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REPORT

Artificial Intelligence in Health

Authors: Takis Vidalis, Vasiliki Mollaki, Theodoros Trokanas

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Neofytou Vamva 6, PC 10674, Athens

Tel. (+30) 210- 88.47.700, Fax (+30) 210- 88.47.701

E-mail: secretariat@bioethics.gr, url: www.bioethics.gr

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1. Introduction

Artificial intelligence (AI) is a rapidly growing technology expected to impact our lives and future significantly. The development and evolution of digital technologies, combining data management and connectivity, offer numerous benefits at various levels, such as public administration, health, entrepreneurship, and security. However, implementing AI poses significant challenges to ensuring democracy and protecting fundamental human rights. Addressing these challenges and establishing an ethical and legal framework for using AI will determine the maximum exploitation of its benefits in a safe way while respecting human rights.

According to the European Commission's original definition of AI, "Artificial Intelligence (AI) refers to systems that demonstrate intelligent behaviour by analysing their environment and taking actions - with some degree of autonomy - to achieve specific goals."[1] In other words, AI systems are designed by humans and have the ability to perceive and interpret data from their environment to make optimal decisions, replicating human cognitive functions such as learning, planning, and decision-making.

Within the expansive discipline of AI, there exist a multitude of approaches and techniques like: a) machine learning, such as deep learning and reinforcement learning; b) machine reasoning, which involves the design, programming, knowledge representation and reasoning, search and optimisation; and c) robotics, which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems.[2]

This Report aims to review the health AI applications in Greece, analyse the ethical issues arising from the use of AI, review the regulatory framework and frame proposals with the goal to create a socially acceptable framework for implementing these systems.

[1] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe, Brussels, 25.4.2018 COM(2018) 237 final.

[2] A definition of Artificial Intelligence: main capabilities and scientific disciplines. The European Commission's High Level Expert Group on Artificial Intelligence. Brussels, 18 December 2018.

2. AI in Health

AI and data analysis promise to revolutionise the health sector, with applications potentially covering the entire spectrum of biomedicine, as well as individual and public health. Looking at the growth of published articles on PubMed, a biomedical literature database, we see a significant increase from 300 articles in 1991 to 59,596 articles in 2021.[3] An exhaustive review of the scientific literature in the PubMed and Embase databases indicates that Artificial Iintelligence (AI) is predominantly used for diagnostic purposes, with COVID-19 being one of the most common diseases studied, while China, the United States of America, South Korea, the United Kingdom, and Canada appear to be publishing the most articles in AI-enabled research.[4]

In broad outline, AI's influence is expected to be decisive in four main categories: 1) clinical practice, 2) biomedical research, 3) public health, and 4) health management.[5] In more detail, AI is already applied or can be applied in various fields of biology and medicine, such as:[6,7,8,9,10,11,12]

- -omics technologies (genomics, transcriptomics, proteomics, metabolomics),
- systems biology,
- disease modelling,

[3] Sardanelli, F., Castiglioni, I., Colarieti, A. et al. Artificial intelligence (AI) in biomedical research: discussion on authors' declaration of AI in their articles title. Eur Radiol Exp 7, 2 (2023).
[4] Hulsen T. Literature analysis of artificial intelligence in biomedicine. Ann Transl Med. 2022 Dec;10(23):1284.
[5] European Parliament, The impact of Artificial Intelligence on the doctor-patient relationship, Report commissioned by the Steering Committee of Human Rights in the fields of Biomedicine and Health (CDBIO), Author: Brent Mittelstadt, December 2021, p. 1.
[6] Athanasopoulou, K.; Daneva, G.N.; Adamopoulos, P.G.; Scorilas, A. Artificial Intelligence: The Milestone in Modern Biomedical Research. BioMedInformatics 2022, 2, 727-744.
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[12] Aung YYM, Wong DCS, Ting DSW. The promise of artificial intelligence: a review of the opportunities and challenges of artificial intelligence in healthcare. Br Med Bull. 2021 Sep 10;139(1):4-15.

- modelling the development of organisms or organs,
- discovering new or repositioning existing drugs/molecules,
- disease diagnosis -especially with imaging methods,
- disease prognosis,
- patient follow-up ,
- choosing more effective treatments,
- public health emergencies management,
- procedure management and management optimisation,
- decision and health policy making,
- precision medicine,
- clinical trial support,
- telemedicine,
- robotic surgery,
- biosensors (mobile phone applications, wearable systems, implants) intended for use by doctors or patients themselves;
- human brain study and neuroscience, etc.

In some cases, the use of AI in health is at an advanced stage, as evidenced by AI systems already approved by the US Food and Drug Administration (FDA),[13,14,15] many of which mainly concern radiodiagnostics and oncology, but also haematology, cardiology, neurology, ophthalmology, gastroenterology and microbiology. At the same time, the European Medicines Agency (EMA) has issued a positive opinion on the use of an AI-based technique (PROCOVA),

[13] Benjamens, S., Dhunnoo, P. & Meskó, B. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an onlinedatabase. npj Digit. Med. 3, 118 (2020).
[14] FDA: Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices . Accessed 23/06/23.
[15] Athanasopoulou, K.; Daneva, G.N.; Adamopoulos, P.G.; Scorilas, A. Artificial Intelligence: The Milestone in Modern Biomedical Research. BioMedInformatics 2022, 2, 727-744.

leading to smaller and shorter clinical trials.[16]

Interestingly, clinical trial data registries list thousands of clinical trials in which AI systems are already being tested at the clinical level in humans. Indicatively, the ClinicalTrials.gov registry has registered more than 1,400 clinical trials using AI,[17] in seven of which Greek institutes/entities are also involved.[18]

2.1 AI applications in Health in Greece

Various Greek institutes/entities are actively involved in multiple AI research programs. The CORDIS database of the European Commission has documented over 83 research projects related to AI in the healthcare sector, which have received EU funding.[19] Table I provides a list of research projects using AI and data analysis for various purposes such as disease diagnosis, precision medicine, public health management, drug repositioning, robot assistant development and more, involving (or coordinated by) Greek research institutes/entities. Table II outlines the Greek research institutes/entities participating in ongoing clinical trials involving AI. Finally, Table III presents AI applications and systems already used by private or public hospitals and private companies in the health sector.

[16] Clinical Trials Arena: EMA qualifies Unlearn's AI-driven approach for smaller trials. Accessed 23/06/23.
[17] ClinicalTrials.gov: Search with the keyword «Artificial intelligence». Accessed 23/06/23.
[18] ClinicalTrials.gov: Search with the keyword «Artificial intelligence» and «Greece». Accessed 23/06/23.
[19] Commission database of EU-funded research and innovation projects (CORDIS). Search with the keywords «Artificial intelligence» and «Healh» and «Greece». Accessed 30/06/23.

Table I. Indicative research projects using AI in Health, involving Greek research institutes/entities.

Research project	Scope/ Target Areas	Greek Institutes/entities
COMFORT	Urological cancer diagnosis and treatment	Aristotle University of Thessaloniki (AUTh) University of Patras (UoP)
IASIS	Precision medicine in lung cancer and Alzheimer's disease	National Center for Scientific Research "Demokritos" Athens Technology Center SA
BigMedilytics	Public health and chronic diseases management	National Center for Scientific Research "Demokritos"
P4-LUCAT	Precision medicine in lung cancer	National Center for Scientific Research "Demokritos"
KATY	Precision medicine in cancer	Health Policy Institute National and Kapodistrian University of Athens (NKUA)
ProCAncer-I	Prostate cancer platform	Center for Research and Technology HELLAS "Agios Savvas" General Anticancer - Oncology Hospital of Athens ADVANTIS Medical Imaging Single Member PC (ADVANTIS)
INCISIVE	Cancer diagnosis and prognosis	Center for Research and Technology HELLAS National and Kapodistrian University of Athens (NKUA) Aristotle University of Thessaloniki (AUTh)
HOMESMARTAI	Digital transformation of the European healthcare sector	Aristotle University of Thessaloniki (AUTh) AHEPA - University General Hospital of Thessaloniki
Alameda	Personalised Rehabilitation Therapy Assessments for Parkinson's, Multiple Sclerosis, and Stroke Patients	University Research Institute of Communication and Computer Systems (ICCS) National and Kapodistrian University of Athens (NKUA) Enora Innovation Center for Research and Technology HELLAS
SIMPATHIC	Drug repositioning	National Center for Scientific Research "Demokritos"
RADIO	Robots in assisted living environments for the elderly	National Center for Scientific Research "Demokritos"
Flagship Action for SARS-CoV-2	Development of domestically innovative molecular and immunological methods to address the SARS-CoV-2 pandemic and further promote COVID-19 research in Greece	National and Kapodistrian University of Athens Biomedical Research Foundation of the Academy of Athens (BRFAA) Hellenic Pasteur Institute (HPI) Biomedical Sciences Research Center "Alexander Fleming" National Center for Scientific Research "Demokritos" Centre for Research and Technology Hellas (CERTH) Aristotle University of Thessaloniki (AUTh) University of Crete Foundation for Research and Technology - Hellas (FORTH)

		University of Ioannina
smartHEALTH	Smart health services (data analysis, precision medicine, health monitoring)	Foundation for Research and Technology - Hellas (FORTH)
PHOOTONICS	Diabetic foot diagnosis and monitoring	National Technical University of Athens EXUS SOFTWARE
ONCODIR	Bowel cancer prevention	Centre for Research and Technology Hellas (CERTH) Ministry of Health Central Macedonia Regional Development Fund University Research Institute of Communication and Computer Systems (ICCS) EXUS SOFTWARE Aristotle University of Thessaloniki (AUTh)
ONCOSCREEN	Bowel cancer prevention and diagnosis	EXUS SOFTWARE University Research Institute of Communication and Computer Systems (ICCS) National Centre for Research and Technological Development (CERTH Ministry of Health Hellenic Society of Gastrointestinal Oncology (HSGO)
REA	Personalised Virtual Agent with interactive abilities through voice and non-voice interaction to monitor and support people with mobility impairments	Centre for Research and Technology Hellas (CERTH) ENTRANET Research and Development of Sprrch Recognition Applications Ltd (ENTRANET) EL.V.I.S. Private Capital Company (ELVIS) Evexia Rehabilitation Center S.A. (EVEXIA)
REBECCA	Collection of real-world data to support clinical trials and research in breast cancer	Aristotle University of Thessaloniki (AUTh) Harokopio University Centre for Research and Technology Hellas (CERTH)
RELEVIUM	Improving the quality of life of patients with pancreatic cancer	Centre for Research and Technology Hellas (CERTH) Harokopio University EXUS SOFTWARE
υποστηρίΖΩ	Independent Living Support System for the Elderly	Centre for Research and Technology Hellas (CERTH) FrontidaZois Arx.Net
uPrevent	"Smart" inner shoe sole to prevent foot ulceration in patients with diabetes mellitus.	Centre for Research and Technology Hellas (CERTH) University of Thessaly PolyTech S.A. Biomechanical Solutions
Trials@Home	Remote Clinical Trials	Centre for Research and Technology Hellas (CERTH)

Table II. Greek research institutes/entities participating in clinical trials involving AI.*

Research project	Scope/ Target Areas	Greek Institutes/entities
ASCAPE	Data analysis to support quality of life of cancer patients	Sismanogleio General Hospital
CardioMining-AI	Analysis of electronic health records for cardiovascular diseases	AHEPA University General Hospital of Thessaloniki University General Hospital of Alexandroupolis, Democritus University of Thrace Hippokrateion General Hospital of Athens University General Hospital of Heraklion University General Hospital of Larissa University of Patras Hippocrates - General Hospital of Thessaloniki G. Papanikolaou General Hospital of Thessaloniki AHEPA University General Hospital of Thessaloniki Aristotle University of Thessaloniki (AUTh)
I3LUNG	Precision medicine in lung cancer	Metropolitan Hospital
COVID-19 Clinical Status Associated With Outcome Severity: An Unsupervised Machine Learning Approach	Managing COVID-19 patients based on disease severity	Aristotle University of Thessaloniki (AUTh)
MES-CoBraD	Brain diseases diagnosis and management	Neurological Institute of Athens
DATASET-PRECISE	Precision medicine in patients with coronary artery disease	Lefkos Stavros Clinic National and Kapodistrian University of Athens (NKUA) Aristotle University of Thessaloniki (AUTh)
FUZE clinical trial	Treatment of solid tumors	Laiko General Hospital of Athens "Sotiria" Thoracic Diseases Hospital of Athens "Alexandra" General Hospital of Athens University General Hospital of Ioannina

*Source: clinicaltrials.gov

Table III. AI applications and systems used by Greek institutes/entities and companies in the health sector.

Application/system	Scope/ Target Areas	Greek Institutes/entities
Precision Medicine Hellenic Network	Health services to cancer patients and promotion of cancer research in Greece	Centre for Research and Technology Hellas (CERTH) Biomedical Research Foundation of the Academy of Athens (BRFAA) National Centre for Scientific Research "Demokritos" Foundation for Research and Technology Hellas (FORTH) National Hellenic Research Foundation (NHRF) Biomedical Sciences Research Centre "Alexander Fleming" University of Crete Athena Research Center Hellenic Pasteur Institute (HPI) National and Kapodistrian University of Athens (NKUA) Aristotle University of Thessaloniki (AUTh) G Papanikolaou General Hospital of Thessaloniki Hellenic Cancer Federation (ELLOK)
IBM Watson for Oncology	Cancer precision medicine platform	Hygeia Group
ERICA	Prognostic software for embryo prioritisation based on implantation capacity	Institute of Life - IASO
Medi ON	Real time detection and evaluation of symptoms	INTERAMERICAN INSURANCE
DeepPath™ – LYDIA	Assisted diagnosis for pathologists	DeepMed IO
AI system for heart hypertrophy	Diagnosis of heart hypertrophy	Ippokrateio General Hospital of Athens
VARA PLATFORM	Breast screening	MITERA Hospital
Digital Dermatoscopy System	Skin cancer diagnosis	General Hospital of Sitia
AI in anesthesiology	Use of ultrasound in anesthesiology	“Agios Andreas” Hospital
SymbIASIS	Integrating digital and other innovative solutions in the health system, connecting hospitals and start-ups	National Documentation Centre, National and Kapodistrian University of Athens (NKUA)
HelloAI RIS initiative	Educational activities for medical students	EIT Health

Based on the data above, it seems that in Greece, AI is predominantly used for research purposes rather than clinical applications. The above AI research programs and applications utilise different approaches, such as machine learning or machine reasoning, and differ in technology levels, ranging from fundamental data analysis to knowledge reasoning. Additionally, they vary in autonomy and the level of human control involved, resulting in differing impact and consequent ethical and social implications.

3. Ethical issues

3.1 Transforming the traditional doctor-patient relationship

The traditional doctor-patient relationship is presumed to be transformed into a new doctor-patient-artificial intelligence relationship.[20] First of all, although AI systems promise greater effectiveness in providing medical care (e.g., reducing the cost of care or waiting lists, filling existing coverage gaps, freeing health professionals from tasks such as data entry, and so on), it is feared that these may ultimately degrade the quality of health service delivered, insofar as they involve less personal contact between doctors and patients.[21] Moreover, using AI systems in healthcare may undermine the traditional doctor-patient relationship by widening the distance between them. More specifically, it is argued that understanding a patient's health will be based more on objective representations of data, with measurable sizes and mechanically interpretable terms, setting aside critical contextual factors, such as the patient's well-being, social, mental or emotional state.[22] Furthermore, it is believed that doctors' reliance on AI systems will affect valuable development, maintenance and implementation skills but also standards of good practice by health professionals, a phenomenon described in the international literature with the term "de-skilling".[23] Equally important is the ethical and legal challenge related to the responsibility of health professionals using AI systems, given the obligation to comply with

[20] European Parliament, The impact of Artificial Intelligence on the doctor-patient relationship, Report commissioned by the Steering Committee of Human Rights in the fields of Biomedicine and Health (CDBIO), Author: Brent Mittelstadt, December 2021, p. 7.
[21] p. 4, 44.
[22] p. 6, 51-52.
[23] p. 53.

professional duties, responsibilities and standards as required by Article 4 of the Oviedo Convention.[24]

3.2 Data management and safety-security

The development of AI applications in Health services faces issues at two main levels: a) at the level of managing critical big data, which allows the development of appropriate algorithms to support either clinical or research applications, and b) at the level of application safety, so that they can be trusted by treating doctors, health staff and especially patients or end-users of healthcare services in general.

At the **first level**, the main problem, in terms of ethics and law, lies in the management of personal data. Individual issues may also arise from the management of other categories of data that feed into the algorithms, in particular those linked to intellectual property rights or population data, the misuse of which may lead to discrimination. However, personal data are the subject of special attention, as, on the one hand, their use in Health services is necessary (especially sensitive data related to the genetic identity and health status of the person) and, on the other, their direct control by their subjects is an essential dimension of their overall autonomy.

Although the value of 'informational self-determination' has been highlighted for decades and detailed arrangements for the protection of personal data have been elaborated internationally, the specific difference in algorithms that can support AI applications, lies in the significant amount of personal data, as well as in the degree of complexity in managing it. These two features raise questions as to:

- Whether the consent of the data subject is in any case necessary to enable their collection and processing to such a large extent
- Whether the established methods of personal data protection (pseudonymisation in particular) or even the collection without the identity of the subjects (anonymous data)

[24] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164).

are sufficient when the processing is carried out in a "big data" environment.

These questions presuppose an answer to a preliminary ethical question: *whether or not the value of personal data outweighs the values of collective interest.* In the case we are examining, algorithms that can support AI applications are thought to serve the value of public health by improving certain services provided to the public.

At the **second level**, the safety-security of applications, the initial ethical issue concerns evaluating benefits/risks before their introduction into medical practice and healthcare services in general.

The approval of such schemes by the competent authorities should be conditional on the determination that the potential risks fall significantly short of the expected benefits. By "risk", one means any possible harm to the patients' goods or rights, therefore not only damage to their health but also any breach of their personal data (e.g. due to incomplete confidential management provisions during the development of the relevant software) with all that this may entail for their personal and social life (e.g. in employment, insurance, education, etc.). This broad concept of "risk" is rrelatively unknown in conventional medical applications (e.g., in drugs), so there is no safe "analogue" to assess an acceptable "threshold" for evaluating applications in the process of their approval. This means that, in this case, a margin of uncertainty remains as to the potential risks, necessitating the application of the *precautionary principle,* as accepted today by legislation and science ethics. According to it, the risk uncertainty situation justifies reasonable precautionary measures, including not approving an AI application, until the likelihood and nature of the actual risk have been specifically tested so that its significance can be assessed against the benefits. This control could adopt organisational models of "laboratory" testing of applications under conditions of simulation of actuals events, such as e.g., regulatory sandbox models[25]. Clinical trials of AI systems can initially ensure an objective benefit-risk assessment (similar to what happens in drugs and medical devices).

The transparency of the AI applications' operation is also a serious ethical issue - given their technological complexity – and, even more so, the introduction of machine learning applications.

[25] See European Parliament press release 14/6/2023.

In the latter, the models' multilevel structure, the algorithm's automatic adjustment, and the constant supply of new data make it difficult for both the user and developer to control the application's operation, turning models into "black boxes". The introduction of such "uninterpretable" AI systems in Health may cause safety issues that are not preventable, but also issues of determining the responsibility of the user (doctor and nursing staff) insofar as (beyond a point) the control of the application is objectively limited. When using more straightforward applications, it's vital to ensure that patients have access to understandable information so that their consent is valid when used by their doctor. "Understandable" information is related to the level of familiarity of the non-expert public with the use of digital technology, which is not self-evident to a large part of the population. Possibly, initiatives of digital literacy focusing on citizens (by the State or private entities) may limit the problem in the future, but today's reality makes it difficult to implement informed consent procedures, that is, conscious acceptance of an AI application by the average patient. On the other hand, “understandable” information does not presuppose the technological training of the layperson: patients are asked to consent to medical procedures, being aware of the actual benefit they can expect and the potential risks to which they may be exposed. In this sense, a qualified doctor can explain the use of even a technologically advanced application, ensuring conditions of valid consent for his/her patient. Perhaps, therefore, the target audience of digital literacy should be the users of the applications as a priority, i.e. doctors and medical staff.

3.3 Basic Principles

The introduction of AI applications should aim to best serve the individual and social right to Health, taking into account the following basic principles.

The *Principle of Beneficence*, according to which a technological application in clinical practice must guarantee a specific benefit for individual health. Therefore, any risks to the patient must be prevented promptly and, in any case, be less important than the expected benefit.

The *Principle of Safety,* which mandates that strict quality criteria must be met before the relevant authorities can approve any application. These quality criteria should follow internationally recognised standards. In this context, safety should not be limited to health risks

alone but should be extended to other aspects that concern individuals, such as protecting their personal data.

The (related to the previous) *Precautionary Principle*, in which a situation of uncertainty as to potential risks entails protective measures, including withdrawing the application from the clinical practice.

The *Principle of Transparency* which imposes measures to ensure that the user (doctor or healthcare professional) and the recipient of the services (patient or not) understand how an application works.

The *Principle of Justice*, according to which access to technologically advanced applications that promise a documented specific health benefit must be ensured by a national health system for all without any economic, ethnic, racial, or other discrimination. A more particular aspect of justice concerns the protection of workers (especially in health administration) whose employment is to be replaced by AI applications. These workers must have the opportunity for appropriate training to move to other jobs without seeing their standard of living being affected.

The *Principle of Autonomy*, according to which any AI application in clinical practice must be subject to the patient's consent after being informed in an understandable way of the benefits and potential risks. Patients must, in any case, retain the right to choose between conventional and technologically advanced methods in the context of the medical care provided.

The *Principle of Accountability* which requires that a specific person (doctor, healthcare professional, administrative officer) is always responsible for the occurrence of negative results, especially from the application of AI in Health services, even in complex machine learning systems.

The *Principle of Complementarity of AI*, in the sense that AI-enabled health applications should not completely substitute human judgment and, therefore, decisions in the healthcare setting should be validated by trained health professionals.[26] Otherwise, the impact of AI systems

[26] Council of Europe, Recommendation 2185 (2020), Artificial intelligence in health care: medical, legal and ethical challenges ahead, Text adopted by the Standing Committee, acting on behalf of the Assembly, on 22 October 2020, under 12.5. European Parliament, The impact of Artificial Intelligence on the doctor-patient relationship, Report commissioned by the Steering Committee of Human Rights in the fields of Biomedicine and Health (CDBIO), Author: Brent Mittelstadt, December 2021. p. 7.

in the health sector is complicated to assess.

4. The law

Following the comments of the European Parliament,[27] the new EU AI Act is now expected to be soon adopted. The Act will be the first binding legislative text on the subject at the supranational level. It will set the basic framework for the national legislation of the Member States. Although its validity is direct in the domestic legal order, its provisions leave a wide margin for regulation to the national legislator, according to the standards adopted by the GDPR. For the time being, however, Law 4961/2022 *("Emerging Information and Communication Technologies, Strengthening Digital Governance and Other Provisions")* has already been enacted in our national law, some provisions of which establish a first outline of substantive regulations (in particular concerning the transparency obligations of entities using AI systems and the obligations of AI system contractors).

It should be noted, however, that, at the level of international law, there are already soft law texts on AI, adopted from 2017 onwards by UNESCO,[28] the Council of Europe[29] and the OECD.[30] The above texts have provided some fundamental guidelines for future binding legislation based on specific principles. Although their content remains general, it is expected that these guidelines a) will be adopted in any relevant legislative initiative, and b) in any case, these texts will be essential tools for interpreting the binding provisions of the Act, which must be taken into account by national legislators.

Important guidelines of these texts concerning health issue are, among others:

- Ensuring proper risk assessment, transparency and interdisciplinary cooperation when

[27] European Parliament (press release) - AI Act: a step closer to the first rules on Artificial Intelligence (11/05/2023).
[28] UNESCO: Recommendation on the Ethics of Artificial Intelligence (2021).
[29] CoE: Recommendation of the Committee of Ministers to member States on the human rights impacts of algorithmic systems (2020), Declaration of the Committee of Ministers on the manipulative capabilities of algorithmic processes (2019), Recommendation of the Parliamentary Assembly of the Council of Europe on Technological convergence, artificial intelligence and human rights (2017).
[30] OECD: Recommendation of the Council on Artificial Intelligence (2019).

developing such applications and establishing appropriate control mechanisms.

- Maintaining human oversight and control of every AI application.
- Respecting fundamental rights when designing AI systems, including assessing their impact on these rights, preventing discrimination and deterring mass surveillance and social scoring applications. Compliance with fundamental rights requirements is particularly emphasised in some texts as an obligation for private sector actors involved in the research, development and commercialisation of AI systems.
- Protecting data, the large-scale processing of which is a crucial prerequisite for developing algorithms. A vital part of this data is personal.
- Promoting digital literacy for citizens to be able to understand the critical features of the AI applications' operation while maintaining a degree of control over how automated decisions are made. This control includes the right to object to an automated decision, an objection which must be evaluated by a human being.
- Maintaining human responsibility and accountability for the decisions made by AI systems, even if those in charge do not have direct control over those decisions, i.e., they have not explicitly programmed the relevant applications (e.g., in machine learning systems).
- Protecting vulnerable individuals and groups to the extent that their care is linked to using AI systems, including the right to choose such use.
- Preventing the use of AI from causing targeted damage to people's property, or making decisions involving the life and death of persons.
- Distinguishing between supporting the freedom of thought and thought manipulation through algorithms, which should lead to developing methods to prevent the risk imposed by the latter.

These guidelines are of particular importance when the legislator is asked to specify the levels of risk provided for by the new Act and, consequently, when the competent authorities are asked to evaluate specific applications based on the latter.

At present, however, the main issues related to Health AI applications are regulated by general rules of law. In particular:

4.1 Data collection for algorithm development

In this regard, a) scientific data that intellectual property rights may cover and, b) personal data are critical.

In the first case, the general rules for the protection of rights (TRIPS Convention, Law 2121/1993, Law 1733/1987 and a series of EU Directives, as in force) apply in our country, under which, in principle, data cannot be used without the permission of the copyright, patent holder, etc. In the latter one, the provisions of the GDPR apply - as specified by Law 4624/2019.

At this point, we must distinguish between personal data already collected and stored for other purposes (e.g. clinical, insurance, etc.) and new data required to feed the algorithms. A (broader) consent is always needed for new data after informing the data subject. For the mainly interesting category of existing databases, the legislation already allows the possibility of secondary use without new consent of the data subject when it comes to purposes of medical interest (especially for public health purposes), provided that technical and organisational conditions for the protection of confidentiality are respected (in particular data pseudonymisation, impact assessment, etc.). In this respect, and in view of the social right to Health (art. 21 para. 3 of the Constitution), legislation may allow access to data collections of public services, hospitals, private health units, insurance agencies or companies, etc.

4.2 Safety issues of applications

According to applicable law, the doctor treating the patient is responsible for the safety of the applications. This responsibility is governed by different provisions in criminal, civil, and disciplinary law. Additionally, the Code of Medical Ethics (CME) outlines the standards for good medical practice and the information that must be communicated to patients.

The use of AI applications in clinical practice depends on the fulfilment of safety criteria (as to the validity of the results yielded by the algorithm) based on a specific assessment. This

assessment may be carried out by a public body (at EU or national level) or by a certification body (accredited by the State). If specific legislation establishes these in medical practice, the doctor must only notify patients about using AI applications during the informed consent process. Alternatively, if the use of specific AI applications is included in internationally recognised medical protocols, with the corresponding implementation effectiveness documentation published, it can be accepted in clinical practice, even without particular legislation, as described above, as long as the doctor informs patients about it and they consent.

This arrangement can guarantee that AI is used within the framework of good medical practices in compliance with the CME and general laws. However, doctors are still accountable for the use of these applications. Therefore, "automated" decisions regarding medical procedures do not absolve them of their personal relationship with the patient.

The safety of AI applications in healthcare is also related to consumer protection laws. These laws hold both the doctor (as a special service provider) and the application manufacturer accountable, emphasising the latter's responsibility to program and maintain proper software functionality (taking mainly into account its use by healthcare professionals). In this case, too, the provision of specific criteria and mechanisms for assessing the quality of applications, either by a public body or a certification body accredited by the state, is considered necessary.

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