

## **Artificial Intelligence in healthcare: Problems and prospects of ethical and legal regulation**

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**Abstract:** The main problems and prospects for ethical and legal regulation of artificial intelligence in the field of healthcare have been researched. It has been stated that artificial intelligence is one of the promising directions in medicine, its implementation will make it possible to analyze significant amounts of information about patients from different databases, which, as a result, will contribute to both saving time and the accuracy and timeliness of prescribing or adjusting treatment. The issues of the legal nature of artificial intelligence, the main legislative acts at the national and international level, which regulate activities in this direction, have been considered. The European Union (EU) draft of Artificial Intelligence Act, which provides for the classification and regulation of an artificial intelligence program based on its potential risk, has been analyzed, its main tasks and requirements for EU member states have been outlined. It has been found that Ukraine is also taking part in the implementation of this bill (the sandbox regulator “was launched”, a working group on the legal regulation of artificial intelligence was created in the National Bar Association of Ukraine). The issues of legal personality of artificial intelligence, protection of the right to privacy in the process of functioning and operation of artificial intelligence have been

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considered. The basic ethical principles of using artificial intelligence in medicine and the main legal aspects of introducing artificial intelligence into the healthcare system have been determined. Attention is focused on the need to regulate native legislation that governs activities in this field, because namely the lack of clear legal regulation of these issues contributes to both rapid technological development in this direction and the emergence of risks that will be accompanied in connection with its popularization.

**Keywords:** artificial intelligence, medicine, legislation, ethical principles, protection of the right to privacy, databases

## **Introduction**

One of the promising directions in medicine is the further introduction and development of artificial intelligence, which has a wide range of applications (prevention, diagnosis, treatment, monitoring and forecasting the course of diseases, development of medicines, as well as their individual selection taking into account the characteristics of a particular patient, genetic research and etc.). Artificial intelligence systems help automate routine processes in hospitals, accelerate them and make them more efficient. This applies to the visualization of various medical images - ultrasound, CT scans, MRI scans. Smart bracelets that are capable of reading a person's vital signs, sending data to a doctor's email and calling an ambulance in cases where it is necessary are quite common today. We should note that since 2016 in the United States of America, companies such as Amazon, Siemens and IBM, have been using artificial intelligence systems, collecting data and processing information and thereby making significant progress in diagnosing skin cancer, sometimes even faster and more efficiently than doctors. In December 2022, there was a scientific breakthrough in the field of reproductive human rights - the Ecto Life company introduced the world's first installation for artificially infants cultivation (the functionality of one artificial intelligence installation includes: bearing up to 30 thousand infants per year; tracking the development of a child; providing notification of any possible deviations, monitoring this process using a mobile app by future parents) (Solution of fertility problems, 2022).

The concept of "artificial intelligence" was first used in 1956 at a conference at Dartmouth College in the United States of America, the main goal of which was to develop computer systems capable of performing tasks that typically require human intelligence. Artificial intelligence is the ability of engineered systems to acquire, process and

apply knowledge and skills (ISO/IECTR 24028, 2020). Nicholas J. Schork notes that artificial intelligence—machine learning, neural network designs, and a wide range of related methods that can be used for searching relevant patterns in vast sets of data (Nicholas J. Schork 2019, 267).

The implementation of artificial intelligence will make it possible to analyze significant amounts of information about patients from different databases, which, as a result, will contribute to both saving time and the accuracy and timeliness of prescribing or adjusting treatment. This, in turn, will lead to a gradual transition of the healthcare sector from a reactionary to a preventive and prophylactic level. In this context, the scientific thoughts of Alan Turing are reasonable: “artificial intelligence is a premonition of the future...” (Androshchuk G.O. 2021) and Yu. Tyuri: “the use of such technologies makes it possible to increase the efficiency and productivity of any processes, helps strengthen competitiveness ... and improves well-being of citizens” (Tyurya Yu. 2022, 145).

At the same time, the presence of obvious advantages of the further implementation of artificial intelligence systems in the healthcare sector also implies corresponding risks that will certainly be accompanied in connection with their popularization.

### **Legal foundations for the use of artificial intelligence in healthcare**

Artificial intelligence is a new challenge for the legal system and the economy, a new phenomenon that has a multiplying effect, a legal phenomenon in the structure of legal relations, a new object of legal regulation (Androshchuk G.O. 2021, 60). As for Ukraine, “the legal regulation of social relations related to the use of artificial intelligence is at the initial stage of its development” (Anishchenko M., Gidenko I. 2023, 66). Certain aspects of this concept are enshrined in the Law of Ukraine “On the Protection of Personal Data” (requirements for the processing of personal data - collection, storage, use, transfer and protection). In December 2020, the Concept for the Development of Artificial Intelligence in Ukraine (hereinafter - Concept) was approved, which defines the goal, principles and tasks of the development of artificial intelligence technologies in Ukraine as one of the priority directions in the field of scientific and technological research (Concept for the Development of Artificial Intelligence in Ukraine, 2020), and also identifies the issues (absence/imperfection of legal regulation of artificial intelligence (education, economics, public administration,

cybersecurity, defense), imperfection of legislation on the protection of personal data, lack of application of these technologies in judicial practice).

It should be noted that in April 2021, the European Commission, in order to create a safe environment for the operation and development of artificial intelligence, developed the Artificial Intelligence Act, which provides for the classification and regulation of an artificial intelligence program based on its potential risk. Among the key tasks of this bill: determining the risk levels of artificial intelligence systems (hereinafter - AIS); introduction of mandatory certification for certain AIS; establishing requirements for certain AIS to inform users that they are interacting with an artificial intelligence system and not a human; introduction of uniform rules for working with artificial intelligence technologies; ensuring security and compliance with current legislation; providing legal certainty to facilitate investment and innovation in artificial intelligence; promoting the development of a unified market for legal, safe and reliable programs using artificial intelligence (AI Act, 2021).

In order to check whether artificial intelligence systems truly comply with the standards, the requirements of the bill stipulate that EU member states must create appropriate authorized bodies that will both conduct conformity assessment and carry out control in this direction. As we can see, the main goal of the Artificial Intelligence Act bill is to create an environment in which "... users can be confident that their rights will be protected, and the developer or supplier of the artificial intelligence system will bear responsibility for negative consequences" (Artificial Intelligence, 2023).

It is expected that the document will come into force no earlier than 2026 and, accordingly, will affect the legal regulation of artificial intelligence in Ukraine, since Ukraine is a candidate country for the EU.

It should be noted that Ukraine is currently taking part in the implementation of this bill, in particular, the sandbox regulator has been "launched" for developers of artificial intelligence programs. As G. Rumyantsev, state expert of the Directorate of European and Euro-Atlantic Integration in the Ministry of Digital Transformation of Ukraine, notes: "... this is a controlled environment within which development companies will be able to develop their product at the initial stage so that it takes into account the requirements of the future act of the European Union" (Artificial Intelligence, 2023).

In addition, the National Bar Association of Ukraine has created a working group on the legal regulation of artificial intelligence, the main tasks of which are to analyze the legal issues of the development and functioning of artificial intelligence, determine the boundaries of its use in various industries, protect personal data collected by artificial intelligence systems (develop an algorithm for their storage and use).

Continuing, we note that in accordance with the Concept for the development of e-healthcare dated December 28, 2020 No. 1671-p and the Action Plan for its implementation dated September 29, 2021 No. 1175-p, as well as the Action Plan for the implementation of the Concept for the Development of Artificial Intelligence in Ukraine for 2021-2024 dated May 12, 2021 No. 438-p the main directions are the implementation and development of personalized medicine, telemedicine, systems for forecasting healthcare needs, as well as resource planning using artificial intelligence technologies. The directions have been defined, however, the creation of an appropriate regulatory framework is not provided for, which, as a consequence, will lead to legislative gaps and will negate "... all the positive aspects from the implementation of artificial intelligence technology into the national healthcare system" (Anishchenko M., Gidenko I. 2023, 67).

In addition, the legal personality of artificial intelligence has not yet been enshrined at the legislative level. The legal personality of artificial intelligence is one of the current topics in jurisprudence. According to Tim Mulgan, there are several main approaches (concepts) to determining the legal personality of artificial intelligence:

- exclusive legal personality (granting the status of a subject of law only to a person);
- minimal inclusivity (artificial intelligence is considered as an autonomous agent);
- moderate inclusivity (artificial intelligence as an autonomous agent or a legally capable agent without legal personality);
- full inclusivity (recognizes artificial intelligence as a person with legal personality similar to human) (Mulgan T. 2018).

Reasonable in this context is the scientific thought of N. Martsenko "... the use of artificial intelligence technologies in fields such as medicine... encourages of thinking about the extension of the legal regime of a source of increased danger to this object of civil rights. Which, as a result, will contribute to better protection of the rights of users of artificial intelligence technologies" (Martsenko N. 2019, 96).

At the same time, when operating and implementing its activities, artificial intelligence can cause harm to both individuals and public relations. Due to the fact that today “artificial intelligence is not recognized at the legislative level as a subject of legal relations, responsibility for its actions must be taken by the person under whose leadership certain actions were performed (Cerka P., Grigiene J. 2015). In addition, we believe that the legal regulation of the activities of artificial intelligence must be regulated with mandatory consideration of the risks of its use.

We are impressed by the scientific opinion of Kenneth Davis, Jr., Francois, A. Camin Murray, who highlight ten legal aspects of the introduction of artificial intelligence into the healthcare system: legislative and regulatory requirements; ethical considerations; compensation; contract law; torts; antimonopoly legislation; employment and labor issues; confidentiality and security risks; intellectual property; compliance programs (Kenneth Davis, Jr., Francois 2021).

### **Ethical principles for the use of artificial intelligence in healthcare**

The World Health Organization has defined the basic ethical principles for the use of artificial intelligence in medicine, which should become the basis for further regulatory and legal frameworks:

- the principle of protecting human autonomy (protection of privacy and confidentiality, obtaining validated informed consent to protect personal data, the use of artificial intelligence should not violate human autonomy);
- the principle of human well-being and safety, as well as public interests (artificial intelligence technologies should not harm humans, developers must take into account regulatory requirements for safety, accuracy and effectiveness for clearly defined cases or indications);
- the principle of ensuring transparency, understandability and legibility (artificial intelligence technologies should be transparent and understandable for developers, healthcare professionals, patients, users and regulatory authorities; ensure responsibility for the use of artificial intelligence in appropriate conditions and by properly trained people);
- the principle of ensuring inclusiveness and equality (artificial intelligence mechanisms should be intended to encourage broad and equitable access and use) (Ethics and Governance of Artificial Intelligence, 2021).

To improve the effectiveness of the application of the above principles, it is necessary to legislatively regulate the contractual obligations of relations in connection with the development and use of artificial intelligence mechanisms for medical purposes, because it is extremely important for both the developer and the medical provider who use it to have clear contractual terms governing the sale and use artificial intelligence technologies. According to O. Rossilna, contractual terms should include: expectations for technical services (definition of efficiency indicators that will be satisfied); guarantees (the developer must define guarantees for the buyer); compensation for damages (the developer and the buyer must determine the procedure for allocating risks); insurance (due to the fact that services provided through using artificial intelligence technologies have associated risks, the buyer has the right to insure his business) (Rossilna O. 2022, 160).

### **Protection of private information in the application of artificial intelligence in healthcare**

The issue of protecting the right to privacy in the process of functioning and operation of artificial intelligence in the healthcare sector is quite relevant at the moment, because medicine is quite closely connected with the accumulation and processing of significant volumes of “sensitive” information. Article 32 of the Constitution of Ukraine defines: “The collection, storage, use and dissemination of confidential information about a person without their consent are not allowed, except in cases determined by law, and only in the interests of national security, economic well-being and human rights” (Constitution of Ukraine, 1996). Human rights to protection their personal data are provided for by the Law of Ukraine “On the Protection of Personal Data” (Article 1,2). Article 39-1 of the Fundamentals of Ukrainian Legislation on Health Care also enshrines the patient’s right “to confidentiality about the state of their health, the fact of seeking medical help, diagnosis, as well as information obtained during their medical examination” (Law of Ukraine, 1992). According to the Convention for the Protection of Rights and Fundamental Freedoms, “... the right to health is also the right to information and confidentiality of information” (Article 8) (Convention for the Protection of Rights and Fundamental Freedoms, 1950). For example, in the decision of the European Court of Human Rights dated August 27, 1997 in the case of “M.S. v. Sweden”, it is noted that confidentiality of health information is a basic principle of

the legal system of the member states. “Personal data, ... as well as health-related data.... cannot be subject to automated processing unless native law provides appropriate guarantees” (Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, 1981).

It should be emphasized that in May 2018, the General Data Protection Regulation (GDPR) came into force, which defines the rules for the collection, processing and storage of personal data in the European Union. The GDPR interprets health data as a “special category” of personal data that is considered to be “sensitive” by nature, and establishes a higher level of protection for its processing. This document defines standards for the protection of “sensitive” information, and also increases the responsibility for the protection of private information, including for developers of artificial intelligence systems. Thus, in France, Clearview AI company (a developer of facial recognition software using artificial intelligence) received significant fines due to the illegal use of private information. According to the Office for the Protection of Personal Data in France, Clearview AI uses private information without the legal consent of users and at the same time there is no legitimate interest for such collection, which is a serious violation of the GDPR (Artificial Intelligence, 2023).

Thus, the development of artificial intelligence systems must be carried out taking into account the principles of legality, consent, limitation of data processing and compliance with the requirements of the GDPR for their protection. In addition, current native legislation must provide appropriate guarantees for the protection of private information, even though the functioning of artificial intelligence systems involves working with large databases.

## **Conclusion**

To summarize, we note that despite the fact that the implementation of artificial intelligence in the healthcare sector has great prospects, it is not without its problems. First of all, native legislation needs additional regulation. After all, it is the lack of clear legal regulation of these issues that contributes to both the rapid technological development in this direction and the emergence of risks that will certainly be accompanied in connection with its popularization. It is necessary to legislatively provide for increased responsibility and accountability when using artificial intelligence technologies in the healthcare sector of Ukraine.



In addition, the implementation of artificial intelligence in medicine involves interaction between software developers, medical professionals, technology experts and lawyers. When developing artificial intelligence algorithms, it is necessary to establish the ability to provide clear, accurate and effective recommendations and standards for well-defined cases or medical indications. Indeed, ensuring transparency and accountability in the process of application of artificial intelligence should be a priority in promoting legal and ethical practices in the healthcare sector.

In our opinion, the use of artificial intelligence in healthcare management is very promising. This greatly reduces or even eliminates corruption risks. For example, carrying out large purchases of medical equipment and medicines using blockchain technologies with the subsequent conclusion of smart contracts, establishing disability and selecting for leadership positions in healthcare institutions using artificial intelligence. All this will contribute to integrity and transparency, strengthening the principles of democracy and human rights in the healthcare sector.

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