May 2021

HOPE Position Paper

on Artificial Intelligence

AI technology starts to be used across the healthcare sector but still not as routine. This can be to assist research by better matching patients to clinical trials, to support the planning of care for patients with complex needs, etc. Prospective uses of artificial intelligence can be found also in robot care support and speech recognition for medical documentation.

Artificial Intelligence (AI) is a complex phenomenon that is interfering with the way medical research is conducted, the biomedical data is used, and the healthcare professions and healthcare organisations are regulated.

Health data is recognised as a special category of data under the General Data Protection Regulation due to its sensitivity.

AI uses in the healthcare field would then also requires a specific regulatory approach, in addition to a strong horizontal cross-sector regulation of AI.

HOPE key recommendations to ensure that the application of AI in healthcare benefit patients and consumers are as follows:

We need to agree at European level on a definition of Artificial intelligence for health care as a basis for further discussion from an ethical or legal perspective or to be used to determine requirements for the quality of AI.

We need to build action on AI on clear citizens' rights (and not only when they are patients):

- right to transparency, explanation and objection;
- right to accountability and control;
- right to fairness;
- right to non-discrimination;
- right to safety and security;
- right to access to justice;
- right to reliability and robustness.

The well-being and autonomy of the AI user should have priority. AI should support the user but not restrict the user's autonomy.

The effects of AI on social and environmental aspects should also be examined. It is important in the development of AI not only to adopt individual perspectives but also to take society as a whole into consideration. It appears useful to establish clarity as to the conditions under which AI processes can be used, especially in view of the medical device regulation.

We need professionals ready for AI

The EU and the Member States should conduct regulatory assessments of the medical professions frameworks to determine whether they are fit for the use of patient/consumer-centred AI in health.
The EU and Member States should put in place mechanisms to ensure professional and educational assistance to both patients and the healthcare professionals to better understand and assess AI decision-making.

We need good quality AI

The EU should facilitate the identification and should promote good practices ensuring robustness of AI systems in the health sector both at the stages of development and actual use to reduce potential biases and errors of AI-based decision-making.
Mechanisms should be in place to make sure developers of AI systems are competent to do so in healthcare sector.

We need adapted legislation

Ethics are a fundamental component for healthcare research and professions. However, an AI ethical code is not sufficient. AI needs that the existing regulatory frameworks are adapted and that a comprehensive AI legislation is created.

The EU should update the EU safety and liability legislation that is relevant to the healthcare sector to ensure that it is still accurate and that citizens are well protected with regards to the use of AI.

The EU and the Member States should ensure that the new Medical Devices Regulation and In-Vitro Diagnostic Regulation are implemented with a view to include artificial intelligence: guidelines and specifications or the evaluation of safety and effectiveness of software, AI and deep learning powered devices throughout the entire usage cycle.

The EU and Member States must ensure that AI in healthcare is applied in full respect of EU data protection rules, while observing the balance between the interests of advancements in medical research and citizen protection. This must be achieved through diligent implementation of the GDPR principles and adequate use of provisions and exemptions on health research.

During the evaluation and review report of the EU data protection legislation, the European Commission should specifically evaluate the need to establish rules on: anonymization techniques of health data; data access and control when it comes to use of data coming from multiply sources; and quality and safety standards for all information systems where health data is processed.

The EU should establish a legal framework for AI integrating the specifics of healthcare.

Finally, financing such innovation and in particular adapting the hospital financing to its development will have to be considered carefully by Member states.

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