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ETHICAL PRINCIPLES FOR THE CREATION AND APPLICATION OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES IN HEALTHCARE**

Albina A. Shutova, Ildar R. Begishev
Kazan Innovative University named after V.G. Timiryasov, Kazan, Russia

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The subject of the study is the norms of current legislation regulating the creation and application of artificial intelligence technology in healthcare, including acts of technical regulation, as well as available scientific research by domestic and foreign scientists in the field presented. In recent years, foreign experts have conducted a significant amount of research on the development of ethical principles for the use of artificial intelligence in healthcare. However, these works tend to be abstract and do not explain what justifies and justifies their recommendations and how these recommendations should be used in practice. In turn, in the Russian Federation at the moment there is a small number of domestic studies devoted to a comprehensive study of ethical principles that should guide subjects engaged in the creation and use of medical devices based on artificial intelligence technologies, which confirms the relevance and significance of our research.
Objective: to develop a system of ethical principles for the creation and application of artificial intelligence technologies in the field of healthcare, which will serve as the basis for the legal regulation of public relations in the presented area.
Methods: the methodological basis of the system of ethical principles for the creation and application of artificial intelligence technologies was made up of general scientific and private scientific methods of scientific cognition, including analysis, synthesis, deduction, induction, classification, analogy and comparison.
Results: to the attention of lawyers, scientists and practitioners, medical professionals, members of clinical ethics committees, medical ethics specialists, representatives of law–making bodies, government departments, the business community and public organizations, patients, as well as a wide range of readers interested in the digital transformation of the healthcare system, ethical principles for the creation and application of artificial health technologies are proposed intelligence in healthcare, which can serve as the basis for the formation of an appropriate system of legal regulation. The stated goal has been achieved, which is confirmed by the development of a system of ethical principles that serve as the basis for the development of a system of legal regulation of artificial intelligence technologies in healthcare. The developed ethical principles can be used to further improve domestic legislation, and also lay the foundation for further research.

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1. Introduction

With the accelerated digitalization of all aspects of social life, the healthcare sector, undoubtedly, has not been left behind and has also become susceptible to the artificial intelligence technologies introduction into clinical practice and science. In some areas of medical diagnostics, medication development, and treatment, including surgery, artificial intelligence may be better than trained medical professionals. Due to the rather new nature of the said end-to-end technology, a lot of questions arise, including those related to the legal assessment of the action of the systems and those who will be responsible in case of harm [1, p. 129].

However, like practically every digital technology, artificial intelligence expands its capabilities in medicine so much (from assessing the risk of a patient developing the disease and the selected treatment effectiveness to assisting in treating patients and automating health care institutions) that legal regulation cannot with the appropriate effectiveness influence the emerging social relations and form a legal regime. We believe that this state of affairs cannot be considered satisfactory. Digital innovations in medicine offer great hopes, but their implementation in healthcare requires appropriate regulations that minimize the associated risks and threats.

As the normative regulation of artificial intelligence technologies will entail drastic changes in the current legislation, we propose to formulate and consider ethical principles that can serve as a basis for the creation and development of the system of legal regulation of artificial intelligence technologies in healthcare.

The number of ethical principles of artificial intelligence, standards and recommendations thereof developed by international organizations, state and research establishments has significantly increased, leading to their scientific comprehension [2, p. 178] and creating a discussion. Experts distinguish four principles of biomedical ethics related to the development and application of artificial intelligence systems in medicine [3]. Despite the available targeted studies devoted to the ethical principles of artificial intelligence technology application in foreign countries [4, p. 750], they are not comprehensive or systematic; their subject composition is not sufficiently clear. We tried to solve this problem in this study. Foreign authors distinguish six key ethical characteristics: fairness, transparency, reliability, accountability, confidentiality, and empathy; they are considered important and emphasized in the works devoted to artificial intelligence in healthcare [5, p. 1090; 6, p. 5520; 7, p. 360; 8, p. 495].

2. General provisions

Before artificial intelligence technologies can be used in healthcare, we must ensure that technology developers and medical organizations comply with the relevant ethical norms and rules when creating and applying these technologies in clinical practice.

It seems that, based on the significant number of subjects involved in the creation (development) and implementation of medical devices based on artificial intelligence technologies, ethical principles should permeate two large groups of subjects in compliance with a certain stage of the artificial intelligence life cycle:

1. ethical principles of the subjects involved in the creation of medical devices based on artificial intelligence technologies;

2. ethical principles of the subjects involved in the application of medical devices based on artificial intelligence technologies.

At present, one can state that artificial intelligence systems in healthcare (intelligent medical technologies, i.e. those based on artificial intelligence) are used in the Russian Federation:

1. as computer software (hereinafter – software) with the use of artificial intelligence systems, in which case the software is registered as a medical device;

2. artificial intelligence may be a component and/or accessory of a medical robot, in which case the robotic device is recognized as a medical device. Then the software is not registered, but is considered an integral part of the medical device.

If artificial intelligence systems are software, they are recognized as a medical device. The above is confirmed by the legislative definition of the term

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"medical device" contained in the Federal Law of November 21, 2011 No. 323-FZ "On the bases of health protection of citizens in the Russian Federation"[1], where specialized software is referred to a type of medical devices.

That is why we believe that medical devices based on artificial intelligence technologies should be developed, produced and used exclusively for the objective of providing medical care to the population [9, p. 10].

The ethical principles of applying artificial intelligence technologies in healthcare provide clear moral guidelines for the professional activities of medical workers, are designed to promote consolidation, increase confidence in digital technology, increase the credibility of medicine and medical activity in general, as well as the development of medicine in Russia and around the world.

3. Ethical principles for the creation of artificial intelligence technologies in healthcare

In our opinion, the important ethical principles, underlying the legal regulation of the creation of medical devices using artificial intelligence technologies in healthcare, should be the following:

3.1. The principle of creativity. Medical devices based on artificial intelligence technology should be aimed at benefiting society and citizens [10]. We believe that such digital products should not be used solely to benefit and enrich a particular organization. This principle also raises a problem that threatens society after the development of artificial intelligence technology – the problem of social divide. All over the world, with every advancement, discovery or invention, people face increasing social inequality and decreasing social justice. Although digital technologies generally improve access to information about science, global events, climate change, and politics around the world, they exacerbate social inequality increasing the gap between developing and developed countries [11].

This principle implies a wish to ensure that medical devices equipped with artificial intelligence technology contribute to the well-being of patients and society as a whole, stimulating its sustainable development.

3.2. The principle of safety. Developers of medical devices equipped with artificial intelligence technology must constantly monitor all artificial intelligence tools in medicine to ensure that they work properly and do not cause harm to a particular patient. Some experts emphasize the issue of safety of medical devices based on artificial intelligence as the most important one [8, p. 45].

The introduction of medical devices based on artificial intelligence technologies into everyday clinical practice should follow the principles of evidence-based medicine, using the methods of verification of their work reliability. Clinical trials of medical devices equipped with artificial intelligence technology, involving humans as research subjects, should be conducted in accordance with ethical principles that ensure the rights, safety and well-being of people, including those based on the World Medical Association Declaration of Helsinki[2].

3.3. The principle of algorithmic transparency. Artificial intelligence technologies should be understandable to developers, healthcare professionals, patients and regulators in relation to the use of solutions, trust in them and the underlying data.

Medical devices based on artificial intelligence should be designed so that they may explain the findings and allow healthcare professionals to interpret the results.

Undoubtedly, human-induced bias is intentionally or unintentionally created by developers, as humans are always influenced by their own moral perceptions and relevant interests. This affects data training [13] and in general negatively influences the quality and effectiveness of the medical care provided. In turn, from a legal and

[1] Federal Law of November 21, 2011 No. 323-FZ "On the bases of health protection of citizens in the Russian Federation". *Collection of legislation of the Russian Federation*. 2011. No. 48. Art. 6724.

[2] World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. URL: https://gkb81.ru/ki-docs/md/helsinki-declar.pdf

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ethical point of view, bias may entail discrimination or violation of individual rights [14, p. 46].

Sufficient information should be published or documented prior to the development or deployment of artificial intelligence technology. Such information should contribute to discussions about how the technology is developed and how it should or should not be used.

3.4. The principle of equality and non-discrimination. Artificial intelligence algorithms should be trained on a sufficient set of complete and representative (unbiased) data. The occurrence of bias in decision-making algorithms, including discrimination [15] on social, sexual, ethnic, religious grounds, should be avoided and possible ways of avoiding bias should be used.

Medical devices based on artificial intelligence should be subject to randomized clinical trials, which is the strongest source of medical evidence.

3.5. The principle of responsibility. It is the responsibility of stakeholders to use medical devices based on artificial intelligence technology for the intended purpose and within the stated conditions. All cases of incorrect operation of artificial intelligence systems should be recorded and further monitored to consider bringing to liability.

Professional activity of medical personnel is aimed at treating patients; on the other hand, it is associated with harm to the patients' health in case of unskilled work of medical workers [16, p. 110], including those who use artificial intelligence technologies in their work.

3.6. The principle of post-registration monitoring. After medical devices equipped with artificial intelligence technology are registered and placed on the market, their safety should be monitored, in order to identify and prevent side effects or adverse reactions that may occur during their use.

For example, monitoring can be carried out by the Federal Service for Supervision of Healthcare. If information about adverse reactions is confirmed, the Service will develop a program of measures aimed at improving the safety of such medical devices. If the manufacturer fails to take the necessary measures, the Service will make a decision to withdraw the medical device equipped with AI technology from circulation.

3.7. The principle of controllability. Medical devices based on artificial intelligence technologies shall be subject to strict control for compliance with safety and reliability requirements.

Artificial intelligence technologies must be subject to regulatory oversight that covers the design, customization and operation of algorithms [17].

4. Ethical principles for the application of artificial intelligence technologies in healthcare

4.1. The principle of creativity. The overriding principle permeating the technology and stating that medical professionals must use medical devices equipped with artificial intelligence technology solely for the objective of providing medical care to patients.

4.2. The principle of safety. This principle states that the use of medical devices based on artificial intelligence technologies must be reliable and safe, and the results obtained must not be aimed at causing harm to the life and health of patients and other legal interests.

4.3. The principle of prohibition of full automation. The final decision on treatment (diagnosis, prescription of treatment) must be made by a medical professional and after discussing it with the patient, taking into account their condition, medical history, available options, preferences and existing risks.

Medical devices based on artificial intelligence technologies will facilitate diagnosis and treatment decisions made by healthcare professionals, but will not replace them entirely as such computer systems are vulnerable to cybersecurity threats. Human beings must be able to override and/or prevent legally relevant decisions and actions of artificial intelligence systems where reasonably applicable.

4.4. The principle of a patient's voluntary informed consent. This principle stipulates that medical professionals and medical organizations are obliged to inform the patient about the benefits of using medical devices equipped with artificial intelligence technology, while enquiring for the patient's consent.

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The doctrine of patients' voluntary informed consent should be based on the following principles:

– provision of reliable information about the medical manipulation (intervention);

– disclosure of objective information about the patient's health and condition;

– voluntary consent of the patient;

– ensuring informed disclosure of information;

– provision of information about relevant risks and potentially harmful consequences.

A medical professional must provide reliable data on how the technology works and explain the relationship between the individual patient's data and the data set that the algorithm uses for training. Medical workers must inform the patient of the right to reject the use of artificial intelligence technologies.

Experts point out that patients have the right to be informed about their diagnosis, health status, treatment process, therapeutic success, test results, costs, share of health insurance, and other healthcare information, and any consent must be specific to each objective, be provided freely and unambiguously. Concerns about this matter have also increased with the growing use of artificial intelligence in healthcare applications [18].

Medical professionals are prohibited from coercing a patient into using artificial intelligence technology. A medical worker must ensure that the patient is satisfied with the information they receive.

Assumingly, patients come into contact with doctors at times in their lives when they are most vulnerable; it is important to bear this in mind [19]. Healthcare professionals are prohibited from coercing a patient to use medical devices based on artificial intelligence technology unless it is absolutely necessary.

4.5. The principle of informing about criminal risk. Medical professionals must assess the risk of using medical devices based on artificial intelligence technologies related to the patient's disease and proposed treatment. The risks of cybersecurity attacks in medicine, which may lead to inaccurate or false diagnoses, or the administration of lethal doses of medication, must be communicated to the patient. After informing the patient about the possible risks and before starting treatment, a medical professional must obtain the patient's consent to continue the treatment option and include this information in the patient's informed consent. I.A. Filippova points out that the threat to the security of brain implants (neurochips) will be a consequence of the spread of neurotechnologies in practice, which will create a problem of ensuring the security of persons using neurotechnologies. In general, digital crimes can be committed in order to obtain information on bank accounts or to manipulate a neuroprosthesis to harm a third person [20, p. 42].

4.6. The principle of ensuring patient's confidentiality and privacy. Artificial intelligence allows analyzing large amounts of data (big data) in real time, providing forecasts that may support doctor's decisions [21].

Patient's personal data collected while providing medical aid with artificial intelligence technology shall not be transferred without the patient's consent or if required or permitted by law.

If personal data are shared or otherwise used for AI research, they must be anonymized so that the patient's identity cannot be reconstructed.

Experts note a significant number of threats that arise from personal data processing, which requires increased attention and control by the state. For example, it is pointed out that clinical data collected by robots can be hacked and used for malicious objectives, eliminating privacy and security [22].

4.7. The principle of patients' rights protection. Patients should understand that their rights and freedoms are protected against the unlawful use of medical devices based on artificial intelligence technologies that do not meet the medical care standards.

If medical devices based on artificial intelligence technologies are used in accordance with applicable standards and cause harm to people or damage property, medical professionals shall not be responsible for the incident.

The occurrence of negative consequences shall be minimized through efforts that are commensurate with the expected consequences of these risks. A healthcare professional shall have the

right to protection of their rights and interests.

4.8. The principle of empathy. Medical professionals are obliged to provide appropriate and competent medical care to patients with understanding, concern and respect for their health status, as well as their rights and freedoms. Medical professionals should assume that artificial intelligence technology lacks contextual knowledge and the ability to read social feelings, so a medical worker shall remain the most important party in communication with a patient.

4.9. The principle of transparency and explainability. When using medical devices based on artificial intelligence technologies, a medical worker must be able to interpret the basis on which the result was achieved, weigh the possibility of algorithmic bias, and make a clinical judgment about the results obtained. One should agree with foreign experts who believe that trust in the work of artificial intelligence algorithms and the ability to interact with them will increase patient's confidence necessary for joint decision-making. Moreover, the model transparency helps to clarify the issues of moral and legal liability in case of errors [23, p. 20].

4.10. The principle of stimulating technological development. It consists in the fact that healthcare organizations and their heads should seek to encourage and incentivize the design, implementation and development of safe and ethical AI technology solutions for healthcare. It is also necessary to provide financial stimuli for medical professionals to be interested in mastering artificial intelligence technologies and information science in medicine.

5. Conclusions

Undoubtedly, each principle of creation and application of artificial intelligence technologies deserves a separate study, as presented in the work by Yu. S. Kharitonova, whose significant publication is devoted to the study of the principle of transparency of artificial intelligence [24, p. 340].

In the present work, we have just succinctly outlined a system of ethical principles that can serve as a starting point for the transformation of legal regulation of the said relations in the Russian Federation.

The formulated principles of creation and application of artificial intelligence technologies, in our opinion, may generally contribute to the growth of public confidence in digital technologies in medicine.

One should agree with those authors who believe that any digital technology as an object of research is a complex phenomenon, comprising various technological, ethical and legal aspects [25, p. 106].

The application of these ethical principles by the medical community and developers of medical devices based on artificial intelligence technologies until a relevant and effective system of legal regulation of digital technology is created will strengthen the authority of medical professionals, increase patients' confidence in artificial intelligence technologies, and prevent potential negative consequences.

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INFORMATION ABOUT AUTHORS

Albina A. Shutova – PhD in Law; Senior Researcher, Institute of Digital Technologies and Law; Associate Professor, Department of Criminal Law and Procedure
Kazan Innovative University named after V.G. Timiryasov
42, Moskovskaya ul., Kazan, 420111, Russia E-mail: shutova1993@inbox.ru
RSCI SPIN-code: 5235-4319; AuthorID: 835100

Ildar R. Begishev – Doctor of Law, Associate Professor, Honored Lawyer of the Republic of Tatarstan; Chief Researcher, Institute of Digital Technologies and Law; Professor, Department of Criminal Law and Procedure
Kazan Innovative University named after V.G. Timiryasov
42, Moskovskaya ul., Kazan, 420111, Russia E-mail: begishev@mail.ru
RSCI SPIN-code: 8859-9395; AuthorID: 595003

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