Hellenic Republic
**National Commission
for Bioethics & Technoethics**

O P I N I O N

on
The applications of Artificial Intelligence in Health in Greece

December 2023

NATIONAL COMMISSION FOR BIOETHICS & TECHNOETHICS

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I. Introduction

During multiple plenary meetings, the National Commission for Bioethics & Technoethics examined the ethical considerations surrounding the development and use of Artificial Intelligence (AI) in the Health sector. The Commission considers this as a particularly relevant issue mainly, for three reasons: a) There has been a surge in global research on AI applications for health services. Many applications have already been implemented in clinical practice for the prevention, diagnosis, treatment, and administrative organization of services. b) Our country has pursued research initiatives in this field, mainly through international collaborations. c) Although legislative initiatives regulating the use of AI in Health and other sectors are yet to be adopted, a binding regulation on AI is imperative for the EU, thus requiring member states to prepare for its implementation and specialization of its provisions in their national context.

Based on the above information, the present Opinion aims to: a) underline that the development and use of AI applications are assessed socially through the prism of fundamental values and ethical principles that ought to govern the relationships between individuals in a democratic state, b) highlight that the dynamic of AI applications must take into consideration specific, critical data that characterize the provision of healthcare services in our country, c) emphasize that the introduction of AI tools in healthcare aims only to enhance patient services tangibly.

The Commission has decided to set up a High-Level Expert Group that will continuously support the Commission on the analysis of AI-related issues. The composition of the Group can be found in Annex I. With the assistance of the High-Level Expert Group, the Commission has organized hearings where scientists and stakeholders' representatives were invited to provide information on the factors that should be considered regarding the Opinion's topic (please refer to Annex II for more details).

II. Points of Reference

An AI system, according to the definition proposed by the OECD in 2019 and adopted by the EU AI Regulation (AI Act - 2023),[1] is a machine-based system that, for explicit or implicit objectives, infers from the input it receives, is able to generate outputs (such as predictions, , recommendations, or decisions) that can influence its environment (physical or virtual).

In the Health sector, the use/application of AI systems is expected to positively impact various levels, such as disease prognosis and diagnosis, improved patient monitoring, development of new treatments, protection of public health, and optimization of administrative processes. To this direction, many Research Centres, Universities, and Hospitals in our country participate in research programs and clinical studies involving AI, while some private or public hospitals already use AI systems, albeit to a limited extent.[2]

A critical benefit of using AI applications in clinical settings or healthcare management is the ability to make faster and better justified decisions at all levels. This is made possible by the applications' complex and integrated processing of large volumes of diverse data supported by appropriately designed algorithms.

Our country is making significant research efforts to participate in the digital transformation of healthcare through AI systems. However, the stakeholder hearings preceding this Opinion have highlighted some rigidities that need to be overcome to improve the integration of digital and other innovative solutions into the health system. The hearings emphasized the need to fully digitize and interconnect information systems between and within healthcare and social care structures, the need to ensure reliability of health data, the need to make it easier for researchers to access health data which will enable analysis of the information and the provision of potential benefits to patients, as well as the need to establish and electronic health record system.

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[1] The definition adopted by the NCBT reflects the point of convergence of the European and American approach to AI, which was achieved at the end of 2023.

[2] T. Vidalis, V. Mollaki. Th. Trokanas 2023. Report for the National Commission for Bioethics and Technoethics "Artificial Intelligence in Healthcare".

III. Ethical issues

The use of AI applications in the health sector is crucial as it can enhance the quality of services provided to the public and lead to rationalising the allocation of resources within the National Healthcare System (NHS) and support its administrative organisation. In this context, AI is considered in the context of the social right to healthcare (Article 21 of the Constitution).

The Commission recognizes that AI is gaining momentum in biomedical research. Relevant research is expected to produce more effective and safer therapeutic means and diagnostic tools. In particular, AI-powered Precision Medicine applications will enhance the performance of targeted and, consequently, more effective medical procedures by correlating biomedical profiles and patterns of homogeneous groups of the population or individuals.

AI technology raises serious ethical concerns that cannot be overlooked, and it's the responsibility of the State to address them.

Given their technical complexity, the most significant concern is the security of AI applications. The data used in AI tools must be thoroughly checked for their reliability, validity, and impartiality e.g. by assessing the methodologies used to produce the data, by ensuring the homogeneity of the population groups, by verifying the submission of study results to public databases, and, by confirming the results from other independent studies.

Besides, the design and development of algorithms are based on technical knowledge that the end user and operator of the application, i.e. the treating physician, cannot fully control. Nonetheless, the treating physician is ultimately responsible for the proper management and care of the patient (or any other person that asks for their services). This means that the recipients of healthcare services (patients or healthy individuals), are asked to consent to medical procedures involving such applications, without necessarily being fully informed about the conditions guaranteeing their safe use. Although the treating physician bears the ultimate responsibility for every medical procedure, this information gap between the physician and the recipient of health services creates an opaque condition inconsistent with the provision of quality healthcare services.

The second important issue that needs to be addressed is the handling of high-volume

data and the diversity of individual characteristics, with a significant portion of these data being sensitive information relating to patients or healthy individuals. Access to such data requires procedures that ensure their use for specific purposes, while mainly preventing leaks and the identification of individuals (even if sensitive personal data have been shared with guarantees for anonymization). In this regard, it is necessary to balance the social interest in developing AI applications in healthcare with the patients' or healthy individuals' right to personal data protection. The Commission believes that such a balance can be achieved by providing appropriate safeguards for data subjects.

Finally, it is important to evaluate AI applications in terms of the fair distribution of limited resources allocated to healthcare, considering the high cost -at least for now- involved in introducing them into clinical practice. Public investment in these applications must be justified on a case by case and compared with other needs of the National Healthcare System.

IV. Ethical principles

From an ethical perspective, the proper introduction of AI systems or tools in the healthcare sector demands that the above-described problems are addressed through the prism of fundamental moral and social principles, as outlined in International and European texts, among which the guidelines of the World Healthcare Organization.[3] According to the Commission the following principles should govern the regulatory framework for developing and using AI applications in healthcare:

- The **principle of autonomy,** which is closely linked to human dignity and requires respect of the individual's right to make free, unhindered, and informed decisions when it comes to the use of AI tools. Patients must be properly informed by the treating physician about the use of AI methods before they consent to medical procedures. However, given the algorithmic opacity of these tools, physicians should only provide information if they have

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[3] WHO, Ethics and Governance of Artificial Intelligence for Health: WHO Guidance Executive summary, 2021: https://iris.who.int/bitstream/handle/10665/350567/9789240037403-eng.pdf?sequence=1

received adequate training to understand how the application operates. Additionally, **respect for privacy**, also linked to autonomy, requires that individuals' anonymity be protected to prevent sharing their data with third parties without informed consent.

- The **principle of beneficence**, according to which every AI application should strive for a reasonable improvement in the patient's health or diagnostic procedure for the benefit of the person involved. In any case, an AI application must not pose any additional harm to health ("do no harm" principle).

- The **principle of safety**, which is linked to the **principle of do no harm**, and requires the implementation of quality control measures for AI applications in Health by authorized bodies to minimize the possibility of errors during relevant medical procedures.

- The **principle of fairness**, which requires that medical decisions involving AI applications be made on the basis of the criterion of fair distribution.

- The **principle of equity**, which is linked to **fairness**. It requires ensuring equal access to medical procedures related to AI applications without discrimination based on economic, social status or any other factors.

V. Operational - procedural principles

The above fundamental ethical principles are specialized in practice through their combination with operational-procedural principles, which are also necessary to be part of an AI governance framework in health.

- The **prevention principle**, which involves halting the use of AI applications if there are specific risks to persons, and the **precautionary principle**, which requires stopping applications even if there is risk uncertainty. More specifically, in the context of research for developing medical AI applications, the precautionary principle requires reasonable protection measures to be taken when there is uncertainty about the occurrence of risks from the clinical use of the application. These measures should identify the risk and plan

to prevent it.

- The **principle of explainability**, which is linked to transparent use and accountability. It requires that the processes leading to decision-making with AI systems be understandable, interpretable, and attributable to their actor. The principle incorporates the epistemological demand of intelligibility (which answers the question "How does a system work?") and the ethical demand of accountability (which answers the question "Who is responsible for how the system works?"). In the clinical application of AI in diagnostic and therapeutic procedures, the accountability principle states that the responsibility for the results must rest with a specific person.

- The **principle of complementarity,** which in the case of AI, means that healthcare applications using AI should not completely substitute human judgment, and therefore, decisions in healthcare provision should be made by trained physicians and other healthcare professionals.

VI. Proposals

According to the Commission the ultimate aim must be that the healthcare system incorporates digital and innovative solutions while prioritizing the needs of those who will benefit from healthcare services. Such solutions should only be implemented if they are expected to bring actual benefits to patients or recipients of healthcare services. To this direction, the Commission suggests the following:

- To establish a governance framework that defines the guidelines for the development and utilization of AI in health, which will accompany the national AI strategy. The governance framework must comply with the fundamental ethical principles and include regulatory rules, policies, institutional initiatives and organizational best practices to ensure responsible management and ethical advancement of AI usage in health.

- In view of the new EU AI Act, the State must establish an appropriate contemporary and specialized legal framework that ensures respect for human dignity and rights, while

emphasizing the delineation and sharing of responsibilities among AI stakeholders.

- Organizations using AI in health must create ethics review codes and internal standards, including impact assessment protocols when needed, based on relevant widely accepted protocols.

- To bridge the existing digital divide and digital inequities in general, the State and other stakeholders, including patient associations, must develop targeted programs and initiatives to enhance digital literacy among the general population, with a particular emphasis on healthcare service users.

- To promote re-skilling and up-skilling of healthcare professionals, such as doctors, administrative staff, and others who use AI applications in health, Universities, Research Centers, Lifelong Learning Centers, Scientific Societies and Healthcare Structures must design appropriate training/education programs.

- The State should adjust the terms and conditions for safe and effective implementation of AI systems in the Greek context. This will require upgrading the operation of all competent control bodies. In this context, it is particularly recommended to assess the clinical applications of AI that have been tested successfully in other countries and explore the possibility of introducing them to the Greek National Health System.

- Healthcare systems and health data (e.g. by expanding electronic health records) must be enhanced and the interconnectivity and interoperability of national networks and relevant healthcare databases must be improved.

- A State framework must be established to enable researchers to access databases of IDIKA (e-Government Center for Social Security) for research and development of AI systems.

- Public debate on the potential applications of AI and their impact is paramount. It must be promoted to involve experts from various disciplines, following Article 28 of the Oviedo Convention. Particular emphasis should be given to updating bioethical and technoethical frameworks of thinking.

- The State and scientific communities should use strategic foresight methods and tools to

understand the impact of digital healthcare, analyze trends, model alternative scenarios, and prepare for possible disruptions to the healthcare system. Through dialogue and scenario modelling, parties can enhance digital inclusion and trust conditions, ultimately protecting future generations.

Athens, December 21, 2023

ANNEX I

High-Level Expert Group on Artificial Intelligence

Members of the High-Level Expert Group on Artificial Intelligence (in alphabetical order):

- Alkiviadis Gounaris, Doctor of Philosophy, Adjunct Lecturer, Department of Philosophy, Applied Philosophy Research Lab, National and Kapodistrian University of Athens.

- Maria Dagioglou, Postdoctoral Researcher in AI in Healthcare Care, AI Ethics, NCSR "Demokritos", Institute of Informatics and Telecommunications.

- Christina Dalla, Associate. Professor of Pharmacology-Psychopharmacology, Medical School, National and Kapodistrian University of Athens, Neuroscientist.

- Nikos Dedes, President of the Greek Patients' Association.

- Theodoros Evgeniou, Professor INSEAD, Co-founder of Tremau.

- Xenia Ziouvelou, Postdoctoral researcher in AI ethics, AI policy, NCSR "Demokritos",

  Innovation expert, Directorate-General for Research and Innovation, EC.

- Anastasia Krithara, Postdoctoral Researcher in AI in Healthcare Care, NCSR "Demokritos", Secretary General of the Hellenic Artificial Intelligence Society (EETN).

- Georgios Kosteletos, Doctor of Philosophy, Adjunct Lecturer, Department of Philosophy, Applied Philosophy Research Lab, Associate Teaching Staff at the Open University of Cyprus (OUC).

- Dimitra Lingri, Supreme Court Lawyer, DEA en Droit Public, Senior legal expert in pricing and reimbursement of medical and pharmaceutical products at the World Healthcare Organization (STAG-MEDEV), Managing Director at the European Healthcarecare Fraud and Corruption Network -EHFCN, Co-Chair of the AI WG EHFCN team, Co-Chair of the RWE & AI HTAi sector.

- Lilian Mitrou, Professor, Department of information & Communication Systems Engineering, University of the Aegean.

- Alexandros Nousias, AI Law & Ethics, Researcher in Responsible and Reliable AI at NCSR 'Demokritos', Institute of Informatics and Telecommunications, AI Ethics Lead Assessor – IEEE.

- Fereniki Panagopoulou, Supreme Court Lawyer, Assistant Professor of Constitutional Law, Data Protection Law and Bioethics at Panteion University.

- Elena Petelos, Lecturer and SRF, Maastricht University and University of Crete, European Public Healthcare Association: Vice-President HTA, HTAi: Co-Chair: RWE and Artificial Intelligence.

- Chrysanthi Sardeli, Obstetrician-Gynecologist, Clinical Pharmacologist, Associate Professor of Pharmacology-Clinical Pharmacology, School of Medicine, Faculty of Healthcare Sciences, Aristotle University of Thessaloniki, Ethics Expert, Directorate-General for Research and Innovation, EC.

- Nicholas Christodoulou, Associate Professor of Psychiatry, Faculty of Medicine, University of Thessaly, Director of the University Psychiatric Clinic of Larissa General Hospital, Secretary, World Psychiatric Association, Section of Disaster.

ANEX II

Scientists and stakeholder representatives invited to the hearings

The hearings on May 30, 2023 were attended by:

- Niki Tsouma, President of the Board and Chief Executive Officer, e-Government Center For Social Security (IDIKA S.A.).

- Giorgos Vasilopoulos, Professor at the University of Thessaly, Hellenic Society of Hematology.

- Dr. Chrysanthi Sardeli, Obstetrician-Gynecologist, Clinical Pharmacologist, Associate Professor of Pharmacology-Clinical Pharmacology, Aristotle University of Thessaloniki, Ethics Expert, EC.

- Nicholas Christodoulou Associate Professor of Psychiatry, Faculty of Medicine, University of Thessaly.

The hearings on June 28, 2023 were attended by:

- Christos Daramilas, Biologist, MSc, President of the Panhellenic Federation of Associations of People with Diabetes Mellitus.

- Anastasios Samouilidis, Lawyer/Public Affairs Officer of the Greek Patients' Association.

- Maria Gazouli, Professor of Biology-Genetics-Nanomedicine, Medical School, National and Kapodistrian University of Athens.

- Pantelis Natsiavas, Researcher at the Institute of Applied Biosciences.

A written memorandum was submitted by:

- Konstantinos Vougas, Founder & CEO DeepMed IO Ltd, Staff Research Scientist, IIBEAA.