REVIEW ARTICLE

CONTENTS

Ethical and legal principles of biomedical research

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ABSTRACT

Aim: To analyze the regulatory and legal foundations of biomedical research by examining key ethical principles, including respect for individual autonomy, human dignity, voluntary informed consent, and benefit, with a particular focus on their implementation in both global and Northern European contexts, while identifying challenges to their practical application in modern healthcare systems.

Materials and Methods: This research employed a comprehensive analytical approach utilizing comparative legal analysis and systematic review of international and national regulatory frameworks governing biomedical research. The methodology included examination of constitutional provisions, specialized legislation, and bioethical guidelines from European jurisdictions, with particular attention to Northern European regulatory models established since the late 1980s. The study incorporated analysis of scholarly literature addressing theoretical foundations and practical implementation of key bioethical principles, focusing on works by established authorities in the field such as J. Hans, O. Pasternak, and S. Shevchuk.

Conclusions: Ethical regulation of biomedical research requires strict adherence to the fundamental principles of respect for autonomy, human dignity, voluntary informed consent, and benefit, which collectively provide a comprehensive framework for protecting research participants while enabling scientific progress.

KEY WORDS: biomedical research, human rights, informed consent, personal autonomy, ethical principles, bioethics, human dignity, informed consent

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INTRODUCTION

The rapid development of biomedical technologies and research in the 21st century is accompanied by the emergence of unprecedented legal, ethical and social challenges that require an adequate response from the legislation. Revolutionary achievements in the field of genetic engineering, cell technologies, bioinformatics, personalized medicine and biobanking open up prospects for significant progress in the treatment and prevention of diseases, but at the same time give rise to complex legal issues regarding patients' rights, data confidentiality, intellectual property and bioethics. Insufficient certainty of the regulatory framework or its inconsistency with modern realities can restrain the innovative potential of biomedical research, jeopardize the rights of participants in experiments and create obstacles to international scientific cooperation.

The implementation of legal norms in the field of biomedical research is characterized by a set of problems, including: inconsistency of national legislation with international standards; variability of interpretation of bioethical principles in different jurisdictions; lagging behind legal regulation from the pace of technological progress; the difficulty of balancing the interests of scientific progress and the protection of fundamental human rights. The problem of implementing adequate mechanisms for monitoring and supervising compliance with ethical and legal norms in biomedical research is of particular relevance. The development of effective models for implementing legal norms is a necessary prerequisite for minimizing the risks of abuse and unethical practices in this area.

Transformational processes in the global health system and medical science, intensified by the COVID-19 pandemic, have revealed a critical need to rethink existing legal approaches to regulating biomedical research. The acceleration of the pace of development of vaccines and diagnostic methods, increased attention to clinical trials in emergency situations, as well as the intensification of international exchange of biomedical data have exacerbated the issues of adequacy and effectiveness of existing legal mechanisms. The study of contemporary problems of implementing legal norms in the field of biomedical research has not only theoretical, but also significant practical significance for the formation of a balanced regulatory policy that will simultaneously promote scientific progress and ensure proper protection of human rights and dignity.

AIM

The aim of this study is to analyze the regulatory and legal foundations of biomedical research by examining key ethical principles, including respect for individual autonomy, human dignity, voluntary informed consent, and benefit, with a particular focus on their implementation in both global and Northern European contexts, while identifying challenges to their practical application in modern healthcare systems.

MATERIALS AND METHODS

This research employed a comprehensive analytical approach utilizing comparative legal analysis and systematic review of international and national regulatory frameworks governing biomedical research. The methodology included examination of constitutional provisions, specialized legislation, and bioethical guidelines from European jurisdictions, with particular attention to Northern European regulatory models established since the late 1980s. The study incorporated analysis of scholarly literature addressing theoretical foundations and practical implementation of key bioethical principles, focusing on works by established authorities in the field such as J. Hans, O. Pasternak, and S. Shevchuk. Primary sources included constitutional texts, decisions of constitutional courts, and international legal instruments that establish normative frameworks for biomedical research involving human subjects.

REVIEW AND DISCUSSION

The tradition of cooperation between the countries of Northern Europe in the field of regulation of biomedical technologies dates back to the late 1980s. In 1989, the Nordic Committee on Bioethics was founded, one of the tasks of which was to monitor legislative developments in the field of biomedical technologies both worldwide and in the countries of Northern Europe in particular, as technologies, research and services in the field under consideration are developing very rapidly and cross national borders [1].

The regulatory and legal framework of biomedical research is based on a number of key practical principles. Let us consider one of the most important among them: the principle of respect for the autonomy of the individual; the principle of respect for human dignity; the principle of voluntary informed consent; the principle of benefit in biomedical research.

The principle of respect for the autonomy of the individual is the fundamental basis of modern approaches to biomedical research. According to J. Hans, this principle symbolizes a significant transformation of the status of patients and research participants in the modern biomedical field. The basis of this principle is the recognition of the ability of a person to autonomous thinking and independent decision-making regarding their participation in research and awareness of their possible results. A crucial element of the implementation of this principle is the formation of such conditions that guarantee the research participant protection from all types of psychological influence or manipulative techniques, including hidden ones. In particular, the formation of artificial interest or the use of other methods of indirect influence on the expression of a person's will is considered unacceptable. Guaranteeing true freedom of choice acts not only as an ethical standard, but also as a prerequisite for the legitimacy and reliability of biomedical experiments conducted with human participation [2-16].

O. Pasternak notes that the autonomy of the individual is considered the moral basis of medicine and implies the need to avoid harm that a doctor can cause to a patient, and the principle itself is based on the recognition of a person as an unconditional value and provides for the free choice of an individual regarding his life and health (choice of a medical institution, doctor, consent or refusal of treatment, etc.), except in cases where this choice may pose a threat to other persons [17]. For bioethics, it is important that an autonomous individual has the right to decide whether other people can do something with his body, when a person can exercise this right by refusing treatment that, in the opinion of the doctor, will bring benefit [18].

The traditionally paternalistic approach in domestic medical practice was based on the assumption that the exclusive right to make decisions belonged to medical professionals, while the patient's position was considered insufficiently qualified and often ignored. This pattern continues to exist in the Ukrainian healthcare system, where there is some resistance to the active integration of patients into decision-making processes regarding their therapy or involvement in medical experiments.

However, it is necessary to understand that such approaches, which ignore the principle of personal autonomy, not only raise ethical concerns, but also pose a potential threat to the basic interests of the patient or research participant. When we put a person in a dependent position, we not only disregard their moral rights, but also create conditions under which their life priorities can be neglected or distortedly interpreted.

However, it is worth recognizing that such methods, which reject the principle of individual autonomy, are

not only ethically problematic, but also carry potential risks for the fundamental interests of the patient or research participant. By placing the individual in a subordinate position, we not only violate his moral rights, but also create the prerequisites under which his key vital interests may be ignored or inadequately treated [3].

The principle of respect for human dignity is the cornerstone of the ethical system that regulates public relations. This complex concept covers various moral and ethical aspects of interpersonal relations in society. It finds its expression through several basic behavioral patterns: expression of benevolence in communication and actions; showing respect for the diversity of thoughts and actions of others; following the norms of correct interaction; the development of politeness as a fundamental form of public communication.

The category of «human dignity» is an integral and important element of building a social state based on respect for human rights, guaranteeing their protection and defense. In a way, it is the quintessence of all other legal values, their reference point and direction. The principle of ensuring respect for human dignity is embodied in almost all world standards of human rights, acts as a determining criterion for the effectiveness of social policy, its reference point. Modern world legal doctrine considers human rights and freedoms as a higher legal value, and their provision is the primary duty of the state. This was a consequence of the recognition of human dignity as the determining basis of human rights and freedoms. The state is obliged to enshrine human rights and freedoms in the form of legal norms in constitutions or laws, in the legislative order to determine the mechanism for ensuring and implementing these rights and freedoms, as well as guaranteeing their protection in accordance with the procedure established by law [14].

This principle is a key guideline for creating a prosperous society in which each person receives recognition and respect regardless of their position or views. In the medical field in a broad sense, and especially in the field of biomedical research involving people, the principle of respect for human dignity acquires exceptional importance. It forms the essence of the relationship between a medical worker (or researcher) and a patient (or research participant), preserving all the above characteristics. It should be noted that following this principle is not only recommended, but absolutely mandatory: without its observance, it is impossible to conduct ethically permissible biomedical research, as well as to create an effective health care system in general [6].

However, despite the undisputed importance of this principle, its implementation in modern society often encounters significant obstacles. Particularly alarming is the tendency to reify the human body, when it or its components are perceived as a commodity or a material object. Vivid illustrations of this are the debates about the commercialization of organ and tissue donation, as well as the issue of prostitution. Such phenomena contribute to the emergence of a dangerous shift in collective consciousness, in which the human body begins to be perceived on an equal footing with other objects of the material world, which runs counter to the fundamental principle of respect for human dignity [5].

When conducting biomedical research involving humans, it is extremely important to understand that it is not only biological material that is being studied, but also a whole human being with his or her life and health. This concept is affirmed as the highest value in the Constitution of Ukraine and fundamental international legal documents. The principle of respect for human dignity requires a special, respectful attitude towards the individual and his or her physical integrity. It is important to note the universality of this principle: human dignity is an integral characteristic of every person, regardless of his or her individual traits or social status. Such universality implies that respect for human dignity cannot be made dependent or limited by factors such as ethnicity, skin colour, religion, socio-economic status, health status or any other external features. Therefore, within the framework of biomedical research, this principle guarantees a fair and ethical approach to all participants, regardless of their individual characteristics [6].

Note that instead of definitions of the concept of «human dignity» in European constitutions and practice of constitutional courts, there are general and abstract characteristics of individual aspects of the concept of human dignity. In European constitutions, dignity is characterized as inviolable, inalienable, supreme, the source of human rights and freedoms, the foundation of political order and social peace [15]. S. Shevchuk rightly emphasizes that human dignity plays a decisive role in the system of constitutional values. Being the core of every constitutional right, it forms the idea of a person as a unique self-determined being who is not under the power of the state. The right to respect for human dignity corresponds to the recognition of a person as «the highest social value, which makes it impossible to interpret a person instrumentally, only as an object of state will» [16].

The principle of benefit in biomedical research is a comprehensive concept that encompasses potential

benefits for both direct research participants and society at large. A central aspect of this principle is a careful analysis of the balance between possible risks and expected benefits from the research. Assessing the acceptability of such a balance requires a comprehensive approach that includes: a comprehensive analysis of all aspects of the research; a systematic consideration of alternative methods and approaches; and a detailed study of all available information related to the research. It is fundamentally important that when assessing potential harm, account is taken not only of the obvious physical and psychological risks to participants, but also of all possible forms of negative impact. This may include social, economic, legal and other aspects that may affect the well-being of research participants or society at large. The principle of benefit thus requires a multifactorial analysis and a balanced approach to assessing the ethical acceptability of biomedical research [5].

The principle of voluntary informed consent is the fundamental basis of modern bioethics and medical practice. This principle not only serves as a protection against "medical dictate" and guarantees personal freedom, but also helps the research participant to make an informed decision with a full understanding of the possible consequences of medical intervention or its absence. The concept of informed consent is a relatively new phenomenon in medical ethics. In the past, many doctors adhered to a paternalistic model, considering it advisable to hide from patients comprehensive information about their health status and treatment features. This practice was based on the belief that such information could harm the patient or complicate the therapeutic process. However, modern medical science and healthcare practice recognize the principle of informed consent as fundamental. It has become one of the defining criteria for respecting the rights of both research participants and patients in general. This reflects a significant transformation in medical ethics from paternalism to a model that emphasizes patient autonomy and their right to comprehensive information and active participation in decisions about their own health and treatment [9].

In the context of biomedical research, the principle of informed consent requires that a potential participant be provided with comprehensive information to make an informed decision about their participation. Such information should include a detailed description of the purpose, objectives, and methods of the study, a clear explanation of the possible risks and expected benefits, an outline of alternative options (especially in therapeutic trials), and an explanation of the participant's right to ask questions and to withdraw from the study at any stage. The information should be provided in a standardized, understandable format and be as complete as possible. Exceptions that allow for partial disclosure of information are only possible when necessary to achieve the research purpose, provided that the undisclosed risks are minimal and that the participants are guaranteed to be fully informed afterwards. Such exceptions should be applied with particular care so as not to violate ethical standards and the rights of the research participants [9].

CONCLUSIONS

The analysis of the regulatory and legal foundations of biomedical research indicates the formation of a comprehensive system of ethical principles that ensure the protection of participants and the legitimacy of research activities. The fundamental principles among them are the principles of respect for the autonomy of the person, respect for human dignity, voluntary informed consent and benefit. These principles reflect the transformation of medical ethics from a paternalistic model to an approach that recognizes the right of a person to independently make decisions regarding their own health and participate in research.

The principle of respect for human dignity acquires special importance in the context of biomedical research, since it is the cornerstone of the entire system of legal values and serves as a determining criterion for assessing the ethical acceptability of research procedures. The universality of this principle guarantees a fair approach to all participants regardless of their individual characteristics, social status or other external characteristics. However, the objectification of the human body remains a worrying trend, which contradicts the principle of respect for human dignity and requires special attention from regulatory authorities.

The principles of beneficence and voluntary informed consent complement the ethical framework of biomedical research, ensuring a balance between scientific progress and the protection of the rights of participants. They require a comprehensive analysis of the balance of risks and benefits, as well as providing participants with comprehensive information to make informed decisions. The Nordic experience in regulating biomedical technologies demonstrates the importance of international cooperation and harmonization of legislation in this area, especially given the rapid development of technologies that cross national borders.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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