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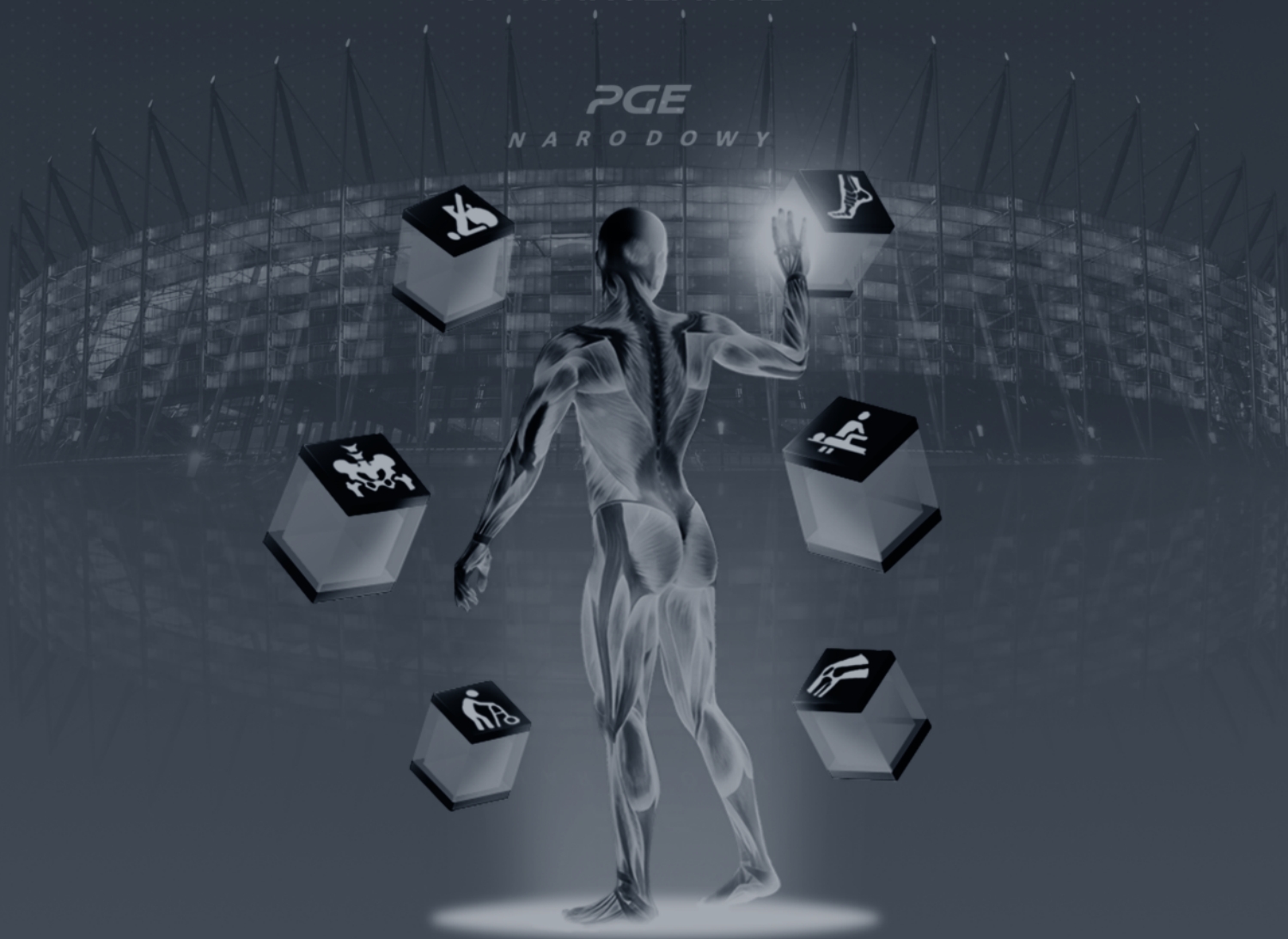
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Legal Aspects of the Informed Consent of the Patient During Physical Therapy in Ukraine

Prawne aspekty świadomej zgody pacjenta na fizjoterapię na Ukrainie

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Abstract

The purpose of the study is to establish the legal features of the use of informed voluntary consent of the patient in providing him/her with physical therapy services in Ukraine.

Materials and methods. The analysis of the normative-legal base of Ukraine with the use of methods of analysis, synthesis, comparative-legal method is carried out.

Research findings. Currently Ukraine has developed and approved the form of primary accounting documentation "Informed voluntary consent of the patient for diagnosis, treatment and surgery and analgesia" and instructions for filling out this form. This form is completed by a patient who has applied to a health care facility and agrees to undergo diagnostic and treatment measures, and if necessary the patient agrees to surgery and analgesia. However, this form is not suitable for legal relations between a physical therapist and a patient. The main features of the application of this consent are determined and its model for use in the practice of physical therapists is developed.

Conclusions. The principle of patient autonomy during physical therapy requires regulation of the patient's right to provide him/her with full information about physical therapy, coordination and approval of the written form of voluntary informed consent of the patient to physical therapy.

Key words:

informed consent, patient, law, physical therapy

Streszczenie

Celem pracy jest ustalenie cech prawnych stosowania świadomej dobrowolnej zgody pacjenta przy wykonywaniu usług fizjoterapeutycznych na Ukrainie.

Materiały i metody. Analiza podstawy normatywno-prawnej obowiązującej na Ukrainie metodami analizy, syntezy, metody porównawczo-prawnej.

Wyniki badań. Obecnie Ukraina opracowała i zatwierdziła formularz pierwotnej dokumentacji księgowej „Świadoma dobrowolna zgoda pacjenta na diagnostykę, leczenie i zabiegi chirurgiczne i przeciwbólowe” oraz instrukcję wypełniania tego formularza. Formularz wypełnia pacjent, który zgłosił się do zakładu opieki zdrowotnej i wyraził zgodę na podjęcie działań diagnostycznych i leczniczych, a w razie potrzeby na operację i znieczulenie. Forma ta nie jest jednak odpowiednia dla stosunków prawnych między fizjoterapeutą a pacjentem. Określono główne cechy stosowania tej zgody i opracowano model jej wykorzystania w praktyce fizjoterapeutów.

Wnioski. Zasada autonomii pacjenta podczas fizjoterapii wymaga uregulowania prawa pacjenta do udzielania mu pełnej informacji o fizjoterapii, koordynacji i akceptacji pisemnej formy dobrowolnej świadomej zgody pacjenta na fizjoterapię.

Słowa kluczowe:

świadoma zgoda, pacjent, prawo, fizjoterapia

Introduction

Today in Ukraine, physical therapy is a well-established and legitimate profession, with special professional aspects of clinical activity and education, which belongs to the health care system [1]. The physical therapist uses various means of influence in the form of both natural and preformed physical factors to achieve the goals of changing the state of health, well-being and the level of support of the physical condition. These can be manual therapy techniques, movement improvement activities, physical factors, electrotherapeutic and mechanical means, functional training, provision of aids, training and patients counseling, record keeping, process coordination and communication [2, 3]. The use of these physiotherapeutic agents in a particular patient can have both specifically beneficial and specifically adverse effects.

Ethical principles require the physical therapist to recognize the right of the patient/client or his or her legal guardian to make independent decisions about receiving physical therapy services [3]. This raises the question of whether additional legal justification is needed for the use of various physiotherapeutic factors and aids. This raises the second question, whether it is necessary to obtain informed consent from the patient to conduct physiotherapy interventions? The second question is based on the fact that at present some features of informed consent in various medical fields, such as pediatrics, surgery, obstetrics, dentistry and psychiatry [4, 5].

Informed consent, in the broadest sense of the word, means "a legal condition, and according to it a person has consented to certain actions based on an adequate assessment and awareness of the facts and possible consequences". Informed consent in medicine has become especially important in connection with the implementation of numerous medical, diagnostic, treatment, prophylactic and rehabilitation interventions for the patient. Informed consent is a procedure by which a patient voluntarily confirms its consent to perform a variety of medical interventions that have been formally approved by the health care regulator. Voluntary informed consent to medical intervention is considered to be one of the main elements of the modern system of legal regulation of medical care, it is the right of the patient and the duty of the medical worker performing the medical intervention.

The necessity to obtain informed consent of the patient for physical therapy is determined by the physical therapist's education. In Ukraine, educational programs in physical therapy, although they belong to the field of knowledge "Health care", but are not purely medical. In other words, the physical therapist is not officially a medical professional, but has the right to perform diagnostic procedures and influences of physical factors on the patient within their competence [1]. Approved by the Ministry of Health of Ukraine, the form of primary accounting documentation № 003-6/o "Informed voluntary consent of the patient for diagnosis, treatment and surgery and analgesia" contains in its title an indication of "...treatment and surgery ...", which are purely medical competencies [6]. However, the description of physical therapy does not say anything about treatment, but it is about providing services. In addition, this form refers only to the attending physician, and other health professionals are not mentioned.

The purpose of the study is to establish the legal features of the use of informed voluntary consent of the patient in providing him/her with physical therapy services in Ukraine.

Materials and methods

The analysis of the normative-legal base of Ukraine with the use of methods of analysis, synthesis, comparative-legal method is carried out.

Research findings

Normative legal acts of Ukraine, in particular the Law of Ukraine "Principles of Ukrainian Health Care Legislation" [7], the Civil Code of Ukraine enshrines the principle of patient autonomy. The importance of this principle is difficult to overestimate, because according to it the patient has the right to receive information about his/her health, medical interventions that can be performed on him/her, to give informed consent to these interventions, partially or completely refuse medical interventions/services, independently choose treatment methods, medical institution and personal physician [8].

The right to inform the patient about the state of his/her health is provided by the international and national legislation of Ukraine. In September-November 1981, the 34th World Medical Assembly was held in Lisbon, Portugal, and Declaration of Lisbon on the Rights of the Patient was adopted, stating the patient's right to agree or refuse treatment after receiving information from a doctor (informing the patient) [9].

The European Charter of Patients' Rights of 2002 stipulates that every person (patient) has the right to access all information that may enable him/her to participate in decisions about his/her health. This information is a prerequisite for any medical procedure and treatment, including participation in scientific research. The Charter requires healthcare professionals to provide the patient with all information about the treatment or surgery, including the associated risks, side effects, and alternative treatments. The peculiarity of this information is the definition of a time frame, in other words, information must be provided at least 24 hours before the medical manipulations, so that the patient can decide on the choice of treatment. The Charter provides for the right of a patient to refuse treatment or medical intervention and to change his/her opinion during treatment, refusing to continue it and to refuse to receive information about his/her health in general [10].

At the national level, a number of regulations have also been enacted that establish the obligation of healthcare professionals to inform patients about their health status and to obtain consent for treatment. Thus, on November 19, 1992, the Law of Ukraine "Bases of the legislation of Ukraine on health care" was adopted, which established the obligation to inform the patient and give consent for the use of methods of diagnosis, prevention and treatment. A patient under the age of 14 (a minor patient), as well as a patient who has been declared incapable according to the procedure established by law, his/her legal representatives must consent to the medical intervention. At the same time, the legislation provides for the right of a patient who has reached the age of majority to receive reliable and complete information about the state of his/her health, including access to relevant medical documents relating to his/

her health, and the medical worker is obliged provide the patient in an accessible form with information about the state of his/her health, the purpose of the proposed research and treatment measures, a forecast of possible disease development, including the risk to life and health. Exceptions are situations when there are signs of direct threat to the patient's life, provided that it is impossible for objective reasons to obtain consent for this kind of intervention from the patient or his/her legal representatives [7].

The patient has the right to refuse medical intervention and not give his/her consent (which determines the patient's right to consent, not obligation). If the lack of consent can lead to serious consequences for the patient, the doctor must explain it. If the patient still refuses treatment, the doctor has the right to take written confirmation from him/her, and if it is impossible to obtain written confirmation the doctor must attest the refusal in the presence of witnesses. It should be borne in mind that the law provides for the patient's right to refuse treatment only if we acquire full civil capacity and awareness of the importance of their actions and their consequences. If this refusal is given by the patient's legal representative and it may have serious consequences for the patient, the doctor must notify the tutorship and guardianship authorities [7, Article 43].

Article 31 "The rights of persons with disabilities in rehabilitation" of the Law of Ukraine "About rehabilitation of persons with disability in Ukraine" provides, among others, the right of persons with disabilities to receive information about their rights, responsibilities, conditions and forms of rehabilitation, and the right to refuse from rehabilitation measures. In addition, persons with disabilities, as well as legal representatives of children with disabilities have the right to participate in the development of rehabilitation measures. However, the right to informed consent and the obligation of medical staff to inform persons undergoing physical rehabilitation is not provided by this law [11].

Many recent regulations contain appropriate requirements for informing patients during treatment. However, even in world practice, this problem is far from being fully resolved [12]. In the process of obtaining informed consent, two stages can be distinguished [4]:

- 1) providing the patient with information on the basis of the principles of voluntariness and competence;
- 2) obtaining and proper execution of the patient's consent.

A review of modern sociological research has shown that there is still a formal attitude to the principles of informed consent in medical institutions [13]. Thus, the physician, offering the patient a letter of informed consent, quickly communicates general information about the contents of the paper and may ask the patient to sign it immediately. The patient signs without hesitation, especially if the physician is trustworthy, and this procedure, often to the satisfaction of the doctor, ends fairly quickly. Sometimes the patient can study the information provided for a long time, believing that there is a danger to his/her health [14]. Some institutions provide their own supplements with informed consent to the medical history or outpatient card, while others require patients to sign informed consent without explaining the medication.

Everything mentioned above can lead to lawsuits with adverse consequences for physicians. Therefore, the voluntary informed consent of the patient, which acts as the legal basis for the relationship "physician – patient", can be considered as a document that protects the physician in the statement of patient's claim [15].

Judicial practice shows that the presence of informed consent is considered as the conclusion of a written contractual agreement and is important in making a decision on compensation for damage caused by lawful acts. The court deciding the validity of the patient's claim for non-pecuniary damage based on whether the patient was informed about the methods of treatment, possible complications in advance, before treatment, and whether the patient voluntarily agreed to this kind of treatment in a written contractual relationship [16].

Today, Order of the Ministry of Health of Ukraine from February 14, 2012 № 110 (as amended on 8.08.2014, № 549) provides for the procedure for filling out the form of primary accounting documentation № 003-6/o "Informed voluntary consent of the patient for diagnosis, treatment and for surgery and analgesia" [6]. However, this informed consent of the patient is purely medical and does not imply consent to physical rehabilitation / therapy, and its services are provided by a physical therapy specialist without medical education.

In Ukraine a physical therapist can work:

in a public or private institution in the relevant position, usually as part of a multi-rehabilitation team;

independently, as a private entrepreneur, providing physical therapy services.

In the first case, all issues of obtaining voluntary informed consent from the patient are resolved "centrally" by the administration of the institution, using the form of informed consent approved by the Ministry of Health of Ukraine (form № 003-6/o), the institution signs the consent of the doctor treating the patient. In this case, usually, the physical therapist does not sign an informed consent and it can be stated that the full legal responsibility for the patient lies with his/her physician.

In the second case, the physical therapist provides physical therapy services as an independent legal entity and already bears full legal responsibility for the patient. Our experience, based on a survey of several dozen physical therapists, shows that physical therapists use various forms of informed patient consent to provide physical therapy services. Someone uses the approved form № 003-6/o, someone uses the recommended form in professional refresher training, someone uses their own form.

In Ukraine at present there is no form of informed consent of the patient to the provision of physical therapy services officially approved by the state regulator or recommended by the professional association. We believe that a physical therapist who informs a patient about physical therapy and then applies it should provide the patient with a special form of voluntary informed consent and sign it. This will protect both the patient and the physical therapist in case of any complications during physical therapy.

Informed consent of the patient to physical therapy, in our opinion, should be voluntary for the patient, mandatory for the

physical therapist, contain key provisions on the patient's awareness of all the characteristics of physiotherapy intervention that will be performed on him/her; risks and complications that may occur during physiotherapy; that failure to follow the physical therapist's recommendations may adversely affect his or her health; indicate that the patient has had the opportunity to ask any questions about his or her health, the means of physical therapy that will be applied to him or her, and have received comprehensive and understandable answers, and an indication that the patient has had adequate time for decision. The informed consent of the patient must be in writing.

An important condition for obtaining consent is the provision of information based on the competence of the patient [17]. It is about informing the patient so that he/she can understand the explanations of the physical therapist, assess his/her condition and the degree of risk proposed by the physical therapist rehabilitation methods, make choices and understand the consequences of the decision, as it is done in the medical field [18]. Thus, when studying the idea of providing patients with clear information about physical therapy, they indicated that despite reading the handouts and instructions on physical procedures, discussing them with a physical therapist, it would be desirable to provide additional sources of information in the form of video recording these procedures. According to patients, this would improve the full understanding of the physiotherapy procedure, its risks, benefits and alternatives [19]. The issue of a person's ability to consciously make decisions with informed consent is also discussed [17]. Copnell G. (2018) points out that giving a person consent requires the ability and freedom to exercise rational thinking, and a person's ability to make rational decisions is increasingly questioned by empirical evidence of behavioral psychology [20]. In addition, in order to make an informed decision about physical therapy, the patient has the right to receive advice on this type of therapy from another physician or physical therapist. For an informed decision, the patient also has the right to receive information about the professional abilities and competencies of the person who will provide him/her with services. In case of termination or refusal of the patient to conduct or continue physical therapy, the physical therapist must suspend the provision of services for the duration of the study and find out the reasons for refusal (feeling unwell, pain, discomfort), eliminate defects and continue physical therapy after patient's consent. In the absence of consent, the physical therapist will be required to draw up the patient's refusal in writing with their signatures, in the presence of a third party. It should be borne in mind that if a physical therapist does not comply with the requirements of informed consent for his/her patients, then judicial proceedings are possible, as it is evidenced in medical practice [21].

With regard to the form of informed consent and the text that should be contained in it, it can be argued that for physical therapy, the existing form of informed consent № 003-6/o, approved by the Ministry of Health of Ukraine, is unsuitable. There are various forms of this informed consent abroad. The most complete solution to the question of "physiotherapeutic" informed consent of the patient was found in Italy. Galeoto

G. et al. (2015) proposed 4 forms of informed consent, which are adapted to the needs of the physiotherapist and are specific to the main areas of rehabilitation [22]. These authors proposed forms of informed consent for orthopedic, neurological, respiratory, and cardiac rehabilitation. Every form of informed consent contains the following standardized structured information: 1) about the patient (passport, clinical, social data, etc., these data are written down by the physical therapist), 2) about the functional assessment of the patient; 3) about physiotherapeutic interventions; 4) the general risks of rehabilitation treatment; 5) about possible specific complications; 6) non-therapeutic risks; 7) other information at the request of the patient, 8) the text of the patient's consent to rehabilitation interventions; 9) the text of the patient's consent to personal data processing.

According to the information, paragraphs from 2 to 5 are specific to every form of informed consent. Let us give an example of the patient's consent translation to rehabilitation interventions, proposed by Galeoto G. et al. (2015): "I, the undersigned,... declare that I have been informed, and I understand the conditions, methods, purpose and nature of the rehabilitation intervention specified in the form. I declare that I am aware of the risks and complications that may arise or be connected with treatment. I am also aware that without my cooperation and willingness to follow some of the behaviors and exercises specified by the physiotherapist, the therapy cannot be considered successful in the long run. I give my full consent to the interventions and therapies that have been illustrated to me, during the rehabilitation treatment for the required period of time" [22].

In our opinion, the content of the informed consent should not be overloaded. It is sufficient to include only those provisions that clearly prescribe the relationship between the physical therapist and the patient mentioned above. It is advisable to tell the patient in an oral conversation about the plan of physical therapy, characteristics of physiotherapeutic interventions that will be used, specific risks and complications that may arise during physiotherapeutic interventions, other advantages and disadvantages of physiotherapy and provide him/her with appropriate printed and video materials.

In addition to the subject physiotherapeutic component, the informed consent of the patient usually includes consent to the use and processing of his/her personal data. In the informed consent № 003-6/o, approved by the Ministry of Health of Ukraine, only the patient is a party to this agreement and agrees to the use of his/her personal data. The foreign authors (Galeoto G. et al., 2015), on the contrary, write in informed consent about the physical therapist's responsibilities to the patient to use his/her personal data according to the law: "...I would like to inform you that regarding to the law ... the data you provide to me for the correct form of informed consent will be used to identify your current state of health and for administrative purposes and will be stored in my archive" [22].

Synthesizing domestic and foreign informed consents of the patient, for discussion we offer the form (formsheet) of the voluntary informed consent of the patient to carrying out physical therapy which can be used in activity of physical therapists.

<p align="center">INFORMED PATIENT CONSENT TO PHYSICAL THERAPY</p> <p>I, _____, (last name, first name, patronymic)</p> <p>confirm that I have received information that is clear to me from a physical therapist</p> <p>_____ (last name, first name, patronymic)</p> <p>about carrying out to me (my child) necessary physiotherapeutic intervention.</p> <p>Being in _____, (name of medical and preventive institution, individual entrepreneur)</p> <p>I was introduced to the physical therapy plan offered to me (my child). I have been explained in an accessible form and I understand the conditions, methods, purpose, nature and consequences of physiotherapy intervention. I declare that I am aware of the risks and complications that may arise or be associated with physiotherapy. I am informed about possible changes in physical therapy in case of problems with my (my child's) health or changes in the course of the disease.</p> <p>I have been explained that failure to follow the physical therapist's recommendations can adversely affect my health, and I realize that without my cooperation and willingness to follow some of the physical therapist's behaviours and procedures, therapy cannot be successful in the long run.</p> <p>I had the opportunity to ask any questions about my (my child's) health, the physical therapy that would be used, and received comprehensive and clear answers. I had enough time to decide whether to agree to the proposed physical therapy.</p> <p>I give consent to enter my personal data to information management system, including data on the state of my (my child's) health, into the information system maintained by the health care institution/individual entrepreneur. I agree to the use and processing of my personal data under observance of their protection according to the requirements of the Law of Ukraine "On protection of personal data".</p> <p>The physical therapist, for his/her part, undertakes that the personal data provided by the patient will be used only to assess the patient's current health, for the purposes of the physical therapy program and for administrative purposes and will be stored only in the physical therapist's archive.</p> <p>Patient _____ (signature of the patient or his/her legal representative, last name, first name, patronymic, document confirming the right to represent the interests of the patient)</p> <p>Physical therapist _____ (signature)</p> <p>Third party _____ (third party signature)</p> <p>Date _____</p>

Fig. 1. Form of the voluntary informed consent of the patient to carrying out physical therapy

Conclusions

The principle of patient autonomy and medical practice necessitates the regulation of the relationship between the patient and the physical therapist in the provision of physical therapy services. This requires the use of voluntary informed consent of the patient to physical therapy. At present, there is no form of informed consent in Ukraine.

Legal regulation of the patient's autonomy during physical therapy requires regulation of the patient's right to provide him with complete information about physical therapy,

coordination and approval of the written form of voluntary informed consent of the patient to physical therapy.

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