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MECHANISMS FOR INTRODUCTION OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE: NEW ETHICAL CHALLENGES

Khokhlov AL1, Zarubina TV2, Kotlovsky MYu1.3 M, Pavlov AV1, Potapov MP1, Soldatova ON1, Gabidullina LF1, Tsybikova EB3

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Currently, systems based on artificial intelligence (Al) are finding increasing application in medicine. Acting as assistants of both the attending physician and managing physician, they can be a good help in solving a number of problems in modern healthcare, such as staff shortage, professional burnout and, in some cases, insufficient staff qualification. However, this leads to increased requirements for reliability of such systems. Introduction of a new advanced technology raises a number of ethical issues and problems, the solution of which is necessary to gain trust of people and reduce distrust associated with the use of Al technologies. It seems that if ethical standards determine and set the progressive development of artificial intelligence, this will lead to the maximum benefit from the use of this technology in healthcare. The paper examines the ethical aspects of transition of software into the category of medical devices. At the same time, legal and organizational mechanisms for solving ethical problems at both the international and domestic levels are provided. The activities of both public and government organizations in this field are considered. The need to obtain the permission of ethical committees for conducting clinical trials and ensuring informed consent of patients is emphasized. It also highlights the importance of integrating medical data into structured datasets that can be registered as databases. This will contribute to improved quality of medical research and practice.

Keywords: artificial intelligence, ethics, ethics committee, code of ethics

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МЕХАНИЗМЫ ВНЕДРЕНИЯ ТЕХНОЛОГИЙ ИСКУССТВЕННОГО ИНТЕЛЛЕКТА В ЗДРАВООХРАНЕНИЕ: НОВЫЕ ЭТИЧЕСКИЕ ВЫЗОВЫ

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В настоящее время системы на основе искусственного интеллекта (ИИ) все больше и больше проникают в медицину. Выступая помощником как лечащего врача, так и врача организатора, они могут стать хорошим подспорьем в решении ряда проблем в современном здравоохранении, таких как кадровый дефицит, профессиональное выгорание и недостаточная, в отдельных случаях, квалификация персонала. Однако это обусловливает повышенные требования к надежности подобных систем. Внедрение новой передовой технологии поднимает и ряд этических вопросов и проблем, решение которых необходимо для завоевания доверия людей и снижения недоверия к применению технологий ИИ. Видится, что, если прогресс в развитии искусственного интеллекта будет определяться и задаваться этическими нормами, это приведет к извлечению максимальной пользы от применения данной технологии в здоровьесбережении. В работе рассматриваются этические аспекты перехода программного обеспечения в категорию медицинских изделий. При этом приводятся правовые и организационные механизмы решения этических проблем как на международном, так и на внутригосударственном уровне. Рассматривается деятельность как общественных, так и государственных организаций в данной сфере. Подчеркивается необходимость получения разрешения этических комитетов для проведения клинических испытаний и обеспечение информированного согласия пациентов. Также указывается важность интеграции медицинских данных в структурированные датасеты, которые могут быть зарегистрированы как базы данных. Это будет способствовать повышению качества медицинских исследований и практики.

Ключевые слова: искусственный интеллект, этика, этический комитет, этический кодекс

Вклад авторов: авторы внесли равный вклад в проведение научно-исследовательской работы и написание статьи.

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The term artificial intelligence was first coined by John McCarthy at Dartmouth Seminar in 1956. This event lasted for 6 weeks. At this time, leading experts interested in human mind modeling (John McCarthy, Marvin Minsky, Claude Shannon, Nathaniel Rochester, Arthur Samuel, Allen Newell, Herbert Simon, Trenchard Moore, Ray Solomonoff and Oliver Selfridge) discussed the fundamental possibility of creating a thinking machine. As a result of this

conference, the main guidelines of the new field of science were announced [1].

The significant events in artificial intelligence (AI) development in general and their application in medicine include Alan Turing's article "Computing Machines and the Mind" (1950) [2], the first scientific article "Some Studies in Machine Learning Using the Game of Checkers" [3], dedicated to AI, published in Pubmed database (1964), one of the first AI-based decision support

systems (MYCIN) (1976) [4], as well as permission to use these systems (IDx-DR) in clinical practice in the USA (2018) [5] and much more. However, it was not possible to avoid the waning interest in this topic caused by insufficient technology development and high expectations [6].

It is no doubt that the decision of the European regulator (CE Mark) regarding the permission to use ChestLink service in the clinic in 2022 can be considered a landmark event. The service was developed by Oxipit, the Lithuanian startup. This software product autonomously analyzes X-ray images of the chest and, in the absence of pathology, independently forms a conclusion for the patient without involving a radiologist [7]. Currently, Russia has come close to development of similar systems.

Thus, AI systems in medicine are becoming more and more autonomous. This can be a good help in solving a number of problems in modern healthcare, such as staff shortages, professional burnout and, in some cases, insufficient staff qualifications. However, this also increases the ethical requirements for reliability of such AI systems. It is of note that none of these systems can guarantee error-free operation in 100% of cases so far.

It seems doubtful that this indicator will be achieved in the future.

Russian analysts identify the following problems associated with the introduction and use of AI in the context of practical healthcare, which make the use of such systems unethical:

- insufficient evidence of effectiveness and safety of solutions in terms of their admission for use by medical professionals;
- increased risk of harm to the health of patients due to potential data processing errors and generated conclusions (recommendations);
- the complexity of interpreting solutions in machine learning (the "black box" problem);
- higher risks of self-learning algorithms that are able to change the way they are functioning due to the emergence of new clinical data, including those obtained during their operation;
- issues of cybersecurity, including unauthorized interference with Al algorithms or access to personal data of patients;
- the problems of data bias, which in turn lead to an asymmetry between the data on which the Al models were trained and the data they analyze when applied in real clinical practice [8].

It is worth noting that the USSR did not only keep up with Western countries in Al development, but was also ahead in a number of topics. At the same time, well-known political events have allowed our partners to get ahead in this area [9]. Currently, Russia is actively developing and increasing its efforts every year.

So, what is artificial intelligence? In the presidential decree on the development of Al in the Russian Federation, the following definition is provided: artificial intelligence is a set of technological solutions that allows simulating human cognitive functions (including self-learning and finding solutions without a predetermined algorithm) and obtaining results comparable to those of human intellectual activity while performing specific tasks [10].

The literature identifies the main characteristics that make it possible to perceive AI systems as cognitive ones. This is the ability to:

 understand (assimilate new content and include it in the system of established views and ideas);

- speculate (the ability to build a series of thoughts and conclusions on a specific topic and present them in a logically consistent form);
- ensure self-learning (activities to change and adapt the behavior of the subject of education following the goals of survival, development, and improvement);
- expand opportunities (to increase the set of tools and methods that ensure the maximum possible productivity) [11].

It is worth saying that these qualities are fully inherent in the so-called strong Al. At the same time, scientists currently differentiate between weak and strong Al. Weak Al is able to solve only simple applied tasks without human involvement, that is, those tasks for which it was directly created. Strong Al is supposed to be autonomous and has the ability to learn and speculate.

It is mentioned in the National Strategy of the Russian Federation for the Development of Artificial Intelligence that the entire fundamental scientific research is aimed towards creation of a universal (strong) AI [10].

The emergence of strong AI is currently associated with the development of generative adversarial neural networks (GANs) and large language models based hereon. Currently, there are already several dozen similar systems, including ChatGPT (Generative Pre-trained Transformer) [12]. These AI systems, in turn, are designed to solve a wide range of issues for almost any text user requests, including writing and programming code. Computer programs have become capable of writing new computer programs on their own. According to quality metrics aimed at measuring associative thinking, these models have approached the basic human level by 2022. Funding for development of these models is also increasing expansively from year to year [13].

From an ethical point of view, it is worth paying attention to the fact that in 2023, more than thousands of experts in the field of Al signed an open letter calling for a 6-month moratorium on strong Al development, to which they refer these models, in order to develop an effective risk forecasting system and ensure control over the development and consequences of introduction of intelligent technologies [14]. WHO also called for the balanced and responsible development and application of large language models [15].

As it has been mentioned already, in 2019, the Russian Federation adopted the national strategy for development of artificial intelligence until 2030. It defines the role of Al in healthcare, which is to improve the quality of services, including:

- preventive examinations;
- diagnostics based on image analysis;
- forecasting the occurrence and development of diseases;
- selection of optimal dosages of medicines;
- reduction of pandemic threats, automation and precision of surgical interventions [10].

It is worth noting that apart from Russia, more than 60 countries have adopted similar documents in the field of Al development [16]. This is due to the awareness of the economic, political and defense advantages provided by the operation of such systems at the state level.

The above strategy states that in order to maximize the effective stimulation of the development and use of AI technologies, it is necessary to adapt regulatory regulation in terms of human interaction with AI and develop fundamental ethical standards [10].

It should be noted that in Russia, the National Committee on Ethics of Artificial Intelligence was established in 2020 under

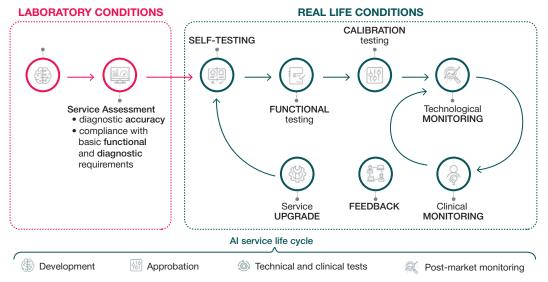


Fig. 1. The life cycle of the AI system in the Moscow experiment [22]

the Commission of the Russian Federation for UNESCO. This is the first such body in the world under the National Commission for UNESCO. This committee includes leading experts in the field [17].

In the international field, 193 countries concluded a global agreement on the ethics of Al within the framework of the 41st session of UNESCO (2021) [18]. Russia acted as one of the most active participating countries in the process of developing recommendations and initiated discussions on a number of key issues in this area.

It is worth noting that at the interstate level, more than a dozen international organizations are developing recommendations and standards for the use of Al in the field of medicine. However, their actions are sometimes insufficiently coordinated [19].

As an example of non-compliance with ethical principles, one can cite the study indicated in the report of British scientists on the development of Al for 2022 (State of Al). According to it, the Al system was tasked by scientists to select a chemical formula of a substance with maximum toxicity and biological activity instead of reducing the toxicity of a drug. The Al system generated the formula of VX warfare agent [20].

Thus, we can say that almost all Al systems are dual-use systems. They can be configured to bring both benefit and harm to a person. It depends on the professionalism and goodwill of their creator and operator.

In 2021, Russia itself adopted a Code of Ethics in the field of artificial intelligence. It was developed by the Al Alliance, which unites leading Russian technology companies with the participation of the Analytical Center under the Government of the Russian Federation and the Ministry of Economic Development. Currently, 303 leading Russian organizations and 41 federal authorities have joined the Code.

Its provisions apply to relations associated with ethical aspects of the life cycle of an AI system, including creation (design, construction, piloting), implementation and use of AI technologies at all stages of their life cycle.

The condition for the application of this Code provisions is that:

- These relations are currently not regulated by the legislation of the Russian Federation and/or acts of technical regulation;
- Al systems are used exclusively for civilian (not military) purposes [21].

This Code proclaims the following fundamental ethical principles and rules of conduct:

- the main priority of the development of AI technologies is to protect the interests and rights of people and the individual;
- 2) it is necessary to be aware of responsibility when creating and using AI;
- the responsibility for the consequences of the use of Al is always borne by a person;
- Al technologies need to be used for their intended purpose and implemented where it will benefit people;
- 5) the interests of AI technology development are above the interests of competition;
- 6) maximum transparency and truthfulness in informing about the level of development of AI technologies, their capabilities and risks [21].

The provisions of this Code permeate the entire life cycle of the AI system. A typical example is the cycle of such systems in the Moscow experiment conducted on the basis of Scientific and Practical Clinical Center for Diagnostics and Telehealth Technologies of the Moscow Healthcare Department (Fig. 1). This world's largest experiment has been ongoing since 2020 and has allowed leading domestic and foreign manufacturers of medical AI systems to demonstrate their capabilities [22].

It is necessary to pay attention to the fact that the cycle should include constant training and retraining of the product. This is because the model becomes outdated from the moment it is created. At the same time, monitoring and control actions should be carried out on the constant basis.

Al-based programs in the Russian Federation can have two forms: information systems and medical devices. In the latter case, they undergo preclinical (laboratory) and clinical studies, are subject to registration by Roszdravnadzor and included in a special register of medical devices.

The software is a medical device in the presence of the following signs:

- It is a computer program, regardless of the hardware platform used, as well as the ways to place and provide access to it;
- It is not an integral part of another medical device;
- It is intended by the manufacturer for medical care;
- It converts the original information.

Clinical trials (studies) of software using AI technologies are conducted on the basis of a permit issued by the registration

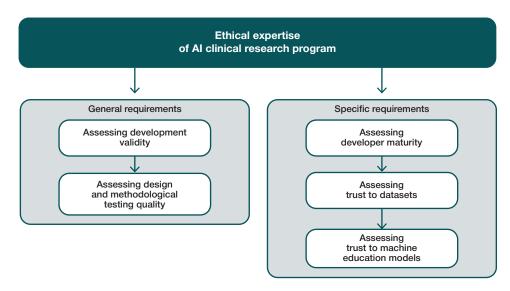


Fig. 2. Algorithm for conducting an examination of the clinical trial program of the Al system for healthcare [8]

authority (Roszdravnadzor), as well as an opinion on the ethical validity of clinical trials issued by the Ethics Council of the Ministry of Health of the Russian Federation in the field of medical device circulation [23].

The Russian Federation has a system of ethical committees, both at the national and local levels. One of the main functions of the local ethics committees is to make sure that patients in clinical trials are fully and in an accessible form informed about the risks and benefits resulted from participation in the study and that they have provided informed consent to participate in the study or consent to use the information received when medical care was provided to them.

Thus, while conducting a clinical trial (research) of Al systems, permission from ethical committees at both levels must be obtained. At the same time, there should be a constant exchange of information with the organization on the basis of which these tests are conducted. The Ethics Committee is notified of the occurrence of serious adverse events. Clinical trials should be conducted in full compliance with ethical principles based on the Helsinki Declaration [20]. At the same time, previously obtained medical information can also be used in the clinical trial of these systems, if direct patient participation is not required (a retrospective study procedure).

Currently, methodological recommendations have been created in Russia for conducting an ethical examination of the clinical trials (research) program of the Al system for healthcare. Figure 2 shows their recommended algorithm for this examination [8].

It is worth noting that apart from state control, systems of voluntary Al certification have now begun to be developed and implemented in Russia. This certification aims to assess the compliance of Al algorithms with the requirements imposed hereon. The INTELLIGOMETRICA system developed by the National Research University Higher School of Economics (no. ROSS RU.B2915.04VSE0) can serve as an example.

A number of ethical issues are raised by the process of collecting and using medical data. It is worth noting that appropriate data is needed to create and monitor AI systems. At the same time, they are diverse and have a complex structure. One of the key tasks of the developer is to ensure the integration of heterogeneous information into a structured dataset. The dataset differs from a simple set of medical data because it is endowed with special properties:

1) it is unified and structured;

- 2) there are no gross inaccuracies, erroneous values;
- 3) it has additional information (categories and values of features or characteristics of data elements) [24].

In Russia, a dataset is equal to a database and, as a result of intellectual activity, can voluntarily undergo through state registration. When conducting clinical trials of an Al system, it is recommended to use only registered datasets [25].

In a foreign practice, datasets are often published not only as datasets available for download, but also as scientific publications in a journal.

Thus, creating high-quality datasets is just as difficult and demanding as writing a software code and teaching a machine learning model.

Whoever owns the data creates AI systems. This is supported by the experience of foreign giant corporations. Western companies are willing to pay billions of dollars to possess the data (IBM Watson Health).

In the Russian Federation, a significant number of open datasets with medical information available for download (mainly marked up computer images) were created by Scientific and Practical Clinical Center for Diagnostics and Telehealth Technologies of the Moscow Healthcare Department [26]. Great hopes in the accumulation of data are placed on the subsystems created within the framework of the Uniform State Health Information System.

Currently, a large number of datasets with medical information (sometimes of unknown quality) remain publicly available on foreign platforms (Kaggle, Google Dataset Search, AWS Public Datasets, etc.).

In the Russian Federation, medical data for training and testing Al systems should not contain any personal information apart from the consent of the patient to whom this data belongs (GOST R 59921.5-2022 Artificial intelligence systems in clinical medicine.

Any such information should be deleted both from metadata and source data. At the same time, it remains an open question how to maintain a balance and not violate the rights and legitimate interests of the patient, without over-regulating this industry by hampering its development. It is no secret that modern systems, including those based on AI, can restore a person's identity based on indirect data (for example, restoring a patient's face from the bones of the skull with subsequent identification through social networks) [27]. Therefore, the question remains open about exactly what

information should be deleted and how to leave information that is at least somewhat useful for machine learning.

In order to eliminate unnecessary administrative barriers, a number of regulatory acts in the Russian Federation allows experimental legal regimes to be established for developers for a limited time, on a limited territory, and for a limited number of subjects [28].

When creating and operating AI systems in medicine, transparency of their application and the possibility of human cancellation and/or prevention of socially and legally significant decisions at any stage of their life cycle should be ensured in order to comply with international and interstate ethical regulations. Leading international organizations (UNESCO, EU, OECD) are calling for increased transparency of AI systems. Meanwhile, transparency means as follows:

- availability of the source code;
- understanding by the user why the machine made this or that decision;
- understanding by the patient of the positive and negative aspects of interaction with AI.

At the international level, the IEEE (Institute of Electrical and Electronics Engineers), a non-profit engineering association from the United States, is engaged in standardization of transparency of Al systems.

It is worth noting that currently AI systems in medicine are not endowed with legal personality. They are only doctor's advisers and do not absolve him of legal responsibility for actions performed during the provision of medical care. The responsibility is currently borne by the attending physician. In some cases, legal responsibility may be assigned to the medical organization on the basis of which these systems are used, their developer and manufacturer [29].

The implementation of the above ethical principles is facilitated by ensuring comparability of technical parameters, unification of AI safety requirements, as well as free cross-border exchange of medical technologies and the results of their implementation in medicine, biology, and pharmacology. This is confirmed in WHO Resolution WHA71.7 dated 05/26/2018 on Digital healthcare [30]. In the Russian Federation, Technical Committee for Standardization 164 "Artificial Intelligence" (TC 164) was established to improve the efficiency of standardization in the field of development and operation of Al systems at the national and international levels. More than 120 specialized organizations take part in the activities of TC164. The subcommittee SC 01 "Artificial Intelligence in Healthcare" was formed as part of this Committee. This subcommittee works on the basis of Scientific and Practical Clinical Center for Diagnostics and Telehealth Technologies of the Moscow

Healthcare Department [30]. In addition, the work of a number of other technical committees and subcommittees may be relevant to the development of fundamental state industry standards in this area including:

- TK-MTK-22 "Information Technology" / SC 132 "Data management and data exchange";
- TK-MTK-22 "Information Technologies" / SC 138 "Platforms and services for distributed applications";
- TK-MTK-22 "Information Technologies" / SC 127 "Information Technology Security";
- TC 96 "Biometrics and biomonitoring";
- TC 164 "Artificial intelligence" / SC 02 "Data";
- TC 194 "Cyber-physical systems";
- TC 362 "Information protection";
- TC 459 "Information support of the product lifecycle".

It is worth noting that the result of SC 01 alone was the entry into force of more than a dozen State industry standards, including GOST 59921 "Artificial intelligence systems in clinical medicine", which examines the procedure for conducting technical and clinical trials of medical systems based on Al and GOST 59276 "Artificial intelligence systems. Ways to ensure trust'.

CONCLUSION

The intensive development of AI systems and their widespread introduction into the healthcare system inevitably pose many ethical questions for Russian society. The importance of ethical regulation in this segment of AI development is due to several key aspects. Firstly, this will protect the rights of patients to the greatest extent possible, which includes ensuring their informed consent, data confidentiality and security. Secondly, it is necessary to take into account justice and equality in access to AI-based medical technologies, preventing possible discrimination. In addition, it is necessary to take into account the potential risks and limitations of the use of AI in medicine (such as algorithm errors, lack of full transparency in decision-making and the need for constant monitoring and updating of systems).

Ethical standards should also include mechanisms to control the responsibility and accountability of AI developers and users. In this regard, development and implementation of AI systems in healthcare should not only be determined, but also strictly controlled by ethical principles. Taking appropriate measures at the national and international levels can significantly increase public confidence in the use of AI in medical institutions, contribute to the overall progress of the modern healthcare system and improve the quality of medical care.

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ETHICAL AND CULTURAL CHALLENGES POSED BY ARTIFICIAL INTELLIGENCE (AI) IN MEDICAL PRACTICE: MULTICULTURAL ANALYSIS

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The use of AI in medical practice offers a number of significant and visible advantages. The problem of the presented research is relevant due to the growing integration of technologies into healthcare. The purpose of this study is to analyze the ethical and cultural challenges associated with integration of artificial intelligence (AI) in medical practice in various cultural contexts. The main objective of the study is to identify specific problems and suggest possible solutions to ensure effective and justifiable use of AI. To achieve this goal, a literary review, a case study, an expert interview, and a questionnaire were used. The main areas of ethical and cultural challenges include the issues of confidentiality and data protection; culturally specific attitudes towards automation of medical decision-making; the impact of algorithm bias on the diagnosis and treatment of various ethnic groups; ethical dilemmas related to access and fairness in the use of medical AI systems. The study highlights the need to develop ethical standards for the use of AI in medicine that will take into account cultural differences.

Keywords: artificial intelligence, medicine, ethics, cultural differences, multiculturalism, technological innovations, ethical problems, technology implementation

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ЭТИЧЕСКИЕ И КУЛЬТУРНЫЕ ВЫЗОВЫ ВНЕДРЕНИЯ ИСКУССТВЕННОГО ИНТЕЛЛЕКТА В МЕДИЦИНСКИХ ПРАКТИКАХ: МУЛЬТИКУЛЬТУРАЛЬНЫЙ АНАЛИЗ

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Использование ИИ в медицинских практиках предлагает ряд значительных и наглядных преимуществ. Актуальность проблемы представленного исследования обусловлена растущей интеграцией технологий в здравоохранение. Цель данного исследования заключается в анализе этических и культурных вызовов, связанных с внедрением ИИ в медицинские практики в различных культурных контекстах. Основная задача исследования — выявить специфические проблемы и предложить возможные пути их решения для обеспечения эффективного и справедливого использования ИИ. Для достижения поставленной цели были использованы следующие методы: литературный обзор, кейс-стади, экспертное интервью, анкетирование. Основными направлениями этических и культурных вызовов являются: вопросы конфиденциальности и защиты данных; культурно-специфичные отношения к автоматизации принятия медицинских решений; влияние предвзятости алгоритмов на диагностику и лечение различных этнических групп; этические дилеммы, связанные с доступом и справедливостью в использовании медицинских ИИ-систем. Исследование подчеркивает необходимость разработки этических стандартов для использования ИИ в медицине, которые будут учитывать культурные различия.

Ключевые слова: искусственный интеллект, медицина, этика, культурные различия, мультикультурализм, технологические инновации, этические проблемы, внедрение технологий

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Artificial intelligence (AI) is a branch of computer science that aims to create machines capable of performing tasks that typically require human intelligence. Such tasks include recognizing speech, identifying patterns, and making decisions, etc. In recent years, AI has significantly revolutionized medical practice by suggesting novel capabilities to improve diagnostics, process big data, for personalized medicine and even automated surgery.

However, integration of AI in medical practice poses not only technical, but also ethical, social and cultural challenges. Studying these aspects is critical because cultural differences can significantly influence perception and acceptance of new technologies. Different cultures may have different approaches to data privacy, the role of the attending physician, and even the very

concept of health and disease. This should be taken into account when developing and implementing AI systems in medicine.

The goals and objectives of the study are as follows:

The goals:

- To conduct a comprehensive analysis of the ethical and cultural challenges associated with integrating AI into medical practice.
- 2) To assess the impact of multicultural factors on perception and use of Al in medicine.
- Develop recommendations for integration of Al, taking into account the cultural and ethical characteristics of different communities.

The objectives:

- To study current research and literature on ethics and culture of Al in medicine.
- Conduct surveys and interviews with medical professionals, patients and AI experts from various cultural groups.
- Analyze the data obtained to identify the main ethical and cultural contradictions and challenges.
- 4) Compare different approaches to AI integration into medical practices in different cultures.
- Develop a set of recommendations for medical institutions and AI developers, taking into account multicultural factors for ethical and effective use of AI in medicine.

Relevance

Integration of artificial intelligence into medical practices results in significant changes in healthcare, including diagnosis, treatment and monitoring of patients. At the same time, it is necessary to take into account not only technological and clinical, but also cultural and ethical issues. The relevance of the study is due to the following factors:

- 1. Ethical risks:
- Ensuring patient data confidentiality.
- Transparency and explainability of Al-made decisions.
- Fairness and non-discriminatory use of Al.
- 2. Cultural differences:
- Perception of technology and trust in AI can vary significantly across cultures.
- Cultural norms and traditions can influence the willingness of patients and doctors to use Al.
- 3. Globalization of healthcare: the increase in migration and multicultural communities is followed by an increasing need to consider cultural factors in healthcare.
- 4. Innovation and development: to make integration into medicine successful, Al accelerated development requires adaptive and universal strategies.

Novelty

The research novelty lies in development of an interdisciplinary approach to the study of AI impact on medical practices, taking into account cultural and ethical aspects:

- 1. A combination of ethical and cultural analysis: conducting a comprehensive analysis combining ethical and cultural aspects, which was not previously widely covered in existing studies.
- 2. Multidisciplinary approach: integration of knowledge from the fields of medicine, sociology, anthropology and artificial intelligence to obtain deeper and more informed conclusions.
- 3. Focus on multiculturalism: the study of specific challenges and opportunities associated with the use of AI in multicultural settings promoting the global adaptation of technologies.

MATERIALS AND METHODS

1. Research design

The study was based on a qualitative multicultural analysis, the purpose of which was to identify the ethical and cultural challenges associated with the introduction of artificial intelligence (Al) into medical practices. Methods of nosological analysis, as well as content analysis of literary sources and expert interviews were used.

2. Selection

To ensure the representativeness of the multicultural aspect, the sample included medical institutions and experts from various regions and cultural contexts. Countries with different levels of economic development and cultural traditions were covered, including but not limited to the following:

- USA
- Europe (Germany)
- Asia (India, Japan)
- Latin America (Brazil)
- 3. Data collection

The data was collected with the following methods:

Analysis of documentary sources. Scientific articles, government documents, as well as reports from international organizations devoted to AI in medicine were analyzed.

- 4. Data analysis methods
- Comparative analysis. Comparative analyses were conducted to identify differences and similarities in Al perception and acceptance in medicine between different cultural and geographical contexts.
- Sociological analysis. The analysis made it possible to identify social determinants that influence AI perception and integration in medical practices, including social norms, traditions and the level of trust in technology in different countries and cultures.

5. Limitations of the study

It is worth noting that this study is limited by time and scope of analysis. The conclusions may be specific to the selected cultural contexts and may not necessarily apply to all other situations and regions. A broader understanding requires further research covering a wider range of cultural contexts and time frames.

THE STUDY RESULTS

The use of artificial intelligence (AI) in medicine represents a great potential for improving the quality and accessibility of treatment, but at the same time it poses a number of ethical challenges to society [1–8]. Let's look at the most significant ones:

- 1. Confidentiality of data. Al often utilizes large amounts of medical data, including personal information of patients. The data should be protected from unauthorized access and leaks. It is important to strictly adhere to the principles of confidentiality and use advanced encryption and security methods.
- 2. Compliance with information consent. It is necessary to make sure that patients are fully aware of how their data will be used and give their consent to such use.
- 3. Management and control of errors. Like any technology, Al is not immune to errors that can lead to incorrect diagnosis or treatment. It is necessary to develop systems that minimize possible errors and establish clear procedures for their correction.
- 4. Inequality in access to health services. There is a risk that the use of AI will increase the gap between those who can afford access to modern medical technologies and those who lack the access. It is necessary to ensure equal access to medical innovations.
- 5. Transparency of algorithms. Al should be transparent in the sense that healthcare professionals and patients should understand how decisions are made. Hidden algorithms can cause mistrust and complications in relation to responsibility and ethics.
- 6. The *principle of justice*. It is necessary to ensure that Al does not create bias against certain groups of the population. This includes monitoring the use of fair data and algorithms that do not reinforce the existing stereotypes.
- 7. Responsibility. In case of medical errors, it should be clear who is responsible for that (Al creators, medical professionals, hospitals or someone else). Clear legislative and legal frameworks are required.
- 8. Making ethical decisions. Addressing life and death is not easy. Al should be designed in such a way as to take into

account not only the technical, but also the ethical aspects of its use in medicine.

The ethical challenges of using AI in medicine require extensive interdisciplinary collaboration, including medicine, law, ethics, and information technology, to ensure that benefits can be implemented without compromising the rights and well-being of patients.

The use of artificial intelligence (AI) in medicine raises a number of cultural challenges and issues that are important to consider for successful integration of technologies into medical practice [9–15]. Attitudes towards AI can vary significantly depending on the cultural environment, the level of trust in technology, and traditional ideas about medical ethics and practice. Let's look at a few key aspects:

- 1. Trust in technology. In some cultures, high-tech medical equipment and AI in general are taken as positive and progressive innovations. However, other communities can experience skepticism and distrust for machines making important decisions, including due to concerns about data privacy and the potential errors of machine algorithms.
- 2. Privacy and privacy issues. Al systems often require large amounts of data for training and analysis, which raises concerns about security and confidentiality of personal medical information, especially in cultures with strict traditions regarding personal space and information isolation.
- 3. Ethical dilemmas. Al may question traditional ethical principles of healing. In some cultures, it may be acceptable for Al to provide treatment recommendations based on statistical data, while in others it may be required that the final decision always remains with the person.
- 4. Social norms and expectations. In some cultures, a doctor is considered an authority, and Al offers can be perceived as a challenge to that authority. Also, different societies may treat medical mistakes made by Al more strictly than mistakes made by humans.
- 5. Accessibility and inequality. All use can exacerbate existing inequalities in access to health services, as access to advanced technologies is often limited in regions with a limited resource capacity or remote regions. This can result in tension between groups with different levels of access to technology.
- 6. Integration into traditional practices. In different cultural contexts, specific traditional practices or beliefs that must be taken into account when implementing AI can be available. Ignoring these aspects can lead to rejection of the technology by medical staff and patients.

DISCUSSION OF THE RESULTS

Taking into account cultural differences and sensitivity to these aspects is a key to creating effective, fair and ethical medical Al systems [16–24]. An approach based on cooperation between engineers, doctors, ethnographers and patients can contribute to the development of Al tools that take into account the cultural context and find support in diverse societies.

In different countries, the cultural challenges of Al implementation are approached in different ways, due to both historical and modern socio-cultural factors [25–30]. Let's look at some examples.

1. The United States of America

In the USA, great attention is paid to the confidentiality of patient data. All in medicine should be used in accordance with the requirements of data privacy legislation such as HIPAA (Health Insurance Portability and Liability Act). All systems that analyze medical data must strictly comply with these standards. In

addition, the startup culture is highly developed. It contributes to rapid integration of new technologies in medicine.

2. Japan

In Japan, respect for the elderly is extremely important. This is taken into consideration when AI systems are developed, especially in the field of care for the elderly. Japan is actively researching and developing AI to support the elderly, taking into account their needs and preferences. This approach makes various aspects of their lives easier.

3. Germany

Germany has strict data protection rules applied while regulating the introduction of AI into medical practices. Ethics committees are actively involved in the process of approving the use of AI to ensure compliance with ethical standards. Germany also focuses on research on AI responsible use, emphasizing the importance of an open dialogue with society regarding these issues.

4. India

In India, there are significant regional differences in access to medical services and Al technologies. Al developers try to make technologies accessible and understandable to a wide range of users, including those regions where medical infrastructure is not developed much. Al projects are often aimed at improving the availability of medical services.

5. Brazil

In Brazil, special attention is given to the social responsibility of technology adoption just like in other Latin American countries. In medicine, Al is seen as a means of reducing social inequalities while getting access to healthcare. Artificial intelligence programs try to be sensitive to different cultural contexts and practices.

To ensure the ethical and culturally sensitive use of Al in medicine, it is necessary to promote interdisciplinary cooperation between specialists in the field of Al, medicine, sociology, law and ethics [31–33]. The public and patients should be actively involved in the processes of development and decision making. This will help not only to promote innovative development, but also to take into account moral, ethical and cultural aspects while introducing new technologies into medicine.

CONCLUSIONS

The integration of artificial intelligence (AI) into medical practice is a complex and multifaceted process, accompanied by significant ethical and cultural challenges. During the multicultural analysis, the following key aspects were identified:

1. Ethical Privacy and Security Concerns:

Considerable attention should be paid to maintaining the confidentiality of personal medical data. The implementation of Al systems requires compliance with strict security standards, as patient data may be vulnerable to leaks and cyber attacks. In addressing these issues, it is important to take into account not only the technical aspects of data protection, but also the ethical standards of each particular culture.

2. Fairness and non-discrimination:

Al systems used in medical practices should be designed to strictly adhere to the principles of fairness and non-discrimination based on race, gender, social status and

other factors. The introduction of algorithms that take into account multicultural diversity and characteristics of each group will contribute to a more just distribution of medical services.

3. Cultural Adequacy:

Different cultural groups may perceive and react differently to the use of Al in medicine. It is important that developers and implementers of Al systems take into account cultural values, customs and biases that may influence the adoption of such technologies by patients of various ethnic and cultural communities.

4. The problem of technology translation:

Al introduction in countries with different levels of technical and social development can face many barriers. In developing countries with limited technical resources, the use of Al requires a special approach focused on infrastructure accessibility and sustainability.

5. Legal and regulatory issues:

Each country has legislative frameworks of its own. They can have a significant impact on the way AI is introduced

into medical practices. Each country should develop clear regulatory mechanisms that take into account local legal and ethical standards, as well as international experience.

6. Interaction with medical staff:

Al introduction is also changing the role of medical personnel and requires their active participation in transition to new technologies. It is important to organize training and retraining programs that will allow medical professionals to effectively interact with Al systems, while respecting traditional methods of treatment and care.

In conclusion, integration of AI into medical practices represents a unique opportunity to improve the quality and accessibility of medical care. However, successful integration of AI requires careful consideration of ethical and cultural aspects, ensuring that new technologies benefit all groups of the population and strengthen trust in the medical system among both medical staff and patients.

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FEATURES OF CULTURAL RESEARCH IN THE FRAMEWORK OF CULTURAL NEUROSCIENCE: DEVELOPMENT PROSPECTS AND ETHICAL DILEMMAS

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The purpose of this article is to determine the objectivity of culture from the perspective of the neuroscience's research interests of and to identify neuroethical problems that arise in the process of using neurotechnologies and applying research results. The following aspects were set: to provide a clear understanding of the reasons behind neuroscience's growing interest in culture; to identify new scientific and neurobiological directions studying the relationship between a culture and humans; to substantiate the importance of the emergence of cultural neuroscience, to identify some ethical categories revealed through analysis of research results; to highlight ethical problems that arise or may arise near future during the application of neurotechnologies and the use of research results in this field. The main conclusion of this article is that the development and application of neurotechnologies will be the main priority for many countries, especially taking into account the interest in understanding the cultural characteristics of all people living in the same territories. On the one hand, the knowledge can help to prevent cross-cultural conflicts and improve the effectiveness of management systems in the social sphere. On the other hand, it may lead to bioethical problems due to possible manipulations in various fields as business and politics.

Keywords: cultural neuroethics, cultural neuroscience, ethical problems, bilingualism

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ОСОБЕННОСТИ ИССЛЕДОВАНИЯ КУЛЬТУРЫ В РАМКАХ КУЛЬТУРНОЙ НЕЙРОНАУКИ: ПЕРСПЕКТИВЫ РАЗВИТИЯ И ЭТИЧЕСКИЕ ДИЛЕММЫ

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Цель данной статьи — определить объектность культуры с точки зрения исследовательского интереса нейронаук и выявить нейроэтические проблемы, возникающие в процессе использования нейротехнологий и применения результатов исследований. В качестве задач были выбраны следующие аспекты: дать четкое представление о причинах появления интереса нейронаук к культуре; определить новые научные нейробиологические направления, изучающие связь между культурой и человеком; обосновать значимость появления культурной нейронауки, выделить некоторые этические категории, которые выявляются благодаря анализу результатов исследований; обозначить этические проблемы, возникающие или которые могут возникнуть в ближайшее время в ходе применения нейротехнологий и использования результатов исследований в этом направлении. Основным выводом данной статьи может быть такое заключение: очевидно, что развитие и применение нейротехнологий будет основным приоритетом любой страны, особенно с учетом интереса к культурным особенностям всех народов, проживающих на одной территории. С одной стороны, такое знание позволит избежать межкультурных столкновений и улучшить работу систем управления в социальной сфере, с другой, оно может привести к появлению биоэтических проблем из-за возможных манипуляций в разных сферах бизнеса и политики.

Ключевые слова: культурная нейроэтика, культурная нейронаука, этические проблемы, билингвизм

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Neuroethics emerged as a response to the consequences of developing new biotechnologies in neuroscience, aimed at studying brain function, consciousness, the psyche, and various cognitive processes. These technologies are also being applied in fields such as business, marketing, and politics. Neuroethics possesses interdisciplinary characteristics that make it difficult to fully delineate its scope and areas of responsibility due to

the limited understanding of many aspects of neuroscience. For instance, research areas like neural networks that underpin conscious experiences and unconscious processes, cognitive functions, and brain plasticity across different age groups remain underexplored. The complexity of neuroethics is further compounded by the inconsistency of research data and the rapid pace of advancements in neurotechnologies.

Originally part of bioethics, neuroethics quickly sought autonomy because the unique and fast-evolving research in neuroscience presents specific ethical challenges that require specialized analysis. Its interdisciplinary nature has also played a role in this shift, as neuroethics draws upon neuroscience, philosophy, psychology, and other fields to address these ethical concerns. A deeper understanding of behavioral mechanisms, decision-making, and cognitive processes holds the potential for significant breakthroughs, with neurotechnologies being increasingly integrated into both the real and digital lives of individuals.

At the same time, the interdisciplinarity of neuroscience can also be examined through the broader lens of culture. Moreover, neuroethics itself is embedded in culture and falls within the purview of cultural studies, which examine various forms and manifestations of culture. "Culture is a complex and multifaceted concept that significantly influences science, including neuroethics, affecting both its development as a scientific field and its role in society. Cultural influence on science and public perception is especially relevant for neuroethics, as it seeks to create an interface between neuroscience and society as a whole, addressing the ethical, legal, social, cultural, philosophical, and scientific issues raised by neuroscience and related technologies" [1]. From a scientific standpoint, cultural studies can suggest that ethics be understood as part of spiritual culture, centered on humanism and spirituality, where the function of ethics in the modern world is to protect human life and health. Alternatively, it can be viewed as a means of preservation. On the other hand, culture encompasses all that humans create with their hands and minds, including the technological advancements that drive our civilization's progress.

In the twentieth century, biologists began to observe that cognitive processes, interpersonal interactions, and behavior could not be fully explained by instincts, genetics, or purely physiological causes. Unlike animals, humans are capable of overriding their instincts and acting contrary to their innate programming. Humanity has developed new capacities that have become part of the cultural framework of individuals, nations, and societies. Humans created culture, and in turn, culture shapes human personality. The Russian philosopher and mathematician Fet A argued that humans possess two hereditary systems: genetics and culture. The genome does not contain all the necessary information for survival. "Instinctive behavioral sequences that other animals automatically perform are typically fragmented in humans, linked by 'conscious' behavior. In certain critical instances, such behavior can only be learned from cultural traditions" [2].

The peculiarities of human cognition have become the focus of a new scientific field known as cultural neuroscience, or cultural biology. Researchers in this area aim to tackle a macro task: studying and comparing how individuals from different cultures perform mental operations and why similar conditions do not lead to identical outcomes in behavior, communication patterns, creation of stereotypes, and other cultural phenomena. On one hand, cultural neuroscience examines values, beliefs, practices, and behavior through the lens of neuroscience by analyzing genetic and neural processes. On the other hand, it investigates neurobiological mechanisms to explore similarities and differences in cultural traits within the genotype.

Cultural neuroscience originated in the twentieth century, with its main objective being to explain the socio-cultural phenomena of human life from the perspectives of biology, medicine, genetics, and physiology, among other disciplines. In essence, it seeks to establish a connection between

human cultural environments and neurobiological systems. Cultural neuroethics incorporates ideas and viewpoints from related fields such as anthropology, psychology, and cognitive neuroscience to study sociocultural influences on human behavior [3]. To date, several subfields have emerged within cultural neuroscience, including cross-cultural psychiatry, cross-cultural psychology, epigenetics (biology), evolutionary anthropology, and sociobiology. Each of these areas has its own history and key figures.

Sociobiology, for instance, was influenced by the work of philosopher Daniel Dennett, who built on the ideas of Thomas Hobbes in explaining the origins of morality through a sociobiological lens. During the twentieth century, prominent interdisciplinary scholars such as geneticist John Paul Scott, biologist Edward O Wilson, ethologist Konrad Lorenz, Russian mathematician and philosopher Fet A, and evolutionary biologist Niko Tinbergen studied human behavior based on animal behavior research. These comparisons allowed for the identification of both similarities and differences, leading to the belief that evolution and genetics unite humans with the broader living world, while culture makes humans unique by granting them capabilities that animals do not possess in their natural environments.

Evolutionary ethics was rooted in the evolutionary theory of Charles Darwin. Scientists such as Herbert Spencer, William Graham Sumner, Moore I, and Williams GC explored this area. The theory of genetic and cultural co-evolution emerged later, toward the end of the twentieth century, and was championed by Luigi Luca Cavalli-Sforza, who argued that sociocultural reality develops in tandem with biological evolution. Co-constructivists attempted to explain cultural biases by focusing on the responses of neurons associated with fear. However, these biases were often found to be more individualistic than societal. Some theories, such as Hofstede's Cultural Dimensions Theory, have also been critiqued. Researcher Danilkina S, for example, concludes in her article that "the possibilities of studying social impact within the framework of the natural science approach are significantly limited" [4], particularly due to the lack of philosophical analysis and deeper understanding of the phenomenon under study.

Cultural neuroscience has the potential to address these limitations by identifying neurophysiological correlates of social behavior and the mechanisms by which individual social processes transition to collective ones. Although cognitive processes were once the focus of cultural anthropology, the integration of neuroscience into this research has led to the development of a new subfield that studies cognitive processes formed within specific cultural groups and social environments.

The idea of integrating different areas of scientific inquiry was proposed by the American researcher Cole M, who, in his article "Culture and Cognitive Science" (2003), emphasized the importance of such collaboration for understanding human and societal social behavior. According to Falikman M and Cole M, authors of the article "The Cultural Revolution in Cognitive Science: From Neural Plasticity to the Genetic Mechanisms of Acquiring Cultural Experience", the field is divided into two main areas. "The first area focuses on studying system formation in the human brain under the influence of culture (e.g., schooling, professionalization, etc.). The second examines the stylistic features of cognition across different cultures, especially those that differ in the relationship between individuals and the group (i.e., 'individualistic' versus 'collectivist' cultures), as well as their evolutionary foundations, neurophysiological correlates, and potential genetic underpinnings" [5]. The authors assert that the first area of research aligns with the ideas of renowned psychologists Vygotsky LS and Luria AR.

The development of functional magnetic resonance imaging (fMRI) in the late twentieth century significantly advanced neuroscience's understanding of neural networks. Previous research using simplified brain circuits often failed to explain why individuals choose certain objects or actions and why predictions about behavior often lacked precision. Data obtained through fMRI provided new insights into cognitive processes, answering some longstanding questions and enabling the inclusion of disciplines such as linguistics, philology, and literary studies into interdisciplinary research.

The addition of the "Philosophy of Consciousness" to cultural neuroethics has been crucial in preventing this field from becoming a purely brain-centric science, detached from human concerns. The aim is to ensure that research results benefit individuals. Socially-oriented programs developed within this framework are now widely applied in various professional domains. For instance, these programs can assess the suitability of job applicants by evaluating their predispositions for certain professional requirements. These tools can also be used to evaluate the suitability of professional groups (e.g., musicians, taxi drivers, etc.). However, it is important to maintain an individualized approach, as an incorrect or overly rigid evaluation process may discourage individuals from pursuing their careers. A template-driven approach that fails to account for individual differences may lack objectivity and accuracy in evaluating personal abilities and professional potential.

There have also been positive results in cultural neuroscience research, particularly in studies on bilingualism. This field not only explores professional groups but also examines the phenomenon of bilingualism, which has long been recognized. Bilingualism refers to the alternate use of two languages by an individual or group of people. Since language reflects culture, it is reasonable to study cultural patterns through language. Bilingualism, which involves the simultaneous use of two languages, offers a unique perspective by encompassing two distinct cultural worldviews. Early twentieth-century linguists were astounded by how individuals could integrate multiple linguistic and cultural semiotic systems within themselves, enabling quick thinking, unique cognitive processes, and the development of creative potential. Research on bilingualism demonstrates that full proficiency in two cultures and languages contributes to an individual's success in both career and life [6]. This success is fostered by a structured educational system and ongoing motivation. Studying brain function as individuals master content in two languages, while maintaining cultural distinctions, offers the potential to develop programs that can effectively integrate monolingual individuals into foreign linguistic and cultural environments, building a bilingual worldview.

Russia's multicultural makeup and the internal migration of various national groups provide a compelling rationale for advancing cultural neuroscience, particularly in developing methodologies for teaching multilingual children and adults. The importance of promoting the neuroscience of bilingualism as a cultural phenomenon is clear. Without a deep understanding of the cultural characteristics of the native speakers of a studied language, full immersion into that language is not possible. The urgency of these studies is underscored by the risks posed by neglecting a country's cultural and linguistic policy, which can lead to ethnic hostility and conflict.

Psychologist Zinchenko YuP identifies key challenges in studying bilingualism, such as "methodological difficulties that hinder the systematization and generalization of data, as well as the application of results in various fields of social practice" [7]. Like other subfields in cultural neuroscience, bilingualism research faces challenges, including data subjectivity,

insufficient interdisciplinary collaboration, a lack of objective data on the relationship between culture and language(s), and inconsistent findings [8]. Psychologist Novitsky NYu notes that "one of the most significant neurobiological issues of our time is understanding the mechanisms of language interaction in the bilingual brain and their effects on speech and non-speech brain functions" [9]. He also highlights the challenge of "cognitive control" in forming bilingual and multilingual subject groups.

A different, anthropological approach is proposed by American psychologist Shinobu Kitayama. To address the issue of identifying the roots of social phenomena, he suggests using genetic markers (known as ancestry informative markers) to determine "whether observed cultural differences are truly cultural (mediated by acculturation) or at least partially genetic (mediated by genetic proximity to certain ethnic ancestors)" [10]. By understanding the foundations of certain cultural phenomena, researchers can effectively resolve methodological challenges in studying bilingualism and apply specific methods in practice.

The ethical orientation of "cultural neuroscience" led to the emergence of a new field in the humanities: cultural neuroethics. This discipline is intended to identify, analyze, and address ethical dilemmas arising from the use of research results in the study of values, beliefs, habits, and behaviors across different cultures. Cultural neuroethics demands that researchers maintain objectivity when analyzing data related to the cultural characteristics of various nationalities and ethnic groups. Failure to uphold this impartiality risks reinforcing artificial stigmas or biases toward certain nations or peoples.

A critical issue is the potential for geographical or cultural stigmatization. For instance, if research suggests that a person born and raised in a valley (with its specific climate) may be less suited for employment than someone from a mountainous region, this could reinforce discriminatory practices. Historically, people have tended to select companions and colleagues based on cultural and national similarities, and the misuse of scientific findings could exacerbate such tendencies, fostering stereotypes and divisions between different groups. Even the scientifically verified differences between people from different regions, such as between the East and West, may intensify pre-existing tensions if misused. Although humans belong to the same species — Homo sapiens — such knowledge could lead to increased feelings of incomprehension and division. The relationship between language and culture is another important consideration in cultural neuroethics. Language serves as a core component of culture, and misinterpretations between languages can give rise to misunderstandings. For example, the phenomenon of "false friends" in translation — where similar words have different meanings in different languages illustrates the complexity of cross-cultural communication. This further highlights the inseparable link between culture and language.

CONCLUSION

Cultural neuroethics is a field faced with numerous ethical challenges, such as brain mapping and research involving human subjects. This makes the study of cultural neuroethics multifaceted and complex. While it is impossible to address all of these challenges in this article, the potential of cultural neuroscience for understanding human consciousness, perception, and creativity is significant. The study of bilingualism is particularly promising, as it provides insights into how the use of two languages influences cognitive processes and personal

development. Research shows that bilingualism fosters unique cognitive and creative abilities, linked to distinct neural connections in the bilingual mind. These insights could help to better understand the emergence of creative potential and the concept of creative freedom.

The significance of cultural neuroscience and neuroethics lies in their ability to explore the interplay between cultural factors and neurobiological processes. This contributes not only to theoretical advances but also to practical applications

in fields such as education, professional development, and cultural integration. Cultural neuroscience approaches can aid in designing programs that facilitate the integration of monolingual individuals into new linguistic and cultural environments — an especially relevant task in multinational and migratory societies. In conclusion, research in cultural neuroscience opens new avenues for understanding the complex relationship between culture and cognitive processes, while offering practical solutions for improving social integration and quality of life.

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BIOETHICS IN THE KYRGYZ REPUBLIC: EXPERIENCE AND PROSPECTS

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This article examines the Kyrgyz tradition of bioethics and the conditions of its use in higher educational institutions of Kyrgyzstan. The article analyzes formation of bioethics as a science closely related to medicine, veterinary medicine and biology, which studies the relationship between men, animals and other creatures. The bioethical aspects of conducting an experimental and preclinical testing of medicinal herbs and other products that have been used in folk medicine for centuries, as well as their application in practical medicine, are presented. The bioethical aspects of brain transplantation, artificial intelligence (AI) and the use of AI robotics to perform medical manipulations, surgical interventions, as well as tactical mistakes made by them (robots) when performing diagnostic manipulations, operations and when new infections and diseases occur, are considered. The issues of obtaining permits to prepare vaccines and drugs and the issues of studying the "non-natural" human nature are highlighted. In this regard, bioethical science will face many complex tasks that require solutions in the future. The laws of the Kyrgyz Republic related to bioethics and teaching of this discipline in universities of the Kyrgyz Republic, adopted in the period from 1992 to the present (August 2024), are presented.

Key words: bioethics, biomedical studies, science, Kyrgyz tradition, students

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БИОЭТИКА В КЫРГЫЗСКОЙ РЕСПУБЛИКЕ: ОПЫТ И ПЕРСПЕКТИВЫ

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В данной статье рассматриваются биоэтика в кыргызской традиции и условия ее использования в высших учебных заведениях Кыргызстана. Анализируется становление биоэтики, прежде всего, как науки, которая тесно связана с медициной, ветеринарией и биологией, изучающей взаимоотношения человека с человеком, животными и другими существами. Приводятся биоэтические аспекты проведения экспериментального, предклинического испытания лекарственных трав и других средств, которые испокон веков используются в народной медицине, а также их применение в практической медицине. Рассматриваются биоэтические аспекты пересадки головного мозга, искусственного интеллекта (ИИ) и использование ИИ-робототехники для выполнения медицинских манипуляций, оперативных вмешательств, а также допущенные ими (роботами) тактические ошибки при выполнении диагностических манипуляций, операций и при возникновении новых инфекций, болезней. Освещены вопросы получения разрешительных документов для приготовления вакцин и препаратов, вопросы изучения «неприродной» природы человека. В этом плане у биоэтической науки возникнет множество сложных задач, в перспективе требующих решений. Приводятся законы КР, связанные с биоэтикой и преподаванием данной дисциплины в вузах Кыргызской Республики, принятые в период с 1992 г. по настоящее время (август 2024 г.).

Ключевые слова: биоэтика, медико-биологические исследования, наука, кыргызская традиция, студенты

Вклад авторов: Р. М. Тойчуев — подготовка материала о кыргызских традициях; Б. А. Абылаева — подготовка материала по учебным заведениям Кыргызской Республики, в которых преподают предмет «Биоэтика», анализ состояния дел в данной области; А. У. Тойчуева — сбор и подготовка материала для статьи; Л. В. Жилова — сбор и обработка данных для статьи, оформление статьи.

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In the context of development of philosophical, ethical, legal and social institutions of public relations, systematization and integration of biological knowledge and accumulated human values, intellectual and humanistic progress, bioethics can be considered as a concept of self-restraint, closely related primarily to medicine, biology and ecology [1–3]. The issues of bioethics concern all aspects and levels of human interaction with the social and natural environment.

Due to intense technification of human activities, new problems arise that require relevant approaches, including in the field of bioethics, primarily in the medical industry [4, 5]. In particular, in modern practical healthcare, there is a tendency to narrow the diagnostic functions of a doctor due to the

growth of technological equipment, expansion of equipment capabilities, complex diagnostic equipment, laboratory and other research methods, and in the future, due to artificial intelligence, neurotechnology and robotics [6]. At the same time, all new drugs go through the modeling stage first. In conclusion, experimental animal studies or trials involving volunteers are traditionally conducted.

Animals put food on the table of the Kyrgyz nomads (their meat and milk was the food; their skin was the clothing, the animals themselves serve as a means of transport, protectors and advisers (in the epic Er Toshtuk, which is a contemporary of the epic Manas). Therefore, the nomads were greeting other people asking: "Mal-Zhan amanby?", i.e., "how are your living

creatures (animals, breadwinners) and soul (well-being of your people)?". Excessive unnecessary extermination of wild animals was not only prohibited, but was also considered as a great sin. It was forbidden to hit animals, especially horses, on the head, to slaughter sick animals for guests, celebrations and sacrifices [7]. Kyrgyz people still follow these traditions, therefore, the use of sick animals in the experiment can also be a subject of discussion.

The history of development of the ethical and philosophical thought of the Kyrgyz people and Kyrgyz thinkers is connected with the activities of the thinkers of the Middle Ages such as Asan-Kaigy (XV century), Tolubai Synchy and Sanchi-Synchy (XVIII century). In fact, Asan-Kaigy proclaims a categorical imperative saying "do as you would be done by", and provides the right of everyone to be understood.

According to the ancient Kyrgyz, initially, nature was the sole ruler of the living system, but then a man was created who became its competitor, i.e. a second ruler. A man, thanks to consciousness, has risen to the highest level of living nature, but he is forced to manage the components of nature in order to meet his needs. The situation resulted in the anthropogenic impact. Unlike nature, which has mechanisms of self-regulation, people began to use their capabilities in an unlimited way; there was a threat of imbalance not only of natural but also of spiritual resources; conflicts between people began to arise due to the clash of interests of various social groups [8–11].

In the Kyrgyz Republic, the current bioethical problem is the experimental, preclinical testing of traditionally used medicinal herbs and other products over a long historical period, since their use requires a huge number of permits, time and other resources. Therefore, when developing a legislative framework for solving modern bioethical issues, it is possible to reflect the provisions that take into account that, due to the long-term practice of using these medicinal products by the population, it is possible to provide for their use without conducting experimental studies.

It should be noted that bioethics has become an academic discipline in many countries of the world. Currently, the regulatory and legal regulation of biomedical research and protection of human rights in this field of activity in the Kyrgyz Republic are carried out by a number of national legal acts, including, in the first place, the Constitution of the Kyrgyz Republic.

The following laws of the Kyrgyz Republic have been adopted:

- "On the protection of citizens' health" (1992);
- "On donation of blood and its components" (1992);
- "On the reproductive rights of citizens" (2000);
- "On the provision of psychiatric care" (2004);
- The laws of the Russian Federation, the successor of the USSR, are also used:
- "On transplantation of human organs and tissues" (1992); "On psychiatric care and guarantees of citizens' rights in its provision" (1992);
- "On the protection of citizens' health" (1993).

At the same time, the country's legislation provides for a mechanism for using international legal norms in their absence in the national legislation. The Ministry of Health of the Kyrgyz Republic is responsible for organizing ethics committees at all levels in the Kyrgyz Republic.

The National Ethics Committee, responsible for making decisions on the ethical examination of both national and international biomedical research, was established in 1998 to implement the state policy of drug provision under the Ministry of Health of the Kyrgyz Republic.

The rules of work and tasks of the ethics committee are defined within the framework of the law "On Medicines" adopted in 1997, supplemented and revised in 2003, in accordance with the basic provisions, tasks and procedures of the Ethics Committee under the Ministry of Health of the Kyrgyz Republic.

Currently, in Kyrgyzstan, bioethics is taught in all higher medical educational institutions and at some veterinary and biological faculties [12–17]. In Kyrgyzstan, the recommendations entitled "Ethical expertise of biomedical research in the CIS member states" are used as a basis for teaching bioethics. The recommendations were developed by scientists from the CIS countries in St. Petersburg in 2007. They are intended for:

- members of ethics committees;
- clinical researchers;
- employees of contract research organizations;
- employees of pharmaceutical companies;
- specialists of the Research Institute and doctors;
- teachers and students;
- employees of regulatory authorities.

The leading educational institutions implementing bioethics programs in Kyrgyzstan are represented by:

- Kyrgyz State Medical Academy named after Akhunbayev IK;
- Medical Faculty of the Kyrgyz-Russian (Slavic) University;
- Faculty of Medicine at the International University of Kyrgyzstan;
- Faculty of Medicine at Osh State University;
- Kyrgyz National Agrarian University named after Scriabin.

It should be noted that bioethics has not been introduced into the state standard of education of the Kyrgyz Republic. Bioethics is taught at the pre-graduate stage at the Kyrgyz State Medical Academy named after Akhunbayev IK according to the curriculum. The course consists of 54 hours, i.e. 36 hours of lectures and 18 hours of practical training at seminars.

Bioethics has been taught at the Department of Anesthesiology, Intensive Care and Intensive Care since 2011. 4th year students who study medicine, pediatrics and dentistry undergo the course of bioethics entitled Bioethics in Anesthesiology and Intensive Care. The teachers are anesthesiologists and intensive care physicians.

At the Medical Faculty of the Kyrgyz-Russian (Slavic) University, the discipline "Ethical and legal control of biomedical experiments" was taught at the department of general medicine with 19 hours of lectures and 19 hours of seminars.

Currently, at the Faculty of Medicine of the KRSU, bioethics is taught to students of medical, pediatric, dental specialties at the Department of Public Health and Healthcare. It is also included into the principal educational program preparing doctors for the humanitarian, social and economic cycle (code C.1). The program of bioethics includes 2 credits, 72 hours (18 hours of lectures, 18 hours of seminars, and 36 hours of independent work), 12 hours of individual work, whereas the subject is studied in the 4th semester of the 2nd year.

At the Faculty of Medicine at the International University of Kyrgyzstan, bioethics is taught at the Department of Public Health (2nd year, medicine). Social doctors are the teachers.

At the Kyrgyz National Agrarian University named after Scriabin, bioethics is taught in the 2nd year and cover the following topics:

- Traditional knowledge of crop production (ethnobotany 20 hours of lectures, 20 hours of practice).
- 2. Traditional knowledge of veterinary medicine.
- 3. Traditional knowledge of animal husbandry (4th year; 17 hours of lectures; specialty biology).
- 4. Traditional food knowledge on agricultural crops.

Bioethics is taught in the 1st year at the Department of Public Health and Medical Faculty of Osh State University. 30 hours total, including 18 hours of practice, 12 hours of lectures.

Bioethics is studied by students of medical and preventive medicine, dentists, physicians, pharmacologists, pediatricians. The subject is taught by social activists. Bioethics is taught to bioengineers at the Faculty of Biology of the same University.

At Jalal-Abad State University, the course in Ethnobotany (taught in the 2nd year) includes Plant Ethology (15 hours of lectures and 15 hours of practice) and Ethology (behavior) of Animals and Insects (15 hours of lectures and 15 hours of practice).

Thus, there is currently no unified approach to teaching Bioethics in Kyrgyzstan, including medical universities. It is taught by teachers of various professions, from teachers of social sciences to doctors. There are very few specially trained teachers. Coordinating bodies with responsible persons are just being created.

Today, achievements of science go hand in hand to new bioethical problems such as growing individual organs from a single cell (stem cells) to replace "worn out" organs in the body [18, 19], growing a whole, so called 'unnatural person' [23–25] from a single cell, including an embryonic one [20–22]; transplantation of head and brain [26–28].

One of the main problems of bioethics is obtaining permits in case of occurrence of new or modified highly pathogenic viruses and microbes in nature [29–31]. In this aspect, the coronavirus pandemic has shown that at least 8–10 months pass before introduction of the vaccine, and in the case of new highly contagious and pathogenic infections, humanity is "exterminated" before the vaccines are introduced [24, 32]. All this requires development of accelerated ways to obtain

vaccines and new drugs, as well as a significant reduction in the time of their testing and approval for use.

These problems require urgent solutions. Bioethical problems related to technologization include creation of "thinking" technologies, up to the production of artificial and later a thinking person, artificial intelligence (Al), robotics, and their admission to manipulation, diagnosis and treatment, and in the future, to performance of complex operations [19, 26].

In this regard, bioethical science will face many complex tasks that require solutions in the future.

To solve existing bioethical problems, it is necessary to optimize the following processes: creation of an "unnatural" person from a single cell, transplantation of a human head and brain, the problems of accelerated vaccination, creation of artificial intelligence such as technologization, robotization and their participation in medical manipulations and surgical treatment.

Against the background of increased entropy, changes in the course of diseases, appearance of new "organisms" and pathologies associated not only with humans, but also with micro-worlds, including an increase in the number of antibiotic-resistant microorganisms, can be predicted in the future [32, 33]. As a result of the appearance of "new" organic compounds, bioethical problems arise that require urgent solutions, new approaches to their consideration on large volumes of materials combined by scientists of the world in order to preserve humanity. In order to solve the priority tasks of training teachers and bioexperts, it is necessary to regularly hold seminars, conferences, develop and implement collective recommendations, and issue methodological manuals.

The bibliographic list below shows that work in this direction is actively underway both at the national level of the Kyrgyz Republic and within the international community.

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ISSUES OF TEACHING BIOETHICS IN THE CURRENT CONTEXT OF KYRGYZSTAN

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Today, the problems of moral education of future doctors are the most acute not only in the Kyrgyz Republic. The consciousness of the youth of the XXI century is sometimes formed in a non-linear way under the influence of pragmatism and utilitarianism. The organization of ethical and moral perception of the world and self-organization in the best positions of humanism is a problem not only of a theoretical but also of a practical nature. Methodological ideas and principles proposed by various researchers in the field of social sciences and humanities are mainly aimed at overcoming both all-encompassing relativism and fundamentalism. However, the way it should be implemented while teaching bioethics is a methodological problem, in particular in the Kyrgyz Republic. The purpose of our work is to consider various approaches in the context of development of our national paradigm of education in medical universities. Modern Kyrgyzstan needs efficient teaching methods, since only they can effectively form the main pillars of moral consciousness of students, which are necessary for implementing medical activities. The educational cornerstone is development of interactive discourse, not only as a comprehensive communication, but also as analysis of all the interacting factors of this process (determining the context, directly affecting the participants and their understanding of the world). The research uses methods of hermeneutics and comparative analysis. Pedagogical approaches and methods of use while teaching bioethics at universities are taken into consideration. Teachers of bioethics in medical institutions of Kyrgyzstan need to develop effective approaches and methods of teaching young people, such as interactive discourse and a dialectical method.

Key words: moral consciousness, ethics, bioethics, student, discussion as communication, interactive discourse, dialectics

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ВОПРОСЫ ПРЕПОДАВАНИЯ БИОЭТИКИ В СОВРЕМЕННЫХ УСЛОВИЯХ КЫРГЫЗСТАНА

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Проблемы нравственного образования будущих врачей в современный период являются наиострейшими не только в Кыргызской Республике (КР). Сознание молодежи XXI в. формируется порой нелинейно под влиянием прагматизма и утилитаризма. Организация этического и нравственного восприятия мира и самоорганизация в лучших позициях гуманизма — проблема не только теоретического, но и практического характера. Методологические идеи и принципы, предложенные разными исследователями в области социально-гуманитарных наук в большей части нацелены на преодоление как всеохватывающего релятивизма, так и фундаментализма. Однако, каким образом оно должно осуществляться в рамках преподавания биоэтики, является методологической проблемой, в частности в КР. Цель нашей работы в том, чтобы рассмотреть различные подходы в контексте развития нашей национальной парадигмы образования в медицинских вузах. В современных условиях Кыргызстана необходимо внедрять эффективные методы преподавания, так как только они могут действенно формировать основные столпы нравственного сознания студентов, столь необходимые для осуществления врачебной деятельности. Краеугольным принципом в сфере образования является развитие интерактивного дискурса, не только как всестороннего общения, но и анализа всех взаимодействующих факторов данного процесса (детерминирующих контекст, непосредственно влияющих на участников и их понимание мира), в исследовании применены методы герменевтики, а также компаративного анализа. Рассмотрены педагогические подходы и методы использования в преподавании биоэтики в вузах. Преподавателям биоэтики в медицинских учреждениях Кыргызстана необходимостью разработки результативных подходов и методов обучения молодежи, таких как интерактивный дискурс и диалектический метод.

Ключевые слова: моральное сознание, этика, биоэтика, студент, дискуссия как коммуникация, интерактивный дискурс, диалектика

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At the present stage, the educational process existing in Kyrgyzstan is going through numerous transformations, transition from the paradigm of classical Soviet education to the transit zone, where the Bologna process was mixed with post-Soviet innovations in the field of education, rising many questions and problems. A decline of humanities in medical education led to a decrease in the speech-thinking functions of the student's cognitive sphere, which in turn gave rise to problems related to critical and logical thinking. Thus, we came across the issues of both methodological and contextual nature of the educational process. The decline in the level of morality and spirituality

of young people is an urgent problem, since a spiritless and immoral doctor in medicine is, in our opinion, means the end of all mankind. Therefore, the return of ethics, deontology and bioethics to the educational process and application of innovative approaches in teaching are an existential necessity of the XXI century. To accomplish this task, we turned to various concepts that exist at the present stage of ethical and pedagogical thought. The existing ethical relativism and fundamentalism produce a negative affect on pedagogical practice in the context of an authoritarian or indifferent nature and create the need for a debatable nature of teaching. Since antiquity, Socrates has

applied an extraordinary pedagogical approach called maieutics, which combined both discussion and elements of the dialectical method subsequently proposed by Hegel.

In modern times, the idea according to which moral education can be sufficiently rational and spiritual is consistently implemented through a communicative approach. Today's student perceives information better if moral principles are taught not in a directive way, but in a communicative way, so that students can form their beliefs and views through the process of communication [1]. It seems that the principle of communicativeness of ethical education is inherent in various pedagogical approaches, where ethical education is positioned as introduction (initiation) of a person to the democratic values of equality, justice and the interests of society [2]. We believe that it is necessary to introduce the method of interactive discourse with elements of dialectical thinking into the educational process of medical university students, since speech-thinking activity activates and forms the cognitive zones of the human brain and promotes development of critical and logical reflection.

LITERATURE REVIEW

In Russian and Western European literature, many papers are devoted to the problem. Thus, for example, the idea that citizenship is connected with the communicative nature of ethical education was confirmed by the need to educate young people in this direction [3]. A similar understanding of the relationship of social justice in the context of universal well-being can be seen in the works of Western authors [4]. Russian works reveal the need to form moral consciousness at a new level, for example, as a project of "integral ethics" [5]. Other authors are also following the path of expanding traditional studies (applied ethics) [6]. Modern authors propose various methodological approaches on how to most effectively implement ethics in the educational process. It is already clear to everyone that the imperative nature of teaching is not the best teaching approach. Russian and Western European researchers have published a number of works devoted to this problem [7-9], which involved methodological approaches of teaching moral values and their relationship with various social phenomena to students. Referring to classical pedagogical excellence, "presentation of the material should correspond to the development of intelligence in all directions" [10]. Developing the idea of coordinating the level of moral and intellectual development, American researchers divided moral development of a person into several levels [8, 11]. To ensure the most advanced teaching of bioethics, it is necessary to turn to the work of the outstanding philosopher of our time J. Ha bermas, where he emphasizes the importance of communication as a tool for the development of moral consciousness [12]. In bioethics, it is necessary to address the practical side of the influence of moral norms on phenomena in medicine, through analysis of historical cases that has received widespread publicity through egregious crimes against humanity. The works of Bakshtanovsky VI should be specifically mentioned among others, using the example of the monograph "Moral choice of the individual: alternatives and solutions" [13], as well as a number of other works written in collaboration revealing the issues of the theory of applied ethics, which are so necessary at the present stage of utilitarianism [14, 15].

METHODOLOGY, METHODS AND TECHNIQUES

Bioethics is an interdisciplinary subject at the intersection of law, medicine, ethics, sociology, pedagogy, philosophy, and psychology. Therefore a whole set of methodological

approaches and methods from different fields of scientific knowledge is needed [16, 17]. Methods used: hermeneutics, which includes techniques of understanding, interpretation, and consideration of the historical context. In due time, the founder of scientific hermeneutics, Schleiermacher E. developed a whole set of techniques for understanding text documents [18]. Comparative analysis makes it possible to see the similarities and differences of different pedagogical techniques in the educational process.

DISCUSSION

In the process of teaching bioethics, many philosophical categories and concepts are touched upon, such as good, evil, love, morality, and morality. In our opinion, students need to know the basic definitions and characteristics of these phenomena, because the difference between morality and morality is significant while training future doctors. In the 21st century, the system of norms and rules of behavior in the society, which are considered "correct", is subjected to significant deformations. Social standards vary significantly depending on a particular culture. Morality is an internal ethics that serves as a guideline for evaluating one's own actions and those of others. It is the individual system of a doctor's values that is the compass of his behavior in the doctor's professional and personal life. That is why it is necessary to mention the importance of different contents, which we can learn by referring to the classics of philosophy.

In the work of a doctor, the fundamental point is to understand the phenomenon of "love". Hegel once justified the concept of "love" as a necessary prerequisite of morality. By love, he meant "a universal human disposition based on sincerity and trust, when you live not only for yourself, but also for others just the way you do for yourself" [19]. Therefore, by revealing the concept of morality through love for one's neighbor, we can touch the sensitive "strings" of young people and help develop empathy, which is so necessary in the medical profession.

There are many examples when something new was born through the prism of past pedagogical ideas, so the combination of three main psychological and pedagogical concepts at the present stage generates a multi-stage system of teaching students. For example, the concepts of modern education are based on the classical theories of behaviorism, cognitivism and constructivism, while the techniques of each direction are still used in practice. Behaviorism: repetition and consolidation of the material studied. Cognitivism, constructivism: to use students' analytical abilities, expand mental structures; the approach of constructing knowledge based on the independent search by using all the established methodological approaches, has become a trend in recent years. In addition to the above, the student is enriched by the social environment and absorbs much of the culture of a particular and world civilization.

Modern researchers have identified several gradations of moral culture: traditional, aristocratic, pragmatic, nihilistic. We must state the fact that some types of moral culture are well pronounced among modern Kyrgyz youth. in the course of research, our Russian colleagues have determined that modern Russian youth is subject to various negative influences, while demonstrating weakness of will as a characteristic feature of the younger generation and that it is educational institutions that can overcome nihilism and pragmatism [20]. We join this position, since Kyrgyz students are subject to similar processes, and we believe that disciplines such as philosophy, ethics, deontology, and bioethics play a huge role in overcoming

the established behavioral patterns, which should be taught using a personality-oriented approach based on interactively organized lectures and seminars. The available classifications of moral culture should be presented in educational materials on bioethics, because familiarization with a diverse set of values allows students to form their own moral coordinate. We agree that there exist ideals of spiritual culture that are close to the same standard, however, they will always be different in proportional relations within different civilizational systems, but the vector towards the ideals of humanism should be unchanged.

Kyrgyzstan has a traditional moral culture, and the requirements of a person's compliance with his stratum are still strong, since we maintain indexation by gender and regional characteristics. Despite the strong influence of globalization, young people, the target audience of the educational process, bear characteristic features of their kind within the basis of their mentality. We should note a global trend according to which universal human positive traits such as mercy, obedience, hard work, patience and other qualities are catastrophically declining among 16-23-year-olds. The young people of today are totally different from those living 30 years ago. That is why the need is specifically acute while training doctors as it helps to educate an "aristocratic moral culture" through subjects of ethics and bioethics. Certain Russian sources reveal the phenomenon of "aristocratic moral culture, which puts forward knowledge and faith in human capabilities as the meaning of life" [21]. It, in our opinion, should be the maxim when teaching medical students. There is more pragmatism and nihilism in a young modern Kyrgyzstani, and moral values appear as needed if they correspond to their goals and objectives. Therefore our teachers need to develop the best moral human traits in students. We believe that a teacher himself should be a moral person, since when forming these constructs in students, the teacher often relies on own judgments and intuition while analyzing specific medical cases. The teacher is completely autonomous in his choice and if he accepts the highest moral imperatives as an axiom, he becomes an accomplice and co-creator of social moral norms.

In modern publications, it was unreasonably forgotten that dialectics was considered as a method of developing critical and logical thinking. In our opinion, the study of the dialectical method in medical universities will allow students to apply a systematic approach (in interrelation and dynamics) in the analysis of not only complex pathological processes and interacting factors, but also in conflicts of an ethical and moral nature. In dialectics, it is important not only to analyze, but also to synthesize data into a single picture of nosological and ethical phenomena. Critical thinking is being developed to overcome the contradictions that inevitably arise in any phenomena that Hegel revealed so well in his time. The point is that when a combination of factors causing the disease and body response (two poles) are comprehended properly, it is obvious that tests fail to display a real picture of the occurring processes. For instance, low Hb is observed in the first 20 weeks of pregnancy, which is shown by tests. However, it doesn't mean that the Hb level should be boosted with medicines. There exist numerous similar examples, and dialectics allows to develop the systemic vision (the world as a whole).

It is the recognition of the possibility of developing contradictions in an unusual way that makes the doctor's thinking more flexible and creative. Almost all categories of dialectics are applicable during consideration of medical cases, therefore, in medical education it is so necessary to introduce the dialectical method so that when analyzing various cases in bioethics classes, students can dive deeply into all the details of the incidents that occurred.

CONCLUSION

Bioethics teachers in medical institutions in Kyrgyzstan came across the need to apply effective approaches to teaching young people, such as interactive discourse and dialectical method. Interactive discourse is a more complex form of communication, as it involves active interaction, constructive exchange and argumentation of own points of view. Unlike communication, interactive discourse involves a cyclical process, mutual awareness, discussion and decision-making. If the goal in communication is just to convey information, in interactive discourse it is also a joint understanding and consensus-building, which is so necessary in medical practice. Consultation and making a final diagnosis can serve as an example.

The expediency of using the dialectical method lies in the development of critical and logical thinking, without which it is impossible to develop medical and subsequently clinical thinking. The difference between medical and clinical thinking is related to the approach to solving medical problems, medical thinking is a fairly broad concept, part of which includes clinical reflection, communication skills, interpretation of medical information, and ethics. However, the analytical part of the medical thought process is more evident in clinical thinking, since it is directly related to diagnosis and treatment. Every doctor has the skills of medical thinking and not everyone has clinical thinking. This is the principal component of medical reflection, since clinical thinking contributes not only to diagnosis, but also to development of tactics and strategies in treatment and further prognosis. Therefore, knowledge of the laws and categories of dialectics is a great help in development of medical thinking. The use of interactive discourse and dialectical method of solving bioethical problems affecting meta-problems is an attempt to harmoniously combine medical and philosophical principles of mentality.

We believe that at the initial stages of teaching bioethics, it is necessary to familiarize students with classical examples of moral culture, standard methods for solving bioethical problems using the above approaches and methods. While considering specific cases, students will create new bioethical norms adapted to modernity through well-known algorithms. Throughout their studies, students should think in different directions and solve bioethical issues, starting from the roots and traditional ethnic values.

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MODERN BIOETHICAL ISSUES IN THE CONTEXT OF THE BASIC PRINCIPLES OF BUDDHIST ETHICS

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The relevance of this research consists in reconsideration of the main approaches to solving bioethical problems based on the religious and ethical principles of Buddhism. The purpose of this research is to analyze Buddhist principles that can be consistently applied to a range of biomedical problems (euthanasia, biomedical experiments with animals, etc.). The subject of our research is ethics in the context of medicine, namely the relationship between Buddhism and medical practice. The research materials are based on many years of teaching the bioethics course at St. Petersburg State University of Chemistry and Pharmacy and Tyumen State Medical University, as well as on the results of research related to the development of scientific research of bioethical issues. The central question of modern bioethics about the nature and status of the moral subject in Buddhism is based on the principle of the moral dignity of all living beings: from human life to the life of animals and, perhaps, even plants. Belief in interspecific rebirth and respect for animal life are typical of Buddhist ethics. In modern ethics, Buddhism is a teleological ethics of virtue, which postulates a certain end result of life as the implementation of human potential and asserts that this goal should be realized through cultivation of certain spiritual practices, which implies the rejection of euthanasia, abortion, artificial insemination and other dvanced medical technologies.

Keywords: buddhist medicine, Tibetan Book of the Dead, euthanasia, biomedical experiments on animals, human birth/death, IVF, transplantation

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СОВРЕМЕННЫЕ БИОЭТИЧЕСКИЕ ПРОБЛЕМЫ В КОНТЕКСТЕ ОСНОВНЫХ ПРИНЦИПОВ БУДДИЙСКОЙ ЭТИКИ

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Актуальность данного исследования заключается в переосмыслении основных подходов к решению биоэтических проблем на основе религиозно-этических принципов буддизма. Целью данного исследования является анализ буддийских принципов, которые могут быть последовательно применены к целому ряду биомедицинских проблем (эвтаназия, биомедицинские эксперименты над животными и др.). Предметом нашего исследования является этика в контексте медицины, а именно взаимосвязь между буддизмом и медицинской практикой. Материалы исследования основываются на опыте многолетнего преподавания курса «Биоэтика» в Санкт-Петербургском государственном химико-фармацевтическом университете и Тюменском государственном медицинском университете, а также на результатах научно-исследовательской работы, связанной с развитием научных исследований по биоэтической проблематике. Центральный вопрос современной биоэтики о природе и статусе морального субъекта в буддизме основан на принципе морального достоинства всех живых существ: от жизни человека — до жизни животных и, возможно, даже растений. Вера в межвидовое перерождение, уважение к жизни животных является характерной чертой буддийской этики. В современной этике буддизм понимается как телеологическая этика добродетели, которая постулирует определенный конечный результат жизни как реализацию человеческого потенциала и утверждает, что эта цель должна быть реализована посредством культивирования определенных духовных практик, что предполагает отказ от эвтаназии, абортов, искусственного оплодотворения и других новейших медицинских технологий.

Ключевые слова: буддийская медицина, Тибетская книга мертвых, эвтаназия, биомедицинские эксперименты над животными, рождение/смерть человека, ЭКО, трансплантология

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In connection with the development of philosophical understanding of medical knowledge in modern culture, there is a need to show the importance of influence of religious and ethical principles on ways to solve the main problems of biomedical ethics. The main purpose of this study is an approach that allows us to rethink the influence of the basic Buddhist principles applied to solution of a number of

biomedical problems (euthanasia, biomedical experiments on animals, human birth and death, etc.).

Buddhism highly valued medical treatment, healing and caring for human health, which was largely determined by the relationship of religion with medicine, where the Buddha is a doctor, his teaching is medical treatment, and the monks are medical personnel. Therefore, each person who suffers is

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a "patient" of Buddha, striving for healing within the framework of Buddhist teaching [1]. For example, the Buddhist monastic order (sangha) has been actively involved in treatment of patients for more than two thousand years: Buddhist monks developed methods of healing diseases, which formed the basis for development of traditional Indian medicine (Ayurveda). In the edict published in 258 BC, the great Buddhist ruler Ashoka introduced an early form of "state medical care", and the Buddhist monasteries of India became the places where significant discoveries in medicine were made: "The codification of medical practices within the framework of monastic rules completed the first systematization of Indian medical knowledge and served as a model for later medical manuals; the spread of healing by monks and emergence of specialized monastic structures performing the functions of hospices and infirmaries ensured the constant support of monasteries by lay people; and the inclusion of medicine in the curricula of large monastic universities made it an academic discipline" [2]. Nowadays, many traditional forms of medical knowledge transfer in the monastic environment of Buddhism are preserved. For example, a Tibetan doctor should receive special initiations from teachers, transfer medical texts, listen to teachings of Buddhist masters, observe vows and many provisions of ethical concepts, whereas the complex of professional and spiritual training of a Tibetan doctor remains relevant for modern medicine [3].

The canonical scriptures of Buddhism (Theravada) are contained in a collection known as the Pali Canon. It consists of three separate collections of texts. The sutta, which for the most part are the teachings and sermons of the Buddha; the monastic Charter (vinaya), which contains ethical and legal norms governing the behavior of the monastic order (sangha) and its members; and scholastic treatises (abhidhamma), which are later texts devoted to the analysis and classification of Buddhist teachings. These sources formulate the basic Buddhist principles that require reflection in connection with the solution of modern bioethical problems.

One of the modern problems of bioethics, which we would like to address first of all, is the problem of a human life beginning. In Buddhism, there is no initial starting point for a number of lives lived by an individual. Life is perceived as a cyclical, potentially eternal course of human existence. It has no beginning, therefore it will have no end. Buddhism adheres to the idea that everything that happens at conception is the rebirth of a pre-existing individual [4]. Some schools of Buddhism (Theravada) believe that rebirth follows death instantly, while according to Tibetan Buddhism, there is an intermediate state that functions as a "buffer" between lives. According to the Tibetan tradition, an intermediate state is formed between a person's life and subsequent rebirth, which is designated as the "bardo" ("gap") concept. According to Buddhist psychotechnics, traces of memory about these experiences, including the ones of previous lives, are preserved at a deep level of human consciousness, and monks can recall and describe a similar experience. Irrespective of the exact nature of this "transition", its completion marks the beginning of a new individual life [5]. In this regard, an abortion or fatal experiments with an unborn child are completely prohibited in Buddhism. For example, Lobsang Dolma Khangkar (1935-1989), the first female doctor in Tibet, distinguished between three types of an infant death: intrauterine fetal death, death during childbirth (or immediately after childbirth) and death of children under one year old. Dolma Khangkar explains that intrauterine death, which is classified as a spontaneous abortion by experts, happens because the fetus naturally dies

in the womb after having lived for a few weeks or months of the previous life (tshe lhag). Two other cases of deaths, as well as an artificial abortion, are due, in her opinion, to the child's *karma* to live a short life. She also notes that for a woman, an abortion results in severe *karmic* consequences [6].

Moreover, Buddhist ethics does not allow to use human embryos for scientific research, especially for testing drugs and toxic substances, since any experiments with embryos represent a direct interference with the basic human welfare. This means that the concept of "life" in Buddhism cannot be considered "in an abstract way" in the sense in which a utilitarian could imagine welfare that should be "maximized". In other words, according to Buddhist ethics, it is impossible to imagine that one death within the framework of a scientific experiment could be justified for the welfare of others, even though it would allow to preserve many lives subsequently. Two arguments in Buddhist ethics prohibit any experiments with human embryos. First, there is no way to determine which embryos have a soul from the point of view of Buddhism and which don't have any. This does not detract from the seriousness of research in this area, because even if the embryo does not have any soul, it remains a biological person who should be treated with respect, and not used as an object of scientific curiosity. The second argument is that compassion for one person cannot justify causing fatal harm to another, since it is an example of "selective" rather than "universal" compassion, which clearly contradicts the Buddhadharma [7].

In modern healthcare, fertility control can be viewed from 2 directions. Fertility control aims to cause pregnancy in a positive form, and prevent it in a negative form. There is a risk that a certain type of pills will act more as an aborticide than as a contraceptive. As for the moral value of those methods that do not lead to abortion, there is often an opinion among Buddhists that although the use of interoception methods is wrong, the use of contraceptive methods is morally acceptable: while introceptive methods involve destruction of a newly formed being, the contraceptive method is not responsible for that. No new life arises when the pills are used and, therefore, no creature is directly harmed [8]. Thus, it can be said that married couples that live in accordance with Buddhist principles remain open to human welfare, providing the opportunity for "rebirth" to the number of children that local conditions reasonably allow (personal and national resources, cultural characteristics, etc.).

If conception, the beginning of the embryo's life, is characterized from the point of view of Buddhism as "the beginning of integrated organic functioning characterizing the life of an ontological individual," death is often understood in the opposite aspect, as "loss of integration in the human body," i.e. the disintegration of the spiritual and biological unity of the individual. Old age and death are two aspects of suffering (duhkha), which are constantly referred to in Buddhist sources. All forms of organic life have a nature of origin, since they arise as integrated entities at a certain point in time, namely at the moment of conception. They are composite entities as such, and according to Buddhist ethics, they eventually lose coherence and disintegrate. Death contains the entire dissatisfaction (duhkha) with the human condition, since it shows impermanence of an individual life, as well as pain and suffering accompanying a person. The problem of death is paradigmatic for Buddhism, because it symbolizes all the troubles of the karmic life. It is no coincidence that in Buddhist mythology, death and its accompanying troubles are associated with Mara, the Buddhist "devil", who is often depicted in art either as death or as time symbolically holding the world in its arms. Buddhist teachings emphasize the inherent impermanence of things (anicca): "Everything that has

the nature of origin has the nature of cessation" [9]. Therefore, it is no coincidence that the most important bioethical problem, which is also rethought by Buddhist ethics, is the problem of the "criterion" of death, which would be as "objective" and "consistent" as possible in the context of the worldview of both an individual and a cultural and religious tradition as a whole.

In Buddhism, there are four key terms associated with the functioning of living organisms: vitality (ayus), heat, physical vitality (Rūpajīvitindriyam) and respiration (prāṇa). According to Wang Lung, "a personality dies when the higher cognitive functions associated with volitional thinking are irrevocably lost or destroyed beyond the possibility of restoration" [10]. Although Buddhism regards life as the basic welfare, it does not mean that it must be preserved at all costs. Death is a natural part of the samsara cycle and must be accepted as such. Death is not the end, but the door to rebirth and a new life. When we realize that it is so, we reject medical treatment. From the point of view of Buddhist ethics, doctors are not obliged to support the lives of patients at any cost. It is much more important to develop the right psychological attitude of the elderly or end-stage patients towards death, rather than trying to deny or postpone it. However, the goal of the doctor here is to eliminate the pain, not the patient.

The above principles of Buddhist ethics do not only help us to understand the problems of human life and death, but also the approach to solving the problem of euthanasia. It is significant that there is no single view on the problem of euthanasia in Buddhism, since opposite opinions are found in Buddhist literature. For example, Nakasone believes that Buddhists recognize the "right to death", while a number of other researchers (Kapleau, Ratanakul and Keown) consider euthanasia as a violation of the principle of ahimsa, which is non-harming not only others, but also themselves from the point of view of Buddhist ethics [11]. From the point of view of Buddhism, euthanasia is an intervention in karma, since euthanasia uses doses of drugs that put the patient into a comatose state, depriving him of a conscious understanding of what needs to be done. Thus, Buddhism opposes euthanasia, since putting death above life by "making death your goal" or by "praising death" and so on means denying that life is the basic welfare. The ultimate goal of Buddhism is to help a person to overcome death once and for all, and any affirmation of death or choice in favor of death is a rejection of this idea of basic welfare. Since such a denial is significant to any form of euthanasia, it means that no form of euthanasia, whether active, passive, voluntary or involuntary, can be morally acceptable. However, when asked about euthanasia, the 14th Dalai Lama (born in 1935) replied in one of his public lectures

that "in general, it is better to avoid it, as well as abortions. When people suffer very much and there is no hope for recovery, euthanasia may be acceptable. And it is always infinitely important that the dying person's mind be at rest" [12]. It can be explained that the instructions in Buddhism are not strict prohibitions and that a person understands the importance of the decision made to form the karmic path [13].

The next problem of modern bioethics, which has been reinterpreted in Buddhism, is the problem of transplantation, which is associated with specific ideas about donation, i.e. the use of human organs, blood, sperm and eggs for medical purposes. The difference in the Buddhist approach to the integrity of the body plays an essential role in relation to the practice of donation. The Buddhist (Theravada) concept of gift is closely related to spiritual perfection, which can be achieved by making the right gifts: the gift must be gratuitous, i.e. performed without expecting the reward. As the researchers note, the gift process is not aimed at creating an additional value for one or another person, but correlates with the demonstration of "non-attachment", which is one of the pillars in Buddhism [14]. For example, organ transplantation is currently the most common and encouraged type of donation in Sri Lanka, as it is based on the idea of donating body parts, supported by numerous jatakas and legends about kings who used to donate parts of their bodies to achieve spiritual perfection. To support the donation initiative, a monastic community that has authority with the Sinhalese population was involved.

Thus, Buddhism's approach to solving bioethical problems can be characterized as a teleological ethics of virtue, which postulates a specific goal or end result (telos) and asserts that this goal should be implemented through cultivation of certain spiritual practices. According to Buddhism, the goal of human perfection is nirvana, which is achieved through the process of spiritual self-transformation of a person, i.e. following the Eightfold Path. According to Buddhist ethics, everything that exists is the product of reasons and conditions (dukkha) caused by longing and ignorance. Therefore, the tradition believes that the "ignorance" is the main and fundamental source of the disease. Moreover, Tibetan medicine claims that "ignorance" (tib. ma rig pa/ skt. avidya) results in "three mental poisons" (tib. dug gsum) such as attachment (tib. dod chags/ skt. raga), anger (tib. zhe sdang / skt. krodha) and obscuration (tib. gti mug/ skt. moha), which are responsible for an imbalance of the three pathogenic principles [15, 16]. If a person eliminates the causes of rebirth, namely longing and ignorance, he or she will be able to avoid the sufferings [17, 18]. Buddhist ethics is based on the belief in reincarnation or rebirth, which makes it different from the Western ethical thought.

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THE ACTIVITIES OF THE LOCAL ETHICS COMMITTEE TO IMPROVE THE QUALITY OF BIOMEDICAL RESEARCH OF YOUNG UNIVERSITY STAFF

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The article is devoted to the issues of clinical research: their ethical and legal regulation at the present time, the history of ethical expertise in the Russian Federation and at Kazan State Medical University. The role of ethical committees as a structure responsible for quality of scientific research and a guarantor of compliance with the principles of ethics, protection of the rights, safety and well-being of research participants is considered. The article presents the working experience of the local ethics committee of Kazan State Medical University on ethical examination of research projects with human participation and analysis of the most common mistakes in preparation of research documentation made by young scientists of clinical departments. The digital information showing typical errors and inaccuracies in the formation of a package of documents for ethical examination, based on the analysis of 284 initiative papers of PhD candidates from clinical departments: every fifth protocol required revision in accordance with the ethical and legal framework adopted in the Russian Federation, in 1.5% of cases the documentation was submitted for already conducted studies (i.e. ost factum), when no changes to its design are possible anymore. Typical mistakes were the following: inability to form research and control groups, calculate a representative number of participants, write an information sheet for a participant in a clinical trial and a sheet of informed consent, going beyond the specialty, desire to prescribe drugs beyond the scope of registered indications, etc. The ways of increasing both the awareness of young researchers and quality of ethical expertise by specialists of the ethics committee are proposed.

Keywords: biomedical research, ethical committees, ethical expertise, clinical trial protocol

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ДЕЯТЕЛЬНОСТЬ ЛОКАЛЬНОГО ЭТИЧЕСКОГО КОМИТЕТА ПО ПОВЫШЕНИЮ КАЧЕСТВА БИОМЕДИЦИНСКИХ ИССЛЕДОВАНИЙ МОЛОДЫХ СОТРУДНИКОВ УНИВЕРСИТЕТА

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Статья посвящена вопросам клинических исследований: их этико-правовой регламентации в настоящее время, истории становления этической экспертизы в Российской Федерации и в Казанском государственном медицинском университете. Рассмотрена роль этических комитетов как структуры, несущей ответственность за обеспечение качества научных исследований и гаранта соблюдения принципов этики, защиты прав, безопасности и благополучия участников исследования. В статье представлен опыт работы локального этического комитета Казанского государственного медицинского университета по этической экспертизе исследовательских проектов с участием человека и разбор наиболее часто встречающихся ошибок при оформлении документации к исследованию, которые допускают молодые ученые клинических кафедр. Представлен цифровой материал свидетельствующий о типичности ошибок и неточностей при формировании пакета документов для этической экспертизы, основанный на анализе 284 инициативных работ диссертантов клинических кафедр: каждый пятый протокол требовал доработки в соответствии с этико-правовой базой, принятой в Российской Федерации, в 1,5% случаев документация была представлена на уже проведенные исследования (т.е. роst factum), когда никакие изменения его дизайна уже невозможны. Типичными ошибками явились следующие: неумение формирования исследовательской и контрольной групп, расчета репрезентативного числа участников, написание листа информационного листка участника клинического исследования и листа информированного согласия, выход за рамки специальности, желание назначения препаратов за рамками зарегистрированных показаний и др. Предложены пути повышения как информированности молодых исследователей, так и качества проведения этической экспертизы специалистами этического комитета.

Ключевые слова: биомедицинские исследования, этические комитеты, этическая экспертиза, протокол клинического исследования

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Clinical trials (CT) in the Russian Federation have been regulated for less than a century and are based on the best international practices. Ethical recommendations for CT were laid down by the Nuremberg Code (1947) [1] and the Helsinki Declaration of the World Medical Association (1964) [2]. Each country had its own unique rules for this process and in order to register a foreign medicinal product (MP), full-scale tests on the territory of this country had to be conducted. The unification of requirements to CT was initiated in 1996 with the release of the first harmonized rules of Good Clinical Practice (ICH GCP), which set out the agreements in Europe, USA and Japan on the harmonization of legislation in the field of CT and elimination

of obstacles to register drugs in different countries, which led to a cheaper product for the consumer due to mutual recognition of the CT results [3].

After adoption of general rules, the process of harmonization of the legislations of different countries was accompanied by the appearance of documents of the Interparliamentary Assembly of the Confederation of Independent States (Eastern Europe and Central Asia); UNESCO; WHO [4–6].

Russia has actively joined the global process. In our country, the legislative framework in the field of CT and drug registration has been fully formed by the end of the last century [7]. For the sake of fairness, it should be noted that

before adoption of the ICH GCP in the USSR, there was a pharmacovigilance system that functioned from 1969 to 1991 and regulated, among other things, the field of clinical research, perhaps even more strictly than the international standard [8]. A significant milestone in development of ethical and legal support for biomedical investigations (BMI) was the creation of a system of ethical expertise with the participation of ethical committees (EC), whose legitimacy was recorded in 1993 in Federal Law No. 5487-1 "Fundamentals of Legislation of the Russian Federation on public health protection". The first ECs at the level of hospitals and research centers (local ethical committees, LEC) were established in the mid-90s. In 1998, the Ethics Committee at the Federal Agency for Quality Control of Medicines under the Ministry of Health of the Russian Federation began to function. The Central EC was actually part of the control and licensing system of the Ministry of Health of the Russian Federation, since in order to obtain permission from the Ministry of Health to conduct a clinical trial, a positive conclusion of this Committee was required. Later, this role was taken over by the Federal Service for Surveillance in Healthcare (Roszdravnadzor), and in 2004, a committee was established within the body issuing approvals for the planned multicenter research.

Since 2010, according to the law "On the Circulation of Medicines", permission for the entire turnover of medicines in the country was provided by the Ministry of Health of the Russian Federation.

Thus, a vertical appeared: federal EC — local ECs. For local ECs, our country has adopted the European model, in which they have a public character and advisory powers [9].

The next step in development of the system of ethical committees was adoption of legislative acts that consolidated the basic principles of CT, standards for planning and conducting BMI, registration and presentation of their results at the state level. It guarantees protection of rights, safety, well-being of research subjects and ensures BMI quality. Today, these ethical structures exist in all major research centers where BMI of different levels are conducted (multicenter and local, initiated by foreign and domestic sponsors, initiative research), they ensure compliance with the GCP rules. The EC activities are based on three principles:

- respect for the personality and rights of the patient;
- predominance of benefit over risk and risk minimization;
- the correct selection of patients to participate in the study.

The first and most important right of the human involved in scientific research represented by voluntary informed consent is enshrined in Article 21 of the Constitution of the Russian Federation, all principles are reflected in current Federal laws such as Federal Law No. 323-F3 "On the Basics of Protecting the health of Citizens in the Russian Federation" (2011), No. 61-FZ "On the Circulation of Medicines" (2010) and others [10].

The history of the EC emergence in the Republic of Tatarstan, a subject of the Russian Federation, is as follows: in 1998, the republic adopted its own law "On the protection of Citizens' Health", where article 14 referred to the possibility of creating an ethics committee (commission) in the healthcare system, which gave rise to the development of a package of documents related to the creation of the EC, and in 1998, by order of the rector of the Kazan State Medical University, the first EC appeared in the Republic of Tatarstan, which was given the republican status in 2003. This committee set goals not only for the ethical examination of BMI conducted at its bases, but also for the protection of patients' rights in the practical healthcare system, under conditions of compulsory

medical insurance and availability of the private medical services market (in fact, it combined tasks and functions of the research and hospital committee based on the experience of foreign countries), and also pursued the task of uniting ethical structures in the republic, personnel training according to GCP standards adopted by our country. In 2006-2008, our EC successfully passed the accreditation procedure by the World Health Organization with a three-stage program "Recognition" (Inspection WHO and program the recognition for the ethics committee), which included both an educational component by WHO experts, and an audit of internal documentation (standard operating procedures), an inspection of the work of the EC and its certification. It should be emphasized that we have become the first ethics committee in the Russian Federation to receive such recognition. Later, when Russia broke into the international CI market, with the increase in the number of BMI at the bases of the Kazan State Medical University, committees were divided by functions into republican and newly created local ones (2009) [9].

We are proud to note that Kazan State Medical University was one of the twenty most involved in international multicenter clinical trials (IMCT) research centers in Russia (fourth in 2015, third in 2016 and 2017, fifth in 2018 and 18th by the end of 2019). Even during Covid 2020 pandemic, our republic demonstrated an increase in the number of studies of new IMCTs (101 in 2020 against 71 in 2019, an increase of 42%) conducted on its territory, and the Republican Clinical Oncology Dispensary of the Ministry of Health of the Republic of Tatarstan (Kazan) took the 11th place in the TOP 20 medical organizations in terms of the activity of participation in the IMCT approved in 2020. In recent years, due to the difficult geopolitical situation in the Russian Federation, multicenter clinical trials of foreign sponsors have practically not been conducted, the BMI market has been reoriented to local research, mainly represented by bioequivalence studies of generics and biosimilars, which is implementation of the state import substitution program announced by the president of the country. The relevance of initiative research has increased many times. In this regard, the activities of the LEC of the Kazan State Medical University are largely reoriented towards

Over the 15 years of our EC work, the number of initiative research projects has not changed significantly and amounts to an average of 60-75 projects per year. A significant failure occurred only during the Covid 2020 pandemic, which was due to restrictions in contacts between researchers and patients. Most of the university's initiative research is traditionally carried out by young researchers during the postgraduate training, which provides for the acquisition of research skills by applicants. In preparation for the exam in the history and philosophy of science, where bioethics issues are discussed, students at our university are taught questions of research ethics — the ethics of working with an experimental animal (mainly for postgraduate students of theoretical departments) or with a human participant in a clinical study (for postgraduate students of clinical departments). Young scientists are taught to choose the design of the study, calculate the number of participants in the experiment so that the results obtained could be representative and meet the requirements of evidence-based medicine, choose methods and strategies for data collection, draw up a protocol, issue patient information sheets and informed consent sheets for study participants, select statistical analysis methods according to the tasks and features of scientific material, ensure the quality of research, identify key procedures, work in a team, manage the data

obtained, prepare reports and publications, properly prepare documentation at all stages, etc. Writing a research protocol with discussion and defense in a group of colleagues is part of the training. We are experienced in interacting with researchers in the framework of additional professional education under the GCP (Good Clinical Practice) and Good Biomedical Research Practice (GBRP) programs, organized by WHO, the Regional Training Center for Scientific Research in Healthcare (RC NIH, Astana, Kazakhstan) and the Kazan State Medical University (Russia). We offer the best available practices to young scientists [11].

After approval of the topic of the dissertation research and graduation, postgraduate students bring their research projects to the LEC, which examines the package of documents for the planned research and approves or justifiably rejects it. The results of internal quality control of the educational process showed 89% satisfaction of postgraduates with this issue.

Unfortunately, unlike commercial research projects written and verified by professionals, initiative research often reveals certain inconsistencies with the ethical and legal standards of this field of activity. In 2023, we analyzed 284 initiative works of PhD candidates of clinical departments of the Kazan State Medical University, identified errors and shortcomings in the documents and established the following: every fifth study, or rather 21.1% of the packages of clinical research documents submitted to the LEC, planned at the university as theses, does not meet the requirements accepted in our country. About 1.5% of the work is submitted to the EC after completion of the study, when no changes to its design are possible. Among the works reviewed during the specified time period, LEC rejected one work on this basis.

According to experts, when conducting an ethical examination of initiative projects, the same type of errors was encountered. The most frequent comments of EC experts were related to the fact that the presented protocol does not substantiate or insufficiently substantiates the sample of patients, comparison groups are carelessly formed (according to the analyzed parameters — age, gender, social status, etc.), which reduces the value of the work and significantly affects its conclusions. Researchers often describe their work as non-interventional trials, but actually work with the documentation of a medical institution retrospectively and/ or their research is purely observational/non-interventional. And conversely, a young scientist has a great desire to test a well-known medicinal product off-label, in a dose or in a mode different from that prescribed in the leaflet.

Although such a study may pose a danger to its participants, such initiative projects, as a rule, do not provide insurance for CI subjects and strict reasonable health monitoring. In fact, this is a phase II CI, and strict GCP requirements are imposed on it [12]

Errors are often found in the registration of the patient's informed consent to participate in the study. The young scientist does not share the standard of medical care provided in a medical organization (MO) and his clinical investigation (CI), believing that if he needs standard hematological or biochemical health indicators of the observed patient for analysis, then this is all about the research work. At the same time, when hospitalized in the MO (inpatient) or during an outpatient visit (polyclinic), the patient signed an informed consent for standard medical care, and repeated consent is not necessary.

About 6% of young researchers believe that if blood sampling for their project is combined with the collection of biomaterials (for example, blood) of a patient according to a standard treatment protocol, then the consent of the

participant to take an additional sample is not required. The standard of treatment of a patient in a medical institution and participation in scientific research are different things. Each participant in a clinical trial should be clearly understand that he is offered the procedures that are not included in the standard of medical care, and that he agrees to them voluntarily, without coercion, understanding the value of this research for himself and the development of science. Accordingly, the information sheet of the CI participant should contain in an accessible form all information about the planned work and clearly prescribe each step of the study, and informed consent should contain only information that relates to this initiative study, and not to all procedures that await the patient/patient at this stage of receiving medical care.

In a number of works, the researcher decides to cross the threshold of his competence and, being, for example, an obstetrician and gynecologist, decides to investigate the cognitive functions of the patient. As a result, he makes a judgment about the presence of the disease and even suggests its correction [12], which is fundamentally wrong and unacceptable.

It is particularly noteworthy that every year more and more comments relate not to the substance of the work, but to its design: negligence in writing documents, when different numbers of expected participants are indicated on adjacent pages of the same document or in different documents of the same package; the criteria for including and excluding patients from the study do not match; in protocols and information leaflets, manipulations with biomaterial are described in different ways, etc. We can also see that postgraduate students have a formal attitude to obtaining LEC approval: they copy other people's documents without understanding the essence, which results in comments from experts and request to finalize documentation. But this is no longer a question of knowledge of principles, rules and standards, but a question of attitude to the work performed [12].

Thus, the local ethics committee sees its mission in improving the quality of research conducted on the territory of its supervision in the education of young people (educational component) and in protecting the rights of patients (thorough examination of submitted projects). The first is carried out by improving the quality of teaching bioethics and medical law at the pre-graduate stage, research ethics issues at the postgraduate stage, involving students in the process of participating in Olympiads, grant events on medical ethics and biomedical research. The second is to improve the skills of the experts of the ethics committees both through internal training based on the materials of clinical databases and external training based on GxP cycles. In the last year, it has become extremely useful to conduct the School of Ethics of Scientific Research, an initiative non-profit educational project for young Russian researchers and members of ethical committees aimed at creating a high level of research culture necessary to achieve national goals and scientific and technical development of the Russian Federation, initiated by the Rector of the Yaroslavl State Medical University Kokhlov AL and Chairman of the Interuniversity Ethics Committee, Chairman of the Independent Interdisciplinary Committee for the Ethical Examination of Clinical Trials Volskoy EA on the basis of the National Research Institute of Public Health named after Semashko NA" The project has not been completed, it will continue during the next academic year. It is attended by leading experts in the field of clinical research, and their recorded lectures are invaluable material for the younger generation.

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