Reviewer's report

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

Version: 1 Date: 14 Feb 2016

Reviewer: Philippa Yeeles

Reviewer's report:

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.

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.

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?

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?).

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?

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.

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?

* 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?

* 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.

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?

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 ….

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.

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.

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

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?

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

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/?

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?
6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

Declaration of interest - though not identified as 'competing interest'.
Current post: Director of Involvement & Engagement, NIHR Central Commissioning Facility
Previous post: Deputy Director, INVOLVE

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal