Author’s response to reviews

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

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Author’s response to reviews:

To the editor

Dear Mr. Giabbanelli,

We are grateful that the reviewers as well as the editor recognised that we have taken their comments seriously and that our revisions have improved the manuscript. However, from the perspective of one reviewer two points require further consideration. In particular,

1. Reviewer 1 asks that we should again reflect on and/or reconsider the term ‘big data’ in light of the following question: to what extent is this only relevant to 'big' data or does this apply to (medical) data in general?

2. Second, reviewer 1 acknowledges that the focus of our paper is on the normative role and practical usage of participation, but points out that it is still important to discuss the 'status aparte' of scientific research within the GDPR because this is highly relevant for practical usage (of participation, and even data more general).

As a response to these concerns of reviewer 1, we made additional changes to our manuscript (all changes of this second round of review are marked green; the first round of revisions is still marked yellow). Our aim was to address the reviewer’s concerns while preserving the original focus of our paper, i.e. participation. In the revised version, we explicitly acknowledge that data protection has an impact on participatory issues. However, the ethical issues that we address with regard to participation go much beyond data protection laws. Issues of data protection have been discussed at length in other papers with a focus on legal issues of research. If we would have to make these legal aspects (as ethicists) even more prominent than we did in this second round of review, this would not only be a presumption of expertise, but also spoil the stringency of the ethical line of argument of our paper. In fact, we are concerned that the more we try to fulfil the reviewer’s interest in this particular topic, the more we will invite criticism by others who miss a
clear focus on participation as promised by our initial description of the paper’s aim. Therefore, we suggest the following solution to the abovementioned concerns of the reviewer:

To the reviewer:

Point 1:

1. We understand that the term ‘big data’ is controversial and may raise more questions than it creates clarity in conceptual terms. This, however, does not reduce its popularity in scientific and public debates. For example, PubMed lists 2011 papers using “big data” in their titles. Just ignoring or abandoning the term in our paper does not help to solve this conceptual problem from our perspective. Rather than deleting the term ‘big data’, we decided to clarify that our analysis is not only relevant for ‘big data’, which is often associated with unstructured data, but also for smaller data collections with structured data. Still we can state and show in our paper that participation has become increasingly important in initiatives that are at least data-intensive. Research projects that are carried out on a rather small data basis (as in traditional clinical research settings) only rarely take specific efforts for public engagement or PPI. Furthermore, in response to the reviewer’s concern about the use of the term ‘big data’ we have

   a) changed the title to avoid the impression that we exclusively talk about big data:

   It reads now:

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

   b), throughout the whole paper, we consistently refer to data-intensive research in medicine and health care, rather than only to big data.

   A clarification of this use of terminology has been added on page 4:

   “In this paper, we choose the umbrella term ‘data-intensive research’ to cover the variety of approaches to the digitalized collection and analysis of larger sets of data, including but not limited to ‘big data’ in particular.”

   c) we have added some explanations: e.g., on page 6:

   “Against this backdrop, our paper focuses on the significance of ‘participation’ in HBDR and similar data-intensive research in medicine and healthcare. Discussing the whole range of other ethically relevant issues related to this kind of research is beyond the scope of the paper and cannot be realized in a systematic manner within the limited space. The central objective is to critically analyse the specific use and ethical role of participatory concepts in data-intensive
research initiatives and discourses in medicine and healthcare. Admittedly, ‘participation’ has become an important topic in medical research in general (see background). Accordingly, many of the points addressed in the subsequent analyses may not be unique or exclusive to data-intensive research but also apply to other fields of medical science. Still, the current boom of participatory claims in the context of ‘big data’ and ‘digitalization’ in medicine and healthcare appears significant and hence deserves closer attention. This is all the more relevant as the range of involved disciplines is expanding far beyond the medical field, life sciences and public health, now also including medical informatics, engineering, mathematics, and computer science.”

Furthermore, we added in the discussion part, on page 15, the following sentence in order to strengthen that the aspects that we have identified as relevant for a normatively justified use of participation in the context of data-intensive research might also be relevant for appeals to participatory notions in medical research in general.

“Specifically, the following five points are worth considering and may also be relevant for participation and PPI in medical research in general:”

Point 2:

We elaborated our discussion of the GDPR by providing more details on its pertinent provisions for research. At the same time, we highlight more clearly that data-intensive research in medicine does not raise completely new ethical issues but rather exacerbates already existing challenges (e.g. with regard to anonymization, the generation of sensitive information etc.).

See the following passage on p. 5:

“While social stigmatization and discrimination can always result if medical data fall into wrong hands, the large-scale analysis of data from different sources increases the amount of sensitive information, e.g. by facilitating more fine-grained stratification. Furthermore, regulations on data protection, e.g. concerning anonymization, aim to protect individuals against problematic usage of their data. However, there is increasing awareness that traditional measures may no longer be sufficient, as re-identification of individuals is getting easier the more data are available [12]. In this regard, medical research with large data sets inevitably entails personal data. Thus, data-intensive research approaches exacerbate the general risk of re-identification.”

While we understand that legal and ethical issues are often closely intertwined in the field of medicine, we do not regard it useful to develop this analysis even further as it would detract readers from the genuine aim of the paper, i.e. the ethical analysis of participatory notions in data-intensive medical research. We suggest that this should be focus of an extra, future paper.