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.

Report on the impact of AI on the 'patient-doctor' relationship

Response to Council of Europe's questionnaire

European Doctors welcome the report prepared by the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) of the Council of Europe, in the framework of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), and the consultation that has been launched in that regard.

CPME would like to offer the following comments to the report:

1. General comment:

   *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' expertise*. (See: CPME Policy on AI in Health Care, 16 November 2019, page 2, https://www.cpme.eu/api/documents/adopted/2019/CPME_AD_Board_16112019_062_FINAL_EN_CPME.AI_.in_.health.care_.pdf, 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).

2. line 314:

   On the 'Challenges' section, consider reflecting on whether a reference should be added on the **role and use of ethics committees** when consent cannot be obtained from humans for different reasons (e.g. unconscious patients, impossible or very difficult to contact patients) and/or the legal basis is other than consent from patients (See CPME flyer on "Role of Ethics Committees in the European Health Data Space", 25 May 2022, <https://www.cpme.eu/api/documents/adopted/2022/04/A4_CPDP_Flyer_220427.pdf>);

3. line 345:

   a. in the table in relation to 'Patients need:' (4th bullet): it is said that *"Patients need: (…) To be able to accept or refuse AI in their care or treatment, and to this end seek a second opinion without the use of an AI-system".* Sometimes it will not be possible for healthcare professional to separate AI, being able to choose to use the system with AI or without AI. We recommend adding some flexibility to the last sentence: *"(…) to be able to accept or refuse AI in their care or treatment, and to this end seek a second opinion without the use of an AI-system, **where possible".***

b. In the table in relation to health professionals (2nd bullet): it is said that *"Health professionals and/or healthcare providers have responsibility to: (…) Inform and explain to patients in clear and simple language what are AI systems, why and how they are being used (i.e., benefits and risks)"*. Health professionals may not be able to explain the *"what"*, and for this reason should be limited to the *"why"* and *"how"* AI systems are being used. The legal definition of AI is still being negotiation at EU level in the AI Act.

4. line 392:

   To the sentence *"Health professionals and/or healthcare providers have responsibility to use them in a way that aligns with ethical and legal guidelines."* It should be added add that "*Health professionals and/or healthcare providers have* ***the*** *responsibility to use* ***AI-systems*** ~~*them*~~ *in a way that aligns with ethical and legal guidelines****, and according to the manual of instructions as provided by the manufacturer."*** The provider of the AI system needs to properly describe the AI-attributes in the instructions for use. For example, what aspects and how the AI provides for human oversight, what aspects and how the AI changes, providing a description of the changes and how humans could control the change. The provider should also inform the user how the system needs to be adjusted to ensure that fairness and accuracy are considered to be aligned, as well as the system precision, confidence and error percentages (See CPME Feedback on Commission Proposal for a Regulation on Artificial Intelligence, August 2021, page 3 https://www.cpme.eu/api/documents/adopted/2021/8/cpme.2021-085.CPME .Feedback.on .Commission.Proposal.Artificial.Intelligence.Act .final .pdf).

5. line 412:

   To the sentence *"Notwithstanding the potential for AI systems to be effective supporting tools, the critical thinking and expertise of health professionals should not be underestimated."* It should be add that *"Notwithstanding the potential for AI systems to be effective supporting tools, the critical thinking and expertise of health professionals should not be underestimated,* ***and appropriate professional oversight should exist over AI clinical validation."*** (CPME Policy on AI in Health Care, 16 November 2019, page 6, https://www.cpme.eu/api/documents/adopted/2019/CPME_AD_Board_16112019_062_FINAL_EN_CPME.AI_.in_.health.care_.pdf). AI in healthcare must be subject to high clinical standards and should be empirically evaluated like any other digital device.

6. line 453:

   It should be added a paragraph to the recommended action in the 'professional standards" chapter that: ***"A healthcare professional that uses an AI system according to the training provided and in adherence with the instructions and guidelines, he/she should be fully indemnified against adverse outcomes. He/she cannot be held liable for the default of the machine. New rules are needed to address liability for self-learning algorithms and to clearly identify who is responsible for what. There should be clarity on to whom a healthcare professional should address in case of a defective product, wrong diagnosis or wrong treatment caused by AI."*** (See CPME Feedback on Commission Proposal for a Regulation on Artificial Intelligence, August 2021, page 3 https://www.cpme.eu/api/documents/adopted/2021/8/cpme.2021-085.CPME .Feedback.on .Commission.Proposal.Artificial.Intelligence.Act .final .pdf).

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