

BIOMEDICAL ISSUES NECESSITATING LEGAL REGULATION OF GENETICS

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Abstract. The article explores the various biomedical issues surrounding genetics that necessitate legal regulation. Genetics is a rapidly advancing field that holds immense potential for revolutionizing healthcare and improving human life. However, with these advancements come ethical and legal concerns that need to be addressed to ensure the responsible and equitable use of genetic technologies.

The article analyzes several medical and genetic technologies that are extensively used in modern medicine. Genealogical analysis, genetic testing, genome editing, screening, genetic therapy, cloning and genetic passports are still not perceived by society unambiguously. The appearance and use of these processes can be said to have a direct impact on the population and the gene pool of the population. The use of each of these medical and genetic methods in research creates moral – ethical and legal problems. As practice shows, international legislation and national jurisdictions of some countries regulate only a small part of this issue, which inevitably leads to ethical and legal dilemmas in society.

One key issue discussed in this article is the protection of individual privacy and the confidentiality of genetic information. With the increasing availability and affordability of genetic testing, individuals are sharing their genetic data with various entities, including healthcare providers, researchers, and direct-to-consumer companies. This raises concerns about who has access to this sensitive information and how it could be used, such as for genetic discrimination or targeted marketing.

Another critical concern highlighted is the potential for genetic discrimination in areas such as employment, insurance, and access to certain services. Employers and insurers may be tempted to use genetic information to make discriminatory decisions, such as denying employment or coverage based on an individual's genetic predispositions. Legal regulations are necessary to protect individuals from such discrimination and ensure equal opportunity for all.

Furthermore, the article delves into the ethical implications of genetic engineering and modifications. The ability to edit or manipulate genes raises questions about the boundaries of natural selection, the potential risks and unintended consequences of genetic modifications, and the need for responsible use of these technologies. Legal regulation is necessary to set guidelines and standards for genetic engineering, specifying what is permissible and what is not. The article discusses the importance of informed consent and transparency when it comes to genetic testing and research. Individuals should have the right to understand the implications and potential risks associated with genetic testing before consenting to it. Furthermore, researchers must adequately inform participants about how their genetic data will be used and ensure their data is protected. Legal regulations play a crucial role in ensuring these principles are upheld.

In conclusion, this article emphasizes the need for legal regulation of genetics to address various biomedical issues. Informed consent, ethical considerations, genetic discrimination prevention, and individual privacy and confidentiality protection are essential components of a responsible and equitable use of genetic technologies. By establishing legal frameworks that govern the field, societies can maximize the benefits of genetics while mitigating potential risks and ensuring fairness for all.

In addition to its comprehensive examination of genetic treatment, this article delves into the legal framework that governs biomedical research in this field. It goes beyond mere discussion of international legislation by conducting a comparative study of different countries' legal systems, providing a profound analysis of the fundamental principles applied across the globe. The importance of addressing these issues in Azerbaijan cannot be overstated, as the country has a notably high percentage of individuals carrying genetic diseases such as thalassemia and hemophilia. This poses a significant risk of future harm to the germline within the Azerbaijani population. Recognizing this, the article emphasizes the urgent need for robust legal regulations in genetics, particularly focusing on the areas where Azerbaijani legislation may have gaps that need to be bridged. It is critical that countries create comprehensive legal frameworks that safeguard their citizens' rights and welfare as genetic research and therapies progress. By examining international legislation and comparing it with the legal systems of various countries, this article provides an extensive analysis that serves as a valuable resource for policymakers and lawmakers in Azerbaijan.

Furthermore, the article highlights the potential consequences of inadequate legal regulation in genetic research. With a specific focus on Azerbaijan, it underscores the pressing need to address and mitigate risks associated with the germline. By doing so, the country can ensure the ethical and responsible application of genetic treatments while safeguarding future generations from potential harm.

In conclusion, this article takes a comprehensive approach to explore the legal framework regulating biomedical research in genetic treatment. By delving into international legislation and comparing it with different countries' legal systems, it sheds light on essential principles applied worldwide. Recognizing the high prevalence of genetic diseases in Azerbaijan, the article underlines the necessity of addressing gaps in the Azerbaijani legislation and emphasizes the importance of protecting the germline to safeguard the well-being of future generations.

Keywords: Medical genetics, confidentiality, genetic test, DNA, legal issues, genealogical analysis, genetic testing, genetic screening, gene therapy, genetic passport, thalassemia.

INTRODUCTION

In recent years, advancements in genetic testing and biomedical research have revolutionized the field of healthcare, offering immense potential for personalized medicine, early disease detection, and improved treatment strategies. However, as these technologies continue to evolve, a critical need arises to address the ethical and legal implications surrounding genetic testing and biomedical research.

In this article, we delve into the complex landscape of ethical considerations and legal regulations that surround the ever-expanding realm of genetic testing and biomedical research. By exploring the ethical principles guiding these practices and examining the legal frameworks that govern their implementation, we seek to shed light on the importance of maintaining rigorous standards that protect individual rights, maintain privacy, and ensure equitable access to these advancements.

Understanding the ethical aspects of genetic testing and biomedical research is vital to navigate the delicate balance between individual autonomy, research integrity, and the broader societal implications. Questions about informed consent, privacy, incidental findings, and the potential for discrimination based on genetic information all highlight the significance of stringent ethical guidelines.

Furthermore, as genetic testing and biomedical research advancements have global implications, it is imperative to examine the legal frameworks surrounding these practices. Laws governing the use of genetic information, protection of personal data, intellectual property rights, and the regulation of clinical trials are just a few areas that

require careful consideration to ensure the welfare of patients, participants, and the public at large.

This article aims to explore the multifaceted challenges posed by the ethical and legal dimensions of genetic testing and biomedical research. Drawing on existing regulations, international guidelines, and case studies, we aim to provide an overview of the current status quo, gaps, and potential solutions to address these complex issues. It presents an in-depth analysis of international legislation and a comparative study of the legislation in various countries, exploring the fundamental principles of legal systems applied worldwide. Moreover, the article addresses biomedical issues that necessitate legal regulation in genetics, with an emphasis on bridging gaps in Azerbaijani legislation. By understanding and addressing the ethical and legal aspects of genetic testing and biomedical research, we can strive towards a future in which these revolutionary advancements are harnessed responsibly and ethically, providing significant benefits to individuals and society as a whole while upholding fundamental human rights. By implementing appropriate regulations, society can harness the potential of genetics while safeguarding individual rights, promoting ethical research practices, and avoiding unethical or unintended consequences.

METHODOLOGY

The author employed the method of deduction to derive specific conclusions and principles from general concepts and laws in genetics and medical law. Additionally, the method of induction was utilized to draw generalizations and formulate hypotheses based on observed patterns and data.

Furthermore, the author used the method of prediction to anticipate potential future developments in the field of genetics and medical law, taking into account current trends and advancements. This allowed them to provide insights and recommendations for appropriate legal regulation. In order to gain a comprehensive understanding of the subject matter, the author employed the method of modeling. By creating simplified representations of complex genetic and legal systems, they were able to simulate various scenarios and evaluate their potential consequences.

The method of analogy was also employed by the authors, as they compared and drew parallels between different biomedical issues and existing legal regulations. This helped to highlight similarities and differences, providing a basis for proposing appropriate legal solutions.

To ensure a comprehensive and balanced analysis, the author utilized the method of dialectics. This involved examining the interplay between different factors and perspectives, as well as addressing contradictions and conflicts that may arise in the context of genetic research and its legal regulation.

Overall, the author's use of these general scientific techniques and methods, combined with a theoretical and methodological basis rooted in fundamental research and various sources of knowledge, allowed for a thorough examination of the Biomedical Issues Necessitating Legal Regulation of Genetics. The application of these methods facilitated the identification of key areas requiring legal attention and provided a solid foundation for the authors' recommendations and conclusions. The article discusses the scientific techniques and methods involved in the field of genetics and highlights the need for legal regulation in this area of research and application.

System-structural, complex and holistic research approaches were also used in the work. Formulation and substantiation of theoretical provisions, proposals, practical recommendations and conclusions are based on the above methods and approaches. Regulations are required to ensure the accuracy and reliability of genetic tests, protect the privacy and confidentiality of genetic information, and prevent discrimination based on genetic results. Additionally, genetic counseling plays a crucial role in interpreting and conveying complex genetic information to individuals or families, emphasizing the

importance of regulating the qualifications, standards, and ethical considerations for genetic counselors.

The work also employed system-structural, complex, and holistic research approaches, enhancing the quality and comprehensiveness of the findings. These approaches allowed for a thorough examination of various interconnected aspects related to the topic. Theoretical provisions, proposals, practical recommendations, and conclusions were formulated and substantiated using these diverse methods and approaches.

RESULTS

1. Ethical and legal regulation of genetic testing and biomedical research.

One of the developing areas of medical law is the sphere of providing medical genetic services. Modern genetics, especially human genetics, is a rapidly evolving field of scientific knowledge. The rapid progress of medical genetics is constantly followed by the emergence of new moral and legal issues. Conducting genetic testing, genetic screening, obtaining genetically identical copies of living and dead people – cloning and preventing the transmission of hereditary diseases to future generations as a result of reproductive processes require serious scientific research.

Medical genetics is a technological process of obtaining new structures of genetic material by transferring the gene systems created as a result of experiments with molecules of ribonucleic and deoxyribonucleic acids outside the cell using genetic engineering (Panchin A. 2017, p. 32-34). The discovery in 1953 of the physical structure of the DNA molecule can be deemed one of the turning points in the history of biology and genetics science. The Nobel Prize in Physiology or Medicine in 1962 was awarded to James Watson, Francis Crick and Maurice Wilkins for this exceptional discovery. DNA (Deoxyribonucleic acid) is a biopolymer that preserves genetic information for the formation and continuation of vital processes of a living organism and is transferred between generations. All organisms, including some viruses, have DNA.

Medical genetics covers the creation of drugs, micro- and transgenic organisms, plants and viruses, including genetic engineering or biotechnological processes, and more importantly, molecular and cellular genetic research for the treatment of various hereditary diseases. For example, Genetic engineering is the reused method for excluding, changing, crossing and recombining genes in different organisms. Genetic engineering is a scientific field of creating new opportunities for living beings by changing their hereditary characteristics (Mammadov V.Q. 2013, p. 323-328). But more dangerous activity is the modification of human essence by interfering with genes or human cloning. In this sense, the legal regulation of any genetic experiment must be aimed at solving vital problems.

The subject of genetic experiments and genetic testing is to care for the health of unborn children and future generations. However, the advent of genetic testing has raised concerns about the protection of genetic information and the potential for discrimination based on one's genetic makeup. Legal regulation is required to ensure that individuals are protected from discrimination in employment, education, insurance, and other areas, based on their genetic information. Genetic testing and research often involve the collection and analysis of individuals' genetic material. Legal regulations are necessary to ensure that individuals are adequately informed about the potential risks, benefits, and implications of genetic testing or research.

Genetic testing has made it possible to identify dangerous diseases in people and anticipate which ones will develop based on a person's inherited constitution. These medical techniques are now more reasonably priced. For example, Legal and ethical issues surrounding genome editing, particularly the use of the CRISPR-Cas9 system, are important considerations. When editing the human genome, informed consent is essential. Individuals must have a clear understanding of the potential risks, benefits,

and limitations of genome editing technologies. It is crucial to respect their autonomy and ensure that informed decisions are made freely and without coercion. Germline editing involves making changes to the DNA that can be inherited by future generations. This raises ethical questions about the potential long-term effects and unintended consequences of altering the germline.

There is ongoing debate about the appropriateness and implications of modifying human germline cells. Genome editing technologies have the potential to create disparities in access to healthcare based on socioeconomic status. Concerns arise over whether genome editing will primarily benefit those who can afford it, leading to an increased divide between the privileged and the disadvantaged. Also, Genome editing techniques are not always 100% accurate, and off-target effects can occur. Unintended changes to the genome might have unforeseen consequences, causing harm to the individual or future generations. Ensuring the safety and minimizing the risk of off-target effects is a significant challenge. There are concerns that genome editing could be used for non-medical purposes, such as creating «designer babies» with enhanced traits. This raises profound moral and ethical questions about the boundaries of genetic intervention and the potential creation of an «unequal playing field» in society.

Addressing these legal and ethical issues requires a robust framework that balances scientific progress, individual autonomy, safety, and social responsibility. Open and transparent dialogue among scientists, policymakers, ethicists, and the general public is crucial to ensure the responsible and ethical use of genome editing technologies.

Developmental abnormalities in humans can be detected through genetic testing. The information obtained as a result of testing makes it possible to diagnose the existence of genetic disease in the person who manifests the symptoms. The study of genetic characteristics can have very serious consequences in the life of each person. Therefore, learning that one has certain terrible and incurable diseases might cause one to experience severe psychological shocks in the future, change one's perspective on life, and ultimately alter society's perception of oneself (Ismayilova Parvina Baku. 2023. p. 108). The results of genetic testing, unlike other medical data, are predictive in nature and can affect the interests of other family members. Summing up, it is necessary to emphasize that genetic experiments and genetic testing that are developing every year raise serious issues for medicine, public health, and social policy.

Genetic testing and biomedical research are aimed at ensuring the efficiency of genetic diagnosis and treatment. Legal issues in medical genetics are of greater interest, mainly in genealogical analysis, testing, screening, and genetic therapy. The application of each of these methods is related to certain moral and legal issues.

Conducting genetic testing is one of the most important services provided to the population in the present-day world. Genetic testing is conducted based on the person's voluntary consent, and the person can withdraw the consent at any time. Medical personnel must inform the patient about both positive and negative aspects of genetic testing. All information must be confidential and the physician must strictly protect medical secrecy and regardless of the medical test result, he/she must provide all kinds of support to the patient. At the same time, during the testing conducted before having symptoms, the physician must protect the confidentiality of the information he/she receives, give detailed information about the impossibility of determining the age and severity of the disease as a positive result and about the availability of counseling and psychological support programs. Since the testing of minors and potential patients can seriously harm children's rights, WHO advises deferring elective genetic testing of minors until reaching maturity.

Genetic testing ensures the confirmation of the genetic basis of the existing disease. Pre-symptomatic testing covers the testing of a person before symptoms of an inherited, genetic disease manifest themselves. So, some genetic diseases, like Huntington's Disease (HD is an inherited disorder that causes nerve cells (neurons) in

parts of the brain to gradually break down and die. The disease attacks areas of the brain that help to control voluntary (intentional) movement, as well as other areas. People living with HD develop uncontrollable dance-like movements (chorea) and abnormal body postures, as well as problems with behavior, emotion, thinking, and personality) which manifest themselves only after 40 years old.

There are several levels of genetic testing in medical genetics: Discussion of genetic problems, consultation with a geneticist, giving consent for testing, collecting samples from the human body, genetic analysis – examining DNA or chromosomes, examining DNA, examining mutations, interpreting results, and finally, the consultation of the geneticist again. As was mentioned above, the legal requirement during all these processes is that the privacy, dignity and individuality of the person must be protected, which is consistent with the no harm or accountability principle.

Another direction of testing in genetics is applied in the case of determining the genetic predisposition to the disease. This testing is specifically aimed at assessing the possible development of the disease and for preventive treatment or prevention. At this point, the physician has to go over with the patient the various testing options and provide comprehensive details regarding the onset of the illness and ways to avoid it. Genetic predisposition to disease testing provides information on the multifactorial disorder in a person, confirmation of the genetic nature of the disease. For instance, if a person has mutations in both the BRCA1 and BRCA2 genes, the likelihood of developing breast cancer after the age of 50 is 20% in the second instance and 40% in the first. WHO recommends conducting multifactorial disease testing willfully and if the test results will help to effectively treat and prevent the disease.

One more direction of the genetic tests is related to the tests that determine the genetic carrier. Even if a person is not symptomatically sick, he/she can be a disease carrier (e.g., Beta-Thalassemia) genetically, and the test is also applied for this case.

Currently, there are more than 10.000 genetic diseases and genetic disorders known to exist in the world. Many of them are related to a specific gene mutation: for example, Down's syndrome (caused by a copy of chromosome 21), Hemophilia disease (widespread in Absheron Peninsula, Azerbaijan) is a genetic disorder of blood coagulation. According to the disease, men are infected, and women (mothers) act as genetic carriers of the disease.

Another type of blood disease - Thalassemia is a hereditary blood disease characterized by impaired hemoglobin synthesis and chronic anemia as a result of a genetic defect. On average, 8 percent of Azerbaijanis are carriers of thalassemia (according to 2016). This indicator is high compared to neighboring countries. One of the ways to prevent the spread of this disease is to undergo by couples a medical examination before getting married (Ismayilova Parvina Baku. 2023. p. 109).

In Azerbaijan, significant efforts have been made to address the rising percentage of genetic blood diseases and protect the rights of individuals living with this. Recognizing the importance of prevention and treatment, various laws and regulations have been adopted to combat genetic blood disorders, particularly thalassemia. One influential initiative in this regard is the «For Life Without Thalassemia» state program, which was launched in 2005 by the First Vice-President of Azerbaijan and the President of the Heydar Aliyev Foundation, Mrs. Mehriban Aliyeva. The program seeks to raise awareness about thalassemia and take proactive steps to prevent its occurrence. One key measure introduced through this program is the mandatory medical examination for couples planning to get married. This examination, which also includes tests for other diseases such as HIV/AIDS and syphilis, aims to identify any genetic blood disorders that may be present in the couple.

Furthermore, the legislative framework supporting the care of individuals suffering from genetic blood disorders, including hemophilia and thalassemia, is well-defined in Azerbaijan. The Law of the Republic of Azerbaijan «On State Care for Persons Suffering

from Hemophilia and Thalassemia Genetic Blood Disorders,» enacted in 2015, focuses on organizing and providing state care for individuals with these conditions. It also deals with matters concerning the prevention, diagnosis, and treatment of genetic blood diseases, including thalassemia. This law establishes the foundation for healthcare services in the country, outlining the responsibilities of relevant authorities and institutions. In addition to legal measures, Azerbaijan implements policies and regulations on genetic screening for thalassemia. These policies guide the procedures and standards for identifying carriers and individuals affected by thalassemia. They also ensure that these individuals have access to healthcare services and support, guaranteeing their rights and well-being. The policy framework extends to the Thalassemia Center, which plays a crucial role in providing appropriate medical care to individuals with thalassemia. This includes access to vital treatments such as medications, blood transfusions, and iron chelation therapy. Importantly, individuals living with thalassemia are also protected by disability rights laws in Azerbaijan. These laws safeguard their rights and ensure equal opportunities for them to participate in society. By upholding disability rights, Azerbaijan aims to improve the quality of life and well-being of individuals affected by thalassemia.

Through these various measures, Azerbaijan has demonstrated its commitment to addressing genetic blood disorders, with a particular focus on thalassemia. By implementing proactive policies, regulations, and support systems, the country has made significant strides in preventing and managing genetic blood diseases, while safeguarding the rights and welfare of individuals living with these conditions.

Genetic screening is one of the biomedical research that is important in terms of the protection of human rights in medical law. Genetic screening is a medical genetic diagnosis that covers mass genetic examination of people. In this case, it is intended to solve issues such as hereditary pathologies, the sex of the child in the embryonic stage, the sex of the child during artificial insemination, and prenatal diagnosis of the fertilized child. Heredity is a combination of several internal (genotype) and external (phenotype) characteristics, long before the child is visible through an ultrasound device, even during fertilization (Ismayilova P. 2023. p. 114-115).

Hereditary diseases are the result of defective changes (mutations) in the structure of the genetic apparatus of the cell. Genetic changes do not manifest themselves in any way in the parents of the fetus but can cause serious hereditary diseases in future generations. Many of these issues can be identified during prenatal examination (diagnosis). «Perinatal» («prenatal») means «before birth» and covers the entire period of pregnancy. Of course, this diagnostic operation makes it possible to prevent several serious diseases while the child is still in the mother's womb, but on the other hand, it allows people to carry out legally and ethically incorrect procedures. For example, choosing the child's sex is possible as a result of prenatal and preimplantation diagnostics. Choosing fetuses and embryos is a violation of the fundamental personal rights of the person born and leads to a violation of the sex ratio in society in the future. Due to becoming the major problem of the world today, Oviedo Convention adopted by the Council of Europe in 1997 (Article 14) prohibits choosing a future child's sex without any reason provided for by national legislation.

In general, it is known that during the application of the genetic screening program in the world, it is possible to have a moral and ethical conflict in relations. The principle of confidentiality underlying this conflict in the field of medicine and the obligation of warning to prevent the occurrence of serious illness conflict with each other (Ismayilova P. 2023. p. 114). Specific issues arise when the medical and genetic testing procedure causes the risk of harm. For example, the diagnosis of some hereditary diseases of the fetus can be made thanks to amniocentesis in a mother's womb. It relates to the risk of accidental termination of pregnancy. If there are medical and genetic indicators that confirm that the child is likely to be born with a genetic pathology, the physician may take this risk (the risk of miscarriage) into consideration. However, if a healthy woman

who does not have appropriate indicators and has a low risk of hereditary pathology personally requests amniocentesis and examination of the fetus, then a serious moral problem arises. Although the unborn child is not protected by law, morally he/she has the right to live, and in this case, his/her interests and also risks must be taken into consideration.

Population genetic screening is conducted only to identify gene carriers of severe hereditary diseases. One of the classic examples of the neonatal screening program is the identification of the hereditary disease phenylketonuria (PKU) in newborns. This disease is a severe hereditary disease that damages the head and spinal cord and, if left untreated, can lead to mental retardation, short stature, cataracts and other serious problems, and an untreated child will become disabled when he/she grows up. Timely diagnosis of genetic defects and the application of a special diet excluding phenylalanine, as well as the combined use of psychological correction therapy and social adaptation methods allow to obtain a positive result in many cases.

Phenylketonuria screening test – known in Azerbaijani medical society as «Ankle analysis», this screening test varies from country to country. In many countries, this screening test is compulsory and free of charge at the state level, to protect the future gene pool. In Azerbaijan, this screening is payable and not compulsory. Because the screening test itself is expensive for middle- and low-income families, parents usually refuse to conduct it. As a result of the development of biotechnology, the simplicity and relative reliability of the screening test method for PKU detection allowed its wide application in medicine.

The problem is that there are no statistics in this field in Azerbaijan. The necessary measures were not taken by the competent state authorities in this field within the framework of the «State Program for Improving the Maternal and Child Health for 2014-2022.» According to the State Statistics Committee, 122.846 babies were born in Azerbaijan in 2022. According to the State Agency for Compulsory Medical Insurance, within the framework of the «Action Plan for the Implementation of the Strategy for Children for 2020-2025», to detect congenital and hereditary diseases among newborns, since May 2022, 700 children have undergone neonatal screening tests in state medical institutions. As a result of screening tests, phenylketonuria was not detected in the children who underwent testing.

This confirms once again that the phenylketonuria screening, which is one of the necessary elements for gene pool protection, and the collection of statistical data in the country is not at the desired level. So, in the statistics of the world countries, the numbers differ between 1:2,500 (in Türkiye), 1:15,000 (in the USA) and 1:200,000 (in Finland). Note that this hereditary disease is more common in children of inbreeding families. Given that this tradition is widespread in Azerbaijan, the number of diseases in the country is not an exception.

The development of modern technologies allows us to determine the risks of this disease even before the child is fertilized in the mother's womb if both parents undergo genetic testing. However, screening for phenylketonuria must be compulsory after birth. So, there is legislative practice in this regard in the world countries. For example, in Russia, this procedure is a compulsory analysis included in neonatal screening. In Russia, for 15 years now, babies have been examined for five hereditary diseases for free at the maternity hospital immediately after birth.

During this period, more than 20 million children have passed such screening, and about 15,000 people have been diagnosed with this disease. Article 44 of the 2011 Law of Russia «On Protection of Population Health» states that neonatal screening for phenylketonuria, which is one of the developing diseases that pose a serious threat to human life and health, is provided at the expense of state funding. The same legislative practice is observed in one of the developed countries of Europe – Portugal.

According to the legislation of the Republic of Azerbaijan, the highest objective

of the state is to ensure people's rights and liberties (Article 12 of the Constitution of the Republic of Azerbaijan). In particular, in the concept of National Security of the Republic of Azerbaijan, in Law «On Protection of Population Health» (Articles 1 and 2), the state guarantee of human and civil rights..., the implementation of preventive measures for population health protection and other provisions include neonatal screening test for phenylketonuria which is one of the diseases that threaten people's health from the day of birth. Taking into consideration the practice of the world countries, the concept of neonatal screening, the list of diseases and their classification system must be established by additions to the Law «On Protection of Population Health» or by a separate legislative act. Screening for diseases that pose a threat to human health from birth can also be conducted by regulating our legislation according to the WHO a short guide on «Screening programmes: Increase effectiveness, maximize benefits and minimize harm» (Copenhagen, 2020; Sushko, 2003,).

In the end, taking into consideration the supreme goal of the state and the protection of the country's gene pool (Article 16.1 of the Constitution of the Republic of Azerbaijan), the analysis and prevention of progressive diseases that pose a serious threat to human life from birth must be ensured either mandatorily or at expense of the state or by including it in the legislation on Compulsory Medical Insurance.

2. Ethical and Legal Aspects of Gene Therapy

Gene Therapy involves the modification of an individual's genetic material to treat or prevent genetic diseases. While it holds great potential for the treatment of various genetic disorders, several ethical and legal aspects need to be considered:

1. Informed consent: Proper informed consent is crucial when conducting gene therapy. Individuals should be fully informed about the risks, benefits, and potential outcomes of the treatment before giving their consent.

2. Privacy and confidentiality: The genetic information obtained during gene therapy carries sensitive personal information. It is important to ensure strict privacy and confidentiality to protect the individual's genetic data from misuse.

3. Access and equity: Gene therapy is a groundbreaking medical intervention that has the potential to significantly improve quality of life. However, ensuring equitable access to therapy for all individuals, regardless of economic status or geographical location, is essential to prevent further disparities in healthcare.

4. Human enhancement: While gene therapy is primarily aimed at treating diseases, the ability to modify one's genetic makeup also raises concerns about the potential for human enhancement. Ethical considerations need to be taken into account to prevent the misuse of gene therapy for non-medical purposes.

5. Long-term effects and safety: Gene therapy is still a developing field, and its long-term effects are not fully understood. A thorough evaluation of safety and efficacy is essential to minimize potential risks to patients.

On the legal front, several regulatory and legal considerations govern gene therapy:

1. Regulatory approval: Gene therapy is regulated by government agencies and must undergo rigorous testing and approvals before being made available to the public. These regulations aim to ensure the safety and efficacy of the treatments.

2. Intellectual property: Gene therapies are the subject of intellectual property rights, including patents. This raises ethical concerns about access to and affordability of these treatments, as well as the potential for monopolies hindering innovation.

3. Liability and accountability: In the event of any adverse effects or harm resulting from gene therapy, legal frameworks and liability systems determine who is accountable and what compensation should be provided.

4. Genetic discrimination: There are legal provisions in many countries that prohibit genetic discrimination, ensuring that individuals are not discriminated against based on their genetic information when it comes to employment, insurance, or other services.

5. Regulatory oversight and monitoring: Gene therapy research and treatments

are closely monitored by regulatory bodies to ensure compliance with ethical and legal standards. This oversight helps maintain public trust and prevents unethical practices.

Overall, gene therapy offers great promise in the field of medicine, but close attention must be paid to ethical and legal considerations. Ensuring informed consent, privacy protection, equitable access, and regulatory oversight are crucial to harness the potential of gene therapy responsibly and ethically.

Gene therapy is one of the newest areas of medical development. This method, which has been applied to hundreds of patients so far, has given quite good results in many cases. Even while gene therapy (Ismayilova P. 2023, p. 117) is thought to be a more promising treatment for monogenic genetic disorders, there are still a number of legal concerns. Thus, it is likely that the introduction of genetic material containing a normally functioning gene into the body will have a decisive therapeutic effect. Currently, there is uncertainty about the effectiveness of gene therapy, as well as the possible negative consequences of transferring genetic material into the patient's body. That is why, for example, testing of gene therapy methods in human germ cells is prohibited in the world. This prevents the transmission and spread of potentially negative genetic changes to future generations. However, note that germ cells are not isolated from the body.

Consequently, there remains the possibility of influencing them by carriers of genetic material during gene therapy of somatic cells. To obtain permission to conduct gene therapy clinical trials, the following conditions must be met:

1) During experiments on animals, it must be proven in advance that the necessary gene can be transferred to suitable nuclear cells and have an active function there for a long time;

2) It is necessary to make sure that the gene transferred to the new environment will maintain its effectiveness;

3) It must be fully guaranteed that the transferred gene will not cause negative consequences in the body (Ismayilova P. 2023. p.117).

As much as personal specificity (individuality) manifests itself as a genetic issue, its protection is as much an issue of Medical law. In this sense, the concept of genetic passportization was created. A genetic passport is a confirmation of information about individual genetic characteristics that distinguish a person from others among citizens. A genetic passport is the result of genetic dactyloscopy (or DNA-dactyloscopy). This type of passport can be referred to as a forensic passport because it determines the unique sequence of nucleotides of a person's DNA. In some cases (investigation of crimes, determination of paternity, identification of human remains, etc.), it enables identification of a person. Moreover, a genetic passport is the profiling of the human genome through biomaterial (saliva and blood) (Cardiological Journal, 2018, p. 85-87).

From a bioethical and legal point of view, the «gold standard» of genetic material donation (without which it is impossible to create a genetic passport) is voluntary informed consent. «Voluntary» means conscious, free, independent and uncoerced consent. «Informed» means that the citizen consciously gives consent based on reliable and detailed information presented to the subject of consent in an understandable form based on the biomedical experiment presented by the physician or organizers.

Detailed information on giving genetic material to a biobank must help the citizen to make an independent decision, and he/she must also give consent for the use of biomaterial in scientific research. The use of diagnostic methods based on the analysis of genetic markers makes it possible to conduct early diagnosis of pathology and diseases that do not manifest in a person and to ensure adequate therapy on time. The effect of drug treatment depends mainly on the individual genetic characteristics of the patient. Thanks to gene diagnostics, it is possible to reduce the time spent on choosing drugs and determining their dosage several times.

The creation of a genetic passport will make it possible to obtain an individual approach to the treatment of a person. However, the main risk when obtaining personal

(genetic) and especially medical information is the protection of personal information and confidentiality. Genetic information is highly personal and sensitive. Legal regulations are needed to protect individuals' privacy and confidentiality concerning their genetic information, including how it is collected, stored, accessed, and shared. The discovery and development of genetic tests, therapies, and technologies raise questions about the ownership and control of genetic material and associated technologies. Legal regulation is essential to ensure that property rights are granted in a manner that promotes innovation, fair access, and ethical considerations.

So, the ethical and legal side of the matter requires confidential and comprehensive protection of data. UNESCO 1997 «Declaration on the Human Genome and Human Rights» states that everyone has a right to respect for their dignity and rights regardless of their genetic characteristics; that dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity”.

The main ethical, legal and social implications of the Human Genome Project are privacy and confidentiality, genetic testing, education, reproductive issues, psychological impact and stigmatization, standards and quality control, commercialization, conceptual and philosophical implications.

Legal regulation is essential to address the potential resurgence of eugenic relations through the use of genetic passports, as it empowers the state to stipulate specific requirements for individuals with genetic issues, such as their ability to live, work, and have children. However, note that there are many positive aspects of the application of genetic passports. States also protect their biological security by applying passports.

In such a way, countries, where hereditary blood diseases are common (Azerbaijan, Türkiye, etc.) can prevent the disease from developing. Thus, 1) the creation of a genetic passport will make it possible to obtain an individual approach to the treatment of a person; 2) genetic passportization, as a new field in medical law, will provide a preventive regulatory function in the fight against various serious diseases.

CONCLUSION

Genetic research and the use of genetic technologies have revolutionized the field of medicine, offering unprecedented opportunities to understand, diagnose, and potentially treat a wide range of diseases. However, these advancements also bring with them a myriad of ethical considerations that must be addressed through legal regulations. Consent is a critical issue in genetic research, as it involves the use of an individual's genetic material, which is inherently personal and private. Therefore, strict guidelines must be established to ensure that individuals understand the implications and potential risks of participating in genetic research and can give informed consent.

Another ethical concern is the potential harm that could be caused by genetic interventions. While gene editing and manipulation technologies hold immense promise, there is also the potential for unintended consequences and long-term effects that may be harmful to individuals and even future generations. Therefore, legal regulations are needed to establish rigorous safety standards and oversight mechanisms to ensure that genetic interventions are conducted responsibly and ethically.

Additionally, the use of vulnerable populations in genetic research raises significant ethical concerns. Minority groups, individuals with disabilities, and socioeconomically disadvantaged individuals should be protected from exploitation and harm. Legal regulations must outline safeguards and ensure that these populations are not disproportionately targeted or subjected to unjust treatment in genetic research. Conflicts of interest also need to be addressed in genetic research. As the field continues to grow, there is a risk of commercial or financial interests influencing research findings or dictating the direction of research. Legal regulations should establish guidelines to minimize conflicts of interest and ensure that genetic research is conducted with the best interests of individuals and society in mind.

Advances in genetics, such as gene editing and manipulation technologies, have also sparked debates about the personhood and rights of individuals whose material is altered. Legal regulation is necessary to define and protect the rights and interests of individuals and to establish ethical boundaries for genetic interventions. This includes issues such as ownership and control over genetic information, privacy concerns, and ensuring equal access to genetic technologies.

In Azerbaijan, there is a pressing need to address these ethical considerations and establish legal regulations in the field of genetics. The article emphasizes the importance of carrying out genetic screening and defining a list of diseases that pose a serious threat to human life. These diseases should be included in the compulsory form of state insurance or regulated under the framework of Compulsory Medical Insurance. This would ensure that individuals have access to necessary genetic testing and interventions without discrimination or financial burden.

Moreover, gene therapy, as one of the newest directions of medical development, requires legal regulation to ensure its safe and ethical use. Proposals have been put forward for the implementation of genetic passports, which would provide an individualized approach to treatment based on an individual's genetic profile. This would allow for more targeted and effective healthcare interventions. Furthermore, genetic passports could serve as a preventive tool, enabling regulation in the fight against various serious diseases by identifying individuals who may be at risk and providing proactive measures to prevent the onset of these conditions.

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