Author’s response to reviews

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

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Anna Lopez Munoz, PhD
Associate Editor, BMC Medicine
Subject: Response to Reviewer Comments

Manuscript Number: BMED-D-19-00534
Dear Dr. Munoz:
Please find attached our revised manuscript addressing reviewer comments provided on June 7, 2019.

Reviewer #1 - Markus Christen

The authors have addressed my critique sufficiently. I think the paper is now ready for publication.
Response: Thank you! We appreciate your comments and believe they have improved our paper.

However, the authors should perform a final language check. Some corrections led to mistakes, e.g.:

Background, first paragraph:
...identifies gaps to be addressed DELETE "TO BE ADDRESSED", ADD SHOWS several efforts underway to address these gaps...

We have changed the last sentence in paragraph one as requested:
“While not a formal review, this opinion essay provides a selective overview of this rapidly changing digital health research landscape, identifies gaps, shows several efforts underway to
address these gaps and concludes with recommendations on how stakeholders can and should take responsibility to advance socially responsible digital health research.”

Section "new initiatives"
Over the past few years, several initiatives have begun to address the ethical, legal and social implications (ELSI) of the digital revolution in healthcare.
We have changed the first sentence under the “new initiatives” section as follows:
“Over the past few years, several initiatives have begun to address the ethical, legal and social implications (ELSI) of the digital revolution in healthcare.”
Furthermore, I suggest to introduce the table as an example as follows (just a suggestion):
... the digital revolution in healthcare. PROMINENT EXAMPLES OF SUCH INITIATIVES CONCERNS AI. The A.I. foci is broad and includes autonomous ...
We have added this sentence. “Prominent examples of such initiatives concern A.I.”
Together the changes read as follows:
“Over the past few years, several initiatives have begun to address the ethical, legal and social implications (ELSI) of the digital revolution in healthcare. Prominent examples of such initiatives concern A.I. Specific to A.I., the foci are broad and include autonomous vehicles, facial recognition, city planning, the future of work and, in some cases health.”

Reviewer #2 - Karsten Weber

The revisions made by the authors are appreciated and have significantly improved the text. A large number of comments and suggestions have been taken into account. However, some questions remain unanswered or have not yet been sufficiently addressed.

Response: Thank you – we have tried to be responsive to your comments, which have greatly improved our manuscript.

It is obvious that the authors focus on the use of AI in healthcare. This does indeed make sense, as the use of AI has great potential for improving health care.

We see A.I. as a tool used in digital health research and, as such, have tried to draw attention to the use of A.I. as a component of digital health/medicine.

However, the authors introduce the text by wanting to discuss fundamental ethical questions regarding the use of digital technology in healthcare. But then focusing on AI is problematic, as digital technology encompasses much more than AI and many moral questions cannot be asked when merely focusing on AI. It would therefore make sense to change the title of the paper and the introduction accordingly in order to make it clear from the outset that the authors want to address ethical aspects of AI in healthcare. This would better represent the structure and content of the text.

We changed the title previously and, it may be this change wasn’t visible to our reviewers. Our new title is: Building the Case for Actionable Ethics in Digital Health Research. Since we discuss A.I. in the context of digital health research, to better represent the structure and content we have added A.I. to revised title. The updated title is now: Building the Case for Actionable
Ethics in Digital Health Research supported by Artificial Intelligence. Given the structure of this paper in terms of journal guidelines, there are only so many examples we can explore and we hope those covering A.I. are representative and will serve the goal of learning for about important issues in this space.

Finally, figure 1 probably should be revised. One can certainly express ethical principles in different ways and, for example, describe autonomy and non-maleficence (in the sense of Beauchamp & Childress) as respect for the person. However, it is difficult to understand why the protection of autonomy does not appear explicitly in the figure. The emphasis on individual autonomy is certainly a rather Western concept, but very relevant there.

Our Figure is based on the principles of biomedical and behavioral research describe in the Belmont Report, which we have cited in our manuscript. The three principles are “Respect for Persons” “Beneficence” and “Justice” which are slightly different than the four principles Beauchamp and Childress identify as the ethical pillars for biomedical ethics. Within the Belmont Report, the principle of Respect for Persons incorporates two ethical convictions as described in this excerpt (see: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html):

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

As our perspective is on the ethical dimensions of digital health research, we believe it is most appropriate to reference the foundational principles of biomedical and behavioral research described in the Belmont Report. Our figure includes the primary domains, which are linked to our checklist. We included a few examples from the checklist to contextualize the domains; however, you can see from the checklist (http://thecore.ucsd.edu/dmchecklist/), that Autonomy is a key factor for researchers to consider when evaluating digital technologies for use in health research.

We are grateful for the reviewer comments, as they have been instrumental in improving our opinion essay. We believe our revisions and clarifications are responsive to the most recent comments. Please do let us know if there are any other comments or questions to address.

With Thanks,

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