Building public trust to successfully deploy AI in EU healthcare

Danielle Brady
Junior Policy Analyst
European Policy Centre

Digital technologies are an increasingly prominent part of our lives. In particular, technologies like artificial intelligence (AI) can transform the way we deliver care, resulting in benefits for patients, healthcare professionals (HCPs), caregivers, organisations, businesses and public authorities. But despite the benefits, the deployment of AI also raises questions on its impact on the health workforce, the potential for new inequalities, the inclusiveness of AI applications, privacy issues, public trust and data access. Not to mention, broader questions on the ethics and social implications of AI.

The Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence and the European Health Data Space offer opportunities to address many of the concerns associated with AI in health and thus must be prioritised. However, these two initiatives alone cannot combat all the challenges associated with deploying AI. Without public trust, acceptance and understanding, AI's full potential will not be realised. To address this, attention must be given to the communication of the benefits of AI in healthcare to the public, Europeans' digital literacy, the upskilling of the EU health workforce, and the investment in AI technologies.

BACKGROUND: THE UNTAPPED POTENTIAL OF DIGITAL HEALTH IN EUROPE

The COVID-19 pandemic has underscored the importance of digital transformation in the health and care sectors. This transformation would strengthen health systems' resilience and make them more effective, sustainable and accessible. The digitalisation of health would help prevent wasteful spending, deliver more patient-centred services, improve people's health and quality of life, empower patients, and enhance their access to services and information.[1] It would aid health systems transition to new care models centred on people's needs; to shift from hospital-centred systems to more community-based and integrated primary care structures. Digital tools also present a potential for the better use of health data in research and innovation to support personalised healthcare, better health interventions, and more effective health and social care systems.

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COVID-19 and the increasing use of digital health

The pandemic has undoubtedly accelerated the use of digital tools in healthcare. In March 2020, 84% of people using virtual care were first-time users.[2] At the onset of the crisis, telemedicine solutions (e.g. mobile apps, websites, robots, chatbots) replaced traditional face-to-face consultations to provide virtual medical visits and primary care; e-prescriptions; remote patient monitoring and screening in real-time; risk assessment and triage prior to hospital admission; and the immediate, widespread dissemination of information.

Countries moved at the speed and scale necessary to deliver such services remotely through digital means. EU member states like Austria, Belgium, Estonia and the Czech Republic – which previously did not have national legislation, strategies nor policies on the use of telemedicine and did not define the jurisdiction, liability or reimbursement of services like telehealth – allowed provider payment for some telehealth consultations and clarified regulations. Other countries like France, Luxembourg and Poland, where telemedicine was already available, relaxed restrictions and/or created new platforms to make it easier for patients and providers to use remote consultations. Meanwhile, Belgium, Estonia, Greece and Ireland allowed prescriptions and certificates of sick leave to be issued and accessed electronically.[3] The crisis eroded many barriers associated with the digitalisation of healthcare.

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A notable increase in the use of AI in healthcare is also observable throughout the crisis. It is used to detect outbreaks, facilitate diagnosis, identify people with fevers and accelerate gene sequencing.

Artificial intelligence's benefits and risks

AI in healthcare evidently holds many potential benefits. AI applications can have positive implications for personalised medicine, drug design, tailored treatment, and the evaluation and monitoring of diseases. Other clear benefits have been observed in relation to prosthetics and companion robots in care for people with disabilities and the elderly and the development of systems for prevention, early detection and outbreak assessment of pandemics and public health events.[4]

One area where AI has much potential is oncology. The Europe's Beating Cancer Plan (EBCP) states that cancer care is one of the major disease areas that will benefit from AI tools and high-performance computing. Real-world electronic records will also be crucial: they ensure that clinical information is shared efficiently between cancer nurses, oncologists, radiologists and surgeons, thus enhancing the patients' treatment and survival chances. The European Cancer Imaging initiative, which is expected this year, will develop an 'EU atlas' of cancer-related images. Anonymised images will become accessible to a wide range of stakeholders across the ecosystem of hospitals, researchers and innovators. This data could 'train' AI tools, enhancing their accuracy and reliability for improved personalised medicine and innovative solutions.

Despite these clear benefits, significant challenges associated with the deployment of AI applications in health also exist, including data-related ones. Malicious use of data, data security and reliability pose risks to AI in general. Such risks become more important in healthcare, given the sensitivity of the data in question. AI also threatens to exacerbate health inequalities. From the patient perspective, digital literacy is required to use many of the tools associated with AI. According to the Digital Economy and Society Index, 4 out of 10 adults, and every third person working in the EU lack basic digital skills.[5] Those who do not possess the necessary skills could be left behind, unable to access the care they require. This would result in wider inequality gaps with negative consequences for already disadvantaged groups.

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Furthermore, health inequalities could be embedded into AI conception, design and use. Existing biases in health practices and institutional policies and norms could become ingrained in the datasets used to train AI systems, allowing algorithmic models to reproduce inequalities. Additionally, challenges arise with data representativeness, as the datasets used to train, test and validate AI models are often unrepresentative of the general public. For example, the datasets often do not have sufficient data on those with limited or irregular access to healthcare systems (i.e. ethnic minorities, migrants, socio-economically disadvantaged groups).[6]

Further challenges to using AI in healthcare include endangering the patient–HCP relationship and the loss of empathy due to less human contact, particularly with long-distance monitoring in the context of telemedicine. However, by streamlining cumbersome and repetitive administrative tasks via AI, HCPs could actually *gain* more time for face-to-face interaction with patients.[7]

AI will undoubtedly impact HCPs, who are key to its success in healthcare – in not just its actual deployment but also building trust and acceptance in its use. HCPs should have the skills to use AI solutions, and for the right patients. As such, attention must be given to the upskilling and reskilling of the health workforce: they must have said skills, knowledge of and confidence in AI. Ensuring a paced approach to the use of AI in healthcare is paramount. HCPs should also be able to explain the use of AI tools to their patients to build the latter's trust in the applications.

STATE OF PLAY: EU ACTION IN THE FIELD

There is a recognition within the EU that certain challenges and concerns accompany AI deployment in general, particularly regarding safety, security and fundamental rights. In February 2020, the European Commission published a White Paper on Artificial Intelligence and proposed a European regulatory framework for trustworthy AI. The European Parliament was also proactive, adopting three legislative resolutions covering ethics, civil liability and intellectual property in October 2020. Additionally, it called on the Commission to propose a comprehensive and future-proof legal framework of ethical principles for developing, deploying and using AI, robotics and related technologies.

The Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence

In April 2021, the Commission published its Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence, proposing to enshrine a technology-neutral definition of AI systems in EU law. This would define AI systems as software developed with one or more of the techniques and approaches listed in Annex I and that can, for a given set of human-defined objectives, generate outputs which influence the environments with which they interact (e.g. content, predictions, recommendations or decisions). The proposed regulation puts forward different sets of rules tailored on a four-level, risk-based approach.

1. **Unacceptable AI:** AI that is deemed harmful, in that they contravene EU values, will be banned because of their unacceptable risk. Examples include national social scoring systems[8] and toys which use voice assistance that encourages dangerous behaviour in minors.

2. **High-risk AI:** AI systems that adversely impact people's safety and/or fundamental rights will be considered high-risk.[9] To ensure trust and the consistent, high-level protection of safety and fundamental rights, a range of mandatory requirements would apply to all high-risk AI systems (e.g. medical devices).

3. **Limited risk AI:** Some AI systems will be subject to a limited set of obligations to make users aware they are interacting with a machine. This will allow them to make informed decisions to continue the interaction or step back (e.g. chatbots).

4. **Minimal risk AI:** All other AI systems (e.g. video games) can be developed and used in the EU without additional legal obligations and only the existing legislation.

Devices that come under the Medical Devices Regulation 2017/745 will be deemed high-risk, meaning that all devices and software with an intended medical purpose will fall into the second category. Such applications will be subject to strict obligations before being put on the EU Single Market. These obligations include adequate risk assessment and mitigation systems; high-quality datasets; logging activity to ensure the traceability of results; detailed documentation; clear and adequate information; appropriate human oversight; and high levels of robustness, security and accuracy.

The mandatory requirements for all high-risk AI systems also aim to mitigate bias. AI systems must be technically robust to guarantee that they are fit for purpose and that false positive/negative results are not affecting protected groups (e.g. of racial or ethnic origin, sex, age) disproportionately. Under the regulation, high-risk systems will need to be trained and tested with sufficiently representative datasets to minimise the risk of its inevitably embedded unfair biases and ensure that they can be addressed through appropriate mitigating measures, such as bias detection or correction.

The European Health Data Space

In addition to the regulation for harmonised AI rules, a European Health Data Space would impact AI deployment. The latter's legislative proposal, for early 2022, would aim to promote better exchange and access to different types of health data, such as electronic health records, genomics data and patient registries, to support healthcare delivery, research and policymaking. The data space will:

► promote the safe exchange of patients' data (i.e. travel destination) and citizens' control over their health data;

► support research on treatments, medicines, medical devices and outcomes;

► encourage the access to and use of health data for research, policymaking and law-making, with a trusted governance framework and data protection rules upheld;

► support digital health services; and

► clarify the safety and liability of AI in health.

While the AI regulation and data space could mitigate the risks related to AI transparency, accuracy, bias and data, many of the general concerns associated with AI also apply in healthcare and pose barriers to patients' trust.

PROSPECTS: BUILDING TRUST AND UNDERSTANDING

If AI in healthcare is to reach its full potential, trust and understanding are essential. The adoption of the Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence must be prioritised to ensure that the outlined risks are mitigated, and public trust can be built. Additionally, the publication of the legislative proposal on the European Health Data Space should not be delayed further. Initially planned for Q4 2021, it now looks set to be published in early 2022. These two initiatives would ensure that AI systems used in the EU are safe, transparent, ethical, unbiased and under human control. Nevertheless, clear and convincing explanations regarding AI use in healthcare are required so that citizens understand their benefit

and trust that their personal data will be handled safely. The EU and its member states should follow these four recommendations to ensure this understanding and trust.

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The European Commission should promote **EU-level communication** to highlight how the future AI regulation and European Health Data Space will ensure safe AI use. Communicating these initiatives' role would help increase the public's understanding and incite increased levels of trust.

Promoting understanding must also be accompanied by **digital literacy training**. Increased understanding of AI tools, combined with the skills to use them appropriately, would encourage public trust in their use, combat digital hesitancy and iron out health inequalities. The Commission has set a target in the European Pillar of Social Rights Action Plan to ensure that at least 80% of people aged 16 to 74 have basic digital skills. Initiatives brought forward by the Commission to tackle digital literacy, such as the European Skills Agenda and Digital Education Action Plan, can play an important role in reaching this 80% target. However, caution must be taken to ensure that those from disadvantaged backgrounds are not left behind. Reaching the target will be essential to ensure that the use of AI applications, particularly in telemedicine, does not exacerbate the health inequality gap.

Along with citizens' digital literacy, attention must be given to **upskilling HCPs**. EU member states must invest in their health and care workforce to ensure they have the skills required to use AI applications. As previously mentioned, HCPs play an essential role in building public trust in AI. However, if they are not appropriately trained and upskilled themselves, they will not be able to advocate for or promote the use of AI in health. An EU-level digital skills training programme – similar to the inter-speciality cancer training programme announced under the EBCP – should be established. Such a programme could provide cross-border training and information-sharing to ensure that HCPs are equipped with the necessary digital skills. It could be linked to the Pact for Skills' framework for health, which aims to secure upskilling opportunities for health professionals.

The COVID-19 pandemic has undoubtedly accelerated the digitalisation of healthcare systems, including the deployment of AI. In order to reap its longer-term benefits, member states must **invest in the implementation of AI applications** and the adoption of technologies in their healthcare systems. They can begin the transformation of their systems and realise the potential of AI in healthcare using financing mechanisms like EU4Health and InvestEU.

AI has the potential to transform healthcare and benefit all stakeholders. But in order to realise this potential fully, investment in AI technologies must be combined with programmes at the EU and national levels to enhance digital literacy for both patients and healthcare workers and efforts to communicate the trustworthiness and benefits of AI to the public. If the EU and its member states fail to build trust in the deployment of AI in healthcare, Europe will miss a chance to reap all the benefits that AI offers to its citizens and their health.

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8   Social scoring systems score citizens based on their social behaviour and/or personality characteristics.

9   High-risk AI includes technology in critical infrastructures (e.g. transport) that could put the life and health of citizens at risk; educational or vocational training that may determine access to education and career paths (e.g. exam scores); the safety components of products (e.g. robot-assisted surgery); essential private and public services (e.g. refusing loans based on citizens' credit scoring); or law enforcement that interferes with people's fundamental rights (e.g. evaluating the reliability of evidence).