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.

Deployment of artificial intelligence in healthcare

Sector-specific challenges and accelerators

Main messages:

- Design AI on actual healthcare demands and in a dynamic loop;

- Evaluate AI efficiency and efficacy;

- Compliance of AI systems with medical ethics, data protection and privacy required;

- Certify AI systems to increase trust among healthcare professionals;

- Demystify AI by improving literacy and foster competence development;

- Mitigate deskilling risks and ensure critical thinking;

- Promote adequate tools and methods to interpret and explain AI output;

- Provide detailed and clear instructions for use for deployers;

- Adequate monitoring and oversight with a clear liability regime for AI in healthcare;

- Encourage AI and cyber insurance coverage;

- Coordinate knowledge environment at EU and national level.

Introduction

Against the background of the rapid development and changes brought by artificial intelligence systems, and the worldwide efforts to regulate artificial intelligence (AI) with legislation such as the EU Artificial Intelligence Act (AIA),[1] the Council of Europe Convention on Artificial Intelligence,[2] European doctors welcome the current EU initiative to study the deployment of AI in healthcare, looking into identifying sector-specific challenges and accelerators, the economic impact and the effective incorporation of AI in clinical practice.[3]

AI systems in healthcare can be broadly divided into two categories:

i) those aimed at optimising administrative or workflow processes, such as speech-to-text systems or scheduling algorithms; and

ii) those designed to support clinical decision-making processes, including tools used for diagnosis and the development of treatment plans.

This policy primarily focuses on using AI systems in clinical decision-making processes.

Why the low AI uptake in healthcare?

European doctors note that the uptake of AI in healthcare may be low due to several factors, particularly:

• the complex, interdependent and dynamic environment of healthcare, which is not compatible with a single prescriptive approach, rendering very difficult the spread of technology across organisations;[4]

• the wide AI product offer available on the market, where the majority is not certified by a third-party to ensure a trustworthy and safe system to be applied in healthcare;

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[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013 (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj. The AIA entered into force on 1 August 2024 and lays down harmonised rules which require AI to be human-centric, trustworthy and safe before being placed on the market, put into service, or used, while complying with the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.

[2] Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law, adopted by the Committee of Ministers on 17 May 2024 on its 133rd Session.

[3] The European Commission's Directorate-General for Health and Food Safety (DG SANTE) has entrusted the consortium led by PricewaterhouseCoopers (PwC) to conduct a study on the deployment of AI in healthcare. The study is scheduled to run for 12 months, from February 2024 to February 2025 and will include several targeted consultations with stakeholders to collect data, insights and views concerning the deployment of AI in healthcare. The European Commission's Directorate-General for Communications Networks, Content and Technology (DG CONNECT) also entrusted a consortium led by Ernest & Young to conduct a study on the economic impact of applying Artificial Intelligence in healthcare in Europe through participation in an online survey and/or interview aimed at specific stakeholders.

[4] Gillner, Sandra. "We're implementing AI now, so why not ask us what to do? How AI providers perceive and navigate the spread of diagnostic AI in complex healthcare systems." Social science & medicine 340 (2024): 116442.

- not feeling confident in using AI systems based on data from unknown data sources, on the data collection processes and the overall data quality of the solutions;
- the amount of time and attention that the new technology can consume from doctors, instead of attending to patients. Individual doctors do not have any spare time to search and explore for high-quality AI systems. Furthermore, currently, no one has the duty or role to carry out these activities, nor the power or permission to act on the insights gained;
- the high financial investment it requires (e.g. basic infrastructures such as graphic processing units' servers, data warehouses, development of platforms), as well as specialised staff (e.g. IT professionals, AI engineers), and the escalating maintenance costs (e.g. software licenses and equipment which depending on the medical speciality become obsolete every 3-5 years, requiring new investments). Unless healthcare professionals can justify the financial investment through improved efficiency and patient benefit or additional reimbursement, implementing AI on a large scale will remain challenging;
- the new obligations that 'deployers'[5] of high-risk AI systems face to ensure that the systems they use are safe, ethical and trustworthy;[6] and,
- the fact that AI systems have to be trained with electronic health data and where this data can easily be related to a natural person (patient), doctors feel reserved or reluctant to provide access to these data for AI-training purposes.

How to improve the uptake in healthcare?

To ensure a higher uptake of AI in healthcare, European doctors recommend the following:

A.   Design AI on actual healthcare demands and in a dynamic loop

1. The main purpose for the integration of AI in healthcare should be the improvement of clinical practice rather than technology innovation *per se*, and the technology needs to be embedded in clinical pathways. To this end, those developing the digital tools need to learn the real needs of the healthcare professionals, patients and their carers / guardians.

2. CPME encourages all providers of AI systems in healthcare to collaborate and involve healthcare professionals in the design of AI systems. AI hubs/departments could be developed locally, at the hospital level, which should identify specific clinical demands to

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[5] Pursuant to Article 3(4) of the AIA, *"'deployer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity;"*
[6] Article 26 of AIA.

create AI projects. To this end, interdisciplinary meetings with healthcare professionals, IT engineers, and AI analysts should be held.

3. The AI design should be dynamic, where the results of post-market monitoring system are fed into the system allowing the latter to be responsive and evolve to adjust to new parameters or user inputs. Re-certification of the process and re-validation of the system should apply, as appropriate.

4. AI products should be seamlessly integrated into the healthcare information system, avoiding situations where they function as standalone tools requiring healthcare providers to input data manually.

B.   Evaluate AI efficiency and efficacy

5. A significant concern for those deploying and scaling up AI is calculating the obtainable investment efficiency of the AI system in the healthcare setting.[7] Criteria for cost-benefit analysis should be developed to facilitate and simplify the calculation of investment efficiency and the efficacy of AI. Criteria such as quality improvement, working efficiency improvement, working pressure reduction, doctor and patient satisfaction improvement, environmental impact (sustainability), and overall result achieved, should be considered in such analysis.

6. Short-term needs should be exploited first. AI should be used to resolve inefficiencies in healthcare provisions, knowledge fragmentation and lack of automatisation of time-intensive routine processes.

7. Once deployed, the AI benefit should be continuously observed and measured. A large-scale, long-term scientific study on the impact of AI in healthcare should be pursued to consider, for example, doctor deskilling, medical education and training, diagnosis and treatment decisions, and the impact of AI-generated or influenced data on the training of next generations of AI models in medicine.

8. The deployment of AI cannot mean a disinvestment in other areas of the healthcare systems. Retention and recruitment of health professionals needs to be a priority as well as for providing safe staffing levels and good working conditions to provide the best patient care.

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[7] Liu, Chung-Feng, Chien-Cheng Huang, Jhi-Joung Wang, Kuang-Ming Kuo, and Chia-Jung Chen. "The critical factors affecting the deployment and scaling of healthcare AI: viewpoint from an experienced medical center." In Healthcare, vol. 9, 685. MDPI, 2021, p 1-12.

C. Compliance of AI systems with medical ethics, data protection and privacy required

9. Applying electronic health data to enhance the capabilities of AI and sharing patients' records with AI systems can affect medical confidentiality. AI systems must comply with medical ethics, data protection, privacy and security rules.[8]

10. Patient's awareness and consent of AI system usage is an ethical requirement to be upheld in the patient-doctor relationship.

11. Doctors should be free to decide whether to use or not an AI system without suffering any repercussions in case of not using the system, bearing in mind that a doctor must always be guided by the best interests of the patient.

12. Anonymisation technology should be available to guarantee that electronic health data that is used for enhancing the capability of AI systems cannot be related to natural persons.

D. Certify AI systems to increase trust among healthcare professionals

13. To mitigate the potential harms associated with AI systems in healthcare and increase trust among healthcare professionals, it is necessary to certify AI-driven software solutions. AI systems may inadvertently propagate stereotypes and social prejudices against vulnerable groups, which can lead to biased outputs and exacerbate disparities in access to and quality of healthcare. Under-represented populations in clinical studies can also lead to implications for medical practice.

14. Certification of AI-driven software solutions is essential and should, at least, address cybersecurity, data privacy, efficiency and workflow integration, interoperability, explainability, model robustness and bias mitigation.

E. Demystify AI by improving literacy and foster competence development

15. The AIA stipulates that deployers of AI should have a sufficient level of AI literacy, training and authority to properly implement the instructions for use and human oversight of the AI systems.[9]

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[8] The General Data Protection Regulation (2016/679), the NIS2 Directive (2022/2555) and Chapter III, Section 2 of the AI Act (Regulation 2024/1689) are among the key EU instruments to consider for an AI system to be compliant with medical ethics, data protection, privacy and security.
[9] Recital 91 and Article 4 of the AIA.

16. The user's (healthcare professionals) comprehension of AI systems and perceived difficulty have an impact on the usage of AI.[10] The higher the AI literacy, including comprehending AI strengths and limitations, more easily will be for deployers to trust their own judgment instead of feeling pressured for complying with AI's recommendations.

17. In healthcare, this needs to be translated into competence development for healthcare professionals and systematic continuing education, as AI will increasingly influence medical decision-making. Ensuring healthcare professionals have the necessary knowledge and skills to handle AI technologies is a significant challenge.

18. CPME encourages the introduction of initiatives at national level to ensure that healthcare professionals receive adequate training, purging the feeling that AI is inaccessible or a competitor. This should include incorporating AI-related training into basic medical education, postgraduate programs, and continuing professional development (CPD) for doctors.

19. CPD training on AI technologies and practices should be taking place on a regular and large-scale basis and during working time to facilitate implementation.

F.   Mitigate deskilling risks and ensure critical thinking

20. The common use of AI to improve the accuracy and efficiency of disease diagnosis should not imply a deskilling of the medical profession. Measures need to be taken to ensure that critical thinking continues in medical practice.

21. AI systems should be used to support decision-making, by assisting and complementing diagnosis, identifying patterns, abnormalities and trends, and offering insights into a patient's predisposition to certain diseases and conditions. It should be a clear principle that AI is not deployed to replace or to compete with health professionals nor to diminish patient autonomy and shared decision-making.

22. Strategies also need to be put in place to avoid 'automation bias' by the medical profession, where decisions or state-of-the-art research on treatment options proposed by AI systems are blindly trusted.[11]

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[10] Kühl, Niklas, Christian Meske, Maximilian Nitsche, and Jodie Lobana. "Investigating the Role of Explainability and AI Literacy in User Compliance." arXiv preprint arXiv:2406.12660 (2024).
[11] Grote, Thomas, and Philipp Berens. "A paradigm shift?—On the ethics of medical large language models." Bioethics 38, no. 5 (2024): 383-390.

G.   Promote adequate tools and methods to interpret and explain AI output

23. When deploying AI, doctors should be able to question the AI regarding its decisions. Doctors should be able to interpret the output of an AI system and it should be made available, if necessary, the possibility to understand the internal functionality and the external behaviour of the AI system. Doctors should also be able to explain to third parties, in a clear and meaningful way, what the AI system does and why.

24. The tools and methods which are to be developed to interpret and explain the AI output need to consider the parties involved and the purposes. Different techniques for providing insights of AI may apply, considering doctors' background and experience, the complexity of the AI system, as well as the targeted audience. Different audiences might also have different needs and requirements for a specific technique.

25. CPME supports personalisation of explainability of AI systems and a minimum common understanding of what should be considered an adequate and sufficiently good explanation, including with black-boxes AI models. The quality of explanations of AI systems should be evaluated and validated. If validated, it should be possible to use the AI system with confidence.

26. CPME further supports systems that are explainable-by-design, also known as white-box models. Such systems can better support and improve a doctor's decision-making processes, clarify how the AI systems' recommendations could have influenced the doctor's decision, and play a positive role for regulators to conduct effective AI audits.

H.   Provide detailed and clear instructions for use for deployers

27. CPME encourages the provider of the AI system to properly describe the AI-attributes in the instructions for use. It needs to be clear for the doctor what aspects and how the AI allows for human oversight, what aspects and how the AI changes, providing a description of the changes and how humans could control the change,[12] including to mitigate reasonably foreseeable misuses.

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[12] CPME Feedback on Commission Proposal for a Regulation on Artificial Intelligence, August 2021.

28. The provider should also inform the deployer how the system needs to be adjusted to ensure that fairness and accuracy are aligned, as well as the system precision, confidence and error percentages and avoid bias.[13]

29. CPME supports transparent models which report the details of the model training, the training data, the model performance, the model hyperparameters, which could then be implemented as model cards.

I. Fundamental Rights Impact Assessment

30. CPME strongly advises that fundamental rights impact assessments (FRIA) are carried out by those with the necessary competences for the assessment to be considered valid and not to burden clinicians. Within a hospital setting, it needs to be clear that the responsibilities related to the FRIA do not fall upon on individual doctors but rather with the staff management.

31. In the context of the AIA, CPME recommends the prompt development of the template for a questionnaire by the European Artificial Intelligence Office (AI Office) to facilitate compliance and reduce the administrative burden on deployers of high-risk AI systems which are obliged to conduct a fundamental rights impact assessment.[14]

J. Adequate monitoring and oversight with a clear liability regime for AI in healthcare

32. As previously noted, one of the key challenges of the deployment of AI in healthcare arises from the 'black-box' nature of AI algorithms, which can obscure the basis for decision-making. This lack of transparency poses a challenge for doctors, as it is currently unclear what responsibility and accountability there is for the doctor (individual user) when decisions are made based on AI support.

33. In many cases, the limitations or biases underlying AI outputs are often impossible for individual users to discern. Furthermore, it is important to note that AI support systems are generally continuously developed while in use, making ongoing monitoring necessary.

34. CPME emphasises the importance of establishing robust systems at European and national levels for the continuous monitoring and oversight of AI technologies in healthcare.

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[13] Ibid.
[14] Recital 96 and Article 27(5) of the AIA.

35. It is critical that national authorities provide clear guidelines on the responsibilities associated with the use of AI support tools in clinical settings. These guidelines should clarify that responsibility for errors arising from AI use lies with the healthcare organisation that adopts and integrates the AI system, potentially in collaboration with the company that developed the product, especially when both parties are involved in its implementation and maintenance.

36. As a result, it should be clear for the doctor who should he/she address in case of a defective product, misdiagnosis and inappropriate treatment caused by AI-enabled products, as well as to provide feedback on what the doctor would prefer to be done differently or improved.

37. A doctor cannot be held liable for the default of the machine. A doctor can only prove what is within the remit of his/her actions, that is that he/she followed the instructions for use and guidelines from the AI provider. CPME supports applying the strict liability regime for AI systems, as there is no need for the victim to prove fault.[15]

38. Efficient clinical guidelines defining the rules on the use of AI as a tool in healthcare are needed to shape the professional standard of care and determine the relative (and acceptable) safety of the system. Healthcare professionals cannot become the 'scapegoat' of AI systems malfunction. Doctors and other healthcare professionals in direct contact with AI should be involved with the drafting and evaluation of these guidelines.

39. Doctors should retain the right to disagree with an AI system without additional repercussions. Doctors must retain their autonomy and be responsible for the final decision-making towards the patient. They should be able to exercise appropriate oversight throughout the entire lifecycle of the AI-system, ensuring the implementation of human-centric AI.

K. Encourage AI and cyber insurance coverage

40. Insurance can play a major role in fostering confidence in AI systems. Cyber and AI insurance, with cross-border coverage, should be promoted and facilitated, covering losses not only from cyber events but also from risks related to algorithmic bias and performance of AI models, such as failure in screening, harm during surgery, mistake in triaging, recommending a wrong medicine, hallucinating and any substantial decision-making errors.

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[15] CPME Response Public Consultation on 'Adapting liability rules to the digital age and Artificial Intelligence', December 2021.

41. CPME supports mandatory insurance for high-risk AI systems, which should include 'tail coverage'.[16] For technical support, it should be possible to use services of computer emergency response teams (CERT). Financial support from national authorities should be considered.

L.   Coordinate knowledge environment at EU and national level

42. Most AI systems are developed and owned by individuals or companies working outside the healthcare system. This can limit access to crucial knowledge about the strengths, weaknesses, and functioning of these AI systems. Furthermore, it is difficult to match the deep understanding and resources of the developers.

43. European doctors stress the importance of publicly coordinated efforts to establish knowledge environments of sufficient scale and clinical expertise within national settings. This coordination is crucial to support sustained AI research collaboration at both the EU and national levels. Universities and hospitals should be involved in building a robust clinical knowledge environment in this field.

44. European doctors also encourage supporting cross-sectoral staff circulation between academia and healthcare providers, improving research and innovation in AI ecosystems at the local level, and creating synergies and knowledge transfer.

M.   Promote reliability of datasets in healthcare

45. The training of datasets in healthcare must be carried out on validated datasets specifically tailored to healthcare. Using non-validated internet content can lead to incorrect information in clinical decision-making system process.

46. Product manufacturers should be transparent about the technology used and the underlying training data.

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[16] 'Tail coverage' is a liability coverage for doctors that comes into play when a former patient claims malpractice took place during the doctor's previous medical insurance plan. Doctors may switch their medical insurance plan for several reasons (e.g. changing practices, leaving a practice for employment at a hospital, retirement, etc.) and 'tail coverage' will allow the insurance provider to cover claims received after the effective policy period, but related to facts taken place during the effective policy period.

References

- Drysdale, Erik, Elham Dolatabadi, Corey Chivers, Vincent Liu, Such Saria, Mark Sendak, Jenna Wiens, Michael Brudno, Amelia Hoyt, and Mjaye Mazwi. "Implementing AI in healthcare." In *Toronto: Vector-SickKids Health AI Deployment Symposium*. 2019.

- European Commission, Directorate-General for Research and Innovation, ERA Forum Stakeholders' document, Living Guidelines on the Responsible Use of Generative AI in Research, first version, March 2024

- Gillner, Sandra. "We're implementing AI now, so why not ask us what to do?–How AI providers perceive and navigate the spread of diagnostic AI in complex healthcare systems." *Social science & medicine* 340 (2024): 116442.

- Grote, Thomas, and Philipp Berens. "A paradigm shift? – On the ethics of medical large language models." Bioethics 38, no. 5 (2024): 383–390.

- Kühl, Niklas, Christian Meske, Maximilian Nitsche, and Jodie Lobana. "Investigating the Role of Explainability and AI Literacy in User Compliance." arXiv preprint arXiv:2406.12660 (2024).

- Liu, Chung-Feng, Chien-Cheng Huang, Jhi-Joung Wang, Kuang-Ming Kuo, and Chia-Jung Chen. "The critical factors affecting the deployment and scaling of healthcare AI: viewpoint from an experienced medical center." In *Healthcare*, vol. 9, no. 6, p. 685. MDPI, 2021.

- Ossa, L. A., Lorenzini, G., Milford, S. R., Shaw, D., Elger, B. S., & Rost, M. (2024). Integrating ethics in AI development : a qualitative study. BMC Medical Ethics, 25(1).

- Standing Committee of European Doctors (CPME):
    - Feedback on Commission Proposal for a Regulation on Artificial Intelligence, August 2021, CPME 2021/085 FINAL, <https://www.cpme.eu/api/documents/adopted/2021/8/cpme.2021-085.CPME_.Feedback.on_.Commission.Proposal.Artificial.Intelligence.Act_.final_.pdf>;
    - Response Public Consultation Civil Liability on AI, December 2021, CPME 2021/134, <https://www.cpme.eu/api/documents/adopted/2021/12/CPME_AD_EC_16122021_FINAL.CPME_.Response.Public.Consultation.Civil_.Liability.AI_.pdf>

- Udegbe, Francisca Chibugo, Ogochukwu Roseline Ebulue, Charles Chukwudalu Ebulue, and Chukwunonso Sylvester Ekesiobi. "The role of artificial intelligence in healthcare: A systematic review of applications and challenges." *International Medical Science Research Journal* 4, no. 4 (2024): 500–508.

- Vandersluis, Robert, and Julian Savulescu. "The selective deployment of AI in healthcare: An ethical algorithm for algorithms." *Bioethics* 38, no. 5 (2024): 391–400.