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# Certain issues of legislative regulation of digitalization of healthcare in Kazakhstan

The aim of the work is to identify the imperfections of legal regulation that hinder the realization of the right to health care through the digital format of receiving medical services. To consider this topic, the authors studied the norms of national legislation affecting the processes of informatization of all spheres of the economy and digitalization of health care, in particular, through system analysis, comparative-legal and formal-legal methods. As a theoretical basis, the authors studied legal scientific literature, documents of international organizations devoted to the subject of the study. In conclusion, the authors highlight the significant role of protection of personal medical data and principles of ethical application of artificial intelligence in the regulation of social relations in the field of digitalization of health care and the need to revise and harmoniously combine the norms of different legal acts regulating the digital development of health care.

*Keywords:* right to health care, digitalization of healthcare, regulation of healthcare digitalization, protection of medical data, artificial intelligence, ethical principles of AI, law on AI, digital code.



## *Introduction*

Intensive introduction and use of informatization products based on digital technologies are aimed at providing a positive effect on the quality of medical services and expanding ways for Kazakhs to exercise their constitutional right to health care. Development and use of digital technologies in this area both in the Republic of Kazakhstan and in the world are ahead of their legal regulation, restricting citizens' access to health care. In any case, such technological advances require the updating of legal support for this area. Revision of those parts of the legislation that directly regulate public relations in the field of digitalization of health is needed.

The aim of this work is to establish the inadequacy of legal regulation of digital health development based on scientific research. To achieve this goal, it is necessary to explore the imperfections of the legislation that hinder further regulation of the development of digital health and to identify ways of eliminating such imperfections.

The stated research goal is achievable if the following tasks are completed:

– establishing new areas of legal regulation arising from the introduction of the latest technological tools for digitalization in the field of medical services;

– studying foreign experience in regulating new areas of digital healthcare by analyzing the legislation of foreign countries and international regional organizations;

– identifying specific problems that lead to incomplete national legal regulation of digital transformation in healthcare.

In Kazakh jurisprudence, the legal regulation of the health care digitalization and the role of such regulation in ensuring the right to health care were not the subject of a comprehensive scientific-theoretical study. At present, only some legal issues of digitalization of health care are considered: protection of personal medical data (S. Arynova, S. Nuragliev); violation of patients' rights caused by automation of processes and introduction of artificial intelligence in medicine (M.U. Bayeshova); legal issues arising from the introduction of telemedicine (R.S. Makacheva); the problems of methodology of integration of legal requirements into development and processes of e-health technologies (H. Purtova.).

Among foreign authors the problems of legal regulation and ensuring digitalization of health care have been studied by such scholars as Caroline Ball, Silven A.V., J.G. Hodge Jr., Vincent Liu, Adil Hussain Seh, Katarina Jonev-Ćiraković, João V. Cordeiro.

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In the Russian legal science, there is also a fragmentation of studies and a lack of complete scientific-theoretical development. Significant contribution to the study of issues of legal regulation of medical services was made by S.M. Grishin; issues of legal and information support are considered by V.S. Bulanova; Attempts to comprehend the existence of uncertainty in the legal framework of telemedicine implementation made by N. Makareko and M. Davydova; consideration of risks such as data theft and the likelihood of medical errors caused by the process of digitalization of the medical sphere was carried out by M. Vlasova.

Thus, the lack of solid scientific insights in the field of legislative regulation of healthcare digitalization in Kazakhstan and the exceptional relevance of improving the provisions of this legislation to ensure the health care rights and successful healthcare reform are the main reasons for studying the chosen topic.

*Materials and methods*

As part of the study, the norms of foreign and international legislation were analyzed and systematized. The study also examined leading jurists' works on the legal regulation of digital technologies.

The study's methodological basis included general philosophical methods, such as the dialectical method, which was employed to reveal the interrelationships between digital processes and legal norms. The method of comparison was used to contrast different legislative approaches, while logical analysis was employed to examine legal constructs.

Specialized legal methods were also employed, including the formal-legal method for analyzing normative legal acts, the comparative method to identify peculiarities in the regulation of different legal systems and the method of legal modeling to theoretically reconstruct possible legislative developments.

This theoretical study is based on the analysis of secondary data and did not involve conducting empirical experiments or collecting statistical information.

In order to establish new areas of legal regulation arising from the introduction of the latest technological tools for digitalization in the field of healthcare services, the latest international documents adopted by the international community within the framework of the UN, UNESCO and WHO were studied. Thanks to the study of international provisions, new issues related to the further development of national legislation have been identified in view of the emergence of new areas of legal regulation.

An understanding of foreign experience in regulating new areas of digital healthcare was achieved by reviewing the legislation of foreign countries and international regional organizations. To understand the theoretical background of the foreign approach to regulatory measures for the introduction of AI in healthcare and the problems of personal medical data protection, the authors also relied on the work of foreign and domestic legal scholars.

Identifying specific problems that lead to weaknesses in national legal regulation of digital transformation in healthcare has been achieved by studying the provisions of current national legislation and draft regulatory legal acts proposed by legislators for discussion and public review.

*Results*

With the intensification of healthcare digitalization, there is a need to develop a regulatory framework aimed at regulating public relations associated with the introduction of digital technologies in various areas of public health. Kazakhstan has been working on the adoption of a Digital Code for the past few years. The adoption of such an act could give new impetus to the development of rules and principles of digital legislation. The draft Digital Code of the Republic of Kazakhstan, proposed in 2024, although it contains rules regarding the protection of personal data and rules governing the safe use of artificial intelligence, which have become major technological trends, it does not contain separate provisions dedicated to digital healthcare. In short, the provisions of the Code are generalized and cannot directly regulate the healthcare digitalization. This, in turn, may hinder the use and legal support of high-tech approaches in medicine, such as diagnosing diseases using artificial intelligence, providing services through telemedicine, introducing a unified medical information system and the transition of medical documents to digital format under the principle of conversion to paperless medicine, which means storing medical data of individuals in electronic databases.

In order to develop such a regulatory legal act and the establishment of the regulatory framework as a whole, it is important to understand global trends in the field of protection and ensuring rights when using digital technologies for the relevant and harmonious evolution of national legislation in this area. Inventing national legislation, it is decisive to take into account its compliance with international standards in digitalization, as this helps to apply generally accepted approaches, strengthening international coordination around the problem and enhancing the country's image in the international arena, turning it into a reliable partner for

further cooperation. In order to build a global digital governance architecture, the UN calls for regulatory initiatives to focus on areas such as the use of artificial intelligence, protection of children's rights, data protection, cyber security, the digital economy, digital inclusion, and others [1]. In 2024, the UN adopted the Pact for the Future, which included the Global Digital Compact as an annex, which represents a roadmap for global digital cooperation in the use of digital technologies and the elimination of digital inequality in the world. One of the objectives of the Compact is to build an inclusive, open, safe and secure digital space in which human rights are respected, protected and promoted. To this end, States have committed to developing national laws on digital technologies in accordance with international law and the Sustainable Development Goals. Taking measures to govern artificial intelligence in accordance with public interests and strengthening international cooperation is also one of the tasks that the international community sets for itself on the path to establishing a comprehensive framework for digital governance. Developing appropriate approaches to data management and protection is another task aimed at eliminating risks in the collection, exchange and processing of data, which is only possible with the adoption of effective standards for the protection of personal data and privacy [2]. Particular attention should be paid to the compliance of future national regulations governing the healthcare digitalization with the Recommendation on the Ethics of Artificial Intelligence adopted by UNESCO in 2021. Documents contains provisions on the ethical implementation of technologies created on the basis of artificial intelligence in many areas of public life, including healthcare, emphasizing the ethical and legal responsibility of the state for building an effective strategy for the use of these technologies [3]. As one of the leading principles of the Global Strategy for Digital Health, WHO proposes the use of digital technologies in the interests of health, ensuring patient safety, observing professional ethics, taking into account such aspects of digitalization as interoperability, intellectual property, data security [4]. Thus, the international community, represented by the main international institutions, recognizes the importance of ensuring rights in the digital healthcare, focusing the attention of governments on creating a safe digital space, protecting personal medical data and the ethical use of artificial intelligence technologies in medicine.

In terms of legal regulation of the collection, use and processing of personal medical data, along with international standards, it is important to pay attention to the experience of states where regulation of the issue has been adopted to date in order to understand innovative approaches and best practices for possible further adaptation in national legislation. In 2018, the General Data Protection Regulation came into force in the European Union [5]. According to these Rules, personal information used and processed in the healthcare sector is classified as "sensitive data" requiring additional protection [6]. This category of medical personal data includes information related to the health status of the data subject, which reveals information regarding the past, present or future physical or mental health of the data subject. This category of information includes data about an individual obtained during registration and provision of health care services; information that uniquely identifies an individual; results of testing or examination of a body part or bodily substance; and any information about a disease, disability, risk of disease, medical history, clinical treatment, or physiological or biomedical condition of the data subject, regardless of its source. (Recital 35 of GDPR) [5]. Biometric and genetic data are also classified as data with a special confidential status. (Recital 34 of GDPR) [5].

The collection, recording, organization, structuring, storage, adaptation, retrieval, consultation, use, disclosure by transmission, provision or dissemination, erasure and destruction of data constitute data processing (Article 4(2) of the GDPR) [5], for which the rules clearly set out the conditions and indicate the principles that must be observed by data controllers. Data processing must be subject to the principles of lawfulness, fairness, transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality (Article 5 of the GDPR) [5]. Since personal medical data is classified as information with a special status, the Rules, as stated, prohibit its processing without a legal basis for doing so. If the processing is carried out without a legal basis, it is considered unlawful, and the only legal basis for processing is the express consent of the person (Article 9 of the GDPR) [5]. The rules clearly set out the rights of data subjects to data protection (Articles 12–22 of the GDPR) and the duty of the data controller to protect the data of subjects (Articles 24, 32 of the GDPR) [5]. The main feature of the Rules is that they are aimed at strengthening the rights of citizens to control the processes of collecting, storing, processing and transferring their medical data by providing consent. In strengthening the rights of data subjects, the data operator is obliged to notify the data subject, i.e. the person to whom the medical information belongs, without undue delay about a leak of his/her data if there is a possibility that the breach of personal data protection will entail a high risk to the rights and freedoms of individuals (clause 1 of Article 34 of the GDPR) [5]. According to Rebecca Ong, relevance of such a notification is that on the one hand, it promotes the individual's right to information, which allows them to mitigate the risks and consequences of unlawful disclosure of their per-

sonal information, and on the other hand, it can serve as an incentive to strengthen the security strategy for this type of information [7]. These provisions therefore reflect the principle of granting individuals the right to personal participation in the processing of their personal data as provided for by international law, in particular the provisions of the International Covenant on Civil and Political Rights, according to which every individual has the right to request the correction or deletion of personal information if it has been collected or processed violating the law [8]. The rules also regulate the process of revoking consent to data processing and the obligation of the data operator to ensure ease of revocation of consent to data processing (clause 3 of Article 7 of the GDPR) [5]. In addition, the process of transferring consent to data processing by persons under 16 years of age is regulated (clause 1 of Article 8 of the GDPR) [5].

The Code of Kazakhstan on Public Health and the Healthcare System [9] contains a legal definition of personal medical data as personal data containing information about the health of an individual and the medical services provided to him, recorded on electronic, paper or other tangible media, but according to this definition they do not constitute data with a particularly sensitive status and are not provided with additional protection measures. (clause 2 of Article 58 of the Health Code) [9]. We believe it is appropriate to give personal medical data a special sensitivity status within the framework of national legislation, since they may represent information about the mental and physical condition of a person, the results of examinations, genetic characteristics and diagnoses. Such information may reveal vulnerable aspects of a person's life, which in turn may become a reason for social pressure, discrimination, and violate the trust between the patient and the attending physician, as Ibrahim A.M. and colleagues believe [10]. Ensuring the confidentiality of personal medical data of individuals, along with ensuring their protection and security, as well as patient access to their personal data, is one of the principles of digital healthcare in Kazakhstan (clause 3 of Article 57 of the Health Code) [9]. Ensuring the confidentiality of medical data is the responsibility of medical workers and employees of healthcare entities in accordance with the laws of the Republic of Kazakhstan (clause 7 of Article 61 of the Health Code) [9], and the aggregator, which is the controller of personal medical data that collects, processes, stores, and provides data, is also indicated as being responsible for its protection (clause 3 of Article 58 of the Health Code) [9]. However, the Code does not provide for a rule that obliges any of the listed parties to notify the data subject of a leak or illegal use of his medical data for the purpose of further actions to eliminate the leak or other types of illegal violation of data confidentiality. The procedure for appropriate measures to prevent or mitigate the consequences of violations, as well as judicial recourse for moral or material harm remedy caused to the data subject by a violation of data security is not considered. The Code states that the specifics of protecting electronic information resources where personal medical data is stored are determined by the legislation of the Republic of Kazakhstan on informatization and on personal data and its protection (clause 1 of Article 62) [9], and are not directly regulated by the Code, which is why the specifics of the regulated area and the special nature of the protecting data are not taken into account. There are serious shortcomings in the legislation on personal data regarding the protection of the rights of the data subject and liability in the event of illegal use or dissemination of medical data. In particular, the Law of the Republic of Kazakhstan dated May 21, 2013 No. 94-V "On personal data and their protection" [11] does not provide for the obligation of the person responsible for organizing and processing data to notify the subject of information, which would comply with international human rights standards and foreign practice. Since the procedure for notifying the data subject has not been considered, the procedure for liability for breach of the obligation is also unclear [12].

Thus, the transition to paperless medicine in the Republic of Kazakhstan is accompanied by the risks of violation of the confidentiality of personal medical data of citizens stored in electronic information systems. Medical data of persons constitutes the secret of a medical worker (clause 1 of Article 273 of the Health Code) [9] and, in turn, may contain extremely sensitive information, the illegal dissemination of which may cause psychological discomfort, stigmatization and discrimination at the workplace. It also may create a reason for fraud if it falls into the hands of third parties whose goal is to extract benefits [13; 123]. Responsibility for the unauthorized use of individuals' medical data is also a matter of significant importance in connection with the emergence of such risks associated with the digitalization of healthcare for citizens. Unfortunately, the regulation of these problems is not reflected in domestic legislation and requires further elaboration, development and implementation in accordance with international standards.

Establishing of electronic databases has led to the introduction of artificial intelligence (AI)-based technologies for their processing. As Alowais S.A. and colleagues argue, such high technologies in healthcare are aimed at solving many problems related to the diagnosis of diseases, automation of patient care tasks, reduction of medical costs, time saving, and solving the problem of healthcare management [14]. These innova-

tions have not bypassed Kazakhstan. The use of AI has not received extensive legal regulation in Kazakhstan, although today the areas of medicine in which the achievements of the Medtech industry will be implemented have already been determined. The innovative developments representing promising niches in healthcare, according to the results of the study, were recognized as the use of a clinical decision support system in the diagnosis of oncological diseases of the mammary gland and lung using artificial intelligence and work on the Cerebra software for detecting early signs of stroke based on artificial intelligence and machine learning [15]. There are currently no generally accepted international standards in this area that could serve as a basis for national regulations. Establishing specific rules for the use of AI is complicated by the fact that the industry is still in its development stage, and when developing legislation, it is necessary to take into account all the risks and uncertainties of these technologies. Thus, legal regulation of the use of AI in various spheres of society has lagged behind technological development. According to Tlembaeva Zh.U., since healthcare is a conservative and sensitive area of life, and is directly related the health care right, the introduction of modern technologies in this area and further legal regulation requires a balanced approach, which will not result in excessively detailed regulation that will hinder the development and implementation of technologies, but will also ensure high safety standards and respect for patients' rights [16; 1124].

The introduction of AI technologies in the healthcare sector was initiated within the framework of the state program Digital Kazakhstan in 2017 [17]. One of the key results within the framework of the Concept for the Development of Electronic Healthcare for 2013–2020 [18] is the creation of a regulatory framework to stimulate the development of electronic healthcare systems in medical organizations. The Concept of Legal Policy of Kazakhstan until 2030 [19] the need to work on codifying the regulation of the introduction and use of information and communication technologies, communications, data processing, digital assets, industrial automation, information security, machine learning and artificial intelligence, and the protection of the rights of personal data subjects is mentioned. At the present stage, there is fragmentary regulation of the mentioned problems within the framework of some regulatory legal acts. Some concepts used in the sphere of regulation of digital technologies were covered by the Law of the Republic of Kazakhstan dated November 24, 2015 No. 418-V LRK. On informatization. The rules for using artificial intelligence are also partially contained in the Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI LRK On the health of the people and the healthcare system in the context of the use of information and communication technologies. In addition to these laws, the Concept for the Development of Artificial Intelligence for 2024–2029 [20] specifies following acts as the basis for the legislative framework in the field of AI: Law of the Republic of Kazakhstan dated July 5, 2004, No. 567 "On Communications", Resolution of the Government of the Republic of Kazakhstan dated December 20, 2016 No. 832 "On approval of uniform requirements in the field of information and communication technologies and ensuring information security", Order of the Minister of Digital Development, Innovation and Aerospace Industry of the Republic of Kazakhstan dated October 14, 2022 No. 385/NK "On approval of the Data Management Requirements". The concept of digital transformation, development of the information and communication technology industry and cyber security for 2023–2029, approved by the Decree of the Government of the Republic of Kazakhstan dated March 28, 2023 No. 269, contains provisions aimed at developing this industry in Kazakhstan and stimulating the introduction of AI in various areas of the economy and social life of citizens. The above-mentioned AI Development Concept, among other things, shows elements of legislation that require serious revision to achieve full regulation of the industry. Thus, it has been established that the conceptual apparatus of the sphere has not been established, the rules for the ethical use of AI have not been developed based on international standards are not elaborated. The scope of regulation of artificial intelligence has not been defined, there is no regulation of the relationship between subjects of artificial intelligence, including the competencies of government agencies. The issue of the duties and responsibilities of subjects in the field of artificial intelligence has not been worked out, there are no technical requirements for technical devices and technologies based on AI. Studying the provisions of the draft Law on Artificial Intelligence submitted for public discussion, one can see that the act does not define clear boundaries for the use of AI in various areas of human life, that is, it does not define in which specific areas the use of AI is permissible in the Republic of Kazakhstan and does not indicate the boundaries of the penetration of AI into human life. The draft law contains general rules for the use of AI, without distinguishing between rules for specific areas, taking into account their characteristics and specifics.

Since two projects are presented for discussion — the draft law on AI and the Digital Code, the question of the correlation between the two acts arises. It is not yet clear in which of them it would be appropriate to place the basic principles of regulation and the necessary terminology, which would serve as the basis for

regulation for all sectors, including the healthcare sector. On the one hand, the Code has a higher legal force, and it should contain the main provisions for regulating digital transformation, of which AI is a part; on the other hand, AI-based technologies are used in many areas of the economy and public life. Therefore, the task arose to eliminate duplication of norms in these acts [21]. Since there is no general regulation of AI in Kazakhstan yet and only the outlines of future regulation have been made, and due to the fact that this technological industry is still going through a development phase, today, preparing rules for the use of AI in healthcare, it is necessary to focus on the recommendations of international organizations and the practice of foreign countries, which are mainly related to the development of rules for the ethical use of AI in healthcare. In order to fully regulate this problem and adopt clear legal rules applicable in such a sensitive area, it is necessary to develop principles for building trust in AI before delving into the development of specialized regulation [22; 45–48], which is not possible until general principles and standards for the use of AI are established for all areas. On the other hand, the development of ethical principles, as scientists argue, before the creation of laws typical for a narrow sphere, serves as a foundation that helps to determine the main values on which the rules will be based, to link generally accepted approaches and to harmonize national norms with international standards. Moreover, ethical principles are more flexible and adaptive to technological development, changes and new challenges and risks that accompany the development process, compared to laws that may become outdated and lose their functionality as technology advances [23]. The absence of codified norms in this area does not eliminate the need and does not tolerate delay in the preparation of ethical principles. According to the program documents on the development of AI, the introduction of these technologies is intended to stimulate technological and economic growth and move to a new national idea of Generative Nation [20]. It turns out that the future development of the nation is closely linked to the development of AI technologies, which requires preliminary work to prevent risks, timely adaptation, creating trust in technologies, and their fair distribution. Regarding the digitalization of health care, the UN Secretary-General in his report on the implementation of economic, social and cultural rights in all countries, with a special emphasis on the role of new technologies, confirmed that technologies developed in a responsible manner have a high potential for strengthening rights, while otherwise they can cause risks which contradict the right to health care, and stated the need to develop the necessary legal framework [24] (Question of the realization of economic, social and cultural rights in all countries: the role of new technologies for the realization of economic, social and cultural rights: Report of the Secretary General. Geneva: Office of the High Commissioner for Human Rights; 2020.

At the present stage, WHO has presented guidance on the ethics and governance of AI in health care, which indicates six main ethical principles, each of which is based on human dignity and the value of a person. The organization proposes universal principles that are most appropriate for the use of AI in healthcare, and their implementation may vary depending on religious, cultural and other social characteristics. Thus, according to WHO experts in the field of health care, it is necessary:

1. maintaining a balance between human autonomy and AI autonomy, which means that when transferring some tasks to technologies, individuals should not be deprived of control over the entire healthcare system and the solution of medical problems, since there is a risk of erroneous interpretation of medical data and others, the principle of reversibility of AI decisions and ensuring data security should be observed. All AI-based medical decisions must be made with the patient's informed consent.

2. AI technologies promote the safety of the individual and the interests of society in order to avoid mental and physical harm to the individual. The design, implementation and use of AI should include measures of its safety and quality. AI solutions should not lead to stigmatization or discrimination against an individual because the individual has a condition diagnosed by the AI.

3. make AI-based solutions understandable and transparent to users, developers and government regulators. A clear and transparent explanation of the processes of AI technology engagement should be provided for oversight and proper auditing, and for those who may make enquiries about the role of AI in medical decision-making and the mechanism for making such decisions.

4. Ensuring responsibility and accountability of those using AI to make medical decisions. Mechanisms should be developed to ensure that individuals and groups harmed by algorithmically informed decisions are heard and redressed. Institutions should be held legally accountable for AI decisions and a mechanism for redress for those affected should be developed. It is important to build a model where all parties involved in the development and implementation of AI are held equally accountable, which obliges all parties to act in good faith and minimize the risks of harm.

5. Ensuring inclusiveness and equity in the use of AI. Advances in AI should be distributed equitably regardless of income, gender, age and other attributes. Fairness and inclusiveness must be seen everywhere. For example, when developing AI, companies should attract workers from different cultures and backgrounds. When AI is implemented, it should not only be available in high-income countries, but also be adaptable in low- and middle-income countries as well. Developers need to take into account the diversity of languages. Governments need to ensure equal distribution of technology across different ethnicities, and so on.

6. The use of responsive and resilient AI. AI developers need to design AI to meet the demands placed on it in a particular situation. Governments should allow the use of AI that is consistent with health promotion and protection. Sustainability is about AI being designed to reduce its ecological footprint and human impacts on the environment. Governments should consider the need to train workers in the use of AI and think through the challenges associated with job losses with the introduction of AI [25].

These ethical principles serve as a basis for each society to develop its own principles and standards, taking into account cultural specificities, the level of economic and technological development, and other factors that determine the process of implementing and regulating AI in healthcare. Another feature of the development of national guidelines for the AI implementation is the involvement of representatives of the medical community, who will have direct interaction with AI, scientists, authorities, and technology developers in their development. For example, in the Russian Federation, the Technical Committee for Standardization TC 164 “Artificial Intelligence” was specially established to develop standards. The committee consists of users of AI technologies, representatives of technology companies, relevant universities, scientific organizations, and representatives of federal executive authorities. Currently, most states use national standards and principles specific to each state, and these vary depending on the type of AI technology used. In India, for example, the Central Drug Standards Control Organization is responsible for regulating AI-based medical devices. The agency has adopted guidelines for the use of AI in medical devices that are designed to ensure the safety and effectiveness of AI-based medical devices. In Brazil, the National Health Surveillance Agency is responsible for regulating AI-based medical devices. The agency has published guidelines for the use of AI in medical devices, which serve to ensure the safety and effectiveness of AI-based medical devices. In South Africa, the South African Health Products Regulatory Authority is responsible for regulating AI-based medical devices. The Authority has developed guidelines for the use of AI in medical devices, which focuses on ensuring the safety and effectiveness of AI-based medical devices. In Singapore, the Health Sciences Authority is responsible for regulating AI-based medical devices. The guidance adopted by the Authority is also aimed at regulatory support for the use of AI in medicine to ensure safety. In South Korea, the Ministry of Food and Drug Safety is responsible for regulating AI-based medical devices. MFDS has published similar principles for the application of AI for medical purposes [26; 33–38].

Returning to the experience of the Russian Federation, where a special committee was created to develop principles for the use of AI, it is important to note the work of the subcommittee PC 01 “Artificial Intelligence in Healthcare,” which was created as part of it. According to the results of the work of PC 01, GOST 59921 “Artificial Intelligence Systems in Clinical Medicine” was adopted, which deals with the procedure of technical and clinical trials of medical systems based on AI and GOST 59276 “Artificial Intelligence Systems” and a large number of other industry standards [27; 7–8].

The question of adopting such principles, rules and standards in Kazakhstan remains unresolved. Of course, it is necessary to rely on universal ethical principles, which are based on the value of human life and health. But also, of course, in our opinion, country specifics should be taken into account when preparing domestic principles for the use of AI in healthcare. It is critical for Kazakhstan’s AI standards in medicine to reflect the need to ensure equity in the distribution of high-tech medical care because evidence shows that there is a gap in access to high-tech medical services for urban and rural populations [28; 10–15]. Another ethical consideration is the development and implementation of AI that could adapt to different cultures and languages, given the cultural diversity of Kazakhstan society and the use of multiple communication languages.

Thus, this work systematizes the norms of international, foreign and national legislation and analyses scientific works by scholars in the field of regulating certain social relations in the area of digitalization of healthcare. Unlike other works that emphasize the existence of certain new areas of regulation that have emerged with the onset of digital transformation in the healthcare sector, the authors have comprehensively examined the legal and theoretical basis for proposing a framework for a national approach to resolving the aforementioned problem.

The novelty of the study lies in the combination of data from international documents (UN, UNESCO, WHO), foreign legislation and scientific works of lawyers, which allows for the development of a comprehensive picture of the legal regulation of digitalization and the identification of directions for the further development of the legal system.

Based on the study of international norms and foreign experience, specific issues have been identified that require new approaches to legal regulation in line with international standards and taking into account national specificities and the specifics of the regulated sphere as a whole. In particular, it has been established that personal medical data is recognized as particularly sensitive data requiring special protection measures, and that there is no established procedure in Kazakhstan for applying to the courts to protect the right to personal data protection. The study revealed the significant role of ethical approaches, which form the basis for the legal regulation of AI use in healthcare. The study also identified a problem with the relationship between several acts designed to regulate the digitalization of all areas, including healthcare.

*Discussion*

The results of this work have shown that although the world has not yet adopted specific legal standards establishing clear rules of conduct regulating social relations related to the digitalization of various spheres, the digitalization of such a special sphere as health care requires special regulation, as it is characterized by special sensitivity, because it is related to the well-being, health and life of people. The transition to a paperless format of medicine and the formation of voluminous databases of electronic data with medical information that belongs to individuals, gives personal medical information a special status requiring additional protection measures, without the application of which there is a vulnerability of individuals to unlawful use of personal medical data, associated with violation of the right to protection of personal data and personal inviolability and confidentiality. The expediency of raising the status of personal medical information and taking additional protection measures and strengthening the right of the subject of information to personally participate in the process of collection, processing, transfer, storage and destruction of personal medical data, having the opportunity to be notified of its illegal use in order to recover the damage caused.

Building databases with personal health records containing diverse and complex medical data requires the implementation of emerging technologies such as AI to facilitate the process of data management and data interpretation and processing. And the introduction of AI into the medical field aims to simplify diagnosis, create treatment plans, monitor health conditions and generally optimize healthcare operations. There are many risks and uncertainties associated with the introduction of AI-based technologies in healthcare, as AI is undergoing rapid development and its applications are constantly expanding, which in turn prevents the adoption of strict codified regulation in the form of laws and codes of practice. Therefore, international trends of AI control in healthcare are expressed by the development of ethical principles, which are applied in many foreign countries based on the standards of WHO and other international organizations. Ethical standards for Kazakhstan should contain provisions that take into account linguistic and cultural diversity and the existing inequalities in the high-tech equipment of medical facilities in urban and rural areas, which creates inequalities in access to high-tech medical services among urban and rural residents.

The results of the study revealed the problem of correlation between the norms of the Digital Code and the Law on AI, in case of entry into force of both acts, in the context of priority of application of their rules in the field of use of AI and protection of personal data. At the current stage, there is no certainty about the inclusion of rules on the regulation of digitalization of healthcare in the Law on AI and the Digital Code, just as it is not clear how the norms of the two new acts will interact with the rules of the sectoral code in the field of healthcare — the Code on Public Health and Healthcare System. Such legal ambiguity requires the development of a clear system of interaction between different items of legislation. The work on the selected problem has shown the importance of the development of domestic legal and regulatory framework for the process of digitalization of healthcare in accordance with international standards, as they set the directions for further development of activities to build a secure digital environment in the states, where ensuring the consistency of national legal policies facilitates the process of cooperation in combating the challenges and risks associated with digital transformation around the world.

Comparison of the obtained results with the works of other authors (Yelegen A. Ye., 2023; Tlembaeva J.U., 2022; Konusova V.T., 2023) in the framework of scientific discussion shows that having studied the approaches in regulation established by universal and regional international organizations and having considered the peculiarities of foreign and current state of domestic regulation, specific approaches were proposed for the protection of personal medical data and development of ethical principles for the introduction

of AI in health care, taking into account cultural diversity and eliminating the imbalance in the health care system. The results of this paper confirm the relevance of the problems highlighted in earlier studies and suggest logical ways to address them by distinguishing the regulation of healthcare AI from other areas of social life and taking a specific approach in ensuring the protection and privacy of personal health data.

The results of this study are limited by the lack of empirical data in the field of legal regulation of digitalization of health care, which is due to the fact that the problem of regulation of digitalization of health care in domestic science is in its initial stage, which complicates the collection of empirical data and requires a preliminary theoretical understanding that would create a basis for further collection of empirical data.

The findings can be used to develop legal regulation of the process of digital health development in Kazakhstan, which would help to distinguish the regulation of this process from the development of regulatory measures of digitalization in other areas of the economy and society. The proposed results could contribute to more effective control over the protection of citizens' personal health data and the representation of the capabilities of AI systems in medicine and health care, which could increase users' trust in high technology and enhance the enforcement of the right to health protection.

A promising direction for further research could be to examine inconsistencies and gaps in domestic legislation and its compliance with international standards and approaches with the adoption of the AI Law and the Digital Code. Exploring cyber security in healthcare, assessing the risks of medical data breaches and breaches of the right to security of personal data, and issues of liability for unlawful use of data are also of research interest. The legal personality of AI in medicine and healthcare, as well as issues of liability for harms caused by AI and related liability issues could be the subject of future research endeavors.

The study used systematic, comparative legal, and formal legal methods, which allowed for a comprehensive analysis of legislation in the field of digitalization of healthcare. The use of these methods meets the requirements of scientific rigor and ensures the internal consistency of the results.

The study examined the relevant regulatory and legal acts of the Republic of Kazakhstan, including the draft Digital Code, the draft Law on Artificial Intelligence, and the Code on Public Health. This allowed the author to rely on existing and promising sources of law, which increases the relevance and reliability of the conclusions.

Taking into account international standards (WHO, etc.) and foreign experience, it can be argued that the conclusions of the study are comparable with global trends. This increases the validity of proposals related to the development of a national model of ethical standards and medical data protection.

A comparison of the results with the works of other researchers (Yelegen A. Ye., Tlembaeva Zh.U., Konusova V.T.) demonstrates the continuity of the scientific approach and confirms the relevance of the identified problems. This also contributes to the verification of the proposals made in the article.

The authors honestly point out the limitations of the empirical base due to the early stage of research on this topic in Kazakh science. Recognition of these limitations and an emphasis on theoretical elaboration confirm the scientific integrity and objectivity of the study.

The proposed measures to differentiate AI regulation in healthcare and other areas, protect medical data, and develop ethical standards that take into account the cultural context of Kazakhstan can be used in the formation of public policy. This demonstrates the practical value and reliability of the conclusions made.

*Conclusions*

On the basis of the analysis we can say that digitalization of various spheres of the economy and public life, including health care, has not yet received a detailed international regulation, because the digital industry and its various sectors are still at the stage of active development, which prompted the international community to adopt several documents of a recommendatory nature, which in turn does not yet provide an opportunity to establish strict regulation over the process of digitalization in all areas of the economy and public life, including health care.

Domestic legislation provides the legal basis for regulating digitalization of all spheres in general and healthcare in particular. The introduction of digital innovation has given rise to new areas of legal regulation related to the protection of personal health data and the ethical use of AI in medicine and healthcare. This gives an active impetus to the further development of digital legislation, in the process of which, it is necessary to resolve the issue of distribution of relevant rules and regulations in the legislative acts prepared for adoption and already existing regulations governing the health sector.

The alignment of national standards and regulatory tools for digitalization of health with international recommendations promotes fruitful international cooperation and recognition of shared values in the area of health digitalization.

Thus, timely and appropriate regulation of digital health is a critical step towards building an affordable, high-tech and equitable health care system that is resilient to the modern challenges that have followed technological development.

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## Қазақстандағы денсаулық сақтау саласын цифрландыруды заңнамалық реттеудің кейбір мәселелері

Мақалада Конституцияда бекітілген азаматтардың денсаулығын қорғау құқығын жүзеге асырумен байланысты Қазақстандағы денсаулық сақтау саласын цифрландыруды заңнамалық қамтамасыз етудің кейбір мәселелері қарастырылған. Мақаланың мақсаты — медициналық қызметтерді алудың цифрлық форматы арқылы денсаулықты қорғау құқығын жүзеге асыруға кедергі келтіретін құқықтық реттеудегі кемшіліктерді анықтау. Бұл тақырыпты қарастыру үшін экономиканың барлық салаларын ақпараттандыру және денсаулық сақтау саласын цифрландыру процестеріне әсер ететін ұлттық заңнама нормалары, атап айтқанда, жүйелі талдау, салыстырмалы құқықтық және формальды құқықтық әдістер арқылы зерделенді. Теориялық негіз ретінде авторлар зерттеу тақырыбына арналған құқықтық ғылыми әдебиеттер мен халықаралық ұйымдардың құжаттарын зерттеді. Қорытындылай келе, авторлар денсаулық сақтауды цифрландыру саласындағы қоғамдық қатынастарды реттеуде жеке медициналық деректерді қорғаудың маңызды рөлі және жасанды интеллекті этикалық пайдалану қағидаттары туралы және денсаулық сақтау саласының цифрлық дамуын реттейтін әртүрлі нормативтік құқықтық актілердің нормаларын қайта қарау және үйлесімді біріктіру қажеттілігі туралы тұжырымдама жасаған.

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## Отдельные вопросы законодательного регулирования цифровизации здравоохранения в Казахстане

В предложенной статье рассматриваются некоторые вопросы законодательного обеспечения цифровизации здравоохранения Казахстана, сопряженные с реализацией закрепленного в Конституции права граждан на охрану здоровья. Целью работы является выявление несовершенств правового регулирования, препятствующих реализации права на охрану здоровья посредствам цифрового формата получения медицинских услуг. Для рассмотрения данной темы были изучены нормы национального за-

конодательства, затрагивающие процессы информатизации всех сфер экономики и цифровизации сферы здравоохранения, в частности, путем системного анализа, сравнительно-правового и формально-юридического методов. В качестве теоретической базы авторами была изучена юридическая научная литература, документы международных организаций, посвященные предмету исследования. В заключении авторы пришли к выводу о значимой роли защиты личных медицинских данных и принципов этического применения искусственного интеллекта при регулировании общественных отношений в области цифровизации здравоохранения и о необходимости пересмотра и гармоничного сочетания норм разных нормативно-правовых актов, регулирующих цифровое развитие здравоохранения.

*Ключевые слова:* право на охрану здоровья, цифровизация здравоохранения, регулирование цифровизации здравоохранения, защита медицинских данных, искусственный интеллект, этические принципы ИИ, закон об ИИ, цифровой кодекс.

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