



Doc. 15508
25 April 2022

Artificial intelligence in healthcare: medical, legal and ethical challenges ahead

Reply to Recommendation¹: Recommendation 2185 (2020)
Committee of Ministers

1. The Committee of Ministers has carefully examined Parliamentary Assembly [Recommendation 2185 \(2020\)](#) "Artificial intelligence in health care: medical, legal and ethical challenges ahead" which is timely and covers a very broad range of relevant issues. The recommendation has been transmitted to the relevant committees for information and possible comments.²
2. The Committee of Ministers agrees that artificial intelligence (AI) applications in healthcare result in a changing environment and that full respect for human rights, including social rights, should underpin public policymaking for healthcare and guide further technological progress.
3. The Committee is aware of the benefits of AI, for example in improving diagnostic and therapeutic outcomes for patients and patient safety, yet remains attentive to the challenges it poses, for example regarding its socio-economic impacts or its potential to discriminate individuals and groups in relation to its predictive capabilities. In this regard, it underlines the importance of guaranteeing patient safety when integrating AI in health care and health research, the need to ensure the quality, necessity and proportionality of data used by AI, and the attention needed to the ethical design of algorithms including in order to reflect the populations which AI serves.
4. When unregulated, AI systems coupled with a lack of transparency and insufficient public scrutiny, and their incorporation into the administration of social services, can pose threats for human rights and freedoms. These systems can, if not developed and used in accordance with principles of transparency and legal certainty, amplify bias and increase risks for members of the community, including those in a situation of vulnerability. In this respect, the Committee of Ministers recalls its Declaration on the risks of computer-assisted or artificial-intelligence-enabled decision making in the field of the social safety net, adopted in March 2021. At the same time, it notes that creating regulations that build public trust and social acceptability will support the development and opportunities given by AI systems. The stakeholders in Council of Europe member States should not be put at a disadvantage in competing with their counterparts in other parts of the world by disproportionately strict regulations.
5. To ensure that more mature AI mechanisms can be deployed safely from a human rights perspective, and that benefits from innovation are spread as fairly as possible across society, a collaborative and multidisciplinary approach is required across the Council of Europe. It also requires open and inclusive dialogue between the public, scientists, and policy makers, in line with the Guide to public debate on human rights and biomedicine, to address the concerns raised by AI for integrity, dignity, autonomy, privacy, justice, equity and non-discrimination among human beings.

1. Adopted at the 1432nd meeting of the Ministers' Deputies (20 April 2022).

2. The Steering Committee for Human Rights (CDDH), the Committee on Bioethics (DH-BIO), the European Social Cohesion Platform (PECS), the Ad hoc Committee on Artificial Intelligence (CAHAI), the European Committee of Social Rights (ECSR) and to the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal data (T-PD).



6. The Assembly will be aware that a number of sectors of the Organisation are carrying out activities in the field of AI, some of which may be of direct or indirect relevance to the issues raised in this recommendation. However, in response to the specific recommendations in paragraph 11, and the committees mentioned therein, the Committee of Ministers can inform the Assembly that whilst the CAHAI – in accordance with the Committee of Ministers’ decision at its 131st Session (Hamburg, 21 May 2021) – is addressing specific risks posed by the design, development and application of AI systems³ to human rights, democracy and the rule of law in general, as well as to the right to non-discrimination, data protection and right to privacy, addressing health care-related issues as such falls outside its mandate. In this respect, it can also inform the Assembly that the new Committee on Artificial Intelligence (CAI) which succeeds the CAHAI has been set up and is tasked to develop an appropriate legal instrument on the development, design, and application of artificial intelligence systems based on the CAHAI’s “Possible elements of a legal framework on artificial intelligence, based on the Council of Europe’s standards on human rights, democracy and the rule of law” and conducive to innovation.

7. With regard to the recommendation to mandate the DH-BIO and the T-PD to seek synergies in their work towards guiding member States on good governance of health data, the Committee of Ministers notes that the two committees have already co-operated on the processing of health related data, including in the context of the preparation of the amending Protocol (CETS No. 223, “Convention 108+”) to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108). The right to respect for private life in relation to personal health related data is laid down in Article 10 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (CETS No. 164, “Oviedo Convention”). Protection of such sensitive personal data helps to steer the innovation process in a way which connects innovation and technologies with social goals and values.

8. Overall, the development and use of AI in biomedicine must be for the common good, people-centred and ensure the full protection and respect for human rights. It is the strategic objective of the DH-BIO to embed human rights in the development of technologies which have an application in the field of biomedicine. To this end, the education of medical professionals, computer scientists and others in the development, design and deployment of AI in biomedicine in an ethically responsible way would be necessary.

9. With regard to paragraph 11.4, the Committee informs the Assembly that it may come back at a later stage to the proposal to instruct the CDDH to consider the feasibility of updating Recommendation [CM/Rec\(2016\)3](#) on human rights and business in order to reflect modern challenges and member States’ obligations under the European Social Charter (including the right to protection of health). It will keep the Assembly informed about any developments in this respect.

10. Finally, with regard to paragraph 12, the Committee encourages member States to give due consideration to the recommendations put forward by the Assembly, with a view to taking concrete action allowing to establish ethical principles for AI and its responsible use, while giving effect to the right to protection of health as set out in the European Social Charter and securing full access to public healthcare services.

11. The Committee reiterates the pertinence of other existing Council of Europe legal instruments, in particular the European Convention on Human Rights (ETS No. 5), the Oviedo Convention and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and its Amending Protocol in relation to AI-driven transformations in healthcare. It encourages those member States which have not yet done so to consider ratifying the latter instruments.

3. At the Hamburg Ministerial Session (May 2021), the Committee of Ministers, *inter alia*, “decided to give priority to the work on an appropriate legal framework for the development, design and application of artificial intelligence based on the Council of Europe’s standards on human rights, democracy and the rule of law, and conducive to innovation;” and invited its Deputies “to focus particularly on a possible legal framework which can be composed of a binding legal instrument of a transversal character, including notably general common principles”.