Author’s response to reviews

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

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Author’s response to reviews:

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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 comments provided on February 24, 2019.

Editorial Comments:

- Manuscripts should have the following subsections: Background/Main text/Conclusion. Please move background heading in a new line and use bold to make it obvious.

Confirmed.

- Please add a list of abbreviations

We have added this list of abbreviations under the Keywords on page 2.

- You should upload your figures as separate files.

Figure 1 has been uploaded as a separate file.

- Please ensure you include the figure legends in the manuscript after the main text.
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).

We agree and have added other authors, including those suggested, in the “background” section on page 3 to present a broader view of work in this space. We hope this offers a better introduction to the topic and we thank the reviewer for such informative resources that we can now share with readers of this paper.

***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.

We agree and now mention the history of this space on pages 3 and 4 and have referenced several scholars contributing to this area. We hope this now helps make the paper stronger.

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.

We have reworked the introduction on pages 3 and 4 to help the reader better understand the flow and scope of the paper and have changed the title so that it clearly focuses on gaps. We thank the reviewer for these useful suggestions.

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").

We thank the reviewer and now feature the framework figure in the paper more prominently on page 6. We have also redone the figure so that it includes examples of items in the companion checklist. Also, the principle of “respect for persons,” as per the Belmont Report, was edited on page 8.

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 recent 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.

We agree the reviewer brings up important resources that we did not mention. We now have included those and also noted this is a ‘selective’ summary, as we do not aim to be inclusive. Throughout the paper we remind readers this is an opinion piece and also remind readers that we offer useful and hopefully representative examples – but do not want anyone to be confused on the type of paper or type of evidence it is providing. We are grateful the reviewer has helped us clarify this critical point.

***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.ooi.ox.ac.uk/research/digital-ethics-lab/)
We have now included these important links and papers. Given the space and format of this paper, we now note in the background section on page 3 that we do not intend for it to be a systematic review of all efforts.

***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 evidence or mostly gray literature (5 out of 13 papers are grey literature; some of the links do not work: ref. 2 and ref. 14). See also the remarks made above.

We have updated references to address the important point raised by the reviewer.

***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

We hope that by addressing the above, we have improved the paper and thank Reviewer 1 for the helpful comments and insights.

Reviewer #2: The opinion paper "Ethics in the New Era of Health Data Science: A Case for Fair, Accountable and Transparent Practices" addresses a very important topic. Many observations and forecasts support the assumption that the digital revolution will and already has far-reaching effects on the health care system. Likewise, the statement that the use of digital technology will change the health care system is without doubt correct, even if it is not yet completely clear in what direction and to what extent this change will take place. It is therefore to be welcomed that such issues are addressed within the health system itself, as this is the only way to shape change in a participatory way. The opinion paper describes the technical and social background of this change triggered by the digital revolution, albeit briefly, correctly.

We thank the reviewer for the positive feedback.
However, the questions asked in the main part of the opinion paper appear to be very strongly posed from a scholarly perspective. For the focus is less on the perspective of the use of digital technology than on that of research and development. This impression may be due to the brevity of the opinion paper, but the perspective of the users of digital technology in health care should be emphasized more. This also applies to the questions that the authors feel should be asked. These are again clearly formulated from an R&D perspective or from a research viewpoint. It is to be assumed, however, that the ethical questions that users of digital technology would ask look very different in many cases. Users are not only private individuals who, for example, use an app with their smartphone, but also physicians, nurses or other healthcare professionals.

The reviewer raises several important points. Given the limits of an opinion piece we are not able to cover all perspectives and have intentionally framed our essay more narrowly from the R&D lens. Given the broad scope of digital health – this is a limitation of the paper and we now have reworked the introduction to make this point clear. We even now mention the word ‘opinion’ several places in the paper and ‘selective review’ to further help readers understand the scope of this work.

It would therefore be important to investigate these different stakeholder perspectives empirically and to derive the resulting consequences for the use of digital technology in health care. Equally important would be to analyse how in different expectations with regard to technology will cause which ethical conflicts. It is to be expected that different stakeholders have different expectations and therefore conflicts arise; however, it is also to be expected that a stakeholder himself has different expectations which in turn produce moral conflicts. The focus on a research perspective becomes clear again in the description of the Decision Making Framework. This tool is undoubtedly helpful in evaluating a research project from an ethical point of view. However, it can be asked with good arguments whether it is appropriate to uncover the ethical conflicts that arise in the context of the use of a product or service from the point of view of the many different stakeholders.

We fully agree it is critical to investigate these different stakeholder perspectives empirically, but note that this paper format and style makes such a challenge. Likewise, the reviewer raises the critical issue if it is appropriate to uncover the ethical conflicts that arise in the context of the use of a product or service from the point of view of the many different stakeholders. In this case we have had to make the assumption of ‘yes’ in order to facilitate this article. We now note such as a limitation in the paper. Please see changes in the background section on page 3.

The topics discussed by the authors under the heading "Digital Research and AI Gaps" are undoubtedly important. However, it should be critically noted that the strong focus on AI may obscure the view that the digital revolution in health care is not just about the use of AI, but includes many other technologies. The table in the "New Initiatives" section is not really helpful in understanding the field of research and actually only considers AI research; once again, it should be stressed that the digital revolution is more than AI. Finally, it is somewhat irritating when the keywords IoT and 5G suddenly appear in the conclusion, even though they have never been mentioned before in the entire text. It is not entirely clear why these keywords are mentioned here.
The reviewer raises good points. We have now removed references to 5G and IoT and reframed the ‘new initiatives’ section to explain it is a selective summary and there are many more efforts we cannot cover (please see pages 9 and 10). We do not want readers to think it represents all efforts as it is clear we have led the reviewer to consider in the first draft. We agree that the digital revolution is more than AI and have included initiatives that are broader than AI to make this point. We hope this is now well addressed. We are also very clear now that this is a selective table and not a comprehensive list.

As a reviewer, I would recommend that authors go into the questions they ask themselves in much more detail: Who is involved? What ethical questions need to be asked? Furthermore, it would be useful to ask what regulatory measures can be taken at all; the reference to IRBs is a first step, but certainly not sufficient. In order to gain the necessary space, it would make sense to delete the Decision Making Framework as well as the Use Case, as these were used to examine detailed questions at the micro level - but much more important would be the discussion of fundamental aspects of the digital revolution in healthcare. The section on 'Digital Research and AI Gaps' should also be expanded and deepened -- important topics are already covered here, but they are not comprehensive. Finally, it would make sense to delete the 'New Initiatives' table, as it cannot and is not representative: 4 out of 6 initiatives mentioned are based in the US, 5 out of 6 in English-speaking countries. The initiative mentioned for Germany is also highly controversial there. This table cannot reflect the diversity of existing initiatives and does not help to get an appropriate overview.

We hope that by reframing the table as ‘selected’ example will help readers understand it aims to simply highlight some efforts but is not meant to be representative. To be a full review would require a different paper format and focus that we want to ensure readers do not confuse with this opinion paper. We have made numerous efforts throughout the paper to help readers understand the important message of this work and the content we are presenting it within. We have reworked the 'Digital Research and AI Gaps' section on page 8 to be deeper in scope as the reviewer suggests. We hope the use case we present is a good way to address ‘who’ is involved in this work so it is clear to readers.