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**BUREAU OF THE CONSULTATIVE COMMITTEE OF
THE CONVENTION FOR THE PROTECTION
OF INDIVIDUALS WITH REGARD
TO AUTOMATIC PROCESSING
OF PERSONAL DATA**

CONVENTION 108

**OPINION ON RECOMMENDATION 2185 (2020) OF THE
PARLIAMENTARY ASSEMBLY OF THE
COUNCIL OF EUROPE**

“Artificial intelligence in health care: medical, legal and ethical challenges ahead”

1. The Ministers' Deputies agreed at their 1388th meeting (12 November 2020) to communicate Recommendation 2185 (2020) of the Parliamentary Assembly of the Council of Europe (hereafter the 'Recommendation') on "Artificial intelligence in health care: medical, legal and ethical challenges ahead"¹ to the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, for information and possible comments.
2. The Bureau of the Consultative Committee welcomes the adoption of Recommendation 2185 (2020) and underlines that personal data should only be processed by data processing techniques and technologies, such as artificial intelligence (hereafter AI), in compliance with the existing human rights legal framework and notably with the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108, hereafter 'Convention 108')² as modernised by the Protocol CETS No. 223 amending Convention 108 (hereafter 'Convention 108+')³.
3. The call (paragraph 3 of the Recommendation) for "Policy makers, including parliamentarians, at national, European and international levels ... [to] seek pragmatic improvements and propose adequate regulatory options that ensure full respect for human dignity and rights through legal and ethical frameworks" is essential and fully echoes the Preamble of Convention 108+ which underlines that "it is necessary to secure the human dignity and protection of the human rights and fundamental freedoms of every individuals". The preamble of Convention 108+ furthermore highlights the notion of "personal autonomy based on a person's right to control his or her personal data and the processing of such data" which is even more so crucial in an AI context.
4. The Bureau recalls that health-related data belong to a special category of personal data which, under Article 6 of Convention 108+, enjoys a higher level of protection notably due to the risk of discrimination and risk of injury to an individual's dignity or integrity which may occur with their processing. The complex and growing use of technologies, including AI, in processing health-related data, may contribute to increasing such risks as highlighted in Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data⁴ which amongst other important points recalled "people's desire to have more control over their personal data and the decisions based on the processing of such data, the increasing involvement of patients in understanding the manner in which decisions concerning them are being taken".
5. The Bureau of the Committee of Convention 108 therefore points to the relevance of the provisions of Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related, notably regarding the legal conditions for the processing of health-related data (Chapter II), the rights of the data subject (Chapter III), security and interoperability (Chapter IV), scientific research (Chapter V), mobile devices (Chapter VI) and transborder flows of health-related data (Chapter VII).

¹ <https://pace.coe.int/en/files/28813/html>

² [Full list \(coe.int\)](#)

³ [Result details \(coe.int\)](#)

⁴ [Result details \(coe.int\)](#)

6. The Committee of Convention 108 stressed in 2019 in the Guidelines it adopted on Artificial Intelligence and Data Protection (document T-PD(2019)01⁵) that “AI applications may represent a useful tool for decision making in particular for supporting evidence-based and inclusive policies. As may be the case with other technological innovations, these applications may have adverse consequences for individuals and society.” The Guidelines contain the following important statements:
- a. Protection of human dignity and safeguarding of human rights and fundamental freedoms, in particular the right to the protection of personal data, notably when AI applications are used in decision-making processes (paragraph 12.5);
 - b. AI development relying on the processing of personal data should be based on the principles of Convention 108+. The key elements of this approach are: lawfulness (legal basis for the processing, such as notably a valid consent or another legitimate basis laid down by law, and legitimate purpose), fairness, purpose specification, proportionality of data processing, privacy-by-design and by default accountability, transparency, data security and risk management (via Privacy Impact Assessment, Data Protection Officer, privacy enhancing technologies, etc.) (paragraph 8);
 - c. A risk-based approach should be adopted during the whole process of the processing of health-related data by AI to avoid and mitigate potential risks (paragraphs 12.2, 12.6);
 - d. A wider view of the possible outcomes of data processing should be adopted. This view should consider not only human rights and fundamental freedoms but also the functioning of democracies and social and ethical values (paragraph 12.1);
 - e. The rights of data subjects shall be respected fully, notably with regards to the “new generation of data subjects’ rights” (paragraphs 11, 12) such as:
 - not to be subject to a decision significantly affecting him or her based solely on an automated processing of data without having his or her views taken into consideration,
 - the right to obtain, on request, knowledge of the reasoning underlying data processing where the results of such processing are applied to him or her,
 - right to object;
 - f. Meaningful control by data subjects over the data processing and related effects on individuals and on society should be ensured (paragraphs 11, 12).
7. The Bureau welcomes the precautionary and participatory approaches recommended in paragraph 12.2, as such approaches are also emphasised in the Guidelines on Artificial Intelligence and Data Protection and can be complemented by algorithmic vigilance programmes⁶ for the potential effects and consequences of AI systems. The Bureau notably encourages engagement with independent committees of experts from a range of fields, as well as with independent academic institutions, which can

⁵ <https://rm.coe.int/2018-lignes-directrices-sur-l-intelligence-artificielle-et-la-protecti/168098e1b7>

⁶ On the notion of algorithmic vigilance, as adoption of accountability, awareness and risk management practices related to potential adverse effects and consequences throughout the entire life cycle of these applications see also the 40th International Conference of Data Protection and Privacy Commissioners, Declaration on Ethics and Data Protection in Artificial Intelligence, guiding principle no. 2. See also the Report on Artificial Intelligence (footnote 2), Section II.4.

contribute to designing human rights-based and ethically and socially oriented AI applications, and to detecting potential bias⁷.

8. As modern technologies and in particular AI, often rely on the use of personal data, and increasingly so in a health care context, privacy impact assessments prescribed by Convention 108+ can be an important element of broader human rights impact assessments as recommended in paragraph 12.4.
9. Regarding the necessary balance to reach between 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 (paragraph 12.7), data protection legal frameworks and their consistent implementation, already allow for the necessary compatibility with other fundamental rights and relevant public interests, such as public health. It is important to recall that data protection can in no manner be an obstacle to saving lives because the applicable data protection principles always allow for a balancing of the interests at stake.
10. Concerning the work of the *Ad Hoc* Committee on Artificial Intelligence (CAHAI), in light of the importance of ensuring an effective articulation of any future legal instrument on AI with existing instruments, representatives of the Consultative Committee of Convention 108 are actively participating in the meetings of the *Ad Hoc* Committee and its working groups.
11. Finally, the Bureau of the Committee of Convention 108 strongly welcomes the encouragement made to member States to accelerate the ratification of and accession to Convention 108+ (paragraph 12.8) and confirms that the Committee of Convention 108 stands ready to assist the Parliamentary Assembly and the Committee of Ministers in raising awareness on the relevance of Convention 108+ and in accompanying countries in their national efforts deployed to that end.

⁷ See the Guidelines on Artificial Intelligence and Data Protection, point II.6.