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

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Author’s response to reviews:

Reviewer 2:

1. The emphasis in the tool seems to focus more on the application of PPI approaches rather than the intended impact of the PPI interventions on the trials themselves. Both are important, so I wonder if the latter needs more emphasis. This mapping to the pathway of the trial is very useful but describing the PPI intervention alone may not be enough. By also describing the intended impact of that intervention demonstrates the direct benefits to the trial CI who as a consequence may be better engaged and prompts intelligent consideration of finer aspects of the approach in the specific trial. More emphasis on impact is also consistent with a later evaluation stage that compares actual impacts with intended impacts.
We have amended the text in two places to address the issues of impact on the trial and mechanisms for evaluating the impact of PPI experience on public contributors and trials teams.

2. The paper acknowledges the weakness to date of not having a patient and public view in the toolkit development, but it is right to take a business approach in the first instance. It is critical to improve the utilisation of PPI in clinical trials for patient benefit - and that means a better structure for PPI in the business of trials. At the same time these structures should not be so rigid as to exclude the possibility of patients influencing the evolution of the structures and approaches themselves where they are for better effect, and better patient relevance now and in future.

We have amended the text to clarify openness to input and feedback from patients over time.

Reviewer 3:

Page 3

1. Line 29- The moral argument also encompasses the view that those affected by research have a right to be involved in prioritising and shaping research. As such, PPI is not just for ‘people affected by a condition’ it could be the wider population if, for example, it was a piece of public health research.

We have amended the text to address this.

2. Line 53-54 – can you clarify what is meant when you refer to the ‘specific agenda’ of patients. Is it when someone’s agenda/ reason for becoming involved is at odds with a predefined research plan?

We have amended the text in relation to this.
3. Line 59- describe the sampling frame for EPIC here rather than later in the text (on line 17 pg 4)?

> We have amended the text to describe this.

Page 5

4. General comment- How did the Working group work together?- regular meetings? Process of developing the resources etc.

> We have amended the text to explain this.

5. Line 7 – Useful for the authors to provide a rationale for publishing the paper whilst the toolkit is in development? i.e. to facilitate engagement of stakeholders in development process? To increase the uptake of work completed so far etc.?

> We have amended the text to provide our rationale.

6. Line 36-39- Sentence not clear- the Consent Working Group produced resources that could be used in the tool kit? It would be useful to give further (but brief) info about the Consent Working Group and their link to paediatric theme of CTRC.

> We have amended the text to provide more information on this group.

Page 6

7. Line 7 – Can authors clarify how they reviewed the ‘type and timing’ of PPI activities. Was this through the survey mentioned on line 17?

> We have amended the text to describe this.
8. Line 8- what did the process of ‘reflection’ entail.

> We have amended the text to describe this.

Page 7

9. Line 23- how did authors select which resources they would provide a rationale for in the paper?

> We have amended the text to explain this.

Page 8

10. Line 9- what does the term ‘suitable’ mean in this context?

> We have amended the text to address this.

11. Line 44- how were indicative rates agreed?

> We have amended the text to explain this.

Page 10

12. Line 7-20- Quite a lot of detail about approach which might work better after the summary of findings [line 22- 37] as indicative of future work which builds on current work.

> We have moved this text.
13. Line 36- grammatical error- should read ‘….develop trials at a fast pace’

> We have amended the text.

14. Line 39- Do trial teams include patients/ the public working in a PPI capacity?

> We have amended the text.

Page 11

15. Line 16-17- The authors note the limited involvement of PPI collaborators in the work- can they expand on the reasons why? Understanding the challenges of PPI is useful for others, be it funding, resources, time etc.

> We have amended the text to expand on the reasons for this.

16. Line 31- sustainability of online resources is notoriously difficult so it would be great if the authors could indicate how this has this has been achieved.

> We have amended the text to explain this.

Reviewer 4:

- An inset box that details more concisely the aim, purpose and - critically - the intended audience might be helpful to emphasise this.

> We have spoken with the journal as this is a stylistic issue and have been, advised to leave the presentation as it is for this word document.
• The authors need to be somewhat careful about the pitch of the article and the expectations it leads to. When I began to read the article I was under the impression that I was about to be presented with a full and operational toolkit. It only becomes clear this is not the case - that it only deals with phases one and two of this work - as one reads the body of the piece. It might therefore be helpful to title this as a 'work in progress' or similar with the intent behind publication to invite comment and involvement (see later point about absence of PPI up until now).

> We have amended the title, abstract, plain language summary and the background.

• That said, there is some really helpful information presented already as, for example, in the section of the toolkit that deals with recruiting suitable public contributors (sample JDs etc.). The figures and graphics look very helpful in the main although the authors need to be wary of being overly technical in their description of the stages in a clinical trial.

> We are unclear what the reviewer is asking. If s/he is asking us to revise Figure 1, we would note that this is to be used with researchers and patient partners within clinical trials teams who are familiar with the terminology used in the trial. Therefore we would prefer to retain the current terminology. Any tools to be used by public contributors will be checked to ensure that the language used is accessible and in plain language.

• Some questions that occurred to me during the course of the article and which could benefit the piece if full answered include: How will the toolkit be shared?

> We have amended the text to describe how the toolkit will be shared.

What do other clinical trials units think about it?

> We have amended the text to explain this.
Can others contribute to the toolkit (including patients) and how?

> We have amended the text describing how others can contribute.

Indeed I felt that the 'Discussion' section of the article could benefit from some sub-heads that looked at some of the next steps underway or under consideration.

> We have added sub headings added in the Discussion.

• I am interested to know why in the 'Supporting PPI' domain focuses on participant information sheets rather than PPI in developing and refining recruitment strategies where there is considerable evidence of impact?

> We have amended the text to show that this is a future area.

• The admission on P11 that patients and the public were not involved in developing the toolkit up to this point will likely - and to some extent rightly - attract some criticism. There needs to be some written justification for this.

> We have provided justification for this.

• the assertion in line 33, P 3 that 'nothing about us...' is five centuries old probably needs a supporting reference

> We have added a reference.
- P44, line 57 to P5, line 4 - the distinctive features of a CTU and why the toolkit is helpful seems an important point that could come earlier in the document. Not a lot of people will know this.

> We have moved this text to raise this point earlier in the text.

- beginning line 42, page 5, there seems a mixture of tenses used at this point

> We have amended the text in this sentence.

Reviewer 5

- 'busy trial teams' - the word busy implies they are too busy to do involvement - while they may have competing priorities, perhaps a more appropriate way of saying this could be 'teams with limited resources (including time) can use this resource and avoid a duplication of work' (similar to later comment) - or something slightly more concise than my suggestion!

> We have amended the text where we used the term ‘busy’ to ‘teams with limited resources’.

- 'nothing about us without us' five centuries old - this is very interesting and perhaps deserves a citation? https://en.wikipedia.org/wiki/Nothing_About_Us_Without_Us

> We have added this reference.

- 'Toolkits for involving the public in NIHR Clinical Research Networks (CRNs) also exist' perhaps a reference to 'Building Research Partnerships' which is relevant to all kinds of research, including clinical trials could be cited? Otherwise, this statement isn't quite accurate. For example these links: http://www.invo.org.uk/building-research-partnerships/ http://www.crn.nihr.ac.uk/blog/events/building-research-partnerships-workshop/ www.macmillan.org.uk/researchlearning -

> We have added this to the list of tools – Training resources.

- Discussion ref 7 (going extra mile) is now a dead link - try this: https://web.archive.org/web/20150831071513/http://www.nihr.ac.uk/documents/about-NIHR/NIHR-Publications/Extra%20Mile2.pdf
We have updated this link.

- Conclusion 'Patient and public involvement in research is often surrounded by fears of tokenistic approaches (Buck 2014)' inconsistent reference format?

> We have addressed the inconsistency in referencing.

- and are not specific to clinical trials which operate under different 'rules' to other areas of research. By signposting’ - missing space before 'By'

> We have amended the text.

- List of abbreviations - other papers have shifted this to the front - maybe more helpful there?

> We have checked this with the journal and been advised to leave this in the current location in accordance with authors instructions for layout.