Reviewer’s report

Title: Public involvement could usefully inform ethical review, but rarely does: what are the implications?

Version: 0 Date: 11 Sep 2017

Reviewer: Jonathan Ives

Reviewer's report:

This paper addresses an important and contemporary problem. Researchers are required to make statements about PPI in the HRA REC process, but it is unclear what end this serves nor that the statements made or required are terribly useful during the review process. As such, I think this is important work that ought to be disseminated. I do, however, have some concerns about the paper as is - which I think could in principle be ameliorated with some additional detail. I have listed them below in the order in which they arose (as I was reading).

1. The statement in the background section of the abstract, repeated in the main body, that "Involving the public in research prior to REC review ensures studies are ethically acceptable to potential participants, thus informing the ethical review process" is to my mind too strong, and unjustified, and is actually undermined later on when results are presented (i.e., from the abstract "This makes it difficult to judge whether the involvement shaped the research design in any way to make it more ethically acceptable"). Improvement to ethical acceptability is one of the putative advantages of PPI, but (a) there is no overwhelming empirical evidence that this occurs and what there is, to my mind, is thin, and (b) it seems to endorse a very thin proceduralistic account of ethics that holds that simply going through a PPI process ensures ethical acceptability. Some changing to wording, to lessen the claim (removing the word 'ensures') is I feel warranted (nb. 'ethical probity' might be considered oxymoronic. The term 'probity' encompasses the ethical and so doesn't need the 'ethical' prefix - but there may be reasonable disagreement about this).
Similar claims are made throughout the paper that use the term 'ensure', or 'ensuring', and to my mind these claims should be weakened to more accurately reflect the current state of knowledge about the impact of PPI. I do not think that doing this will undermine the message of the paper in any way.

NB. The claim made in the first line of the conclusion, that 'PPI has the potential to increase the ethical acceptability of research' is, to my mind spot on. It may just be worth going through the paper and making all claims of that kind consistent with that final one.

2. The general claim on the first line of the first page 'Researchers conducting most types of research in the NHS in England are required to submit their study for ethical review by an NHS Research Ethics Committee' might be true, may also be wrong. Many kinds, and specific kinds, yes, but do we know that it is 'most'? Perhaps specify the kind of research (i.e. research involving patients or patient data) to avoid a hostage to fortune in the first line?

3. A statement about ethical review may have been made elsewhere in the submission process, but seems to be very obviously missing from the paper. As I read, I started to ask myself if I was aware that my own HRA RES submission would or could be made available to researchers. I have no problem with this, but I think it may be worth including a brief statement about how these data were accessed and that this is consistent with HRA data sharing policy. I'm sure it must be, but a clear statement would, I think, be helpful as other readers may be taken by surprise that their own submissions may be part of this analysis.

4. Overall I felt that the methods section was very brief and contained insufficient information for me to really get to grips with what was done and why. Some specific points of clarification in the methods section that would be useful are:
   a. What was done with those applications of the 2748 that stated there was PPI but did not meet the criteria for the INVOLVE definition of genuine' involvement? Were they discarded or retained in subsequent analysis?
   b. I do have a difficulty with the way the term 'genuine' is used, which is very normative and value laden. I think the paper would benefit from being much clearer about the fact that it is
making a pre-judgment about what counts as good/genuine PPI, and so the analysis involves
a normative judgement. My view is that whether or not PPI is genuine depends on what it's
aim is, and whether it is undertaken in good faith to meet that aim. My point is that there
can be disagreement, and when you are assessing whether PPI is genuine, you need to very
clearly acknowledge that this is a normative judgement and make clear what you are
assessing in that normative judgement (as opposed to a factual assessment). I think this is
something on which reasonable people can disagree, but I would urge the authors to tackle
this head on, so as not to turn off readers who might not agree with the starting assumptions
on which this research is based.

This is important because when, on page 6 you report that "public involvement was confirmed in
only 36% of the total number of these studies from 2014" what I assume you mean is that only
36% of the reported PPI met the definition of genuine involvement as set out by INVOLVE. The
analysis, as reported, ignores that those studies that did meet the 'genuine' criteria may well have
had PPI, but you and INVOLVE do not think it is genuine or sufficient. This calls for greater
exposition of what you really mean by 'genuine' and the pejorative meaning that it conveys.

c. What is the authors' understanding of inductive thematic analysis, and what steps did this
involve? The terminology of qualitative analysis is very ambiguous and means different
things to different people, and so simply naming a technique is not very edifying. Can
reference, at least, be provided to make it clear what approach was used, but ideally detail of
the analytic steps involved would be included.

d. Why was this kind of analysis the most appropriate? My immediate thought is that with this
amount of data some form of directed Framework analysis would be more appropriate. This
is another reason why more detail about the analytic process is needed.

e. Who conducted the analysis? I assume KS given the statement about agreeing themes with
JE. Given that, how were disagreements managed and resolved? Also, can some reflexivity
be included here, to consider how the personal perspectives of the researchers were
managed in the analytic process? You state that the analysis was shaped by the author's
experience of promoting and developing PPI and experience of sitting on RECs. This now suggests to me that the data were approached from particular theoretical and normative perspectives (this ties in with comment 4b above). I do not see this as necessarily a problem, but the need for credibility and rigour in qualitative research requires that this is explored reflexively.

5. When the results on involvement and design are reported, we get the first indication of the criteria that are used to assess whether PPI has been conducted. These do, however, seem to set the bar very high, and the question arises how these criteria were devised, about which we have no information. Actually demonstrating that these criteria have been met might very burdensome, and it is possible that a judgement is being made about the level of 'genuine' PPI involvement on the basis not of what was actually done, but the way it was reported on the REC form. This is still, of course, a problem, because it means that RECS are not given sufficient information about how PPI might have helped the process, but it is a different claim to the one about the genuine involvement that is repeatedly made in the paper. I feel that a much greater distinction needs to be made between the claim that (a) genuine PPI did not occur in these studies and (b) the information provided in the REC forms was not sufficient to allow RECs to determine whether PPI was conducted in way that informed ethical design. I think you are probably entitled to the latter claim, but not to the former. The former claim is, however, repeatedly made, even though the paper seemed at the start to be about the latter.

Also, as I read this passage, a question about the normative assumptions behind this research raised its head. These criteria are very normative, requiring a very high standard, but no justification is given for them at all, and this seems like a significant omission given the nature of the work.

6. In general, I did not find the way that data are presented in the paper to be terribly helpful. This is presented as a qualitative analysis, and yet very few quotations are provided that give confidence in the credibility of the analysis. Numbers are very often reported in the text, suggesting that responses to QA14-1 had been coded and counted (suggesting that in fact a numerical content analysis has been conducted, rather than a thematic content analysis), but no
numerical data are provided in tables 2-4. As such, the paper as it stands provides the authors' interpretation of their data, but does not present sufficient data in a format that allows the reader to see for themselves - which acts as a barrier to credibility.

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