



**GE HEALTHCARE
SPECIAL SUPPLEMENT**

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Hotspot: AI and Ethics in Health Innovation

Summary: AI holds great promise, yet also raises many ethical questions. The field of health and care has much to contribute to and a huge interest in the related technology, governance and regulatory debates.

Artificial Intelligence (AI) was certainly a hotspot of attention last year. It is likely to continue to attract much attention this year, even if we may be reaching the peak of a hype curve. We can expect new and amazing applications of AI in 2020, notably based on big data machine learning, as well as fundamental progress. Recent emerging and exciting areas include creative AI, scientific discovery by AI, and AI to test AI.

There may be no field that has more interest in making use of AI than healthcare, given its huge data intensity. Massive amounts of data are generated by medical imaging, hospital information systems, and recording of activities of daily life. These are all areas where today's machine and deep learning are strong. Moreover, it is in health that we already see progress that immediately benefits patients. AI is as good as world-leading doctors to determine the correct treatment for over 50 eye diseases (De Fauw et al. 2018). Health apps offer advice by a virtual doctor with the help of natural language recognition and AI-powered diagnostics. 80% of health executives think that by next year AI will work next to humans in their organisation (Accenture Consulting 2018).

Such great progress is not without significant concerns about AI. All of us have heard of deepfakes, ie AI-generated fake videos, photos and texts that are almost impossible to distinguish from real. They are spread around in order to trick us into political bias, identity theft and financial scams. Here, however, I do not intend to focus on such misuse, but rather on the more general ethical concerns with AI. Many AI and ethics frameworks have been developed. A recent analysis by ETH Zürich (Venema 2019) showed convergence around ethical principles of transparency, justice and fairness, non-maleficence, responsibility and privacy.

Putting AI and Ethics to the Test

AI and ethics frameworks are being put to the test. One

of the more well-known exercises is the piloting of the AI and Ethics guidelines (European Commission 2019) of the European Commission's High-Level Group on AI. In the summer of 2019, EIT Health decided to also contribute to such piloting by running a survey and a set of case studies as reported (EIT Health 2019a) and presented at the World Health Summit (EIT Health 2019b) in October in Berlin. EIT Health is a short name for the European Institute of Technology's Innovation Community on Health and Ageing. This EU-wide initiative funds innovation projects, stimulates entrepreneurship, and advances professional education.

Obviously, but still important to recall, the health community and its researchers and innovators have much to say about ethics. Ethics is after all a key consideration in their daily health and care practice. Ethics is at the sharp edge as individuals and their lives are at stake. Perhaps less obvious is that the health innovation community is also already much engaged in AI. An estimated 20% of EIT Health activities utilise AI in some form. A conservative estimate is that this will double in the next few years.

The EC High-Level Group's AI ethical guidelines address seven areas:

- Human agency and oversight.
- Technical robustness and safety.
- Privacy and data governance.
- Transparency including traceability.
- Diversity, non-discrimination and fairness.
- Societal and environmental wellbeing.
- Accountability.

The EIT Health survey found that respondents give the highest priority to privacy and data governance (which includes data protection and access to data) as well as to technical robustness and safety (which includes cyber-resilience and reproducibility of the AI). These were followed by traceability and human agency and oversight. Not quite expected was a rather strong confidence in existing



procedures and methods for accountability. Respondents also expressed needs for further clarification of the guidelines and concerns about bureaucracy.

Learning from Health and Care

Respondents to the survey also provided insight in their concrete practices. These show that ethical considerations are often part and parcel of innovation and application. These practices also illustrate ways of working with ethics (including ethics and AI) that many other sectors may not yet be familiar with. For instance, ex-ante ethical impact assessment committees and (clinical) trial guidelines. These also include ex-post deployment practices such as post-market surveillance in order to frequently monitor the performance and related ethical impact of health innovation, as well as auditing, reporting and redress procedures.

These established procedures may not always, and not by everyone, be appreciated. They can be costly, may stifle innovation, and can, at times, be gamed (Dillner 2012)

massive amounts of data and AI, early detection of certain health conditions now becomes possible, enabling the prevention of huge treatment costs. A case study in the EIT Health report concerns brain stroke. As we are also faced with exploding health and care costs one could argue for a collective obligation to make use of such cost-containing AI analysis. But such economic-health public interest may not be enough ground to allow overriding individual rights such as personal data protection. The debate is still open!

Watch This Space

In the meantime, important developments are ongoing that should be closely watched by the health innovation community and – in my view – also actively involve that community. Firstly, in the technology realm: AI continues to develop at great speed where from a health innovation perspective we need to particularly be attentive to security and safety issues, such as the risk of data poisoning. We need to insist on improving transparency of algorithms. Most importantly,

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or bypassed by rogue actors. Health scandals are all too familiar as are price hikes that are justified by supposedly high innovation costs. Nevertheless, ethics procedures in health and care give us a most valuable reference point for the governance of AI and ethics. Exchange between health and other sectors on best and bad practices could much contribute to building understanding of options for the practical governance of AI and ethics.

Dilemmas

The EIT Health survey and case studies also provide interesting examples of ethical dilemmas that come with AI. Let me mention two of these: human vs machine and individual vs collective.

The human versus machine dilemma is related to safeguarding human oversight and respect for human autonomy. One fear is that human judgment gets sidelined as AI is so much faster and possibly more accurate than humans. Generally, however, respondents to the EIT Health survey stressed that – currently – AI provides an input only, while human judgment prevails. This situation must, however, be carefully monitored as it will likely evolve. Another fear is that jobs of medical professionals will be taken over by ‘the machine.’ That fear is not confirmed by the survey.

The second dilemma is a well-known one: the interests of the individual versus the interests of the public. It is getting more pronounced due to AI and big data. Thanks to

we need to resolve data access and data usage issues, from dynamic consent to dealing with heterogeneous data (in terms of their format, semantics, quality and their variability over space and time).

Secondly, industry and civil society are advancing in governance and understanding of the use and impact of AI. A range of consortia address this. A few prominent include openAI (openai.com), FutureSociety (thefuturesociety.org) and AI4People (eismd.eu/ai4people). I’d love to see such a responsible-AI platform for health innovation too! Perhaps a joint venture of WHO and innovation initiatives across the world? The opportunity but also the urgency is to develop global governance: health is after all a global common good, a shared interest that can transcend national sovereignty concerns.

Thirdly, regulatory and self-regulatory initiatives are advancing at great speed. Health innovation should be a partner in these developments. A clear majority (60%) of respondents to the EIT Health survey expect that their AI solution will require regulatory approval. Even large digital platform companies, such as Google, are now calling for regulatory conditioning of AI.

In Europe, recently the German Datenethikkommission (Data Ethics Commission) published an extensive analysis of responsible AI with an interesting five-level AI risk classification scheme. The EC’s High-Level AI Group has come up with recommendations on investment, with reporting from piloting of their AI and ethics guidelines provided by

the European AI Alliance (ec.europa.eu/futurium/en/eu-ai-alliance). Another expert group has analysed the impact of AI on liability regulation in Europe. They concluded that while existing liability regimes provide basic protection AI comes with potential complexity and limited predictability that make it more difficult for victims to claim compensation. The European Commission is preparing further measures, possibly also regulatory ones, on AI as well as on data access and reuse and health data spaces.

Challenges of the Year 2020

Let me wrap up by raising three issues that I would like to see addressed in 2020. First, we need to develop specific health innovation guidelines for AI and ethics. The general guidelines are very helpful but need to be tuned to the specific, high sensitivities as well as to the wealth of risk management experience in health and care.

Second, we should actively engage in exchanging insights between sectors, in order to transfer the important experiences from health and also for health to learn from the emerging and possibly more flexible approaches in other sectors such as smart mobility.

Third, a health and care innovation community, we should actively take part in shaping AI (and data) regulatory frameworks, in particular as regards governance, ie processes, procedures and authorities. We should take care to keep flexibility rather than cast governance forever into stone as I have argued elsewhere (Timmers 2019). As 'law' and 'code,' ie governance and technology, are to a degree interchangeable, we should actively stimulate technological innovation to keep governance effective, efficient and lean. This is generally true, but of specific relevance in healthcare where there are established health authorities yet where there is scope for new governance schemes.

In conclusion, 2020 will be an exciting year, a year of great opportunity and of great responsibility for the health and care innovation community to engage in responsible progress of AI. ■

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Key Points

- AI holds great promise especially for health and care, yet raises many ethical questions.
- Health and care have much to contribute on both ethics and AI, being at the sharp edge of both.
- EIT Health recently reported valuable insights on AI and ethics guidelines from its European innovation community. These include practical guidance, ways of responsibly managing risks but also ethical dilemmas and the need for further clarification specific to health and care.
- Health and care innovation should in 2020: 1) develop specific AI and ethics guidance, 2) engage with other sectors for mutual learning on AI and ethics, and 3) be part of actively shaping AI and data regulatory frameworks.

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