Author’s response to reviews

Title: Leaving Patients to Their Own Devices? Smart Technology, Safety and Therapeutic Relationships

Authors:
Anita Ho (anitaho.ethics@gmail.com)
Oliver Quick (Oliver.Quick@bristol.ac.uk)

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Author’s response to reviews:

Phillipa Malpas (Reviewer 1): Thank you for the opportunity to review this timely and interesting paper that explores some of the implications of increasing utilisation of health monitoring devices, through an ethical lens. Overall I felt the paper contributed a sound critical exploration of some of the ethical issues arising from smart technology.

Comments:

Little discussion centres on current worldwide regulatory measures, other than a sentence in the concluding comments, however I think some further discussion is needed to contextualise this fast developing area of e-health. The FDA issued guidance in 2015: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

See also (USA Govt): https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm255978.htm
Response: We thank the reviewer’s suggestion to include some references to the regulatory measures. Given the nature of a short debate piece, we thought it would be beyond the scope of the paper to get into great details the regulatory landscape. However, we have now added a few sentences in the main text to contextualize the discussion.

Page 3, line 50-: The authors state that health tracking devices may facilitate more informed clinical counselling - "Patients can ask more relevant and timely questions based on the recorded information…..". However such a claim rests on the assumption that patients using such devices not only understand what information is being recorded by the device, but also the significance of that information in order to seek clinical oversight. I wonder if the claims made by the authors (in regards to promoting ethical and effective care delivery) overly simplifies the predicted benefits of smart technology.

Response: We agree with the reviewer’s concern. Our paper starts out by explaining the common arguments regarding the utilities of health tracking devices. But the second half of the paper provides a critique of this very argument. We have clarified a few additional sentences to highlight this critique.

The use of smart technology to assist health professionals working in rural and isolated areas may be of benefit in providing recorded information traditionally unavailable to such communities. Issues such as equity of access and privacy and protection of personal data have not been addressed but seem an important aspect in this context. Whilst clear, regulatory guidance is needed, more research needs to be done into the efficacy and effectiveness of smart technology in terms of improving adherence and clinical outcomes.
Response: We thank the reviewer for bringing up the access issue for those in remote communities. We have now added the following sentence: “Smart devices may help health professionals and patients in rural and isolated areas to share and coordinate recorded information that is traditionally unavailable to such communities, thereby promoting more equitable access to health information and corresponding management options.”

We did not address the privacy and data protection here because they are beyond the scope of the paper. We agree that these are important issues in general regarding health tracking devices. However, our paper is focusing on the patient safety and therapeutic relationship issues, and hence these issues are not part of our discussion. We have, however, made the following comment in the concluding section of the paper: “There are also privacy and data confidentiality considerations that go beyond the scope of this brief debate.”

Elizabeth Cummings (Reviewer 2): This is an interesting and important discussion article.

Some of the arguments are not fully formed. I found that the important section on patient safety and ethical concerns regarding self-monitoring devices provided little direct relationship to the ethical concerns. I would like to see these emphasised more clearly as this is essentially the original section of the paper as the safety of self-monitoring devices has been investigated widely in the research literature.

Response: We thank the reviewer’s comments and suggestions. Because of the general length for a debate article, we are limited in terms of the depth of some of the discussions in this piece. However, we have added some more pertinent points linking patient safety issues to ethical concerns.

The conclusions are not well related back to the discussion and whilst I do not dispute them I would prefer to see a clear link back to the discussion in the paper.

Response: We thank the reviewer’s suggestion, and have now made a more direct link between the conclusion and the discussions.

There are a few small questions I have:
P2 L48 you refer to the 'profession's basic ethical tenet' but you are not referring to a single profession and I suggest change to 'healthcare's basic ethical tenet' instead.

Response: We appreciate the reviewer’s comment, and have made the change as suggested.

P4 L115 you use HCP without previously identifying the acronym and do not use again so I suggest spell in full

Response: Thank you for pointing out the oversight – we have made the change accordingly.

P5 L144 spelling mistake 'twenty-five'

Response: Thank you for pointing out the error – we have corrected the typo accordingly.

P5 L161 please clarify you distinction between patient and consumer. the use of patient could be disputed throughout the paper but the sudden introduction of consumer here is potentially problematic.

Response: We thank the reviewer for this comment. We have taken the opportunity to clarify that health tracking devices are “reaching not only patients but also healthy consumers.” We also explain that “the democratization of health information may allow consumers to access information for disease and illness prevention.”

Finally please ensure that you are always referring to multiple patients or clinicians when using apostrophes. At times this could be challenged as it could be single patients or clinicians.

Response: We have now made the appropriate changes.