Reviewer’s report

Title: Taking patient involvement seriously: A critical ethical analysis of participatory approaches in data-intensive medical research

Version: 0 Date: 27 Nov 2018

Reviewer: Laura Schmitt Olabisi

Reviewer’s report:

I am not in the biomedical field, nor do I work extensively with big data. I believe I am reviewing this manuscript on the basis of my expertise in participatory and engaged research (so that the authors and editors have context for my comments!)

This is a very well-written and thoughtful piece. I have some (minor) suggestions below.

In the abstract 'negligence' is misspelled

In the discussion of co-production of knowledge, the authors state that this represents the most encompassing realization of citizen science. However, in order for citizens to have true co-ownership over the research, they would need equal access to funding mechanisms and knowledge produced (e.g. scientific journals). So co-producing knowledge alone would not meet this criterion unless the power-sharing and knowledge-sharing between citizens and researchers were truly equal. Obviously, this is extremely rare in practice but it is a vision some projects are working towards (the Flint, Michigan Healthy Flint Research Coordinating Center is one example). The authors give an example of the MIDATA study which might (partially) fulfill this vision also.

Relatedly, I am curious about an aspect of the MIDATA study which perhaps deserves more discussion in the manuscript—specifically, the interpretation and use of information. One of the barriers to participation is that scientific findings—even if co-produced by citizens—are often reported and interpreted in a way that is difficult or impossible for nonscientists to understand. Moreover, most citizens do not have access to academic journals. Science communication is therefore a vital part of participation which is not touched on here. I am curious how results of research were reported in the MIDATA study and if the participants found these results intelligible and satisfactory.

Page 11, line 26: I think you can say a bit more here. Can you give a specific example of these biases, and what it would look like to remove them?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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

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