LAW DRAFTS / ЗАКОНОПРОЕКТЫ

Rubric editor *Z. I. Khisamova* / Редактор рубрики *З. И. Хисамова*

Scientific article **https://doi.org/10.21202/2782-2923.2023.3.873-881**

UDC 34:004.8:615.47(0.041)

A. A. Shutova[1],

I. R. Begishev[1]

[1]*Kazan Innovative University named after V. G. Timiryasov, Kazan, Russia*

Draft of an ethical code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies

Contact:

Albina A. Shutova, Candidate of Juridical Sciences, Senior Researcher of Scientific-research Institute for Digital Technologies and Law, Associate Professor of the Department of Criminal Law and Procedure, Kazan Innovative University named after V.G. Timiryasov

E-mail: shutovaaa@ieml.ru

ORCID: https://orcid.org/0000-0003-3015-3684

Scopus Author ID: https://www.scopus.com/authid/detail.uri?origin=resultslist&authorId=57219032918

Web of Science Researcher ID: https://www.webofscience.com/wos/author/rid/GOG-9089-2022

eLIBRARY ID: SPIN-code: 5235-4319, AuthorID: 835100

Ildar R. Begishev, Doctor of Law, Associate Professor, Chief Researcher of the Institute of Digital Technologies and Law, Professor, Department of Criminal Law and Procedure, Kazan Innovative University named after V.G. Timiryasov

E-mail: begishev@ieml.ru

ORCID ID: https://orcid.org/0000-0001-5619-4025

Scopus Author ID: https://www.scopus.com/authid/detail.uri?authorId=57205305394

Web of Science Researcher ID: https://www.webofscience.com/wos/author/record/637461

SPIN-code: 8859-9395, AuthorID: 595003

Abstract

Objective: to develop a draft Ethical Code aimed at establishing ethical norms and rules of official behavior of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies.

Methods: the methodological basis of the draft Ethical Code aimed at establishing ethical norms and rules of official behavior of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies consists of general and specific methods of scientific cognition, including analysis, synthesis, deduction, induction, classification, analogy, and comparison.

Results: To the attention of lawyers – legal scientists and practitioners, medical professionals, members of clinical ethics committees, medical ethics specialists, representatives of law-making bodies, government agencies, business community and public organizations, patients, and a wide range of readers interested in the digital transformation of the healthcare system, we present the first in the Russian Federation draft of an Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies.
Scientific novelty: the draft Ethical Code comprises general principles of professional service ethics and basic rules of official behavior, which should guide the subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies. It is aimed at strengthening the authority of medical personnel, increasing patient confidence in artificial intelligence technologies, and preventing potential negative consequences as a result of their use.
Practical significance: the draft Ethical Code is based on a systematic and comprehensive approach to the study of ethical norms and rules of official behavior, which should be followed by the subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies. The principles specified in the Ethical Code are a basis for the development of the legal regulation system for artificial intelligence technologies in healthcare.

Keywords:
health care, medicine, medical care, medical service, medical ethics, medical professional, medical product, artificial intelligence, patient, law, principle, manufacturer, developer, digital technologies, ethics, Ethical Code

The article was published as a preprint "Pilot project of an ethical code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies" and placed for open access on the website of Kazan Innovation University named after V. G. Timiryasov before being published in the *Russian Journal of Economics and Law* federal peer-reviewed scientific journal. URL: https://ieml.ru/podrazdeleniya-universiteta/izdatelstvo-poznanie/preprinty-kiu/1-2023/

For citation: Shutova, A. A., & Begishev, I. R. (2023). Draft of an Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies. *Russian Journal of Economics and Law*, *17*(4), 873–881. https://doi.org/10.21202/2782-2923.2023.4.873-881

Научная статья

А. А. Шутова[1],
И. Р. Бегишев[1]

[1]*Казанский инновационный университет имени В. Г. Тимирясова, г. Казань, Россия*

Проект Этического кодекса субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интелмекта

Контактное лицо:
Шутова Альбина Александровна, кандидат юридических наук, старший научный сотрудник Научно-исследовательского института цифровых технологий и права, доцент кафедры уголовного права и процесса, Казанский инновационный университет имени В. Г. Тимирясова
E-mail: shutovaaa@ieml.ru
ORCID: https://orcid.org/0000-0003-3015-3684
Scopus Author ID: https://www.scopus.com/authid/detail.uri?origin=resultslist&authorId=57219032918

Web of Science Researcher ID: https://www.webofscience.com/wos/author/rid/GOG-9089-2022
SPIN-код: 5235-4319, AuthorID: 835100

Бегишев Ильдар Рустамович, доктор юридических наук, доцент, главный научный сотрудник Научно-исследовательского института цифровых технологий и права, профессор кафедры уголовного права и процесса, Казанский инновационный университет имени В. Г. Тимирясова
E-mail: begishev@mail.ru
ORCID ID: https://orcid.org/0000-0001-5619-4025
Scopus Author ID: https://www.scopus.com/authid/detail.uri?authorId=57205305394
Web of Science Researcher ID: https://www.webofscience.com/wos/author/record/637461
SPIN-код: 8859-9395, AuthorID: 595003

Аннотация

Цель: разработка проекта Этического кодекса, направленного на установление этических норм и правил служебного поведения субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта.
Методы: в качестве оснований исследования избраны общенаучные и частнонаучные методы научного познания, в том числе анализ, синтез, дедукция, индукция, классификация, аналогия и сравнение.
Результаты: проект Этического кодекса представляет собой свод общих принципов профессиональной служебной этики и основных правил служебного поведения, которыми должны руководствоваться субъекты, осуществляющие деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта, и направлен на укрепление авторитета медицинских работников, повышение доверия пациентов к технологиям искусственного интеллекта и предотвращение потенциальных негативных последствий в результате их применения.
Научная новизна: проект Этического кодекса основан на системном и комплексном подходе к исследованию этических норм и правил служебного поведения, которыми должны руководствоваться субъекты, осуществляющие деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта. Принципы, указанные в Этическом кодексе, служат основой для развития системы правового регулирования технологий искусственного интеллекта в здравоохранении.
Практическая значимость: вниманию юристов – ученых и практиков, медицинских работников, членов комитетов по клинической этике, специалистов по медицинской этике, представителей правотворческих органов, государственных ведомств, бизнес-сообщества и общественных организаций, пациентов, а также широкого круга читателей, интересующихся вопросами цифровой трансформации системы здравоохранения, предложен первый в Российской Федерации проект Этического кодекса субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта.

Ключевые слова:

здравоохранение, медицина, медицинская помощь, медицинская услуга, медицинская этика, медицинский работник, медицинское изделие, искусственный интеллект, пациент, право, принцип, производитель, разработчик, цифровые технологии, этика, Этический кодекс

Статья была опубликована в виде препринта «Инициативный проект Этического кодекса субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта» и размещена в открытом доступе на сайте Казанского инновационного университета имени В. Г. Тимирясова до публикации в федеральном рецензируемом научном журнале *Russian Journal of Economics and Law*. URL: https://ieml.ru/podrazdeleniya-universiteta/izdatelstvo-poznanie/preprinty-kiu/1-2023/

Как цитировать статью: Шутова, А. А., Бегишев, И. Р. (2023). Проект Этического кодекса субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта. *Russian Journal of Economics and Law*, *17*(4), 873–881. https://doi.org/10.21202/2782-2923.2023.4.873-881

Introduction

Artificial intelligence technologies can fundamentally change the healthcare system by producing new and important insights from a vast amount of digital data created during medical care delivery. Today, medical robots and other autonomous systems equipped with artificial intelligence technologies are actively introduced; they are designed to qualitatively change medicine, taking it to a new level.

To the attention of lawyers – legal scientists and practitioners, medical professionals, members of clinical ethics committees, medical ethics specialists, representatives of law-making bodies, government agencies, business community and public organizations, patients, and a wide range of readers interested in the digital transformation of the healthcare system, we present the first in the Russian Federation draft of an Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies.

The principles described in the draft Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies are aimed at the development and formation of a system of legal regulation of artificial intelligence technologies in healthcare. In our opinion, the Ethical Code adoption will contribute to strengthening the authority of medical professionals, increase patients' confidence in artificial intelligence technologies in general and help to prevent potential negative consequences of their use. The developed ethical principles serve as a basis for forming a regulatory environment, which will thereby enable the Russian Federation to become attractive as a territory of advanced development and innovation in the field of artificial intelligence in healthcare.

The ethical issues of creation (development) and application of medical devices based on artificial intelligence technologies are becoming more and more common; hence, it is necessary to eliminate or minimize the possibility of errors related to the use of patients' personal data used for development and testing in the field of artificial intelligence technologies, as well as other errors. Before artificial intelligence technologies can be used in healthcare, we must make sure that both the developers of technologies and medical institutions observe the relevant ethical norms and rules when creating (developing) and clinically applying these technologies. That is why the ethical issues of creation, application and disposal of medical devices based on artificial intelligence technologies are a crucially important area of research and their solution will create a favorable environment for the transformation of ethical principles into specific legal norms.

The structure of the Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies

1. Preamble
2. General provisions
3. Specific provisions
4. Ethical principles of developers and manufacturers of medical products based on artificial intelligence technologies
   4.1. Principle of wellness
   4.2. Principle of safe development
   4.3. Principle of safe introduction
   4.4. Principle of safe application
   4.5. Principle of coordination
   4.6. Principle of algorithmic transparency
   4.7. Principle of equality
   4.8. Principle of nondiscrimination
   4.9. Principle of liability

Draft of the Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies

1. Preamble

Given the importance of digital innovations and technologies in the healthcare system and the traditionally great significance of ethical principles in medicine, guided by the recognized moral principles and norms of the medical community, documents on medical ethics, and industry standards in the field of classification, registration and certification of medical devices based on artificial intelligence technologies, as well as quality control rules for the production of such products, we adopt this Ethical Code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies (hereinafter – Ethical Code).

2. General provisions

2.1. The Ethical Code comprises general principles of professional service ethics and basic rules of official behavior, which must be followed by subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies.

2.2. The Ethical Code is aimed at establishing ethical norms and rules of official behavior of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies, at promoting the authority of medical professionals, increasing patients' confidence in artificial intelligence technologies, and preventing potential negative consequences as a result of their use.

2.3. The principles specified in the Ethical Code shall serve as a basis for the development of the legal regulation system for artificial intelligence technologies in healthcare.

2.4. Medical products based on artificial intelligence technologies shall be developed, produced and used exclusively for the purpose of providing medical care (medical service) or for research purposes.

2.5. Medical professionals are prohibited to force a patient to use medical products based on artificial intelligence technologies, unless it is determined by emergency.

2.6. Medical organizations shall provide financial support for research and development in the field of artificial intelligence technologies, as well as for their introduction into clinical practice.

3. Specific provisions

3.1. The Ethical Code does not detract from the dignity and validity of the codes of professional ethics of medical professionals, but supplements and discloses the peculiarities of their activities when they use medical products based on artificial intelligence technologies.

3.2. An official of an enterprise, institution, organization of a developer (manufacturer) of medical products based on artificial intelligence technologies shall be obliged to familiarize oneself with the provisions of the Ethical Code and comply with them in the course of their professional activity.

3.3. A medical worker working in a medical organization shall familiarize himself/herself with the provisions of the Ethical Code and comply with them in the course of his/her professional activity.

3.4. Each medical professional shall take all necessary measures to comply with the Ethical Code provisions, and each patient shall be entitled to expect compliance of their behavior with the Ethical Code provisions.

3.5. Knowledge and compliance of medical professionals with the Code of Ethics provisions shall be a criterion for assessing the quality of their professional activity and official behavior.

4. Ethical principles of developers and manufacturers of medical products based on artificial intelligence technologies

4.1. Principle of wellness

The development and production of medical products based on artificial intelligence technologies should be aimed at the benefit of patients and society, not just business interests.

Developers and manufacturers of medical products based on artificial intelligence technologies must ensure that their products provide clinical efficacy, improve the quality of medical care (medical service) and improve the health of patients.

4.2. Principle of safe development

Developers and manufacturers of medical products based on artificial intelligence technologies must verify all artificial intelligence algorithms and models used in the medical product.

Developers and manufacturers of medical products based on artificial intelligence technologies must ensure that their products work correctly and cannot cause harm to patients and society.

4.3. Principle of safe introduction

The introduction of medical products based on artificial intelligence technologies into clinical practice should be justified and based on evidence-based medicine and methods of validation, reproducibility and reliability.

4.4. Principle of safe application

Developers and manufacturers of products based on artificial intelligence technologies should ensure that the products are consistently installed, configured, maintained and repaired and that safety protocols are followed.

Documentation on the safe use of products based on artificial intelligence technologies should be clear and accessible.

4.5. Principle of coordination

Developers and manufacturers of medical products based on artificial intelligence technologies should ensure that the artificial intelligence algorithms and models used in such a product are designed to produce uniform and consistent results when analyzing medical data.

This will enable medical professionals to more accurately analyze large amounts of medical research data and use machine learning and statistical analysis techniques to find patterns that will help them to diagnose and treat patients' conditions.

4.6. Principle of algorithmic transparency

Developers and manufacturers of medical products based on artificial intelligence technologies should ensure that their products are designed with transparency and explainability in mind.

Developers and manufacturers of medical products based on artificial intelligence technologies should provide medical professionals with comprehensive information on how their product works, what algorithms and artificial intelligence models are used in the product, what data was used for training and how it was processed.

4.7. Principle of equality

Developers and manufacturers of medical products based on artificial intelligence technologies should strive to ensure that the artificial intelligence algorithms and models used in the product are completely unbiased and based on comprehensive and representative data.

Developers and manufacturers of medical products based on artificial intelligence technologies should encourage the use of open algorithms and free data, since they can enable everyone, regardless of their social status or nationality, to have access to reliable and validated artificial intelligence algorithms and to promote equality.

4.8. Principle of nondiscrimination

Developers and manufacturers of medical products based on artificial intelligence technologies, in order to avoid possible discrimination by religious, ethnic, cultural, social, gender and other characteristics, should ensure that a data set used for the preliminary training of algorithms and artificial intelligence models in their product is representative and corresponds to the population diversity.

Developers and manufacturers of medical products based on artificial intelligence technologies should conduct randomized preclinical and clinical studies (trials) of the product in order to establish the accuracy and effectiveness of the algorithms and artificial intelligence models used.

4.9. Principle of liability

Developers and manufacturers of medical products based on artificial intelligence technologies must ensure that their products meet high quality and safety standards before making them available on the market.

Developers and manufacturers of medical products based on artificial intelligence technologies must be prepared to be liable for any problems arising from incorrect use of the product.

4.10. Principle of post-registration monitoring

A manufacturer of medical products based on artificial intelligence technologies shall, after the product is registered and placed on the market, continuously monitor its performance in order to detect side effects or unforeseen reactions during its use.

Post-registration monitoring of medical products based on artificial intelligence technologies shall be carried out by the federal executive body exercising control and supervision functions in the field of health care.

4.11. Principle of accountability

Developers and manufacturers of medical products based on artificial intelligence technologies must strictly control the products brought to the market for compliance with the safety, reliability and effectiveness requirements.

In the course of testing medical products based on artificial intelligence technologies, conditions that may endanger human life and health must not be created.

5. Ethical principles of medical professionals applying medical products based on artificial intelligence technologies

5.1. Principle of construction and improvement of quality

Medical professionals shall use medical products based on artificial intelligence technologies exclusively for the purpose of providing medical care (medical service).

The use of medical products based on artificial intelligence technologies may significantly improve the quality of medical care (medical service), accelerate the process of medical examination, or help to choose the best treatment method for a patient.

5.2. Principle of safety

The use of medical products based on artificial intelligence technologies should be reliable and safe, and the results obtained on their basis should not be aimed at causing harm to the life and health of patients.

Medical professionals should ensure the creation of a transparent system of preclinical and clinical studies (trials) that guarantee the compliance of such products with high quality and safety standards.

5.3. Principle of prohibition against complete automation

A decision made by a medical professional based on the data from a medical product based on artificial intelligence technologies must not contradict the standards of medical care and cannot be the sole basis for completely automatic diagnosis, treatment and medical examination.

Artificial intelligence algorithms and models used in the medical product can be used to assist medical professionals in making accurate diagnostic and treatment decisions, but the final decision shall be always made by a medical professional based on their knowledge, experience and judgment.

5.4. Principle of voluntary informed consent

Medical professionals must inform patients about all aspects of their medical examination and treatment, including the possible use of medical products based on artificial intelligence technologies under their consent.

The consent to the use of medical products based on artificial intelligence technologies must be voluntary.

A patient must be informed about which medical products based on artificial intelligence technologies will be used in their medical examination and treatment, how they work, what benefits and risks they pose, and how they will affect their health and general condition.

5.5. Principle of qualification of medical personnel

Medical professionals must know and comply with current regulatory legal acts governing their professional activities, shall be trained in the use of medical products based on artificial intelligence technologies, shall know the standards of medical care with the use of medical products based on artificial intelligence technologies.

Medical professionals shall be entitled for professional training or advanced training under the programs "Application of medical products based on artificial intelligence technologies" in the system of continuous medical education on a free of charge basis.

5.6. Principle of data storage and protection

Medical professionals must store patients' personal data in a database observing information safety requirements.

5.7. Principle of data confidentiality

Medical professionals must notify patients that their personal data are being collected and processed.

Information about the fact of a patient's request for medical care (medical service) with the use of medical products based on artificial intelligence technologies, about the patient's health condition and diagnosis, and other information obtained during high-tech medical intervention shall constitute a medical secret.

5.8. Principle of compliance

Medical products based on artificial intelligence technologies must comply with applicable healthcare standards.

5.9. Principle of protection of patients' rights

A patient shall have the right to protection of their rights and interests when medical products based on artificial intelligence technologies are used in relation to them.

Medical professionals must notify patients about which medical products based on artificial intelligence technologies are used in their medical examination and treatment and what side effects or unforeseen reactions are possible during their use.

When using medical products based on artificial intelligence technologies, it is necessary to minimize the risks of possible negative consequences for patients.

5.10. Principle of protection of the rights of medical personnel

A medical professional shall have the right to protect their rights and interests when using medical products based on artificial intelligence technologies in relation to patients.

When applying medical products based on artificial intelligence technologies, it is necessary to minimize the risks of possible negative consequences for medical professionals.

5.11. Principle of empathy

Medical professionals must show sympathy and understanding to patients, take interest in their psychological and emotional state when providing medical care (medical service) with the use of medical products based on artificial intelligence technologies.

5.12. Principle of algorithmic transparency

Medical professionals must understand how a medical product based on artificial intelligence technologies generated a recommendation for medical examination and treatment of a patient.

6. Ethical principles of subjects engaged in the utilization of medical products based on artificial intelligence technologies

6.1. Principle of natural utilization

Medical products based on artificial intelligence technologies beyond their expiration dates must be disposed of. In this case, patients' personal data and other proprietary information used in the medical product based on artificial intelligence technologies must be destroyed.

6.2. Principle of special utilization

Medical products based on artificial intelligence technologies beyond their expiration dates may be used for scientific and educational purposes not related to the provision of medical care (medical service). In this case, depersonalization of personal data of patients treated with the medical product based on artificial intelligence technologies must be organized.

References

1. Shutova, A. A., Begishev, I. R. (2023). *Pilot project of an Ethical code of subjects implementing activity of creating, applying and utilizing medical products based on artificial intelligence technologies*: Preprint No. 1. Kazan: Publishing House "Poznaniye" of Kazan Innovative University named after V. G. Timiryasov. https://doi.org/10.21202/978-5-8399-0803-1_2023_1_16

Список литературы

1. Шутова, А. А., Бегишев, И. Р. (2023). *Инициативный проект Этического кодекса субъектов, осуществляющих деятельность по созданию, применению и утилизации медицинских изделий на основе технологий искусственного интеллекта*: препринт № 1. Казань: Изд-во «Познание» Казанского инновационного университета. https://doi.org/10.21202/978-5-8399-0803-1_2023_1_16

Conflict of Interest / Конфликт интересов

One of the authors (I. R. Begishev) is a member of the Journal Editorial Board of the Russian Journal of Economics and Law. The article has been reviewed on the usual terms.

Один из авторов (И. Р. Бегишев) является членом редколлегии журнала Russian Journal of Economics and Law. Статья прошла рецензирование на общих основаниях.

Article history / История статьи

Received / Дата поступления 26.08.2023
Date of approval after reviewing / Дата одобрения после рецензирования 12.10.2023
Accepted / Дата принятия в печать 12.10.2023