Breakout #2: Privacy

Attendees: Elaine Gibson (rapporteur), Saly Sadek (scribe), Geneviève Lavertu, Sarah Grieve, Teresa Scassa, Colleen Flood, Justine Gauthier, Dahlia Kairy, Rona Fleming

The members of the privacy breakout group began by talking about the mapping of sensitive private and commercial spaces, such as homes, changerooms, banks, and airports. Like the informed consent breakout group, the group drew a comparison to the Roomba vacuum, noting that concerns have been raised about that device's collection of personal information that could, in theory, be sold.[14] Members considered the importance of having an easy way to disconnect the mapping functionality in these environments. However, they also raised an important point about discrimination; an IPW user might have disabled recording in, say, a bank, but bank personnel might still refuse access, not trusting that the mapping technology is off.

Members of this group also discussed who should have the responsibility to ensure appropriate data and privacy protections, and to communication those protections. For instance, they considered that where a health professional is recommending use of the IPW, potential users might erroneously believe they can trust that their information will be appropriately managed. This risk is perhaps compounded by the tendency for patients to think positively about new devices, downplaying the risks. Yet information can easily get out of hand. The group suggested that 'getting this right' should not be the sole responsibility of individual healthcare providers and wheelchair users navigating informed consent. They considered that regulation may be required to set out clear standards and responsibilities relating to data and privacy, especially on the part of developers. One member offered the caveat that patients already access information from various sources (e.g., the internet) and we should not assume naivety. The group agreed a balance must be struck between allowing some individual autonomy, including the voluntary assumption of risk, while also protecting against undue harm.

[14] Maggie Astor, "Your Roomba May Be Mapping Your Home, Collecting Data That Could Be Shared", *The New York Times* (25 July 2017), online: <https://www.nytimes.com/2017/07/25/technology/roomba-irobot-data-privacy.html>.

Breakout #3: Liability

Attendees: Lara Khoury (rapporteur), Michelle Rodrigues (scribe), Lorian Hardcastle, François Ferland, Lindsay Thompson, Bryan Thomas, Tanya Horsley, Catherine Régis, Cécile Bensimon, Jennifer Chandler.

A broad theme taken up by the liability breakout group was the tolerability of some risk. Group members discussed how aspiring to perfect safety can delay access to beneficial technology. They noted that this issue intersects with informed consent, as users may voluntarily accept certain risks in order to benefit from IPW technology. Indeed, healthcare routinely involves such trade-offs, where patients give informed consent to undergo even risky procedures and treatments. Like members of other groups, they also discussed the risks of overmedicalizing the IPW, asking: Is this a medical device, a mode of transportation, or a hybrid of the two?

The group also discussed the responsibility for ensuring adequate information regarding a technology's risks and benefits. They emphasized that developers must be responsible for ensuring sufficient information is conveyed to users and their care teams, along with the value of having wheelchair users involved to inform both the understanding of risk, and its effective communication to users and their caregivers. One participant also noted the value in having an interdisciplinary support team, including a person with technological expertise, around the wheelchair user to help translate technical information.

Members of this group also talked about the allocation of responsibility in cases of user or third-party harm. They considered that where insurance is required for, say, self-driving cars, it is unclear what role insurance would play in the IPW context, or who would pay for any insurance. More broadly, they discussed the critical responsibility of regulators, and the need for regulation that is appropriately protective, yet not "overzealous" such that it impedes access to beneficial technology.

Discussion

As in our past case study events, some noteworthy themes emerged across the discussions and analyses. We set out some of these below.

A. How we characterize a technology has important implications for regulation and access

The importance of preliminary categorization choices – to call a device "medical" nor not – emerged as a significant theme throughout the workshop. Participants raised these questions at numerous junctures asking, as AI and other technologies are increasingly integrated into our lives, what makes the IPW "medical"? They discussed a range of possible analogies, comparing the IPW to driverless cars, Roomba vacuums, motorized scooters, and even bicycles, recognizing the significant implications of these characterization decisions.

The general tension and question that emerged was, what categorization will best respect patient autonomy and choice while also protecting against undue risk? Some cautioned that "over medicalizing" the IPW will impede access to an essential mobility device by requiring potential users to go through a healthcare provider. Yet others noted that medical devices are sometimes accessible under public funding programs; they worried that putting the IPW on the open market could widen existing gaps in who can access emergent technologies. Related questions relate, for instance, to whether we should require users to have liability insurance (as we do with motor vehicles), and at whose expense?

Participants also wrestled with other potential implications of a de-medicalized, direct-to-consumer process that does not keep a health professional "in the loop". For instance, they asked, without healthcare's legal requirement of informed consent, how would we ensure that IPW users are fully informed of the devices benefits and risks? That responsibility would presumably shift to developers and device providers, however, what regulation would best ensure that disclosure is effective and meaningful? Yet, having health professionals as gatekeepers could pose other risks – e.g., that their involvement will erroneously be seen to imply a trusted process for data and privacy protection. There is a confusing blurriness, in some health AI contexts, between the

information regarding a *treatment's* risks and benefits (which clinicians must disclose to obtain informed consent to healthcare) and information about the *data security and privacy risks* that might flow from health AI use. Where these risks intertwine, they may be more difficult to address through our traditional legal structures.

B. Technology users should be involved at every stage of development and discussion

A second prominent theme was the importance of user involvement at every stage of health AI development and regulation. Participants noted that involving users early, at the development stage, could shape the very understanding of "risk", as users are best placed to identify which wheelchair features feel risky, especially as public perceptions of technology can change rapidly.[15] For instance, a member of the innovation team noted that some wheelchair users have expressed concerns that overreliance on IPW technology will lead to a loss of ability. Having user perspectives integrated early can help to ensure responsive design and regulation.

Early and consistent user involvement could also help with the appropriate management and communication of risks. Participants emphasized, for instance, that wheelchair users should have "a say" in balancing a technology's risks and benefits, and in determining what information is required to do that balancing. For example, they queried whether meaningful informed consent requires that users be informed about the nature of AI or machine learning. While this issue was not resolved, the essential point, repeatedly raised in discussions, is that users must be included in these discussions and decisions, from the research and development stages, through to commercialization and regulation.

C. The risks of commercialization warrant early and careful consideration

A third key theme was the importance of thinking about regulation in an integrated way, from research and development, through to the commercialization and consumer stages. Participants worried that researcher concerns and priorities – e.g., for the protection of personal information – could get lost at the commercialization stage where data can be monetized. They questioned, for instance, how realistic it is to assume that commercial providers will maintain rigorous safeguards on data collection and use. This came up especially in discussion of privacy.

[15] For instance, Kairy explained that in early consultations, wheelchair users were asked how they would feel about a wheelchair moving independently – e.g., would it be feared? Yet now, as technologies like self-driving cars have become better known, this is unlikely to be a concern.