REVIEW ARTICLE

CONTENTS

Informed consent of the patient for medical intervention for conducting biomedical research

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ABSTRACT

Aim: is to find out the peculiarities of informed consent of the patient for medical intervention during biomedical research.

Materials and Methods: The dialectical method was used as a universal and general scientific method, which made it possible to consider the peculiarities of the content of the patient's informed consent. Using the logico-semantic method, the essence and features of biomedical research with the patient's participation were determined. The formal-legal method is used to analyze adaptation processes of biomedical research. System-structural method were applied when comparing the content of the patient's informed consent in separate legislation. The work also used such methods of cognition as comparative-legal, systemic-logical, and logical-legal.

Conclusions: "Informed consent" includes not only the concept of consent itself, i.e. the free decision of a person, but also an explanation of a specific case or research procedure. And it largely depends on the specialist. Will he be able to convey and explain the patient's problem, illness, actions correctly, fully and in an accessible form? Yes, free consent is given by a person, but the doctor also influences this decision to some extent. Patients' freedom in choosing medical care methods is somewhat limited.

KEY WORDS: human rights, medicine, biomedical research, subject during biomedical research, informed consent of the patient

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INTRODUCTION

The right to life is the main and basic human right. All civilized, conscious society recognizes human rights as fundamental and tries to preserve them. The mission of doctors is to save, heal, help.

However, in various complex medical cases, a person faces a difficult choice, and only with his consent can doctors begin their actions [1].

In order for a person to fully understand his situation in which he is, first of all, the doctor must give him an informative and accessible explanation about the nature of this disease and about the consequences that may occur when the recommended treatment is carried out or when such treatment is refused [2].

But before starting treatment, it is necessary to carry out all prescribed medical examinations and establish the correct diagnosis.

It is the patient who makes the decision to conduct this or that biomedical research.

It would seem that every patient seeks help voluntarily, in need of medical assistance. But, in practice, we observe that almost every medical intervention requires the patient's written consent. Sometimes this does not create any problems, but in most patients, it causes a feeling of wariness - there are probably high risks if it is necessary to sign such a piece of paper [3].

The patient's rights are absolute, regardless of whether assistance is provided on the basis of state guarantees of free medical care or on the basis of paid contracts for the provision of medical services. In other words, whether it is a state or commercial medical institution, doctors cannot ignore these rights. Moreover, the patient himself cannot ignore them.

AIM

The aim is to find out the peculiarities of informed consent of the patient for medical intervention during biomedical research.

MATERIALS AND METHODS

The methodological basis is a system of methods and techniques of scientific knowledge. The dialectical method was used as a universal and general scientific method, which made it possible to consider the peculiarities of the content of the patient's informed consent. Using the logico-semantic method, the essence and

features of biomedical research with the patient's participation were determined. The formal-legal method is used to analyze adaptation processes of biomedical research. System-structural and system-functional methods were applied when comparing the content of the patient's informed consent in separate legislation. The work also used such methods of cognition as comparative-legal, systemic-logical, and logical-legal.

REVIEW AND DISCUSSION

The legislation does not contain a clear definition of the term "patient's informed consent to medical intervention during biomedical research". However, based on the content of Article 28 of the Constitution of Ukraine, Article 39, 43 of the Law of Ukraine "Basics of Ukrainian legislation on health care" (hereinafter - Basics), Article 284 of the Civil Code of Ukraine (hereinafter - CCU), it can be concluded that: the patient's informed consent for medical intervention during biomedical research is a free, informed decision of the person who sought medical help or his legal representatives regarding the selection and application of methods of diagnosis, prevention and treatment, which is based on receiving from the doctor in an accessible form information about his state of health, the purpose of the proposed research and treatment measures, the prognosis of the possible development of the disease, including the presence of a risk to life and health [4].

The decision to give the patient's consent to medical intervention must be free. It cannot be the result of external coercion or active persuasion by anyone, including a doctor.

The decision should only be the result of a personal choice based on full health information. The medical worker is obliged to provide the patient in an accessible form with information about his health, the purpose of the proposed research and treatment measures, the prognosis of the possible development of the disease, including the existence of a risk to life and health [5].

If information about a patient's illness can worsen his health or the health of his representatives, harm the process of treatment, medical workers have the right to provide incomplete information about the patient's health, limit their access to individual medical documents [6].

According to the general rule, consent to medical assistance is provided by a person who needs medical assistance - from the age of 14 [7] or legal representatives - if patients under the age of 14 and patients recognized as incompetent need medical assistance.

In the event that a person between the ages of 14 and 18 needs medical intervention, it is advisable to notify their legal representatives. This is due to the need to comply with the provisions of Art. 31, 32, 37, 39 of the CCU and Article 150 of the Family Code of Ukraine [8].

The Ministry of Health of Ukraine has provided and approved a unified form of such patient consent. Namely, we are talking about the Form of primary accounting documentation No. 003-6/o and the instructions for filling it out, approved by the order of the Ministry of Health No. 110 of 02.14.2012 [9, 10].

The latest changes to form 003-6/o and the instructions were made by the order of the Ministry of Health dated 09.12.2020 No. 2837: "Informed voluntary consent of the patient for diagnosis, treatment and for surgery and anesthesia and for the presence or participation of participants in the educational process".

The medical documentation - form 003-6/o - is filled out by the patient who applied to the health care institution and gives his consent to diagnosis, treatment, if necessary, to surgical intervention and anesthesia, the presence or participation of participants in the educational process in the presence of the attending physician.

The patient himself indicates his last name, first name, patronymic; the attending physician provides him with information regarding the diagnosis and treatment plan, provides in an accessible form information about the probable course of the disease, the consequences of refusing treatment.

The patient's consent to the proposed treatment and diagnosis (form No. 003-6/o) is certified by the signatures of the attending physician and the patient [10].

Consent to medical intervention is not taken if there are signs of a threat to the patient's life and it is not possible for objective reasons to obtain consent to the intervention. In this case, the doctor makes the decision regarding medical intervention.

If it is established that a person is unable to give consent, the authorized person (representative, relatives) must make a decision exclusively in the interests of this person. Such a decision must be as close as possible to the likely decision of the person to be interfered with, if he had the opportunity to express it in any way.

A person has the right to refuse intervention at any stage of the process. She must also be informed about the possible consequences of withdrawing consent. Her decision must be respected. Protection against discrimination should be guaranteed for the decision to intervene [11].

A patient over 18 years of age, whose legal capacity is not limited, or legal representatives of patients under 18 years of age and patients recognized as incompetent or whose legal capacity is limited, has the right to refuse treatment [7].

If the lack of consent can lead to serious consequences for the patient, the doctor is obliged to explain this. If the patient refuses treatment even after that, the doctor has the right to take a written confirmation from him, and if it is impossible to receive it, to certify the refusal with an appropriate act in the presence of witnesses. In the event that the legal representative's refusal of treatment may have serious consequences for the patient, the doctor must inform the guardianship and guardianship authorities [9].

In Ukraine, there is no separate normative document regarding the rights of patients. The Constitution of Ukraine guarantees every citizen the right to health care, medical assistance and medical insurance. At the same time, the state creates conditions for effective and accessible medical care for all citizens. The relationship between the doctor and the patient is regulated by a wide range of legal acts.

In turn, the law of Ukraine "Fundamentals of the legislation of Ukraine on health care of citizens" provides that every citizen has the right to health care, a standard of living, including food, clothing, housing, medical care and social services and provision, which is necessary for maintaining human health; a natural environment that is safe for life and health; sanitary-epidemic well-being of the territory and settlement where he lives; safe and healthy conditions for work, study, living and recreation; qualified health care, including the free choice of a doctor, the choice of treatment methods in accordance with his recommendations and the health care institution [7].

For many conditions and diseases, there are one or more established effective treatments. Doctors and hospitals may use different methods to treat the same condition. However, the relative merits of these treatments are often unknown.

Comparative effectiveness studies, as well as systematic reviews, have received increasing attention over the past few years. A comparative effectiveness study directly compares two or more interventions that are considered the standard of care. This research may help determine which standard of care has better outcomes and more acceptable risks.

The risks of standard care procedures do not necessarily qualify as minimal simply because the treatment has become standard practice. Risks to participants must be minimized and properly balanced against the prospects for potential individual benefit or social value of the research [12-23].

The principle of voluntary informed consent implies that every person has the right to access information about the purpose and nature of such an intervention, as well as about the possible consequences and risks for his life and health.

Such consent contains an important component of the person's awareness of the decision made on the basis of the information provided to him (regarding the content, order and consequences of the intervention).

At the same time, it should be taken into account that consent as an element of the voluntariness of decision-making and its result often depends on many objective and subjective factors (for example, it is given under the influence of pain, fear, etc.), which can significantly affect a person's assessment of the situation in which he finds himself, as well as on reducing control in making one's own decisions [11].

The legal basis for conducting biomedical interventions consists of numerous international legal acts, which are based on the principle of voluntary and informed consent: the Convention on the Protection of Human Rights and Dignity in the Use of Biology and Medicine; The 1997 Convention on Human Rights and Biomedicine (also known as the Oviedo Convention) [15]; Additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Human Organs and Tissues of 2002 (hereinafter - Additional Protocol on Transplantation) [16]; Additional Protocol to the Convention on Human Rights and Biomedicine in the Field of Biomedical Research of 2005 (hereinafter - Additional Protocol in the Field of Biomedical Research) [17]; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Medical Purposes of 2008 (hereinafter - Additional Protocol on Genetic Testing) [18]; The 1997 Universal Declaration on the Human Genome and Human Rights [19], the 2005 Universal Declaration on Bioethics and Human Rights [20], as well as the 2000 Charter of Fundamental Rights of the European Union [21] and a number of EU directives, recommendations and regulations.

The Oviedo Convention defines a general rule according to which: "Any intervention in the field of health may be carried out only after the voluntary and informed consent of the person concerned". Such a person is provided with appropriate information in advance about the purpose and nature of the intervention, as well as about its consequences and risks" [15], "persons on whom research is conducted must be informed about their rights and guarantees established by law for their protection; the necessary consent provided for in Article 5 must be given clearly, specifically, and must be documented".

The Universal Declaration of Bioethics and Human Rights proclaimed the important principle of consent: "Any medical intervention for preventive, diagnostic or therapeutic purposes must be carried out only with the prior, free and informed consent of the person concerned on the basis of adequate information. Consent in appropriate cases must be clearly expressed" [19].

A person's awareness of decision-making is one of the essential conditions for biomedical intervention. At the same time, in addition to the general provisions for the protection of persons capable of giving consent, special protection is needed for persons who are unable to give their consent. Thus, according to the Oviedo Convention, "... intervention with regard to a person who is incapable of giving consent may be carried out only on the condition that it will have a direct benefit for such person" [15].

Provisions regarding consent to biomedical interventions are contained in the Charter of Fundamental Rights of the European Union in the context of the right to the integrity of the person: "In the fields of medicine and biology, the following shall be respected, in particular: the voluntary and informed consent of the person concerned, in accordance with procedures established by law" [21].

Enshrining the principle of voluntary informed consent in numerous international legal acts is an important component of the right to life in international law, as well as the protection of human rights in judicial practice [24].

Informed consent is a process. The initiation of this process requires the provision of appropriate information to the potential participant, ensuring that the individual has adequately understood the relevant facts and consented or refused to participate without coercion, undue influence, or misrepresentation [25].

Informed consent is based on the principle that individuals who are capable of giving informed consent have the right to voluntarily decide whether to participate in research. Informed consent protects individuals' freedom of choice and respects individual independence.

CONCLUSIONS

Having studied, analyzed and researched the issue of "informed consent of the patient for conducting biomedical research", it is possible to come to the unequivocal position that this issue is very relevant and important today. It is mentioned and constantly improved in both international and national legislation. A person repeatedly needs medical assistance during his life.

The right to life and health is guaranteed to everyone by the Constitution of Ukraine and should be unhindered for a person to exercise this right. The process of diagnosis and treatment depends only on the person himself and his free decision. Only with the patient's consent is this or that study conducted. International legal acts indicate that a person's failure to consent to medical intervention is considered an interference in his personal private life, a violation of his dignity and freedom.

"Informed consent" includes not only the concept of consent itself, i.e. the free decision of a person, but also an explanation of a specific case or research procedure. And it largely depends on the specialist. Will he be able to convey and explain the patient's problem, illness, actions correctly, fully and in an accessible form? Yes, free consent is given by a person, but the doctor also influences this decision to some extent. Patients' freedom in choosing medical care methods is somewhat limited. The patient can choose only among those methods of medical intervention recommended by the attending physician or refuse treatment.

That is why the question of "informed patient consent" will continue to be one of the most debated issues and will repeatedly be an excellent topic for research by young scientists.

REFERENCES

1. Bielov DM, Hromovchuk MV, Hreca YaV, Tymchak VV. Essence of somatic human rights in the process of biomedical research. Wiad Lek. 2021;74(10):2663-2668. doi: 10.36740/WLek202110226. DOI
2. Bielov DM, Petsa DD, Svyshcho VY, Novytsky VV. The human right to transplantation of organs and tissues: medicine, ethics and law. Wiad Lek. 2022;75(10):2519-2525. doi: 10.36740/WLek202210138. DOI
3. Hromovchuk M, Brych V, Sabadosh M. Euthanasia: some aspects of bioethics. Visegrad Journal on Human Rights. 2019;4:33-38.
4. Byelov D, Hromovhcuk M. The constitution of the state in the context of its functions. Visegrad Journal on Human Rights. 2017;4:41-49.
5. Hromovhcuk M. Human Rights for Life: selected aspects. Visegrad Journal on Human Rights. 2017;2:39-46.
6. Byelov D. The paradigm of constitutionalism as a theoretical and legal category. Visegrad Journal on Human Rights. 2021;5:34-37.
7. Tsyvilnyi kodeks Ukrainy. [The Civil Code of Ukraine]. 2003. № 40-44. Art. 356. https://zakon.rada.gov.ua/laws/show/435-15#Text [Accessed 11 January 2024] (Ukrainian)
8. Simeinyi kodeks Ukrainy. [Family Code of Ukraine]. 2002. № 21-22. Art. 135. https://zakon.rada.gov.ua/laws/show/2947-14#Text [Accessed 11 January 2024] (Ukrainian).
9. Osnovy zakonodavstva pro okhoronu zdorovia. [Basics of health care legislation]. 1993. №4. Art.19. https://zakon.rada.gov.ua/laws/show/2801-12#Text [Accessed 11 January 2024] (Ukrainian)
10. Nakaz Ministerstva okhorony zdorovia Ukrainy. [Order of the Ministry of Health of Ukraine]. 14.02.2012 p. №110. https://zakon.rada.gov.ua/laws/show/z0661-12#Text [Accessed 11 January 2024]] (Ukrainian)
11. Ostrovska BV. Dobrovilna informovana zghoda na biomedychni vtruchannia yak skladova prav liudyny. [Voluntary informed consent to biomedical interventions as a component of human rights]. Filosofski ta metodolohichni problemy prava. 2018;1-2(15-16):170-183. https://elar.naiau.kiev.ua/items/b73ef4e7-b0c2-4211-86a9-4ae0727311f1 [Accessed 11 January 2024] (Ukrainian)

12. Sizintsova yuiu. Informovana z·hoda: chy ye mistse "tsyvil'nym" protseduram pid chas poryatunku viys'kovykh. [Informed consent: is there a place for "civil" procedure during a military rescue]. https://cedem.org.ua/analytics/informovana-zgoda-medytsyna/ [Accessed 11 January 2024] (Ukrainian)
13. The Nuremberg Code –A critique. Perspect Clin Res. 2011; 2(2): 72–76. doi: 10.4103/2229-3485.80371. DOI
14. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects. [Accessed 11 January 2024]
15. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997). URL: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164. [Accessed 11 January 2024]
16. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, No. 186 (Strasbourg, 24.I.2002). https://rm.coe.int/1680081562. [Accessed 11 January 2024]
17. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, CETS No. 195 (Strasbourg, 25.I.2005). https://rm.coe.int/168008371a. [Accessed 11 January 2024]
18. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, No. 203 (Strasbourg, 27.XI.2008). https://rm.coe.int/1680084824. [Accessed 11 January 2024]
19. Universal Declaration on the Human Genome and Human Rights, adopted unanimously and by acclamation at UNESCO' s 29th General Conference on 11 November. http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights. [Accessed 11 January 2024]
20. Universal Declaration on Bioethics and Human Rights of 19 October 2005. http://unesdoc.unesco.org/images/0014/ 001428/142825e.pdf#page=80. [Accessed 11 January 2024]
21. Charter of Fundamental Rights of the European Union of 7 December 2000. Official Journal of the European Communities (2000/C 364/01). http://www.europarl.europa.eu/charter/pdf/text_en.pdf. [Accessed 11 January 2024]
22. Convention on the Rights of the Child, adopted by General Assembly resolution 44/25 of 20 November 1989. http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx. [Accessed 11 January 2024]
23. Mizhnarodni etychni rekomendatsii shchodo doslidzhen, poviazanykh iz zdoroviam za uchastiu liudei. Rozrobleni Radoiu mizhnarodnykh orhanizatsii medychnykh nauk (CIOMS) u spivpratsi z Vsesvitnoiu orhanizatsiieiu okhorony zdorovia (VOOZ). [International ethical guidelines for health-related research involving human subjects. Developed by the Council of International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)]. https://www.dec.gov.ua/wp-content/uploads/site/files/klinika/cioms.pdf [Accessed 11 January 2024] (Ukrainian)
24. Bielov D, Hromovchuk M. The basic law of the state: legal and political content. Baltic Journal of Economic Studies.2019;5(3):59-66. doi:10.30525/2256-0742/2019-5-3-59-66. DOI
25. Hromovchuk M. Euthanasia and bioethics: correlation issues. Visegrad Journal on Human Rights. 2020;5:76-80.

CONFLICT OF INTEREST

The Authors declare that there is no conflict of interest

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