Reviewer's report

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

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Reviewer: Karsten Weber

Reviewer's report:

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.

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.

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.

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.

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.

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