Reviewer’s report

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

Version: 0 Date: 05 Dec 2018

Reviewer: Marcello Ienca

Reviewer’s report:

This is an informative and well-written review article, which seems suitable for the Debate section of the journal. The article introduces some useful conceptual distinctions and suggests some basic criteria for ethically justified participatory approaches to BDMR.

A few minor remarks:

- The most original part of the paper is relegated to the "conclusion" section. Ideally, the conclusion is the section where the most important discussion points of the article are summarised, not the one where new ideas are presented. While I understand that these conclusions logically follow from the premises delineated in the previous sections, I would recommend re-organizing the paper's structure or, at least, considering to rename the final section.

- Authors have emphasised that, in a big data ecosystem, it is hard to distinguish strictly medical from non-medical data, hence have suggested to use the language of "big data health research" or "health-related big data research" to underscore how non-medical data sources can be used for health-related research purposes. It would be advisable that the authors include a mention to this conceptual discussion in the background section of their manuscript.

- The article is full of quotations. While I understand this stylistic choice is aimed at minimizing the risk of misrepresenting the cited papers, this unusual -and, from my perspective, excessive- number of direct quotations makes the paper uneasy to read.

- Background/p.2, l45-50: Since the care.data program was abandoned in July 2016 it would be preferable to use the preterite instead of, respectively, the present and present perfect. E.g. "was introduced", "it aimed at" etc.

- P.3, l 51: "Against this background": ambiguous formulation, please rephrase.

- P.4, 116-17: Reference needed.

- P.7, l15: Do you mean "line of reasoning"?

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.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

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:

Needs some language corrections before being published

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