Appendix 1 (as supplied by the authors): Supplementary material

FULL STUDY PROTOCOL

Generating the vignette

Narrative review of the literature

Guided by the larger question of "what are the ethical issues associated with AI methods in health information research?", a non-systematic literature search was performed using PubMed, Medline, JSTOR, and PsycInfo, as well as using Google for publication of conference proceedings and other reports. Search terms were chosen to maximize the number of papers identifying ethical concepts relevant to our proposed work, while remaining focused on biomedical issues (versus a larger concept of AI, for example). The title and abstract of each article was reviewed to determine relevance. Articles were included if they were in English and involved explicit discussion of ethical issues surrounding both AI and Big Data within a biomedical context. We did not place limitations on the length or quality of included articles nor did we exclude specific types (i.e., gray literature, commentaries, opinion articles), but did aim to review only papers published within the past 10 years. The main articles we drew from included high-level white papers that explicitly described ethical principles for AI.

Articles were read and summarized, with key ethical messages highlighted and reviewed by members of the research team (SA, MDM). These were collected and refined to represent bioethical concepts that were relevant to our AI approach that could be operationalized to elicit participant responses. The final set of ethical concepts was identified by aiming for convergence across multiple sources, and each concept in this manuscript was represented multiple times. Initially, three scenarios were developed to target attitudes toward big data/data-driven approaches to research, unintended consequences and discrimination, and secondary use of data, as these were determined by members of our group (AS, MDC, MDM) to be the most relevant to the immediate context of AI in healthcare research.

The initial vignettes were constructed to reflect hypothetical but realistic situations that warrant public input regarding AI in healthcare. The bioethics concepts were kept opaque to avoid directly querying participants on these constructs as this was felt to be likely to elicit a social desirability bias. Hypothetical scenarios are well recognized to impose a distance between the participant and the vignette, which can minimize social desirability bias.(1-3)

After initial construction of the vignettes, the research team presented them to a diverse group of undergraduate and graduate students, postdoctoral fellows, data scientists, and healthcare practitioners, each having expertise or experience in one of the following areas: computer science/AI, healthcare, ethics. The vignette has undergone a total of three rounds of review with the research team and healthcare colleagues. The group provided specific feedback regarding language use, balancing of the vignettes for neutrality (avoiding guiding the participant toward a particular response), accuracy (but low specificity), and whether they felt the questions had construct validity. The initial vignettes were revised and presented again to the group, with further revisions to arrive at the final script.

Extended interview protocol

The interviews were initially conducted by a postdoctoral fellow (MDM) and a research assistant (AB; both female) together for 6 interviews to establish consistency in interviewing style before dividing the remaining interviews between them. Both interviewers have extensive experience with both patient contact and counselling.

No prior relationship existed between the participants and the interviewers, with the exception of two healthcare providers who had collaborative relationships with the PI of this project. Members of our research team (AS, on this paper, and others) are currently involved in AI and as such the interviewers hold a generally positive view of the technology, which can be construed as a form of bias. That the interviewers were part of a lab conducting AI work was disclosed to participants as the rationale for the project they were participating in. To mitigate such bias, the interview protocol underwent several reviews by many individuals prior to the first interview. Both interviewers were cognizant of potential framing effects, and took care to refrain from expressing a view on AI as either positive or negative, and, as mentioned, elected not to provide any feedback to participants on their responses.

Additional methodological details

There was one additional patient who was approached, but who elected not to participate in the study due to wanting to move on from anything associated with her disease. Some patients were interviewed with their caregivers present for a portion.

Previous research has demonstrated that views on issues such as use of health data for research are highly diverse, and even divisive on certain issues, thus we were unsure of whether saturation would be reached for this project. The endpoint for the interviews was decided mutually by the two interviewers when it became clear after a few interviews that no new perspectives were coming about. The range of perspectives was discussed with the PI and other team members, and it was agreed that an acceptable level of saturation had been reached.

References

1. Finch, J. The Vignette Technique in Survey Research. *Sociology* **21**, 105–114 (1987).
2. Alexander, C. S. & Becker, H. J. The Use of Vignettes in Survey Research. *Public Opin. Q.* **42**, 93 (1978).
3. Hughes, R. Considering the Vignette Technique and its Application to a Study of Drug Injecting and HIV Risk and Safer Behaviour. *Sociol. Health Illn.* **20**, 381–400 (1998).

Appendix to: McCradden MD, Baba A, Saha A, et al. Ethical concerns around use of artificial intelligence in health care research from the perspective of patients with meningioma, caregivers and health care providers: a qualitative study. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190151.

INTERVIEW GUIDE

Scenarios were presented uniformly and questioning proceeded based on the participant's initial responses. Interviewers gave no feedback on participant's responses as to the 'correct' response.

Scenario 1: *Jaimie is a researcher who wants to treat disease Z, which affects a lot of people in the country of Atlantis. Jaimie knows that patients' data (like medical records, X-ray or MRI pictures, and medications) is stored in big databases where they can get a lot of information that can help them answer the question of how to treat disease Z. Jaimie is thinking about whether or not to ask the people of Atlantis for permission to see their information.*

- *Do you think that Jaimie should have to ask every resident of Atlantis for permission to use their information?* [Prompt: *what if there was no identifying information included in the database?* If asked for a definition, clarify that de-identification means removal of things like health care number, name, full address, date of birth, medical record number]
- *What if there were so many people in Atlantis that it was nearly impossible for them to do so without seriously slowing down their ability to research disease Z?*
- *Do you think children can consent to the use of their health information? How do you feel about parents consenting to the use of their children's health information?* [Prompt for a suggested age]

Disease X is extremely lethal and there was just an outbreak in Atlantis. Researchers want immediate access to the health information of disease-sufferers in the hopes of finding useful information, but it is unclear what they might find. Normally, consent would be required to access this information.

- *Do you think the consent rule should change under circumstances like these? Why or why not?*

Jaimie wants to make sure that the people of Atlantis are aware of the study and wants to provide them with the opportunity to have a say in the research.

- *Do you think people in general want to be involved in research?*
- *How do you think Jaimie should involve them?*
- *Do you think that the population of Atlantis has a duty to participate in research as research subjects or use of their information?*
- *Do you think that Jaimie has the same or a different opinion about whether people have a duty to participate?*

Scenario 2: *Jaimie has started the study on disease Z. The computer*[1] *goes through all of the data and uncovers that there is a particular group of people (Profile X) who will not be able to recover from the disease no matter what treatments they try. People with profiles D and F* are *able to recover with treatment.*

Atlantis does not have enough treatment programs to treat everyone with disease Z. The waitlists are months long and many patients urgently need help. The treatment programs consider using the profile information to decide who gets admitted for treatment and who does not.

---

[1] The term 'computer' was chosen to avoid using technical jargon but to connote that a machine (and not a human clinician or health expert) would essentially divide people in treated and untreated groups.

Appendix to: McCradden MD, Baba A, Saha A, et al. Ethical concerns around use of artificial intelligence in health care research from the perspective of patients with meningioma, caregivers and health care providers: a qualitative study. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190151. Copyright © 2020 Joule Inc. or its licensors

- *Do you think treatment programs should be allowed to use the profile information to decide who gets admitted for treatment? Why or why not?*

It is later discovered that there was a mistake in the way the data was collected, and it turns out that a lot of Profile X patients actually do respond to a particular treatment regime.

- *What should happen now?* [Prompts: for Jaimie, Atlantans, the government, the untreated patients]
- *Whose responsibility is the mistake?*
- *What would Atlantans think?*

Scenario 3: *Ali is the manager of Knytes – a health information company that stores data for researchers to use to understand diseases. The people whose information is stored with Knytes agreed to let the company give their data to researchers who had received funding to do research through government granting agencies. Another company, Marcotier Health Corporation, approaches Ali about purchasing some of the data so that they can design a medical product to address the needs of a group of patients with disease A. Ali is not sure what they will design or whether it will work. The money that Knytes will receive can help fund more research and would be beneficial to the company. People who agreed to allowing their data to be used in research were never asked if their data could be used for other purposes as well.*

- *What should Ali should do in this situation?*

Suppose Ali sells the data and Marcotier developed a product for disease A. Now Marcotier is asking Ali if they can sell the identifiable data so that Marcotier can contact these patients and try to sell them the new device.

- *What do you think Ali should do?*
- *Do you think Marcotier should be allowed to do this?*

Let's say that all companies found out that they could purchase this information – some are selling life-changing products with huge benefits to patients, while others are selling ineffective products and are looking for profit.

- *What problems do you think there might be with companies accessing this sort of information?*
- *What do you think the public could do about it?*