Reviewer’s report

Title: Building the Case for Actionable Ethics in Digital Health Research Supported by Artificial Intelligence

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Reviewer: Markus Christen

Reviewer's report:

Review of: Ethics in the New Era of Health Data Science: A Case for Fair, Accountable and Transparent Practices

The contribution "Ethics in the New Era of Health Data Science: A Case for Fair, Accountable and Transparent Practices" addresses an important and recent topic of biomedical research, namely the impact of the digital transformation of healthcare practices and the associated ethical issues. In the following, I provide an assessment of this opinion article based on the criteria provided by BMC Medicine (indicated by ***).

***Opinions should present a balanced view of the field in terms of representation of research from all groups concerned, but they should also include personal and original perspective on an important research-related topic of interest to the general medical community.

The opinion paper is unbalanced with respect to representing the field. 5 out of 14 papers are self-citations. Self-citations are basically OK, as own research needs to be demonstrated as well (and the authors indeed have done good work in the field). But from an opinion paper I would expect to find also some references to the most often cited papers in the field in order to demonstrate the embedding of the opinion (e.g., Lupton D, 2014, sociology of health & illness; or the paper of Boyd & Crawford, 2012, Information, Communication & Society as a general reference). I recommend that the authors check publication databases such as Web of Science and check for reference publications in the field and add them to the argumentation in order to better embed the opinion paper into the general debate (maybe also by replacing 1-2 self-citations).

***Does the opinion article present a novel argument, or a novel insight into existing work?

Partly. The fact that the digital transformation affects the health system in many ways is a well-known and broadly disputed topic. Also the discussion of the ethical issues of these developments (for example ethical issues of electronic health records) has a history that goes back more than 20 years (e.g., Kluge 1994, Int. J. Biomed Comp); although it was not so prominent in the medical ethics domain. This historical embedding of the discourse should briefly be mentioned.

The paper provides a rather unstructured assembly of ethical issues ranging from health apps, IoT and G5 (which may have health implications due to radiation) to the use of AI in its various
forms (which are not well explained). The title implies that the focus is on the data aspect (i.e., gathering, managing, using new data sources), but it interferes with many other aspects. It may be better for the overall structure of the paper to set a clearer focus, as the analysis of "gaps" is sound and interesting.

The presented checklist is a very useful instrument presented in the paper and deserves a more prominent placement in the paper. The use case is also well-chosen to outline some of the issues addressed in the opinion paper (small remark concerning the analysis on page 7: the principle they refer to is "respect for autonomy" and not "respect").

The table on initiatives presented is useful but lacks an clear criteria which initiative is listed an which not (small remark for page 9: the correct order for ELSI is "ethical, legal & social", not "ethical, social & legal"). For example, the resent work of the High-Level Expert Group on Artificial Intelligence of the European Commission surely needs to be integrated in the table (https://ec.europa.eu/digital-single-market/en/high-level-expert-group-artificial-intelligence). The authors may also consider, whether recent initiatives in China should be included in the table given the enormous investments made in China in this domain. Finally, including the URLs of the initiatives mentioned would be useful for the readers to quickly get additional information.

***Does the piece address an important problem of interest to a broad biomedical audience?***

Yes. As mentioned above, digital transformation is (and should be!) indeed a major topic in current health research and practice and deserves to be investigated further. However, the paper gives a bit the impression that research on ELSI aspects just has started. This is incorrect, several initiatives are underway and also have led to published research. For example, the recent work of van Velthoven et al on digital health app development standards (BMC 2018). The research of the Digital Ethics Lab of the Oxford Internet Institute may also be helpful here (https://www.oii.ox.ac.uk/research/digital-ethics-lab/)

***Is the article well-argued and referenced?***

No. The paper starts with quite some platitudes on the impact of digital transformation on the health system. The reader would profit a lot if some of the claims are backed by data or well-known review papers outlining the degree of digital transformation in the health sector. For this aspect, the paper either provide no eviduyd or mostly gray literature (5 out of 13 papers are grey literature; some of the lins do not work: ref. 2 and ref. 14). See also the remarks made above.

***Has the author used logical arguments and sound reasoning?***

Partly; see the remarks above.

***Is the piece written well enough for publication?***

Formally, the paper is well-written.
Overall assessment

The paper needs a major revision that should take into account the following two aspects:

- Better embedding into the current debate with respect to factual and ethical issues
- Clearer focus on the problem, taking the presented guidelines and gap analysis as center

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