Parliamentary Assembly
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COUNCIL OF EUROPE
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Recommendation 2185 (2020)[1]

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

Parliamentary Assembly

1. Good health is a precondition for more fulfilling individual lives and the progress of society as a whole. Artificial intelligence (AI) is the latest technological innovation to rapidly impact healthcare. Like many technological innovations in healthcare, it harbours considerable potential for improving both individual and public health, but also presents risks for individual rights and public health. Furthermore, the speed of the development and deployment of these technological advances is much faster than that of the legal framework regulating them, which requires close attention by policy makers and politicians.

2. AI applications in healthcare represent the paradigm shift that is taking place in healthcare generally, by moving the focus away from disease and therapy towards self-managed health, well-being and prevention, and away from "one-size-fits-all" treatment protocols to precision medicine tailored to the individual. In this changing environment, full respect for human rights, including social rights, needs to underpin public policy making for healthcare and guide further technological progress. This is required to ensure that more mature AI mechanisms can be deployed safely from a human rights perspective, and that benefits from innovation are spread fairly and equitably across society.

3. The Parliamentary Assembly notes that the scientific community has urged public debate on the implications of AI applications in healthcare and has highlighted the need for all stakeholders to be more accountable. Policy makers, including parliamentarians, at national, European and international levels must better understand the wide-ranging risks, socio-economic impacts and opportunities inherent in the design, development and deployment of AI technologies in healthcare, so that they can seek pragmatic improvements and propose adequate regulatory options that ensure full respect for human dignity and rights through legal and ethical frameworks – as far as possible with a global reach. This requires a collaborative, multidisciplinary approach to defining AI-related risks and challenges in healthcare.

4. The Covid-19 outbreak has focused attention on the role that AI can play through real-time surveillance, assessment and management of data on disease. It has also revived the much-needed debate on acknowledging the right to health as a fundamental human right, which should be secured through legal instruments and appropriate healthcare systems that are publicly provided and that ensure universal access.

5. The Assembly heeds with concern the warning from the World Health Organization (WHO) that the existing digital divide and inequalities (within and between countries, as well as societal groups), coupled with the spread of AI, might exacerbate the unequal distribution of healthcare and problems of effective access to healthcare, reduce the number and skills of health professionals, accentuate bias and increase "disrespectful clinical interactions", thus *de facto* worsening healthcare inequalities and outcomes. The Assembly underlines that there is a broad global consensus around the essential ethical principles of AI. It strongly supports the work of WHO on developing ethics guidance on AI in healthcare on the basis of the shared perspectives of various stakeholders, including the Council of Europe and its Parliamentary Assembly.

1. *Text adopted by the Standing Committee*, acting on behalf of the Assembly, on 22 October 2020 (see Doc. 15154, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Ms Selin Sayek Böke).

6. Given that to date the private sector has driven most of the research and development of AI applications for healthcare, national public healthcare authorities should adopt a strategic approach to co-ordinating digitalisation policies, research and investment, as well as management and exploitation of personal data, with a view to ensuring full protection of fundamental rights and striking a healthy balance between individual, business and public interests. In this context, the Assembly reaffirms its call, in Recommendation 2166 (2019) "Human rights and business – what follow-up to Committee of Ministers Recommendation CM/Rec(2016)3?" to reflect on modern challenges and member States' obligations under the European Social Charter (ETS Nos. 35 and 163), including the right to health.

7. The Assembly stresses the pertinence of existing Council of Europe legal instruments, in particular the European Convention on Human Rights (ETS No. 5), the Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention") and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) and its amending protocol (CETS No. 223, "Convention 108+") in relation to AI-driven transformations in healthcare. However, it believes that the scope and depth of these transformations and the undeniable impact of AI technology on human dignity and fundamental rights are such that the Council of Europe, as the guardian of human rights, should prepare a dedicated legal instrument on AI. It thus strongly supports the work of the Ad hoc Committee on Artificial Intelligence (CAHAI) towards preparing such a dedicated legal instrument.

8. The Assembly notes that privacy, confidentiality of personal data and informed consent are the cornerstones of patient rights worldwide. At the same time, certain restrictions on the use of personal health data may disable essential data linkages and induce distortions, even errors, in AI-driven analysis. It is debatable whether the anonymisation or pseudonymisation of personal health data are appropriate solutions.

9. The Assembly welcomes the intention of the Council of Europe Committee on Bioethics (DH-BIO) to work on trust, safety and transparency in the application of AI in healthcare. The Assembly encourages it to take a comprehensive approach, to proceed with this work as a matter of priority and to seek synergies with other Council of Europe bodies working in this field.

10. Moreover, the Assembly considers that cybersafety requirements for AI-enabled medical devices (including implantable and wearable healthcare products) should be further explored in the framework of the Convention on Cybercrime (CETS No.185), whereas the Committee of Experts on Human Rights Dimensions of Automated Data Processing and Different Forms of Artificial Intelligence (MSI-AUT) could complement DH-BIO work by helping to define the liability of stakeholders – from developers to regulatory authorities, intermediaries and users (including public authorities, healthcare professionals, patients and the general public) – with regard to the development, maintenance and use of medical AI applications, and any damage caused by them.

11. The Assembly therefore recommends that the Committee of Ministers:

11.1. instruct the CAHAI to prepare a dedicated legal instrument on AI, preferably a binding instrument with a global reach, such as a convention open to non-member States, with an emphasis on the human rights implications of AI in general and on the right to health in particular;

11.2. involve other relevant Council of Europe bodies in CAHAI work with a view to adequately covering health-related challenges, notably in terms of privacy, confidentiality and cybersafety of sensitive personal health data, informed consent and liability of stakeholders;

11.3. mandate the DH-BIO and the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data to seek synergies in their work towards guiding member States on good governance of health data, with a view to preventing any sovereign or commercial misuse of personal data through medical AI applications;

11.4. update 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 health).

12. The Assembly furthermore recommends that the Committee of Ministers encourage member States to:

12.1. build a holistic national approach, involving national parliaments, to the use of AI technology in healthcare services based on multistakeholder involvement and accountability, as well as adequate evaluation of socio-economic and human rights impacts, with a view to consolidating their population's full access to public healthcare services and giving effect to everyone's right to health as set out in the European Social Charter;

12.2. participate more actively in the development and deployment of AI applications for healthcare services at national level and provide for sovereign evaluation and screening of such applications by independent institutions, as well as an exhaustive authorisation process for their deployment, in particular in public health services, to counter risks to individual rights and public health, in accordance with the precautionary principle;

12.3. examine legal and technical options for certification and validation of both publicly and commercially developed AI applications for health (covering the end product and every stage of the AI design process) at both national and European levels;

12.4. strengthen their national human rights impact assessment framework for all health-related AI applications;

12.5. guarantee that AI-driven health applications do not replace human judgment completely and that AI-enabled decisions in professional healthcare are always validated by adequately trained health professionals;

12.6. elaborate a legal framework for clarifying the liability of stakeholders for the design, deployment, maintenance and use of health-related AI applications (including implantable and wearable medical devices) in the national and pan-European contexts, redefine stakeholder responsibility for risks and harm from such applications and ensure that governance structures and law-enforcement mechanisms are in place to guarantee the implementation of this legal framework;

12.7. discuss how to balance the requirement of strong protection of personal data and the need to use certain types of personal health data for the public good in the context of AI-powered enhancements in public health, while respecting human rights, including as regards the better preparedness of governance structures to anticipate and manage the pandemic response;

12.8. accelerate their accession, if they have not yet done so, to the Oviedo Convention and its protocols and to the Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data;

12.9. adapt their education and training systems to integrate AI literacy into the curricula of schools and medical training institutions, with an emphasis on the ethical principles of AI and responsible uses of AI applications;

12.10. enhance investments in building the necessary digital infrastructure to overcome the prevailing digital divide and to ensure that AI-driven innovations do not exacerbate existing health inequalities;

12.11. engage a national debate on AI for health in order to raise the population’s and health professionals’ awareness of both the risks and the benefits inherent in the use of AI applications for wellness and healthcare, in particular with regard to certain commercially developed applications already on the market which take advantage of current legal voids;

12.12. consider options for harmonising the interconnectivity of national health data networks and databases so as to enable human rights compliant data linkages for AI-powered analysis and build “learning health systems”.