome clarification on when measuring the impact of involvement IS worth doing. I hope this article will stimulate that debate.

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2 July 2015