Author’s response to reviews

Title: A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials - a work in progress

Authors:
Heather Bagley (heather.bagley@liverpool.ac.uk)
Hannah Short (Hannah.Short@liverpool.ac.uk)
Nicola Harman (nharman@liverpool.ac.uk)
Helen Hickey (hickeyh@liverpool.ac.uk)
Carrol Gamble (carrolp@liverpool.ac.uk)
Bridget Young (byoung@liverpool.ac.uk)
Kerry Woolfall (woolfall@liverpool.ac.uk)
Paula Williamson (prw@liverpool.ac.uk)

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Response to Reviewers. RIAE-D-15-00005

A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials – a work in progress

Dear Editor,

Thank you for the reviewers’ comments on the revision of manuscript number RIAE-D-15-00005
We have been asked to respond to the reviewers’ comments. Our responses to each of the points listed by reviewers are included in this letter and I attach the amended article with amendments completed in track changes and highlighted to differentiate changes made in the response to the second set of reviewers.

Kind regards

Heather Bagley

On behalf of the authors.

Reviewer #7: Page 1: Title

The changes requested by the reviewers actually take this away from the recognised MRC Guidelines for complex interventions https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/ that have a development, evaluative and implementation/process evaluation stages. I think the authors have obliged the reviewers but now risk down playing their achievement. My suggestion would be to realign with this MRC Guidelines as a recognised robust methodological approach:

A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials - The development stage.

> Happy to accept editorial opinion, comment not taken.

Page 2 Methods Section Line 10-19

1) They should be permitted to reinstate that this article describes the development stage and that feasibility and evaluation will follow in accordance with the MRC Guidelines for a complex intervention. This means they should be permitted to revert back to the 'development of a toolkit' and acknowledge that subsequent evaluation and process evaluation stages will allow reiterative modifications of the toolkit to ensure it is fit for purpose in a real world scenario. Their compromise to accommodate the reviewer's feedback to avoid "development" and replace with "developing" deviates from the MRC Guidelines and actually down plays what they have achieved and will likely affect the impact of the paper which would be disappointing given the calibre of the team and the
research produced. If the editor permits my suggestion would be that the authors need to acknowledge that they are following the MRC Guidelines e.g. Page 5 lines 35-45 and in the methods section Page 6 Line 28-46 (on Page 6 they need to align this to the 1] Development, 2] Evaluative (feasibility and definitive evaluation) and 3] Implementation (Process Evaluation) stages of the MRC Guidelines and this they should set the scene for this methodological approach and that this paper covers the development stage. I believe that clarity will really help the reader and addresses the reviewers concerns. This will require a modification of the article but in my opinion it will be a stronger publication.

> Happy to accept editorial opinion, comment not taken.

2) PPI page 3 line 41

….decisions about research priorities add "that affect them".

→ Text amended

3) PPI page 3 line 39-41

The addition of "or the wider public in the case of public health research", clause here isn't quite working for me I would prefer they reference back to the INVOLVE definition "…When using the term 'public' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services…." http://www.invo.org.uk/posttyperesource/what-is-public-involvement-in-research/

Replace with:

Morally, PPI is advocated on the grounds that people affected by a condition , or the wider public in the case of public health research, have a right to have a say in decisions about research priorities that may affect them.

→ Text amended

4) Page 4 Line 52 - replace 'an' with 'a'
> Text amended

5) Page 9 line 6 & 7 Page 13 Line 19- replace public contributors with patient/public contributors in alignment with PPI

> We have realised the star for the footnote indicating the first time we refer to public contributors is in the wrong place – we have amended this

6) Page 9 line 32 " …developed a document "Budgeting for Involvement"…" should be referenced

> Reference added

7) Page 11 line 13 & Line 36"developing" to be replaced with the "development of a PPI toolkit"

> Happy to accept editorial opinion, comment not taken.

8) Page 13 Line 42 replace "further developed" with "further refined" through a reiterative evaluative and process evaluation stages in line with the MRC Guidelines

> Happy to accept editorial opinion, comment not taken.

Reviewer #8: 1. General point: Thank you. An interesting and thought-provoking article. I particularly like the way that reference has been made to alignment with NIHR strategic goals in the Going the Extra Mile report.

> No response required

2. General point: I am listed a 'public reviewer' and the only option appears to be to change this to 'author'. However, I work in the field of developing and supporting PPI in research and have done so for 10+ years. So my comments are written from that perspective.
3. General point: Is this a research article? It struck me in reading this article that it is a valuable and detailed description of the rationale for, process and product(s) development - but possibly not research? Though I fully appreciate I'm not a researcher.

> No response required

4. General point: The article raises the issue of a plethora of resources being used inconsistently. It would be really interesting to know about the work the team did to understand what makes a successful toolkit. For example, the Clinical Trials Toolkit - http://www.ct-toolkit.ac.uk - seems relevant here. Is this toolkit a 'success'? How is success of a toolkit measured? What is an example of a successful toolkit and what makes it a success?

> Digging around the literature it is hard to find information about how others have evaluated the utility of their toolkits. One toolkit (https://www.k4health.org/sites/default/files/monitoring-evaluating.pdf) kept data on visitors to the web-site including whether tools were downloaded / time spent on the website / number of new visitors and returning visitors / most and least frequently viewed pages / source of traffic / where visitors are coming from (through web searches or directly visiting url / top key words that have led users to web site. They also did user surveys & interviews to look at satisfaction with the toolkit – interesting findings: “Also among the findings was that information overload can be a barrier to information access in some Toolkits. As a TWG determines the scope of a Toolkit or the inclusion criteria for resources, there is value in limiting the number of resources included in the Toolkit to the essentials so that users do not feel overwhelmed. Respondents also stressed the value of providing an informative summary for each resource included in the Toolkit so that users faced with time constraints and information overload can more effectively select and prioritize information”. Useful survey example: https://www.k4health.org/sites/default/files/online-survey-toolkit-review.pdf I think that success of our toolkit can be measured in terms of uptake and the desire to develop new tools collectively to add to the toolkit from the wider network of PPI reps in trials units. We have added text under Next Steps to indicate that we plan to consider how success of the toolkit should be measured.

5. General point: I haven't commented on any of the appendices because they seem to me to be project work in development rather than a part of the article for review.
6. P3/L41 - is it 'decisions about research.' Rather than 'decisions about research priorities.'?
(Too narrow?).

> Text amended

7. P4/L1-4: 'There are times when researchers need to sensitively address the challenges of PPI, for example if public contributors have an overly narrow or specific self-serving agenda or are not engaging sufficiently, despite being given opportunity and support.' Is this meant to be an example of a negative report/impact? If so, does it need a reference, as for positive? Would perhaps be good to refer to PiiAF summary update of positive and negative impacts - http://piiaf.org.uk/documents/impacts-summary-1113.pdf? I think the idea of public contributors being 'self-serving' and /or 'overly narrow' is an interestingly one. Seems quite subjective and perhaps equally applicable to researchers? Does this relate to clarity of expectations on all sides? And could this be described in those terms?

> We have amended the text to highlight negative reports of impact on research, referencing the PiiAF.

8. P4/L21 - Is it worth mentioning that this article is about surgical research? As the abstract of this article itself only makes conclusions about PPI and surgical research.

> Text amended

9. P5/L0-1: 'Gamble et al132 found that although INVOLVE resources do exist to support public contributors; they are often not used in practice.'

* Is this meant to be focused only on resources for supporting public contributors or to support PPI more generally?
> The question asked in EPIC was just about use of INVOLVE resources to support and train public contributors in research – Text amended

* It might be helpful to provide a bit more info here. Was it the interviews that established resources often not used? Was there any indication as to why?

> Text amended. No it was in the surveys and no question was asked in the survey about why these resources were not used.

* Is there anything to report here on the use of the INVOLVE Briefing Note Supplement for Clinical trials? As it was specifically developed by people working in CTUs for CTUs.

> We have no information on this. The EPIC survey of CTUs did not ask specifically about this document. We have made further reference to the Briefing Notes in the ‘Background’

10. P5/L17-18: ’Toolkits for involving the public in NIHR Clinical Research Networks (CRNs) in the UK also exist.’ If this relates to the NIHR CRN only then needs to be England not UK. Also, is it possible to reference or give example of such a toolkit here?

> Removed ‘in the UK’, reference added

11. P5/L48: ‘Reviewing PPI and developing a PPI Working Group’. Would this section be a good place to acknowledge and briefly reflect on the lack of PPI in the project to date as well as in the discussion? The PPI Working Group did not involved any public members because … we plan involve public contributors by ….

> Text amended

12. P9/L17: ’Finding public contributors is one challenge but the suitability of those who volunteer should also be taken into account.’ Is this paragraph unduly negative in tone? L17 is
an example. It could instead, for example, say something along the lines of - Another important aspect is to be clear about the skills and experiences that are relevant to public contributors' roles.

> We accept this point - Text amended

13. P9/L26: 'Once the PPI activities of a trial have been identified …' Would it be better to say 'As' rather than 'Once'? In reality the two need to be consider together and often budget will impact on PPI processes.

> Text amended

14. P11/L8: '…in the UK …'. NIHR focus is on England rather than UK. Perhaps omit 'in the UK'?

> Text amended

15. P12/L22-25: 'One of the problems with existing resources not being used is that they are not immediately visible to all researchers and trials teams, often working on many other aspects of the trial.' This is a hugely important issue. What will make this toolkit any more successful than previous resources? This paragraph goes on to detail what will happen at a local level. But how scaleable is this nationally? In the ‘Next Steps’ we have clarified that the toolkit will be discussed with other registered CTUs. We will also contact the NIHR Clinical Trials Toolkit to request a reference to our toolkit as other tools e.g. COMET database are now referenced: http://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design. Our toolkit is a one stop shop for PPI in clinical trials signposting other resources in one place. We have added emphasis in two places (method and discussion) that this is an online resource.

16. P12/L42-51: This paragraph isn't clear. I think the amendments need reviewing.

> Text amended
17. P13/L59 & p14/L0: ‘...’ and are not specific to clinical trials...’ How does this statement square with, for example, the INVOLVE supplementary guidance for clinical trials and e.g. the MRC CTU PPI resources - http://www.ctu.mrc.ac.uk/our_research/patient_and_public_involvement/?

> Text amended in the ‘Background’.

Reviewer #9: This version of the manuscript addresses the reviewer comments from the earlier version. It describes a process at a particular point in time, and a very useful point for people following a similar course. It invites involvement from others and sets up a baseline for a very useful and potentially very valuable collaboration with others. I will follow this story with great interest.

> No response required.

Reviewer #10: This account of the development of a toolkit to assist researchers with the involvement of patients and the public in research trials is important. It is important because it attempts to take a systemic approach to the process of involvement and because it specifically seeks to identify resources to assist with the measurement and evaluation of the impact of PPI activities. It is to be welcomed as a substantive attempt to provide a comprehensive aid for researchers on the involvement of patients and the public.

> No response required.

There are limitations. These limitations are, in large part, identified by the authors.

• Firstly, they admit to not having undertaken a systematic review of this area of activity. The virtue of their approach is that it has been borne out of the opportunistic and pragmatic necessity of their own practice. Can we be confident that they are not themselves re-treading or duplicating established territory?
As the reviewer points out we have acknowledged this limitation in the manuscript. We hope that through open access publication readers will identify any relevant resources that we ourselves have not found to date.

- Secondly, they admit to having had no PPI involvement to date. If they had, and if a less opportunistic review of current work had been undertaken, they may have become acquainted with the toolkit developments pioneered by patients and lay people themselves that have been designed to support their peers in becoming effective research partners. Neglect of this evolving strand of activity reflects this limitation.

- We have added text to reflect specifically on this in the discussion and to propose a way to address it in the future.

- Finally, I am not sure from the paper how the developed structure of the Toolkit is envisaged. A principle claim is that it will prevent duplication of effort for other researchers in that it will collect together an extensive range of resources around the authors' framework. Perhaps it is clearer to the authors than to me as to how this will occur. Will the Toolkit end up as a pick and mix assortment of resources or will there be an editorial hand guiding users to best practice?

Sentence added to end of the first paragraph under ‘Next steps’ to reflect our anticipated approach to assessment