
On 16 November 2019, the CPME Board adopted the 'CPME Policy on AI in Health Care' (CPME 2019/062 FINAL).

CPME Policy on AI in Health Care

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Policy Summary

AI has a potential to transform health care delivery by facilitating equal access to efficient treatment and enhancing accuracy of diagnosis and the workflow of physicians.

To convert this potential into reality, CPME advocates the development of health care AI that is based on robust evidences; its use must be accountable, non-discriminatory and respect patients' privacy. The safe use of health care AI and understanding of its advantages and limitations should be part of basic medical education and continuing medical education. Additional regulatory steps are needed to adapt intellectual property, liability, privacy and governance regimes.

CPME recognises the efforts made by the EU on AI so far. However, CPME calls on the European Commission to put greater emphasis on trustability and safety of AI applications in health care and to better engage health care professionals in its work.

A. AI in Health Care

Digital transformation is changing medical practice.

New technology, if designed properly and implemented responsibly can deliver innovative approaches to health and care delivery, from health promotion to disease prevention to integrated health and social care. This potential is also recognised by the European Commission¹.

AI constitutes a unique instrument in the set of emerging health care tools, from 'weak' AI systems that can perform one or few specific tasks, to 'strong' systems which are intended to be able to perform

¹European Commission, [Communication on enabling the digital transformation of health and care...](#), 25.04.2018.

most activities that humans can do². Today, the omnipresence of data, improvements in storage, exponential increase of computing powers and advanced algorithms make AI increasingly available, affordable and powerful.

CPME endorses a conceptualisation of artificial intelligence that focuses on artificial intelligence's assistive role. In health care, the term 'augmented intelligence' more accurately reflects the purpose of such systems because they are intended to coexist with physicians' decision-making and enhance physicians' expertise³. Such systems do not attempt to imitate all human intelligence to replace professionals, they rather improve specific capabilities and leverage decision and cognitive power. Therefore, with 'AI', this policy refers to augmented intelligence in health care.

B. Physicians Involvement

AI systems have a capability to increase the accuracy of diagnosis and efficiency of treatment. They can create new possibilities offered by robotics for complex surgeries as well as help to determine, inform, or influence the processes for the adoption and change in a patient's medication adherence, resulting in more personalised medicine.

AI's ability to mine, analyse and personalise immense quantity of data can provide physicians with relevant information to keep them up to date on medical progress and deliver accurate input into their decision-making process.

Furthermore, AI's potential to automate hospital and office processes can improve the physicians' workflow increasing their time to focus on patients and streamlining the operations of health care systems.

In many fields, health care AI is already a reality, embedded in physicians' practice, including medical imaging, echocardiography, screening for neurological conditions or surgery, amongst others. Its potential is recognised by the European Commission in its 'Coordinated plan on Artificial Intelligence' acknowledging a need to undertake regulatory steps to encourage appropriate AI development in Europe and fully benefit from it in health care sector⁴. However, this benefit will depend on how the investment in equipment and software and the use of AI is financially supported by national health systems.

²Artificial intelligence is understood as defined by the High-Level Expert Group on Artificial Intelligence set up by the European Commission, see: AI HLEG, [A Definition of AI: Main Capabilities and Disciplines](#), 8.04.2019.

³See: American Medical Association, [Augmented Intelligence in Health Care](#), 14.06.2018 and World Medical Association, [WMA Statement on Augmented Intelligence in Medical Care](#), 27.10.2019.

⁴European Commission, [Coordinated Plan on Artificial Intelligence](#) and [Annex to the Coordinated Plan on Artificial Intelligence](#), 7.12.2018.

Moreover, to ensure appropriate design, validation, calibration and implementation of health care AI, practicing physicians' and patients' perspectives have to be integrated at each stage of this process.

C. Digital Literacy and Skills

The acceptance of AI by physicians depends on its ability to deliver real benefits to patients, how can it be integrated into their current practice and how can it improve health care delivery and the patient-physician relationship.

Health care AI can live up to the expectations only if practicing and future physicians possess adequate knowledge about the technology's capabilities and limitations, and if they have the skills to safely, confidently and effectively work with it. Therefore, AI systems have to be part of curricula in basic medical education, specialist training and continuing medical education to broaden knowledge on the appropriate use of AI algorithms. Moreover, AI instruments have a potential to transform a medical education itself, providing more personalised methods and objective assessment tools.

D. Trustability and safety of AI

The potential of health care AI cannot be achieved without improving trust in it. The mechanisms supporting trust in medicine are multiple. They include integrity, transparency, methodology, reproducibility, generalisability and explainability, amongst others. Not all dimensions can be always reached, especially in the complex field of medicine. If health care AI cannot be fully explainable, it must at least meet the criteria of other dimensions, such as reproducibility.

AI properties have to be translated into information physicians can interpret and use. To comfortably rely on AI assistance, health care professionals need to understand clearly the power and reliability of AI in their context, for example with proper understanding of the positive and negative predictive value of decision support or predictions. Only then algorithms' output can be consciously assessed resulting in a decision.

E. Health Data Governance

Development of AI is interrelated with the transformational approach to the use of health data having an impact on its security, governance, ownership, sharing or application to train AI systems.

1. Data security, privacy and medical confidentiality

It is necessary to take all the required precautions to ensure data security and privacy when applying new digital solutions.

The Commission recognises that patients need to be in control of their health data, how and to what purpose the data are used. They need to be confident that such data are protected and that their privacy assured, including sufficient data anonymisation, considering AI extraordinary ability to re-connect information⁵. Provided this premise is fully complied with, the Commission's strategy, i.e. to merge and connect existing databases 'to boost health care data sharing' is valuable⁶.

Applying health data to enhance capabilities of AI and sharing patients' records with AI systems can affect medical confidentiality. Medical confidentiality and patient privacy not only form the basis of a trusting patient-physician relationship but are also essential for unrestricted access to medical care and good and effective medical practice⁷. Patients have to be assured that the 'third party' AI will not breach confidentiality – a principle that benefits patients and society.

2. Data sharing and systems' interoperability

As the European Commission has pointed out, secure access to and sharing of health data as well as interoperability and appropriate semantic annotation of datasets have a great potential to improve population health, increase effectiveness of cross-border health care and enable personalised diagnoses and medical treatment⁸. However, any specific rules on sharing and protection of health-related data should be based on the necessity to obtain the patient's informed consent and must respect the level provided for by the EU General Data Protection Regulation as a minimum.

Reliable health data acquired from various national systems constitute a significant asset for Europe in training AI algorithms. Creating common European databases of available and structured data of known origin and quality is in the centre of the Commission's plan on development of AI in health care⁹.

3. Data quality

It is of utmost importance to minimise risks which may come with building AI on existing data. Incorporating health data into systems during its training can prompt bias and inequality. Data is

⁵European Commission, [Vision on the future of healthcare at the European Health Summit](#), 28.11.2018.

⁶European Commission, [Data in the EU: Commission steps up efforts to increase availability and boost healthcare data sharing](#), Press Release, 25.04.2018.

⁷CPME, [CPME Statement on confidentiality](#), 31.10.2015.

⁸Regulation (EU) 2016/679, [General Data Protection Regulation](#), 27.04.2016

⁹European Commission, *Annex to the Coordinated Plan...*, op. cit. and [Declaration on Cooperation: Towards access to at least 1 million sequenced genomes in the European Union by 2022](#), 10.04.2018.

imperfect and not free from numerous bias, such as selection bias, or humans' biases which can be inherited and further reproduced by the systems.

One sensitive aspect of AI is that it is trained on existing knowledge and existing data. For various reasons, this can introduce biases, e.g. gender bias as already seen for cardiovascular ischemic diseases, with underrepresentation of women. Still, several other population bias can occur with population-specific conditions and introduce or aggravate disparities and discrimination of minorities. AI's analysis of minority populations may become less precise as there is less data available on it. Therefore, systematic quality checks should be established and performed to secure safety and precision of AI outputs throughout the lifecycle of an AI tool.

F. Legal Challenges

Regulatory steps are needed to ensure alignment with health care AI.

1. Data ownership and intellectual property

Regulators, according to their national laws, may address the ownership of data generated by AI devices, its secondary use and commercialisation while these devices are applied in health care and once, they are no longer in use.

In particular, it should be allowed to share relevant healthcare information such as a diagnosis or images and healthcare professionals should be able to continue using and sharing this information in case of a change of provider of health care AI.

For the confident use of health care AI systems physicians need them to be trustable. This requires, amongst others, integrity, transparency and reproducibility, while research and development to improve explainability have to be reinforced. These requirements must be adequately balanced with the protection of developers' intellectual property.

2. Accountability

To encourage the confident use of AI systems it should be clear who is liable for AI failure or misdiagnosis. The limits of the physician's liability when using AI have to be clearly defined. Certainty and stability through appropriate legislation will stimulate and entrench new digital solutions within physicians' practice.

G. Governmental, Independent Non-governmental and Professional Oversight

Governmental and independent non-governmental oversight on building evidence-based, trustworthy, equitable, non-discriminatory and patient-centric AI systems is indispensable¹⁰.

The appropriate professional oversight over clinical validation including health technology assessment (HTA) and usefulness is essential once an AI system is integrated into health care practice. Health care AI must be subject to high clinical standards and should be empirically evaluated like any other digital device. While technology is evolving faster than ever, it's crucial that physicians stay alert about its outcomes once applied to health care services.

Recommendations

- CPME calls for integration of the physicians' perspective into the process of health care AI design and development and professional oversight over AI clinical validation and usefulness once it is applied in health care delivery. Physicians should be represented in the relevant advisory bodies at EU and national level.
- CPME calls for a sound, evidence-based implementation of AI with proven benefits for health care providing improvement in quality of care or lowering use of resources.
- CPME calls for enhancing digital literacy of medical students, professionals and patients. CPME recommends the inclusion of AI in medical curricula and continuing medical education.
- CPME calls for transparent, explicable and trustable health care AI being understandable for physicians.
- CPME calls for maintaining a high level of health data protection, patients' privacy and medical confidentiality which are at risk with the application of new technologies.
- CPME calls for addressing a risk of potential bias and discrimination which can be prompted by health care AI training on existing, imperfect human-made data.
- CPME calls for systematic quality checks to be established and performed to secure safety and precision of AI outputs throughout the lifecycle of an AI tool and for enabling physicians to enrich data pools with AI supporting semantic annotations enhancing their quality and usability.

¹⁰European Commission, [Artificial Intelligence for Europe](#), 25.04.2018 and CPME, [CPME statement on the ethics guidelines for trustworthy AI](#), 6.10.2019.

- CPME calls for regulatory steps to assure appropriate intellectual property and liability systems which are fit for purpose and adapted to new technology.

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