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# Artificial Intelligence in Healthcare as a Driver of Sustainable Development: Ethical and Legal Aspects

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Abstract : Given the fact that AI is developing very quickly and penetrating into many areas of public and state life, the issue of its legal regulation is becoming more and more relevant. In this regard, the need to develop the most optimal model of legal, technical and ethical regulation of the use of artificial intelligence becomes obvious. The most " sensitive " for states , and therefore the priority areas for legal regulation are those where the use of AI is associated with the implementation of constitutional human rights and, in particular, the right to medical care. In this study, the use of artificial intelligence systems to provide medical care in Russia will be considered in three aspects: regulatory regulation, technical regulation, and ethical issues. The purpose of the article was to describe the optimal model of economic and legal regulation of the use of artificial intelligence technologies in the implementation of citizens' rights to medical care, as an element of achieving sustainable development goals. The key results of the study were proposals for optimizing legislation in the field of regulatory, technical and ethical regulation of the use of AI in the implementation of citizens' rights to quality medical care.

## 1 INTRODUCTION

The UN resolution on sustainable development by 2030 contains provisions on universal health coverage and access to quality essential health services for all (Resolution, 2015). Indeed, the quality of life of the population and the sustainable development of territories, along with various economic and environmental factors, are significantly affected by the state of the health care system.

According to the results of a number of studies, the Russian Federation is far from being one of the world's leading countries in terms of the level of medical care for the population (Rating, 2021), which is due to the inequality in the availability of medical care and the shortage of qualified personnel in the regions of a large country.

Digitalization of healthcare, telemedicine and the introduction of artificial intelligence systems into the practice of medical organizations can be used as an effective tool to improve the availability of medical care . In support of this thesis, on April 17, 2024, the Government of Russia approved the Strategic Direction in the Field of Digital Transformation of Healthcare (Order, 2024).

The use of artificial intelligence (hereinafter AI) is becoming an integral part of medical practice, in particular, AI can help doctors in the following activities:

1. Diagnostics.

An example of the use of AI in diagnostics is its application for the analysis of images and pictures (CT, radiography). This kind of software received an impetus for development during the COVID-19 pandemic, when doctors had an urgent need to quickly and efficiently diagnose the presence and stage of lung disease based on the results of computed tomography. Today, programs with AI elements are actively used in Russia that successfully solve the problems of image analysis, in particular, Botkin.AI ( Artificial Intelligence, 2025) , Care Mentor AI» (

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Official website of the company «KAREMENTORAYAI», 2025) .

2. Support for decision making.

This type of AI helps doctors choose the most optimal treatment plan for a patient based on the analysis of data from the patient's medical history; specialized software is capable of anonymizing data and creating a digital profile of patients. An example is the WEBIOMED system (Platform, 2025).

3. Design of medicinal products.

In this case, AI, thanks to algorithms, predicts the structure of proteins in order to predict their folding ("reaction prediction"), which significantly facilitates the search for new drugs and vaccines. The most famous analogue of such a program in the world is the AlphaFold system ( AlphaFold , 2025) .

4. Wearable medical devices.

These are AI systems that are designed to collect, transmit and analyze data on human body parameters due to the fact that the medical device is wearable (rings, bracelets, etc.). Such "gadgets" are useful for diabetics and people with cardiovascular diseases. This area of AI use is actively developing in the Russian Federation, so within the framework of the implementation of the experimental legal regime "Personal Medical Assistants" (Resolution, 2022), on April 13, 2024, the successful results of the experiment on remote monitoring of patients with hypertension and diabetes mellitus using portable devices with AI elements were summed up (EPR, 2024).

In total, according to Roszdravnadzor, at the beginning of 2024, 26 medical products with AI elements were registered in Russia; in addition to the areas listed above , one can note the use of *virtual assistants, predictive analytics systems and assistive surgical robotics by doctors* (Gusev, 2024).

In 2024, the All-Russian Public Opinion Research Center (VTsIOM) conducted a survey of Russians on the use of AI in healthcare. Based on the results of the study (1,600 respondents aged 18 and over were interviewed), VTsIOM came to the following conclusions:

- 43% of Russians believe that the use of AI will lead to improvements in the health of patients;
- men (47%) have a more positive view of AI in healthcare than women (40%);
- only a quarter of respondents (25%) have heard about the successful use of AI in healthcare;
- 4 out of 10 respondents (41%) believe that the use of AI will reduce the number of medical errors ( Neural Network , 2019).

Thus, we see the presence of broad opportunities for the implementation of AI technologies in the provision of medical care (and therefore in the implementation of the relevant constitutional rights of the population), but the widespread use of AI faces certain regulatory, technical, socio-economic and ethical problems, the solution of which requires special attention from scientists and practitioners.

## 2 MATERIALS AND METHODS

In the course of the study, the authors proceeded from a system-integrated approach to the problem under consideration, the goal was to comprehensively dynamically analyze the phenomenon of medical artificial intelligence (AI) in the context of its impact on the achievement of sustainable development goals. The main research methods used in the article are the dialectical-materialistic method, as well as analysis and synthesis, with the help of which the selection of optimal recommendations for selecting an AI regulation model was carried out. An array of regulatory legal acts, technical regulation documents and ethical standards was analyzed by means of the formal-legal method and the method of legal hermeneutics. The methodology of comparative law was used to develop proposals for optimizing the regulatory framework for the use of AI in order to implement the rights of citizens to quality medical care.

## 3 RESULTS

Although trust in artificial intelligence in medicine is gradually growing, there are still a number of barriers to overcome, including:

- low quality of data used in AI training;
- the impossibility of explaining the results of AI work;
- "bias" of the result obtained by AI;
- imperfect regulatory framework;
- undeveloped ethical framework for interaction between AI and humans;
- conservatism of doctors;
- weak digital transformation of medical education;
- poor provision of the regional healthcare system with digital equipment.

In this study, the use of artificial intelligence systems to provide medical care in Russia will be considered in three aspects:

1. Normative regulation.
2. Technical regulation.

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3. Ethical issues.

## 3.1 Normative Regulation

Even the philosophers of Antiquity (Zolotareva, 2019), discussing possible experiments using the first "Machines", asked questions about the management of "non-living" intelligence and reflected on the ethics of its use. However, despite a significant technological breakthrough, all the same aspects of the interaction of "living and non-living matter" cause concern for our contemporaries ( Mindigulova , 2023).

There are quite a large number of works on the topic of artificial intelligence among foreign scientists, the most interesting for us are the works of A. Turing (Turing, 2018), F. Fukuyama ( Fukuyama , 2004), José Ortega y Gasset ( Ortega y Gasset , 1997), George F. Luger ( The Pre - History , 2024) , M. Fromhold- Eisebith , R. Peters ( Fromhold - Eisebith , 2021) , Woo KJ, and C. P. Young ( Woo , 2021) , Nils J. Nilsson ( Nils , 2010) and Crevier D. ( Crevier , 1993).

Russian science also makes its contribution to the study of AI in a wide variety of areas of its application. It is worth paying attention to the analysis of modern trends in the development of AI, reflected in the works of I.Yu. Alekseeva (Alekseeva, 1987), P.M. Gotovtsev ( Gotovtsev , 2020; Guseinov, 2004), B.V. Biryukov (Biryukov, 1985), G.S. Pospelov (Pospelov, 1972), Z.V. Nagoeva (Autonomous formation, 2020) and others.

The controversial aspects of legal regulation of AI, in the context of its legal essence, the consolidation of intellectual property rights and public administration in the era of AI, are considered in the works of P.M. Morhat ( Morhat , 2017), V.V. Blazheev , M.A. Egorova (Legal Regulation, 2020), I.V. Ponkin , A.I. Redkina ( Ponkin , 2018; Ponkin , 2022), R.A. Atabekov (Atabekov, 2023), V.V. Arkhipov, V.B. Naumov, K.M. Smironova (Arkhipov, 2021) A.V. Neznamov (Neznamov, 2019) and A.E. Kirpichev (Kirpichev, 2024), the problems of criminal liability of AI are devoted to the studies of I.R. Begisheva ( Begishev , 2021).

The essence of legal regulation, as is known, is based on the targeted influence of the state, which is built through the provision of rights and the imposition of duties. According to N.I. Matuzov , the legislator in the process of regulation "determines the main areas of activity of members of society, the scope of their social opportunities and social freedom, the scope of what is permitted and not permitted, lawful and unlawful" ( Matuzov , 1972).

When considering the regulation of the use of AI for medical purposes, we must apparently search for and analyze a certain homogeneous group of social relations "linked" to each other by interaction with AI systems. It is obvious that the implementation of legal regulation of a particular area of social relations implies the presence of a certain object and subject of regulation, as well as the identification of a set of methods that will most effectively influence the behavior of participants in legal relations. Defining the subject of regulation in terms of the use of AI immediately encounters the lack of a generally accepted conceptual apparatus, since this issue has not yet found a common understanding in the scientific community.

One of the main barriers to developing a definition is that AI is the object of study of many sciences, including programming, psychology, linguistics, mathematics, physics, physiology, jurisprudence, etc. ( Morhat , 2018). The specificity of the search for a common approach to understanding AI also lies in the fact that the content of this concept is directly related to the need to interpret such ambiguous terms as "intelligence", "artificial intelligence", "cognitive processes", "strong and weak AI", "quality of intelligence" from different angles ( Bostrom , 2016).

It is believed that the first to use the term "artificial intelligence" in their works were American scientists M. Minsky and D. McCarthy, who in the 1950s noted that artificial intelligence is essentially a machine that has been forced to behave like an intelligent person ( McCarthy , 1955).

Considering the ideas of modern scientists, we can distinguish several points of view on understanding AI. Some researchers suggest that AI is any computerized system that can demonstrate signs of intelligence and is capable of rationally solving the tasks assigned to it ( Preparing , 2016) . Others characterize AI as a hypothetical intelligent agent (machine, program) capable of understanding or learning any intellectual task that people can perform (Grinin, 2023).

In science, there is also a more technological approach to characterizing AI, so I.V. Ponkin and A.I. Redkina see artificial intelligence as a complex cybernetic system with a cognitive -functional architecture and its own computing power ( Ponkin , 2018).

Let us also turn to the normative interpretation of the concept of AI, according to the Decree of the President of the Russian Federation No. 490 of October 10, 2019, artificial intelligence is a technological solution that allows simulating human cognitive functions, while it is separately noted here

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that AI allows obtaining, among other things, results that exceed human capabilities (Decree, 2019).

It is also advisable to develop a concept of artificial intelligence used in medicine; such an approach will allow us to more clearly define the area of social relations that need to be regulated by legal, ethical and technical norms. By artificial intelligence in medicine, we propose to understand *the use of software with a certain set of algorithms, in order to collect data on the state of the patient's body for the purpose of their intellectual assessment for the subsequent development of the most optimal treatment and preventive tactics.*

Thus, the subject of legal regulation in the context of the use of AI in medicine will be *a group of social relations associated with the use of intelligent software for the purpose of collecting data on the condition of patients and subsequent evaluation of treatment and preventive tactics for their management* .

As for the methods of legal regulation (methods in this case are understood as a set of techniques and means by which the results of legal influence are achieved), the optimal model for regulating relations involving AI should depend on the goals that the state wants to achieve, as well as the characteristics of the subjects involved and the grounds for the emergence of legal relations ( Boshno , 2014).

The strategic planning document for AI development in Russia is the National Strategy for AI Development until 2030 (hereinafter referred to as the Strategy). This document has established as the main objectives of AI development in Russia the growth of welfare and quality of life of the population. According to the Strategy for AI Development in Russia, a regulatory system should be formed to ensure the safety of all participants in the processes of its development and application. One of the priorities of such a regulatory system should be the protection of human rights and freedoms and the inadmissibility of using AI for the purpose of intentionally causing harm to individuals and legal entities (Decree, 2019).

According to the Strategy, the main principles of regulatory policy in the field of AI development and application should be:

- safety;
- humanism ;
- non-discrimination ;
- risk-oriented approach.

The strategy also establishes the principle of safety, which should form the basis for legal regulation of the area under consideration. In accordance with the principle of safety, artificial intelligence cannot be delegated the making of decisions that can affect human life or health, and responsibility for the consequences of AI's work is always borne by an individual or legal entity, but not by the artificial intelligence itself . We believe that the implementation of this principle in healthcare is possible only on the basis of creating such a mechanism of legal regulation, thanks to which an optimal balance of rights and legitimate interests of patients and doctors will be maintained. At the same time, no technical shortcomings of AI should become the basis for exempting from liability persons guilty of causing harm to the life and health of patients.

Despite the fact that the Decree of the President of the Russian Federation No. 490 in 2019 appeared in a legal vacuum (in terms of AI regulation), it immediately had a positive impact on the development of this technology in our country. We agree with the thesis of A.V. Neznamov that the Strategy for the first time defined a number of important terms, enshrined the basic principles of AI development, and also “highlighted” the main areas for improving the current legislation (Neznamov, 2019).

It is also important that, according to the Strategy for the Development of AI in Russia, legal regulation is being created, thanks to which the development and use of AI will be provided with a favorable investment climate. At the same time, this strategic planning document proclaims the protection of the rights and freedoms of individuals and legal entities involved in working with artificial intelligence systems as a priority.

Despite the positive trends in regulating the AI sector, we note the presence of many unresolved problems:

1. So far, no effective mechanisms for assigning (distributing) responsibility for the “harmful” negative results of AI activity have been developed anywhere in the world.

There are three prevailing views in science on responsibility for AI actions, namely:

- the AI itself (or rather its carrier, as an individual) is responsible for its actions;
- the responsibility lies with the AI carrier, but it is given a status similar to that of a legal entity;
- responsibility lies with the developers, producers and operators of AI.

In this regard, there is also a debate in scientific and professional circles about who should bear responsibility for erroneous conclusions of medical AI that lead to adverse health consequences for patients. Examples of such a situation are the cases recorded in the United States in 2018 (when doctors’ use of the predictive capabilities of an IBM supercomputer led to several incorrect recommendations for the treatment of cancer patients ( Brown , 2018)), or in France in 2020 (when a research group at Nabla discovered that the language model GPT-3 from OpenAI advised patients to commit suicide to alleviate suffering ( Riera , 2020)).

2. The question of the legal status of AI developers, as well as technical intermediaries who support the daily operation of such technologies (providers, service companies), also remains open.

Today, if harm is caused to a patient due to a doctor's error, the victim has the right to seek compensation for harm from a medical organization, which is directly regulated by the Civil Code of the Russian Federation and Federal Law No. 323 (Federal Law, 2011), that is, civil liability for damage caused in the process of providing medical services falls on the medical organization. The doctor also bears disciplinary and criminal liability for his actions (inactions) in certain cases, but the legislation does not directly impose on him compensation for damage caused to the patient.

If artificial intelligence, as well as its developers and technical staff, are implemented into the system of relationships between a medical institution, a doctor and a patient, many questions immediately arise. As E.P. Tretyakova rightly notes, the lack of legal certainty may lead to patients filing lawsuits against doctors and their employers, while those actually responsible for causing damage (developers or exploiters of AI) will remain in the shadows (Tretyakova, 2021).

3. The specifics of using generative AI (language models, chat bots) presupposes the presence of queries entered into the program, thanks to which the machine understands the task set before it. Such queries are called " prompts " (from the English " prompt ") and the correct result of the machine's work often depends on how understandable the prompt is entered for the AI. Thus, in the context of establishing the foundations of legal regulation in the field of medical use of AI, the task of determining the legal nature and classification of prompts is also relevant (Kirpichev, 2024).

4. Unfortunately, today in practice there is a discriminatory approach to the contractual consolidation of rights, obligations and responsibilities between consumers of services and developers of AI systems. As an example of such an approach, we can consider the Agreement (offer) on the use of the GigaChat service (Agreement, 2024) ( a neural network language model developed and operated by Sberbank of Russia).

Thus, there is a clear disproportion in the distribution of responsibility between the user of the AI service and its developers, which is intended to protect the latter from any risks of being held legally liable for using this language model. In particular, clause 7.3. of the Agreement states that the Bank does not provide any guarantees, results of use and compliance with the expectations of the Client (user), and clause 7.7. establishes the full responsibility of the client for all risks associated with the use of AI.

And although, according to paragraphs 3.1.2., 3.1.6. of the Agreement, the use of AI services for the purpose of carrying out illegal activities, as well as for providing medical consultations, is prohibited, unfortunately, compliance with these points is not supported by any legal mechanisms today, in connection with which the risks of self-medication of citizens using neural networks remain quite high.

It seems that the transfer of such discriminatory practices to consumers of medical services is unacceptable, in connection with which not only public-law aspects of the use of AI require special attention from the legislator, but civil-law norms also need to be supplemented.

In our opinion, the solution to the listed problems will be facilitated by a gradual increase in public confidence in AI services used in medicine, which will occur due to an increase in the level of citizens' awareness and their digital literacy. In this sense, we believe it is important to legislatively establish the obligation for patients and their representatives to sign a separate written informed consent for the use of AI systems in the process of their examination and treatment.

In our opinion, the doctor and the patient should have a legally enshrined right to receive up-to-date and reliable information about what kind of AI is used in the process of their interaction. In addition, the regulation of the content of contracts for the provision of telemedicine services and offers for the use of AI systems, which should be regulated by analogy with contracts for the provision of face-to-face paid medical services, is of significant importance for the proper implementation of the right to receive medical care ( Dzhikiya , 2024).

## 3.2 Technical Regulation

The system of legal regulation of AI is built, among other things, on the basis of technical standards, which are designed to establish the specifics of the use of complex technological products, taking into account the regulation of all processes of its life cycle (from design to disposal).

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The foundations of technical regulation and admission of medical devices (hereinafter MD) to the market are laid down by Law No. 323 “On the Fundamentals of Health Protection of Citizens in the Russian Federation” (Federal Law, 2011), as well as the relevant Resolutions of the Government of Russia, which define what a medical device is, what the procedure for its state registration is, as well as the safety parameters of MD, its quality, requirements for clinical trials and much more.

These regulatory legal acts, along with various documents of the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare (Roszdravnadzor), also apply to MI that operate with and/or based on artificial intelligence. Information on duly registered MI with AI elements is posted in the specialized register of Roszdravnadzor (Electronic Services, 2025).

For a long time, in practice, the classification of certain computer programs with AI elements as medical devices caused serious problems, but in 2020, Roszdravnadzor in its letter No. 20-297/20 (Letter, 2020) explained that the following criteria must be used to classify products as medical devices with AI:

- MI is a computer program with AI elements;
- MI is not an integral part of another product;
- the result of the operation of such a product is the automatic interpretation of parameters and a set of data for the purpose of providing medical care.

In turn, Order No. 4n of the Ministry of Health of Russia dated 06.06.2012 approved the classification of computer programs recognized by MI by classes in accordance with the potential risks of their use (Order, 2021).

Despite the existence of a prescribed procedure for testing and registering medical software products with AI elements, for further progressive development and activation of entrepreneurial activity in the area under consideration, scientists propose reducing the duration of clinical trials, introducing post-registration monitoring of programs into practice, and developing quality management systems in Russia among artificial intelligence developers (Gusev, 2021) .

As a guarantee of the safe use of medical devices (including those with AI), the Russian Federation has established a ban on the introduction of unregistered medical devices into medical practice; such violations entail administrative (Article 6.33 of the Code of Administrative Offenses of the Russian Federation) and criminal liability (Article 238.1 of the Criminal Code of the Russian Federation).

An important part of the mechanism for implementing the right to health protection and medical care is also the establishment of technical standards responsible for the safe, effective and scientifically based use of artificial intelligence in the healthcare system (Since January 1, 2025). Standards act as part of the life cycle of MI with AI elements and are designed to guarantee their technical compatibility and reliability.

An example of GOSTs used in work with medical products operating on the basis of AI can be - GOST R 71738-2024 - "Artificial Intelligence Systems in Radiation Diagnostics" or GOST R 71671-2024 - "Systems for Supporting Medical Decision-Making Using Artificial Intelligence" (Standards, 2025). It should be noted that in accordance with Art. 26 of the Federal Law of 29.05.2015 No. 132-FZ (Federal Law, 2015), documents of the national standardization system are used in Russia on a voluntary basis, but we believe that, along with ethical codes (which will be discussed below), GOSTs play a positive role and contribute to the creation of a self-regulation system for the professional community of AI developers.

Thus, in Russia a hierarchy of normative and technical acts is gradually being formed, designed to regulate the specifics of the development, circulation and use of artificial intelligence systems for the implementation of high-tech and safe medical care to the population.

## 3.3 Ethical Problems

Another layer of problems associated with the use of artificial intelligence in general, and specifically in medical practice, is the ethical issues.

The fact is that since the creation of the first AI prototypes, people have been asking themselves whether it is morally and ethically correct to use technology that to some extent replaces humans? Is it really right to hand over cognitive activity to a computer program, the result of which are decisions that are important for small and large social groups?

A person tends to be guided in his actions not only by cold calculation, but also by emotions, conscience, moral and religious principles, but this is precisely the part of mental activity that AI does not possess, at least not yet.

The views of scientists on ethical issues are reflected in many studies, among which the works of S. Nyholm D., Gordon ( Gordon , 2021), V. Muller ( Muller , 2020), and K. Darling ( Darling , 2021) stand out. An important issue for legal scholars is raised by E.V. Skurko and A.R. Atabekov, noting that a global ethical challenge is how the use of AI can affect

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fundamental rights and the transformation of basic legal values (Atabekov, 2024; Skurko, 2021).

If we synthesize the main scientific views on the ethical issues of using artificial intelligence, we can identify the following problems:

1. Ensuring data confidentiality;
2. Moral and ethical responsibility for the actions of AI;
3. Presence/absence of value systems in AI systems;
4. Potential perception of AI as a human.

A fairly large layer of moral contradictions opens up before us if we consider the use of AI to perform socially important functions (nursing care; care for the elderly; care for people with disabilities using robot assistants) that traditionally imply the manifestation of empathy , compassion, as well as taking into account the gender and age characteristics of a person.

Will robots be able to properly understand the elderly and disabled? Is it true that people who are being cared for will interpret the motives of AI? In this context, various aspects of establishing a trusting relationship between the patient and the doctor are relevant, because it is believed that AI is not capable of establishing friendly or amicable relationships, which means that the communication process suffers as a result, and, ultimately, the establishment of the correct diagnosis. Here we should agree with J. Loh, who mentions the tendency of a person to become attached to someone who helps him, including when it comes to robot assistants ( Loh , 2019).

To overcome the ethical problems of using AI in the international arena, attempts are being made to agree on common basic principles of work. Examples of such interstate cooperation in search of ethical compromises on the topic of AI include:

- the European Union's Artificial Intelligence Regulation (2024 Regulation), which aims to "promote the deployment of human-centred and trustworthy AI";
- Interstate declaration of the EU countries emphasizing the consideration of human dignity, justice and equality in the process of working with AI (ROC, 2021);
- The Bletchley Declaration, which proclaimed the principle of "AI conformity with human intentions" ( The Bletchley , 2021).

In the Russian Federation, within the framework of the concept of self-regulation (Legal means, 2024) , The AI Alliance, business representatives, scientists and government bodies have developed and voluntarily adopted the “AI Ethics Code”.

The main provisions of this code are based on the development of AI solely in the interests of protecting human rights, the priority of a responsible attitude to the creation of AI, and also taking into account maximum transparency and truthfulness in the publication of information about the level of development of this technology and the potential risks of its use (Code, 2024).

For the purposes of medical activities, the expert community, with the assistance of the Russian Ministry of Health, developed a code of ethics for the use of AI in medicine in 2024. The purpose of developing this document was to increase public confidence in AI technologies, as well as to develop a responsible approach for doctors and patients to working with such intelligent systems (Ministry of Health, 2024).

One way or another, the search for an ethical framework for interaction between humans and AI will continue.

# 4 DISCUSSION

The choice of the optimal model for regulating AI in medicine is directly related to the discussion about the most effective model for regulating artificial intelligence as a technology in general; in this case, we are talking about the so-called “soft” or “hard” regulation option.

"Soft" regulation ( *soft " law - English)* implies the use of a large number of non-binding norms (or norms that have less legal force than the law), principles, codes and standards. Apologists of "soft" regulation (the concept developed in the Western European legal doctrine of the second half of the 20th century) in the person of J. Gold , J.P. Burgess , P. Cottrell ( Gold , 1983) believed that self-regulation and the encouragement of subjects to voluntary compliance are the most important principles for the implementation of effective state influence on social relations.

Other scholars, for example, P. Weil, in the 80s of the 20th century, disagreed with this formulation of the question and called “soft law” a source of “disorder” and “blurring of boundaries” between generally binding and voluntary norms.

We, for our part, while paying tribute to the means of self-regulation, nevertheless agree with those who question the possibility of completely delegating the process of regulating the use of AI to the level of corporations and entities ( Arzamasov , 2023).

Different and more traditional For Russia , the approach to regulating AI is called “ hard ” law –

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*English* ), is based on the classical system of influencing the behavior of subjects through generally binding prohibitive and obligatory legal norms (primarily through laws, by-laws and standards).

Apparently, the scientific discussion about which regulatory model is more suitable for a particular branch of law will continue for a long time (Popova, 2017; Glebova, 2023, however, the most universal option in relation to AI should be the use of a “mixed” model, which synthesizes all the best practices of “soft” and “hard” regulation.

# 5 CONCLUSION

International competition in the field of AI, the internal needs of modern society, as well as the accelerated development of technologies, leave states no time to "get going", in this regard, the creation of an effective mechanism for implementing the right to medical care and health protection using artificial intelligence systems must be addressed today.

The system of legal and technical acts governing the use of AI in medicine is designed to provide a regulatory environment for the active and safe use of the latest technologies. The expert community should pay special attention to mitigating the risks of personal data leakage and delineating responsibilities between doctors, medical organizations, patients, and AI developers. Regulation of this area in Russia in the interests of achieving sustainable development goals should be built taking into account the constitutional rights of patients and on the principles enshrined in Presidential Decree No. 490 of October 10, 2019.

We consider it important to continue the search for universal definitions related to AI. In this regard, artificial intelligence in medicine is proposed to be understood as *the use of software with a specific set of algorithms, in order to collect data on the state of the patient's body for the purpose of their intellectual assessment for the subsequent development of the most optimal treatment and preventive tactics.*

The subject of legal regulation in the context of the use of AI in medicine will be *a group of social relations associated with the use of intelligent software to collect data on the condition of patients and the subsequent assessment of treatment and preventive tactics for their management.*

The authors of the study express confidence that in the context of the digital transformation of healthcare (with all the accompanying ethical and technical challenges), the patient and doctor should have a legally enshrined right to receive up-to-date and reliable information about what AI is used in the process of their interaction.

As a measure to increase patient awareness, it is proposed to legislate the requirement for patients (and their representatives) to sign a separate written informed consent for the use of artificial intelligence systems in the examination and treatment process.

In conclusion of this study, I would like to note that the digital transformation of healthcare and the use of artificial intelligence capabilities make it possible to solve a number of problems aimed at achieving sustainable development goals, especially in the context of organizing universal access of the population to medical care.

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# REFERENCES

2024 Regulation European Soyuza ob artistic intelligence , ANO " Digital ekonomika ". URL: https://ai.gov.ru/knowledgebase/dokumenty-po-razvitiyu-ii-v-drugikh-tranakh/2024_reglament_evropeyskogo_soyuza_ob_iskusstvennom_intellekte_ano_cifrovaya_ekonomika_/ (data obrashcheniya 07.02.2025)

AlphaFold Protein Structure Database. URL: https://alphafold.com/ (data obrashcheniya 20.03.2025)

Brown J., 2025. IBM Watson Reportedly Recommended Cancer Treatments That Were 'Unsafe and Incorrect'. URL: https://gizmodo.com/ibm-watson-reportedly-recommended-cancer-treatments-tha-1827868882 (data obrashcheniya 03/01/2025

Burgess, JP, 2002. What's so European about the European Union? Legitimacy between Institution and Identity. *European Journal of Social Theory.* Vol. 5. N 4. P. 467-489.

Crevier , D., 1993. AI: The Tumultuous Search Artificial Intelligence - New York, NY: BasicBooks . R. 399 - ISBN 0-465-02997-3.

Darling, K., 2021. The new breed: How to think about robots. Penguin UK.

Fromhold-Eisebith , M., Marschall , P., Peters, R., Thomes , P., 2021. Torn between digitized future and context dependent past - How implementing 'Industry 4.0' production technologies could transform the German textile industry. Technological Forecasting and Social Change, vol. 166.

Gold, J., 1983. Strengthening the Soft International Law of Exchange Arrangements. *American Journal of International Law.* Vol. 77, no. 3. P. 443–489.

DOI: 10.63550/ICEIP.2025.15.42.032

Gordon, J.-S., Nyholm , S., 2021. Ethics of artificial intelligence. Internet Encyclopedia of Philosophy.
Loh , J., 2019. Roboterethik : Eine Einf'hrung .
McCarthy, J., Minsky, M.L., Rochester, N., Shannon, C.E., 1955. A proposal for the Dartmouth summer research project on artificial intelligence. USA: Darthmouth .
Muller, V., 2020. Ethics of artificial intelligence and robotics. Stanford Encyclopedia of Philosophy.
Nilsson, N.J., 2010. The Quest for Artificial Intelligence, Cambridge.
Preparing for the future of artificial intelligence artistic intellekta ] / Executive Office of the President National Science and Technology Council Committee on Technology of USA //URL: https://obamawhitehouse.archives.gov/sites/default/files/whitehouse_files/microsites/ostp/NSTC/preparing_for_the_future_of_ai.pdf. – 48 p. – P. 6. (data obrashcheniya 7.03.2025).
Riera , K., Rousseau, A.-L., Baudelaire, C., 2025. Doctor GPT-3: hype or reality?. URL: https://www.nabla.com/blog/gpt-3/ (data obrashcheniya 06.02.2025)
The Bletchley Declaration by Countries Attending the AI Safety Summit, 1-2 November 2023. URL: https://www.gov.uk/government/publications/ai-safety-summit-2023-the-bletchley-declaration/the-bletchley-declaration-by-countries-attending-the-ai-safety-summit-1-2-november-2023 (data obrashcheniya 01/15/2025)
The Pre-History of Artificial Intelligence December 2024 DOI:10.1007/978-3-031-57437-5_1 In book: Artificial Intelligence: Principles and Practice (pp.3-25)
Woo, KJ, Young, CP, Jae, WL, Eun , SS, 2021. Simulation-based hybrid optimization method for the digital twin of garment production lines. *Journal of Computing and Information Science in Engineering*, vol. 21.
Nagoev , ZV, Bzhihatlov , K.CH., Nagoeva , OV, Sundukov , ZA, Kankulov , SA, 2020. Autonomous formation models users po dannym digital Sleda v internet- prostranstve na basis training multi-agent neurocognitive architecture [ Text ] . Russia academy nauk . Prezidium . Kabardino-Balkanskij scientific center . News Kabardino-Balkar scientific RAN center : scientific zhurnal . N 6. S. 52-67.
Alekseeva, I. YU., 1987. Knowledge how object computer modeling . *Questions Philosophy* . No. 5. pp. 42-49.
Arzamasov , YU. G., 2023. Optimal model of law regulation in the sphere artistic intelligence . *Vestnik VGU. Series : Law* . No. 2 (53).
Arhipov , VV, Naumov , VB, Smirnova , KM, 2021. Previously prinyatiya legal significant solutions and uses artistic intellekta . *Vestnik SPbGU . Series 14. Law* . No. 4.
Atabekov , AR, 2023. Region realizations publichnyh funkcij sophisticated intelligence in Russia i world. *Current problems rossijskogo law* . No. 5 (150).
Atabekov , AR, 2024. Conceptual'nye podhody i practice pravovogo regulation artistic intelligence in public sphere : equal-legal research : special'nost ' 12.00.14 " Administrative law ; administrative process" : dissertation na search learned steps doctor legal science . 486 s.
Begishev , IR, Hisamova , ZI, 2021. Artistic intelligence i corner law " (Moscow: Prospekt , 2021. 192 p.). *Vserossijskij criminal zhurnal* . №1.
Biryukov , BV, 1985. ZHar cold number i pafos passionless logics . formalization myshleniya ot antique times before the era cybernetics . 192 s.
Bostrom , N., 2016. Artistic intelligence : Etapy . Threats . Strategies : Trans. s angl. S. 103.
Boshno , SV, 2014. Sposoby i methods pravovogo regulation . *Law i modern state administration* . No. 3.
Glebova , DA, 2023. Evolyuciya definitions categories « myagkogo prava » in studies *of* the 1970s– 2020s . *science* . No. 9.
Gotovcev , PM, Rojzenson , GV, 2020. Characteristics projects standard na ethical sophisticated intel lect IEEE. 390 Ethics i « cifra » 2020.
Grinin , LE, Grinin , AL, Grinin , IL, 2023. Iskusstvennyj intelligence : development i worries . A look into the future . Articles first . Information technology i sophisticated intelligence : past , present i some prognoses . *Philosophy i society* . No. 3 (108).
Gusev , AV, Morozov , SP, Kutichev , VA, Novickij , RE, 2021. Normativno-pravovoe regulation programmnogo provision for health protection created with the use of technology artistic intelligence , in Russia Federacii . *Medicinskie technologies* . *Rating i choice* . No. 1 (43).
Gusev , AV, Artemova , OR, Andrejchenko , AE, Ivanov, IV, 2024. Formulation market programmnyh medical made in Russia Federations in 2007–2024: practical rezul'taty . *National'noe zdravoohranenie.* ;5(3):53-61.
Gusejnov , AA, 2004. Thoughts on the subject etike . Doklad na basis Articles : Thoughts on the subject etike . Vedomosti NIIPE, July . 25: General professional etika . Tyumen ': NIIPE, 148 p.
Dzhikiya , MD, Koltyrin , VI, 2024. Pravovaya nature dogovora rendering telemedicine uslug : aspekty definitions obligatory uslovij . *Yuridicheskaya science* . №3.
Zolotareva , TA, 2019. Idea technology in antiquity . *Humanitarian vector* . №2.
Artistic intelligence for medical images . URL: https://botkin.ai/ (data obrashcheniya 22.03.2025)
Kirpichev , AE, 2024. Prompty ( zaprosy ) dlya generativnogo artistic intelligence in law diskurse . *RUDN Journal of Law.* T. 28. No. 4. S. 906–918.
Codes ethics in the sphere artistic intellekta . URL: https://ethics.a-ai.ru/assets/ethics_files/2023/05/12/%D0%9A%D0%BE%D0%B4%D0%B5%D0%BA%D1%81_%D1%8D%D1%82%D0%B8%D0%BA%D0%B8_20_10_1.pdf (data obrashcheniya 28.03.2025)
Matuzov , NI, 1972. Personality . Law . Democracy . Theoretical problems sub"ektivnogo right . Saratov, p.50.
Mindigulova , A.A., 2023. Fenomen artistic intelligence : history emergence i development . *Sociology* . No. 5. S. 239.

Minzdrav developed codes ethics Primary II in medicine. RIA News publication registered in the Federal Republic service po nadzoru v sfere communications , information technology i mass kommunikacij ( Roskomnadzor ) 08 April 2014. URL: https://ria.ru/20241210/minzdrav-1988408460.html (data obrashcheniya 25.12.2024 )

Morhat , PM, 2018. The legal sub-category of art intelligence in the sphere right intelligent'noj properties : civil-legal problem : dis... d- ra yurid . science . Moscow.

Morhat , PM, 2017. Artistic intelligence : righteous view : scientific monograph . ROO « Institute state-confessional relationships i right ". M.: Buki Vedi , 257 s.

Neznamov , AV, 2019. Legal aspekty realizations National strategies developments artistic intelligence until 2030. Vestnik *University imeni OE Kutafina (MGYUA )* .;( 12):82-88.

Nejroset ' v lom halate , or new era of medicine ? WCIOM publication registered in the Federal Republic service po nadzoru v sfere communications , information technology i mass kommunikacij ( Roskomnadzor ) 01 February 2019. URL: https://wciom.ru/analytical-reviews/analiticheskii-obzor/neiroset-v-belom-khalate-ili-novaja-ehra-mediciny (data obrashcheniya 11.03.2025 )

Ortega- i - Gasset , H., 1997. Reflections on technology / H. Ortega- i - Gasset . Selected trudy per. s isp .; sost ., predisl . i obshch . red. A. M. Rutkevicha . M.: Ves ' Mir, S. 164-232.

Official site company «KEREMENTOREJAJ». URL: https://navigator.sk.ru/orn/1123009 (data obrashcheniya 18.03.2025)

Write to me Federal'noj services po nadzoru v sfere health from February 13 , 2020. N 02I-297/20 "About the program obespechenii ". URL: https://www.garant.ru/products/ipo/prime/doc/73467702/ (data obrashcheniya 12.02.2025)

Platforma prognostic analitiki Webiomed . URL: https://webiomed.ru/ (data obrashcheniya 21.03.2025)

Ponkin , IV, 2022. State management i regulatory transit to the sphere artistic intellekta . *Vestnik University imeni OE Kutafina* . No. 11 (99).

Ponkin , IV, Red'kina , AI, 2018. Artistic intelligence with your fingers visions right . *Vestnik Russian university druzhby narodov . Ser. « YUridicheskie nauki ".* T. 22. – No. 1. – S. 91–109.

Popova , SM, 2017. New trend in space right : creation of " good " legal aid " for cosmic activities . *Research cosmos* . №1.

Pospelov , DA, 1972. VN Pushkin myshlenie i avtomaty . Izdatel'stvo « Sovetskoe radio» Moscow.

Postanovlenie Government Russian Federacii from 09.12.2022 No. 2276 "On installation experimental pravovogo regime in the sphere cifrovyh innovations i affirmations Programs experimental pravovogo regime in the sphere cifrovyh innovations po direction medical activities with primeneniem technology sbora i processing knowledge about conditions health i Diagnoses citizens in relations realizations initiators socio-economic developments Russian Federations " Personal medical pomoshchniki ". URL: http://publication.pravo.gov.ru/Document/View/0001202212150019 (data obrashcheniya 26.02.2025)

Righteous regulation artistic intelligence in usage pandemic i infodemii / VV Blazheev [ i dr. ] ; pod obshch . red. VV Blazheeva ; Mosk . gos . yurid . un-t im . OE Kutafina (MGYUA). - 2020.

Legal means smart regulations in conditions more call / ML Davydova , MD Dzhikiya , DV Zykov [ and others]. – Moscow: Society with limited Responsibility " Rusajns ", 2024. – 242 p.

Order Ministership RF health from June 6 , 2012 No. 4n "On approval nomenclature Classification medical made " (with changes) i dopolneniyami ). URL: https://base.garant.ru/70199586/ (data obrashcheniya 13.02.2025)

Rasporyazhenie Government Russian Federacii from April 17, 2024 No. 959-r Approved strategicheskogo administration in the region digital transformations health care . URL: https://base.garant.ru/408913257/ (data obrashcheniya 20.03.2025)

Resolution , acceptance General'noj Assembly September 25 , 2015. URL: https://unctad.org/system/files/official-document/ares70d1_ru.pdf (data obrashcheniya 01.03.2025)

Rating stran po level medicine // Information portal NoNews . URL: https://nonews.co/directory/lists/countries/health-care-index (data obrashcheniya 26.03.2025)

RPC: Strategies developments artistic intelligence needed eticheskij reglament . URL: https://rg.ru/2021/08/26/rpc-strategii-razvitiia-iskusstvennogo-intellekta-nuzhen-eticheskij-reglament.html (data obrashcheniya 03.02.2025)

January 1 , 2025 stupefied in power ryad GOST po II v zdravoohranenii . URL: https://oncology.ru/news/2025/01/15/?ysclid=m6un2dhocj19287749 (data obrashcheniya 11.01.2025)

Skurko , EV, 2021. Ethics artistic intelligence in development legal systems modern times . *Social i gumanitarnye science . technical i zarubezhnaya literatura . Ser. 4, Gosudarstvo i right : abstract zhurnal* . № 1. S. 79-89.

Agreement ob use service GigaChat for physical lic . // Official sajt PAO SberBank . URL: https://developers.sber.ru/docs/ru/policies/gigachat-agreement/individuals?ysclid=m6peo1gn6q118574327 (data obrashcheniya 12.03.2025)

Standard po napravleniyu « Iskusstvennyj intellekt » // oficial'nyj site Federal'nogo agentstva po technical regulation i metrologii . URL: https://www.rst.gov.ru/portal/gost/home/standarts/aistandarts (data obrashcheniya 26.03.2025)

Tret'yakova , EP, 2021. Used artistic intelligence in health care . *Digital law* . Vol. 2, No. 4, pp. 51–60.

DOI: 10.63550/ICEIP.2025.15.42.032

Tyu'ring , A., 2018. Numerical machines i razum / Alan T'yuring ; [translated into English by K. Koroleva ]. Moscow: Izdatel'stvo AST, 128 s.

Ukaz President of the Russian Federation from October 10 , 2019. N 490 "On the development artistic intelligence in russia Federacii ". URL: https://base.garant.ru/72838946/ (data obrashcheniya 04.03.2025).

Federal Law "On Standardization in Russia" Federation " from 29.06.2015 N 162-FZ ( last redakciya ). URL: https://www.consultant.ru/document/cons_doc_LAW_181810/ (data obrashcheniya 29.01.2025)

Federal law "About the foundations guard health citizen in Russia Federation " from 21.11.2011 N 323-FZ ( last redakciya ). URL: https://www.consultant.ru/document/cons_doc_LAW_121895/ (data obrashcheniya 13.03.2025)

Fukuyama, F., 2004. Nashe posthuman future : consequences biotechnological revolutions ; trans. s angl. MB Levina / F. Fukuyama. – M.: AST : LYUKS, 349 s.

Electronic service Roszdravnadzor . URL: https://roszdravnadzor.gov.ru/services/misearch (data obrashcheniya 02.02.2025)

EPR « Personal medical assistants » preparing for signing ob efficiency // Official site Ministership economic development of the RF. URL: https://economy.gov.ru/material/news/epr_personalnye_medicinskie_pomoshchniki_podgotovyat_k_zaklyucheniyu_ob_effektivnosti.html (data obrashcheniya 01.04.2025)