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И РОССИЙСКОГО НАЦИОНАЛЬНОГО ИССЛЕДОВАТЕЛЬСКОГО МЕДИЦИНСКОГО
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Eregina NT ✉, Eregin SYa

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The article analyzes the historical and medical literature devoted to the life and work of Matvey Yakovlevich Mudrov (1776–1831). The first stage in the historiography of this issue was the pre-revolutionary interpretation of Mudrov's personality and his contribution to the development of clinical medicine. The main attention was paid to biographical facts, assessments of Mudrov's professional activity by the medical community, and a general description of his role in Russian medicine. In the middle of the 20th century, a canon emerged that consistently described the main milestones of his biography. This narrative formed the basis of educational, reference, and popular science publications. Since the mid-1990s, the interest of practitioners in Mudrov's legacy has come to the fore launching reassessment of his personality. In recent decades, the research has shifted to examining his impact as a reformer of medical education, organizer of clinical teaching, and creator of ethical medical standards. The implementation of research tasks contributed to the introduction of new archival data into scientific circulation, clarifying previously existing estimates and conclusions. The conducted historiographical review comprehensively covers the multifaceted activities of Mudrov MY and outlines possible prospects for further study.

Keywords: M. Y. Mudrov, history of medicine in Russia, historiography of M. Y. Mudrov, medical faculty of Moscow University, medical ethics

Author contribution: Eregina NT, Eregin SYa — text preparation.

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МАТВЕЙ ЯКОВЛЕВИЧ МУДРОВ В ИСТОРИКО-МЕДИЦИНСКОЙ ЛИТЕРАТУРЕ (ИСТОРИОГРАФИЧЕСКИЙ ОБЗОР)

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В статье предпринят анализ историко-медицинской литературы, посвященной жизни и деятельности Матвея Яковлевича Мудрова (1776–1831). Первым этапом историографии данного вопроса стало дореволюционное осмысление личности М. Я. Мудрова и его вклада в развитие клинической медицины. Основное внимание уделялось биографическим фактам, оценкам М. Я. Мудрова со стороны врачебного сообщества, общей характеристике его роли в отечественной медицине. В середине XX в. утвердился канон изложения, в котором последовательно воспроизводились основные вехи его биографии. Этот нарратив лег в основу учебных, справочных и научно-популярных изданий. С середины 1990-х гг. на первый план вышел интерес практических врачей к наследию М. Я. Мудрова, что способствовало переоценке масштаба его личности. В последние десятилетия исследовательский акцент сместился в сторону его изучения как реформатора медицинского образования, организатора клинического преподавания, создателя фундамента основ врачебной этики. Реализация исследовательских задач способствовала введению в научный оборот новых архивных данных, уточнению существовавших ранее оценок и выводов. Проведенный историографический обзор свидетельствует о всестороннем освещении многогранной деятельности М. Я. Мудрова, намечает возможные перспективы для дальнейшего изучения.

Ключевые слова: М. Я. Мудров, история медицины России, историография М. Я. Мудрова, медицинский факультет Московского университета, врачебная этика

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The 250th anniversary of Matvey Yakovlevich Mudrov (1776–1831), a remarkable Russian physician, scientist, and reformer of medical education, was celebrated on March 23, 2026 (Fig.). He is one of the most prominent figures in 19th-century Russian healthcare. His name is indispensable to the history of medicine of that period. A native of Vologda province, who graduated from a theological seminary, he decided to become a doctor. After graduating from the Medical Faculty of the Imperial Moscow University (IMU) (1800) and a one-and-a-half-year internship at marine hospitals of Moscow and St. Petersburg, M. Y. Mudrov was sent abroad to improve his knowledge. He actively visited the clinics of Bamberg, Landshut, Berlin, Göttingen, Vienna, Sorbonne, listening to famous professors, mastering surgery (which was the main purpose of the business trip), treatment of internal diseases, obstetrics, eye, skin and sexually transmitted diseases, organization of hospital care, sanitary measures, and learning how to teach theoretical and practical medicine. During his internship abroad (1804),

he prepared a thesis, which was sent to the IMU, and was awarded the Doctor of Medicine degree. Having returned to his homeland in 1807, he was appointed head of the 1,200-bed hospital of the active army in Wilno.

Subsequently (1808–1831), Dr. Mudrov's life was associated with the Imperial Moscow University where he was an extraordinary professor of military medicine and surgery (1808–1809), head of the Department of Pathology and Clinic and at the same time director of the Clinical Institute (1809–1831). He was also elected dean of the Faculty of Medicine four times (1813/14; 1819/20; 1825/26; 1828/29). In 1813–1817, he was a full-time professor of pathology, therapy and clinic at the Moscow Department of the Medical and Surgical Academy; in 1830–1831, he was a senior physician at the Central Commission for Combating the Cholera Epidemic in Saratov and St. Petersburg. He was personally involved not only in organizational matters, but also in the direct fight against cholera, and was in charge of two cholera hospitals in St. Petersburg. On July 8, 1831, he unexpectedly died of this disease. These are the main milestones of his biography [1].

Matvey Yakovlevich Mudrov left a lasting legacy as a brilliant clinician, internist, talented organizer, initiator of medical education reforms, propagandist of the most important principles of medical ethics, author of the first national code of the medical profession, and a man of deep religiosity and service. In this study, an attempt is made to trace the historiography devoted to Dr. Mudrov's life and work, identify the principal topics, characterize the established historiographical tradition, determine the most significant studies and how their impact on the person's role in the history of Russian medicine is understood today.

G. A. Kolosov, a renowned historian of medicine of the beginning of the XX century, was the first to give a detailed assessment of Dr. Mudrov's life and professional activity. His research was published across two newspaper issues of "Russkiy Vrach" ("The Russian Physician") in 1914 and 1915. The historian used numerous archival data to retell M. Y. Mudrov's biography for the first time and referred to him as one of the founders of clinical medicine in Russia. Despite the fact that G. A. Kolosov failed to provide a continuous critical evaluation of sources he relied upon, the narrative presented became the starting point for further research [2].

A small book by Professor V. N. Smotrov, limited to 20,000 copies, issued in 1947, and being part of a larger set entitled "The Outstanding Figures of Russian Medicine", has been the most complete and detailed work devoted to M. Y. Mudrov to date [3]. It seemed to serve as an example for all subsequent publications, establishing a historiographical canon. Most subsequent publications devoted to M. Y. Mudrov reproduce its plot and facts with a broader (or narrower) interpretation of individual issues, simply retelling his text and even using the same structure of the presentation. The author made an extensive use of Dr. Mudrov's characteristics present in the literature of the 19th century. For example, P. I. Strakhov described his teacher as a deeply religious man with sincere faith, who was far from esoteric hobbies of those years, as a humane person who had compassion for all living things being crafted by the Creator including mice and dogs, and as a strict and caring mentor to students who trusted and considered him an ideal "Hippocratic physician" with high clinical culture, personal decency and rare humanity [4]. The ability of V. N. Smotrov to collect and properly submit all the most important assessments of M. Y. Mudrov and vivid and comprehensive portrayal of his image turned the book into an important historiographical source.

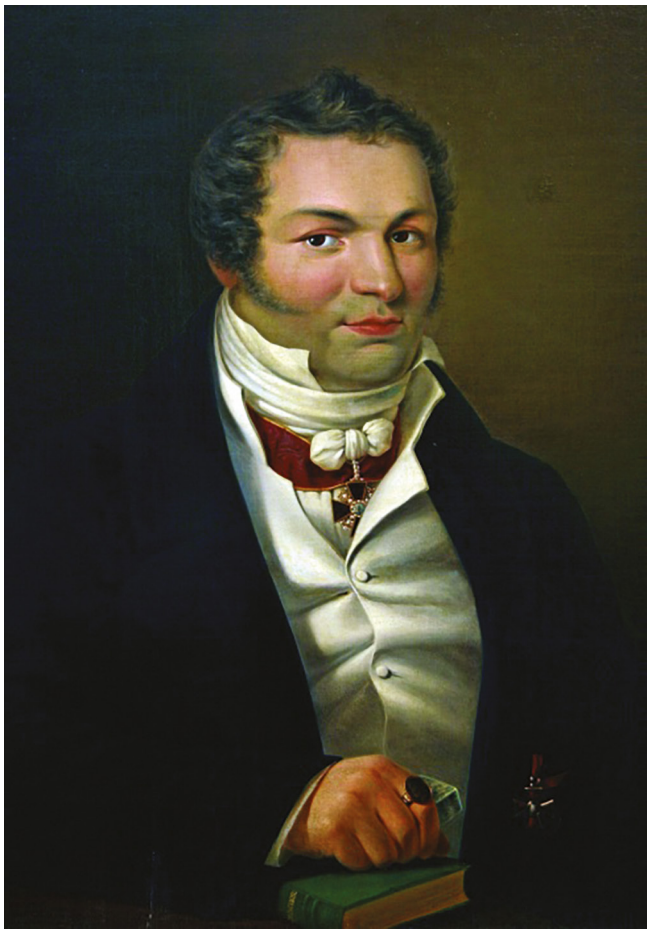

Fig. Matvey Yakovlevich Mudrov

An extensive article by A. G. Gukasyan that served as an introduction to the main edition of selected works by Dr. Mudrov, published two years later, was still inferior to the book by V. N. Smotrov, despite the wide range of sources used (mainly journal publications of the 19th and early 20th centuries) and the 100-page volume [5]. It is logical to assume the reasons for that. The selected works by M. Y. Mudrov were published as a separate book in 1949. During the period, the struggle against cosmopolitanism reached its peak. The cold war in the field of medical science and medical education was taking ugly forms. The struggle for medical priorities often reached the point of absurdity. Doctors were not so much looking for the truth as competing to find the names of those Russian doctors who had allegedly been actively fighting against "foreign domination" in Russian science throughout their lives [6]. Thus, the essay by A. G. Ghukasyan, that was strongly ideologically tinged and based on the "friend-foe" idea of those years, often replaced objective assessments with established cliches. Nevertheless, it is an important stage of Soviet historiography, which formed the official idea of Dr. Mudrov and correctly outlined his connection with the subsequent Russian therapeutic tradition.

In a brief essay devoted to M. Y. Mudrov (text editor, full member of the USSR Academy of Medical Sciences, Professor) and published in "People of Russian Science", a fundamental four-volume edition, in 1963, the reader comes across the established manner of how the information is presented, but without the harsh ideological cliches typical of publications in the second half of the 1940s and 1950s. A fair assessment of M. Y. Mudrov's main merits for national medicine in the

context of the main stages of his biography has been given here in a concise form [7]. This publication, as well as most of all subsequent similar publications that briefly described the life of M. Y. Mudrov, clearly relied on the book of V. N. Smotrov.

Until the early 1990s, M. Y. Mudrov's name was briefly mentioned in articles and monographs on the history of Russian healthcare among other prominent medical names. More attention to this name was given after the publication of academician E. I. Chazov's book. The book was more journalistic than strictly scientific. An outstanding Russian cardiologist, the former Minister of Health of the USSR (1987–1990) E. I. Chazov does not introduce new sources into scientific circulation, but relies on already published works and scientific works of Dr. Mudrov [8].

It is believed that it was the book by E. I. Chazov that has largely spurred a new wave of interest in rethinking the personality of the outstanding Russian scientist, primarily owing to the new approach itself. In this book, a practitioner talks about his colleague, a practicing physician of the last century, showing that despite the existing high evaluation, the contribution of Dr. Mudrov to Russian healthcare is clearly underestimated. According to the book, Dr. Mudrov insisted on understanding a disease as suffering of the whole organism long before the great Russian clinicians (N. I. Pirogov, S. P. Botkin, G. Zakharin et al.) did so. Dr. Mudrov was the first to emphasize etiology and pathogenesis, and the need for comprehensive treatment. He formulated the ideas of preventive medicine earlier than others, and he was the first person who said that a doctor should be educated continuously. Without a doubt, the book of E. I. Chazov represents an important attempt to rethink the legacy of M. Y. Mudrov in the context of modern therapy, personalized and preventive medicine.

L. B. Lazebnik and V. S. Belyaeva try to pay tribute to Dr. Mudrov in "Russian Therapist", a popular scientific biobibliographic essay. The epigraph written by academician B. V. Petrovsky fully reflects the modern assessment of this remarkable doctor: "The fate of some physicians, especially those who could preserve their personalities despite the difficult life paths, obstacles, and collisions, should serve as an example for us, the doctors". The popular style of presentation does not reduce, but rather increases interest in the book, designed to show the continuity and importance of therapeutic traditions [9].

In recent decades, scientific interest in the personality of Dr. Mudrov has grown significantly. This is associated not only with anniversaries in the history of healthcare, often marked by memorable articles or publication of reputable biographical dictionaries, but also with certain circumstances such as frequent appeal to prominent names and authorities in Russian science against the background of the emerging ideological struggle for norms and values; interest in bedside clinical training established by Dr. Mudrov and his reformatory activities related to practical and theoretical training of doctors; studying the patient's clinical examination scheme and case history while discussing the problems of personalized and evidence-based medicine; updating attention to issues of military medicine and military hygiene against the background of the ongoing special military operation (SMO), and finally, with increased attention towards medical ethics and discussions about medical duty and codes of professional conduct.

Each of these theses is reflected in modern publications based on existing works. Many authors of articles in medical journals try to characterize Dr. Mudrov as a founder of internal medicine in Russia through assessment of his holistic system of clinical diagnosis, which is based on the well-known Hippocratic principle of "treating the patient, not the disease", and analysis of systematic clinical examination in medical practice (including mandatory detailed medical history, consistent examination of organs, comparison of subjective complaints and objective data, analysis of symptoms in connection with personality traits, lifestyle, and living conditions of the patient). Almost all authors agree that, owing to Dr. Mudrov, separate observations in Russian therapeutic practice were included into the system of mandatory clinical bedside monitoring, which in turn became a solid foundation for internal medicine in Russia [10–12].

The issues of military medicine in practical and scientific activities of M. Y. Mudrov are important. They are covered in the article entitled "Matvey Yakovlevich Mudrov and military medicine" by A. A. Mikhailenko et al. Having briefly outlined the main facts of Dr. Mudrov's biography that preceded his work at the military hospital in Wilno, the authors analyze in detail his speech "A word about the benefits and subjects of military hygiene or the science of preserving the health of military personnel", delivered in 1809. It is one of his most important works relevant even today. The speech is interesting not only from a theoretical perspective as an introduction to the course of military hygiene at Moscow University and Medical and Surgical Academy, but also practically as a short set of rules for the Russian army of the early 19th century, involved in a long-term military conflict. Analyzing the most important theses of his speech, the authors rightly note that Dr. Mudrov was the first Russian doctor who identified military hygiene as the "first and most important" subject of military medicine, the task of which is not just to ensure "an absence of diseases", but also to preserve strength, endurance and combat capability of a soldier [13].

Numerous articles that later served as the basis of monographs by A. M. Stochik, M. A. Paltsev, and S. N. Zatravkin with a novel and original scientific approach hold a special place among the studies of the last three decades that affect the scientific and practical activities of Dr. Mudrov [14–16]. Their merits include not only creating the fundamental history of medical education in Russia in the XVIII–XIX centuries and history of the Medical Faculty of the Imperial Moscow University, not only clarification of numerous facts of the history of medicine, which were often presented incorrectly, but also an in-depth study of the multifaceted activities of Dr. Mudrov and primarily assessment of his role in the development of clinical teaching at Moscow University. It starts with a detailed analysis of Dr. Mudrov's letter to M. N. Muravyov, the trustee of the Moscow Educational District, that was sent from Paris on March 27, 1805. The publications add numerous details to the portrait of Dr. Mudrov. They refute the statement of G. A. Kolosov about the "complete destruction" of the IMU Faculty of Medicine [17–18] and analyze in detail the multifaceted activities of Dr. Mudrov devoted to the development of clinical education at Moscow University in 1818–1828.

Based on the analysis of a massive corpus of archival and epistolary sources, researchers have been able to reconstruct the full scale of changes in the system of clinical training and to formulate important conclusions about the personal contribution of Dr. Mudrov into its implementation [19]. One more important topic is related to ethical issues in the work of Dr. Mudrov, a pioneering Russian physician, who established the foundation for medical ethics. Most authors mention the fact, referring to his speeches including the famous speech "Word about piety and moral qualities of a Hippocratic

doctor". Nevertheless, the informative article by Siluyanova IV, published in 2014, is very interesting in this regard. The author provides a clear classification of the ethical principles of Dr. Mudrov for the first time. The schematic diagram is given below. First, choosing a medical profession is not a game of chance, but a calling, since not everyone can be a doctor. This conclusion is in direct agreement with one of Dr. Mudrov's most important theses stating that "a mediocre doctor does more harm than good". Secondly, the doctor must adhere to "long-term thoroughness," which means that continuous study is necessary.

The third includes high moral qualities of a doctor, such as love for one's neighbor, willingness to help, selflessness, chastity, modesty, sense of shame, etc. and their external manifestations such as friendliness, calmness, cleanliness, moderation, and neatness. The fourth concerns respectful relationships with colleagues and gratitude to teachers. The fifth is strict adherence to medical confidentiality. The sixth is a critical attitude towards superstition and "internal and external worship of God." The seventh is selflessness and willingness to help with no expectation of receiving anything in return [20]. The author recalls that the "Faculty Promise of Russian Doctors" (1845), which was valid until 1917, was drawn up based on these principles.

In conclusion it should be noted that the main stages of Matvey Mudrov's life and work have been fully and comprehensively researched to date. A range of areas for further development are, however, still present. They include a more detailed research into the life and contacts of M. Y. Mudrov during his internship abroad; search for information about the army hospital in Wilno to obtain a fuller picture of Russian military medicine in the early 19th century; showing the life and work of M. Y. Mudrov in Moscow in the context of the historical and cultural everyday reality of that time, as well as other issues that will eventually allow to compile a comprehensive narrative about this wonderful Russian doctor.

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THE ETHICAL AND PSYCHOLOGICAL DETERMINANTS OF A DOCTOR'S PROFESSIONAL ACTIVITY

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The professional activity of a doctor focuses on the intersection of clinical knowledge and ethical principles. Meanwhile, medical ethics establishes the value and ideological foundations of the profession, whereas deontology serves as a tool that implements the principles within particular standards and rules of behavior. The contradiction between the importance of ethical and deontological regulators and the lack of empirical data on their relationship to the psychological characteristics of the doctor's personality makes the study relevant. The aim of the paper is to study the relationship between deontological competence of a doctor and communicative competence, metacognitive characteristics and socio-psychological attitudes. 72 internists participated in the study (the average age was 48.5 years; the average proven record was 21.6 years). The methods of diagnosis of communicative competence, metacognitive knowledge and activity, social and psychological attitudes, as well as the author's methodology for assessing deontological competence were used. Statistical processing included correlation analysis using the *r*-Spearman coefficient. Significant positive links of deontological competence with communicative ideals, metacognitive knowledge, metacognitive activity, concentration, choice of main ideas, time management, focus on altruism, as well as negative links with focus on selfishness and material values have been established. Deontological competence is an integrative education that combines value-semantic, reflexive-regulatory and motivational components, which allows it to be considered as a key mechanism for the implementation of ethical principles in clinical practice.

Keywords: medical ethics, deontological competence, professional activity of a doctor, communicative competence, metacognitive skills, value-based orientations, altruism, internists, clinical practice

Compliance with ethical standards: the study was approved at a meeting of the local ethics committee of the Federal State Budgetary Educational Institution of Higher Medical Education Yaroslavl State Medical University of the Ministry of Health of the Russian Federation (Protocol No. 67 dated 04/18/2024).

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ЭТИКО-ПСИХОЛОГИЧЕСКИЕ ДЕТЕРМИНАНТЫ ПРОФЕССИОНАЛЬНОЙ ДЕЯТЕЛЬНОСТИ ВРАЧА

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В профессиональной деятельности врача пересекаются клинические знания и этические принципы, при этом медицинская этика задает ценностно-мировоззренческие основания профессии, а деонтология выступает инструментом реализации этих принципов в конкретных нормах и правилах поведения. Актуальность исследования обусловлена противоречием между значимостью этико-деонтологических регуляторов и дефицитом эмпирических данных об их связи с психологическими характеристиками личности врача. Цель работы — выявить взаимосвязь деонтологической компетентности врача с коммуникативной компетентностью, метакогнитивными характеристиками и социально-психологическими установками. В исследовании приняли участие 72 врача-терапевта (средний возраст — 48,5 лет, средний стаж — 21,6 года). Применялись методики диагностики коммуникативной компетентности, метакогнитивных знаний и активности, социально-психологических установок, а также авторская методика оценки деонтологической компетентности. Статистическая обработка включала корреляционный анализ с использованием коэффициента *r*-Спирмена. Установлены значимые положительные связи деонтологической компетентности с коммуникативными идеалами, метакогнитивными знаниями, метакогнитивной активностью, концентрацией, выбором главных идей, управлением временем, ориентацией на альтруизм, а также отрицательные связи с ориентациями на эгоизм и материальные ценности. Деонтологическая компетентность представляет собой интегративное образование, объединяющее ценностно-смысловой, рефлексивно-регулятивный и мотивационный компоненты, что позволяет рассматривать ее как ключевой механизм реализации этических принципов в клинической практике.

Ключевые слова: медицинская этика, деонтологическая компетентность, профессиональная деятельность врача, коммуникативная компетентность, метакогнитивные навыки, ценностные ориентации, альтруизм, врачи-терапевты, клиническая практика

Соблюдение этических стандартов: исследование одобрено на заседании локального этического комитета ФГБОУ ВО ЯГМУ Минздрава России (протокол № 67 от 18.04.2024).

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The relevance of the problem. Medical professional activity integrates clinical knowledge with high ethical principles that determine the attitude to a patient's life and health. However, the rapid technologization and bureaucratization of medicine, driven by evidence-based requirements, create tension between standardized care and unique ethical needs of patients [1]. Thus, the problem of ethical and psychological regulation in medicine becomes particularly acute, since the ability of doctors to fulfill their professional duties humanistically is based on the intersection of moral choice and psychological capabilities of the individual [2].

Theoretical foundations. Today, the concepts *medical ethics* and *deontology* are commonly used as synonyms. Nevertheless, to solve research problems related to the study of a doctor's personality, they should be taken as hierarchical concepts. Medical ethics is a branch of applied ethics serving as the foundational philosophy of healthcare and governing the moral and social responsibilities of medicine. It applies concepts of good and evil, justice, mercy and humanism, addressing the 'why' question. Medical ethics constitutes the value system for doctors that shapes their character and professional worldview.

Deontology, in turn, acts as a structured framework and applied continuation of ethics that prioritizes duties and proper behavior. Derived from the Greek *deon* (duty), medical deontology defines the moral duties, standards, and rules regulating behavior of healthcare professionals [3]. If ethics defines the "spirit" of a profession, deontology sets its "letter" by answering the practice-oriented question "how?" and offering the algorithm of professional conduct. Deontological standards are formalized in codes, oaths, and rules of medical etiquette, setting forth mandatory professional behaviors.

Thus, ethics and deontology relate as theory and practice, as strategic goals and tactical tools to achieve them. Ethics forms the value consciousness of a doctor, while deontology translates these values into specific behavioral acts. We perceive deontological competence as an integrative personality quality that enables doctors to implement ethical principles in daily clinical practice. The ability is not innate or reduced to interiorization of professional codes only; its formation and implementation are largely driven by a healthcare professional's psychological profile, and the level of emotional intelligence in particular. It allows the doctor to recognize and adequately interpret the patient's experiences, as well as ensures communicative competence that fosters a therapeutic dialogue aligning with deontological norms. Consequently, it is methodologically incomplete to analyze deontological competence apart from the psychological characteristics of the subject. An empirical study investigating relationships stated in a title is therefore required.

Metacognitive abilities, including monitoring and regulation of one's own cognitive processes, activity planning and reflection play a special role in the structure of deontological competence [4]. In accordance with empirical data, a higher level of metacognitive skills among doctors significantly reduces diagnostic errors, increases critical evaluation of personal judgments, and promotes continuous professional development [5].

Metacognitive competence enables specialists to monitor their professional thinking, analyze errors and adapt strategies for improvement of clinical reasoning, which is directly related to ethical reflection. Metacognitive mechanisms that implement the functions of analysis, integration and reflexive processing of accumulated professional experience are a significant factor in the professional development of a doctor and reveal a relationship with the level of deontological competence [6].

Since effective therapeutic interaction relies heavily on a doctor's professional knowledge, practical (clinical) skills, and personal characteristics, metacognitive processes acquire the status of metaregulators of professionalization, mediating effectiveness of a medical activity [7], and also largely determine the style of behavior in conflict situations [8].

In this context, metacognitive predictive activity is of particular importance. It creates a cognitive basis for prompt and informed decision-making, providing an in-depth and systematic analysis of professional situations, including ethically complex ones [9].

The obtained empirical data show that effective implementation of medical deontology requires both adhering to regulatory requirements and developing high-level communicative competence [10], which is essential for constructive communication in challenging situations [11].

Thus, the theoretical analysis allows us to consider deontological competence in medicine as a complex ethical and psychological phenomenon that combines value-semantic (ethical) and instrumental-behavioral (deontological) components of a professional activity. Ethics sets the coordinate system defining a doctor's humanistic character, while deontology acts as the practical application, translating these ethical values into specific acts of professional interaction. At the same time, the doctor's ethical behavior is influenced by certain psychological characteristics such as effective communicative competence for a dialogue with patients; metacognitive skills that allow reflection and informed choice in case of moral uncertainty, as well as motivational and value attitudes prioritizing the patient's interests.

Despite the recognized importance of ethical and deontological regulators in medical practice, empirical studies of the systemic relationship between psychological variables and a doctor's deontological competence remain insufficient. This is how the necessity for the present study was acknowledged.

The purpose of the study is to identify and analyze the relationship between doctors' deontological competence and communicative skills, metacognitive characteristics and socio-psychological attitudes of a personality.

Objectives of the study

1. To empirically identify the correlation between doctors' deontological and communicative competence (communicative ideals, communicative skills, professional communicative ideals, professional communicative skills).
2. To determine the presence and direction of correlations between deontological competence of a doctor and the metacognitive characteristics of a personality (metacognitive knowledge, metacognitive activity, concentration, acquisition of information, choice of main ideas, time management).
3. To establish the correlation between deontological competence and socio-psychological attitudes of a doctor in the motivational and need sphere (focus on the process, result, altruism, selfishness, work, money, freedom, and power).
4. To characterize the psychological features of an internist's deontological competence based on the analysis of the revealed correlations.

MATERIALS AND METHODS

72 internists (66 women, 6 men) participated in the study. The average participant was 48.5 ± 8.6 years old (ranging from 30 to 68) with a long average career tenure of 21.6 ± 9.11 years (ranging from 4 to 41). 44 people (61%) work in the outpatient clinic, 10 people (14%) are employed by hospitals, and 18 people (25%) are department heads.

The respondents were asked to fill out the Communicative competence of a doctor questionary (by Yakovleva NV, Urvantsev LP) [12], Methodology of self-assessment of metacognitive knowledge and metacognitive activity questionary (by Kashapov MM, Skvortsova YuV) [13], Methodology for diagnosing socio-psychological attitudes of an individual in the motivational-need sphere questionary by Potemkina OF [14], Methodology Deontological competence of a doctor questionary (by Filatova Yu.S., Lutova NB) [15] diagnostic questionary on an anonymous and voluntary basis. Data underwent statistical processing with Statistica 12.0 software.

STUDY RESULTS

At the first stage of the analysis, the normality of empirical data distribution was checked using the Shapiro–Wilk criterion. It was found out that the distribution of the studied indicators differed from the normal one. Thus, nonparametric statistical methods (*r*-Spearman rank correlation coefficient) were chosen for subsequent data processing.

Table 1 presents the results of a correlation analysis of general deontological competence (DC) of a doctor with key scales of communicative competence, diagnosed using the Communicative Competence of a Doctor method (Yakovleva NV, Urvantsev LP). The analysis incorporated four scales described below. Communicative ideals (CI) assess how individual value systems prioritize communication and its expression. Communicative skills (CS) evaluate an individual's proficiency in using technical, verbal, and non-verbal techniques to achieve successful interaction. Professional communicative ideals (PCI) measure how deeply an individual integrates these communicative values into their professional concept. Professional skills (PS) measure professional communication skills based on self-assessment. They explain the technical essence of professional communication.

Communicative ideals are interrelated with the general deontological competence of a doctor. Thus, positive doctor's perception of patients, especially those deemed pleasant, correlates with reduced use of avoidance strategies like ignoring or avoiding patients, fostering a less indifferent professional interaction.

Subsequently, we analyzed the relationship between deontological competence and metacognitive characteristics of the doctor's personality. The Methodology of Self-Assessment of Metacognitive Knowledge and Metacognitive Activity (by Kashapov MM, Skvortsova YuV) was used as a diagnostic tool measuring integral indicators such as metacognitive knowledge (MK), metacognitive activity (MA), and components of metacognitive regulation of an activity such as concentration (C), information acquisition (IA), choice of main ideas (CMI), and time management (TM) (Table 2).

The association of deontological competence of a doctor with metacognitive characteristics determines high assessment of the general functioning of own cognitive mental processes (attention, memory, thinking), the degree of ease in acquiring new knowledge and the ability to cope with situations, using various methods of information structuring and cognitive activity planning, skills of managing own cognitive processes, ability to focus on the task, reducing the impact of distracting stimuli, skills to identify key content for further study and to differentiate between essential and secondary sources, as well as time management.

The final stage of statistical analysis in the study that likely involved correlating deontological competence with socio-psychological attitudes of a person in the sphere of motivation and needs was studied according to the method by Potemkina OF. This method allows us to identify the dominant focus of a person on the process (PF) or the activity result (RF), altruism (AF) or egoism (EF), labor (LF) or freedom (FF), as well as the importance of material values (money) (MF) and power (PF) (Table 3).

A direct association with the focus on altruism and an inverse association with focus on egoism and money were determined.

Table 1. The association of general deontological competence of a doctor with communicative competence (r-Spearman rank correlation coefficient)

	CI	CS	PCI	PS
General DC	0.28 *	0.03	0.17	–0.02

**p < 0.05*

Table 2. The association of deontological competence of a doctor with metacognitive characteristics of the doctor's personality (r-Spearman rank correlation coefficient)

	MK	MA	C	IA	CMI	TM
General DC	0.31**	0.30**	0.28*	0.15	0.42***	0.26*

**p<0.05 **p<0.01 ***p<0.001*

Table 3. The association of deontological competence of a doctor with socio-psychological attitudes of a person in the sphere of motivation and needs (r-Spearman rank correlation coefficient)

	PF	RF	AF	EF	LF	FF	MF	PF
General DC	–0.21	–0.16	0.27*	–0.33**	0.14	–0.41***	–0.15	–0.14

**p<0.05 **p<0.01 ***p<0.001*

DISCUSSION OF RESULTS

The conducted empirical study showed that an internist's deontological competence is significantly correlated with the psychological characteristics. The data confirm the theoretical assumption that implementation of medical ethical and deontological norms relies on both regulatory knowledge and a doctor's personal psychological traits.

Association of deontological competence with communicative features. The detected positive correlation of general deontological competence with communicative ideals in the absence of significant links with communication skills and professional communication skills is of particular interest. This result may suggest that the observance of deontological norms by doctors is driven more by their inner value system and attitude toward the patient than by proficiency in communication skills. In other words, effective medical care depends more on the doctor's respectful, empathetic attitude toward the patient as a person rather than just their technical communication skills. The high level of communicative ideals shows that a doctor treats his patients as pleasant partners, which, according to our data, contributes to the rejection of ignoring and avoidance strategies, whereas professional communication skills, which are not supported by appropriate values, do not ensure deontologically verified behavior. Doctors can recognize the patient as an equal participant of the treatment process when they have developed communication skills and deep personal dispositions.

The role of metacognitive characteristics in the structure of deontological competence. The revealed significant positive correlations of deontological competence with most indicators of metacognitive regulation (metacognitive knowledge, metacognitive activity, concentration, choice of main ideas, time management) confirm the hypothesis about the important role of reflective mechanisms in an ethically verified professional behavior. The most severe correlation was seen with the Choice of Main Ideas scale that allowed to assume that a doctor's ability to identify key content and differentiate between essential and secondary information was directly associated with the ability to recognize the ethical component of the clinical situation and take adequate deontological decisions. The obtained data agree with the results of research showing that doctors with more developed metacognitive skills make fewer diagnostic mistakes and perceive own judgements in a more critical way [4].

In the context of our study, we can say that metacognitive competence serves as both a cognitive and ethical regulator in medicine by enabling doctors by enabling doctors to reflect on their actions, predict the consequences and take responsibility for the decisions made. This is aligned with the current discussion about the need to integrate epistemological competencies into medical training, as the ability to work in conditions of diagnostic uncertainty and reflect on one's own cognitive processes is becoming a key quality of a modern clinician. A significant, moderate relationship between *concentration* and *time management* deserves special attention. The data may indicate that a deontologically competent doctor focuses on the individual patient as a primary duty, which is crucial for ethical care under high-workload and time-constrained conditions.

Motivational and value determinants of deontological competence. The most expressive results were obtained when the relationship between deontological competence and socio-psychological attitudes of a personality was analyzed. The value of deontological competence is empirically confirmed by the detected positive correlation with the focus on altruism and negative relations with the focus on egoism and money. These results suggest that the observance of professional duty and ethical standards in medical practice is rooted in a stable internal drive of the doctor to act in the best interest of the patient, while prioritizing personal gain over patient care is a factor hindering the implementation of deontological principles. The absence of significant links with the focus on process, result, work, freedom, and power indicates that deontological competence prioritizes altruistic, value-based actions over merely instrumental or technical skill. The conclusion finds theoretical justification in the concept of virtues, which emphasizes that a doctor's ethical behavior stems from internalized moral and intellectual traits rather than just following external rules. Our empirical data confirm that altruism (as a moral virtue) is a significant predictor of deontological competence, while selfishness and money are its inhibitors.

Thus, summarizing the results obtained, we can characterize deontological competence of an internist as an integrative education, including a value-semantic component manifested through altruism and positive communicative ideals; a reflexive-regulatory component driven by developed metacognitive skills that allow for informed choice and control of professional behavior; and a motivational component characterized by relative independence from external material stimuli and selfish motives.

Limitations of the study. Acknowledging limitations is essential when interpreting research results. First, the sample, which is mainly represented by internists (72 people) with a predominance of women (91.7%), limits extrapolation of conclusions to doctors of other specialties and to male population. Second, the used methods are based on self-reports vulnerable to social desirability bias. Third, the correlational design of the study does not allow us to draw unambiguous inferences about the direction of cause-effect relationships. The prospects for further research are related to the expansion of the sample, inclusion of doctors of various specialties, as well as use of observation and expert assessment methods to verify the data obtained.

CONCLUSIONS

1. Empirical research suggests that an internist's deontological competence strongly aligns with their communicative ideals. However, this ethical competence does not significantly correlate with communicative skills, professional practical ideals, or professional communicative skills. This indicates that observance of deontological norms in the professional activity is driven more by a doctor's value-semantic attitude (positively viewing the patient as a subject of interaction) than by technical communication skills.
2. Direct statistically significant correlations are detected between deontological competence and specific metacognitive personality characteristics such as metacognitive knowledge, metacognitive activity, concentration, identification of main ideas and time management. The most pronounced relationship with the "choice of main ideas" value indicates the special role of the ability to structure information and identify what is essential in ensuring ethically sound professional behavior. The data obtained confirm that metacognitive regulation is crucial for aligning clinical practice with deontological principles.

3. It has been established that deontological competence of a doctor is positively associated with the focus on altruism and negatively with the focus on selfishness and material values (money). Correlations with the focus on process, result, labor, freedom, and power have not reached the level of statistical significance. These results empirically confirm the value-based nature of deontological competence, based on the priority of the patient's interests and relative independence from external material stimuli and selfish motives.
4. Based on the analysis of the revealed correlations, deontological competence of an internist can be characterized as an integrative psychological education that includes three interrelated value-semantic, reflexive-regulatory and motivational components.

Conclusion

Thus, deontological competence acts as a bridge between moral principles and psychology-driven behavior. Its formation cannot be reduced to the translation of normative knowledge, as it requires purposeful development of the value-semantic sphere, reflexive abilities and communicative attitudes of the future doctor. Research findings can be used to design professional training and advanced training programs for medical personnel that focus on clinical competence as well as the ethical and psychological aspects of patient care. Further research in this area seems promising for an in-depth understanding of the mechanisms of deontological competence formation among doctors of various specialties and at different stages of professionalization.

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ETHICS AS AN ACADEMIC DISCIPLINE AND AN INTEGRAL PART OF PHARMACY PROFESSION

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The paper explores the role of professional ethics in establishing moral, value-based foundations, and modern pharmacy guidelines. The topic is relevant because compliance with ethical and deontological principles is an essential component of the pharmacy profession that ensures provision of high-quality pharmaceutical care as the primary task. Taking into account the requirements of regulatory documents and professional standards, the objective necessity of including a specialized discipline in 33.02.01 Pharmacy education has been reviewed. This discipline introduces students to the specifics of pharmaceutical ethics and deontology. The experience of developing and implementing the discipline of Ethics and Deontology of a Pharmacist at Yaroslavl State Medical University is described, its purpose and objectives are formulated, the topics of training sessions and approaches to their implementation are shown. The necessity of applying a practice-based approach to teaching the discipline is emphasized in order to train highly moral and socially responsible specialists who are deeply aware of their professional role in society.

Keywords: ethics, deontology, pharmacist, pharmacy, professional activity, education

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ЭТИКА КАК УЧЕБНАЯ ДИСЦИПЛИНА И КАК НЕОТЪЕМЛЕМАЯ ЧАСТЬ ПРОФЕССИИ ФАРМАЦЕВТА

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Статья посвящена анализу роли профессиональной этики в формировании морально-ценностных основ и ориентиров деятельности фармацевтических работников аптечных организаций в современном обществе. Актуальность обращения к данной теме связана с тем, что соблюдение этико-деонтологических принципов — неотъемлемая составляющая профессии «фармацевт», способствующая надлежащему выполнению его главной задачи по оказанию качественной фармацевтической помощи населению. С учетом требований нормативных документов и профессиональных стандартов рассмотрена объективная необходимость включения в учебный процесс образовательных организаций, осуществляющих подготовку по специальности 33.02.01 «Фармация», специальной дисциплины, знакомящей обучающихся со спецификой фармацевтической этики и деонтологии. Охарактеризован опыт разработки и внедрения дисциплины «Этика и деонтология фармацевтического работника» в Ярославском государственном медицинском университете, сформулированы ее цель и задачи, описана тематика учебных занятий и подходы к их проведению. Подчеркивается необходимость применения практико-ориентированного подхода к преподаванию дисциплины для подготовки высоконравственных и социально-ответственных специалистов, глубоко осознающих свою профессиональную роль в социуме.

Ключевые слова: этика, деонтология, фармацевтический работник, аптечная организация, профессиональная деятельность, образование

Вклад авторов: О. А. Куликова — постановка проблемы, подбор и анализ литературы и источников, написание и оформление текста; Л. И. Лаврентьева — редактирование текста.

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Russian society is undergoing profound, social and technological transformations. It currently faces an acute shortage in skilled professionals trained to ethically assess the impact of their activities on humans and society. The professionals are required to be aware of their social goals and values approved and implemented by their field. Under modern socio-economic conditions, educational institutions must balance specialized training with the cultivation of ideological and moral qualities, as well as ethical, moral, and value-based foundations to guide professional conduct and foster creative activity within the Russian society [1–3].

Focus of modern pharmaceutical education on training and producing a qualified and competent specialist requires developing a highly moral and socially responsible future pharmacist. Professional ethics in pharmacy hinges on a pharmacist's awareness of their role, as well as an appropriate behavior model that should be followed when providing pharmaceutical care and interacting with colleagues [4].

The acting Russian Pharmacist Competency Standard [5] contains key competencies of a pharmacist with secondary vocational education that should become a guideline for building

a personal growth plan and professional development plan of an educational organization. This standard ensures compliance with ethical and deontological principles in professional practice of pharmacists including building professional communication with adherence to business etiquette and pharmaceutical deontology, as well as observing ethical norms and knowing the rules of business communication, culture and professional ethics [5,6].

The need to integrate professional standards into pharmacy curricula forces educational institutions to create conditions for formation of necessary knowledge, skills, and abilities in future pharmacists.

As pharmacists must adhere to strict ethical and deontological principles, it is necessary to model the moral character of a pharmacist and familiarize pharmacy students with professional ethics during training.

Russian secondary vocational education programs are strictly based on Federal State Educational Standards (FGOS/FSES) and approximated basic educational programs (ABEP) [7].

According to the Federal State Educational Standard (FGOS) for 33.02.01 Pharmacy [8], minimum requirements for pharmacist competence (Wholesale and Retail of Medicines and Dispensing Medicinal Products for Medical and Veterinary Use) focus on knowing the basics of pharmaceutical ethics and deontology in accordance with regulatory documents.

Meanwhile, related ABEP [9] indicate that the issues of professional ethics are only explored in interdisciplinary course IDC 01.02 Retail of Medicines and Dispensing Medicines and Pharmacy Products within the professional module entitled Wholesale and Retail of Medicines and Dispensing Medicinal Products for Medical and Veterinary Use. This interdisciplinary course covers three essential pillars of pharmaceutical practice such as basics of ethics and deontology, selling techniques and sale procedures of medicines and pharmacy products.

In our opinion, insufficient attention is paid to professional ethics in 33.02.01 Pharmacy secondary education. Thus, it is essential to introduce into the curriculum a separate additional discipline that addresses understanding and acceptance of the professional ethics of behavior and responsibility of pharmacists. The subject can be introduced into the educational program due to its variable part, which provides tools for in-depth training of students and obtaining additional competencies.

To prepare qualified pharmacy personnel in 33.02.01 Pharmacy secondary vocational education, Ethics and Deontology of a Pharmacist was included into the curriculum by the Department of Pharmacy Management and Economics of Yaroslavl State Medical University.

This discipline is mastered in the second semester of initial professional education. It belongs to the variable part of the educational cycle.

The goal of the discipline is to guide students through key aspects of pharmaceutical ethics and deontology, including the principles of professional behavior and business etiquette in various work conditions, professional duty and honor, proper attitude to the chosen specialty and the ability to maintain occupational prestige.

The discipline aims to equip pharmacists with essential knowledge of ethical principles, codes of conduct, and moral values. It also focuses on fostering practical skills.

The discipline consists of 42 total academic hours. It is structured into 36 hours of direct training sessions and 6 hours of independent study.

Integrating Ethics and Deontology of a Pharmacist into 33.02.01 Pharmacy education has long been overdue. Since each profession, including pharmacists, rests on certain moral rules and norms, the absence of a dedicated, independent course on pharmacy ethics and professional aspects has driven educators to integrate these topics across the curriculum. This is related to their key role in shaping a qualified specialist, because understanding ethical requirements is essential for developing professional moral principles. And most importantly, ignoring pharmaceutical ethics and deontology hinders delivery of high-quality care, which is the main task of the pharmacist.

Ethics and Deontology of a Pharmacist is an applied discipline focusing on the professional responsibilities and competencies necessary for pharmacists to provide high-quality care.

The discipline program includes three modules. Professional Ethics and Continuous Development of Pharmacists, the first module, focuses on the historical aspects of pharmaceutical ethics and deontology, principles of professional ethics in pharmacy, professional qualities and possibilities for professional development.

Organizing High-Quality Public Pharmacy Services, the second module, is devoted to specifics of pharmacy service and customer types, using both verbal and non-verbal types of communication and applying service standards.

Management of Conflicts, Aggression and Stress, the third module, is aimed at acquiring knowledge and skills of conflict resolution in pharmacy, working with stress and burnout syndrome of pharmacists, principles of work with aggressive customers and manipulators.

Students will acquire expertise in managing consumer conflicts, mastering effective communication, and understanding various pharmacy customer profiles; they will master both verbal and non-verbal communication to provide responsible self-medication advice.

The approach to teaching this discipline consisting in familiarizing students with the ethical and deontological features of the chosen profession and requirements of the pharmaceutical industry has been chosen as first-year pharmacy students often have a limited understanding of the profession's scope and lack familiarity with the necessary professional and interpersonal qualities of a pharmacist.

Practical training in pharmacy focuses on developing essential ethical and deontological skills, enabling students to behave professionally in real-world patient interactions and team collaborations. Most questions in the classroom are debatable. It should be noted that pharmacy students increasingly recognize the need for strong interpersonal skills to manage complex pharmacist-visitor relationships and resolve conflicts in the workplace. Pharmacists frequently encounter with such cases and pharmaceutical students engage in team collaboration and solving professional challenges.

Independent study hours provide time for students to solidify and comprehend knowledge while stimulating activity and interest of students in qualitative curriculum adoption and focusing on in-depth learning. It includes self-preparation for classes and presentations, writing research papers and essays.

Intermediate certification in Ethics and Deontology of a Pharmacist is conducted via testing to evaluate students' mastery of ethical principles and deontological knowledge.

CONCLUSION

Thus, the discipline entitled Ethics and Deontology of a Pharmacist builds competencies essential for interpersonal interaction in pharmaceutical care. It equips future pharmacists with a practice-oriented understanding of ethical obligations for pharmacy employees.

Moreover, the academic discipline directly correlates with the educational function of the learning process, which is reflected in student's personal results and forms professional consistency.

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THE ROLE OF PROFESSIONAL ETHICS IN THE FIGHT AGAINST GERONTOLOGICAL AGEISM WHILE TRAINING SOCIAL WORKERS

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The article shows how gerontological ageism can be prevented by embedding professional ethics in training of social workers. The ageism is often manifested through emotional alienation of young people and discriminatory practices towards the elderly. Survey data on social work students from the Yaroslavl State Medical University (YSMU) confirm the need for the training. During the survey, the KPAINS Freedom from Age questionnaire, which is a widespread gerontology tool, was used for early assessment of attitudes to aging. Young people's psychological trends have confirmed that deeper ethical study is essential for those professionals who work with older adults. Students learn to apply the basic ethical principles of autonomy, dignity and justice while exercising complex interaction with older adults through analysis of practical cases. It confirms that training competent social professionals is ethically relevant.

Keywords: professional ethics, gerontological ageism, students

Compliance with ethical standards: during the research and preparation of this paper, all necessary ethical standards and principles were observed. It ensured the scientific and moral correctness of the paper. Measures have been taken to ensure the confidentiality and anonymity of participant data. Personal information of the participants was not disclosed and was used exclusively for scientific purposes.

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РОЛЬ ПРОФЕССИОНАЛЬНОЙ ЭТИКИ В ПРЕОДОЛЕНИИ ГЕРОНТОЛОГИЧЕСКОГО ЭЙДЖИЗМА НА ЭТАПЕ ПОДГОТОВКИ СПЕЦИАЛИСТОВ ПО СОЦИАЛЬНОЙ РАБОТЕ

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В статье обоснована роль профессиональной этики при подготовке специалистов по социальной работе в профилактике геронтологического эйджизма, который нередко проявляется в эмоциональном отчуждении молодежи и дискриминационных практиках по отношению к пожилым людям. Потребность обучения подтверждена данными опроса студентов ЯГМУ, обучающихся по направлению подготовки «Социальная работа». На этапе опроса студентов использовался распространенный в геронтологии для раннего выявления эйджистских установок опросник «Свобода от возраста «KPAINS». Выявленные психологические особенности молодежи подтвердили актуальность более глубокого изучения вопросов этики для работы с людьми старших возрастных групп. Через разбор практических ситуаций студенты учатся шире применять основные этические принципы автономии, достоинства и справедливости в сложных вопросах взаимодействия с пожилым человеком, что подтверждает актуальность подготовки компетентных специалистов социальной сферы с позиции профессиональной этики.

Ключевые слова: профессиональная этика, геронтологический эйджизм, студенты

Соблюдение этических стандартов: в ходе проведения исследования и подготовки настоящей статьи были соблюдены все необходимые этические стандарты и нормы, что обеспечило его научную и моральную корректность. Были приняты меры для обеспечения конфиденциальности и анонимности данных участников. Личная информация участников не разглашалась и использовалась исключительно в научных целях.

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The world, including Russia, experiences a rise in the elderly populations, which naturally intensifies gerontological ageism at the present stage.

Gerontological ageism is a social phenomenon manifested through negative stereotypes and discrimination toward elderly and senile individuals. State social policy prioritizes measures to reduce ageism, which are included into the Strategy of Action in the Interests of Older Citizens approved by the Government of the Russian Federation until 2030 [1].

Implementation of these measures means that professionals, and social service workers in particular, must adopt ethical approaches to interaction with the elderly that prioritize dignity, autonomy, justice, and mercy. Previous research in gerontology and geriatrics confirms that gerontological ageism and negative stereotypes toward older adults frequently emerge among students [2–4].

Meanwhile, professional education is a critical period when motivation, needs, and personality traits of future social workers are solidified. It places increased demands on training of these professionals who should effectively shape the quality of life for older adults. This confirms that teaching professional ethics to social work students is essential to form anti-ageist ethical

Table. Student survey results

Показатель (n = 18)	Yes, I agree	More likely yes than no	More likely no than	No, I disagree
Do you feel shy while communicating with older adults?	5.3 ± 1.1	4.6 ± 1.2	51.4 ± 2.1*	38.7 ± 2.5*
Do you feel extra stress when communicating with elderly patients?	4.4 ± 1.2	3.5 ± 1.1	58.3 ± 2.1*	33.8 ± 2.4*
Do you try to maintain distance to minimize odors associated with aging?	10.3 ± 1.6	10.9 ± 1.5	31.8 ± 1.9*	47.0 ± 2.1*
Do you believe that memory loss, hearing loss, and visual impairment become more common with age?	38.8 ± 3.2	35.3 ± 3.1	17.7 ± 2.2*	8.2 ± 1.6*
Do you agree that loneliness is a common human experience that can occur at a certain age?	29.4 ± 1.5	23.1 ± 1.2	35.2 ± 1.8	12.3 ± 1.3*
Is it interesting for you to communicate with older individuals?	43.4 ± 1.9	44.3 ± 2.2	10.9 ± 1.3*	1.4 ± 1.2*
Do you like learning something new from talking with the elderly?	43.7 ± 2.1	41.3 ± 2.2	13.2 ± 1.3*	1.8 ± 1.1*

competencies and combat gerontological ageism among students [5–7].

The purpose of the study is to assess the need of students trained as future social workers in studying professional ethics to combat gerontological ageism by analyzing their psychological profile.

MATERIALS AND METHODS

The psychological profile of the students was constructed based on the KPAINS Freedom from Age questionnaire. This questionnaire is used as a tool for early detection of attitudes toward ageing, which is foundational to anti-aging management and quality-of-life improvements. [8].

The study involved 18 students (2nd and 3rd year of education) from Yaroslavl State Medical University studying Social Work, consisting of 15 females (83%) and 3 males (17%), aged 17–20.

The questionnaire allowed to identify the students' communication abilities and their readiness to communication with elderly interlocutors, assess psychological characteristics of future social workers and get an idea of the ethical foundation for youth working with the elderly and senile people. Students had to answer the following questions:

- Do you feel shy while communicating with older adults?
- Do you feel extra stress when communicating with elderly patients?
- Do you try to maintain distance to minimize odors associated with aging?
- Do you believe that memory loss, hearing loss, and visual impairment become more common with age?
- Do you agree that loneliness is a common human experience that can occur at a certain age?

The next questions were used to assess willingness of the students to work with the elderly:

- Is it interesting for you to communicate with elder individuals?
- Do you like learning something new from talking with the elderly?

The interest of students in communication with older populations has been assessed. The students were offered to choose one of the following answers: 'yes, I agree', 'more likely yes than no', 'no, I disagree', and 'more likely no than yes'.

During the statistical analysis, the average relative values and their errors (M ± m) were calculated. The differences were considered significant at $p < 0.05$.

RESEARCH RESULTS

During the research, 9.9% of social work students reported shyness when communicating with the elderly, whereas 7.9% of them indicated that their stress level was increased ($p < 0.05$).

It is noteworthy that 21.2% of students try to keep their distance when communicating with the elderly due to the fear for unpleasant smells and the associated feeling of disgust ($p < 0.05$).

The study also determined high internal motivation among students planning to work in the social sphere. Thus, most of them (87.7%) are interested in communication with older people. Therefore, they are ready to consciously transform their views and study to foster greater tolerance for the process of aging. The results of the student survey are presented in the table.

DISCUSSION OF RESULTS

According to the survey results, social work students often face emotional and communicative barriers that impede effective engagement with older adults. It reinforces gerontological stereotypes and serves as a foundation for ageism in professional practice.

As the students are ready to change their internal motivation, they have good empathy skills and are sincerely interested in the problems of older population. They are required to develop effective communication with older adults during the educational process based on ethical principles.

Though the problem is recognized, insufficient hours are allocated to professional ethical education of social work students, since the curricula focus on legislative and technological issues.

To improve ethical education of young people and develop healthy intergenerational relationships during the academic and industrial practice, we have proposed various formats of work such as group classes and business games to develop social skills of students that could use the student-to-student and student-to-elderly interaction model as an example. Meanwhile, interactions with the elderly are shifting from paternalism to partnership based on human rights and respect for life experience [9–11].

As ethical principles form the basis of interaction with the elderly, practical classes address tools to resolve ethical dilemmas where the interests, rights and needs of an elderly person may be ignored or violated due to age-based stereotypes. The principle of autonomy and respect for the dignity of older persons establishes that older populations maintain the fundamental right to independent choice and decision-making. The principles of mercy (benevolence) and non-maleficence ("do no harm") ensure safety and well-being and prevent physical or psychological damage. The principle of justice demands an equal and unbiased attitude toward an elderly person, regardless of their condition and appearance. Future social workers should apply ethical principles in situations where ageist attitudes can provoke discriminatory practices when interacting with older people. This makes it possible to identify and reduce the manifestation of ageism among young people in a timely manner.

It is relevant and appropriate to include mandatory classes on age, ageing and health in the training program of students as it allows to improve the competence of future social workers and has an anti-ageist tendency, including the Long and Active Life national project [12–16].

CONCLUSIONS

Thus, the conducted research and integration of ethical principles into social work curricula confirm the relevance of teaching professional ethics to competent specialists and are the necessary conditions for the educational process to prevent and overcome gerontological ageism in the social sphere. Overcoming ageism through ethical education helps to build an inclusive society for all ages, directly affects the mental well-being of not only the elderly, but also the young, and fosters healthy intergenerational relationships.

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INCLUSIVE HIGHER EDUCATION: ETHICAL IMPERATIVES OF BIOETHICS

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This article provides an ethical review of inclusive education based on the four pillars of bioethics such as autonomy, beneficence, non-maleficence, and justice. The authors are convinced that the inclusive educational paradigm is not just a pedagogical technology, but a moral imperative that directly results from modern bioethical approaches and a social model of understanding disability. Moral and ethical challenges at the intersection of medical diagnosis and pedagogical process are carefully analyzed. The new and collaborative role of medicine in inclusive practice is substantiated. The article considers the paradigm shift from the medical to the socio-ethical model of disability, analyzes the main ethical dilemmas of inclusion (resource dilemma, reasonable accommodation, professional boundaries) and substantiates the role of the medical community as a defender of rights and a partner in building an inclusive environment. It is concluded that principles of bioethics provide a reliable conceptual foundation for overcoming practical and ideological barriers to inclusive education for students with special educational needs (SEN).

Keywords: bioethics, inclusive education, medical ethics, the principle of justice, respect for autonomy, disability, special educational needs, reasonable accommodation

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ИНКЛЮЗИВНОЕ ВЫСШЕЕ ОБРАЗОВАНИЕ: ЭТИЧЕСКИЕ ИМПЕРАТИВЫ БИОЭТИКИ

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В статье проводится этический анализ инклюзивного образования через призму основных принципов биоэтики: уважения автономии личности, благодеяния, непричинения вреда и справедливости. Авторы убеждены, что инклюзивная образовательная парадигма является не просто педагогической технологией, а моральным императивом, прямо вытекающим из современных биоэтических подходов и социальной модели понимания инвалидности. Особое внимание уделяется анализу морально-этических противоречий, возникающих на стыке медицинского диагноза и педагогического процесса, и обоснованию новой, партнерской роли медицины в инклюзивной практике. Рассматривается смена парадигмы от медицинской инвалидности к социально-этической модели инвалидности, анализируются основные этические дилеммы реализации инклюзии (дилемма ресурсов, проблема «разумного приспособления», профессиональные границы) и обосновывается роль медицинского сообщества в качестве защитника прав и партнера в построении инклюзивной среды. Делается вывод о том, что принципы биоэтики предоставляют надежный концептуальный фундамент для преодоления практических и идеологических барьеров на пути реализации права на инклюзивное образование для обучающихся с особыми образовательными потребностями (ООП).

Ключевые слова: биоэтика, инклюзивное образование, медицинская этика, принцип справедливости, уважение автономии, инвалидность, особые образовательные потребности, разумное приспособление

Вклад авторов: все авторы внесли существенный вклад в подготовку работы, прочли и одобрили финальную версию статьи перед публикацией. С. В. Калабекова — планирование исследования, анализ, интерпретация данных; К. К. Фидарова — поиск источников литературы, редактирование черновика рукописи; О. В. Соколова — планирование исследования, интерпретация данных, подготовка черновика рукописи; А. В. Смирнова— редактирование черновика рукописи.

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Modern societies are predominantly focused on inclusive education that ensures equal access to quality education for all students and takes into account the diversity of their special educational needs (SEN). Inclusive education in Russia is formally secured by the Federal Law On Education in the Russian Federation [1] and a number of ratified international

conventions, primarily the Convention on the Rights of Persons with Disabilities [2].

Traditionally, the issues of education of students with SEN were considered from the point of view of pedagogics, psychology and special medicine. However, inclusive education is fundamentally grounded in ethics and human rights. The goal of this article is to demonstrate that inclusive higher education is a direct ethical imperative arising from the fundamental principles of bioethics, and that the medical community, built on these principles, is obliged to play an active role in its approval.

Objectives:

1. to analyze the paradigm shift from the medical to the socio-ethical model of disability;
2. to look at inclusion through the lens of autonomy, beneficence, non-maleficence, and justice;
3. to detect essential ethical dilemmas while inclusion is implemented;
4. to determine the ethically justified role of a health worker (pediatrician, neurologist, psychiatrist, rehabilitation therapist) in the inclusive process.

FROM THE MEDICAL MODEL TO THE BIOETHICAL PARADIGM: CHANGING CONCEPTUAL FOUNDATIONS

The medical (or rehabilitation) model of disability describes a historically widespread approach to disability. According to it, a problem exists within the person. It views disabilities as abnormalities that need to be cured, corrected or isolated in specialized institutions [3]. The model-based educational system is associated with segregation at specialized schools where they focus not on social integration but on how to compensate a defect. The model is problematic from an ethical point of view because it makes a diagnosis, limits autonomy, and results in stigmatization and social isolation.

Starting from the 2nd half of the XX century, a social model of disability is developed alongside with the development of bioethics [4]. Its core message states that physical dysfunctions occur not due to disturbed health but because of inadaptability of the physical and social environment (architectural, information, communication, attitude barriers). Thus, the "problem" is shifted from the individual to the society. The task of the latter is to eliminate the barriers.

The system of bioethical principles (Beauchamp TL and Childress JF) offers a solid foundation for a social model. The discourse is shifted from a purely medical plane to the plane of rights, dignity and social justice. According to this logics, inclusive education is not a "service" for the "patient" but the right and condition for treating any society member with dignity.

PRINCIPLES OF BIOETHICS AS THE FOUNDATION FOR INCLUSIVE EDUCATION

1. Respect for autonomy (principle of self-determination). The principle means that an individual has a right for their own choice, opinion and participation in life-related decisions [5]. For a child with SEN, it is about shifting from the paternalistic approach (when a doctor/teacher knows better what you need) to the partnership model. Autonomy is implemented through:
   - the individual educational program (IEP) developed based on the opinion and potential of the child and the child's family;
   - assistance in taking decisions about the form and place of education;
   - recognizing the right for the voice. Even a non-verbal child has some preferences that have to be understood and respected.

   Violation of this principle results in a forced enrollment in specialized schools, ignoring the family's opinion, and treating the child as a passive object for intervention.
2. Beneficence and non-maleficence. The traditional segregation system was often justified to be selected for the "benefit" of the child and for the purpose of placing such a child in a "safe" and "comfortable" environment. From the bioethical point of view, however, the assumption could be disputed.

   Beneficence in inclusion means an active creation of conditions for the best development of social, academic and personal competencies. The research shows that in case of an adequate support, inclusion leads to better academic and social results for children with SEN, and to empathy and tolerance in their neurotypical peers [6]. Non-maleficence is an obligation that prevents from creating conditions leading to isolation, low self-esteem, or learned helplessness. Even if the conditions are good, isolated education does harm by depriving the child from the social experience and attaching the label of "someone who is different from others" [6]. Thus, refusal from inclusive conditions can be taken as an ethical violation of the "non-harm" principle.
3. The principle of justice is the core inclusion principle. Justice is rather taken not as something that makes everyone equal but as redistributive justice (distribution of resources according to needs) [7]. In education, the principle requires to ensure equal possibilities but not similar conditions. This means that a child in a wheelchair needs a ramp, and a child with dyslexia (impaired ability to read and understand a written text) needs a text typed in a special font. It is a "reasonable accommodation", a significant term of the Convention on the Rights of Persons with Disabilities. Health discrimination should be avoided. Financing, personnel, and methodological support should be distributed to exclude privileges or discrimination because of developmental challenges.

ETHICAL DILEMMAS OF INCLUSION IMPLEMENTATION

The ethical principles implemented in practice face dilemmas that require a balanced approach. First, it is a dilemma of resources and limits of "reasonable accommodation". The principle of justice demands nothing impossible. But where is the border of the "reasonableness"? This is an ethical question. When does the environment accommodation stop being "reasonable", start disturbing education of other children or become unbearable for the institution? The decision requires an open dialog between all parties (parents, teachers, administration of the educational institution, medical personnel) and search for creative compromises but not for an administrative prohibition.

Second, it is the conflict of interests such as the family autonomy, the child's well-being and interests of the group. It can happen that what the family wishes (if they insist on inclusion though the child experiences constant stress because of the unprepared environment) can conflict with the current benefit of the child. Third, it is the problem of the limits of professional competence and interdisciplinarity.

A health worker's role in inclusive education is one of the most complicated ones. On the one hand, its expertise (diagnosis, prognosis, support recommendations) is essential. On the other hand, there is a risk of medicalization of an educational process when only diagnosis determines the pedagogical route.

A doctor has an ethically suitable position when they submit objective information about educational needs based on health and when they serve as consultants in a team of psychological and pedagogical support instead of directly instructing the school ("the child can't join a regular class") [8].

Resolution of these conflicts should be very delicate. It requires respect for the family autonomy and fair instructions about the risks and possibilities.

THE ETHICALLY PROVEN ROLE OF THE MEDICAL SOCIETY

Taking into account bioethical principles, a health worker should move beyond just diagnosing illnesses and focus on advocating for a patient's rights and health in a broader sense. The ethical responsibilities include as follows:

1. protection from discrimination: do not use a dialog as a sentence limiting life chances;
2. interdisciplinary partnership: work in collaboration with teachers, psychologists, and speech pathologists respecting their professional expertise;
3. enlightment and destigmatization: explain the essence of a social model and bioethical basis for inclusion to colleagues, teachers and society;
4. family support: submit information that helps the family to make a conscious choice and support it while the child's rights are asserted.

Inclusive education is not an experimental pedagogical method but a complex social and ethical project deeply held in the system of modern bioethical values. Whenever it is implemented, the principles of respect for human dignity, autonomy and justice declared by the society are checked for validity. The principles of bioethics such as respect for autonomy, beneficence, non-maleficence, and justice give a clear regulatory direction to overcome the practical and ideological barriers on the way to inclusion. They are used to solve issues, determine the borders of responsibility and build constructive interdisciplinary interaction.

The medical community that acts as the guardian of these core ethical principles incurs special responsibility. Doctors, medical specialists, clinical psychologists, social workers, and healthcare officials are called upon to become active participants in changes rather than passive observers, translating the ethical imperatives of bioethics into the practice of building an inclusive society starting in the classroom at school. Thus, they serve as expert intermediaries who navigate patients through difficult healthcare decisions and help them find an ethically sound path. Refusal from an outdated model in favor of the bioethical inclusion paradigm means both a professional duty and contribution to the formation of a more humane and just society for everybody.

The research shows that inclusive education is not just a pedagogical trend but also an ethical imperative grounded in the fundamental principles of bioethics. However, systemic steps are required to include the ethical imperative into the daily practice. We use the analysis to offer the following recommendations to different layers of the professional community and management system.

The medical community members and health professionals should do as follows:

1. to change the format of medical reports for the PMPC (psychological, medical and pedagogical commission) and educational organizations. Instead of diagnosis ("not capable"), the report should contain a structured description of educational needs of a student (in communication, movement, information perception, activity organization) and certain recommendations on creating conditions (technical means, regime, interaction specifics);
2. to implement obligatory educational modules on the basis of bioethics, social model of disability and interdisciplinary interaction into the continuing medical education program for pediatricians, neurologists, psychiatrists and doctors of other related specialties;
3. to create positions of clinical bioethicists or ethical consultants at large medical centers who will, among other tasks, deal with problems across medicine and education, support doctors in taking non-paternalistic decisions and resolve conflicts with families.

The system of education and interdepartmental communications should perform the following tasks:

1. to capture an obligatory participation of a doctor (or a medical representative) as a full member of the academic psychology and pedagogical council at the regulatory level. His role is not to provide instructions but to submit expert information and participate in the joint development of the individual educational route;
2. to develop and introduce clear interdepartmental (Ministry of Health — Ministry of Science and Higher Education, Ministry of Education) protocols transferring information about students with SEN from the healthcare system to the system of education. The protocols should warrant confidentiality and translation of medical data to the language of pedagogical tasks;
3. to develop the system of independent ethical expertise of complex inclusion cases when conflicts of interests or disputes about the "reasonability of accommodation" arise. The commissions should include not only teachers and officials, but also bioethicists, human rights lawyers and representatives of non-state commercial organizations (All Russia Association of the Blind).

The scientific and expert community should do as follows: to initiate interdisciplinary research to estimate long-term effects of inclusion from the bioethical point of view. Its effect on the quality of life, self-regulation, and social health of all participants of the educational process should be examined.

Ultimately, successful inclusion requires doctors to move beyond just diagnosing illnesses and setting standards and focus instead on advocating for a patient's rights, health, and ability to thrive within their daily life. Implementation of the suggested measures allows not only meeting formal legislation requirements but also turning the bioethical principles into a living guideline for action by providing every student with a right for education and decent life not just on paper, but in reality.

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NORMATIVE DISSONANCE IN PEDIATRIC PHARMACOTHERAPY: BIOETHICAL ANALYSIS

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In this paper, we present a comprehensive bioethical and regulatory analysis of the use of drug therapy in children with oncological, rheumatological, cardiological and psychiatric diseases in the Russian Federation based on official Instructions for Medical Use and the latest clinical recommendations. This paper focuses on significant contradictions between clinical recommendations and drug registration documents registered in the State Register of Medicines of Russia. Insufficient scientific data on safety and effectiveness of medicines among children deserve particular attention as it results in serious therapy restrictions worsened by regulatory and legal barriers for pediatricians. The study is focused on medications for treatment of follicular lymphoma, systemic lupus erythematosus, schizophrenia and familial hypercholesterolemia, with an emphasis on age restrictions and contraindications.

Key words: follicular lymphoma, systemic lupus erythematosus, schizophrenia, familial hypercholesterolemia, pediatrics

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НОРМАТИВНЫЙ ДИССОНАНС В ПЕДИАТРИЧЕСКОЙ ФАРМАКОТЕРАПИИ: БИОЭТИЧЕСКИЙ АНАЛИЗ

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В статье представлен комплексный биоэтический и нормативный анализ применения медикаментозной терапии у детей с онкологическими, ревматологическими, кардиологическими и психиатрическими заболеваниями в Российской Федерации на основе официальных инструкций по медицинскому применению лекарственных препаратов и современных клинических рекомендаций. Основное внимание уделено выявлению существенных противоречий между клиническими рекомендациями и регистрационными документами лекарственных средств, зарегистрированных в государственном реестре лекарственных средств. Особое значение уделено проблеме отсутствия достаточной доказательной базы по безопасности и эффективности лекарственных препаратов у детской аудитории, что приводит к значительным ограничениям в назначении терапии, усугубляемым нормативными и правовыми барьерами для врачей-педиатров. Исследование охватывает лекарственные средства, применяемые при лечении фолликулярной лимфомы, системной красной волчанки, шизофрении и семейной гиперхолестеринемии, с акцентом на возрастные ограничения и противопоказания.

Ключевые слова: фолликулярная лимфома, системная красная волчанка, шизофрения, семейная гиперхолестеринемия, педиатрия

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A contradiction between the latest clinical recommendations and Instructions for Medical Use registered in the State Register of Medicines of Russia is an essential problem of pediatric pharmacotherapy. Some drugs recommended for treatment of adults lack prospective studies in pediatrics or are prohibited for use in children due to the absence of data on safety and effectiveness. Thus, significant difficulties for doctors in choosing therapy arise [1]. Because of the failure to perform prospective pediatric research or because of the lacking data on safe and effective treatment in children, it is difficult for doctors to supply children with access to certain medicinal preparations used in adults [1].

The goal of this study is to provide for a comprehensive bioethical and regulatory evaluation of drug therapy in children with oncological, rheumatological, cardiological and psychiatric diseases in the Russian Federation, to identify contradictions between clinical recommendations and official Instructions for Medical Use, and to highlight the ways to minimize regulatory and legal barriers to improving pediatric pharmacotherapy.

MATERIALS AND METHODS

Research analyzes Instructions for Medical Use of the medicinal products registered in the State Register of Medicines of Russia (as of August 2025) and the latest clinical recommendations for pediatric patients. Medicinal preparations were chosen based on four groups of diseases: oncological (follicular lymphoma) [2], rheumatic (systemic lupus erythematosus) [3], psychiatric (schizophrenia) [4] and cardiological (familial hypercholesterolemia) [5]. Contraindications, Pediatric population and Age groups were examined for each medicinal product. Methods of comparative analysis used in this paper allowed to identify discrepancies between clinical guidelines

Table. The most significant data on indications and contraindications for use of the investigational preparations in pediatric population with regard to age limitations and special conditions of use [1]

Group of diseases	Medicinal product, INN	Approved for use in children	Age limitation/notes[6]
Oncological diseases			
Follicular lymphoma	Mosunetuzumab	No	Do not use the drug in children below 18 years of age due to potential lack of effectiveness and safety (safety and effectiveness of Lunsumio® in children below 18 years of age have not been established yet)
	Bendamustine	No	Bendamustine-TL: Contraindications: pediatric population (lack of effectiveness and safety data)
	Obinutuzumab	No	Do not use the drug in children below 18 years of age due to potential lack of effectiveness and safety (safety and effectiveness of Gazyva® in children below 18 years of age have not yet been established)
	Lenalidomide	No	Do not use Mielanix in children below 18 years of age, as safety and effectiveness of the drug in children below 18 years of age have not yet been established
	Rituximab	No	Do not use Mabthera® 1400 mg in children and adolescents below 18 years of age
Rheumatic diseases			
Systemic lupus erythematosus	Methotrexate	Yes	Children and adolescents: do not use Methotrexate in children below 3 years of age due to limited effectiveness and safety data. When Methotrexate is used as an immunosuppressant to suppress immunity in children (in psoriasis, rheumatoid arthritis, juvenile chronic arthritis, dermatomyositis, and systemic lupus erythematosus), determine the appropriate risk/benefit ratio.
	Ciclosporin	Yes	Patients below 18 years of age: patients below 18 years of age may exhibit faster recovery of Ciclosporin as compared to adults. Therefore, pediatric patients require higher doses of Ciclosporin per kilogram of body weight to achieve the desired drug concentrations in the blood.
	Azathioprine	Yes	Overweight children: in a clinical trial, 18 children (3 to 14 years of age) were undergoing maintenance treatment with 6-MP, whereby the body surface was the basis for the dose calculation. The average area under the concentration-time curve from time zero to infinity (AUC0-∞) of 6-MP in the group greater than the 75th percentile was 2.4 times lower than that in the group less than the 75th percentile. Therefore, overweight children may need higher Azathioprine doses, and close monitoring of their response to treatment is advised.
	Cyclophosphamide	Yes	Rhadbomyosarcoma in children: Cyclophosphamide is used in complex polychemotherapy regimens depending on the stage of a disease and histological type of tumor. In standard cases, dose for III (residual macroscopic tumor after surgery) and IV (remote metastases) stage patients is 10 mg/kg of body-weight IV for 3 consecutive days. The treatment is repeated multiple times in combination with Vincristine and Actinomycin D (rhadbomyosarcoma international study II that established the VAC-protocol).
	Prednisolone	Yes	Do not use the preparation in children under 3 years of age
	Methylprednisolone	Yes	Methyliof must be cautiously used in children. The physician should carefully control growth and development of children who have been treated with Methyliof on a continuous basis. Children receiving prolonged daily therapy divided into several doses may have growth retardation. Long-term daily use of the product is possible only in children on absolute indications. Administration of the drug every alternate day may reduce the risk of the adverse effect or allow to avoid it. Children receiving long-term therapy with Methyliof are high-risk due to increased intracranial pressure (intracranial hypertension). High doses of Methylprednisolone can result in inflamed pancreas (pancreatitis) among children.
	Mycophenolic acid	No	Children and adolescents: children under 18 years of age should not be given the product due to non-effectiveness and probable lack of safety (safety and effectiveness of Mycophenolic acid in children under 18 years of age have not been established)
	Belimumab	Yes	Benlysta is used to – reduce disease activity in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) receiving standard therapy; – treat active lupus nephritis in patients aged 5 years and older in combination with standard background immunosuppressive therapy.
	Tofacitinib	No	Children under 18: Children under 18 should not take Tofacitinib for rhematoid arthritis, psoriatic arthritis, ulcerative colitis, ankylosing spondylarthritis, novel coronavirus infection caused by COVID-19, as effectiveness and safety have not been established. Children aged 2 to 18 years: Tofacitinib might be used as monotherapy or in combination with Methotrexate for polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis (see Administration of Tofacitinib). Children under 2 years old: children under 2 years of age must bot be given the drug for polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis as its effectiveness and safety have not been established.
	Hydroxychloroquine	Yes	Contraindications: children under 6 years of age.

Table (continued)

Group of diseases	Medicinal product, INN	Approved for use in children	Age limitation/notes[6]
Psychiatric disorders			
Schizophrenia	Heloperidol	No	Children and adolescents: Heloperidol must not be used in children and adolescents under 18 years of age due to the lack of data on effectiveness and safety in this group of patients.
	Olanzapine	No	Children and adolescents: the drug must not be used in children under 18 years of age due to the lack of data on effectiveness and probable safety in this group of patients. Olanzapine must not be used in children and adolescents under 18 years of age.
	Clozapinum	No	Children and adolescents under 18 years of age (effectiveness and safety have not been established)
	Aripiprazole	Yes	Aripiprazole pharmacokinetics are comparable between children aged 10–17 years old and adults. Thus, no body weight correction is required.
	Quetiapine	No	Contraindications: children under 18 years old (effectiveness and safety have not been established)
	Chlorpromazine	Yes	Indications: it can be used in adults and children (1 year of age and older)
	Thioridazine	Yes	Indications: disturbed behavior and symptoms of a psychomotor activity
	Levomepromazine	No	Do not take Tisercin® if you are under 12 years of age
	Sulpirid	No	Children: safety and effectiveness of the drug in children under 18 years of age have not been established. Sulpirid is contraindicated in children under 18 years of age.
	Periciazine	Yes/No (depending on the dosage form)	1.Contraindications: children under 18 years of age (for capsules). 2. Neuleptil® can be used in children older than 3 years of age for severe behavioral disorders, agitation, and excitation.
	Biperiden	Yes	Biperiden is approved for use in children aged 3 years and older and adults
Cardiological diseases			
Familial hypercholesterolemia	Rosuvastatin	No	Safety and effectiveness in children below 18 years of age have not been established; limited drug data are available
	Bempedoic acid	No	Safety and effectiveness in children below 18 years of age have not been established; limited drug data are available
	Inclisiran	No	Safety and effectiveness in children below 18 years of age have not been established; limited drug data are available
	Fenofibrate	No	Safety and effectiveness in children below 18 years of age have not been established; limited drug data are available
	Omega 3 unsaturated fatty acids	No	Safety and effectiveness in children below 18 years of age have not been established; limited drug data are available
	Ezetemibe	Yes	Officially approved in children who are 10 years of age and older
	Evolocumab	Yes	Officially approved in children who are 10 years of age and older
	Simvastatin	Yes	Officially approved in children 10 years of age and older
	Atorvastatin	Yes	Officially approved in children 10 years of age and older
	Alirocumab	Yes	Contraindicated in children under 8 years of age due to the lack of data on safety and effectiveness for this group of patients.
	Pitavastatin	Yes	It is contraindicated in children under 6 years of age due to the lack of sufficient clinical data for this age group

and official instructions, reveal regulatory and bioethical aspects, and detect key challenges of choosing drug therapy in underage patients. This complex approach ensures systemic understanding of the problem and offers solutions.

RESEARCH RESULTS

Analysis of Instructions for Medical Use of the medicinal products during the research has shown as follows. The majority of registered medicinal products to treat oncology (follicular lymphoma) including Mosunetuzumab, Bendamustine, Obinutuzumab, Lenalidomide, and Rituximab are contraindicated for use in children under 18 years of age due to the lack of established safety and effectiveness data [6]. It significantly limits the choice of therapy in children and adolescents. The rate of rheumatic (systemic lupus erythematosus) drugs approved for pediatric pharmacotherapy was higher. Methotrexate, Ciclosporin, and Azathioprine can be used in the pediatric population but with regard to their age and need for proper monitoring of a patient's clinical condition [6]. Mycophenolic acid and Tofacitinib are contraindicated to children under 18 years of age due to the risk of non-effectiveness and potential side effects. Belimumab is used in patients aged 5 years and older in the presence of certain indications. Research has shown that the majority of antipsychotic agents (to treat schizophrenia) such as Haloperidol, Olanzapine, Clozapinum, Quetiapine, and Levomepromazine are contraindicated to children and adolescents under 18 [6]. However, Apiprazole and Chlorpromazine are approved for use

in pediatric pharmacology though additional consideration with regard to special conditions and age limitations is required. Certain drugs such as Periciazine and Biperiden have been approved in some children and adolescents depending on the dosage form and age. While studying cardiological drugs (to treat familial hypercholesterolemia), it has been established that some more frequently used statin-containing and lipid-lowering drugs such as Rosuvastatin, Bempedoic acid, Inclisiran, Fenofibrate and Omega-3 are contraindicated in children and adolescents under 18 due to the lack of safety and effectiveness for children. Meanwhile, Ezetimibe, Evolocumab, Simvastatin, Atorvastatin and Alirocumab are used in children with age restrictions, usually from 6–10 years of age. Pitavastatin should not be given to children under 6 years of age [7].

Thus, document analysis highlights significant gaps and limitations in the regulation of drug therapy in children with severe diseases. To ensure a wide and safe use of drugs in pediatric pharmacotherapy, further research and review of established standards are required.

The table presents the most significant data on indications and contraindications for use of the investigational preparations in pediatric population with regard to age limitations and special conditions of use.

If prescribing the drugs in pediatrics is associated with limitations, an obligatory collective decision is required. The therapeutic indications require prior medical consultation with a complex assessment of the possible risk and benefit ratio [8].

Documentary analysis shows significant gaps in the evidence and regulatory base regarding drug therapy of children with severe diseases. The obtained regulatory restrictions do not only narrow the therapeutic arsenal of a pediatrician but also underline the vital need in targeted clinical trials and subsequent review of regulatory documents. This is an essential condition for expanded possibilities of safe and effective use of novel medicinal products in pediatric practice.

COCLUSIONS

Thus, pediatric pharmacotherapy comes across an entire set of objective limitations that significantly narrow the therapeutic arsenal of a physician. The gap in evidence base seen among pediatric patients is the key factor that forms the basis of the issue. The gap is due to a number of challenges faced by pharmaceutical companies during organization of clinical trials. The challenges include an exceptional complexity of methodological planning, required ethical regulations and extremely high cost of such a research. As a result, the doctor is often forced to extrapolate the data obtained in the adult population, which inevitably involves an increased share of risk and professional responsibility.

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LEGAL, CLINICAL, AND ETHICAL ISSUES IN BIOEQUIVALENCE RESEARCH

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Real-life clinical practice requires to confirm bioequivalence of medicinal products in everyday settings resulting in adequately assessed effectiveness and tolerability of drugs in diverse patient groups. When the studies are lacking, it cannot be warranted that therapeutic effects or safety profiles of the reproduced drug will be identical to those of original brand medicines, which may decrease the trust of doctors and patients in generics and, as a consequence, limit treatment affordability. Assessment of bioequivalence (or pharmacokinetic equivalence) of medicinal products (drugs) is currently considered one of the main types of biomedical quality control of reproduced (generic) medicines. The Russian pharmaceutical market is heavily dominated by generic drugs, which significantly outnumber original products. Thus, bioequivalence studies are of a huge economic and clinical value.

Keywords: bioequivalence studies, ethical aspects, legal issues

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ПРАВОВЫЕ, КЛИНИЧЕСКИЕ И ЭТИЧЕСКИЕ ВОПРОСЫ ИССЛЕДОВАНИЙ БИОЭКВИВАЛЕНТНОСТИ

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Реальная клиническая практика требует подтверждения биоэквивалентности препаратов в условиях, максимально приближенных к повседневному использованию, что позволяет адекватно оценить эффективность и переносимость лекарств в разнообразных группах пациентов. Без таких исследований нельзя гарантировать, что воспроизведенный препарат будет иметь равные терапевтические эффекты и безопасность, что может привести к снижению доверия врачей и пациентов к дженерикам и, как следствие, ограничению доступности лечения. Оценка биоэквивалентности (или фармакокинетической эквивалентности) лекарственных средств (ЛС) в настоящее время считается одним из основных видов медико-биологического контроля качества воспроизведенных (генерических) лекарственных препаратов. Среди препаратов, которые ежегодно регистрируются в России, отмечается значительно большее количество дженериков, чем оригинальных препаратов. В связи с этим исследования биоэквивалентности имеют большое экономическое и клиническое значение.

Ключевые слова: исследования биоэквивалентности, этические аспекты, правовые вопросы

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Now, when Russian generic pharmaceutical markets are expanding and regulatory requirements are getting stricter, bioequivalence (BE) studies become crucial at the stage where original and generic drugs are compared based on their pharmacokinetics ad safety profile. This is how risks for patients are minimized, therapy is optimized and an uninterrupted access to highly effective drugs to treat cardiovascular, oncological and other chronic diseases is provided. It increases the economic affordability for the healthcare system [1].

It is essential to develop national Russian programs targeted at the technological sovereignty in pharmaceutics where BE studies serve as the foundation for development of own medicinal products that correspond to the international standards. Meanwhile, modern international requirements and methods are integrated making data obtained for regulatory bodies and clinical practice reliable and pressing [2, 3].

In Russia, BE studies have seen significant growth during the last years. The record was reached in 2023 with 473–576 approvals contributing to 75.7–76.1% of all clinical trials (CT). In 2024, a decline was observed when the Ministry of Health issued 446–429 approvals for BE trials contributing to 67–71.5% of the total number of CT (628–600). This drop by 17–25% from 2023 is driven by the saturation of the market with generic medicines and tighter regulatory scrutiny (Table) [4–6].

The data show that BE studies for generic drugs currently dominate Russian clinical trials in spite of the massive

Table. Comparison of BE studies by year (according to the data of the Ministry of Health of Russia and Association of Clinical Research Organizations, 2021–2024) [4]

Year	Total CT	BE trials	BE rate (%)
2021	~908	218–369	41
2022	~740	367	~50
2023	761	473–576	75.7–76.1
2024	600–629	429–446	67–71.5

reduction in the market following the departure of foreign companies.

BE and pharmacokinetics studies have been conducted at the Department of Clinical Pharmacology of Yaroslavl State Medical University of the Ministry of Health of the Russian Federation based on Clinical Hospital No. 2 in accordance with article 21 of the Constitution of the Russian Federation and Federal Law No. 1-FZ On Circulation of Medicines as of 12 April 2010 (revision as of 23.07.2025) since 2011. The works are conducted in line with the national standard of the Russian Federation GOST R 52379–2005 Good Clinical Practice. It sets the international ethical and scientific standard for designing, conducting, monitoring, documenting and presenting the results of CT involving humans [7, 8].

The standard has come into force since 1 April 2006 based on the Law of the Federal Agency on Technical Regulation and Metrology as of 27 September 2005 No. 232-ст and remains unchanged in 2026. The research activity is also based on the ethical principles of Declaration of Helsinki of the World Medical Association and takes into account additional regulatory requirements and methodical recommendations of the Ministry of Health of Russia that show modern requirements to BE clinical trials. It makes the results reliable and reproducible both in the national, and global pharmaceutical industry [9].

In Russia, the regulatory documents that establish the rules of BE studies have been in effect since 2025.

1. Order No. 157n of the Ministry of Health of the Russian Federation dated 31 March 2025, which amends the rules for the examination of medicines, including bioequivalent drugs (it establishes requirements for the composition and documentation, the procedure for conducting examinations and issuing bioequivalence conclusions) [10].
2. Methodological guidelines of the Ministry of Health of the Russian Federation for conducting qualitative and quantitative studies of bioequivalence of medicinal products for human use dated 08/10/2004 (valid in 2026), (it regulates methods for assessing pharmacokinetic parameters, selecting a group of volunteers, monitoring the condition of participants and statistical analysis of the results) [11].
3. Decision of the Council of the Eurasian Economic Commission (EEC) dated November 3, 2016 No. 79 On Approval of the Rules of Good Clinical Practice of the Eurasian Economic Union (EEU), https://docs.cntd.ru/document/456026110 [12].
4. Eurasian Economic Commission (EEC) Decision No. 85 dated November 3, 2016 On Approval of the Rules for Conducting Bioequivalence Studies of Medicinal Products within the Eurasian Economic Union (updated in 2026), containing rules for the development of research design, requirements for methods of selection and formation of groups, data blinding and grounds for replacing *in vivo* studies with *in vitro* studies [13].
5. Also, in order to compare the effectiveness and safety of drugs, minimize the variability of factors and harmonize with international GCP standards, the standard of the Russian Federation GOST R 57679–2017 Medicines for Medical Use. Bioequivalence Studies of Medicinal Products (approved by Rosstandart Order No. 1165 dated 19.09.2017) is used [14].

These documents provide a comprehensive regulatory framework that covers all stages of BE research from planning to examination and confirmation of compliance of medicines with established standards.

In 2024–2025, the following key changes were made to the Russian legislation regulating the BE study [15].

1. On September 1, 2025, new Rules for the Examination of Medicines, including BE studies, entered into force. They update the requirements for documentation procedures, research and expert opinion. These changes are aimed at increasing transparency and standardization of examination processes, taking into account modern international practices.
2. In 2024, the Methodological Guidelines of the Ministry of Health of the Russian Federation were updated. They regulated the procedure for planning and performing BE studies, including strict criteria for selecting research subjects and conducting control pharmacokinetic measurements.
3. Regulation regarding the ethical review of bioequivalence research has been strengthened, review of protocols in specialized ethics committees became mandatory considering the latest requirements of the Helsinki Declaration and international GCP standards.
4. Adjustments have been made to combine *in vitro* studies with pharmacokinetic data in some cases to confirm bioequivalence, which accelerates research processes and reduces the burden on volunteers.
5. The rules of interaction with the EEC have been improved, providing for the harmonization of requirements and mutual recognition of research results between the EEU countries.

All these updates show that Russian legislation is brought into compliance with international standards, improves the quality and safety of BE research and strengthens control over it while the domestic pharmaceutical industry is developed.

When conducting bioequivalence and pharmacokinetic studies, certain difficulties arose both at the stage of the clinical part and in subsequent phases. The problems of bioequivalence research include difficulties in assessing

bioavailability for certain dosage forms (for example, for dermatological products where skin penetration assessment is required), potential discomfort for study participants (blood collection, hospital monitoring), as well as possible misperception of differences between original drugs and generic medicines. Using non-specific methods for evaluating effectiveness and safety of drugs, as well as difficulties in providing standardized research conditions can serve as an example [16].

In this paper, we focus on the clinical issues of bioequivalence research. The ethical difficulties reported in practice of our clinical center over the past decade are also important. The issue of a unified volunteer database is still pressing for managing numerous clinical research centers across Yaroslavl and neighboring regions. Our clinical practice maintains its own database designed to track the last participation dates of volunteers, which allows us to control the minimum intervals between their participation. The lack of the centralized registration system, however, makes it difficult for volunteers to comply with the intervals when they change centers. The lack of centralized control leads to the possible participation of the same volunteers in several centers without observing minimum intervals, which threatens their health. Commercialization of clinical trials turns healthy people into "professional volunteers" who ignore long-term bodily effects. A unified database of volunteers for the Yaroslavl Region and surrounding regions could solve the problem.

Violation of data confidentiality or invasion of privacy during monitoring is another problem that is the reason for a psychological and social trauma among subjects [17, 18].

Violation of data confidentiality in bioequivalence research involves the unauthorized disclosure of volunteers' personal and medical information to third parties. This raises serious ethical concerns, as such data often contains sensitive information that can affect a person's reputation or social status [19].

Invasion of privacy in research occurs when monitoring methods become extremely aggressive or exceed necessary boundaries of medical supervision, involving overly intimate surveillance of participants. For example, constant monitoring or collection of excessive data without transparent information violates the subject's rights to personal space and autonomy [20].

Psychological trauma from personal data misuse or fear of disclosure triggers significant anxiety, stress, and feelings of vulnerability. Social trauma stemming from health-related stigma involves the fear or experience of condemnation and discrimination if personal health information or participation in clinical trials is revealed.

Thus, protecting confidentiality and respecting the privacy of volunteers are key elements of ethical research used to avoid negative consequences for participants and maintain trust in the research process.

The experience of our clinical center shows that ethical challenges seen while working with volunteers are inevitably combined with a whole range of methodological difficulties that arise during research planning and conducting. Therefore, along with ethical aspects, it is important to analyze methodological problems that affect accuracy of bioequivalence assessment and reproducibility of results [21].

Many daily challenges that formerly dominated clinical research are currently practically not recorded or minimized. This is due to a significant improvement in the quality of preparation of pharmacokinetic and bioequivalence research protocols, which are now being developed with more accuracy and at a high professional level. In addition, monitoring in clinical research by research organizations and sponsors has become more thorough and systematic, which ensures strict adherence to established standards. Regularly conducted, specialized staff training on interacting with volunteers improves team competence. The staff of the research center face almost no difficulties in monitoring volunteers, and subjects are always hospitalized before dosing to minimize risks and ensure data accuracy [22].

However, despite the successes achieved, difficulties in post-discharge study protocol compliance still arise in clinical practice from time to time. Informed consent often fails to ensure strict participant adherence to established requirements such as restrictions on driving, smoking, and behavioral norms while on medications affecting reaction, attention, and cognitive functions. These disorders can significantly distort the pharmacokinetic data and undermine the reliability of the study results. To solve this problem effectively, it is advisable to increase the length of stay of volunteers at hospitals until the investigational drug is completely eliminated from the blood, which will ensure full compliance control and minimize external factors of influence. However, there remains a dilemma that prolonged hospitalization of volunteers, when participants regularly undergo numerous procedures, including multiple blood draws, can become a source of physical discomfort, stress, and psychological stress, as well as restrict freedom and make daily lives of volunteers inconvenient. In addition, the specific requirements for diet, physical activity, and lifestyle during hospitalization add additional restrictions, which can also affect the motivation and morale of participants. All these factors must be taken into account when planning and conducting research to minimize the negative impact on volunteers and obtain high-quality data [21, 23].

There are some other problems in the clinical part of BE research that can be noted. They include genetic and physiological factors (polymorphism of CYP3A4 enzymes, influence of gender, age, ethnicity), volunteers or patients as subjects of BE research (BE is usually proven in healthy people, but pharmacokinetics may vary in patients).

CONCLUSION

Bioequivalence studies are still critical for ensuring that Russian-manufactured generic drugs are safe and effective, supporting technological sovereignty of Russia in the pharmaceutical sector, minimizing risks for patients and increasing the availability of therapy for chronic diseases. Despite advancements in regulatory harmonization and methodology, significant hurdles to clinical practice still persist including genetic polymorphism, the choice of healthy volunteers or patients with altered pharmacokinetics, as well as ethical dilemmas.

Future development focuses on integration of pharmacogenetics to create personalized protocols, a combination of *in vivo/in vitro* methods, and digitalization of volunteer records, which will enhance drug reproducibility and safety. Taking into account ethical issues, we are still continuing our BE studies at the Department of Yaroslavl State Medical University of the Ministry of Health of the Russian Federation based on Clinical Hospital No. 2 and are trying to contribute to real clinical practice under realistic, everyday conditions.

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GUT MICROBIOTA BIOBANKING IN A COLOPROCTOLOGICAL HOSPITAL: ETHICAL AND LEGAL CONFLICTS AND REGULATORY PERSPECTIVES

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Biobanking of patient-isolated microbial strains is a critically important tool for modern biomedical research, though it is associated with a complex of unresolved ethical and legal issues. The goal of this paper is to analyze the issues based on biobanking case studies at the National Medical Research Center of Coloproctology named after Ryzhykh AN. The focus is on the contradictions between the need for scientific progress and respect for the rights of donors, including obtaining informed consent and ensuring data confidentiality. The study material included legal documents and internal regulations describing how to work with microbial collections. During the analysis, isolated Russian legislation, lack of a clear legal status for biological samples and dependence of ethical aspects of work on local protocols and internal policy of the institution have been found out. The key conclusion is the urgent need to develop a specialized regulatory system that harmonizes the principles of bioethics with the practical tasks of biobanking, establishing clear rules for handling a patient's microbiota and consent management mechanisms.

Keywords: biobanking, microbial strains, bioethics, informed consent, legal regulation, microbiome, personal data

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БИОБАНКИРОВАНИЕ КИШЕЧНОЙ МИКРОБИОТЫ: ЭТИКО-ПРАВОВЫЕ КОЛЛИЗИИ И РЕГУЛЯТОРНЫЕ ПЕРСПЕКТИВЫ НА ПРИМЕРЕ КОЛОПРОКТОЛОГИЧЕСКОГО СТАЦИОНАРА

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Биобанкирование штаммов микроорганизмов, изолированных от пациентов, является критически важным инструментом для современных биомедицинских исследований, однако сопряжено с комплексом не до конца решенных этико-правовых проблем. Целью данной работы является анализ этих проблем на примере практики биобанкирования в ФГБУ «НМИЦ колопроктологии имени А. Н. Рыжих». Основное внимание уделяется противоречиям между необходимостью научного прогресса и соблюдением прав доноров, включая получение информированного согласия и обеспечение конфиденциальности данных. Материалом исследования послужили правовые документы и внутренние регламенты, регулирующие работу с микробными коллекциями. В результате анализа выявлена фрагментарность российского законодательства, отсутствие четкого правового статуса биологических образцов и, как следствие, зависимость этических аспектов работы от локальных протоколов и внутренней политики учреждения. Ключевым выводом является настоятельная необходимость развития специализированной нормативно-правовой базы, которая гармонизирует принципы биоэтики с практическими задачами биобанкинга, устанавливая ясные правила обращения с микробиотой пациента и механизмы управления согласием.

Ключевые слова: биобанкирование, микробные штаммы, биоэтика, информированное согласие, правовое регулирование, микробиом, персональные данные

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Biobanking of human biological samples is crucial to personalized medicine and biomedical research [1]. However, the rapid technological advancement has exposed specific and insufficiently regulated ethical and legal aspects of formation and use of patient-isolated microbial biobanks. Despite the regulatory standards for human tissues and DNA, the status of microbial strains remains legally uncertain. Their dual nature (they function as integral components of the human microbiome, yet exist as independent, culturable, and reproducible biological entities) generates a number of difficulties. The difficulties include choosing an adequate informed consent model for the potentially indefinite use of samples, rights to commercial products developed on their basis, and regulation of rights to the samples. Kaprin AD et al. [2], note general legal gaps in Russian biobanking, while foreign researchers such as Kinkorova J [3] focus on regulatory challenges in the era of personalized medicine. Foreign practice suggests that the most promising solution is to develop multi-level consent models that respect the donor's autonomy. The purpose of this study is a comprehensive analysis of ethical and legal conflicts that arise during biobanking of patient strains of microorganisms. Using the practical cases of Ryzhykh AN National Research Medical Center for Coloproctology, the authors aim to formulate the principles for the development of internal regulations and recommendations for improvement of national regulation in this area.

Biobanking of microbial strains: scientific and clinical significance

Patient-isolated collections of authentic strains of microorganisms form a critical infrastructure of modern biomedicine. They go far beyond archiving, having a direct impact on scientific progress and clinical practice. In gut microbiome research, which is the key to coloproctology, such biobanks serve as a tool for shifting beyond just metagenomic correlations to establishing causal relationships. Access to pure cultures makes it possible to experimentally verify the role of specific bacterial taxa in the pathogenesis of colorectal cancer and inflammatory bowel diseases [4]. In the therapeutic aspect, these collections are the foundation for the development of innovative approaches from the creation of personalized probiotics and bacteriophages to the standardization of fecal microbiota transplantation [5]. In addition, the systematic accumulation of strains with clinical and epidemiological metadata creates the basis for global monitoring of antimicrobial resistance (AMR), allowing tracking the evolution of resistant clones [6]. However, the specifics of working with microbial strains create a unique ethical and legal paradox. After isolation and cultivation, the microorganism loses its direct physical connection with the donor's body, acquiring the properties of an independent biological object, which may be an object of intellectual property (for example, a patentable producing strain). It seems that it removes them from the scope of full bodily autonomy principles. But the paradox is that the scientific and clinical value of the strain is inextricably linked to the confidential data of the donor (diagnosis, treatment history, outcome). Thus, an object (thing) that is legally separable from a person retains a deeply personalized informational entity [7]. This conflict, according to which an object is separable from the body, but inseparable from personal data, constitutes the main problem that requires development of special regulatory approaches.

Ethical aspects of biobanking microbial strains

The ethics of biobanking microbial strains hinges upon solution of certain interrelated problems. The key problem is obtaining informed consent in the face of uncertainty of future research. The classical model is unacceptable here. Thus, modern practice offers to choose between the pragmatic but wide consent to the general research and a more flexible multi-tiered or dynamic consent that makes it possible for the donor to occasionally select acceptable types of research. It complies to the principle of respect for autonomy to a greater extent. Meanwhile the donor should be informed of continuous storage, possible commercialization and right to withdraw consent irrespective the selected model [8].

The issue of confidentiality is closely related to the issue of consent, as complete anonymization, where samples are totally unlinked from clinical data, is often impossible, and deprives the strain of its scientific value. Thus, pseudonymization is used that strictly limits access to data that connects the sample with the personality, requiring strict protection measures due to re-identification. The issue of ownership of the biomaterial remains unresolved in the Russian legal field: the isolated strain is not considered a "part of the body", and the right of disposal is usually assigned to the biobank institution, which creates a zone of legal uncertainty for the donor. The ethics of recycling samples for purposes not originally specified requires special attention. International standards allow such use with the approval of the ethics committee and appropriate anonymization, and a step-by-step approach is proposed: the more sensitive a new study is, the stricter the requirements for depersonalization of data should be.

Legal regulation of biobanking in the Russian Federation

The legal regulation of biobanking in the Russian Federation currently represents a multi-level and actively developing system of regulatory legal acts, which, in relation to the collection, storage and use of strains of microorganisms isolated from patients, can be divided into legislative acts, subordinate regulatory documents and national standards. The foundation of technical and terminological regulation in this area consists of national standards harmonized with international approaches. The key standard is represented by GOST R ISO 20387-2021 "Biotechnology. Biobanking. General requirements", which establishes general requirements for the competence, impartiality and consistency of the functioning of biobanks, including the processes of acquisition, identification, processing, storage and transfer of biological material and related data for research. GOST R 71251-2024 "Biotechnology. Biobanking. Terms and definitions", which establishes basic concepts such as "biobank", "biological material", "biological sample", and introduces a classification of biobanks, which allows for the unification of documentation, including the informed consent form and internal regulations for working with samples was used to ensure the uniformity of the conceptual framework.

The activities directly related to microorganisms are additionally regulated by the specialized standard GOST R ISO 24088-1-2024, which establishes requirements for the collection, processing, storage and transportation of bacteria and archaea. Practical implementation of these requirements for a medical institution is based on GOST R 59781-2021, which serves as a guide for the implementation of ISO 20387 requirements. A landmark in legal regulation was adoption of Federal Law No. 428-FZ dated November 30, 2024 "On Bioresource Centers and Biological (Bioresource) Collections". However, in the context of this study, it is important to note that according to part 2 of Article 1 of this law, its provisions do not apply to collections of pathogenic microorganisms and viruses, as well as to collections of human biological materials, which creates a legal vacuum regarding strains isolated from patients and underlines the need to develop special regulations for clinical collections. The turnover of pathogenic biological agents is regulated more strictly by Decree of the Government of the Russian Federation No. 1668 dated 30.09.2021, which approved the Rules for the Creation, Replenishment, Maintenance and Use of Collections of pathogenic microorganisms and viruses, as well as the maintenance of a national catalog of strains, and additional procedural aspects are disclosed in the Methodological Recommendations "Procedure for maintaining collections of pathogenic microorganisms", which establish requirements for accounting, storage and issue of strains.

Since working with microbial strains involves potential biological risks, the biobank's activities must strictly comply with sanitary rules. The fundamental document here is SanPiN 3.3686-21 "Sanitary and epidemiological requirements for the prevention of infectious diseases", which combined the requirements for the prevention of infectious diseases, including rules for working with pathogenic biological agents, requirements for biological safety and protection, as well as organization of premises, sterilization regime, waste disinfection and personal hygiene measures

for personnel. Other problems are related to the legal regime of information about donors, since strains of microorganisms stored in biobanks are frequently linked to clinical data, which may be subject to medical secrecy and personal data regulated by Federal Law No. 152-FZ "On Personal Data". In the context of strain biobanking, the problem of sample de-identification becomes particularly acute for research purposes while maintaining the possibility of their verification for clinical needs. The analysis shows that the legal framework of biobanking in the Russian Federation is fragmented: though the technical aspects of the activity are sufficiently regulated by national standards, the legal status of clinical collections of microorganisms, as well as the relationship between the rights of donors and the interests of researchers remain unresolved at the legislative level.

DISCUSSION OF RESULTS

The analysis helps identify a key ethical and legal contradiction attributable to biobanking of microbial strains: their dual nature, acting simultaneously as a patentable biological object and information carrier, the scientific value of which critically depends on the donor's personal data. While international research primarily focuses on human tissue biobanks, this paper focuses on the legal uncertainty that arises when patenting strains and commercializing developments based on the strains. The revealed fragmentation of Russian legislation, combined with the leading role of local ethical protocols, confirms the need to shift from the lack of a single law to the hierarchical model of management.

The solution is represented by a two-tier system that includes a framework federal law setting general principles and detailed local acts of biobanks, as it provides for the necessary flexibility in the context of the dynamic development of scientific knowledge and technological capabilities. The evolution from broad consent to multilevel models in informed consent is justified, which is a logical and necessary stage preceding the full-fledged introduction of digital platforms for dynamic consent in Russian clinical settings; this gradualness is due to both socio-cultural factors and the need to adapt the existing models of interaction with the patient to the specifics of microbial collections. The interdisciplinary approach to the development of biobank's internal policies, combining legal, ethical and scientific expertise, makes it possible to balance potential risks and integrate Russian experience in working with microbial collections into the global discussion devoted to biobanking standards, offering practical solutions that take into account both national regulatory specifics and universal ones.

CONCLUSIONS

The conducted research shows that biobanking of microbial strains isolated from patients operates under a specific ethical and legal dualism. On the one hand, the samples are independent, reproducible biological objects potentially suitable for patenting. On the other hand, their scientific and clinical value inextricably depends on confidential personal data of the donor, which creates legal uncertainty and ethical challenges that are fundamentally different from those found when working with human tissues.

The aim of the study is a comprehensive analysis of ethical and legal conflicts that arise during biobanking of microbial strains, and it can be said that principles for their regulation have been formulated. The analysis revealed that the current Russian legislation forms only a basic and insufficient framework for regulating this activity: the key gaps include the lack of a legal status for microbial strains and clear procedures for obtaining informed consent for their future uncertain research use. The area requires a specialized regulatory framework as a matter of priority, however, before the relevant federal law is adopted, it is advisable to introduce standardized local protocols at the institutional level based on the principles of responsible sample management, multilevel informed consent and transparent data management as an initial step. The results obtained can be used to develop model regulations on microbial biobanks in clinical and scientific institutions, as well as to create educational modules on bioethics for researchers and doctors working with microbial collections. Hypotheses for further study are formulated using the analysis: first, introduction of digital platforms for dynamic consent in Russian clinical practice can significantly increase the level of involvement and trust of donors in biobanking; second, a centralized national catalog of anonymized metadata of biobanks of microbial strains will increase the effectiveness of scientific collaboration and attract international investment in appropriate research in the Russian Federation.

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