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ARTIFICIAL INTELLIGENCE IN HEALTHCARE: LIMITS OF CRIMINAL LIABILITY OF DOCTORS**

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Artificial intelligence technologies are changing the medical care provision, which corresponds to a new healthcare paradigm.

The subject of the study is regulatory legal acts, including subordinate (departmental) ones, acts of technical regulation, statistical data, doctrinal provisions, and Internet resources on the problems under investigation and crimes committed by medical professionals.

The purpose of the article is to form a conceptual legal framework for the introduction of artificial intelligence technologies in healthcare. This includes defining the limits of liability of medical professionals who use intelligent systems while providing medical care. For the introduction of artificial intelligence to have only a positive impact on the healthcare system with minimal risks and threats, it is necessary to develop standards and procedures of medical care using intelligent systems. There is a need to develop a clear legal framework for the use of intelligent systems in medical sphere to ensure patient safety and confidentiality, while preserving the potential of artificial intelligence as an assistant. In this article, the author examines the specifics of using artificial intelligence in medical practice, including issues related to the personal responsibility of a doctor when making decisions about diagnosis and treatment based on the proposal of an algorithm (a medical decision support system).

Methodology. Using the method of legal analysis and the comparative legal method, the author analyzes the existing trends in the distribution of liability for harm in the provision of medical care in cases of an error and/or inaccuracy in making a medical decision. The article demonstrates possible future options for the distribution of responsibility between a medical organization and a medical professional. The paper systematizes approaches to legal regulation and criminal legal protection of public relations that arise if a medical professional provides assistance using artificial intelligence systems.

The results of the study. The main results and conclusions suggest that medical professionals must always have control over artificial intelligence systems when implementing them. Doctors should be able to reasonably trust the digital tools at their disposal, notice signs of error in such systems, and timely take a new course of action. This should be reflected in the standards of medical care using with artificial intelligence technologies as the responsibility of a medical professional. In addition, the author proves that it is necessary to include the rights and obligations regarding the use of intelligent systems in medical practice in the documents regulating medical care and job descriptions of doctors. The article forms models of the distribution of doctor's responsibility for harm caused to the life and health of patients in connection with the use of intelligent systems.

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1. Introduction

Digitalization has a tremendous impact on the healthcare system and its legal framework. This is confirmed by the adoption of numerous regulations governing the specifics of providing medical care and other areas of this field using digital technologies¹. In addition, the Decree of the Russian Government No. 959-r, dated April 17, 2024, approved the strategic direction in the field of digital transformation of health care. It should be noted that it is the strategic direction that has been approved, and not the strategy itself in the field of digital transformation of healthcare, which indicates the need for a special strategy consisting of a variety of strategic initiatives covering all areas of the medical industry. The integration of artificial intelligence has great potential for revolutionary changes in patient care and treatment outcomes [1]. *Brainphone* company uses artificial intelligence technologies to detect Parkinson's disease by voice and speech, as well as disorders of the speech muscles based on voice analysis. Artificial intelligence systems can view brain scans of people suffering from memory loss and determine who will develop Alzheimer's disease².

¹ See, for example, Decree of the Russian President No. 254 dated June 6, 2019 "On the Strategy for the Development of Healthcare in the Russian Federation for the period up to 2025". Collection of legislation of the Russian Federation. 2019. No. 23. Art. 2927; Decree of the Russian President No. 309 dated May 7, 2024 "On the National Development Goals of the Russian Federation for the period up to 2030 and for the future up to 2036". Collection of legislation of the Russian Federation. 2024. No. 20. Art. 2584; Decree of the Russian Government No. 1640 dated December 26, 2017 "On Approval of the Russian State Program 'Healthcare Development'". Collection of legislation of the Russian Federation. 2018. No. 1 (Part II). Art. 373.

² An accurate technique to forecast Alzheimer's disease is developed. URL: Law Enforcement Review 2025, vol. 9, no. 3, pp. 144–153

Many works have been devoted to the impact of artificial intelligence technologies on healthcare and the legal regulation of public relations in this sphere. Among the specialists dealing with the problems of introducing intelligent systems into medicine, it is worth noting the works of I.R. Begishev [2; 3], P.S. Gulyaeva [4], L. V. Ladochkin [5], P. M. Morkhat [6], E. E. Chernykh [7], and B. A. Shakhnazarov [8]. The problems of distributing responsibility when using digital technologies in medicine were considered in the works of A. R. Atabekov [9], A.V. Afanasyevskaya [10], E. P. Tretyakova [11] and E. E. Chernykh [12]. However, the options for distributing responsibility of medical professionals in regulatory documents on healthcare provision using digital technologies have not been studied.

One should not underestimate the risks of digital technology. A. A. Melnikov points out that algorithms can miss a neoplasm on an X-ray image, suggest the wrong dose or an irrelevant drug [13, p. 78]. There may be malfunctions in the operation of an AI robot, solved by disabling it and installing troubleshooting software [14, p. 964]. According to O. S. Erakhtina, patient registration, processing and analyzing of medical data, and automatic notification of medical personnel can be classified as a limited risk [15, p. 426]. There are threats of privacy violation and discrimination [16, p. 410]. Important are the issues of technology usefulness for the doctor and safety for the patient [17]. Inaccurate artificial intelligence algorithm can lead to incorrect decisions made by the doctor, causing harm to the patient's life and health. It is necessary to understand which actions of doctors, mediated by the use of artificial intelligence technologies, entail criminal liability and what regulatory prospects exist, before the use of intelligent systems can become part of the

<https://lenta.ru/news/2021/09/05/neuro/> (access date: 12.07.2024).

medical care standards.

2. Subjects of criminal liability: issues of bringing to liability

Many subjects are involved in developing and applying medical devices based on artificial intelligence technologies; therefore, it will be problematic for law enforcement agencies to identify the direct cause of harm to the patient's health or life due to negligence and will require computerized and technical expertise. Harm can be caused due to a software failure, as a result of maintenance, the actions of doctors, or an artificial intelligence algorithm [18]. Conducting an expert examination during the investigation will allow identifying the subject, whose actions (inactions) caused negative consequences [19, p. 116]. Doctors will not be criminalized for the quality of products; conversely, algorithm developers will be responsible for the quality of products, but not for the improper performance of professional duties by a medical professional, which led to the death of a patient by negligence. Technology manufacturers are responsible for creating accurate algorithms, ensuring patient safety and confidentiality, but not for improper performance of doctor's duties [20]. Today, intelligent digital services cannot completely replace the doctor [21]. The current level of artificial intelligence development excludes its criminal liability and requires a transformation of criminal legislation.

3. Artificial intelligence systems in medicine: technical regulation

In order to ensure that the use of artificial intelligence systems in medicine is safe, the standardization process has begun in Russia in 2022 and many technical regulation acts have been adopted since then. For example, on January 1, 2025, GOST R 71738-2024³ began to

³ GOST R 71738-2024 Artificial intelligence systems in radiation diagnostics. Algorithms for analyzing medical images. Testing methods for the ability and stability of working with heterogeneous

operate, which defined methods for testing artificial intelligence systems for the ability and stability of working with heterogeneous data in radiation diagnostics. The Russian national standards can be classified into the following types: the standards that should be followed when preparing an artificial intelligence system for state registration as a medical device⁴; the standards used in testing algorithms⁵; the recommended standards for launching artificial intelligence systems for healthcare⁶. While such technical regulation acts mainly concern the actions of developers, the legal assessment of the actions of doctors using such systems causes questions.

4. Use of artificial intelligence systems by doctors: normative regulation

Medical professionals are held liable for negligent infliction of harm to life or serious harm to the health of patients as a result of

data.

<https://protect.gost.ru/v.aspx?control=8&baseC=6&page=3&month=1&year=-1&search=&RegNum=1&DocOnPageCount=15&id=252123&pageK=409E4052-A325-4C2E-9749-9EF3DBFCE8DB> (access date: 02.01.2025).

⁴ For example, GOST R IEC 62304-2022. Medical products. Software. Life cycle processes and GOST ISO 14971-2021. Medical products. Application of risk management to medical devices; GOST R ISO/IEC 90003-2014. Software product development. Guidelines for the application of ISO 9001:2008 in the development of software products.

⁵ For example, GOST R 71674-2024. Artificial intelligence systems in clinical medicine. A data set in DICOM format for testing algorithms. Methods for depersonalizing a data set and controlling a data set for the absence of personal data, GOST R 59921.9-2022. Artificial intelligence systems in clinical medicine. Algorithms for data analysis in clinical physiology. Testing methods. General requirements.

⁶ For example, GOST R ISO 9127-94. Information processing systems. User documentation and packaging information for consumer software packages.

improper performance of professional duties (Part 2 of Art. 109, Part 2 of Art. 118 of the Russian Criminal Code⁷). Undoubtedly, the judicial investigative authorities are to establish a direct causal relationship between the doctor's deed while providing medical care and the consequences that have occurred; they also must determine which standards and procedures for providing medical care, as well as clinical recommendations, the doctor had violated. For example, if a doctor chooses a treatment that does not meet the medical care standards, as a result of which the patient dies, then the doctor's actions contain signs of a crime provided for in Part 2 of Article 109 of the Russian Criminal Code. The documents regulating medical care provision do not mention the use of intelligent systems. The exception is para. 9 of the "Rules for X-ray examinations", approved by Order No. 560n of the Russian Ministry of Healthcare dated June 9, 2020⁸, which allows the use of medical decision support systems. If the standards are developed and the specifics of using artificial intelligence is included in them, then deviation from the requirements of such documents (non-compliance, partial compliance, disregard) can be criminalized. Doctors should know how the law would assign responsibility for injuries resulting from the interaction of algorithms and practitioners, and law enforcement agencies should know how to apply criminal liability measures to doctors using artificial intelligence technologies and how to qualify their deeds.

⁷ Criminal Code of the Russian Federation dated June 13, 1996. No. 63-FZ. Collection of legislation of the Russian Federation. 1996. No. 25. Art. 2954.

⁸ Order No. 560n of the Russian Ministry of Healthcare dated June 9, 2020 "On approving the Rules for X-ray examinations". Official Internet portal for legal information (www.pravo.gov.ru). September 14, 2020. No. 0001202009140035.

Let us consider possible ways to improve legislation in this area.

4.1. Artificial intelligence systems as an additional source of information for a medical professional

The decision on the use of medical devices based on artificial intelligence remains with the medical organization and the doctor. A similar approach is observed in the "Rules for X-ray examinations" approved by Order No. 560n of the Russian Ministry of Healthcare dated June 9, 2020. The reformed legal regulation of the Russian Ministry of Healthcare will contain the wording "recommended" and "may be used", which allows for a dispositive attitude towards applying intelligent systems. At the same time, the final decision on making a diagnosis, choosing a treatment method, and prescribing medications will remain with the doctor, while the data obtained using intelligent systems will be advisory. Legal acts will require the doctor to check the diagnosis and other decisions formulated by the system. Therefore, in case of adverse consequences, the criminal liability measures applied to a medical professional using digital technologies will remain the same.

The doctor may be guided by the decision support system and the primary diagnosis based on data analysis and prescribe the wrong treatment. If it results in serious harm to the patient's health, the doctor must be responsible for the decision made. This includes the adverse consequences in the form of causing harm to the patient's life or health through negligence. It does not matter if the doctor was guided by the "second opinion" of an artificial intelligence or a colleague; the responsibility lies with the medical organization and the doctor. According to Parts 3 and 4 of Article 80 of Federal Law No. 323-FZ dated November 21, 2011 "On the fundamentals of public health protection in the Russian

Federation”⁹ (further referred to as Federal Law No. 323-FZ), harm caused to the life and/or health of citizens while providing them with medical care shall be compensated by medical organizations. At the same time, compensation for harm and bringing medical organizations to responsibility does not exempt doctors from criminal liability in case of adverse consequences (if there are signs of a crime). Therefore, the regulatory legal acts of the Russian Ministry of Healthcare and the job descriptions of doctors using intelligent systems should state that when performing official duties to provide assistance using intelligent systems, a medical professional must verify the results obtained (data, treatment method, etc.). A provision must be made that ignoring this verification may result in legal, including criminal, liability, if the consequences cause serious harm to the patient’s health or death by negligence. The main legislative norm shall read that the attending physician, and not the artificial intelligence system, organizes timely qualified examination and treatment of the patient, provides information about their state of health (part 2 of Article 70 of Federal Law No. 323-FZ).

Thus, according to the first approach, when considering this category of cases in law enforcement, it is necessary to establish which medical care procedures and standards the doctor applied, regardless of the results of the artificial intelligence functioning. Doctors may use the systems results as an additional source of information about the diagnosis and treatment method.

Due to the digitalization of medicine, doctors’ job descriptions should specify the obligation to verify data obtained using artificial intelligence and responsibility for violating rights

in the field of health protection, as well as causing harm to life and/or health while providing medical care, including using medical devices based on artificial intelligence technology.

Thus, within Model 1, artificial intelligence systems are used as decision support. Hence, for example, a radiologist bears personal responsibility for an adverse outcome after using intelligent systems in accordance with the medical care standards and procedures (regardless of their being guided by the technology decision or their own opinion).

4.2. The use of artificial intelligence systems in medical care provision is mandatory, but the final decision shall be made by a doctor after studying the system’s solution

The decision of the artificial intelligence system is an additional source of information, and the doctor is obliged to justify their disagreement with its conclusions and forecasts. The regulation must define the algorithm of the medical professional’s action in case their opinion about the diagnosis and the choice of treatment method differs from the solution developed by the artificial intelligence system. In case of disagreement with the recommendations of the artificial intelligence system, the attending physician may, for example, convene a council of doctors, mandatorily notifying the chief physician of the medical institution. The problem is that artificial intelligence algorithms cannot be explained, and it can be difficult for doctors to assess whether the system’s diagnosis or recommendations are justified in relation to their own knowledge [22]. Moreover, inexperienced doctors may blindly trust the diagnosis of algorithms [23].

If the Russian Ministry of Healthcare regulations require that a medical professional shall verify the results (data, treatment method) obtained using artificial intelligence technologies, ignoring these regulations may

⁹ Federal Law No. 323-FZ of November 21, 2011 “On the fundamentals of public health protection in the Russian Federation”. Collection of legislation of the Russian Federation. 2011. No. 48. Art. 6724.

entail bringing the latter to legal responsibility. If the doctor's actions involve a violation of the medical care order or standard and it is established that it was these violations that led, for example, to the patient's death by negligence, then the doctor will be considered criminally liable. It should be noted this norm excludes situations when the AI system error was obvious to a medical professional, in which case the doctor must make an independent decision.

4.3. Artificial intelligence systems independently make a diagnosis based on the patient's medical history and data from medical records and make decisions

If regulatory legal acts establish that the artificial intelligence solutions are independent, then a medical professional shall not be made criminally liable in case of an unfavorable outcome. Such an approach will require transforming the entire legal regulation system because it completely eliminates the doctor's position and the medical care provided by doctors. What functionality this doctor will have and how will they participate in the medical care provision if the key decisions remain with the artificial intelligence system? In such a futuristic situation, doctors are not criminally liable in case of a patient's serious injury or death due to negligence, because their official duties (defined by the medical care standards) did not include verifying the diagnosis made by digital technology.

Of interest is the position by T. M. Lopatina, according to which many doctors resort to telemedicine technologies in medical care and counseling. Therefore, if the attending physician agreed with the opinion of the remote medical council, and the patient's health was harmed because of this treatment, then the doctor shall not be criminally liable. "If the doctor had a dissenting opinion, recorded in the patient's medical history, then their guilt should

be questioned. In this case, the responsibility falls on the council members who recommended the wrong treatment tactics" [24, p. 72].

It is worth paying attention to the proposal to introduce insurance for doctors when regulating intelligent systems in the standards of medical care to cover the erroneous use of artificial intelligence in practice [13, p. 80]. There are studies abroad that indicate that doctors cannot interfere with decisions made by artificial intelligence, but must take into account their suggestions and recommendations. In this case, doctors should not be responsible for decisions made by technology [25].

5. Conclusion.

The use of artificial intelligence technologies in healthcare carries a lot of risks. The transformation and development of regulatory norms in this area is a guarantee of minimizing risks and threats [26, p. 134].

Observing the developed technical regulation devoted to artificial intelligence technologies in medicine, one may assume that they can become part of the medical care system (they will be introduced into standards and procedures for healthcare provision). At the moment, medical organizations are deciding on the use of technology as an additional source of information. Doctors remain criminally liable for improper performance of their professional duties involving the use of intelligent systems that have led to serious injury or death of the patient due to negligence, as well as for other crimes. At the same time, the use of artificial intelligence technologies is not defined by standards and procedures for healthcare provision. Consequently, the qualification of the deed will not be affected by providing an incorrect diagnosis or prescribed treatment by a system that has not been checked and evaluated by a doctor. It is the doctor who is personally responsible for examining and treating the patient.

As the limits of liability of both artificial intelligence technologies and a doctor, as well as the procedure for their interaction, have not been legally defined (and it is not clear which way the legislator will follow), experts propose to introduce ethical principles aimed at creating the basis for legal regulation of public relations [3].

We believe that medical professionals should have control over artificial intelligence systems. The possibility for doctors to reasonably trust the digital tools at their disposal, to notice systems' errors, and to adopt a new course of action should be reflected as an obligation in the standards of medical care equipped with artificial intelligence technologies. Doctors should be aware of penalties for the harm to the patient because of the interaction between doctors and algorithms [27].

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