Reviewer's report

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

Version: 0 Date: 17 Aug 2015

Reviewer: Simon Denegri

Reviewer's report:

- This is an important and potentially highly useful article by a group with immense expertise in the field of clinical trials and public involvement.

- While 'toolkits' are two-a-penny these days and have lost some of their currency as a result the toolkit being developed here is an excellent example of where they have the potential to make a real difference because a) the purpose is clearly defined and b) the intent is highly practical in nature. An inset box that details more concisely the aim, purpose and - critically - the intended audience might be helpful to emphasise this.

- 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).

- 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.

- 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? What do other clinical trials units think about it? Can others contribute to the toolkit (including patients) and how? 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.
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?

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.

A few other minor points include:

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

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

On the whole I think this is an interesting and important article about a potentially very helpful product but there are some issues to address in the text as presented.

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An article of importance in its field

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