



FACTSHEET

Artificial Intelligence in healthcare

AI in healthcare: Robots or what?

Digital tools such as online consultations and electronic health records have become mainstream in healthcare, and the COVID-19 crisis has only bolstered this trend. All these tools generate data, a lot of data. Artificial Intelligence (AI) is making use of this data to analyse patterns, learn and make predictions, for instance how

likely one is to develop a certain illness. So, AI is not about robots. Instead it is all about intelligent algorithms which have entered virtually every area of healthcare, from the prediction of pandemics to the development of personalised treatments.

Risks and benefits

AI will have a lasting impact on healthcare and comes with a lot of promises: smart algorithms might be able to detect diseases quicker, treatments could become more targeted as AI will make recommendations based on a person's entire patient history and it could boost

medical research. But there are also concerns. Can we trust algorithms when it comes to our health? What are our rights when the use of AI leads to a wrong diagnosis? Furthermore, health data is by definition sensitive data and the data protection stakes are thus high.

Ethics is no silver bullet

One possible avenue to mitigate risks is to rely on strong ethics. After all, with or without AI, the starting point for healthcare professionals is to follow the Hippocratic principle of 'first, do not harm'. Therefore, ethical principles such as those devised by an EU expert group are important. Concretely said expert group made a series

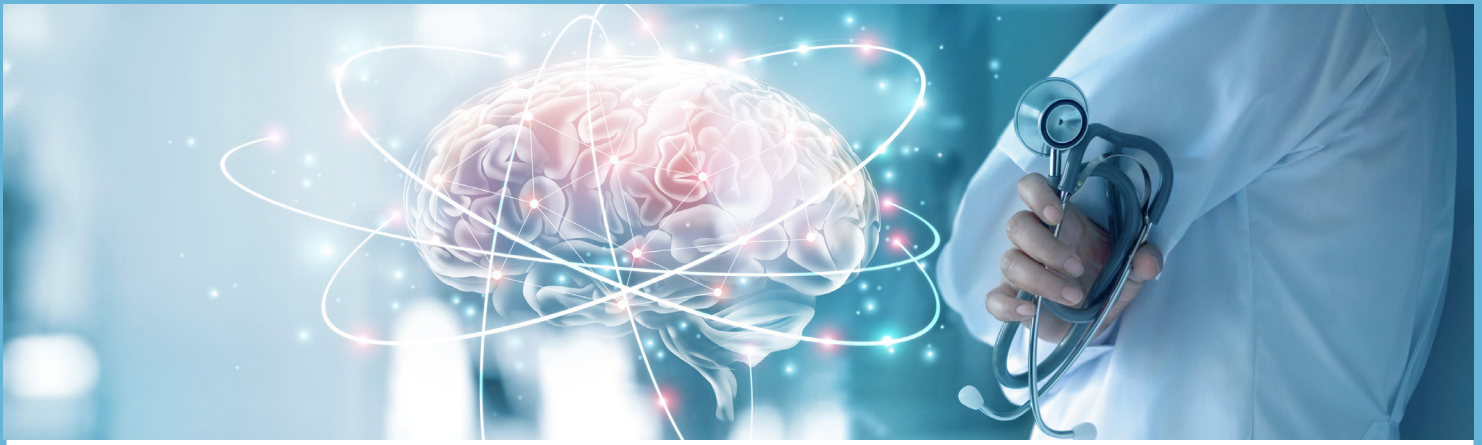
of recommendations for principles about transparency, non-discrimination, accountability and safety.¹ But as ethical principles are non-binding and non-enforceable, legislation is needed, particularly because health data do not always stay in the hands of ethical healthcare professionals.

Liability in case things go wrong

Binding rules are particularly needed for when things go wrong. AI-driven decisions can lead to outcomes with potentially devastating consequences. However, existing liability rules do not cover digital content products and services, so the EU product liability framework needs to be brought into the digital age. EU product liability

rules should ensure fair compensation to consumers when a product is unsafe (e.g. due to cybersecurity failures). Compensable harm should also not be limited to just physical injuries and damage to property, as harm can also be done to consumer well-being and lead to economic losses.

¹ European Commission's High Level Expert Group on Artificial Intelligence, Ethics Guidelines for Trustworthy AI, April 2019, <https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top> (BEUC was a member of the expert group.)



🗨️ Data protection: Isn't the GDPR enough?

AI is all about automatically sifting through huge amounts of data. This naturally brings the GDPR to the fore – the EU's General Data Protection Regulation, which lays down the bloc's rules for dealing with personal data. Some believe the GDPR's strict rules are holding back the uptake of AI in healthcare. We disagree. But it is important to have a closer look whether the GDPR on its own is adequate to actually protect the data AI is using.

This is where the difference between personal and anonymised/non-personal (health) data comes into play. Personal data means that the individual can be identified and therefore falls within the scope of the GDPR. While personal data that has been rendered anonymous is no

longer considered personal data and is not regulated by the GDPR.

What happens when AI combines both personal and non-personal data for its analysis? The possibility of re-identification of previously anonymous individuals increases, and data becomes poorly protected, which can endanger individuals' privacy.

It is not only important how data is used but also where it is stored: to secure health data, quality and safety standards are needed in addition to the GDPR. We do not leave our storage rooms without locking them – the same principle should apply to all information systems where health data is processed.



AI WILL ALSO PLAY A BIG ROLE IN MEDICAL DEVICES (think remote blood pressure tools with feedback loop). They will have to comply with EU laws such as the Medical Devices Regulation which will apply EU-wide as of 26 May 2021. While Member States are still reflecting on how to implement them in national law, it's paramount that the specificities of AI, including for risk classification, are taken into account to make these devices safe to use for consumers.

Recommendations

- The EU must check if measures in place are fit for the use of AI in health and review the EU consumer, safety and liability laws.
- While ethics is a fundamental basis of medical science, AI can only be used in healthcare if rules are adapted and with universal, comprehensive and binding legislation to support patient and consumer rights.
- The European Commission should put in place rules – such as third-party assessment, transparency and oversight – for placing algorithm-based medical devices on the market (and after their sale in case of self-learning devices).
- The European Commission should assess whether additional measures to the GDPR are needed, such as anonymisation techniques for health data and quality standards when storing it.